Tampere University

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Vaccination Coverage and Factors Associated with Routine Childhood Vaccination Uptake in India

Findings from a National Survey and Household Surveys in Vellore, Southern India

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Dedicated to my wife, Tripti Bara, my parents, Drs. Paul and Suzie Francis, and my late grandparents, Mr. Simpson Poddar and Mrs. Sushila Poddar

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ABSTRACT

The Indian Universal Immunization Program (UIP) was established in 1985 and is tasked with vaccinating nearly 27 million children every year. Its most recent achievements include India being certified polio-free in 2014 and the subsequent elimination of neonatal tetanus in 2015. Despite these successes, reports of persistently suboptimal full vaccination coverage (children aged 12-23 months who receive three doses of DPT and OPV and one dose of BCG and measles vaccination) in many Indian districts led to the launching of the Mission Indradhanush (MI) campaign in 2014. This campaign aimed to increase full immunization coverage in the poorest performing districts to 90% by 2020, mainly through special immunization sessions and enhancing community engagement and mobilization of beneficiaries. While early administrative reports suggested improved immunization coverage in the MI districts after the first two phases of the campaign, these improvements were considered insufficient to achieve the MI coverage goal. Concurrent research assessing demand-side disparities (including individual and household characteristics such as children's age and gender, parental education and occupation, socio-economic status, religious affiliation, and health-seeking behavior) in routine childhood vaccination uptake can bolster these governmental efforts to increase vaccination coverage uniformly. Therefore, the overall aim of this dissertation was to assess vaccination coverage and the factors associated with routine vaccination uptake among children aged 12-23 months, both nationally and subnationally, in the Vellore district of Tamil Nadu, southern India.

The first objective of this dissertation was to investigate the factors associated with routine vaccination uptake and describe the reasons for non-vaccination among Indian children aged 12-23 months nationally during 1998 and 2008 using the publicly available district-level household and health facility survey (DLHS) datasets (Study I). The study estimated that 53%, 32%, and 15% of children were fully vaccinated, partially vaccinated, and unvaccinated. Multivariate analysis revealed that children's vaccination status was inversely associated with female

gender, Muslim religion, lower caste, urban residence, lower maternal education, fewer antenatal visits, and non-receipt of maternal tetanus vaccination. Furthermore, a qualitative analysis of the mothers' reasons for not vaccinating their children revealed gaps in awareness (of the need for vaccines), acceptance (including fears of side effects), and affordability (mainly due to indirect costs) as the main reasons for non-vaccination.

The second objective of this dissertation was to estimate vaccination coverage and investigate the factors associated with routine vaccination uptake among children from rural (Study II) and disadvantaged communities (Study III) in Vellore, southern India, during 2017 and 2018. Vellore and 600 other Indian districts were selected for intensified routine immunization through the MI campaign in 2015. Cross-sectional household surveys and focus group discussions were conducted among parents of children aged 12-23 months from rural and disadvantaged (Nomadic, tribal, and migrant) communities in Vellore. The proportions of fully vaccinated children were 96% and 65% based on information from vaccination cards or parental recall for children from rural and disadvantaged communities. While no socio-demographic characteristics were associated with childhood vaccination uptake, parental familiarity with the vaccination schedule and receiving information on vaccinations during antenatal visits were positively associated with children's vaccination status in rural Vellore. However, maternal employment was negatively associated with children's vaccination status in the survey among the known disadvantaged communities in Vellore. Focus group discussions with parents in these communities identified difficulties accessing routine immunization when travelling for work, knowledge gaps regarding the benefits and risks of vaccination, and fears due to common side effects following childhood vaccination.

In summary, the studies in this thesis reveal differences in vaccination coverage and the demand-side factors associated with routine childhood vaccination uptake nationally and subnationally in the Vellore district. The persisting disparities in childhood vaccination uptake by maternal and household characteristics nationally call for targeted interventions and additional research on the causal pathways through which maternal characteristics influence decision-making for childhood vaccinations in India. In addition, the household surveys in Vellore provide preliminary evidence that the MI campaign may have increased full vaccination coverage in some but not all communities or regions within the targeted districts.

Finally, the identified knowledge gaps regarding the need for vaccinations and fears due to vaccination in general or vaccine side effects highlight the potential for utilizing ongoing information, education, and communication interventions to simultaneously improve parental awareness and build trust in childhood vaccines. Collectively, the quantitative and qualitative findings of these studies provide valuable demand-side perspectives toward routine childhood vaccines and actionable evidence to inform targeted interventions to sustain or increase childhood vaccination uptake in Indian settings.

TIIVISTELMÄ

Intian kansallinen rokotusohjelma (UIP) perustettiin vuonna 1985 ja se vastaa lähes 27 miljoonan lapsen rokottamisesta vuosittain. Ohjelman viimeaikaisiin saavutuksiin lukeutuvat Intian julistaminen poliovapaaksi vuonna 2014 sekä sitä seurannut vastasyntyneiden jäykkäkouristuksen eliminointi vuonna 2015. Näistä menestystarinoista huolimatta on useilla Intian alueilla raportoitu jatkuvasti puutteita pikkulasten rokotusohjelmaan kuuluvien rokotteiden rokotekattavuudessa (12-23 kuukauden ikäiset lapset, jotka ovat saaneet kolme DTP- ja OPV-rokoteannosta sekä yhden BCG- ja tuhkarokkorokoteannoksen). Tämä johti Mission Indradhanush (MI)- kampanjan aloitukseen vuonna 2014. Kampanjan tavoitteena oli nostaa perusrokotteiden rokotekattavuus huonoimmin suoriutuvilla alueilla 90 prosenttiin vuoteen 2020 mennessä pääasiassa erityisten rokotustilaisuuksien sekä yhteisön osallistumisen ja asukkaiden aktivoinnin avulla. Vaikka hallinnolliset raportit aluksi viittasivatkin lisääntyneeseen rokotekattavuuteen MI-kampanjan alueilla sen ensimmäisten kahden vaiheen jälkeen, tuloksia pidettiin riittämättöminä MI:n rokotuskattavuustavoitteen saavuttamiseksi. Tutkimuksella, joka arvioi eroja lasten rokotemyöntyvyydessä ja rokotteiden ottamisessa (ml. yksilön- ja kotitalouden piirteet, kuten lasten ikä ja sukupuoli, vanhempien koulutus ja ammatti, sosioekonominen status, uskonto, terveyskäyttäytyminen) on mahdollista tukea Intian hallituksen pyrkimyksiä lisätä rokotekattavuutta yhdenmukaisesti koko maassa. Näistä syistä tämän tutkimuksen ensisijainen tavoite oli arvioida rokotekattavuutta ja tekijöitä, jotka liittyvät lasten rokotusohjelmaan kuuluvien perusrokotteiden ottamiseen 12-23 kuukauden ikäisillä lapsilla sekä kansallisesti että alueellisesti Velloren piirikunnassa, Tamil Nadun osavaltiossa, Etelä-Intiassa.

Väitöstutkimuksen ensimmäinen tavoite oli tarkastella tekijöitä, jotka liittyvät perusrokotusten ottamiseen ja kuvata syitä rokottamattomuuteen intialaisilla 12-23 kuukauden ikäisillä pikkulapsilla kansallisesti vuosina 1998 ja 2008 hyödyntäen

avointa kotitalous- ja terveyspalvelututkimuksen (DLHS) aluetason tietoaineistoa (I osatutkimus). Tutkimuksessa arvioitiin, että 53% lapsista oli täysin rokotettuja, 32% osittain rokotettuja ja 15% rokottamattomia. Monimuuttuja-analyysi osoitti, että lasten rokotusstatus oli käänteisesti yhteydessä naissukupuoleen, islaminuskoisuuteen, alempaan kastiin kuulumiseen, kaupungissa asumiseen, äidin alempaan koulutustasoon, pienempään määrään äitiysneuvolakäyntejä sekä äidin tetanusrokotteen puuttumiseen. Kvalitatiivisessa analyysissä äitien antamia pääsyitä lastensa rokottamattomuuteen olivat puutteet tiedossa (rokotteiden tarpeellisuudesta), rokotusten hyväksymisessä (ml. sivuvaikutusten pelot) sekä liian korkea hinta (pääasiassa johtuen välillisistä kustannuksista).

Väitöstutkimuksen toinen tavoite oli arvioida rokotekattavuutta ja tarkastella tekijöitä, jotka liittyivät perusrokotusten saamiseen maaseudun lapsilla (II osatutkimus) ja haavoittuvassa asemassa olevissa yhteisöistä (III osatutkimus) Velloressa, Etelä-Intiassa, vuosina 2017 ja 2018. Vellore ja 600 muuta Intian piirikuntaa valittiin MI-kampanjan tehostettuun rokotusohjelmaan vuonna 2015. Poikkileikkauskyselytutkimus ja fokusryhmäkeskustelut 12-23 kuukauden ikäisten lasten vanhemmille tehtiin maaseudun ja haavoittuvassa asemassa olevissa (paimentolais-, heimo- ja maahanmuuttaja-) yhteissä Velloressa. Kaikki perusrokotukset saaneiden lasten osuudet olivat rokotuskorttitietojen mukaan 96% tai vanhempien ilmoituksen mukaan 65%. Vaikka minkään rokotusten ottaminen ei ollut yhteydessä sosiodemografisiin muuttujiin, vanhempien tietämys rokotusaikataulusta ja informointi rokotteista äitiysneuvolakäyntien yhteydessä olivat yhteydessä korkeampaan rokotuskattavuuteen Velloren maaseudulla. Toisaalta äidin työssä käyminen oli yhteydessä matalampaan rokotuskattavuuteen haavoittuvassa asemassa olevissa yhteisöissä Velloressa. Fokusryhmäkeskustelut vanhempien kanssa tunnistivat vaikeuksiksi säännöllisten rokotusten saatavuuden työmatkan yhteydessä, puutteet tiedoissa rokotusten hyödyistä ja haitoista sekä pelot rokotteiden tunnetuista sivuvaikutuksista.

Yhteenvetona tämän väitöskirjan osatutkimukset paljastivat eroja pikkulaten rokotekattavuudessa sekä vanhempine rokotushalukkuuteen liittyvissä muuttujissa, kansallisesti Intiassa ja alueellisesti Velloren piirikunnassa. Pysyvät eriarvoisuudet rokotemyöntyvyydessä, jotka perustuvat äitien ja kotien ominaispiirteisiin vaativat kansallisen tason kohdennettuja interventioita ja lisätutkimusta niistä syyseuraussuhteista, joiden kautta äiteihin liitetyt tekijät vaikuttavat lasten rokotuspäätöksiin Intiassa. Lisäksi kyselytutkimukset Velloressa antavat alustavaa viitettä siitä, että MI-kampanja on voinut lisätä rokotekattavuutta joissain yhteisöissä tai alueilla, mutta ei kaikissa kampanjaan kuuluvissa piirikunnissa. Havaitut puutteet tiedossa rokotteiden tarpeellisuudesta ja rokotteista yleisemmin sekä sivuvaikutuksia koskevat pelot korostavat jatkuvan viestinnän, koulutuksen ja terveysinterventioiden roolia vanhempien rokotteita koskevan tietämyksen ja luottamuksen lisäämisessä. Yhdistämällä määrällisten ja laadullisten osatutkimusten havainnot saadaan tärkeää tietoa pikkulasten rokotuskattavuuteen vaikuttavista kysyntäpuolen tekijöistä sekä käytäntöön sovellettavissa olevaa tutkimustietoa kohdennettujen interventioiden kehittämiseksi, joilla voitaisiin ylläpitää tai lisätä pikkulasten rokotuskattavuutta ja vanhempien rokotusmyönteisyyttä Intiassa.

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ABBREVIATIONS

UIP	Universal Immunization Program
MI	Mission Indradhanush
DLHS	District-level Household & Facility Survey
EPI	Expanded Program on Immunization
LMICs	Low- and Middle-Income Countries
WHO	World Health Organization
BCG	Bacille Calmette-Guerin
DPT	Diphtheria-Pertussis-Tetanus
DPT3	Third or three doses of Diphtheria-Pertussis-Tetanus
OPV	Oral Polio Vaccine
GAVI	Global Alliance for Vaccines and Immunization
UN	United Nations
MCV	Measles Containing Vaccine
MICS	Multiple Indicator Cluster Survey
UNICEF	United Nations International Children's Emergency Fund
DHS	Demographic Health Survey
LQAS	Lot Quality Assurance Sampling
VPDs	Vaccine-preventable diseases
TT	Tetanus toxoid
IPV	Inactivated Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
NFHS	National Family and Health Surveys
GOI	Government of India
NPSP	National Polio Surveillance Project
NRHM	National Rural Health Mission
IMI	Intensified Mission Indradhanush
GVAP	Global Vaccine Action Plan
PACV	Parental Attitudes about Childhood Vaccines
HBM	Health Belief Model

ANM	Auxiliary Nurse Midwives
ASHA	Accredited Social Health Activist
PSU	Primary Sampling Unit
PPS	Probability Proportional to Size
FGD	Focus Group Discussion
IIPS	Indian Institute of Population Sciences
CI	Confidence Interval
POR	Prevalence Odds Ratio
IRB	Institutional Review Board
SD	Standard Deviation
PHC	Primary Health Center
MR	Measles-Rubella
VHN	Village Health Nurse
MRMBS	Muthulakshmi Reddy Maternity Benefit Scheme
ANC	Antenatal Care

ORIGINAL PUBLICATIONS

Publication I **Francis MR**, Nohynek H, Larson H, Balraj V, Mohan VR, Kang G, Nuorti JP. Factors associated with routine childhood vaccination uptake and reasons for non-vaccination in India: 1998 – 2008. *Vaccine* 36 (2018) 6559–6566. doi: 10.1016/j.vaccine.2017.08.026

Publication II **Francis MR**, Nuorti JP, Kompithra RZ, Larson H, Balraj V, Kang G, Mohan VR. Vaccination coverage and the factors associated with routine childhood vaccination uptake in rural Vellore, southern India, 2017. *Vaccine* 37 (2019) 3078 – 3087. doi: 10.1016/j.vaccine.2019.04.058

Publication III **Francis MR**, Nuorti JP, Lumme-Sandt K, Kompithra RZ, Balraj V, Kang G, Mohan VR. Vaccination coverage and the factors influencing routine childhood vaccination uptake among communities experiencing disadvantage in Vellore, southern India: a mixed-methods study. *BMC Public Health*. 2021 Oct 7;21(1):1807. doi: 10.1186/s12889-021-11881-8.

1 INTRODUCTION

Immunization is one of the safest, most cost-effective, and most potent means of preventing deaths and promoting well-being today. Vaccination prevents an estimated 2-3 million child deaths worldwide every year (WHO, 2013, 2020). Vaccination helped eradicate smallpox and is vital to global efforts to eradicate poliomyelitis and eliminate maternal and neonatal tetanus. The benefits of vaccinating children and adults cut across many of the UN Sustainable Development Goals (SDGs), specifically, SDG3 to *"Ensure healthy lives and promote well-being for all at all ages*." However, despite the established value of vaccines, nearly 20 million infants still do not receive an entire course of primary vaccinations, leaving them vulnerable to vaccine-preventable diseases (World Health Organization, 2020d). Just three countries account for a third of the world's unvaccinated or partially vaccinated children – Nigeria (3 million), India (2.1 million), and the democratic republic of Congo (2.1 million) (World Health Organization, 2020d). Reducing global childhood mortality due to vaccine-preventable diseases depends significantly on these countries improving the coverage of existing routine vaccinations and introducing additional lifesaving vaccines (V. Mitchell et al., 2013). Therefore, it is vital to understand the factors contributing to unvaccinated or partially vaccinated children in these countries despite established routine immunization programs for over three decades.

The Universal Immunization Program (UIP) in India was established in 1985 to provide pregnant women and infants with a primary series of vaccinations (Sokhey et al., 1989). For nearly two decades, the UIP focused on increasing the coverage of four vaccines (Bacille Calmette-Guerin [BCG], Diphtheria-Pertussis-Tetanus [DPT], Oral Polio Vaccine [OPV], and Measles) to protect children against six vaccine-preventable diseases (Vashishtha & Kumar, 2013). As a result, childhood vaccination coverage increased rapidly during the first decade of the UIP. For example, the coverage of three OPV (OPV3) doses among infants was nearly 80% in 1990, bolstering India's resolution to eradicate polio by 2000 (John & Vashishtha, 2013). However, the first National Family Health Survey (NFHS-1, 1992-93) reported significant inter-state disparities in childhood vaccination coverage, highlighting potential differences in UIP functioning, vaccine demand, and other social barriers at the state and regional levels (Pande & Yazbeck, 2003). Furthermore, an analysis of data from three consecutive rounds of the NFHS (NFHS 1-3, 1992–2006) surveys revealed persisting disparities in vaccination coverage levels between the Indian states and lower coverage for children from rural areas and female children, necessitating government intervention (P. K. Singh, 2013).

The government of India launched the Mission Indradhanush (MI) campaign in 2014 to increase full vaccination coverage (children who received three doses of DPT and OPV and one dose of BCG and measles vaccination) to 90% by 2020 (Ministry of Health and Family Welfare, 2016). Leveraging successful strategies from India's successful polio eradication program, the MI campaign targeted children in the districts with the lowest full vaccination coverage with periodic fixed and outreach catch-up immunization sessions and enhancing community engagement and mobilization (Ministry of Health and Family Welfare, 2016). Although administrative reports suggested increased full vaccination coverage by 5-7% in the targeted districts after the first two phases of MI, this increase was insufficient to achieve 90% coverage by 2020 (Ministry of Health and Family Welfare, 2018a). Monitoring the progress of the MI and subsequently launched Intensified Mission Indradhanush (IMI) campaigns is primarily done through national, state, and district-level task forces, reviewing indicators on vaccine availability and supply, numbers and quality of the vaccination sessions conducted, percentages of children with due vaccinations, and healthcare workers disseminating information on routine vaccinations to caregivers (Ministry of Health and Family Welfare, 2018c). Concurrent research examining the demand-side factors (including individual and household characteristics such as children's age and gender, parental education and occupation, socio-economic status, religious affiliation, and health-seeking behavior) associated with routine childhood vaccination uptake and perspectives on childhood vaccines can bolster these governmental efforts to increase vaccination coverage uniformly.

This thesis describes the findings of analyses conducted to assess vaccination coverage and the factors associated with routine childhood vaccination uptake, nationally and subnationally, in the district of Vellore, southern India. Primary data collected through community-based household surveys and focus group discussions in Vellore during 2017-18 and secondary data obtained from the nationally-representative district-level household and facility surveys (1998-2008) are utilized in this thesis. These data, representing multiple methodological approaches, geographic resolutions, and time frames, provide an important opportunity to identify existing demand-side disparities in childhood vaccination coverage and enumerate the reasons for suboptimal vaccination uptake to support the MI and IMI campaign goals.

2 LITERATURE REVIEW

2.1 The WHO Expanded Program on Immunization (EPI)

2.1.1 Introduction, implementation, and vaccine antigens

The Expanded Program on Immunization (EPI) was established by the World Health Organization (WHO) in 1974 to ensure that all children could access life-saving vaccines (Keja et al., 1988). Before the launch of the EPI, a large proportion of child deaths and severe illnesses in the developing world were attributed to infectious diseases such as tuberculosis, measles, diphtheria, pertussis, tetanus, and poliomyelitis (Henderson, 1984). Despite effective vaccines against these diseases, less than 5% of children in developing countries received a third dose of diphtheria-pertussis-tetanus (DPT3) and polio vaccines during their first year of life in the 1960s (Chan, 2014; Keja et al., 1988). The EPI set out to increase the coverage of existing childhood vaccines by promoting the establishment of strong immunization infrastructure, coordinating the production and supply of vaccines, improving the training of health workers, and guiding the development of vaccine cold chain infrastructure (LaForce et al., 1987).

The EPI focused on protecting children against six diseases (tuberculosis, measles, diphtheria, pertussis, tetanus, and polio) by increasing the coverage of Bacille Calmette-Guerin (BCG), measles, and three doses of DPT and polio vaccination globally to 80% by 1990 (Keja et al., 1988). The EPI recommended an immunization schedule that could be tailored to the needs of participating countries but stressed the importance of immunizing children when at their highest risk of infections, *i.e.*, during the first year of life (LaForce et al., 1987). Based on EPI recommendations, children were to receive a BCG and Oral Polio vaccine (OPV) dose at birth, three doses of DPT and OPV at the age of 6,10, and 14 weeks and a single dose of measles at first contact after nine months of age (LaForce et al., 1987). This schedule ensured that five contacts of an infant and mother with a health facility would provide sufficient protection to the infant against the six EPI target diseases

(LaForce et al., 1987). By the mid-1980s, most developing countries had based their national immunization programs on EPI guidelines and adopted the EPI-recommended immunization schedule (Henderson et al., 1988).

In the 1990s, the EPI began recommending the widespread use of newer vaccines such as yellow fever, hepatitis B, and Japanese Encephalitis B (Henderson et al., 1988; Kim-Farley, 1992b). However, many developing countries could not afford to add these vaccines to their routine immunization programs, which led to the establishment of the Global Alliance for Vaccines and Immunization (GAVI) in 2000 (Lob-Levyt, 2011). The GAVI alliance aimed to bring together the key stakeholders of global immunization efforts, including UN agencies, the Bill & Melinda Gates Foundation, country governments, donors, industry, and academia, to increase access to new and underused vaccines in the poorest countries globally (Berkley, 2019; Lob-Levyt, 2011). Since its inception, GAVI has supported the introduction of yellow fever (in 14 countries), pentavalent (73 countries), inactivated polio (16 countries), measles or measles-rubella (73 countries), pneumococcal (60 countries), and rotavirus (48 countries) vaccines in eligible countries (GAVI, The Vaccine Alliance, 2020). The EPI currently recommends childhood vaccines against 11 diseases (including the original six target diseases) through all national immunization programs (World Health Organization, 2020c) (Table 1).

Table 1. The Expanded Program on Immunization (EPI) and the Indian Universal Immunization Program (UIP) immunization schedules for infants

Antigen	*EPI schedule*		*UIP schedule*	
	Doses in primary series	**Age at administration**	**Doses in primary series**	**Age at administration**
BCG	1 dose	At birth	1 dose	At birth or as early as possible
Hepatitis B	3 - 4 doses	At birth, and other doses at the same time as DPT-containing vaccine, with one-month intervals	4 doses	First dose at birth, and subsequent doses combined with the pentavalent vaccine at 6,10 and 14 weeks of age
Polio	3 - 4 doses (with at least one dose of IPV)	At birth, and at 6, 10, and 14 weeks (OPV), IPV dose at 14 weeks of age	6 doses	OPV at birth, and subsequent doses at 6, 10 and 14 weeks and IPV at 6 and 14 weeks of age
DPT-containing vaccine	3 doses	At 6, 10, and 14 weeks of age	3 doses	Provided as part of the pentavalent vaccine at 6,10 and 14 weeks of age
Hib	3 doses	First dose at 6 weeks of age, and subsequent doses with one-month intervals between doses	3 doses	Combined with the pentavalent vaccine at 6,10 and 14 weeks of age
Pneumococcal conjugate	3 doses	First dose at 6 weeks of age, and subsequent doses with one-month intervals between doses	3 doses*	At 6 and 10 weeks, and 9 months of age
Rotavirus	2 - 3 doses	First dose at 6 weeks of age, and subsequent doses with one-month intervals between doses	3 doses	At 6, 10, and 14 weeks of age
Measles	2 doses	In countries with ongoing transmission, first dose at 9 months of age and the second between 15-18 months of age	2 doses	First dose between 9-12 months of age and second dose between 16-24 of age
Rubella	1 dose	One dose at 9-12 months of age	2 doses	Combined with the measles vaccine and provided between 9-12 and 16-24 months of age

* Provided in 5 Indian states (Bihar, Himachal Pradesh, Madhya Pradesh, Rajasthan, and Uttar Pradesh)

Sources: (Ministry of Health and Family Welfare, 2018a; World Health Organization, 2020c)

2.1.2 EPI progress over the years

2.1.2.1 Vaccination coverage

Since launching in 1974, the EPI achieved its target of 80% coverage among infants with the BCG and measles vaccines and three doses of DPT and OPV vaccination in 1990 (Kim-Farley, 1992b). While this global target was achieved, there were important disparities in vaccination coverage between the WHO regions and individual countries, highlighting important differences in the level of primary health care infrastructure and other inequities in service delivery that needed to be addressed (Kim-Farley, 1992b). For example, DPT3 coverage in the WHO Africa region was below 60% despite coverage having crossed 80% in the Europe, America, Western Pacific, and South-East Asia regions (Cutts, 1998; Kim-Farley, 1992b). The disparities in routine vaccination coverage persisted into the early 90s, and global vaccination coverage plateaued at around 80% between 1990 and 1996 (Cutts, 1998).

Global vaccination coverage increased slightly in the 2000s - the coverage of infants who received three doses of DPT (DPT3) and one measles dose in countries with available data was 86% in 2018 (Peck, 2019). However, this coverage estimate was similar to estimates from 2010, indicating another stalling of global vaccination coverage in recent years (Peck, 2019). While DPT3 coverage has increased across the WHO regions since the 90s, the African region still has the lowest DPT3 coverage (74%), and all other regions have coverage over 80% (World Health Organization, 2020d). Furthermore, within these regions, there are reports of declining coverage among countries in historically well-performing regions such as the America (Brazil, Bolivia, Venezuela, Haiti, and Honduras) and Western Pacific (Samoa, Papua New Guinea, and Lao PDR) regions in the past five years which is concerning (World Health Organization, 2020d). On the other hand, global coverage of newer EPI vaccines such as hepatitis B, *Haemophilus influenzae* type B (often combined with DPT), inactivated polio, and rotavirus vaccines have rapidly crossed 80% in recent years due to GAVI support, improved vaccine manufacturing and development, and more robust health systems for vaccine delivery (J. Smith et al., 2011; World Health Organization, 2020d).

2.1.2.2 Polio eradication, measles elimination, and other contributions of the EPI to global health

While the EPI initially focused on six target diseases, special efforts were directed to control polio and measles in the 1990s (R. H. Henderson et al., 1988). The EPI target for global polio eradication was set for 2000 (R. H. Henderson et al., 1988). There was a 79% decrease in paralytic poliomyelitis cases in the early 90s compared with annual case estimates that would occur in the absence of immunization programs worldwide (Kim-Farley, 1992). By 2000, the American and Western Pacific WHO regions were certified polio-free, and the European region had not reported wild polioviruses for at least two years prior (World Health Organization, 2001). However, twenty countries in the other three WHO regions remained endemic to polio, and the coverage of three doses of OPV (OPV3) among infants was lower than 50% in many of these polio-endemic countries (Centers for Disease Control, 2001). The main challenge to eradication efforts in these countries was to provide polio vaccines to children in conflict-affected areas (World Health Organization, 2001). Currently, polio is endemic to two countries (Afghanistan and Pakistan), but 26 countries have reported outbreaks of imported wild or vaccine-derived polioviruses in recent years, complicating global poliovirus eradication efforts (World Health Organization, 2020a). Introducing a novel oral poliovirus vaccine (nOPV2) is expected to control ongoing transmission and prevent future outbreaks of vaccine-derived polioviruses in countries with reported outbreaks (World Health Organization, 2020b).

The EPI aimed to reduce global measles deaths by 95% and cases by 90% compared with pre-immunization levels by 1995 (Kim-Farley, 1992b). Before the launch of the EPI, nearly 8 million deaths and 130 million cases were attributed to measles every year (World Health Organization, 1996). By 1995, although the EPI measles reduction targets had not been achieved, measles deaths and cases were reduced by 85% and 78%, respectively (World Health Organization, 1996). These global estimates masked important disparities between the WHO regions- only two countries in the WHO Southeast Asia region and five in the Africa region had achieved a 90% reduction in measles cases by 1995 (World Health Organization, 1996). Low measles vaccination coverage (<50%) among infants was cited as the main reason for these regions failing to achieve the EPI measles reduction targets (World Health Organization, 1996). Global coverage with the first dose of measles-containing vaccine (MCV1) among infants increased from 72% to 85%, and reported measles cases and deaths decreased by 83% and 80% during 2000 - 2017 (compared with estimates from the 1990s) (Dabbagh, 2018). Despite these gains, measles incidence increased in all WHO regions during 2017 - 2019, stalling ongoing progress toward global measles elimination (M. K. Patel, 2020). Several countries across the six WHO regions, such as the Democratic Republic of Congo, Madagascar, Samoa, China, India, Ukraine, Brazil, and Venezuela, have reported outbreaks in the past three years (M. K. Patel, 2020). The decreasing MCV1 and MCV2 coverage in many communities in these countries, due partly to declining vaccine confidence among the public and health care professionals, is a key driver of the global resurgence in measles cases (M. K. Patel, 2020).

Promoting universal immunization for all children has led to benefits beyond the reduced morbidity and mortality due to infectious diseases globally. Vaccination programs are the cornerstones of primary health care services in many developing countries (Andre et al., 2008). The EPI focus on infants and their mothers has contributed to strengthening other primary health services directed toward maternal and child well-being, such as nutrition, diarrheal disease control, family planning, and vitamin A and iodine supplementation programs (Kim-Farley, 1992a). The EPI also promoted routine national systems to surveillance infectious diseases (Chan, 2014). In 2018, nearly 700 WHO-accredited laboratories across 164 countries undertook laboratory-based surveillance for measles, rubella, and other vaccine-preventable diseases (World Health Organization, 2019). These systems have served as platforms for integrating the surveillance of other infectious diseases (such as influenza, HIV, cholera, and Ebola) and enabled the detection and management of numerous epidemics and outbreaks of infectious diseases over the years (Andre et al., 2008; Wassilak et al., 2017). The EPI has pioneered research and development on immunization strategies, equipment for vaccine cold chains, technology and delivery systems for vaccines, and information systems to manage vaccine stocks and monitor immunization programs globally (Henderson et al., 1988). For example, in 1990, the EPI developed a computerized information system that provided data on disease incidence and logistical and technical issues among staff and detailed ongoing immunization-related activities (Hu et al., 1994). This system is a model for regional- and national-level immunization information systems, including birth and vaccination registration data, vaccine stocks, cold chain management, and adverse events following immunization in diverse settings (Namageyo-Funa et al., 2018; Pabst & Williams, 2015).

2.1.3 Monitoring EPI performance

2.1.3.1 Indicators of immunization program performance

In its early years, the EPI promoted three principal indicators to monitor the performance of routine immunization programs – the incidence of target diseases, vaccination coverage, and the quality of vaccines in use (Henderson, 1984). Vaccination coverage was included as an "intermediate indicator," with disease incidence being the "outcome indicator" for immunization programs globally (Bos & Batson, 2000; Kim-Farley, 1992b). Other performance indicators such as cold chain quality, adverse events following immunization, and costs per fully immunized child or per dose administered were added in the 1990s (Cutts, 1998). Countries generally emphasize vaccination coverage as the primary measure of performance of their immunization programs because it is widely used and relatively straightforward to estimate (Henderson & Keja, 1989; Sodha & Dietz, 2015). Measuring vaccination coverage periodically provides the benefit of timely evidence of improvement or deterioration in the performance of routine immunization programs (Bos & Batson, 2000).

Vaccination coverage is calculated as the percentage of people in a target age group that received a particular vaccine dose by a specific age (Sodha & Dietz, 2015). The coverage of specific vaccine doses reflects different attributes of immunization program performance (Sodha & Dietz, 2015) (Table 2). For example, coverage of the first DPT (DPT1) vaccine dose indicates access to health services, whereas the coverage of three DPT doses reflects both the ability to access and utilize immunization services over multiple visits (Sodha & Dietz, 2015). The coverage of infants under one year of age with one dose of measles-containing vaccine (MCV1) was closely followed as an MDG indicator for the quality of child healthcare systems globally (United Nations Development Group, 2003). The percentage of fully vaccinated children (children vaccinated with all the recommended vaccines during their first year of life) is a composite indicator that highlights the ability to access and utilize immunization services over multiple visits during the first year of an infant's life (Cutts et al., 1989).

Other performance indicators such as dropouts between early and final doses of primary vaccination series, missed opportunities for vaccination during health facility visits and timeliness of vaccination doses have also been employed, but to a lesser degree (V. Mitchell et al., 2013) (Table 2). Dropout rates reflect the ability of immunization programs to provide the recommended number of doses for vaccines that require multiple doses (Bos & Batson, 2000). High dropout rates may indicate health system barriers, inadequate tracking of children at health facilities, or a failure to educate mothers on the need to return for vaccinations (Cutts et al., 2016). A missed opportunity for vaccination is a failure to vaccinate children eligible for immunization (and who have no contraindications to immunization) during visits to health facilities (Hutchins et al., 1993). Missed opportunities for vaccination may occur due to vaccine stock-outs, mistakes in tracking vaccinations for children, or parental reluctance to vaccinate sick children (Hutchins et al., 1993; Sridhar et al., 2014). Vaccination timeliness refers to the age at receipt of individual vaccine doses relative to the ages recommended by routine immunization schedules (Clark & Sanderson, 2009). Untimely vaccination increases a child's risk of contracting vaccine-preventable diseases, which in turn may limit the ability of immunization programs to reduce the burden of infectious diseases in specific settings (Clark & Sanderson, 2009; Luman et al., 2005).

Table 2. Indicators commonly used to monitor immunization program performance

Program component	Indicator	Definition	Purpose
Program outputs	1 dose of DPT (DPT1)	Percentage of children who received one DPT dose	Access to immunization services
	1 dose of Measles containing vaccine (MCV1)	Percentage of children who received one measles dose	Quality of immunization services
	3 doses of DPT (DPT3)	Percentage of children who received three doses of DPT	Access to and utilization of immunization services
	Fully vaccinated children	Percentage of children aged 12-23 months who receive all the recommended vaccines	Access to and utilization of immunization services over multiple visits
Tracking activities	Dropouts between DPT1/OPV1 and DPT3/OPV3	Difference in percentage receiving DPT1/OPV1 and DPT3/OPV3	Health system barriers, or a failure to educate mothers on the need to return for vaccinations
Missed opportunities for vaccination	Children who did not receive all vaccines for which they are eligible during health facility visits	Percentage of children not receiving all the vaccines for which they are eligible at each visit	Vaccine stockouts, mistakes in tracking vaccinations or parental reluctance to vaccinate sick children

Source: (Cutts et al., 1989; Felicity T. Cutts et al., 2016; Hutchins et al., 1993; Luman et al., 2005; V. Mitchell et al., 2013; Sodha & Dietz, 2015)

2.1.3.2 Methods to monitor immunization program performance

Reliable data are critical to monitoring the progress of health-sector programs globally (Boerma et al., 2014). As a widely-used indicator of immunization program and health system performance, vaccination coverage is estimated through direct measurements of vaccination levels or indirectly through surveys or administrative reports (Chen & Orenstein, 1996). Direct measurements of vaccination coverage include vaccination registries and school entry censuses, whereas indirect measurements utilize community surveys or administrative reports of vaccines delivered to beneficiaries (Chen & Orenstein, 1996). Each measurement method has advantages, disadvantages, and scope for use (V. Mitchell et al., 2013).

Electronic vaccination registries provide data to continuously monitor coverage by tracking all the vaccines administered to children in each birth cohort (Cutts et al., 2016). Data from these registries are also used to monitor vaccine supply and send automated vaccination reminders to parents (Cutts et al., 2013). The usefulness of electronic registries depends on the completeness, accuracy, and timeliness of data entry and the denominators used to calculate vaccination coverage (V. Mitchell et al., 2013). Currently, electronic registries are mainly used in high- and some middle-income countries; however, there are reports of pilot studies of electronic vaccination registries in Tanzania, Zambia, Kenya, Pakistan, Bangladesh, and India (Pancholi et al., 2020). The primary challenges to the widespread use of electronic registries in low-resource settings include difficulties accounting for migrations within populations, avoiding record duplication, and adequate funding and human resources for running them (Cutts et al., 2013; Mitchell et al., 2013) (Table 3).

Most low-income countries rely on paper-based systems to calculate administrative coverage estimates using aggregated reports of the number of vaccines administered and estimating the number of children in the target age group at a given time (Cutts et al., 2016). This method provides information at different administrative levels (local, district, and provincial) and is relatively inexpensive (V. Mitchell et al., 2013). In addition, through routine reports, the doses administered to children can also be compared with the total doses distributed to estimate vaccine wastage rates (V. Mitchell et al., 2013). However, the reliability of administrative coverage estimates depends primarily on the quality of the primary recording of vaccinations and the transcription and compilation of information at the different levels of aggregation (Cutts et al., 2013). Besides, overestimation or underestimation of vaccination coverage is likely due to the inclusion of children outside the target age group, private practitioners not reporting vaccination information, and inaccurate population denominators (Cutts et al., 2013; Mitchell et al., 2013). Due to these limitations, other data sources such as surveys are often considered for the WHO-UNICEF estimates of national immunization coverage (WUENIC) (Cutts et al., 2013).

Community surveys often serve as a complementary data source to administrative reports to estimate vaccination coverage in many countries (V. Mitchell et al., 2013). The most common coverage surveys include the Multiple Indicator Cluster Survey (MICS) and Demographic Health Survey (DHS), the Expanded Program on Immunization (EPI) cluster survey, and Lot Quality Assurance Sampling (LQAS) surveys (Cutts et al., 2013). The MICS and DHS are nationally representative household surveys that employ probability sampling to provide information on various health indicators such as mortality, reproductive and child health, HIV/AIDS, malaria, and nutrition (Cutts et al., 2013; V. Mitchell et al., 2013). The WHO developed the EPI cluster survey in 1982 as a practical tool to estimate vaccination coverage within ten percentage points of the point estimate (Henderson & Sundaresan, 1982). The LQAS surveys use stratified sampling to estimate health intervention coverage in many low- and middle-income countries (Cutts et al., 2013). Coverage surveys provide an opportunity to capture other relevant indicators such as vaccine timeliness and missed opportunities for vaccination and can also assess the reasons for failure to vaccinate and capture the occurrence of adverse events (V. Mitchell et al., 2013). However, potential sources of error such as biases due to the exclusion of subpopulations, accuracy of primary vaccination recording and oral history of vaccinations (for children without written records), or due to limited sample sizes limit the reliability of estimates from coverage surveys (Cutts et al., 2016; Mitchell et al., 2013) (Table 3).

Table 3. Strengths and limitations of the different methods to measure vaccination coverage

Method	Type of measurement	Strengths	Limitations
Electronic registries	Direct	• Can give accurate information on the vaccination status of individuals and populations • Can be used to set appointments and issue reminders • Reduces time spent on paper registers	• Requires good computer access • Requires a complete birth registry to calculate population denominators • Difficult to track vaccinations among migrants • Requires adequate funding and human resources
Administrative reports	Indirect	• Simple to set up • Allows monitoring of vaccination coverage through the year and by district or health facility • Can be used to track coverage and dropouts at the local level	• Population are denominators often inaccurate • Private sector vaccinations not reported • Exaggeration of administered doses possible • Transcription errors possible at the various levels of aggregation
Surveys	Indirect	• Can provide accurate information if well-conducted • Other indicators such as missed opportunities can be assessed • Large-scale surveys can be run for multiple programs to reduce costs	• Sampling frame for surveys often based on outdated census information • High-risk subgroups such as migrants may be missed • Home-based records may be missing or incomplete, accuracy of verbal history varies • Small samples give imprecise results

Source: (V. Mitchell et al., 2013)

2.2 The Universal Immunization Program (UIP) in India

2.2.1 Introduction, implementation, and vaccine antigens

India launched its EPI in 1978, aiming to reduce the morbidity and mortality due to diphtheria, tetanus, pertussis, poliomyelitis, and tuberculosis by vaccinating all eligible children and pregnant women by 1990 (Vashishtha & Kumar, 2013). The annual incidence of vaccine-preventable diseases (VPDs) such as tuberculosis (102 cases per 100,000 people) and pertussis (48.7 per 100,000 people) was exceptionally high prior to the launch of the Indian EPI (Basu, 1980). Despite the high incidence of VPDs, only 7.9% of eligible children and 6.8% of pregnant women received two doses of DPT and TT vaccination, respectively, based on reported data during 1975-76 (Basu, 1980). While the EPI aimed to improve the coverage of recommended vaccines across the country there were reports that EPI vaccines were mainly administered in major hospitals and urban areas, which stalled progress in its early years (Lahariya et al., 2013).

The EPI was converted into the Universal Immunization Program (UIP) in 1985, which aimed to rapidly increase vaccination coverage across India and improve the quality of immunization services available to eligible populations (Sokhey et al., 1989). The UIP initially covered 31 districts but planned to systematically expand its services to cover all Indian districts by 1990 (Sokhey et al., 1989). The UIP also focused on establishing reliable cold chain systems at health facilities, promoting district-level monitoring and evaluation of programs, and achieving self-sufficiency in producing the recommended vaccines (Lahariya et al., 2013). The program initially recommended that infants receive three doses of DPT and OPV (with one-month intervals between doses), one dose of BCG between 3 – 9 months of age, and a measles dose during 9 – 12 months of age (Basu, 1980). Under the UIP, it was also recommended that pregnant women receive three doses of TT, beginning at the 16th week of pregnancy and with one-month intervals between the doses (Basu, 1980).

For nearly two decades, the UIP primarily focused on increasing the coverage of four vaccines (BCG, DPT, OPV, and Measles) to protect infants against six VPDs (Vashishtha & Kumar, 2013). Newer vaccines such as Hepatitis B, a second dose of measles, and Japanese Encephalitis (in endemic districts) were introduced during 2006 – 10 (Lahariya et al., 2013). In 2011, the UIP introduced the pentavalent vaccine (a combination vaccine against diphtheria, pertussis, tetanus, hepatitis B, and

Hib) with support from the GAVI Alliance (Lahariya et al., 2013). The pentavalent vaccine was expected to reduce the morbidity and mortality associated with Hib disease among children under five years of age in India (Bairwa, Pilania, et al., 2012). Between 2015 and 2018, the UIP added many vaccines, including the IPV, Rotavirus, Measles-Rubella, and PCV vaccines, to the existing schedule (Malik et al., 2019; Varghese et al., 2019; Vashishtha et al., 2016; Winter et al., 2018). The introduction of the Rotavirus vaccine in India was considered a landmark achievement as this was the first time a low-cost indigenous vaccine was developed and distributed nationally (Malik et al., 2019). Currently, the UIP provides free childhood vaccines against twelve VPDs, including tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus, hepatitis B, Hib, rotavirus diarrhea, Japanese Encephalitis, measles, rubella, and pneumococcal pneumonia (Ministry of Health and Family Welfare, 2018a) (Table 1).

2.2.2 UIP progress over the years

2.2.2.1 Vaccination coverage

National coverage of the BCG, DPT, and OPV vaccines among infants increased rapidly during the first decade of the Indian EPI (Sokhey et al., 1989). By 1986, estimated vaccination coverage in India was comparable to average levels in South-East Asia and other WHO regions based on information from the Global EPI information system (Sokhey et al., 1989). For instance, DPT3 coverage during 1986-87 was 57% in India, compared with 48% in the South-East Asian region, 59% in the Eastern Mediterranean region, 61% in the Western Pacific Region, and 32% in the Africa region (Sokhey et al., 1989). On the other hand, measles vaccination coverage among infants in India was much lower (16%) during 1986-87; this was primarily because the measles vaccine was newly added to the existing schedule in 1985 (Sokhey et al., 1989; Vashishtha & Kumar, 2013). The WUENIC (based on data reported by the national government and administrative surveys) for India revealed a steady increase in the coverage of all four childhood vaccine antigens (BCG, DPT, OPV, and measles) nationally during 1985-95, with declining coverage in the years immediately following this period (1996 – 2002) (See Figure 1) (WHO & UNICEF, 2020).

The first National Family and Health Survey (NFHS-1), conducted during 1992-93, provided subnational estimates of childhood vaccination coverage and other health indicators. The proportion of fully vaccinated children (children aged 12-23 months who received one dose of BCG and measles and three doses of DPT and OPV) during 1992-93 was as high as 75% for the state of Goa and 65% for Tamil Nadu, and as low as 4% for Nagaland and 10% for Meghalaya (IIPS, 1995). The large inter-state variations in childhood vaccination coverage pointed to possible differences in UIP functioning, demand for vaccines, and other social barriers at the level of the states (Pande & Yazbeck, 2003). The NFHS surveys were rerun during 1998-99 (NFHS-2), 2005-06 (NFHS-3), and 2015-16 (NFHS-4), making it possible to track vaccination coverage over time. An analysis of data from NFHS 1-3 (1992 – 2006) found persisting disparities in vaccination coverage levels between Indian states and broader geographic regions over time (P. K. Singh, 2013). Other national surveys, such as the District Level Household Survey (DLHS), were designed to provide disaggregated health indicator data at the district level. A study analyzing data from DLHS-3 (2007-08) found wide district-level disparities in DPT3 and measles vaccination coverage in well-performing states (>80% measles and DPT3 vaccination coverage) such as Punjab, Tamil Nadu, and Karnataka, which is concerning (Rammohan & Awofeso, 2015).

The most recent WUENIC estimates for India reveal that the coverage of older UIP vaccines (BCG, DPT, OPV, and measles) increased gradually between 2003 and 2019 (Figure 1) (WHO & UNICEF, 2020). For example, DPT3 (or pentavalent vaccine) coverage among children aged 12-23 months nationally increased from 61% in 2003 to 91% in 2019, and measles vaccination coverage increased from 60% to 95% in the same period (WHO & UNICEF, 2020). However, there were sharper increases in the coverage of newer vaccines like the IPV (47% in 2016 to 82% in 2019) and rotavirus (4% in 2016 to 53% in 2019) vaccines since their introduction into the UIP schedule (WHO & UNICEF, 2020). In addition, the latest NFHS survey (NFHS-5, 2019-20) reports a DPT3 and measles vaccination coverage of above 80% for most Indian states (with available data), except Nagaland, Meghalaya, and Manipur (IIPS, 2020).

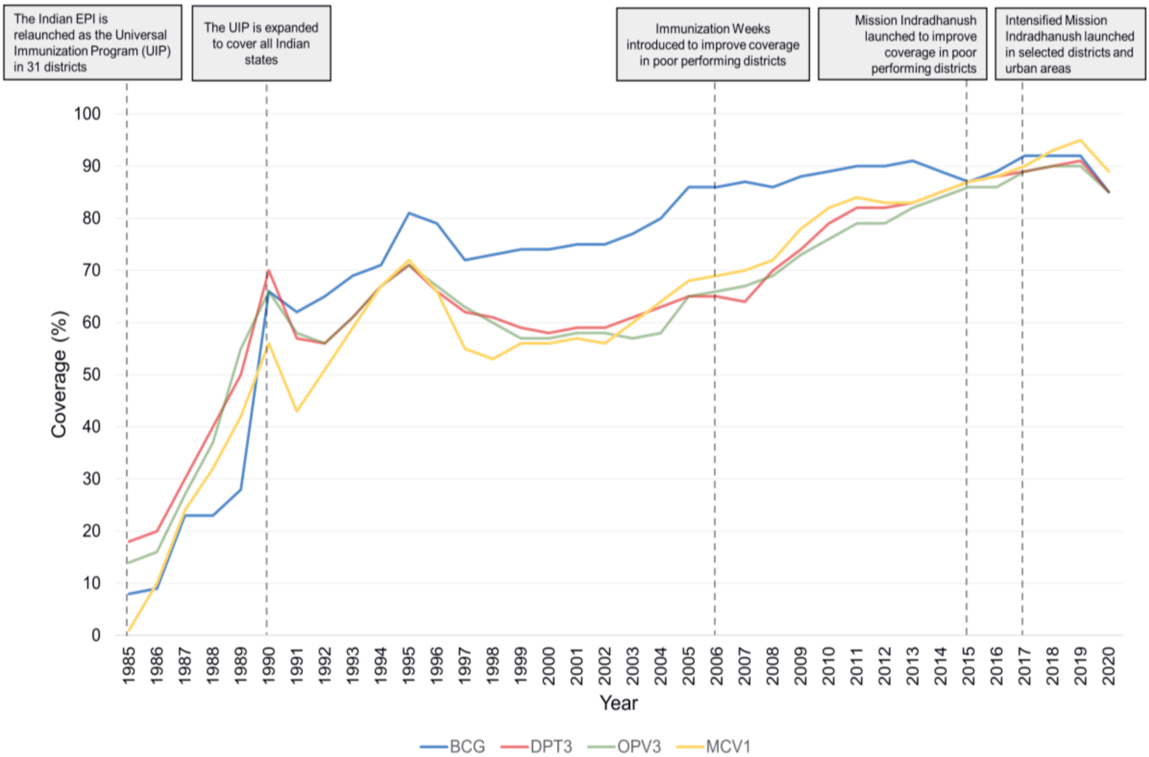

Figure 1. Routine childhood vaccination coverage (WUENIC estimates) and key UIP interventions in India, 1985-2020

2.2.2.2 Polio eradication and maternal and neonatal tetanus elimination

The Government of India (GOI) adopted the World Health Assembly (WHA) resolution to eradicate polio by 2000 in 1988 (Lahariya et al., 2013) (Table 4). The coverage of three doses of OPV (OPV3) among infants was nearly 80% in 1990, but there was an urgent need for systematic nationwide polio surveillance to measure and monitor the disease burden (John & Vashishtha, 2013). The southern Indian states of Tamil Nadu and Kerala were among the first to conduct intensive state-wide polio vaccination campaigns between 1993 and 1994 (Lahariya et al., 2013). These efforts were followed by nationwide supplementary immunization campaigns targeting children under the age of five years between 1995 and 1999, called "national immunization days" or "pulse polio immunization" (John & Vashishtha, 2013; Lahariya et al., 2013). Active surveillance for acute flaccid paralysis (AFP) in

India was initiated in 1996 by the National Polio Surveillance Project (NPSP), a collaborative initiative by the GOI and WHO (Banerjee et al., 2000). The NPSP reported 13,917 AFP cases nationally during 1998-99, of which 4,990 cases were confirmed as polio (Banerjee et al., 2000).

India failed to achieve the WHA polio eradication target in 2000 and was one of six countries globally to have sustained wild poliovirus transmission (John & Vashishtha, 2013). Sub-national immunization campaigns in states with low OPV coverage and house-to-house vaccination of missed children were added to bolster national polio eradication efforts in 2000 (John & Vashishtha, 2013). By 2001, wild poliovirus (WPV) circulation was mainly limited to two large Indian states – Bihar and Uttar Pradesh, which also had the lowest OPV coverage in the country (John & Vashishtha, 2013). During 2003 and 2005, the GOI introduced several strategies to improve OPV coverage, including the use of intensive community mobilization through the Social Mobilization Network and "transit vaccination" targeting the children of seasonal migrant workers at bus stands, railways stations, market places and other congregational sites (Bahl et al., 2014). In 2005, monovalent OPV vaccines (type 1 and 3) were licensed for use in supplementary immunization campaigns and specific eradication efforts in polio-free states due to their higher efficacy than the trivalent OPV vaccine widely in use (Bahl et al., 2014; John & Vashishtha, 2013). These monovalent OPV vaccines significantly reduced the incidence of WPV type 1 but the incidence of WPV type 3 increased until bivalent OPV (type 1 and 3) vaccines were introduced nationally in 2010 (Bahl et al., 2014). India's last WPV type 3 case was reported in 2010, and the last WPV type 1 case was reported in 2011 (Lahariya, 2014). The WHO removed India from the list of polio-endemic countries in 2012, and the South East Asia Region (to which India belongs) was officially certified polio-free in 2014 (Bahl et al., 2014) (Table 4). The UIP added the IPV to the existing schedule during 2015-16 to reduce the incidence of vaccine-associated paralytic polio and to boost population immunity against WPV type 2 (Vashishtha et al., 2016).

Another significant milestone for the UIP in India was its contribution to maternal and neonatal tetanus elimination. The GOI introduced two doses of TT vaccine for all pregnant women as a part of its national neonatal tetanus elimination strategy in 1983 (Bairwa, S.K., et al., 2012). The coverage of TT vaccination during pregnancy (at least two doses) increased gradually in the 1980s to nearly 40% in 1987 (Sokhey et al., 1989). In the early 1990s, the government began prioritizing districts based on TT vaccination coverage, neonatal incidence rates, and the proportion of deliveries attended by skilled personnel to accelerate India's progress towards NT elimination (Annadurai et al., 2017). The coverage of TT vaccination among pregnant women increased significantly in the 1990s; NFHS-1 reported a national coverage (at least two doses of TT during pregnancy) of 55% during 1992-93 and 67% during 1998-99 (NFHS-2) (IIPS, 2000, p. 2). Despite this progress, India was listed among the 57 priority countries for the renewed global target of maternal and neonatal tetanus elimination set for 2005 (Roper et al., 2007). Unfortunately, India did not achieve the 2005 global tetanus elimination target. However, the GOI continued to promote safe deliveries under the National Rural Health Mission and strengthen routine immunization services (especially to underserved and unreached regions) in the late 2000s (Sidhu et al., 2016). By 2012, nearly half the Indian states were validated to have eliminated maternal and neonatal tetanus (Verma & Khanna, 2012). Nationally, neonatal tetanus cases decreased from 11,849 cases in 1988 to 492 cases in 2014 (a 96% reduction in NT cases) (Sidhu et al., 2016). The WHO declared India free of maternal and neonatal tetanus in 2015, following nearly three decades of concerted national and subnational efforts (Cousins, 2015).

Table 4. Important milestones of the Indian UIP since its launch

Year	Milestone
1978	Expanded Program on Immunization (EPI) launched in India
1985	The EPI was converted into the Universal Immunization Program (UIP), initially covering 31 districts/ Measles vaccination added to national schedule
1988	The Government of India (GOI) adopts the World Health Assembly resolution to eradicate polio by 2000
1990	The UIP is expanded to cover the entire country
1995-96	National Immunization Days for polio eradication launched and acute flaccid paralysis (AFP) surveillance initiated with support from the WHO
2006	First "immunization weeks" conducted to improve coverage with UIP antigens in poor-performing districts
2006-10	Hepatitis B, second dose of measles and Japanese Encephalitis vaccines introduced
2011	Last wild poliovirus case reported from India
2014	India officially certified "polio-free" by the WHO/Mission Indradhanush campaign launched by the GOI targeting poor-performing districts

2015	The WHO declares India free of maternal and neonatal tetanus
2015-18	Indigenously developed rotavirus vaccine and the pentavalent, IPV, measles-rubella, and PCV vaccines added to the UIP schedule
2017	Intensified Mission Indradhanush launched by the GOI to target all children missed in the four phases of MI

Source: (Lahariya, 2014; Ministry of Health and Family Welfare, 2018a)

2.2.2.3 Other UIP achievements

From its early years, the UIP focused on strengthening the surveillance of vaccine-preventable diseases in India (Lahariya, 2014). Measuring and tracking the disease burden due to vaccine-preventable diseases required robust surveillance systems. The GOI launched India's Integrated Disease Surveillance Program (IDSP) in 2004 to detect and respond to disease outbreaks (Ministry of Health and Family Welfare, 2018a). The IDSP is a network of surveillance units established at the state and district levels that routinely collect and compile data on vaccine-preventable diseases such as Acute Encephalitis Syndrome, diphtheria, measles, rubella, and AFP (Ministry of Health and Family Welfare, 2018a). Another national surveillance network, the NPSP, initially set up for laboratory-based AFP surveillance, now conducts surveillance for measles and rubella outbreaks across the country (Ministry of Health and Family Welfare, 2018a). In addition, the National Rotavirus Surveillance Network was initiated in 2005 to estimate and monitor the burden of rotavirus disease among children under five years of age hospitalized due to diarrhea (Ministry of Health and Family Welfare, 2018a). This hospital-based surveillance network supported the phased introduction of the rotavirus vaccine in India and provided an opportunity to assess the impact of vaccination on the rotavirus disease burden among young children (Mehendale et al., 2016).

India is a major global vaccine manufacturer and exporter, with nearly 43% of the global EPI vaccines sourced from indigenous manufacturers (Vashishtha & Kumar, 2013). Several new vaccines have been developed and licensed for use in India in recent years, such as bivalent oral cholera, meningitis A, typhoid conjugate, and rotavirus vaccines (Lahariya, 2014). Of special mention is the indigenously developed rotavirus vaccine added to the UIP schedule in 2016 (Malik et al., 2019). The rotavirus vaccine was developed through the Indo-US Vaccine Action Program, which supported an Indian manufacturer, Bharat Biotech International Ltd., to formulate vaccines based on two strains (116E and I321) (Kang, 2016). The 116E strain was found to seroconvert more than 80% of children in phase II trials and was selected to continue into phase III trials (Kang, 2016). The indigenously developed ROTAVAC (116E) was reported to have a 55% efficacy, comparable to the performance of other licensed vaccines in developing countries (Bhandari et al., 2014). Data from the first two phases of the national rotavirus surveillance network (2005-09 & 2012-14) revealed that rotavirus caused a significant proportion (~40%) of hospitalizations due to acute gastroenteritis in young children (Mehendale et al., 2016). These data, along with several other factors, including the availability of an affordable vaccine, evidence of the cost-effectiveness, and other aspects of vaccine introduction, led to the phased introduction of the rotavirus vaccine in India in 2016 (Kang, 2016) (Table 4).

2.2.3 Monitoring UIP performance

2.2.3.1 Indicators of immunization program performance in India

The Indian EPI (as it was called in the 1970s) assessed program performance by reviewing vaccination coverage estimates among eligible children and pregnant women and reports on the incidence of target diseases in its early years (Basu, 1980). Updated and reliable data on the incidence of the EPI target diseases were lacking and based on passive reporting (from hospital-based surveillance) in the 1980s (Sokhey et al., 1989). Large sample surveys were conducted across the country in the 1980s to measure the incidence of poliomyelitis and neonatal tetanus (Sokhey et al., 1989). Vaccination coverage was mainly estimated using administrative reports of the numbers of doses administered to eligible children and pregnant women (Sokhey et al., 1989). Numerous coverage evaluation surveys were conducted in the 1980s to independently assess vaccination coverage levels and suggest ways to improve program operations (Sokhey et al., 1989).

Vaccination coverage became the preferred indicator of UIP program performance in the absence of a robust surveillance system for vaccine-preventable diseases (Vashishtha & Kumar, 2013). Most UIP targets aimed to achieve high coverage of the recommended vaccines among beneficiaries in specific periods (Sokhey et al., 1989). The coverage of two doses of TT vaccination among pregnant women and DPT3 coverage among infants were indicators of particular interest in the 1980s

(Basu, 1980; Sokhey et al., 1989). Coverage of the first dose of measles vaccination among infants was another important indicator for tracking the timely delivery and uptake of the measles vaccine, introduced in 1985-86 (Sokhey et al., 1989). During 1991-93, coverage evaluation surveys reported the proportions of "fully immunized children," based on EPI recommendations as children aged 12-23 months who received three doses of DPT and OPV and one dose of BCG and measles vaccination (Mehra et al., 1990; B. Mukherjee et al., 1990; J. Singh et al., 1996). The two NFHS surveys conducted in the 1990s reported full immunization coverage as one of the primary indicators of the performance of the district- and state-level health programs (IIPS, 1995, 2000). Full immunization coverage is currently a widely used indicator of UIP performance in administrative, demographic and health, and other population-based surveys across the country (Devasenapathy et al., 2016; Government of India, 2015; Kusuma et al., 2010; Murhekar et al., 2017; Shrivastwa et al., 2015; P. K. Singh, 2013).

Other indicators such as dropouts between early and final doses in the primary vaccination series for infants were reported in independent evaluations of UIP performance in the 1990s (Mehra et al., 1990; B. Mukherjee et al., 1990). Most studies estimate dropouts between the DPT1/OPV1 and DPT3/OPV3 doses (Ghosh & Laxminarayan, 2017; Mehra et al., 1990; B. Mukherjee et al., 1990; Yadav & Shekhar, 2013). The UIP currently promotes supplemental research and strategic planning to assess and decrease the proportion of dropouts at the district and state levels as part of its "Comprehensive multi-year plan" to ensure high full immunization coverage levels (Ministry of Health and Family Welfare, 2018a). More recently, studies have evaluated the timeliness of childhood vaccines delivered in the UIP using data from the NFHS and DLHS surveys (Awofeso et al., 2013; Choudhary et al., 2019; Shrivastwa et al., 2015). These studies report significant delays in administering UIP vaccines across the Indian states, especially for the DPT3 and measles doses (Awofeso et al., 2013; Shrivastwa et al., 2015). While not a widely used performance indicator, researchers have called for its inclusion as a core indicator to monitor UIP performance nationally (Awofeso et al., 2013; Choudhary et al., 2019; Shrivastwa et al., 2015).

2.2.3.2 Methods to monitor immunization program performance in India

Vaccination coverage in India is estimated through indirect methods using information from administrative reports or community surveys (Basu, 1980;

Bhatnagar et al., 2016; Sokhey et al., 1989). Administrative coverage estimates are available annually; however, their reliability depends on an accurate recording of the number of doses administered by health workers (numerator data), the availability of updated information on the target population size (denominator data), and the prompt transfer of data across the various levels of aggregation (Bhatnagar et al., 2016). The quality of administrative data is variable across different states, and these data either underestimate the true vaccination coverage due to a lack of data from private practitioners or overestimate true coverage if vaccines provided to children outside the target age group are added to the numerator for vaccination coverage calculations (Basu, 1980; Ministry of Health and Family Welfare, 2018a; Sokhey et al., 1989). Data quality audits for administrative vaccination coverage estimates are infrequently conducted; one study from a rural district in Gujarat found significant discrepancies between reported and validated coverage (15 – 25% differences) (Ministry of Health and Family Welfare, 2018a; S. V. Patel et al., 2015). Administrative coverage estimates are the primary data source to monitor UIP performance at the state and national levels without regularly updated nationally representative community surveys (Bhatnagar et al., 2016).

Large-scale, nationally representative household surveys such as the NFHS, DLHS, and the Annual Health Survey (AHS) have been conducted periodically since the early 1990s (Dandona et al., 2016). These surveys collect information on various health indicators, including childhood immunization, at the state and district levels in India (Ministry of Health and Family Welfare, 2018a). Vaccination histories are collected for the latest two to five children born to ever-married (in the NFHS & AHS surveys) or currently-married (DLHS) women aged 15-49 years during the time of the survey (Dandona et al., 2016). Information on specific vaccinations is either recorded from vaccination cards (if available during the survey) or a caregiver's recall of the doses (IIPS, 2000, 2006). Vaccination coverage is generally estimated for the youngest child or the two youngest children aged 12 months or older during the survey (Bhatnagar et al., 2016; Pande & Yazbeck, 2003; Shrivastwa et al., 2015; P. K. Singh, 2013). As is standard practice for the EPI cluster surveys, coverage estimates from the demographic and health surveys are presented by combining information from vaccination cards and caregiver recall and separately for information from vaccination cards (Bhatnagar et al., 2016; Chandran et al., 2011; Kusuma et al., 2010). The UNICEF Coverage Evaluation Surveys (CES) were designed to evaluate maternal and child health programs, including information on specific aspects of immunization such as accessibility, availability, and utilization of immunization services at the state and national levels (UNICEF, 2010). Despite their benefits, nationally representative surveys are resource-intensive, infrequent, and not designed to provide rapid information to monitor program performance (Bhatnagar et al., 2016). Smaller population-based coverage surveys are also conducted to estimate vaccination coverage in specific regions (or communities) or for newly introduced vaccines or to assess the impact of interventions to improve vaccination uptake (Devasenapathy et al., 2016; Kusuma et al., 2010, 2018; Murhekar et al., 2017; Varma & Kusuma, 2008).

It is often complicated to compare vaccination coverage estimates from administrative and population-based surveys and monitor coverage trends over time using one or more vaccination data sources (Bhatnagar et al., 2016). However, examining vaccination coverage trends helps monitor program performance at various levels to identify areas that may require additional resources and guide the eradication or control of vaccine-preventable diseases (Burton et al., 2009). The WUENIC methodology combines administrative and survey-based coverage estimates to produce annual estimates that qualitatively consider potential biases from the data sources (Burton et al., 2009). The WUENIC estimates for India provide national vaccination coverage trends for nearly four decades (WHO & UNICEF, 2003, 2020). A recent study has published annual state-level estimates for India during 1999-2013, combining administrative and survey-based data using the WUENIC methodology (Bhatnagar et al., 2016). The Government of India used these estimates to assess the performance of the UIP in 2015, and the methodology will facilitate future estimations of district-level vaccination coverage within individual states (Bhatnagar et al., 2016).

2.2.4 Introduction and implementation of the Mission Indradhanush campaign

The GOI launched the Mission Indradhanush (MI) campaign in December 2014 to fully vaccinate at least 90% of children in India by 2020 (Ministry of Health and Family Welfare, 2016). This decision was based on numerous reports of persistently low full vaccination coverage (~65%) among Indian children despite over three decades of functioning of the UIP (Ministry of Health and Family Welfare, 2016). This estimate entails that annually, nearly 7 million children do not receive all the vaccines currently available under the UIP in India (Ministry of Health and Family Welfare, 2016). The MI campaign built on the success of India's polio eradication program and targeted children in high-risk, hard-to-reach, and underserved communities (Ministry of Health and Family Welfare, 2016). The specific objectives of the MI campaign were to improve the demand for immunization services, enhance political, administrative, and financial commitment to the UIP and ensure that all unvaccinated and partially vaccinated children were fully vaccinated based on UIP recommendations (Ministry of Health and Family Welfare, 2016).

Indian districts were categorized into high, medium, and low-focus districts based on their immunization coverage and the number of unvaccinated children (Ministry of Health and Family Welfare, 2016). The MI campaign was initially conducted in four phases; Phase 1 targeted the high-focus districts (201 districts) during April and July 2015, phase 2 targeted a mix of high- and medium-focus districts (352 districts) during October 2015 and January 2016, phase 3 targeted 216 districts that were part of phases 1 and 2 during April and July 2016, and phase 4 targeted 254 districts from phases 1, 2 and 3 during February to July 2017 (Ministry of Health and Family Welfare, 2016). These campaigns targeted "high-risk" areas within the selected districts identified during the national polio eradication drive (Ministry of Health and Family Welfare, 2016). The high-risk areas included urban slums, nomadic sites, brick kilns, construction sites, migrant settlements, and hard-to-reach populations such as forest-dwelling or tribal populations (Ministry of Health and Family Welfare, 2016). Special, week-long fixed and outreach immunization sessions were held as part of the Mission Indradhanush campaign within the high and medium-focus districts (Ministry of Health and Family Welfare, 2016). These immunization sessions were conducted by frontline workers such as the auxiliary nurse midwives (ANMs), who were also responsible for communication and social mobilization efforts (Ministry of Health and Family Welfare, 2016). Task forces were set up at the state and district levels to periodically monitor the status of the immunization sessions, identify programmatic gaps, and develop strategies to improve vaccination coverage based on local needs (Ministry of Health and Family Welfare, 2016).

Administrative reports suggested that full vaccination coverage among children aged 12-23 months increased by an average of 7% across the districts selected for the first two phases of Mission Indradhanush (Ministry of Health and Family Welfare, 2018a). However, even though this increase in vaccination coverage was significant, the annual increase in coverage was not considered sufficient to achieve the MI goal of fully vaccinating at least 90% of Indian children by 2020 (Ministry of Health and Family Welfare, 2018a). Therefore, the GOI launched the Intensified Mission Indradhanush (IMI) campaign in October 2017, aiming to target the children missed in the four phases of MI (Ministry of Health and Family Welfare, 2018c). Particular priority was given to urban areas, as administrative reports suggested that rural areas had a significantly higher increase in full vaccination coverage than urban areas after the first two phases of MI (7.9% versus 3.1%, respectively) (Ministry of Health and Family Welfare, 2018a). The IMI campaign employed a similar strategy to MI; however, it included a more rigorous listing of children due for vaccines, identified through surveys, intensive planning and implementation of need-based interventions to improve vaccination coverage, and improved mobilization of resistant families and communities by facilitating partnerships with non-health sector organizations and influencers (Ministry of Health and Family Welfare, 2018c). The IMI covered 170 districts and 17 cities in four rounds conducted between October 2017 and January 2018 across India (Ministry of Health and Family Welfare, 2018c). The progress of IMI was monitored through district and state task forces along with EPI cluster surveys in the selected districts at the end of the fourth round of IMI (Ministry of Health and Family Welfare, 2018c). Key programmatic aspects of the MI and IMI campaigns are summarized in Table 5.

Table 5. Comparison of the Mission Indradhanush and Intensified Mission Indradhanush campaigns

	Mission Indradhanush	Intensified Mission Indradhanush
Primary aim	To fully vaccinate all infants by 2020	To fully vaccinate all infants by 2018
Campaign period	April 2015 - July 2017	October 2017 - January 2018
Selection of districts	Districts with lowest full vaccination coverage and districts with intermediate coverage (528 districts across India)	Districts and areas with <70% coverage full vaccination coverage after the first MI campaign (173 districts and 17 urban areas across India)
Phases	Four phases, each consisting of four monthly catch-up sessions, lasting 1 week each	One phase with four monthly catch-up sessions, each lasting 1 week
Key programme aspects	• Improved microplanning, monitoring, social mobilization and strengthened vaccination systems • All vaccines under the routine immunization schedule offered to children ≤ 2 years and pregnant women	• Rigorous headcounts for tracking and identifying children ≤ 2 years and pregnant women • More intensive planning and monitoring of vaccination systems • Greater involvement of non-health sector organizations to mobilize resistant families

Source: (Gurnani et al., 2018)

2.3 Factors associated with childhood vaccination uptake

2.3.1 Description of the factors associated with childhood vaccination uptake

A wide range of factors influences whether children are vaccinated or not. Understanding the drivers of vaccination uptake helps assess the performance of immunization programs and address deficiencies in service delivery through robust and evidence-based interventions (LaFond et al., 2015; Thomson et al., 2016). The Global Vaccine Action Plan (GVAP, 2011-20) and the Immunization Agenda 2030 emphasize the need for countries to identify the drivers of vaccination uptake to reduce subnational inequities, better engage communities and encourage greater use of immunization services (WHO, 2013, 2020). Broadly, the numerous factors influencing vaccination uptake can be categorized as "supply-side" or "demand-side" factors (Cooper, Okeibunor, et al., 2019). These are discussed in greater detail in the subsequent subsections.

2.3.1.1 Supply-side factors

The supply-side factors cover immunization system-related issues such as the availability of and access to immunization services, attitudes and behavior of healthcare workers to parents or caregivers, and the quality of vaccines and routine vaccination services (Jheeta & Newell, 2008; Streefland et al., 1999). Ensuring equitable access to quality vaccines was a core objective of the EPI, reflected in the GVAP and Immunization Agenda 2030 (WHO, 2013, 2020). Several studies, especially from LMICs, highlight supply-side issues such as canceled immunization sessions due to vaccine stockouts, cold chain failures or absence of staff, and missed opportunities to vaccinate children who attend health centers due to concerns about vaccine wastage or false contraindications to vaccination, as important availability-related barriers to children completing the primary immunization series (V. Mitchell et al., 2013). Research examining access-related issues generally reports the distance of households or communities to health centers and geographic barriers such as mountains or rivers as important reasons for inequitable access to childhood vaccines in LMICs (Glatman-Freedman & Nichols, 2012; Thomson et al., 2016). Bad experiences during previous immunization sessions, due to discourteous treatment by healthcare workers or fear of being reprimanded if a child's vaccination record was lost or damaged, have been listed as important barriers from LMICs and other countries (V. Mitchell et al., 2013). Opportunity costs such as lost earnings or time incurred by parents also influence childhood vaccination uptake (Jheeta & Newell, 2008; Thomson et al., 2016). Immunization programs may fail to consider the convenient location and timing of sessions, resulting in reduced uptake or delayed vaccinations for children (Jheeta & Newell, 2008).

2.3.1.2 Demand-side factors

The demand-side factors cover a range of individual (child- and parent-specific) and household characteristics that are likely to influence childhood vaccination uptake (Favin et al., 2012; Glatman-Freedman & Nichols, 2012; Jheeta & Newell, 2008). Child characteristics such as age, gender, birth order, and place of delivery are associated with suboptimal vaccination uptake in LMICs (Rainey et al., 2011; Tauil et al., 2016). Parental characteristics, including their level of education or literacy, socio-economic status, type of occupation, religious affiliation, health-seeking behavior, maternal age, and decision-making power, are reported to influence childhood vaccination uptake in a wide range of settings (Glatman-Freedman & Nichols, 2012; Rainey et al., 2011; Tauil et al., 2016). In addition, knowledge and attitude-related parental characteristics such as awareness of the need for vaccines and disease prevention, perceptions of adverse events from vaccination, trust in the government or health care system, and vaccine-specific perceptions, including preferences for natural immunity or their stance regarding combination or multiple vaccines have been reported as influencing vaccination uptake by many studies in developed countries and LMICs (Rainey et al., 2011; L. E. Smith et al., 2017; Tauil et al., 2016). Other household or family characteristics like family size and composition, urban or rural residence, and ethnicity have also been linked to childhood vaccination uptake in developing countries (Favin et al., 2012; V. Mitchell et al., 2013; Rainey et al., 2011). Understanding the demand-side factors linked to vaccination uptake can help identify the families to be targeted by contextual interventions (V. Mitchell et al., 2013).

Table 6. List of factors associated with childhood vaccination uptake

Supply-side factors

Availability of vaccination services

- Canceled sessions (vaccine stockouts, cold chain failure or staff absence)
- Missed opportunities to vaccinate children (concerns about vaccine wastage, false contraindications to vaccination)

Access to vaccination services

- Distance of households to health centers (including travel difficulties)
- Other geographic barriers (rivers, mountains)

Attitudes and behavior of healthcare workers

- Bad experiences during previous immunization sessions (discourteous treatment by healthcare workers or parent's fear of being reprimanded)

Other factors

- Opportunity costs (lost earnings or time due to inconveniently planned vaccination sessions)

Demand-side factors

Individual

- Child-specific characteristics (age, gender, birth order)
- Parental characteristics (age, education, employment, socioeconomic status, religious affiliation, mothers decision-making autonomy, attitudes towards and awareness about vaccines, and information- and health-seeking behaviour)

Household or family

- Family size
- Family composition or type (nuclear, extended or mixed)
- Urban or rural residence
- Ethnicity or caste

Sources: (Glatman-Freedman & Nichols, 2012; Jheeta & Newell, 2008; V. Mitchell et al., 2013; Rainey et al., 2011; Tauil et al., 2016; Thomson et al., 2016)

2.3.2 Study designs and instruments to evaluate the factors associated with childhood vaccination uptake

2.3.2.1 Study designs

When low vaccination coverage is observed in specific regions, it is crucial to investigate the reasons for the suboptimal coverage through different data sources and methods. Information on potential supply- or demand-side barriers can be obtained from secondary data sources such as previous program reviews or direct observations of vaccination practices at immunization centres, discussions with health workers, or community meetings (V. Mitchell et al., 2013). There may be a need for more in-depth evaluations to investigate the reasons for incomplete childhood vaccination through supplementary research. Using a mixture of direct observations and interviews with health providers and mothers, health facility-based surveys can evaluate dropout rates and missed opportunities for vaccination and assess provider knowledge and practices relating to vaccination (V. Mitchell et al., 2013). Quantitative studies (including cross-sectional surveys and case-control or cohort studies) may be needed to assess the factors associated with vaccination uptake by comparing vaccinated and unvaccinated children (V. Mitchell et al., 2013). The EPI coverage surveys, the UNICEF Multiple Indicator Survey (MICS), and DHS surveys are well-known examples of cross-sectional surveys that include components to assess vaccination coverage and the reasons for incomplete childhood vaccinations in a variety of settings (Cutts et al., 2013; V. Mitchell et al., 2013; World Health Organization, 2008). Qualitative evaluations can be performed independently or combined with quantitative studies to evaluate the knowledge and attitudes of health providers and parents (or communities) towards childhood vaccination (V. Mitchell et al., 2013).

Three recent systematic reviews report that most studies assessing the factors associated with childhood vaccination uptake used quantitative methods. The proportion of quantitative studies in these reviews from Southeast Asia, Africa, and Latin America were 100%, 86%, and 79%, respectively (Galadima et al., 2021; Guzman-Holst et al., 2020; Kalaij et al., 2021). Of the quantitative studies in the three systematic reviews, cross-sectional surveys were the most frequently included. The proportion of cross-sectional studies were 94%, 82%, and 64% in the reviews from Southeast Asia, Africa, and Latin America, respectively (Galadima et al., 2021; Guzman-Holst et al., 2020; Kalaij et al., 2021). Few studies in these reviews utilized qualitative or mixed-methods research. The systematic review from Latin America had the highest proportion (16%) of qualitative studies, and the review from Africa had the highest proportion (8%) of mixed-methods (employing both quantitative and qualitative methods) studies (Galadima et al., 2021; Guzman-Holst et al., 2020; Kalaij et al., 2021).

2.3.2.2 Study instruments

The EPI coverage survey guidelines recommend a standard questionnaire administered to parents, which captures information on children's age and gender, along with their vaccination histories (from vaccination cards or parental recall) and the reasons for incomplete vaccination (if applicable) (World Health Organization, 2008). This questionnaire was designed to be short to reduce the likelihood of interviewee fatigue during coverage surveys (World Health Organization, 2008). Numerous studies have utilized these questionnaires to estimate childhood vaccination coverage and investigate the reasons for non-vaccination in different settings (Cutts et al., 2013, 2016). Extended versions of the EPI questionnaire have included questions on parental knowledge, attitudes, and practices relating to childhood vaccinations and indicators relevant to other health programs (World Health Organization, 2018). Some studies from Africa and other LMICs use a combination of items from the EPI coverage survey and DHS questionnaires to evaluate a range of individual and household factors that may be associated with childhood vaccination uptake (Legesse & Dechasa, 2015; Mansour et al., 2019; Shrestha et al., 2016; Tefera et al., 2018). Community-based studies from India generally include specific questions adapted from the NFHS or other national surveys or based on previous literature, covering socio-demographic characteristics (child, parent, and household characteristics), parent's or caretaker's knowledge, attitudes, and beliefs about childhood vaccinations, and health care utilization (Awasthi et al., 2015; Chhabra et al., 2007; Devasenapathy et al., 2016; Kusuma et al., 2018; B. Mukherjee et al., 1990; Murhekar et al., 2017).

Efforts have been made to measure better parental attitudes, beliefs, and behavior towards childhood vaccinations. A recent systematic review reported that the most commonly used survey tool to measure parental attitudes and beliefs towards childhood vaccinations globally is the parental attitudes about childhood vaccines (PACV) survey tool (Dyda et al., 2020). The PACV survey, designed initially to identify vaccine-hesitant parents during clinic visits in the United States, has since been validated and standardized for use in different settings (Dyda et al., 2020; Opel, Mangione-Smith, et al., 2011). The PACV survey consists of 18 items covering immunization behavior, vaccine safety and efficacy beliefs, attitudes towards vaccine mandates, trust in healthcare workers, and vaccine-related information (Opel, Mangione-Smith, et al., 2011). The previously mentioned systematic review also reported that the "Health Belief Model" (HBM) was the most frequently cited (19%) as guiding questionnaire development in the included studies (Dyda et al., 2020). The HBM relates people's beliefs, particularly their perceived severity and susceptibility to diseases, and the perceived benefits and risks of health interventions such as vaccination, to their health behaviors (Zampetakis & Melas, 2021). Many qualitative studies investigating the determinants of childhood vaccination acceptance use thematic guides or analytical frameworks based on the health belief model and other psychological models of decision-making behavior like the "Theory of Planned Behavior" (Cooper, Schmidt, et al., 2019; Dyda et al., 2020).

2.3.3 Research from LMICs and India

2.3.3.1 Research from LMICs

Several studies have examined the factors potentially linked to childhood vaccination uptake in LMICs. Supply-side factors such as limited or poor access to immunization services are correlated to suboptimal childhood vaccination uptake in studies from sub-Saharan Africa, as well as in recent reports from Lebanon, Afghanistan, Lao People's Democratic Republic (Lao PDR), and Indonesia (Bangura et al., 2020; Mansour et al., 2019; Mugali et al., 2017; Nanthavong et al., 2015; Syiroj et al., 2019). For example, an increasing distance between households and health centers was associated with a sixfold increase in the odds of children being unvaccinated in Lao PDR (Nanthavong et al., 2015). The unavailability of vaccines during scheduled appointments has also been shown to significantly increase the odds of non-vaccination among children in several cross-sectional studies from Nigeria (Adeloye et al., 2017). Poor interactions between health workers and parents are another important supply-side barrier to childhood vaccination uptake reported in studies from Africa and Asia (Bangura et al., 2020; Streefland et al., 1999). While most reported as a barrier in qualitative studies, encountering rude or impatient healthcare workers was associated with a nearly fourfold increase in the odds of children being unvaccinated in Cameroon (Kwedi Nolna et al., 2018).

Parental characteristics such as education levels, especially maternal education, are strongly linked to childhood vaccination uptake in many countries globally (Forshaw et al., 2017; Rainey et al., 2011). A recent global systematic review and meta-analysis reported that the pooled odds ratios for children being fully vaccinated in Africa and Asia increased two- to threefold if their mothers were educated to a secondary level compared with no or primary education (Forshaw et al., 2017). The evidence for associations between parental employment and childhood vaccination uptake in LMICs is contradictory; Children with parents who were employed were less likely to be fully vaccinated (compared with children who had unemployed parents) in studies from Nepal and Kenya and more likely to be fully vaccinated in Bangladesh (Calhoun et al., 2014; Shrestha et al., 2016; Vasudevan et al., 2014). Parent's religious affiliations are also observed to be related to children's vaccination status; A recent study analyzing data from sub-Saharan countries reported that children with Muslim parents (compared with Christian parents) had an increased likelihood of being unvaccinated in six countries - Benin, Chad, Guinea-Bissau, Nigeria, Côte d'Ivoire and Ethiopia (Costa et al., 2020). Maternal decision-making authority is positively associated with children's vaccination status in studies from South Korea, China, Japan, and Nigeria (Antai, 2012; Jung, 2018).

Parental knowledge and attitudes towards childhood vaccines are strongly linked to vaccination uptake in many studies in Asia and Africa (Bangura et al., 2020; Jheeta & Newell, 2008; Rainey et al., 2011). The most frequent knowledge gaps reported in a systematic review focusing on LMICs were related to caregivers' awareness of the need for (or benefits of) vaccination and the importance of disease prevention for their children (Rainey et al., 2011). Although highly correlated with their level of education, parents being aware of the benefits of vaccination was associated with a four- to sixfold increase in the odds of their children being fully vaccinated in studies from Pakistan, Nepal, and Ethiopia (S. Mitchell et al., 2009; Shrestha et al., 2016; Yismaw et al., 2019). Links between social and cultural beliefs regarding childhood vaccines (especially polio vaccines) held by parents and vaccine uptake have been reported in studies from Nigeria and Pakistan (Adeloye et al., 2017; Hennessey et al., 2000; S. Mitchell et al., 2009; Rainey et al., 2011). Parental fears about vaccine side-effects are a frequently reported barrier to childhood vaccination in several studies from sub-Saharan Africa and Asia (Bangura et al., 2020; Jheeta & Newell, 2008; Mugali et al., 2017; Rainey et al., 2011; Shrestha et al., 2016; Syiroj et al., 2019). Confidence in the importance of vaccines was positively associated with childhood vaccination uptake in a large global study (Figueiredo et al., 2020).

2.3.3.2 Research from India

Several national-level studies have reported on the factors potentially linked to childhood vaccination uptake in India. These studies primarily utilize data from the NFHS or DLHS surveys and analyze information from a single or multiple rounds of these surveys. The main supply-side factor reported in these studies pertains to access to routine healthcare services, as indicated by the proximity to and availability of all-weather roads to health facilities, place of delivery, and the frequency of antenatal care visits (Datar et al., 2007; Ghosh & Laxminarayan, 2017; Rammohan & Awofeso, 2015; Sahu et al., 2010). Living close to a government health facility (≤ 3 kilometers), having all-weather road connections to villages, and women who delivered in government or private facilities and made two or more antenatal care visits were all positively associated with children's vaccination status nationally (Sahu et al., 2010). In another study, children delivered in non-institutional settings were reported to have a twofold increase in their odds of being unvaccinated than children delivered in government health facilities (Shenton et al., 2018). Other government services such as the presence of Anganwadis (public childcare centers) and community health workers (such as the ANMs and Accredited Social Health Activists [ASHAs]) have also been positively correlated with DPT vaccination coverage in rural regions of India (Ghosh & Laxminarayan, 2017; Rammohan & Awofeso, 2015).

Most national-level studies examine demand-side factors likely to influence the uptake of childhood vaccines in India. Characteristics of children such as gender and birth order are frequently found correlated to their vaccination status in several studies (Corsi et al., 2009; Mathew, 2012; Prusty & Kumar, 2014; Sahu et al., 2010). For instance, a study analyzing data from three rounds of the NFHS (1992 – 2006) reported significantly lower coverage for the BCG, DPT, and measles vaccines among female children than in males (Corsi et al., 2009). Of the parental factors, maternal characteristics such as age at delivery, education or literacy level, and the number of antenatal care visits are the most commonly reported factors associated with children's vaccination status in several national studies (Ghosh & Laxminarayan, 2017; Mathew, 2012; Shenton et al., 2018; Shrivastwa et al., 2015; Vikram et al., 2012). Children with younger mothers (<19 years) had 1.5 times greater odds of being under-vaccinated compared with children whose mothers were aged 20 years or older in a recent study (Shenton et al., 2018). Another nationwide study found that children with mothers who had any length of schooling (versus children with illiterate mothers) had a significantly lower odds of being unvaccinated using data from DLHS-3 (2007-08) (Shrivastwa et al., 2015). Parents' religious affiliation is also strongly linked to children's vaccination status; Children from Muslim families were found to have 1.5 – 2 times higher odds of being unvaccinated than children from Hindu families (Shenton et al., 2018; Shrivastwa et al., 2015).

Region-specific research studies generally report similar factors associated with childhood vaccination uptake as the studies with a national focus. Children born in government or private facilities were more likely to be fully vaccinated in studies from Delhi, Bihar, and West Bengal (D. Barman & Dutta, 2013; Chhabra et al., 2007; Pandey et al., 2019). Higher maternal education levels (literacy and length of schooling) were reported to be positively associated with children's vaccination status in several studies from different parts of the country (Awasthi et al., 2015; Chhabra et al., 2007; Devasenapathy et al., 2016; Geddam et al., 2018; Kusuma et al., 2010; Pandey et al., 2019). Children with parents who received a regular salary were reported to have 1.5 – 5 times greater odds of being fully vaccinated than children with daily-wage laborer or unemployed parents in previous studies from Delhi and Uttar Pradesh (Awasthi et al., 2015; Chhabra et al., 2007; Kusuma et al., 2010). A few regional studies also present parental factors such as their awareness regarding and perceptions towards childhood vaccines and information- and health-seeking behavior and their correlations with children's vaccination status. Parents' positive perceptions of the effectiveness of childhood vaccines and their proactively asking healthcare workers for information on vaccines were positively associated with children's vaccination status in a study from Mysore, Karnataka (S. Mukherjee et al., 2015). Children with mothers who made three or more antenatal care visits were more likely to be fully vaccinated than children whose mothers had lower than three antenatal care visits in studies among migrant populations in Delhi and Hyderabad (Geddam et al., 2018; Kusuma et al., 2010).

2.3.4 Rationale for the dissertation

Nearly a third of Indian children do not receive all the vaccines available during their first year of life despite more than three decades of functioning of the UIP (International Institute for Population Sciences (IIPS), 2016). There is an urgent need to examine the reasons for the persistently low childhood vaccination coverage in India using available data sources and innovative analytical methods. Identifying the factors linked with vaccination uptake nationally provides an opportunity to focus public health interventions on reducing any observed coverage disparities and designing better studies to diagnose the root causes of vaccination coverage gaps at the state and regional levels (Thomson et al., 2016). The launch of the Mission Indradhanush campaign in 2014 provided an impetus to India's universal immunization program, but concurrent efforts are needed to monitor its progress in the targeted districts. Region-specific research assessing the barriers and facilitators of childhood vaccination uptake can provide a crucial demand-side perspective on the different aspects of routine immunization programs and support the development of context-specific interventions to ensure high vaccine acceptance.

3 OBJECTIVES OF THE STUDY

The overall aim of this dissertation was to assess vaccination coverage and the factors associated with routine vaccination uptake among children aged 12-23 months, both nationally and subnationally, in the Vellore district of Tamil Nadu, southern India.

The specific objectives studied were as follows:

1. To investigate the factors associated with routine vaccination uptake and describe the reasons for non-vaccination among Indian children aged 12-23 months nationally during 1998 and 2008 using publicly available district level, household and health facility survey datasets (Study I)

2. To estimate vaccination coverage and investigate the factors associated with vaccination uptake among children aged 12-23 months from rural and disadvantaged communities in Vellore, southern India, during 2017 and 2018 using a combination of household surveys and qualitative interviews (Study II & III)

4 SUBJECTS AND METHODS

4.1 Data sources

4.1.1 The District Level Household and Facility Surveys (DLHS)

The data used in study I was obtained from the publicly available District Level Household and Facility Surveys (DLHS). The DLHS surveys were launched to provide rapid and reliable data to monitor various national-level reproductive and child health interventions implemented by the Government of India (IIPS, 2006). They specifically aimed to estimate the coverage of antenatal care and immunization services, safe deliveries, contraceptive use, and public awareness about reproductive tract and sexually transmitted infections at the district level (IIPS, 2006). The DLHS surveys were coordinated by the International Institute for Population Sciences (IIPS) and their local partner organizations. Four rounds of the DLHS have been conducted since its launch: DLHS-1 during 1998-99, DLHS-2 during 2002-04, DLHS-3 during 2007-8, and DLHS-4 during 2012-14 (Dandona et al., 2016). The first three rounds of the DLHS were nationally representative, covering all Indian states and union territories, but DLHS-4 covered all but nine states (Uttar Pradesh, Uttarakhand, Rajasthan, Madhya Pradesh, Chhattisgarh, Bihar, Jharkhand, Odisha, and Assam) (Dandona et al., 2016). Data from DLHS-4 were not included in study I, as this study aimed to examine the factors associated with childhood vaccination uptake nationally.

The DLHS utilized a systematic, stratified sampling design, conducted in two stages in rural and three stages in urban areas (IIPS, 2006). In the first stage, primary sampling units (PSUs) were selected with probability proportional to size (PPS) in each district using the most recently available census. The PSUs in rural areas were villages, and wards were sampled in urban areas. In rural areas, the second sampling stage involved selecting households from the selected PSUs (IIPS, 2006). The households were selected using systematic random sampling after an extensive list of all households (in PSUs with ≤300 households) or households along specific segments (in PSUs >300 households) was compiled in the selected PSUs (IIPS, 2006). In urban areas, the second stage of sampling included selecting census enumeration blocks, followed by households at the final (or third) stage using a similar methodology to the rural areas (IIPS, 2006). No replacement was made if the households did not have respondents available during the survey, and a 10% oversampling of households was conducted to account for non-response during the surveys (IIPS, 2006). The survey design and sampling methodology were generally consistent among the DLHS surveys, as presented in Table 7.

Table 7. Comparison of the DLHS surveys

	DLHS-1	DLHS-2	DLHS-3	DLHS-4
Survey years	1998-99	2002-04	2007-08	2012-14
Survey design/sampling	Systematic, multi-stage stratified design (50 PSUs per district)	Systematic, multi-stage stratified design (40 PSUs per district)	Systematic, multi-stage stratified design (50 PSUs per district)	Systematic, multi-stage stratified design (50 PSUs per district)
Districts/states covered	504 districts across 34 states and union territories	593 districts across 35 states and union territories	601 districts across 34 states and union territories	336 districts across 26 states and union territories
Number of households surveyed	529,817	620,107	720,320	378,487
Respondents	Head of household, currently married women aged 15-44 years	Head of household, currently married women aged 15-44 years	Head of household, ever-married and never-married women aged 15-49 years	Head of household, ever-married women aged 15-49 years
Key survey themes	- Birth history - Maternal and child health - Family planning - Quality of health services - STIs and HIV/AIDS	- Birth history - Maternal and child health - child mortality - Family planning - Quality of health services - STIs and HIV/AIDS	- Birth history - Maternal and child health - Child mortality - Family planning and fertility preferences - Reproductive health - STIs and HIV/AIDS - Use of government health programmes	- Birth history - Maternal and child health - Family planning and fertility preferences - Socio-demographic characteristics - STIs and HIV/AIDS - Reproductive health - NCDs and behavioural risk factors

Sources: (Dandona et al., 2016; IIPS, 2000, 2006; International Institute for Population Sciences (IIPS), 2016)

4.1.2 Community-based surveys and focus group discussions in Vellore, southern India

4.1.2.1 Study setting

The community-based surveys and focus group discussions (FGDs) which contributed data for studies II and III, were conducted in the Vellore district (12° N to 13° N latitude and 78° E to 79° E longitude) of the southern Indian state of Tamil Nadu. Vellore and 600 other Indian districts were selected for intensified routine immunization through the MI campaign in 2015 (Ministry of Health and Family Welfare, 2016). The Vellore district has a population of 3,936,331, with 432,550 children aged six years or younger, according to the 2011 census (Census of India, 2011). More than half (~57%) of Vellore's inhabitants live in rural areas, which are divided into administrative subunits called "blocks" (Census of India, 2011). Vellore has 20 rural blocks, each comprising between 20 to 50 villages. The community survey and FGDs for study II were conducted in the Thimiri block, one of the largest blocks in Vellore, with a population of 105,691 and 11,242 children aged six years or younger (Census of India, 2011). The survey and FGDs among disadvantaged communities for study III were conducted in the Thimiri and Kaniyambadi blocks and settlements around Vellore. These studies (studies II and III) were conducted in Vellore due to an ongoing research collaboration with the Wellcome Trust Research Laboratory at the Christian Medical College (CMC), Vellore, a teaching hospital with decades of research experience in improving preventive and curative health services in underserved communities.

Routine immunization services in Vellore are offered at primary health centers (PHCs), childcare centers (Anganwadis), and the government district hospital at no cost to parents. These public facilities provide vaccines to children and pregnant women following the UIP immunization schedule outlined in Table 1. The Measles-Rubella vaccine replaced the monovalent measles vaccine in the UIP schedule, initially launched through a national campaign to vaccinate all children aged nine months to 15 years during February and March 2017. The pneumococcal conjugate vaccine was not yet introduced, and the rotavirus vaccine was newly introduced during the fieldwork (August – December 2017). Childhood vaccines are also provided in private clinics and hospitals in Vellore which provide UIP and non-UIP vaccinations for a fee, following Indian Academy of Pediatricians (IAP) guidelines

(Balasubramanian et al., 2018). Studies II and III were conducted soon after the first phase of Mission Indradhanush was completed in Vellore (April 2015 – July 2017).

4.1.2.2 Study design and sampling

We conducted cross-sectional household surveys among parents of children aged 12-23 (henceforth called eligible children) in Vellore for studies II and III. For study II, we used a two-stage cluster sampling design based on the EPI coverage survey methodology (World Health Organization, 2008). In the first stage, we selected 30 clusters in the Thimiri block with probability proportional to size (PPS) using a list of villages and their population sizes. A *cluster* was defined as a village or a group of congruent villages with ≥ 2000 individuals or 500 households. In the second stage, we sampled households once the first house in each cluster was selected randomly. Since this survey was conducted in rural areas where household lists were not available, a central location in each village was identified, a direction randomly selected, and the first household was selected randomly from the street nearest to the indicated direction using EPI guidelines (World Health Organization, 2008). We selected subsequent households based on their proximity to previously surveyed households, and sampling continued until the required number of eligible children per cluster was achieved or the last household with an eligible child reached. The sample size calculation for this survey was based on an estimate of 70% full vaccination coverage among children aged 12-23 months in rural Vellore, according to the NFHS-4 (IIPS, 2017). We estimated that a total of 750 children (or 30 clusters with 25 children) were required to estimate vaccination coverage with an absolute precision of ± 5%, accounting for a design effect of 2 and inflating the sample by 15% for potential non-response. We also invited parents who participated in the household surveys from two large villages in the Thimiri block to form a purposive sample for the FGDs in study II. A total of 4 FGDs (2 FGDs in each village) were conducted in these villages.

We conducted a household survey using snowball sampling for study III since a predefined list of disadvantaged communities, or their population sizes were unavailable. Snowball sampling is a form of nonprobability sampling generally used in qualitative research to locate hidden or vulnerable populations such as the homeless or drug users (*Snowball Sampling*, 2008). We used snowball sampling to identify additional participants once initial contact with each community was made. The *disadvantaged communities* in this study were broadly defined using Mission

Indradhanush guidelines as populations living in nomadic sites, brick kilns, construction sites, and other hard-to-reach communities such as tribal or forested populations (Ministry of Health and Family Welfare, 2016). The specific groups surveyed were the Narikuravar, Irular, and stone quarry and brick kiln dwellers. The Narikuravar are a semi-nomadic group characterized by low literacy, poor access to public welfare services, and limited income (Zafiu, 2017). The Irular are a tribal group with low literacy levels and face geographic and cultural barriers to public welfare services (Saheb et al., 2011). Brick kiln and stone quarry workers are migrants from neighboring districts or states known to reside in makeshift homes and have limited access to public welfare services (Thomas et al., 2015). Since estimates of routine vaccination coverage were unavailable for children from the communities experiencing disadvantage in southern India, we calculated that 110 children were required to estimate vaccination coverage with absolute precision of ± 10%, using an anticipated proportion of 50% full vaccination coverage. Similar to study II, parents who participated in the household surveys in study III were invited to form a purposive sample for a total of 6 FGDs (2 FGDs in each settlement) conducted in Narikuravar, Irular, and stone quarry settlements.

4.2 Data collection and study instruments

4.2.1 The DLHS Surveys

Trained fieldworkers conducted interviews with survey participants after obtaining informed consent. The DLHS used two structured questionnaires: the household questionnaire and a women's questionnaire. The household questionnaire was administered to the head of the household (or any family member 18 years or older) to collect information on every household member (age, sex, marital status, education, and other household characteristics) (IIPS, 2006). The women's questionnaire collected information from currently or ever-married women aged 15-44 years (or 15-49 years in DLHS-3 & 4), covering the following key themes: antenatal and post-natal care, immunization and childcare, contraception, assessment of the quality of public health services, and awareness regarding reproductive tract infections (RTIs) and sexually transmitted infections (STIs) (Table 7). Both DLHS questionnaires were bilingual, including questions in the regional language and English. The IIPS designed the questionnaires in consultations with the Ministry of Health and Welfare in India and the World Bank. We used data from the women's questionnaire for study I as it included all relevant information on the individual and household characteristics and children's vaccination histories (from vaccination cards or parental recall).

4.2.2 Community-based surveys and focus group discussions in Vellore, southern India

We used a structured, interviewer-administered questionnaire (Appendix 1) to survey parents or primary caretakers (relatives involved in childcare and knowledgeable of their immunization history) of eligible children for studies II and III in Vellore. After obtaining informed consent, field workers collected information from parents or primary caretakers (henceforth called parents). All fieldworkers participated in a three-day training to familiarize them with the survey design, sampling methodology, consent forms, questionnaire, interviewing techniques, and data entry. The survey questionnaire included questions on parents' socio-demographic characteristics, such as age, education, occupation, religion, caste, and non-socio-demographic characteristics, outlined using the "5As taxonomy" for the determinants of vaccination uptake domains (Thomson et al., 2016). The 5As: access, affordability, awareness, acceptance, and activation, and their definitions are presented in Table 8. The non-socio-demographic characteristics enquired were the mode of transport to vaccination facilities (access), the timing of immunization services (affordability), familiarity with the UIP schedule (awareness), trust in information provided by health care workers, and reported hesitancy about childhood vaccines (acceptance), and receipt of a financial incentive for completing the pentavalent series for children and information on the UIP schedule during antenatal visits (activation).

Table 8. Definitions of the "5As taxonomy" for determinants of vaccine uptake

Themes	Definition
Access	The ability of individuals to be reached by, or to reach, recommended vaccines
Affordability	The ability of individuals to afford vaccination, both in terms of financial and non-financial costs (e.g., time)
Awareness	The degree to which individuals have knowledge of the need for, and availability of, recommended vaccines and their objective benefits and risks
Acceptance	The degree to which individuals accept, question, or refuse vaccination
Activation	The degree to which individuals are nudged towards vaccination uptake

Source: (Thomson et al., 2016)

Children's vaccination histories (for the first year of life) were collected from vaccination cards (including the number of doses and dates of vaccination) and parents. Parents were asked about the reasons for missed vaccination doses if vaccination dates were not recorded on their child's vaccination cards. The questionnaire was translated to vernacular (Tamil) and programmed using the "KoBo Toolbox" suite. The KoBo Toolbox is a free, open-source digital data collection suite of tools initially used by humanitarian organizations to conduct needs assessment surveys and monitor disaster relief operations (KoboToolbox, 2015). The toolbox is increasingly being used for data collection, storage, and analysis by public health researchers in LMICs (Mehmood et al., 2019). The paper and electronic versions of our study questionnaire were piloted in a village that did not participate in the surveys. Minor modifications were made to the questionnaire, including rearranging sections, better phrasing questions, and prompts to assist the fieldworkers with specific questions. The same questionnaire was used for the community-based surveys in rural Vellore (study II) and among the communities experiencing disadvantage (study III).

A pre-tested thematic guide (Appendix 2) with open-ended questions to explore parents' perceptions of childhood vaccines, immunization safety, parent and health care worker interactions, and the routine immunization program was used in the FGDs in studies II and III. This guide was developed in English, translated to Tamil, and revised using feedback from a pilot FGD conducted in a non-study settlement. The FGDs were conducted by a field supervisor with extensive experience in community engagement for various health programs in the study region. The FGDs were conducted separately for mothers and fathers to ensure their free participation and audio-recorded after obtaining verbal consent.

4.3 Study measures

4.3.1 Socio-demographic and other explanatory variables

4.3.1.1 National study (study I)

A range of socio-demographic variables were included in the DLHS women's questionnaire for study I. We investigated individual, household, and regional characteristics known to be associated with children's vaccination status, with complete data available across the surveys (DLHS 1-3). Child-specific characteristics such as gender and age and maternal characteristics such as mother's age, education, antenatal participation, tetanus vaccination status, and place of delivery were considered for the analysis. Household characteristics such as the caste and religious affiliation of the head of the household were included along with urban/rural regions of residence and dwelling type, used as a proxy indicator for household wealth. The geographic region of households was also considered in the analysis, categorized as north, central, north-east, west, and south India. The detailed categorization of each socio-demographic variable, along with the specific questions and possible responses, is presented in Table 9.

Table 9. Socio-demographic variables and their categorization in study I

Variable	Question and possible responses	Categories used in the analysis
Age of child	"In which month and year was your child born" (Month and year)	Age of child in months used as a continuous variable
Child's gender	"Is your child a boy or a girl?" (Male, female, don't know)	Male, female
Mother's age at birth of child	"How old are you at the time when your child was born?" (Age in years)	Age in years recoded as ≤ 18, 19-25, 26-35, >35 years
Mother's education	"What is the highest standard you have passed?" (Years)	No schooling, primary (1-5 years of schooling), middle (6 - 8 years), high school and above (9 years and above)
Number of antenatal care visits	"How many times did you received antenatal check-up during your last pregnancy?" (Number of times)	None, 1 - 2, 3 - 6, ≥ 7 antenatal care visits
Maternal tetanus vaccination status	"Were you given an injection during your last pregnancy to prevent Tetanus?" (Yes, no)	Yes, no
Place of delivery	"Where did your last delivery take place?" (Government/NGO or Trust hospital/Private clinic or hospital)	Institutional (Government), institutional (private), non-institutional
Social group	"What is the caste or tribe of the head of the household?" (Specify caste or tribe)	General classes, scheduled caste, scheduled tribe, other backward classes
Religion	"What is the religion of the head of the household?" (Hindu, Muslim, Christian, Sikh, Buddhist, Jain, Jewish, Parsi, No religion, Others)	Hindu, Muslim, Christian, Other (Sikh/Buddhist/Jain/Jewish/Parsi/No religion/others)
Location	"Type of locality" (Rural, urban)	Rural or urban location
Type of dwelling	"Type of house" (Kaccha, semi-pucca, pucca)	Mud (kuccha), semi-cemented (semi-pucca), cemented (pucca)

Source: (International Institute for Population Sciences (IIPS), 2010)

4.3.1.2 Community-based studies in Vellore, southern India (studies II and III)

We analyzed various socio-demographic and non-socio-demographic parental factors previously linked to children's vaccination status as outlined in section 4.2.2. These variables, the questions used during the survey, possible responses, and categorization for the analyses, are presented in Table 10.

Table 10. Socio-demographic and non-socio-demographic variables and their categorization in studies II and III

Variable	Question and possible responses	Categories used in the analysis
Socio-demographic		
Age of child/ respondent	"Date of birth" (Date, month, and year)	Childs's age coded to 12-17 and 18-23 months, mother's age at birth of child coded as <20, 20-30 and >30 years
Child's gender	"Gender" (Male or female)	Male or female
Child's birth order	"How many children have you had before the birth of your last child?" (Number of children)	1, 2, 3 or higher
Place of delivery of child	"Place of delivery" (Government hospital or clinic, private hospital or clinic, home, others)	Public facility, private facility, home, or others
Place of vaccination	"Which facility did your child receive most of his/her vaccines?" (Name and address of facility)	Public or private facility
Marital status of the respondent	"Marital status of the respondent" (Single, married, widowed, divorced, or separated)	Single, married, divorced, separated, or widowed
Mother's/father's education	"Education in years" (Number of years)	Illiterate (0 years of education), up to 12th standard (12 years), diploma or degree (13 years or higher)
Mother's/father's occupation	"Occupation" (Specify)	Homemaker or unemployed, wage earner, salary earner or business owner
Religion	"Religion" (Hindu, Muslim, Christian, others)	Hindu and others (Muslim, Christian, other)
Household size	"Number of members in the household" (Number)	<5 members, 5 - 10 members, >10 members
Type of dwelling	"Type of house" (Pukka, mixed, kutcha)	Cemented (pukka), semi-cemented (mixed), mud (kutcha)

Social group	"Caste of the family" (Schedule caste, scheduled tribe, other backward class, general class)	Scheduled caste, scheduled tribe, other backward or general classes
<u>Non-socio-demographic</u>		
Travel to immunization facility	"How did you generally travel to the facility to vaccinate your child?" (Walking, on vehicle, public transport, don't know)	Walking, private, or public transport
Perception of the importance of childhood vaccines	Respond to the following statement: "I think immunization is important to keep my child healthy" (Strongly agree, agree, neutral, disagree, strongly disagree)	
Timing of immunization sessions	Respond to the following statement: "The timing of immunization sessions was convenient for me" (Strongly agree, agree, neutral, disagree, strongly disagree)	Don't agree (neutral, disagree and strongly disagree) and agree (agree, strongly agree)
Familiarity with the immunization schedule	Respond to the following statement: "I am familiar with the immunization schedule [individual vaccines and timing of doses] (Strongly agree, agree, neutral, disagree, strongly disagree)	Same as above
Trust in information provided by health workers	Respond to the following statement: "I trust the information provided by the health workers on immunizations" (Strongly agree, agree, neutral, disagree, strongly disagree)	Same as above
Self-reported hesitancy with one or more childhood vaccines	"Overall, how hesitant about childhood vaccinations would you consider yourself to be?" (Not at all hesitant, not too hesitant, not sure, somewhat hesitant, very hesitant)	Hesitant (not sure, somewhat hesitant, very hesitant), not hesitant (not at all hesitant, not too hesitant)
Health worker home visits	"Did a health worker visit your home to inform you about the immunization schedule for your child?" (Yes, no, don't know)	Yes, no or don't know
Received information about vaccines during antenatal visits	"Were you told about the recommended immunization schedule for your child during antenatal care visits?" (Yes, no, don't know)	Same as above
Received an incentive for completing pentavalent/DPT series	"Did you receive any money from the government for getting your child immunized?" (Yes, no, don't know)	Same as above

4.3.2 Outcome definitions

The primary outcome in all three studies was the vaccination status of children aged 12-23 months, based on EPI and UIP recommendations for vaccinating children during their first year of life (Ministry of Health and Family Welfare, 2018a; World Health Organization, 2008). We used a three-category outcome variable (fully vaccinated, partially vaccinated, or unvaccinated) in study I, as the factors associated with partial-vaccination and non-vaccination among children was expected to differ (Favin et al., 2012; Rainey et al., 2011). We later used a dichotomous (fully vaccinated or undervaccinated) variable to classify children's vaccination status in studies II and III due to the low proportion of unvaccinated children in Vellore. We also used a previously published indicator to assess the timeliness of receiving individual vaccine doses as a secondary outcome in study II (Murhekar et al., 2017). The definitions of these outcomes and the sources of vaccination information used in each study are presented in Table 11.

Table 11. Definitions of outcomes used in studies I-III

Study	Outcome(s)	Definition	Source of information
I	Vaccination status (by 12 months of age)	**Fully vaccinated:** Children who received one dose of BCG, three doses of DPT, three doses of OPV, and one dose of measles containing vaccine; **Partially vaccinated:** Children who received at least one but not all the recommended vaccine doses; **Unvaccinated:** Children who did not receive any of the recommended vaccine doses	Vaccination cards + parental recall
II	**Primary:** Vaccination status (irrespective of age at receiving individual doses)	**Fully vaccinated:** Children who received one dose of BCG, three doses of pentavalent or DPT, three doses of OPV, and one dose of measles containing vaccine; **Undervaccinated:** Children who missed one or more doses, or those who received none of the recommended doses	Vaccination cards
	Secondary: Schedule-appropriate vaccination status (considering the timing of individual doses with a cut-off at 12 months of age)	**Schedule-appropriate:** Children who received (1) BCG at birth or as early as possible, (2) pentavalent/DPT and OPV doses - first dose 6 weeks after birth and subsequent doses with at least four-week intervals, and (3) measles containing vaccine between 9-12 months of age; **Not schedule-appropriate:** Children who either missed one or more doses, or those who did not receive one or more doses at the recommended age and interval according to the definition above	Vaccination cards
III	Vaccination status (by 12 months of age)	**Full vaccinated**: Children who received one dose of BCG, three doses of pentavalent or DPT, three doses of OPV, and one dose of measles containing vaccine; **Undervaccinated:** Children who missed one or more doses, or those who received none of the recommended doses	Vaccination cards + parental recall

Source: (Ministry of Health and Family Welfare, 2018a; Murhekar et al., 2017; Shrivastwa et al., 2015; World Health Organization, 2008)

4.4 Data analysis

4.4.1 Statistical analysis

4.4.1.1 Data entry and cleaning

Data for the DLHS surveys (study I) were double-entered, cleaned, and weighted using a standard process by the Indian Institute of Population Sciences (IIPS) and its local partners (IIPS, 2006). Data cleaning included validation and range and consistency checks for the entered data from the paper questionnaires. A standard software was used for data entry, validation, and consistency checks developed by the IIPS. In addition, sample weights for households and women were calculated to adjust for differential nonresponse in the different geographical regions (IIPS, 2006).

Field workers entered data in real-time for studies II and III on the KoBoCollect application for Android™ devices (*KoBoCollect - Apps on Google Play*, 2012). We programmed range and consistency checks, skip patterns for specific questions, and pictures of children's vaccination cards into the application interface to minimize data entry errors. Data were uploaded to the KoBo server and accessed through a password-protected website. These data were reviewed for their completeness and validity, and the dates of birth and vaccination for eligible children were verified using the pictures of their vaccination cards, if available during the survey. We readministered the surveys to 10% of randomly selected households in both studies (studies II & III) to compare the accuracy of field data collection.

4.4.1.2 Analytical dataset (study I)

Study I used data from three rounds of the DLHS surveys (DLHS 1, 2 & 3). We combined these datasets to examine the factors associated with the vaccination status of children aged 12-23 months over the years covered by the surveys (1998-2008). Combining these data was possible as consistent questions and response categories were used in the surveys. We restricted the analysis to children of currently married women aged 15-44 years at the survey time for consistency between the three DLHS datasets. Data from ever-married women and women above 44 were excluded as their information was only collected in DLHS-3. In addition, the DLHS women's questionnaire collected vaccination histories for the last two surviving children, but we restricted the analytical sample to the most recently born children to reduce the potential for recall bias for the older children.

4.4.1.3 Descriptive analyses and estimation of vaccination coverage

All analyses in study I accounted for the complex, stratified sampling design of the DLHS surveys. We used the "*svy*" package in Stata version 12 (StataCorp LP, College Station, TX, USA) to specify the primary sampling units and national-level sampling weights provided with the DLHS datasets. Using these weights enabled the calculation of unbiased population-level estimates for the national sample. The proportions of children who received the individual vaccine doses and their full vaccination status (using vaccination card and parent recall) were weighted and presented with design-adjusted 95% confidence intervals (CIs). These proportions were presented by survey and compared by estimating relative percentage changes between DLHS 1 and 3 and the chi-square test of trend with Rao-Scott adjustment for the complex survey design. Univariate analyses were performed to examine associations between the socio-demographic variables (Table 9) and children's vaccination status on the combined datasets from DLHS 1-3 using chi-square tests with the Rao-Scott design adjustment.

The analyses for studies II and III also utilized the *"svy"* package in Stata to account for the survey design, using the village cluster id and community id in studies II and III, respectively, as the primary sampling units for cluster specification. Next, we estimated the unweighted proportions of children who received the individual vaccine doses and their full vaccination status, presented with design-adjusted 95% CIs in studies II and III. We calculated these estimates using information from vaccination cards alone, and vaccination cards and parent recall combined, as recommended for the EPI coverage survey estimates (World Health Organization, 2008). We also calculated the sensitivity and specificity of parental recall (compared with vaccination card information) to estimate children's vaccination status using the *"diagt"* package in Stata version 14 (StataCorp LP, College Station, TX, USA). The timeliness of individual vaccination doses was estimated for children with vaccination cards available during the survey by subtracting the vaccination dates from their birthdate in study II. Finally, we examined univariate associations between the independent variables (outlined in Table 10) and vaccination status using logistic regression for children with a vaccination card in study II and chi-square (or Fisher's exact) tests for the children surveyed in study III.

4.4.1.4 Multivariate analyses

All socio-demographic variables associated with children's vaccination status at the $p \leq 0.05$ level were included in the multivariate analyses for study I. We used multinomial logistic regression to model associations between the socio-demographic variables and children's vaccination status (the outcome) since the outcome was coded using three categories (fully vaccinated, partially vaccinated, and unvaccinated). We calculated adjusted prevalence odds ratios (aPORs) and corresponding 95% CIs, controlling for the age of children, dwelling type, and geographic region of residence. Due to the complexity of estimating prevalence ratios while simultaneously adjusting for multiple covariates, prevalence odds ratios were considered the more appropriate measure of relative effect for the multivariate analyses (Thompson et al., 1998). The reference group for all adjusted effect measures was fully vaccinated children, *i.e.,* the multivariate models calculated the odds that children were partially vaccinated or unvaccinated relative to being fully vaccinated. The importance of each socio-demographic variable in the multivariate model was assessed using the Wald test statistic *p*-values estimated using the *"mlogtest"* post-estimation commanded in Stata version 12.

In study II, all the independent variables with a significant univariate association with children's vaccination status at $p \leq 0.20$ were included in multivariate logistic regression models. We constructed these models to assess the variables independently associated with children's full and schedule-appropriate vaccination status. The reference group for the individual regression models was undervaccinated children (versus fully vaccinated children) and not-schedule-appropriately vaccinated children (versus schedule-appropriately vaccinated children). We restricted the multivariate analyses to children with a vaccination card; however, supplementary analyses were performed, including all the surveyed children, irrespective of the source of vaccination information. In study III, all independent variables associated with children's vaccination status at the $p<0.05$ threshold were added to a multivariate logistic regression model to assess the factors associated with full vaccination (versus under vaccination). The results of the logistic regression modeling (in studies II and III) are presented as prevalence odds ratios (PORs) and adjusted prevalence odds ratios (aPORs) with 95% CIs derived from design-adjusted standard errors. The significance level for all the multivariate analyses was set at 5%, and no adjustment was made for multiple comparisons.

4.4.2 Qualitative analyses

We used a semi-qualitative methodology in study I to organize mothers' responses to the question *"Why was your child not given any vaccination?"* if their child was found to be unvaccinated during the DLHS surveys. Mothers answered this question by choosing either one important reasons (in DLHS 1 & 2) or one or more reasons (in DLHS 3) from a list of pre-determined responses to this question in the surveys. We used a framework-based methodology to map the mother's responses to the "5As taxonomy" domains to identify the reasons for non-vaccination among Indian children (Thomson et al., 2016). The definitions of the 5As taxonomy domains are presented in Table 8. Unweighted proportions of the unmapped and mapped responses are presented for the individual DLHS surveys and combined sample.

We translated the audio-transcripts from the FGDs conducted in studies II and III, from Tamil to English, and the participant responses in Microsoft Word for preliminary analysis. The data were reduced using open coding, and common categories (sub-themes) were identified using an inductive approach. These sub-themes were subsequently mapped to the 5As taxonomy domains to triangulate the qualitative findings with those from the quantitative household surveys. Another investigator checked the consistency of the open-coding, initial sub-themes, and mapping of these categories to the 5As domains. The categories and associated responses were mapped using Microsoft Excel (2017). Illustrative quotes from participants are presented to support the findings from the FGDs where appropriate.

4.5 Ethical considerations

Study I used de-identified data from the DLHS surveys, which are available in the public domain. The study protocol and instruments for the DLHS surveys were reviewed by the IIPS ethics committee and an independent technical advisory committee appointment by the Ministry of Health and Welfare in India. Respondents were only surveyed if they provided voluntary and written informed consent. We did not seek a separate institutional review board (IRB) clearance for this study as it was a secondary analysis of data from respondents that could not be identified or contacted.

The study protocol and instruments for studies II and III received ethical clearance from the Institutional Review Board (IRB) of the Christian Medical College, Vellore (*IRB no. 10691, dated 21.06.2017*). Data collection for the community surveys was conducted after written informed consent was obtained from study participants. Verbal consent was obtained from participants in the FGDs for studies II and III, including its audio-recording. The survey data were anonymized using unique identification codes for each household after downloading them from the KoBo Toolbox server. Once data were uploaded to the KoBo Toolbox server, they were encrypted and stored in accounts protected by usernames and passwords. Data were deleted after backups were maintained in the candidate's personal computer. No financial compensation was offered to survey participants to prevent the undue inducement of economically disadvantaged communities to participate in the studies.

5 RESULTS

5.1 Characteristics of the study population

5.1.1 National study (study I)

There were a total of 58,777 (31% of all surveyed children), 58,416 (30%), 61,280 (28%), and 178,473 (30%) eligible children aged 12-23 months in the DLHS-1, DLHS-2, DLHS-3 and the combined surveys, respectively. In the combined survey dataset, 29% of the children lived in northern Indian states and 74% in rural locations across India (Table 12). Half (53%) of the children were male, and most (78%) belonged to Hindu households. Half (50%) of the children had mothers who were not formally educated. More than half (59%) of the mothers delivered their children in non-institutional settings (delivered at home with or without the presence of a skilled birth attendant). Most mothers (76%) had received at least one dose of tetanus vaccination during pregnancy, and 69% reported making one or more antenatal care visits.

Table 12. Socio-demographic characteristics of children aged 12-23 months and their parents in India, 1998 – 2008

Characteristic	***n*[1]**	**Proportion[2]**	**95% CI[3]**
Gender of eligible child			
Female	83,920	47.2	46.9 - 47.4
Male	94,552	52.9	52.6 - 53.2
Mother's age at birth of eligible child			
≤ 18	17,524	10.0	9.7 - 10.2
19-25	93,733	53.9	53.6 - 54.2
26-35	59,945	32.5	32.2 - 32.9
> 35	7,255	3.5	3.4 - 3.6
Mother's education			
Illiterate (no schooling)	90,127	49.5	48.9 - 50.1

Primary (1 - 5 years of schooling)	22,727	13.1	12.9 - 13.3
Middle (6 - 8 years of schooling)	24,770	14.6	14.4 - 14.8
High school and above (9 years & above)	35,238	22.8	22.2 - 23.4
Place of delivery			
Institutional government	37,481	23.0	22.6 - 23.3
Institutional private	26,675	18.6	18.2 - 19.0
Non-institutional	111,449	58.5	57.8 - 59.1
Number of antenatal care visits			
None	63,067	31.5	31.1 - 32.0
1 - 2	40,574	22.3	22.0 - 22.6
3 - 6	55,041	33.3	33.0 - 33.8
>=7	18,566	12.9	12.5 - 13.1
Maternal tetanus vaccination			
No	45,020	23.7	23.3 - 24.0
Yes	130,597	76.3	76.0 - 76.7
Social group			
Scheduled caste	32,703	20.0	19.6 - 20.2
Scheduled tribe	30,740	12.7	12.4 - 13.0
Other backward classes	66,224	40.3	40.0 - 40.8
General class	45,487	27.0	26.6 - 27.4
Religion			
Hindu	133,848	78.1	77.7 - 78.5
Muslim	24,614	14.9	14.6 - 15.3
Christian	11,595	3.5	3.3 - 3.6
Others	8,405	3.5	3.4 - 3.6
Location			
Rural	140,593	74.1	72.1 - 76.0
Urban	37,880	25.9	24.0 - 27.9
Type of dwelling			
Mud	74,824	38.7	38.1 - 39.3
Semi-cemented	59,392	33.5	33.1 - 33.9
Cemented	44,245	27.9	27.1 - 28.6
Region			
North	50,876	29.0	28.7 - 29.4
Central	17,364	9.1	8.9 - 9.3
East	38,014	22.4	22.0 - 22.7
North-East	23,075	6.7	6.5 - 6.9
West	27,318	17.1	16.8 - 17.5
South	21,826	15.7	15.5 - 16.0

[1] Unweighted sample size

[2] Weighted proportions; [3] 95% Confidence Interval

5.1.2 Community-based studies in Vellore, southern India (studies II and III)

Six hundred forty-three children aged 12-23 months were included in the study among rural communities in Vellore (study II). One family declined to participate, and the survey response proportion was 99.8%. The mean (SD) age of children included in the study was 18.2 (3.6) months. Half (53%) of the children were boys, and 43% were firstborn (Table 13). Most (92%) of the children lived in cemented houses, and 97% came from Hindu families. Most (94%) children were vaccinated in public facilities such as primary health centers (PHCs) and childcare centers (Anganwadis). Most children had mothers (82%) and fathers (81%) with high school education. Almost all (99%) parents agreed (strongly agreed or agreed) that vaccination was important to keep their children healthy (Table 14). However, just over half (57%) of the parents were either "strongly hesitant" or "very hesitant" towards childhood vaccines. Furthermore, while 90% of parents reported receiving information about childhood vaccines during antenatal visits, only 72% agreed that they were familiar with the immunization schedule for their children.

Table 13. Socio-demographic characteristics of children aged 12-23 months and their parents in a rural community and among disadvantaged communities in Vellore, 2017-2018

Characteristic	**Rural community (N = 643)**		**Disadvantaged communities (N = 100)**	
	***n*[1]**	**Percentage (%)[2]**	***n*[1]**	**Percentage (%)[2]**
Child's age				
12-17 months	308	47.9	36	36.0
18-23 months	335	52.1	64	64.0
Child's gender				
Female	305	47.4	47	47.0
Male	338	52.6	53	53.0
Child's birth order				
1	275	42.8	29	29.0
2	279	43.4	40	40.0
≥3	89	13.8	31	31.0
Place of birth				
Public facility	518	80.6	78	78.0

Private facility	119	18.5	12	12.0
Home/Others	6	0.9	10	10.0
Place of vaccination				
Public facility	605	94.2	98	98.0
Private facility	38	5.8	2	2.0
Survey respondent				
Mother	611	95.0	89	89.0
Father	17	2.6	4	4.0
Others	15	2.4	7	7.0
Mother's education				
Illiterate	17	2.6	46	46.0
Up to 12th standard	527	82.0	52	52.0
Diploma/Degree	99	15.4	2	2.0
Father's education				
Illiterate	31	4.8	39	39.0
Up to 12th standard	522	81.2	59	59.0
Diploma/Degree	90	14.0	2	2.0
Mother's occupation				
Homemaker	561	87.2	51	51.0
Wage earner	68	10.5	17	17.0
Salary earner/business	14	2.2	32	32.0
Father's occupation				
Unemployed	16	2.5	2	2.0
Wage earner	457	71.6	60	60.0
Salary earner/business	165	25.9	38	38.0
Religion				
Hindu	623	96.9	83	83.0
Others	20	3.1	17	17.0
Social group				
Scheduled caste	164	25.5	16	16.0
Scheduled tribe	68	10.6	80	80.0
Other backward class/Others	411	63.9	4	4.0
Type of dwelling				
Mud	19	2.9	55	55.0
Semi-cemented	32	5.0		
Cemented	592	92.1	45	45.0

[1] Unweighted sample size

[2] Unweighted percentage

One hundred eligible children were included in the survey among disadvantaged communities in Vellore, with a survey response proportion of 98% (study III). The mean (SD) age of surveyed children was 18.7 (3.4) months. A little over half (53%) of the children were from Narikuravar settlements, and the rest (47%) from Irular, stone quarry, and brick kiln settlements. Slightly over half (53%) of the children were male, and 29% were firstborn (Table 13). Most (89%) respondents were mothers, 46% of the mothers had no formal education, and 51% were homemakers (Table 13). Almost all (98%) children were vaccinated in public facilities, and 95% of parents agreed that vaccination is important to keep their children healthy. However, nearly a quarter (22%) of parents were "strongly hesitant" or "very hesitant" towards vaccines for their children. While 91% of parents reported that they had received information on the recommended childhood vaccines during antenatal visits, only 56% were familiar with the immunization schedule for their children (Table 14).

Table 14. Non-socio-demographic characteristics of children aged 12-23 months and their parents (*outlined using the 5As taxonomy*) in a rural community and among disadvantaged communities in Vellore, 2017-2018

Characteristic	**Rural community (N = 643)**		**Disadvantaged communities (N = 100)**	
	n[1]	**Percentage (%)**[2]	***n***[1]	**Percentage (%)**[2]
<u>Access</u>				
Travel to immunization facility				
Walking	420	65.3	54	54.0
Private/public transport	223	34.7	46	46.0
<u>Awareness</u>				
I think immunization is important to keep my child healthy				
Do not agree[3]	4	0.7	5	5.0
Agree	639	99.3	95	95.0
I am familiar with the immunization schedule				
Do not agree[3]	180	28.0	44	44.0
Agree	463	72.0	56	56.0
<u>Affordability</u>				
The timing of immunization sessions was convenient for me				
Do not agree[3]	45	7.0	11	11.0
Agree	598	93.0	89	89.0

<u>Acceptance</u>				
Self-reported hesitancy with one or more childhood vaccines				
Hesitant[4]	365	56.8	22	22.0
Not hesitant	278	43.2	78	78.0
I trust the information provided by the health workers on immunizations				
Do not agree	12	1.9	6	6.0
Agree	631	98.1	94	94.0
<u>Activation</u>				
Health worker home visits				
No/not sure	139	21.6	23	23.0
Yes	504	78.4	77	77.0
Received information about vaccines during antenatal visits				
No/not sure	65	10.1	9	9.0
Yes	578	89.9	91	91.0
Received an incentive for completing pentavalent/DPT series				
No/not sure	208	32.4	51	51.0
Yes	433	67.6	49	49.0

[1] Unweighted sample size

[2] Unweighted percentages

[3] "Do not agree" = Neutral, disagree and strongly disagree, and "Agree" = Agree and strongly agree

[4] "Hesitant" = Strongly hesitant and very hesitant, and "Not hesitant" = Neutral, not too hesitant, and not hesitant

5.2 Antigen-specific and combined vaccination coverage measures

5.2.1 National study (study I)

Less than half (38%) of the eligible children across the DLHS surveys had a vaccination card, and the rest (62%) either did not have a card or could not present it during the survey data collection (Table 15). Vaccination coverage estimated using vaccination cards or parental recall was the highest (81%) for BCG vaccination. The coverage of BCG vaccination increased from 74% during 1998-99 (DLHS-1) to 87%

during 2007-08 (DLHS-3), with a relative change of 18%. The coverage of the third dose of the DPT (DPT3) vaccine was 62%, similar to OPV3 coverage at 68% across the surveys. Measles vaccination coverage was 66% overall, increasing from 60% during 1998-99 to 74% during 2007-08. Slightly more than half (53%) of the children were fully vaccinated, with 32% and 15% partially vaccinated and unvaccinated, respectively (Table 15). The proportion of fully vaccinated increased slightly from 54% during 1998-99 (DLHS-1) to 56% during 2007-08 (DLHS-3). However, the proportion of partially vaccinated children increased from 27% to 35%, and unvaccinated children reduced from 18% to 9% during 1998-99 and 2007-08, respectively.

The coverage of BCG vaccination was 98% for children with a vaccination card. While DPT3 vaccination coverage reduced from 89% to 84% during 1998-99 and 2007-08, OPV3 coverage increased from 89% to 92% for the same period. Measles vaccination coverage was 86% overall, increasing from 82% during 1998-99 to 91% during 2007-08. The proportion of fully vaccinated children (among children with a vaccination card) was 76% overall, similar across the DLHS surveys. The proportion of partially vaccinated children increased slightly from 22% to 23%, and unvaccinated children increased from 0.6% to 1%, during 1998-99 and 2007-08, respectively.

Table 15. Coverage and vaccination status of Indian children aged 12-23 months, 1998-2008[1]

Vaccine antigen[2]	Weighted proportion (95% CI)				Relative change (%)[3]	P-value for trend[4]
	DLHS-1 (1998-99)	DLHS-2 (2002-04)	DLHS-3 (2007-08)	DLHS 1-3		
Vaccination card status						
No or not seen (parental recall)	65.9 (65.3 – 66.4)	68.6 (67.9 – 69.3)	56.1 (55.6 – 56.7)	61.9 (61.5 – 62.3)	-14.9	<0.001
Yes	34.1 (33.6 - 34.7)	31.4 (30.7 - 32.1)	43.9 (43.3 - 44.4)	38.1 (37.7 – 38.5)	28.7	
Vaccination card or parental recall						
BCG	73.9 (73.4 - 74.4)	75.4 (74.7 - 76.1)	87.4 (87.0 - 87.8)	80.7 (80.4 - 81.0)	18.3	<0.001
DPT3	65.9 (65.3 - 66.4)	58.6 (57.8 - 59.3)	60.8 (60.3 - 61.4)	62.2 (61.8 - 62.6)	-7.0	<0.001
OPV3	67.9 (67.3 - 68.4)	59.4 (58.6 - 60.2)	71.2 (71.4 - 72.4)	67.5 (67.1 - 67.9)	4.9	<0.001
Measles	60.0 (59.3 - 60.5)	56.8 (56.0 - 57.6)	73.9 (73.4 - 74.4)	65.7 (65.2 - 66.1)	23.2	<0.001

Fully vaccinated	54.3 (53.7 - 54.9)	47.9 (47.1 - 48.7)	56.0 (55.5 - 56.6)	53.4 (52.9 - 53.8)	3.1	
Partially vaccinated	27.4 (26.9 - 27.9)	32.1 (31.5 - 32.8)	34.6 (34.2 - 35.1)	32.1 (31.7 - 32.4)	26.3	<0.001
Unvaccinated	18.3 (17.9 - 18.8)	20.0 (19.4 - 20.6)	9.4 (9.0 - 9.7)	14.5 (14.3 - 14.9)	-48.6	
Vaccination card only						
BCG	96.6 (96.2 - 96.9)	97.0 (96.5 - 97.4)	98.9 (98.7 - 99.1)	98.0 (97.8 - 98.2)	2.3	<0.001
DPT3	88.7 (88.2 - 89.4)	83.1 (82.1 - 84.0)	83.7 (83.2 - 84.1)	84.7 (84.4 - 85.1)	-5.6	<0.001
OPV3	88.7 (88.1 - 89.3)	81.4 (80.5 - 82.4)	92.0 (91.6 - 92.4)	89.0 (88.6 - 89.3)	3.7	<0.001
Measles	81.7 (81.0 - 82.4)	78.7 (77.7 - 79.7)	90.6 (90.1 - 91.0)	86.0 (85.6 - 86.4)	10.9	<0.001
Fully vaccinated	77.8 (77.0 - 78.6)	71.7 (70.5 - 72.8)	76.4 (76.0 - 77.0)	75.7 (75.3 - 76.1)	-1.8	
Partially vaccinated	21.5 (20.8 - 22.3)	27.6 (26.5 - 28.8)	22.6 (22.0 - 23.1)	23.4 (23.0 - 23.8)	5.1	<0.001
Unvaccinated	0.6 (0.5 - 0.7)	0.7 (0.5 - 1.0)	1.0 (0.8 - 1.2)	0.8 (0.7 - 0.9)	66.7	

[1] N = 58,777 for DLHS-1 (1998-99); 58,416 for DLHS-2 (2002-04); 61,729 for DLHS-3 (2007-08)

[2] BCG: Bacillus Calmette-Guerin; DPT3: Three doses of Diphtheria-Pertussis-Tetanus; OPV3: Three doses of Oral Polio Vaccine

[3] Relative change calculated as [(DLHS-3 (%)/DLHS-1 (%))- 1] x 100

[4] P-value for trend from the Chi-square test for trend with Rao-Scott design adjustment

5.2.2 Community-based studies in Vellore, southern India (studies II and III)

The coverage of UIP vaccines during the first year of life of the surveyed children in the community-based studies in Vellore is presented in Table 16. Most children (94%) in the rural community (study II) had a vaccination card available during the survey. Vaccination coverage estimated using information from vaccination cards or parental recall (*n* = 643) was 100% for BCG, and 99% and 98% for the third dose of pentavalent/DPT and measles/MR vaccination, respectively. The coverage of BCG, third dose of pentavalent/DPT, and OPV doses among children with a vaccination card (*n* = 606) was 94%, 96%, and 93%. Oral polio vaccination coverage was similar to pentavalent/DPT vaccination coverage as these vaccines were co-administered (>98% of all doses).

The proportion of fully vaccinated children in rural Vellore was 96% and 84% for information from vaccination cards or parental recall and vaccination cards alone. The sensitivity and specificity of parental recall to classify children's vaccination status (using vaccination card information as the gold standard) were 95% and 21%, respectively. Of the children with a vaccination card, one child was completely unvaccinated, whereas the others (*n* = 97) were partially vaccinated. A majority (72%, n = 70) of the partially vaccinated children had missed 1-2 UIP doses, and the most frequently missed vaccines were the measles/MR (22% of all missed doses) and BCG (18%) vaccination, and the first OPV dose (17%) (Figure 2). A majority (71%) of children with a vaccination card (*n* = 606) had received all vaccination doses at the prescribed age and interval according to the UIP schedule. A small proportion of children (13%) had received all the recommended doses, but at least one dose was not according to schedule. Failure to adhere to the UIP schedule among these children was mainly due to early (<9 months of age) measles/MR vaccination (32% of doses not provided to schedule) or an interval less than 28 days between pentavalent/DPT doses (32%).

Vaccination card retention was 51% for the surveyed children in the communities experiencing disadvantage in Vellore (study III). Vaccination coverage using information from vaccination cards or parental recall (*n* = 100) was 97% for BCG, 81% for the third dose of pentavalent, and 75% for the measles vaccination (Table 16). For children with a vaccination card (*n* = 51), coverage of BCG, third dose of pentavalent/DPT, and measles vaccination was 94%, 90%, and 90%, respectively. The proportions of fully vaccinated children were 65% and 77% for information based on either vaccination cards or parental recall and vaccination cards alone. The sensitivity and specificity of parental recall to classify their child's vaccination status was 100% and 58%, respectively. None of the children with a vaccination card were unvaccinated, and 12 (23%) were partially vaccinated. Two-thirds (67%, *n* = 8) of the partially vaccinated children had missed 1-2 UIP doses, and the most frequently missed doses were the third dose of OPV (24% of all missed doses), the third dose of pentavalent/DPT (20%), and measles/MR (20%) vaccination (Figure 2). Little over half (55%) of the children with a vaccination card received all the recommended UIP vaccines at the prescribed age and interval during their first year of life. A fifth (22%) of the children were fully vaccinated but had untimely vaccinations, mainly due to measles vaccinations provided after their first birthday (50% of doses not provided to schedule) and suboptimal intervals between the pentavalent/DPT doses (44%).

The coverage of three doses of pentavalent/DPT and measles/MR vaccination and fully vaccinated children (using vaccination cards or parental recall information) was significantly lower for children from the disadvantaged communities than the rural communities in Vellore ($p<0.001$ for all comparisons) (Figure 3). However, there was no significant difference in these coverage indicators when comparing the disadvantaged and rural communities for children with a vaccination card (Figure 3).

Table 16: Coverage and vaccination status of children aged 12-23 months in a rural community and among disadvantaged communities in Vellore, 2017-18

Vaccine antigen[1]	Vaccination card or parental recall		Vaccination card only		Schedule-appropriate vaccination[3]	
	Number vaccinated	Proportion (95%CI)[2]	Number vaccinated	Proportion (95%CI)[2]	Number vaccinated	Proportion (95% CI)[2]
Rural community (*N* = 643)						
BCG	642	100.0 (-)	572	94.4 (91.8 - 96.2)	567	93.5 (91.2 - 95.9)
DPT-1/Penta-1	640	99.8 (98.8 - 99.9)	590	97.4 (95.1 - 98.6)	572	94.4 (92.2 - 96.5)
DPT-2/Penta-2	636	99.5 (97.9 - 99.8)	590	97.4 (95.3 - 98.5)	571	94.2 (92.0 - 95.8)
DPT-3/Penta-3	632	99.2 (97.1 - 99.7)	580	95.7 (93.2 - 97.2)	567	93.6 (91.3 - 95.3)
OPV-1	641	99.8 (98.8 - 99.9)	593	97.9 (96.6 - 98.7)	575	94.9 (93.0 - 96.7)
OPV-2	636	99.3 (97.9 - 99.8)	589	97.2 (94.7 - 98.5)	570	94.0 (91.9 - 95.7)
OPV-3	635	99.2 (97.1 - 99.7)	579	95.5 (92.8 - 97.3)	565	93.2 (90.9 - 95.0)
Measles or MR	630	98.1 (95.3 - 99.3)	563	92.9 (89.7 - 95.2)	517	85.3 (81.7 - 88.3)
Fully vaccinated	619	96.4 (93.4 - 98.1)	509	84.0 (79.0 - 87.9)	429	70.8 (65.6 - 75.5)
Disadvantaged communities (*N* = 100)						
BCG	97	97.0 (92.4 - 98.8)	48	94.1 (84.8 - 97.9)	48	94.1 (84.8 - 97.9)
DPT-1/Penta-1	90	90.0 (83.0 - 94.3)	48	94.1 (85.2 - 97.8)	48	94.1 (85.2 - 97.8)
DPT-2/Penta-2	86	86.0 (78.3 - 91.3)	50	98.0 (89.7 - 99.7)	42	82.4 (66.0 - 91.8)
DPT-3/Penta-3	81	81.0 (70.2 - 88.5)	46	90.2 (76.0 - 96.4)	42	82.4 (71.1 - 89.9)
OPV-1	92	92.0 (84.6 - 96.0)	50	98.0 (89.7 - 99.7)	50	98.0 (89.7 - 99.7)
OPV-2	86	86.0 (78.3 - 91.3)	50	98.0 (89.7 - 99.7)	44	86.3 (71.1 - 94.1)
OPV-3	80	80.0 (68.9 - 87.8)	45	88.2 (74.8 - 95.0)	41	80.4 (69.2 - 88.2)
Measles or MR	75	75.0 (65.3 - 82.7)	46	90.2 (76.9 - 96.2)	38	74.5 (60.2 - 85.0)
Fully vaccinated	65	65.0 (52.5 - 75.8)	39	76.5 (58.2 - 88.4)	28	54.9 (40.9 - 68.2)

[1] BCG: Bacillus Calmette-Guerin; DPT: Diphtheria-Pertussis-Tetanus; Penta: Pentavalent (DPT + Hepatitis B + Hib); OPV: Oral Polio Vaccine; MR: Measles-Rubella

[2] Weighted proportions and 95% confidence intervals (accounting for clustering of surveyed children)

[3] Children with a vaccination card who received their doses according to the UIP recommended ages, and before their first birthday (BCG: birth to 1 year; DPT-1/Penta-1/OPV-1: After 6 weeks; DPT-2/Penta-2/OPV-2: ≥ 28 days after first dose; DPT-3/Penta-3, OPV-3: ≥ 28 days after second dose; Measles or MR: 9 – 12 months)

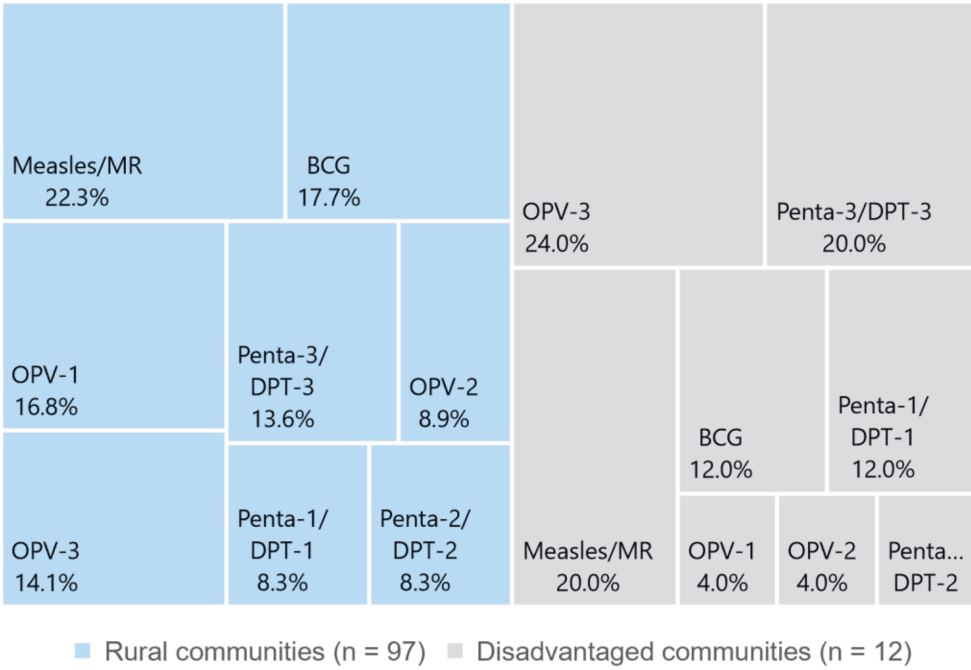

Figure 2. Missed vaccination doses among the children aged 12-23 months with a vaccination card in the community-based surveys among the rural and disadvantaged communities in Vellore, southern India, 2017-18

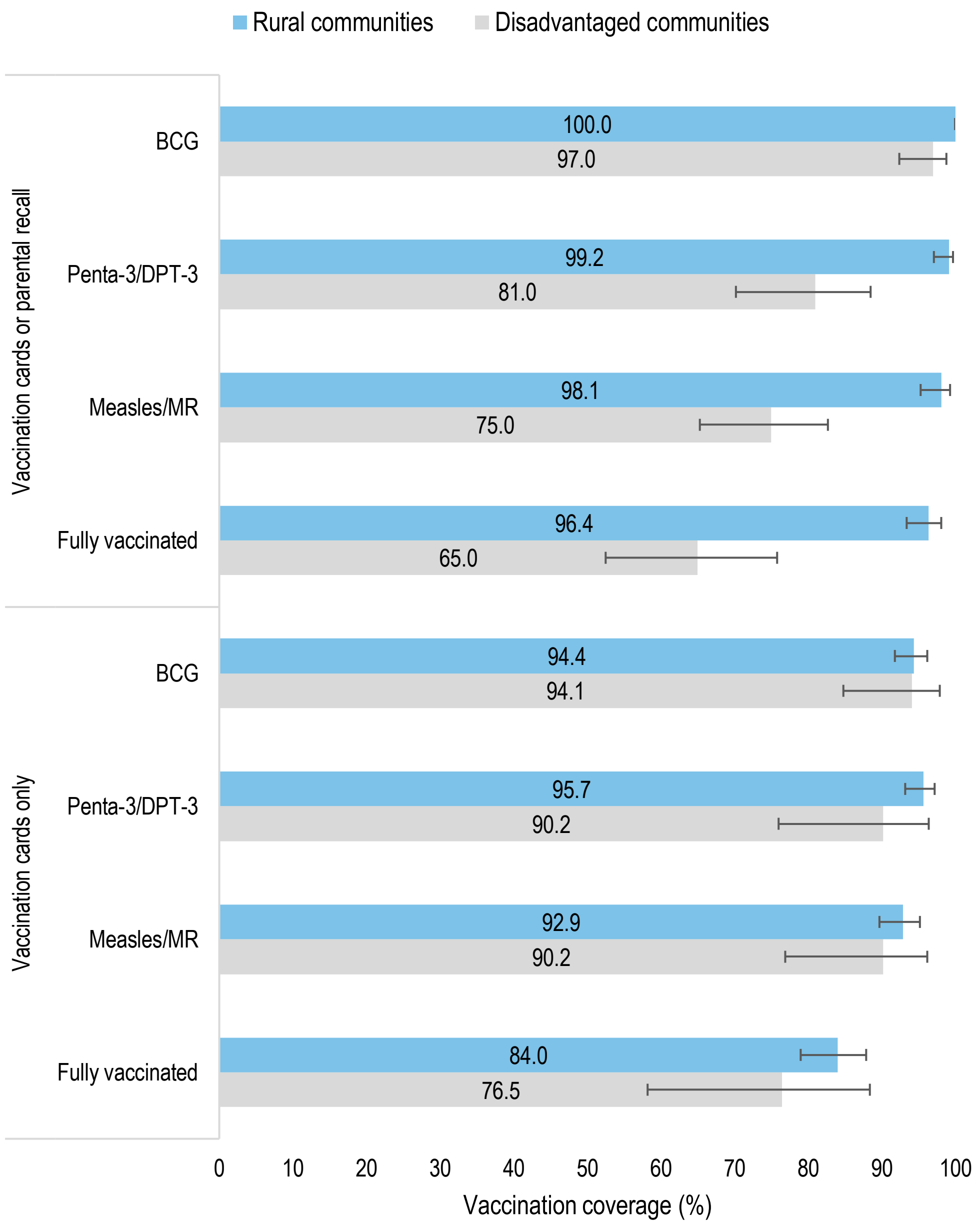

Figure 3. Comparison of the coverage proportions among children (aged 12-23 months) vaccinated with selected UIP antigens in the surveyed rural and disadvantaged communities in Vellore, 2017-18. The Horizontal bars represent design-adjusted 95% confidence intervals for the coverage proportions.

5.3 Factors associated with routine childhood vaccination uptake

5.3.1 National study (study I)

All the socio-demographic variables assessed in the univariate analysis were significantly associated with children's vaccination status for the combined DLHS surveys. Vaccination status was negatively associated with rural residence, Muslim religion, schedule caste affiliation, child characteristics such as female gender and not having a vaccination card, and maternal characteristics such as higher age (26-35 & >35 years), illiteracy, non-institutional delivery, fewer antenatal care visits and non-receipt of maternal tetanus vaccination (p<0.001 for all associations). Results from the multinomial regression modeling of the factors associated with children being partially vaccinated or unvaccinated (versus fully vaccinated) are presented in Table 17.

In the multivariate analysis, children in the 2007-08 (DLHS-3) period were less likely to be unvaccinated (Adjusted prevalence odds ratio (aPOR): 0.92, 95% CI = 0.86-0.98) but more likely to be partially vaccinated (aPOR:1.58, 95%CI = 1.52-1.65) compared to the 1998-99 (DLHS-1) period. Female children were more likely to be unvaccinated than males (aPOR: 1.16, 95%CI = 1.10-1.21). Similarly, children living in urban households (compared with rural households) were also more likely to be unvaccinated (aPOR: 1.37, 95%CI = 1.26-1.49). Compared to Hindu children, Muslim children were more likely to be unvaccinated (aPOR: 2.03, 95% CI = 1.89–2.18) and partially vaccinated (aPOR:1.44, 95%CI = 1.37–1.51). Relative to children from the general class, those from the scheduled castes and other backward classes were more likely to be unvaccinated and partially vaccinated. Lower maternal education, fewer antenatal care visits, non-institutional delivery, non-receipt of maternal tetanus vaccination, and non-retention of children's vaccination cards were also associated with an increased odds of children being unvaccinated and partially vaccinated during 1998-2008.

Table 17. Multinomial logistic regression for the socio-demographic factors associated with routine childhood vaccination uptake among Indian children aged 12-23 months, 1998-2008

Characteristic	Weighted proportion (95% CI)[1]			Adjusted Prevalence Odds Ratio (95% CI)[2]	
	Fully vaccinated	Partially vaccinated	Unvaccinated	Partially vaccinated versus fully vaccinated	Unvaccinated versus fully vaccinated
Survey period					
1998 - 1999	54.3 (53.7 - 54.9)	27.4 (26.9 - 27.9)	18.3 (17.9 - 18.8)	**Ref**	**Ref**
2002 - 2004	47.9 (47.1 - 48.7)	32.1 (31.5 - 32.8)	20.0 (19.4 - 20.6)	1.51 (1.44 - 1.58)***	1.57 (1.47 - 1.67)***
2007 - 2008	56.0 (55.5 - 56.6)	34.6 (34.2 - 35.1)	9.4 (9.0 - 9.7)	1.58 (1.52 - 1.65)***	0.92 (0.86 - 0.98)**
Location					
Rural	49.4 (48.6 - 50.2)	32.3 (32.0 - 32.7)	18.3 (17.7 - 18.9)	**Ref**	**Ref**
Urban	65.2 (63.8 - 66.6)	25.1 (24.0 - 26.2)	9.7 (9.2 - 10.3)	1.03 (0.98 - 1.07)	1.37 (1.26 - 1.49)***
Religion					
Hindu	54.3 (52.9 - 55.7)	30.7 (30.1 - 31.2)	15.0 (14.1 - 15.9)	**Ref**	**Ref**
Muslim	43.9 (42.4 - 45.4)	31.7 (30.9 - 32.5)	24.4 (23.2 - 25.6)	1.44 (1.37 - 1.51)***	2.03 (1.89 - 2.18)***
Christian	58.8 (56.5 - 61.1)	29.0 (27.6 - 30.5)	12.2 (10.8 - 13.5)	1.01 (0.92 - 1.12)	0.90 (0.76 - 1.07)
Other[3]	70.5 (69.0 - 72.0)	21.6 (20.2 - 22.9)	7.9 (7.1 - 8.8)	0.62 (0.56 - 0.67)***	0.58 (0.50 - 0.69)***
Social class					
General class	50.6 (49.5 - 51.7)	31.6 (30.9 - 32.3)	17.8 (16.8 - 18.7)	**Ref**	**Ref**
Scheduled caste	47.1 (45.4 - 48.7)	35.7 (34.8 - 36.7)	17.2 (16.2 - 18.2)	1.11 (1.06 - 1.16)***	1.29 (1.20 - 1.39)***
Scheduled tribe	51.1 (49.8 - 52.4)	30.9 (30.3 - 31.6)	18.0 (17.0 - 18.9)	1.04 (0.98 - 1.11)	1.09 (0.99 - 1.19)
Other backward classes	61.7 (60.5 - 62.9)	26.5 (25.8 - 27.2)	11.8 (11.1 - 12.5)	1.16 (1.12 - 1.21)***	1.42 (1.34 - 1.52)***
Mother's age at birth of eligible child					
≤ 18 years	48.2 (46.7 - 49.8)	34.5 (33.5 - 35.4)	17.3 (16.1 - 18.5)	1.23 (1.17 - 1.30)***	1.21 (1.12 - 1.32)***
19-25 years	56.8 (55.7 - 57.9)	30.2 (29.7 - 30.7)	13.0 (12.3 - 13.7)	**Ref**	**Ref**

26-35 years	51.2 (49.6 - 52.9)	29.6 (28.8 - 30.4)	19.2 (18.1 - 20.2)	0.95 (0.92 - 0.98)**	1.05 (0.99 - 1.10)
> 35 years	37.8 (35.8 - 39.8)	31.0 (29.7 - 32.4)	31.1 (29.4 - 32.9)	0.95 (0.88 - 1.03)	1.19 (1.08 - 1.32)***
Mother's education					
High school and above (9 years & above)	76.9 (76.2 - 77.5)	20.3 (19.7 - 20.8)	2.8 (2.6 - 3.1)	**Ref**	**Ref**
Middle (6 - 8 years of schooling)	65.1 (64.3 - 66.0)	28.2 (27.4 - 28.9)	6.7 (6.3 - 7.1)	1.19 (1.13 - 1.26)***	1.17 (1.03 - 1.33)*
Primary (1 - 5 years of schooling)	56.2 (55.4 - 56.9)	32.6 (31.8 - 33.3)	11.2 (10.7 - 11.8)	1.33 (1.27 - 1.41)***	1.50 (1.32 - 1.70)***
No schooling	37.4 (36.5 - 38.1)	35.8 (35.5 - 36.2)	26.8 (26.1 - 27.6)	1.77 (1.68 - 1.86)***	2.61 (2.33 - 2.93)***
Number of antenatal care visits					
≥ 7	78.5 (77.5 - 79.5)	18.6 (17.7 - 19.5)	2.9 (2.6 - 3.2)	**Ref**	**Ref**
3 - 6	68.7 (68.1 - 69.3)	26.3 (25.8 - 26.8)	5.0 (4.7 - 5.3)	1.13 (1.06 - 1.20)***	0.68 (0.58 - 0.80)***
1 - 2	50.4 (49.6 - 51.1)	37.1 (36.5 - 37.7)	12.5 (12.1 - 13.0)	1.60 (1.50 - 1.70)***	1.09 (0.92 - 1.28)
None	29.1 (28.3 - 30.1)	35.1 (34.6 - 35.6)	35.8 (34.9 - 36.7)	1.92 (1.78 - 2.07)***	1.75 (1.50 - 2.06)***
Maternal tetanus vaccination					
Yes	61.7 (60.7 - 62.7)	29.1 (28.5 - 29.7)	9.2 (8.7 - 9.7)	**Ref**	**Ref**
No	26.2 (25.2 - 27.1)	35.1 (34.5 - 35.6)	38.7 (37.6 - 39.9)	1.35 (1.29 - 1.42)***	2.82 (2.64 - 3.01)***
Gender of eligible child					
Male	54.4 (53.1 - 55.7)	30.4 (29.8 - 31.1)	15.2 (14.4 - 16.0)	**Ref**	**Ref**
Female	52.4 (51.1 - 53.4)	30.5 (29.9 - 31.0)	17.1 (16.2 - 18.0)	1.03 (1.00 - 1.06)*	1.16 (1.10 - 1.21)***
Place of delivery					
Institutional government	69.9 (69.2 - 70.6)	25.3 (24.6 - 25.9)	4.8 (4.6 - 5.1)	**Ref**	**Ref**
Institutional private	71.7 (70.7 - 72.7)	23.1 (22.4 - 23.9)	5.2 (4.7 - 5.6)	1.07 (1.02 - 1.13)**	1.11 (0.98 - 1.26)
Non-institutional	41.0 (40.2 - 41.8)	34.9 (34.6 - 35.3)	24.1 (23.4 - 24.8)	1.22 (1.17 - 1.27)***	1.53 (1.41 - 1.67)***
Vaccination card					
Yes (seen)	75.7 (75.0 - 76.4)	23.4 (22.7 - 24.1)	0.9 (0.7 - 1.0)	**Ref**	**Ref**

Yes (not seen)	57.5 (56.8 - 58.2)	37.8 (37.1 - 38.3)	4.7 (4.5 - 5.1)	1.90 (1.83 - 1.97)***	6.53 (5.51 - 7.75)***
No	22.4 (21.6 - 23.1)	32.0 (31.4 - 32.5)	45.6 (44.8 - 46.4)	3.57 (3.43 - 3.72)***	118.0 (100.24 - 138.83)***

[1] Coverage proportions (and 95% CIs) are presented for the combined DLHS surveys and are calculated using the total weighted sample of children in each covariate category as the denominator

[2] Multivariate model adjusted for type of dwelling, age of child in months and geographical region; Analytical sample (*N*) = 159,647; * p<0.05, ** p<0.01, *** p<0.001

[3] Other religions include Sikh, Buddhism, Jainism, Zoroastrianism, Judaism and Atheism

5.3.2 Community-based studies in Vellore, southern India

5.3.2.1 Community-based survey in rural Vellore (study II)

The univariate and multivariate analyses of the factors associated with children's vaccination status (*full versus under vaccination*) for children with a vaccination card in rural Vellore are presented in Table 18. In the univariate analysis, children vaccinated in private facilities had a lower odds of being fully vaccinated than those receiving vaccination in public facilities (prevalence odds ratio (POR): 0.40, 95%CI = 0.17 – 0.97). Children whose parents agreed (strongly agreed or agreed) that they were familiar with the universal immunization program (UIP) schedule had a higher likelihood of being fully vaccinated compared with those who did not agree (neutral, disagreed, or strongly disagreed) to be familiar with the schedule (POR: 2.02, 95%CI = 1.23 - 3.33). In addition, children whose parents reported receiving information on the UIP schedule during antenatal visits were more likely to be fully vaccinated than those who did not receive this information during these visits (POR: 2.53, 95%CI = 1.25–5.11). In the multivariate analysis, self-reported familiarity with the UIP schedule (adjusted prevalence odds ratio (aPOR): 2.06, 95%CI = 1.26 – 3.38) and receipt of information on the UIP schedule during antenatal visits (aPOR: 2.16, 95% CI = 1.13 – 4.12) were the only factors significantly associated with the full vaccination status of children (Table 18). These factors remained significantly associated with full vaccination status in the supplementary analysis, including all children regardless of the source of their vaccination information (*n* = 643) (Data not presented). However, children from other backward or general classes were also more likely to be fully vaccinated than children from the scheduled castes in this analysis (aPOR: 6.02, 95%CI = 1.82 – 19.90).

Table 18. Univariate and multivariate logistic regression for the socio-demographic and non-socio-demographic characteristics associated with the vaccination status of children aged 12-23 months in rural Vellore, southern India, 2017-18 (*N* = 606)

Characteristic	**Proportion, *n* (%)**		**Prevalence Odds Ratio (95% CI)[1]**	
	Fully vaccinated	**Undervaccinated[2]**	**Unadjusted**	**Adjusted**
Socio-demographic				
Child's age				
12-17 months	236 (46.4)	56 (57.7)	**Ref**	**Ref**
18-23 months	273 (53.6)	41 (42.3)	1.58 (0.94 - 2.65)*	1.64 (0.99 - 2.70)*
Child's gender				
Male	257 (50.5)	62 (63.9)	**Ref**	**Ref**
Female	252 (49.5)	35 (36.1)	1.74 (0.97 - 3.01)*	1.70 (0.92 - 3.11)*
Birth order				
1	210 (41.3)	49 (50.5)	**Ref**	**Ref**
2	230 (45.2)	37 (38.1)	1.45 (1.01 - 1.95)**	1.24 (0.86 - 1.79)
≥3	69 (13.6)	11 (11.3)	1.46 (0.70 - 3.09)	1.77 (0.77 - 4.10)
Place of vaccination				
Public facility	484 (95.1)	86 (88.7)	**Ref**	**Ref**
Private facility	25 (4.9)	11 (11.3)	0.40 (0.17 - 0.97)**	0.62 (0.20 - 1.92)
Mother's age at birth of child				
< 20 years	60 (11.8)	9 (9.3)	**Ref**	
20 - 30 years	417 (81.9)	81 (83.5)	0.77 (0.34 - 1.73)	-
> 30 years	32 (6.3)	7 (7.2)	0.69 (0.20 - 2.39)	
Mother's education				
Illiterate	11 (2.2)	5 (5.2)	**Ref**	
Up to 12th standard	424 (83.3)	73 (75.3)	2.64 (0.54 - 13.02)	-
Diploma/Degree	74 (14.5)	19 (19.5)	1.77 (0.34 - 9.09)	
Father's education				
Illiterate	23 (4.5)	4 (4.1)	**Ref**	
Up to 12th standard	417 (81.9)	76 (78.4)	0.95 (0.16 - 5.52)	-
Diploma/Degree	69 (13.6)	17 (17.5)	0.71 (0.11 - 4.56)	
Mother's occupation				
Homemaker	448 (88.0)	80 (82.5)	**Ref**	
Wage earner	51 (10.0)	14 (14.4)	0.65 (0.32 - 1.31)	-
Salary earner/business	10 (2.0)	3 (3.1)	0.60 (0.17 - 2.06)	

Father's occupation				
Unemployed	12 (2.4)	4 (4.1)	**Ref**	**Ref**
Wage earner	365 (72.4)	63 (65.0)	1.93 (0.73 - 5.13)*	1.51 (0.61 - 3.79)
Salary earner/business	127 (25.2)	30 (30.9)	1.41 (0.43 - 4.64)	1.22 (0.42 - 3.60)
Religion				
Hindu	495 (97.3)	94 (96.9)	**Ref**	-
Others	14 (2.7)	3 (3.1)	0.89 (0.16 - 4.81)	
Household size				
< 5	171 (33.6)	34 (35.1)	**Ref**	
5 - 10	331 (65.0)	62 (63.9)	1.06 (0.71 - 1.58)	-
> 10	7 (1.4)	1 (1.0)	1.39 (0.14 - 13.84)	
Social group				
Scheduled caste	127 (24.9)	23 (23.7)	**Ref**	**Ref**
Scheduled tribe	47 (9.2)	18 (18.6)	0.47 (0.17 - 1.29)*	0.50 (0.18 - 1.35)
Other backward classes/General class	335 (65.9)	56 (57.7)	1.08 (0.57 - 2.04)	1.50 (0.80 - 2.84)
Type of dwelling				
Mud/semi-cemented	44 (8.6)	3 (3.1)	**Ref**	-
Cemented	465 (91.4)	94 (96.9)	0.33 (0.05 - 2.44)	
Non-socio-demographic				
Travel to immunization facility				
Walking	337 (66.2)	61 (62.9)	**Ref**	-
Private/public transport	172 (33.8)	36 (37.1)	0.86 (0.49 - 1.53)	
I think immunization if important to keep my child healthy				
Do not agree[3]	2 (0.4)	1 (1.0)	**Ref**	-
Agree	507 (99.6)	96 (99.0)	2.64 (0.21 - 32.81)	
I am familiar with the immunization schedule				
Do not agree[3]	127 (25.0)	39 (40.2)	**Ref**	**Ref**
Agree	382 (75.0)	58 (59.8)	2.02 (1.23 - 3.33)**	2.06 (1.26 - 3.38)**
The timing of immunization sessions was convenient for me				
Do not agree[3]	262 (51.5)	58 (59.8)	**Ref**	-
Agree	247 (48.5)	39 (40.2)	1.40 (0.80 - 2.45)	

Self-reported hesitancy with one or more vaccines				
Hesitant[4]	302 (59.3)	52 (53.6)	**Ref**	-
Not hesitant	207 (40.7)	45 (46.4)	0.79 (0.49 - 1.28)	
Health worker home visits				
No/not sure	107 (21.0)	22 (22.7)	**Ref**	-
Yes	402 (79.0)	75 (77.3)	1.12 (0.57 - 2.12)	
Received information about vaccines during antenatal visits				
No/not sure	42 (8.3)	18 (18.6)	**Ref**	**Ref**
Yes	467 (91.8)	79 (81.4)	2.53 (1.25 - 5.11)**	2.16 (1.13 - 4.12)**
Received an incentive for completing pentavalent/DPT series				
No	157 (30.9)	38 (39.2)	**Ref**	**Ref**
Yes	351 (69.1)	59 (60.8)	1.44 (0.91 - 2.29)	1.48 (0.83 - 2.58)

[1] * p< 0.10, ** p< 0.05

[2] Undervaccinated includes children who were partially-vaccinated and unvaccinated (*n* = 1)

[3] Do not agree = Neutral, disagree, strongly disagree; Agree = Agree, strongly agree

[4] Hesitant = Neutral, very hesitant, strongly hesitant; Not hesitant = Not too hesitant and not hesitant

Univariate and multivariate analyses were also performed to assess the factors associated with the schedule-appropriate vaccination status for children with a vaccination card available during the survey (Table 19). Birth order, social group, self-reported familiarity with and receipt of the information on the UIP schedule, and receiving an incentive for completing the pentavalent/DPT vaccination series were associated with the schedule-appropriate vaccination status of children in the univariate analysis ($p \leq 0.20$). In the multivariate analysis, children belonging to families of the other backward classes or general classes were more likely to be vaccinated according to schedule than those belonging to the scheduled castes (aPOR: 1.69, 95%CI = 1.04 – 2.73).

Table 19. Univariate and multivariate logistic regression for the socio-demographic and non-socio-demographic characteristics associated with the schedule-appropriate vaccination status of children aged 12-23 months in rural Vellore, southern India, 2017-18 (N = 606)

Characteristic	Proportion, *n* (%)		Prevalence Odds Ratio (95% CI)[1]	
	Schedule-appropriate	Not schedule-appropriate	Unadjusted	Adjusted
Socio-demographic				
Child's age				
12-17 months	206 (48.0)	86 (48.6)	**Ref**	-
18-23 months	223 (52.0)	91 (51.4)	1.02 (0.74 - 1.43)	
Child's gender				
Male	217 (50.6)	102 (57.6)	**Ref**	-
Female	212 (49.4)	75 (42.4)	1.32 (0.83 - 2.14)	
Birth order				
1	174 (40.6)	85 (48.0)	**Ref**	**Ref**
2	198 (46.2)	69 (39.0)	1.40 (1.04 - 1.88)**	1.36 (0.98 - 1.88)
≥3	57 (13.2)	23 (13.0)	1.21 (0.75 - 1.95)	1.64 (0.84 - 3.19)
Place of vaccination				
Public facility	407 (94.9)	163 (92.1)	**Ref**	-
Private facility	22 (5.1)	14 (7.9)	0.62 (0.30 - 1.30)	
Mother's age at birth of child				
< 20 years	46 (10.7)	23 (13.0)	**Ref**	
20 - 30 years	354 (82.5)	144 (81.4)	1.22 (0.69 - 2.19)	-
> 30 years	29 (6.8)	10 (5.6)	1.45 (0.58 - 3.64)	
Mother's education				
Illiterate	10 (2.3)	6 (3.4)	**Ref**	
Up to 12th standard	357 (83.2)	140 (79.1)	1.53 (0.36 - 6.58)	-
Diploma/Degree	62 (14.5)	31 (17.5)	1.20 (0.29 - 4.99)	
Father's education				
Illiterate	19 (4.4)	8 (4.5)	**Ref**	
Up to 12th standard	353 (82.3)	140 (79.1)	1.06 (0.37 - 3.08)	-
Diploma/Degree	57 (13.3)	29 (16.4)	0.83 (0.27 - 2.49)	
Mother's occupation				
Homemaker	378 (88.1)	150 (84.8)	**Ref**	
Wage earner	42 (9.8)	23 (13.0)	0.72 (0.33 - 1.49)	-
Salary earner/business	9 (2.1)	4 (2.2)	0.89 (0.28 - 2.82)	

Father's occupation				
Unemployed	10 (2.4)	6 (3.4)	**Ref**	
Wage earner	311 (73.3)	117 (66.1)	1.59 (0.58 - 4.38)	-
Salary earner/business	103 (24.3)	54 (30.5)	1.14 (0.39 - 3.33)	
Religion				
Hindu	419 (97.7)	170 (96.0)	**Ref**	-
Others	10 (2.3)	7 (4.0)	0.58 (0.17 - 1.92)	
Household size				
< 5	147 (34.3)	58 (32.8)	**Ref**	
5 - 10	276 (64.3)	117 (66.1)	0.93 (0.65 - 1.33)	-
> 10	6 (1.4)	2 (1.1)	1.18 (0.21 - 6.62)	
Social group				
Scheduled caste	101 (23.5)	49 (27.7)	**Ref**	**Ref**
Scheduled tribe	39 (9.1)	26 (14.7)	0.73 (0.34 - 1.54)	0.73 (0.34 - 1.57)
Other backward classes/General class	289 (67.4)	102 (57.6)	1.37 (0.84 - 2.24)	1.69 (1.04 - 2.73)**
Type of dwelling				
Mud/semi-cemented	36 (8.4)	11 (6.2)	**Ref**	-
Cemented	393 (91.6)	166 (93.8)	0.72 (0.25 - 2.09)	
Non-socio-demographic				
Travel to immunization facility				
Walking	285 (66.4)	113 (63.8)	**Ref**	-
Private/public transport	144 (33.6)	64 (36.2)	0.89 (0.55 - 1.44)	
I think immunization if important to keep my child healthy				
Do not agree[2]	2 (0.5)	1 (0.6)	**Ref**	-
Agree	427 (99.5)	176 (99.2)	1.21 (0.1 - 15.1)	
I am familiar with the immunization schedule				
Do not agree[2]	108 (25.2)	58 (32.8)	**Ref**	**Ref**
Agree	321 (74.8)	119 (67.2)	1.44 (0.91 - 2.30)	1.42 (0.90 - 2.22)
The timing of immunization sessions was convenient for me				
Do not agree[2]	31 (7.2)	12 (6.8)	**Ref**	-
Agree	398 (92.8)	165 (93.2)	0.93 (0.44 - 1.99)	
Self-reported hesitancy with one or more vaccines				

Hesitant[3]	259 (60.4)	95 (53.7)	**Ref**	-
Not hesitant	170 (39.6)	82 (46.3)	0.76 (0.54 - 1.07)	
Health worker home visits				
No/not sure	88 (20.5)	41 (23.2)	**Ref**	-
Yes	341 (79.5)	136 (76.8)	1.16 (0.68 - 2.00)	
Received information about vaccines during antenatal visits				
No/not sure	36 (8.4)	24 (13.6)	**Ref**	**Ref**
Yes	393 (91.6)	153 (86.4)	1.71 (0.97 - 3.01)*	1.42 (0.90 - 2.22)
Received an incentive for completing pentavalent/DPT series				
No	130 (30.3)	65 (36.9)	**Ref**	**Ref**
Yes	299 (69.7)	111 (63.1)	1.35 (0.98 - 1.86)*	1.55 (0.82 - 2.94)

[1] * p< 0.10, ** p< 0.05

[2] Do not agree = Neutral, disagree, strongly disagree; Agree = Agree, strongly agree

[3] Hesitant = Neutral, very hesitant, strongly hesitant; Not hesitant = Not too hesitant and not hesitant

5.3.2.2 Community-based survey among disadvantaged communities in Vellore (study III)

In the univariate analysis, children from Narikuravar communities were less likely to be fully vaccinated than children from the Irular, stone quarry, and brick kiln worker communities (POR: 0.25, 95%CI = 0.08 - 0.81) (Table 20). Children with a vaccination card available during the survey were nearly three times (POR: 2.88, 95% CI = 1.38 - 5.99) more likely to be fully vaccinated than children without a vaccination card. While maternal education (primary education or higher) was positively associated with children's vaccination status, parental occupation (wage earners, salaried or small business owners) was negatively associated with children's vaccination status (Table 20). Parental familiarity with and receipt of the information on the UIP schedule during antenatal visits and receiving a financial incentive for completing the pentavalent/DPT series were also associated with an increased odds of full vaccination among these children. On multivariate analysis, children whose mothers were wage earners (aPOR:0.21, 95%CI = 0.07 – 0.64) or salaried/small business owners (aPOR: 0.18, 95% CI = 0.04 – 0.73) were significantly less likely to be fully vaccinated compared with children who had homemaker mothers (Table 20).

Table 20. Univariate and multivariate logistic regression for the socio-demographic and non-socio-demographic characteristics associated with the vaccination status of children aged 12-23 months among disadvantaged communities in Vellore, southern India, 2017-18 (*N* = 100)

Characteristic	Proportion, *n* (%)		Prevalence Odds Ratio (95% CI)[1]	
	Fully vaccinated	Undervaccinated[2]	Unadjusted	Adjusted
Socio-demographic				
Child's age				
12-17 months	21 (32.3)	15 (42.9)	**Ref**	-
18-23 months	44 (66.7)	20 (58.1)	1.57 (0.74 - 3.34)	
Child's gender				
Male	35 (53.9)	18 (51.4)	**Ref**	-
Female	30 (46.1)	17 (48.6)	0.91 (0.41 - 2.01)	
Birth order				
1	22 (33.9)	7 (20.0)	**Ref**	
2	27 (41.5)	13 (37.1)	0.66 (0.24 - 1.81)	-
≥3	16 (24.6)	15 (42.9)	0.34 (0.11 - 1.06)*	
Mother's age at birth of child				
< 25 years	33 (50.8)	15 (42.9)	**Ref**	-
≥ 25 years	32 (49.2)	20 (57.1)	0.73 (0.37 - 1.44)	
Mother's education				
No formal education	23 (35.4)	23 (65.7)	**Ref**	**Ref**
Primary school or higher	42 (64.6)	12 (34.3)	3.50 (1.15 - 10.64)**	0.99 (0.20 - 4.94)
Father's education				
No formal education	20 (30.8)	19 (54.3)	**Ref**	-
Primary school or higher	45 (69.2)	16 (45.7)	2.67 (0.83 - 8.63)*	
Mother's occupation				
Homemaker	43 (66.2)	8 (22.9)	**Ref**	**Ref**
Wage earner	10 (15.4)	7 (20.0)	0.27 (0.09 - 0.82)**	0.21 (0.07 - 0.64)
Salary earner/business	12 (18.4)	20 (57.1)	0.11 (0.04 - 0.31)**	0.18 (0.04 - 0.73)
Father's occupation				
Unemployed/wage earner	47 (72.3)	15 (42.9)	**Ref**	**Ref**
Salary earner/business	18 (27.7)	20 (57.1)	0.29 (0.11 - 0.77)**	1.30 (0.40 - 4.22)
Religion				
Hindu	57 (87.7)	26 (74.3)	**Ref**	-
Others	8 (12.3)	9 (25.7)	0.41 (0.12 - 1.33)	

Community type				
Other communities[3]	38 (58.5)	9 (74.3)	**Ref**	**Ref**
Narikuravar	27 (41.5)	26 (25.7)	0.25 (0.08 - 0.81)**	0.33 (0.06 - 1.91)
Type of dwelling				
Mud/semi-cemented	28 (43.1)	17 (48.6)	**Ref**	-
Cemented	37 (56.9)	18 (51.4)	0.80 (0.41 - 1.56)	
Vaccination card				
Not available	26 (40.0)	23 (65.7)	**Ref**	**Ref**
Yes	39 (60.0)	12 (34.3)	2.88 (1.38 - 5.99)**	1.59 (0.61 - 4.19)
<u>Non-socio-demographic</u>				
Travel to immunization facility				
Walking	32 (49.2)	22 (62.9)	**Ref**	-
Private/public transport	33 (50.8)	13 (37.1)	1.75 (0.73 - 4.15)	
I think immunization if important to keep my child healthy				
Do not agree[4]	1 (1.5)	4 (11.4)	**Ref**	-
Agree	64 (98.5)	31 (88.6)	8.26 (0.80 - 85.33)*	
I am familiar with the immunization schedule				
Do not agree[4]	22 (33.9)	22 (62.9)	**Ref**	**Ref**
Agree	43 (66.1)	13 (37.1)	3.31 (1.09 - 10.02)**	2.89 (0.90 - 9.28)
Self-reported hesitancy with one or more vaccines				
Hesitant[5]	14 (21.5)	8 (22.9)	**Ref**	-
Not hesitant	51 (78.5)	27 (77.1)	1.08 (0.42 - 2.76)	
Health worker home visits				
No/not sure	13 (20.0)	10 (28.6)	**Ref**	-
Yes	52 (80.0)	25 (71.4)	1.60 (0.63 - 4.09)	
Received information about vaccines during antenatal visits				
No/not sure	2 (3.1)	7 (20.0)	**Ref**	**Ref**
Yes	63 (96.9)	28 (80.0)	7.89 (1.86 - 33.28)**	4.55 (0.58 - 35.38)
Received an incentive for completing pentavalent/DPT series				

No	27 (41.5)	24 (68.6)	**Ref**	**Ref**
Yes	38 (58.5)	11 (31.4)	3.07 (1.26 - 7.49)**	1.18 (0.26 - 5.28)

[1] * p< 0.10, ** p< 0.05

[2] Undervaccinated includes children who were partially-vaccinated and unvaccinated

[3] "Other communities" include the Irular, brick kiln, and stone quarry worker communities

[4] Do not agree = Neutral, disagree, strongly disagree; Agree = Agree, strongly agree

[5] Hesitant = Neutral, very hesitant, strongly hesitant; Not hesitant = Not too hesitant and not hesitant

5.4 Findings from the qualitative analyses (study I, II & III)

5.4.1 Reasons for non-vaccination in India, 1998 – 2008 (study I)

Across the DLHS surveys, the mothers' most frequently reported reason for non-vaccination among children aged 12-23 months was that they were "unaware of the need for immunization" (Figure 4). Other important reasons were not knowing the place for and timing of vaccinations, fear of side-effects following vaccination, access to immunization facilities ("place of immunization too far"), and the absence of health workers ("ANM absent"). The reported reasons for non-vaccination were then categorized using the "5As taxonomy" domains. Most of the reasons were categorized as issues of "awareness," "acceptance," or "affordability" (Figure 4). There were reasons including supply-side issues such as the absence of health workers, vaccine stocks outs, and missed opportunities for vaccination which could not be categorized using the 5As taxonomy. Over the ten years spanning the surveys, poor parental awareness (regarding the need for, place, and timing of vaccinations), acceptance of vaccines (fears of side-effects, lack of trust, and false contraindications), and affordability (financial and non-financial costs) were the most important underlying reasons for non-vaccination among Indian children (Figure 5).

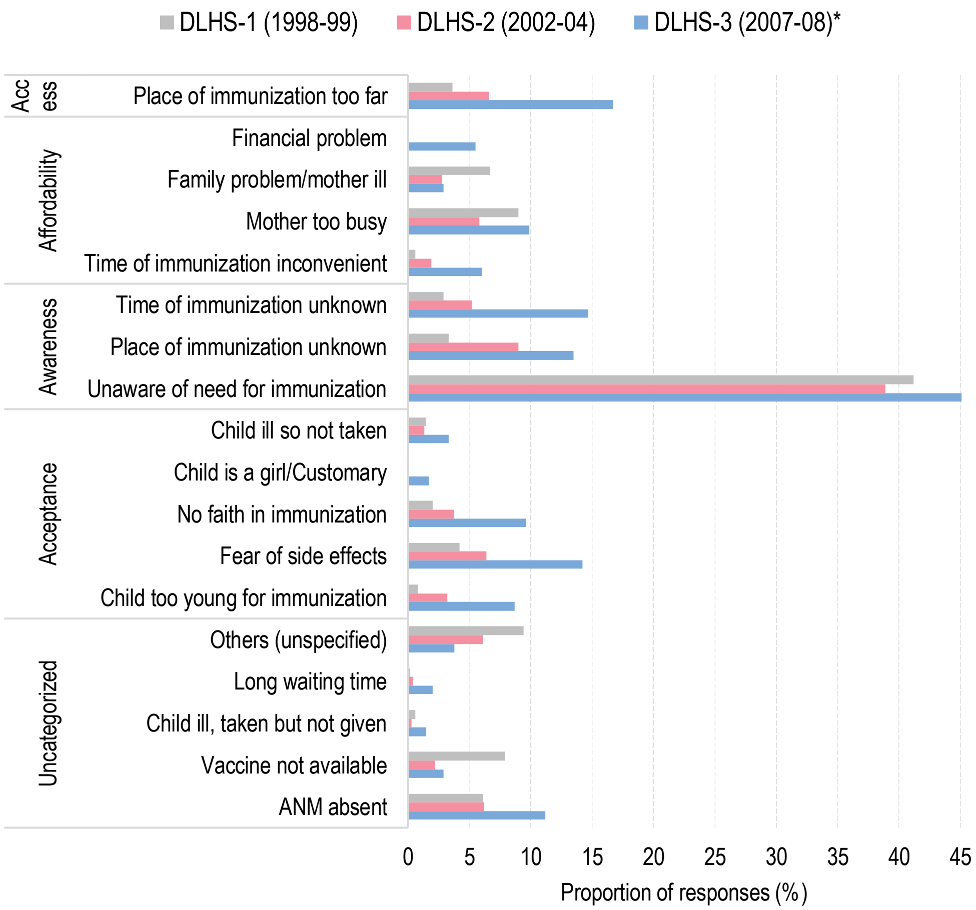

Figure 4. Reported reasons for non-vaccination (organized using the "5As taxonomy" domains) among children aged 12-23 months in India, 1998-2008. *N* = 10,679 responses for DLHS-1; 11,751 for DLHS-2; 5,471 for DLHS-3. *Multiple responses were allowed in DLHS-3.

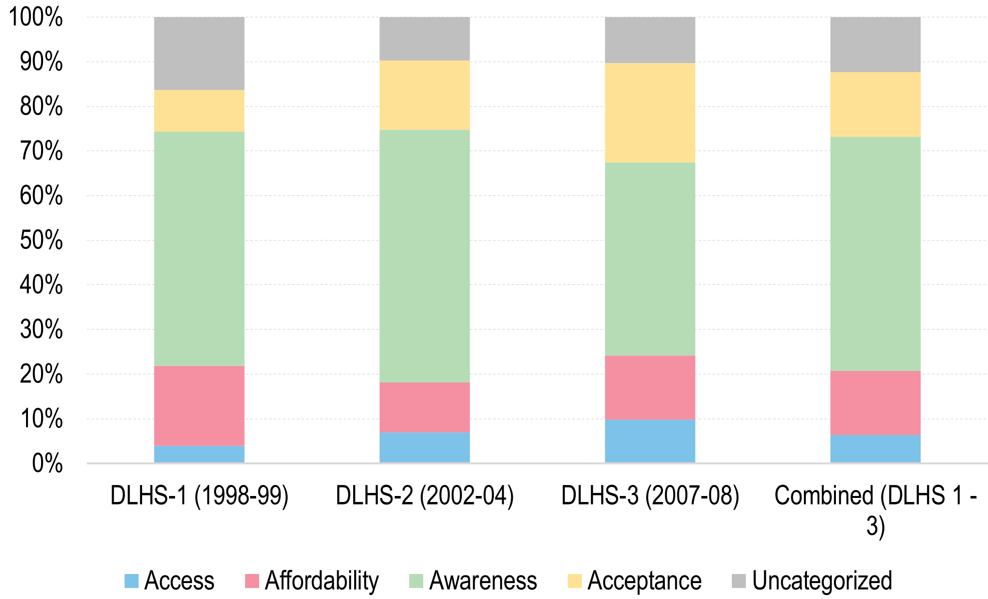

Figure 5. Categorized reasons for non-vaccination among children aged 12-23 months in India for DLHS 1-3, 1998-2008. *N* = 9,669 responses for DLHS-1; 11,081 for DLHS-2; 4,963 for DLHS-3, and 25,713 for DLHS 1-3.

5.4.2 Barriers and facilitators of childhood vaccination among rural and disadvantaged communities in Vellore, 2017-18 (studies II and III)

A total of 31 parents (16 mothers and 15 fathers) and 43 parents (22 mothers and 21 fathers) participated in the FGDs in the rural and disadvantaged communities in Vellore. Each focus group had 7 – 8 parents and lasted for a mean (SD) of 33 (6.9) minutes. Parents discussed all the 5As taxonomy domains organically in the FGDs, and the mapping of sub-themes (generated using open-coding on participant responses) to the 5As domains is presented in Table 21. The findings of the FGDs are outlined by the 5As domains hereafter.

Table 21. Mapping of the sub-themes from the focus group discussions among the parents of children aged 12-23 months from rural and disadvantaged communities in Vellore to the 5As taxonomy domains

5A's taxonomy themes	Sub-themes (open coding)
Access	Good access to vaccines, travel out of town as reason for missed or delayed doses, time of travel out of town
Affordability	Convenient timing of immunization sessions, free vaccination provided by the government a benefit
Awareness	Benefits of vaccination, names of vaccines (or diseases prevented), knowledge sharing by health care workers, other sources of vaccination information, limited awareness of benefits/risks of vaccination, more information requested
Acceptance	Positive view of vaccines in general, vaccination as a social responsibility, influence of health care worker on parents, family or peer influence on attitudes, impact of negative news on parental attitudes, experiences with vaccination, fear of vaccine side-effects
Activation	Government ads and campaigns, prompts and reminders by health care workers, provisions for delayed doses, financial incentives for vaccination
Uncategorized	Suggestions for improvement of immunization services, choice of vaccination centres

5.4.2.1 Access

Parents across the communities did not report issues accessing routine immunization services in their regular places of residence. However, parents from the disadvantaged communities (Narikuravar and Irular communities) expressed difficulties getting children vaccinated when travelling "out of town" for work (primarily during the summer months) or leisure. Parents from the Irular communities discussed this as an important reason for missed or delayed vaccination doses for children.

> *My child has missed vaccines. We were out of town for a long time while she was younger. As far as I know, she only received two vaccines.*
>
> (Father, Irular community)

> *There are parents [in the community] who delay vaccines by a month or two, may be because they travel out of the town [...].*

(Mother, Irular community)

5.4.2.2 Affordability

Parents did not generally discuss the financial costs surrounding vaccinating their children. However, a few parents from the disadvantaged communities (Irular and stone quarry communities) discussed the benefit of receiving routine childhood vaccines for free. A father from an Irular community compared the routine vaccines to vaccines available in private clinics, which he felt were for the more affluent.

> *The government is giving vaccination free, if we had to get those vaccines in private clinics it would cost us 1000 or 2000 INR [15 – 30 USD], we cannot afford that, so we take the vaccines given by the government.*

(Father, Irular community)

A few parents in the rural and disadvantaged (Narikuravar) communities discussed the convenient timing (a non-financial cost described in the 5As taxonomy) of routine vaccination sessions as facilitating vaccination uptake.

> *This time [10 – 12 am] is the best for us, if we leave the house by 10, we are able to get the vaccine by 11 and return home.*

(Mother, Narikuravar community)

5.4.2.3 Awareness

There was widespread understanding of the general benefits of childhood vaccines, with parents mainly describing the utility of vaccines to prevent diseases and keep children healthy. For example, a father in a rural community spoke of the importance of vaccines to build children's immunity.

> *If we vaccinate our children, their power to resist disease will be higher, they won't get sick as often.*

(Father, Rural community)

A mother from a disadvantaged community (Narikuravar community) discussed the benefits of vaccination in general and specific terms, referring to her child's protection against measles.

> *If we vaccinate our children, they are healthy and well, no problems will come to them. Many other children get measles, but my child does not have it because she has been vaccinated.*
>
> (Mother, Narikuravar community)

However, fathers from across the communities commonly expressed their desire for more information on how diseases occur, how vaccines work, and if there were more specific benefits or risks from vaccination that they needed to know.

> *We want to know more about the diseases, how they come and how vaccines help reduce them, this advice would be very helpful to us. […] We want to keep our children safe and healthy, that is very important to us.*
>
> (Father, Irular community)

> *The problem in villages like ours is that fathers generally go for work 6 days a week, we are free on Sundays only. So we don't get a chance to go for vaccination sessions. Most people don't have much awareness about vaccines.*
>
> (Father, Quarry worker community)

Parents across the communities highlighted the important role of village health nurses (VHNs) in disseminating vaccination-related information.

> *We are told [by the VHN] to vaccinate our children at the right time, that is very important to us.*
>
> (Mother, Rural community)

> *The nurse sometimes seats a few of us parents and explains why the vaccine is being given and when the next vaccine is due. They tell us where the vaccine must be given also [site of administration].*
>
> (Mother, Quarry worker community)

Parents from a disadvantaged community (Narikuravar community) discussed their lack of awareness about where to get their child vaccinated when travelling out of town as a reason for missed vaccinations.

We do not know anything there, it is a new place. We do not know where to get it done [vaccinations]. We wait till we return back home, and get our child vaccinated then.

(Mother, Narikuravar community)

5.4.2.4 Acceptance

Parents from all the communities were largely accepting of vaccinations for their children. In addition, any mothers were the primary decision-makers for vaccinating their children and appeared proactive in following up on vaccinations for their children and other children in their neighbourhood.

If there is anyone [an unvaccinated child] like that , we tell them to vaccinate their child. It is good for the child. There are 12 months in a year and 24 hours in a day, what if anything happens to the child at that time? It is important to vaccinate children to keep them protected at all times.

(Mother, Narikuravar community)

Some people don't like to vaccinate their children, they have some fear, we tell them to definitely vaccinate their child.

(Mother, Rural community)

Parents in all communities discussed the influence of VHNs on decision-making for vaccinations for their children.

The Sister (VHN) is good at counselling us about vaccines, she speaks to us individually and convinces us of the need for vaccination for the safety of our child.

(Mother, Rural community)

Parents at times expressed fears due to negative reports about certain childhood vaccines in the media or potential side effects following vaccination as reasons for children not being vaccinated in their respective communities.

Many parents got scared because of that [the news], some did not want to give their children polio drops. People saw some news on TV and some video, and got afraid, will anything like this happen to our children?

(Mother, Narikuravar community)

In one other area, I once heard that a child died after being vaccinated. When I saw the news on the TV, I didn't know whether the news was confirmed or not. I don't remember the channel, but it was a popular one.

(Father, Rural community)

There are many parents who are afraid that their child may get fever after vaccination, or that their child may have some defects.

(Mother, Irular community)

Some parents don't like to vaccinate their children, because they cry a lot after vaccination and cannot sleep well at night.

(Mother, Narikuravar community)

5.4.2.5 Activation

Prompts and reminders about due vaccinations were commonly discussed in rural communities and by a small number of Narikuravar and Irular parents as facilitating timely vaccination. Telephonic reminders and house visits by the VHNs were discussed as the most effective mode of "nudging" parents towards vaccinating their children.

They inform us about vaccination sessions one day in advance that we must vaccinate our children on that day, so all mothers listen and take their children promptly for immunization sessions.

(Mother, Rural community)

The VHN comes home and tells us about vaccination for our children.

(Mother, Rural community)

[…] *Even if we miss immunization sessions in the Anganwadi [public childcare centers], she [the VHN] comes in search of the specific houses with such children and organizes special sessions to get them vaccinated the following day.*

(Father, Irular community)

5.4.2.6 Uncategorized

A few parents offered suggestions for the improvement of routine vaccines or immunization services for their children.

> *It would be good if they give better vaccines, it would be nice if there is no fever or other effect from vaccination.*

(Father, Irular community)

> *If the doctor comes to our village once a week, it would be best for our children. He can check to see if our children are well [after vaccinations] and that would be nice.*

(Father, Rural community)

Some parents from the rural and Narikuravar communities expressed possible reasons why some parents choose to vaccinate their children in private immunization facilities instead of public facilities.

> *Some people think that vaccination in private centers is slightly better, so they take their children there.*

(Mother, Narikuravar community)

> *Government vaccines have slightly bigger needles, children cry more because of that, I think. In the private center, the needles are smaller, the children don't even know when they are poked, as soon as they poke the child they take the needle out, that is good.*

(Mother, Narikuravar community)

6 DISCUSSION

6.1 Summary of the findings across the studies

The national study (study I), which utilized publicly available, district-level household and facility survey (DLHS) data, revealed that routine vaccination coverage among children aged 12-23 months during 1998-2008 was low. Estimates from three DLHS (DLHS1-3) rounds showed that 53%, 32%, and 15% of children were fully vaccinated, partially vaccinated, and unvaccinated, respectively. While the proportions of unvaccinated children decreased, the pool of partially vaccinated children increased during 1998-2008, suggesting an increase in vaccine dropouts over time. The community-based surveys in Vellore, a southern Indian district selected for intensified routine immunization through the Mission Indradhanush campaign in 2015, revealed a high childhood vaccination coverage (84-96% fully vaccinated) of UIP vaccines in rural communities. However, suboptimal vaccination coverage (65-77% fully vaccinated) was observed among children in traditionally disadvantaged communities, including nomadic, tribal, and migrant groups.

In the multivariate analysis for the national study, children's vaccination status was inversely associated with child and household characteristics such as female gender, Muslim religion, lower caste, and urban residence, and maternal characteristics such as lower education, fewer antenatal care visits, and the non-receipt of tetanus vaccination during pregnancy. For example, children whose mothers had not received a tetanus vaccination during pregnancy were nearly three times more likely to be unvaccinated (aPOR: 2.82, 95% CI = 2.64 – 3.01) than children whose mothers had received a maternal tetanus vaccination. Similarly, children with illiterate mothers were nearly three times more likely to be unvaccinated (aPOR: 2.61, 95% CI = 2.33 – 2.93) than children with high school-educated mothers. No socio-demographic variables were associated with children's vaccination status in the multivariate analysis conducted on the rural community survey in Vellore. However, parental familiarity with and receiving information on the UIP schedule during antenatal visits was associated with an increased likelihood of full vaccination among children. Only maternal occupation was associated with children's vaccination status in the survey among the disadvantaged communities in Vellore; Children whose mothers were wage earners or salaried/small business owners were less likely to be fully vaccinated than children who had homemaker mothers.

The top reason given by mothers for not vaccinating their children nationally during 1998-2008 was that they were "unaware of the need for immunization." Categorizing the mothers' responses using the 5As taxonomy indicated gaps in awareness (regarding the need for vaccines and the timing and places to be vaccinated), acceptance (fear of side effects or a general lack of faith in vaccines), and affordability (due to indirect costs such as time constraints) as the main underlying reasons for non-vaccination among Indian children. The focus group discussions with parents from rural and disadvantaged communities in Vellore revealed that Narikuravar and Irular families faced difficulties accessing routine vaccination services for their children when travelling out of town for work. Knowledge gaps related to how diseases occur, how vaccines work, and the specific benefits and risks of vaccination were discussed across the communities. Moreover, while trust in routine childhood vaccines was generally high, these discussions revealed a degree of hesitancy among parents across the communities due to negative reports about specific vaccines in the media and the common side effects following vaccination.

6.2 Antigen-specific and combined routine childhood vaccination coverage measures

6.2.1 Routine childhood vaccination coverage nationally (study I)

Coverage of the BCG vaccination was the highest among the vaccines provided to children during their first year of life, regardless of the source of vaccination history. Nearly 81% of children aged 12-23 months in the combined surveys (DLHS 1-3) had received a BCG vaccination; BCG vaccination coverage based on parental recall or vaccination cards increased from 74% during 1998-99 to 87% during 2007-08. Recent estimates from NFHS-4 (2015-16) reveal that BCG vaccination coverage is even higher at 92%, suggesting a high level of access to routine immunization services (International Institute for Population Sciences (IIPS), 2016). Since the BCG vaccination, along with one dose each of Hepatitis B and OPV, is provided to children at (or soon after) birth, the increased BCG vaccination coverage over the years may be due in part to an increase in the proportion of institutional deliveries, especially since the launch of National Rural Health Mission (NRHM, now called the National Health Mission (NHM)) by the Government of India in 2005 (Shenton et al., 2018; Vellakkal et al., 2017). According to estimates from the DLHS surveys, the proportion of women who reported delivering in public or private health facilities increased nationally from 34% during 1998-99 to 47% during 2007-08 (International Institute for Population Sciences (IIPS), 2010). Another potential reason for the high BCG vaccination coverage among children may be the increased advocacy or mobilization towards health services (including routine immunization) by community health workers, which was a focus area of the NRHM in rural regions of the country (Srivastava et al., 2020; Vellakkal et al., 2017).

Fewer children received the third dose of DPT (DPT3) than BCG vaccination in India, suggesting a decline in vaccination coverage during the first three to four months of a child's life. The UIP schedule recommends that children receive three doses of DPT vaccination by 14 weeks of age (Ministry of Health and Family Welfare, Government of India., 2018). Nationally, 62% of children had received a third dose of DPT vaccination (than 81% who had received a BCG vaccination) during 1998 and 2008, combining parental recall and vaccination card information. However, DPT3 vaccination coverage was higher at 85% when calculated using the children's vaccination cards. The DPT3 coverage estimates in our study are similar to previous studies conducted during the same period, but recent estimates from the NFHS-4 point to a substantial increase in DPT3 coverage to 78% (International Institute for Population Sciences (IIPS), 2016). A study based on DLHS-3 data reported wide variations in DPT3 coverage by states, and demand-side factors such as birth order, maternal education and health knowledge, caste, religion, and household wealth associated with both non-receipt of DPT3 and dropouts between the first and third DPT doses (Ghosh & Laxminarayan, 2017). As DPT3 coverage represents both the ability of beneficiaries to access and utilize immunization services over multiple visits, demand-side interventions could be considered to better educate and remind parents about scheduled vaccination sessions for their children (Ghosh & Laxminarayan, 2017; S. Mitchell et al., 2009).

Coverage of the first dose of measles among children aged 12-23 months was generally similar (~60%) for the 1998-99 (DLHS-1) and 2002-04 (DLHS-2) surveys but higher (74%) during 2007-08 (DLHS-3) when information from vaccination cards and parental recall was combined. A similar increase in measles vaccination coverage was observed when only vaccination cards were used to estimate coverage. The increase in measles vaccination coverage during 2007-08 is also possibly attributable to the NRHM, which was set up to improve the available public health infrastructure and reduce child and maternal mortality in rural areas across 18 Indian states (Ministry of Health and Family Welfare, 2005). More specifically, increased access to routine immunization through the organization of special campaigns and "*health days*" in Anganwadis (public childcare centers) and greater availability of and mobilization through trained community health workers through the NRHM may have contributed to the increased measles vaccination coverage during 2007-08 (Ministry of Health and Family Welfare, 2005). Measles vaccination coverage among children under two years of age appears to have increased gradually since 2007-08, with NFHS-4 reporting a national coverage of 81% (International Institute for Population Sciences (IIPS), 2016). Despite the relatively high coverage of measles vaccination, a study using data from DLHS-3 reported that nearly one in four (23%) measles doses were administered to children prematurely (before nine months of age) or after the child's first birthday (Awofeso et al., 2013). Untimely measles vaccination can increase the window of susceptibility to measles infections, contributing to potential outbreaks and mortality that can be averted through timely vaccinations.

In line with the UIP recommendations for childhood vaccinations, we calculated the proportion of "fully vaccinated" children, *i.e.*, children aged 12-23 months who received three doses of DPT and OPV and one dose of BCG and measles vaccination, using data from three DLHS surveys (DLHS 1-3). The proportion of fully vaccinated children in the combined survey dataset was 53% and 76% for information from vaccination cards and parental recall and vaccination cards alone. This large discrepancy between the two estimates of full vaccination coverage could be due to the variable quality of the information obtained from the parental recall of children's vaccination doses (Miles et al., 2013). More than half the children (62%) in the combined dataset did not have a vaccination card available during the surveys, and parental recall had to be extensively relied upon to calculate vaccination coverage. Categorizing children's vaccination status using information from their vaccination cards and parental recall also revealed a significant decrease in the proportion of unvaccinated children (18% during 1998-99 to 9% during 2007-08) and an increase in the proportion of partially vaccinated children (27% during 1998-99 to 35% during 2007-08). Two previous studies also found a similar reduction in the proportion of unvaccinated children and an increase in partially vaccinated children using data from three consecutive rounds of the NFHS (1992-2006) (A.

Kumar & Mohanty, 2011; Prusty & Kumar, 2014). While these findings are contingent on the quality of the parental recall of childhood vaccination doses, they imply that while more children are being reached with routine vaccinations nationally, there is a need for subnational research to estimate the proportions and outline the reasons why children do not receive all the primary vaccinations due to them.

6.2.2 Routine childhood vaccination coverage in Vellore, southern India (studies II and III)

We conducted community-based household surveys in Vellore during 2017-18 to assess routine childhood vaccination coverage following intensified intervention through the Mission Indradhanush campaign. Coverage of BCG vaccination was high (>94%) regardless of the source of vaccination information for children in the rural and disadvantaged communities. This estimate is similar to the NFHS-4 (2015-16) coverage proportion of 94% for the Vellore district but slightly lower than an estimate of 99% BCG vaccination coverage reported during 2011-14 in an urban settlement in Vellore (Hoest et al., 2017; IIPS, 2017). Since the BCG vaccine is provided at or soon after a child's birth, the high BCG vaccine coverage in Vellore could be attributed to the NRHM's promotion of institutional deliveries nationally. However, it may specifically be linked to the Tamil Nadu government's "Muthulakshmi Reddy Maternity Benefit Scheme" (MRMBS) (Vellakkal et al., 2017). The government of Tamil Nadu introduced the MRMBS in 1987 in response to the high infant and maternal mortality rates across the state. This conditional cash transfer scheme distributed financial incentives to poor pregnant women who completed three antenatal visits by the seventh month of pregnancy, delivered in government health facilities, and whose children received three doses of DPT/pentavalent vaccination (Government of Tamil Nadu, India, 2018; Srinivasan et al., 2017). While there is no formal evidence to support an increase in BCG vaccination coverage due to the promotion of institutional deliveries through the MRMBS in Tamil Nadu, a recent study reported an increased utilization of public health care services, which was linked to the receipt of the MRMBS financial incentives in rural Vellore (Srinivasan et al., 2017).

There was a slight decline in the coverage of the third dose of DPT/pentavalent (DPT-3/penta-3) vaccination compared with BCG vaccination coverage among children in the rural and disadvantaged communities in Vellore. Combining children's vaccination histories from their vaccination cards and parental recall revealed an important difference in DPT-3/penta-3 vaccination coverage between the two communities (99% versus 81%) (see Figure 3 in section 3.2.2). However, this disparity was less pronounced (96% versus 90%) when vaccination coverage was estimated using information from the children's vaccination cards alone. While our estimate of DPT-3/penta-3 vaccination coverage for children in rural Vellore is comparable to the NFHS-4 estimate of 92% for the Vellore district, there is some indication that coverage is lagging among children from the known disadvantaged communities in Vellore (IIPS, 2017). A slightly higher proportion of children from the disadvantaged communities had received the first dose of DPT/pentavalent compared to the third dose of DPT/pentavalent vaccination (90% versus 81%, for children overall), pointing to possible dropouts over time. More in-depth research is needed to examine the reasons for the lower DPT-3/penta-3 coverage among children from disadvantaged communities, despite targeted intervention to underserved and tribal communities through the MI campaign in Vellore.

Coverage of the first dose of measles/MR vaccination among children was high in rural Vellore regardless of the source of children's vaccination histories (>92%). The NFHS-4 estimated measles vaccination coverage at 84% for Vellore overall, with a slight difference in the coverage proportions for urban and rural Vellore (85% versus 81%, respectively (IIPS, 2017). The high measles vaccination coverage in rural Vellore could be due to the monthly catch-up vaccination sessions organized by the MI campaign (between April 2015 and July 2017) or the mass vaccination campaigns conducted when the MR vaccine was added to the UIP immunization schedule (during February – March 2017) (Ministry of Health and Family Welfare, 2016, 2017). There was, however, a large difference in measles/MR vaccination coverage (similar to DPT-3/penta-3 coverage) between children from the rural and disadvantaged communities in Vellore (98% versus 75%) when estimated using vaccination cards and parental recall information (see Figure 3 in section 3.2.2). Since the measles/MR vaccine is the last dose in the primary series of UIP vaccines provided to children before their first birthday, this finding potentially highlights gaps in accessibility, parental awareness, or mobilization of parents from the disadvantaged communities in Vellore (Panda et al., 2020).

A large proportion of children were fully vaccinated in the survey among the rural communities in Vellore. The proportion of fully vaccinated children was 96% when vaccination cards and parental recall information were combined, and 84% estimated using vaccination cards alone. These coverage estimates are substantially higher than the NFHS-4 estimate of 74% for Vellore overall and 69% for rural Vellore during 2015-16 (IIPS, 2017). Since most (94%) children in the rural community survey were vaccinated in public facilities, the increased full vaccination coverage could be due to improved access to or availability of routine immunization services during the MI campaign in Vellore. The community survey in rural Vellore was conducted in August and September 2017, more than two years after the MI campaigns in Vellore began in April 2015. Administrative reports estimated an average increase in full immunization coverage of 5-7% for every year of implementation of the MI campaign after its first two phases (Ministry of Health and Family Welfare, GOI, 2017). Since Vellore was not considered for the follow-up Intensified Mission Indradhanush (IMI) campaign conducted in districts with <70% full vaccination coverage (after the first phase of MI), it may be inferred that vaccination coverage had begun to increase early during the MI campaign (Ministry of Health and Family Welfare, 2018c). However, there is a lack of evidence on the specific components of the MI campaign that may have contributed to increasing full vaccination coverage in rural Vellore and other MI districts in India.

We found an important difference in the proportion of fully vaccinated children in the rural and disadvantaged communities in Vellore. The percent difference in full vaccination coverage between the communities was as high as 31% when coverage was estimated using vaccination cards and parental recall and 8% when restricted to information from vaccination cards. While there are no similar studies from Vellore for comparison, studies from other parts of India have reported a wide variation in full vaccination coverage (31% - 89%) for children from disadvantaged communities (Priya P et al., 2020). Thus, while it is likely that children from disadvantaged communities in Vellore had lower DPT-3/penta-3, measles/MR, and full vaccination coverage (than rural communities), it is also important to consider the differing proportions of children with a vaccination card available during the surveys. More children in the rural communities (94%) than the disadvantaged communities (51%) had a vaccination card available during the surveys, highlighting the differential weight of information obtained from parental recall in estimating vaccination coverage in these communities. When vaccination cards are unavailable, vaccination histories from parental recall are frequently used to estimate vaccination coverage despite its variable quality (Bhatnagar et al., 2016; Cutts et al., 2016; V. Mitchell et al., 2013; Valadez & Weld, 1992). Although the sensitivity of parental recall to estimate children's vaccination status (using vaccination cards as the gold standard) was >95% in the community surveys, the specificity of parental recall was much lower, 21% in the rural communities and 58% in the disadvantaged communities. The low specificity implies that parents in the community surveys tended to overreport childhood vaccines, possibly pointing to lower than estimated vaccination coverage in the disadvantaged communities (where vaccination card retention was low). Since the vaccination status of children from other disadvantaged communities in India is positively correlated with the availability of vaccination cards (Priya P et al., 2020), it is essential to educate parents from these communities about the utility of the vaccination cards and the need to retain them to ensure that their children receive all the vaccines they are due.

We also estimated the "schedule-appropriate" vaccination status for children with a vaccination card which took into account if they had received all the recommended doses at the prescribed age and interval (for vaccines with multiple doses) according to the UIP schedule (Murhekar et al., 2017). Most (>90%) early vaccinations (BCG, DPT/pentavalent, and OPV) were administered according to the UIP schedule in rural Vellore. However, lower proportions of the measles vaccination (85%) and combined primary vaccination series (71%) were administered to children according to the prescribed schedule. The proportion of UIP vaccines administered according to the recommended schedule in rural Vellore was comparable to a previous estimate of 70% for five districts in Tamil Nadu (including Vellore) (Murhekar et al., 2017). Adherence to the UIP schedule for the individual and combined primary vaccination series was lower for children in the disadvantaged communities in Vellore. Only 55% of the UIP vaccines administered to children during their first year of life were administered according to schedule in these communities. The most frequent reasons for untimely vaccinations to children in the surveyed communities were early or delayed measles doses (before nine months or after one year of age) and suboptimal intervals (<28 days) between the DPT/pentavalent doses. Although the schedule-appropriate vaccination status of children is not a commonly used indicator of UIP program performance in India, it is vital to ensure that children receive vaccines on time to reduce their period of susceptibility to the diseases the available vaccines can prevent.

6.3 Factors associated with routine childhood vaccination uptake

6.3.1 Factors associated with routine childhood vaccination uptake nationally (study I)

We performed multivariate analyses on pooled data from DLHS 1-3 to examine the factors associated with partial-vaccination and non-vaccination (compared with full vaccination) for children aged 12-23 months during 1998-2008. After adjusting for children's age, type of dwelling (as a proxy for household wealth), survey period, and geographic region, we found that female children were more likely to be unvaccinated than male children. Based on NFHS data, previous studies have shown persisting gender inequities in the coverage of individual UIP doses and full vaccination in most Indian states (Corsi et al., 2009; Pande & Yazbeck, 2003; Prusty & Kumar, 2014). Within the states, gender disparities in full vaccination coverage tend to become more apparent in urban regions, poor households, and Muslim families (Prusty & Kumar, 2014). Thus, the disparities in vaccination uptake by child gender are believed to reflect deep-seated familial and societal factors instead of health system issues (Pande & Yazbeck, 2003). The chronic issue of gender discrimination for preventive health care services contributes to disproportionate morbidity and mortality borne by female children (Corsi et al., 2009; Willis et al., 2009), which needs to be addressed by the Indian UIP through appropriate, culturally sensitive and regionally implemented interventions.

Children from Muslim families (compared to Hindu families) and scheduled castes/other backward castes (compared to general classes) were more likely to be partially vaccinated and unvaccinated. Muslim children have had consistently lower full immunization coverage than children from families with other religious affiliations in various national and regional surveys (Mathew, 2012; Shenton et al., 2018; Shrivastwa et al., 2015). There is, however, limited research examining the reasons for the persistently low vaccination coverage among Muslim children. Available research tends to highlight a lack of trust in the government, beliefs that certain vaccines (specifically the polio vaccine) could sterilize children, and other community-held beliefs rejecting the need for vaccines and medicines in general as potential reasons for the lower uptake of childhood vaccines in Muslim families (Hussain et al., 2012; Jheeta & Newell, 2008; Mathew, 2012). Similarly, children from the scheduled castes and other backward classes (also considered socially disadvantaged) have historically had lower vaccination uptake than children from the general or other caste categories (considered to have higher social status) (Mathew, 2012). While no studies directly link caste-based discrimination to childhood vaccination uptake, a recent study has reported social discrimination related to accessing maternal healthcare services nationally (Mishra et al., 2021). More detailed qualitative investigations can help investigate the relative influences of potential service-side discrimination and individual- or community-level health beliefs or attitudes (due to religious or caste affiliations) on childhood vaccination uptake in different settings in India.

We found a range of maternal factors associated with routine childhood vaccination uptake in the pooled multivariate analyses. Children with relatively younger (≤ 18 years) or older mothers (>35 years) were found to have a higher odds of being partially vaccinated and unvaccinated compared with children with mothers aged 19-25 years. Similar associations have been reported by studies analyzing data from various national surveys, including the UNICEF coverage evaluation surveys and the NFHS and DLHS surveys (C. Kumar et al., 2016; Mathew, 2012; Shenton et al., 2018; Shrivastwa et al., 2015; UNICEF, 2010). Younger mothers can have lower educational levels (due to expectations from their families to leave school to look after their children) and limited freedom of movement, making it harder for them to access and provide adequate healthcare to their children (C. Kumar et al., 2016). The association between older maternal age and non-vaccination is more challenging to describe. It may suggest a higher workload due to increased childcare commitments (for mothers with more children) or the family's financial support. In our analysis, lower maternal education (less than a high school education) was associated with an increased odds of children being partially vaccinated and unvaccinated. Maternal education is often listed among the most important factors associated with a range of child health outcomes in various settings (Vikram et al., 2012; Vikram & Vanneman, 2020). A previous study suggests the role of increased health knowledge (for mothers with some education) and ability to communicate (for mothers with higher education) as possible pathways through which maternal education may influence decisions for childhood immunizations in India (Vikram et al., 2012).

The other maternal characteristics associated with childhood vaccination uptake in our analyses were related to the mother's utilization (or receipt) of maternal health services. Fewer antenatal visits, non-receipt of maternal tetanus vaccination, and non-institutional delivery were associated with increased odds of children being partially vaccinated and unvaccinated. Pregnant women in India are offered a minimum of four ANC checkups (Ministry of Health and Family Welfare, 2010).

Women who participate in antenatal care services regularly are known to differ in terms of their attitudes and beliefs towards pregnancy or healthcare in general and various socio-demographic characteristics such as their place of residence, household wealth, decision-making autonomy, and educational attainment, than those who do not regularly participate (Dixit et al., 2013; Ministry of Health and Family Welfare, 2010; Ogbo et al., 2019). During ANC visits, pregnant women are offered three doses of maternal tetanus vaccination (Ministry of Health and Family Welfare, 2010). While there is limited research examining the factors associated with maternal tetanus vaccination uptake, it is plausible that factors similar to those correlated with ANC participation are associated with receiving one or more tetanus vaccines during pregnancy. Pregnant women have also been encouraged to deliver in public or private health facilities by numerous supply- and demand-side interventions through the NRHM since 2005 (Ministry of Health and Family Welfare, 2005). Despite these interventions, a recent study using NFHS-4 data found significant disparities in the proportions of women delivering in health facilities related to their educational status, religious affiliation, participation in antenatal care checkups, and decision-making autonomy (B. Barman et al., 2020). Further research is needed to understand the specific factors that influence women's utilization of the continuum of care that covers maternal health services and newborn and child health services, including childhood vaccinations.

Apart from the individual-level (child and maternal) characteristics previously described, the non-retention of vaccination cards was associated with an increased odds of children being partially vaccinated and unvaccinated in the multivariate analyses. Vaccination cards also called mother and child protection (MCP) cards in India, are used to educate parents, facilitate access, and capture the utilization of the various maternal and childcare services available through India's National Health Mission (Ministry of Health and Family Welfare, 2018b). Numerous studies covering different regions and populations report positive correlations between the availability of vaccination cards during surveys and children's vaccination status (Chhabra et al., 2007; Goli et al., 2020; Pandey et al., 2019; Priya P et al., 2020; Shrivastwa et al., 2015; Srivastava et al., 2020). Not having a vaccination card can limit parents' access to routine immunization services or make it difficult for healthcare workers to ascertain due vaccinations (in the absence of provider-maintained records) for children during vaccination appointments (Wagner, 2019). Therefore, it is essential to regularly educate parents about the need and utility of these cards to ensure that their children receive all the available vaccines.

We also organized nearly 26,000 responses from mothers for not vaccinating their children during the DLHS surveys using the "5As taxonomy for the determinants of vaccination uptake". Gaps in awareness (regarding the need for, timing, and place of childhood vaccination) were the most important underlying reason for non-vaccination among Indian children between 1998 and 2008. Despite the mediating role of maternal education in decision-making for child healthcare (Vikram & Vanneman, 2020), these findings underscore the value of educating mothers about the benefits of childhood vaccines, the routine immunization schedule, and the available immunization services. To a lesser degree, but important nonetheless, gaps in the acceptance (fear of side effects or a general lack of faith in vaccines) and affordability (due to indirect costs such as time constraints) of routine vaccinations were the other important reasons why children were unvaccinated. These findings suggest that education and communication strategies that only focus on improving parental awareness about childhood vaccines or immunization services may not be sufficient to change vaccination behavior as previously indicated (Nyhan et al., 2014). Reports of vaccine hesitancy and refusal linked to the OPV and DPT vaccines from different parts of the country and the clustering of vaccine-refusing households can provide some insights into the other dynamics that may influence parents' decisions for childhood vaccines in India (Bahl et al., 2014; Hussain et al., 2012; Onnela et al., 2016; Priya P et al., 2020). The social mobilization approach employed by the National Polio Eradication Programme, which included local religious leaders and community influencers, may improve trust between parents and health providers (Bahl et al., 2014). The Indian UIP should also consider parental time constraints as they were among the main reported reasons for non-vaccination categorized under "affordability". This could be done through organizing regular catch-up sessions for missed vaccinations, as conducted during the MI/IMI campaigns, and potentially scheduling vaccination sessions based on the availability of target communities.

6.3.2 Factors associated with routine childhood vaccination uptake in Vellore (studies II and III)

A range of socio-demographic and non-socio-demographic parental characteristics and their association with children's vaccination status was studied using data from the community surveys from Vellore. Of the factors assessed in the multivariate analysis, only parents' familiarity with the UIP schedule and receiving information on the UIP schedule during antenatal care visits were significantly associated with increased odds of full vaccination in rural Vellore. Nearly one-third of the parents in this survey reported not being familiar with the UIP schedule, and a majority (>80%) had not heard about the measles-rubella vaccine, newly added to the UIP schedule in early 2017. Few studies have specifically investigated links between parents' familiarity with the recommended immunization schedule and children's vaccination status in India. A household survey conducted in urban slums in Varanasi, northern India, found that children whose mothers were "aware of the type of vaccines" provided had nearly two times higher odds of being fully vaccinated than children with mothers who were unaware (Awasthi et al., 2015). Some studies, however, report a lack of awareness or familiarity with the immunization schedule as a reason why some children are unvaccinated (Geddam et al., 2018; Murhekar et al., 2017; Priya P et al., 2020). With the recent addition of the IPV, rotavirus, and pneumococcal conjugate vaccines to the routine immunization schedule in Tamil Nadu, it is crucial to utilize every opportunity possible to educate parents about the currently available and newly introduced UIP vaccines to ensure that no children miss out on available vaccines.

Few Indian studies have reported a positive association between parents' receiving information about routine vaccinations from healthcare workers and children's vaccination status (Kusuma et al., 2018; S. Mukherjee et al., 2015). We specifically enquired during the household surveys if mothers received information about the UIP schedule during antenatal care visits. Children whose parents reported receiving information about the UIP schedule during ANC visits were twice more likely to be fully vaccinated than children whose parents had not received any information about the immunization schedule in rural Vellore. During antenatal care visits, the services generally offered to pregnant women include general physical examinations, laboratory investigations, iron, folic acid supplements, tetanus toxoid vaccinations, and counseling on various aspects of pregnancy management and safe delivery. Healthcare workers (such as auxiliary nurse midwives and village health nurses) generally counsel mothers and other family members on childhood vaccinations during post-partum visits (Ministry of Health and Family Welfare, 2010). While we are uncertain if the parents in our survey received information on the recommended childhood vaccines during antenatal or postnatal visits, pregnant women (and their families) must continue to be targeted for educational interventions to sustain the high coverage or increase the coverage of routine immunizations in Vellore.

Despite investigating numerous child, parent, and household-specific characteristics, we did not find significant socio-demographic disparities in the coverage of fully vaccinated children in rural Vellore. Many independent surveys conducted prior to the launch of the MI campaign in India and covering different regions and population groups have reported socio-demographic disparities in childhood vaccination coverage (Awasthi et al., 2015; Chhabra et al., 2007; Devasenapathy et al., 2016; Geddam et al., 2018; Kusuma et al., 2010, 2018; Murhekar et al., 2017; Pandey et al., 2019). These studies mainly report disparities in vaccination uptake, which are linked to parental education and occupation, household wealth, and place of residence (Awasthi et al., 2015; Chhabra et al., 2007; Devasenapathy et al., 2016; Geddam et al., 2018; Kusuma et al., 2010; Murhekar et al., 2017; Pandey et al., 2019). We are unaware of any recent independent surveys (post-MI/IMI) conducted to estimate vaccination coverage and the characteristics associated with routine childhood vaccination uptake. Our findings suggest a uniform delivery and uptake of routine childhood vaccinations immediately following the MI campaign in rural Vellore.

While no socio-demographic disparities in childhood vaccination uptake were found in rural Vellore, maternal employment was negatively associated with children's vaccination status in our survey among disadvantaged communities in Vellore. Children whose mothers were wage earners or salaried/small business owners were less likely to be fully vaccinated than children who had homemaker mothers. Few studies from India have reported associations between maternal occupation and children's vaccination status (Awasthi et al., 2015; Murhekar et al., 2017). A survey among children in urban slums of Varanasi, northern India, found that children with working mothers had twice the odds of being fully vaccinated compared to children with unemployed or homemaker mothers (Awasthi et al., 2015). Maternal employment is hypothesized to improve vaccination uptake by removing any financial obstacles to vaccination but may also contribute to missed immunization appointments due to work commitments (Awasthi et al., 2015; Mindlin et al., 2009). This may have been true of the children with working mothers in these communities; mothers from the Narikuravar communities discussed conveniently timed immunization sessions facilitating childhood vaccination uptake in the focus group discussions. The district health authorities could collaboratively plan immunization sessions based on the availability of working parents from the disadvantaged communities in Vellore.

While access to routine immunization services was not correlated with childhood vaccination uptake in the community surveys, parents from the Narikuravar and Irular communities (disadvantaged communities) sometimes expressed difficulties accessing routine immunization services when traveling out of town for work or leisure in the focus groups. Two-thirds (66%) of the parents in rural communities and a half (54%) of the parents in disadvantaged communities reported "walking" as the most frequent mode of travel to their children's vaccination appointments in the surveys, suggesting possible differences in access to routine services. However, parents from the disadvantaged communities did not express any difficulties accessing routine immunization services at their regular residences during the FGDs. Instead, some parents discussed not knowing where to get vaccinated when traveling away from home for extended periods as an important reason for delayed or missed vaccinations. While there are no similar studies for comparison from India, a study among Gypsy and Irish Traveler communities in the United Kingdom reported that parents had similar difficulties getting appointments to vaccinate their children when away from their usual residence (Jackson et al., 2017). Potential solutions to the difficulty of getting children vaccinated when traveling could include scheduling childhood vaccinations around travel commitments, receiving reminders about due vaccines from health care workers, and having access to walk-in immunization clinics (Jackson et al., 2017).

Parents from the rural and disadvantaged communities highlighted the crucial role of the village health nurses (VHNs) in disseminating information on routine vaccinations and reminding them about missed or due vaccines for their children during the FGDs. The VHNs are trained health workers employed to provide a range of maternal and childcare services to rural communities (with up to 5000 inhabitants) in Tamil Nadu (Parthasarathi & Sinha, 2016). They are generally familiar with the needs of mothers and children in the communities they serve as they make regular house visits. In addition to providing healthcare, they offer nutrition advice (for pregnant mothers and children), safe delivery, family planning, and childhood immunizations (Parthasarathi & Sinha, 2016). In our study, parents spoke of an individual (held on the phone or during home visits) and group knowledge-sharing sessions (during immunization sessions) to improve their familiarity with childhood vaccinations. Mothers sometimes spoke of the influence of the advice provided by VHNs in their decision-making for childhood vaccines. Parents frequently discussed prompts and reminders (before scheduled appointments or after missed appointments) in rural and disadvantaged communities of Vellore to facilitate childhood vaccination uptake. A good relationship between the VHNs and parents appears key to generating awareness about and mobilizing parents towards utilizing routine vaccination services. Since parents reported fears due to negative reports about certain vaccines in the media or potential side effects following vaccination during the FGDs, it may be helpful to train the VHNs to specifically address these concerns and build vaccine confidence in their target communities.

6.4 Strengths and limitations of the study

This thesis estimated vaccination coverage and the factors associated with routine childhood vaccination uptake among children aged 12-23 months, nationally and subnationally, in the Vellore district, Tamil Nadu. The relative strengths and weaknesses of the study designs, questionnaires, and analytical techniques used in studies I-III are discussed hereafter.

6.4.1 Strengths of the study

Study I utilized data from three rounds of the nationally-representative DLHS surveys to investigate the factors associated with routine childhood vaccination uptake over ten years (1998-2008). The DLHS surveys were conducted to provide district-level estimates to monitor the various maternal and childhood health programs implemented by the Government of India (IIPS, 2006). Data from the DLHS surveys could be pooled as the surveys utilized a consistent sampling methodology, data collection protocol, and study instruments for the different rounds (Dandona et al., 2016). The pooled dataset contained information on nearly 178,000 children aged 12-23 months during the surveys, which facilitated a robust estimation of vaccination coverage and multivariate analyses of various socio-demographic factors putatively linked to routine childhood vaccination uptake nationally. In addition, our categorization of children's vaccination status using a three-level variable (fully vaccinated, partially vaccinated, and unvaccinated) enabled the simultaneous assessment of the factors associated with non-vaccination and partial vaccination, which are known to differ (Rainey et al., 2011; Shrivastwa et al., 2015).

The DLHS questionnaires also included a follow-up question to mothers whose children were found to be unvaccinated during the surveys - "*Why was your child not given any vaccination?*". We organized the mother's responses to this question through a semi-qualitative, framework-based methodology using the previously published "5As taxonomy for determinants of vaccine uptake" to identify the underlying reasons for non-vaccination among Indian children during 1998-2008. Traditionally the barriers and facilitators of childhood vaccination uptake have been categorized as supply-side or demand-side factors (Cooper, Okeibunor, et al., 2019; Jheeta & Newell, 2008). While these broad categorizations are helpful, diagnosing more specific target areas is vital when designing and deploying interventions to improve vaccination uptake in various socio-cultural settings (Thomson et al., 2016).

Studies II and III provide the most recent estimate of vaccination coverage and the factors associated with routine childhood vaccination uptake in different communities of the Vellore district, selected from intensified routine immunization through the MI campaign in 2015. We are not aware of any independent studies that have evaluated the factors linked to routine childhood vaccination uptake after the MI/IMI campaigns in India. The rural community survey (study II) employed two-stage cluster sampling based on the standard EPI coverage survey methodology (World Health Organization, 2008). This methodology was advantageous as it provided a practical way to sample the rural communities in Vellore (beginning at the geographic center of each cluster, then selecting a random direction and starting household for the survey) where household lists were not readily available. Since an important MI objective involved targeting children from migrant, tribal, and other hard-to-reach groups, we conducted a household survey among the known disadvantaged communities in Vellore. We adapted the snowball sampling methodology (due to the lack of a pre-existing sampling frame) to survey children from the disadvantaged communities, utilizing the communities' knowledge to help identify other settlements that would not easily have been located otherwise.

The community surveys in Vellore utilized the same pre-tested questionnaire for data collection. A wide range of socio-demographic and non-socio-demographic (parent's awareness, attitudes, and concerns regarding childhood vaccines) characteristics were captured through the study questionnaire. The section on children's vaccination histories was adapted from the EPI cluster survey questionnaire, and questions on the non-socio-demographic characteristics of the parents were outlined using the "5As taxonomy" domains (Thomson et al., 2016; World Health Organization, 2008). The questionnaire was translated to local vernacular and programmed using the Kobo Toolbox, a free, open-source application for mobile data collection (KoboToolbox, 2015). Mobile data collection enabled real-time entry and minimized data-entry errors with programmed range checks, skip patterns, and pictures of children's vaccination cards (to verify children's vaccination histories). Previous studies from Africa report that mobile data collection improves the real-time supervision of data collectors and reduces the duration and cost of interviewing participants, which was confirmed in our surveys as well (Medhanyie et al., 2015; Tomlinson et al., 2009). We also triangulated data from the household surveys by conducting focus group discussions in the rural and disadvantaged communities, which helped identify additional barriers or facilitators to routine childhood vaccination uptake that may have been missed otherwise.

Collectively, these studies demonstrate the utility of analyzing publicly-available data (such as the demographic and health survey datasets) and conducting more in-depth research to estimate routine vaccination coverage and assess the reasons for suboptimal childhood vaccination uptake in the Indian context. In addition, the multiple methodologies (quantitative and qualitative) and analytical techniques represented in these studies provide valuable insight into the performance of the UIP before and after the implementation of the MI and IMI campaigns.

6.4.2 Limitations of the study

Study I utilized relatively old datasets to estimate routine vaccination coverage and the factors associated with childhood vaccination uptake nationally. This analysis was restricted to the first three rounds of the DLHS, as DLHS-4 was not nationally representative (excluding nine Indian states). Furthermore, we could not use the NFHS datasets as NFHS-3 was less recent (covering 2005-06), and data collection for NFHS-4 (2015-16) was underway when the analysis was conducted. Despite not analyzing more recent data, our use of the DLHS datasets facilitated pooled analysis, increasing analytical power for the quantitative analyses and categorizing the mother's reasons for not vaccinating their children over a decade. It is unlikely that the factors associated with childhood vaccination uptake in India have changed substantially over the years, as persisting disparities in childhood vaccination coverage linked to various maternal and household characteristics have been reported in the years prior to and following our analysis (C. Kumar et al., 2016; Mathew, 2012; Shenton et al., 2018; Srivastava et al., 2020; Vashishtha & Kumar, 2013).

In the DLHS (and other national health surveys), children's vaccination histories are generally collected through maternal recall when vaccination cards are unavailable (Dandona et al., 2016). More than half (62%) of children in the combined DLHS dataset analyzed in study I did not have a vaccination card during the surveys. Therefore, we attempted to reduce the potential for maternal recall bias by restricting the analytical sample to the most recently born children, as vaccination histories in the DLHS were enquired for the last two surviving children. Nevertheless, mothers may still have recalled their children's vaccination histories differentially, especially for the multi-dose vaccines and those later in the primary vaccination series (such as the DPT, OPV, or measles vaccines), resulting in under or overestimated routine vaccination coverage for the study period. The variable quality of parental recall to estimate children's vaccination coverage in low and middle-income countries is a widely acknowledged limitation in the absence of more reliable sources such as immunization registries or provider-maintained records (Miles et al., 2013; Modi et al., 2018). Most (89%) unvaccinated children would have been excluded from our study if the analysis had been restricted to children with a vaccination card. Subsequent studies can implement recall bias adjustments utilizing latent class analysis or multiple imputations based on the characteristics of children with vaccination cards to provide more reliable estimates for children without vaccination cards (Luman et al., 2009).

Associations between other important socio-demographic characteristics such as birth order (or the number of children), parental employment, household size, and children's vaccination status could not be assessed as large proportions of these data were incomplete in one or more DLHS datasets (in study I). In addition, a wealth index for households was unavailable in the DLHS-1 dataset. Therefore, our analyses adjusted for the type of housing (construction quality of households) of respondents, which is generally combined with the ownership of durable assets such as motor vehicles, televisions, and refrigerators, and access to infrastructure (such as an electricity supply, drinking water and sanitation) to generate household wealth indices in demographic and health surveys (Howe et al., 2012). The type of housing was used as a proxy "asset-based" measure of the economic status of respondents, which are considered more resistant to short-term economic fluctuations (Howe et al., 2012). Our analyses also did not investigate potential associations between supply-side infrastructure at the community-, district- or state-level factors, including the availability of (or proximity to) health facilities, road connectivity to public infrastructure, the presence of community health workers, and childhood vaccination uptake such as investigated in a recent study (Ghosh & Laxminarayan, 2017). The multivariate analyses focused on assessing the individual and household-level socio-demographic factors associated with childhood vaccination uptake during 1998 and 2008. Through multi-level regression modeling, future studies could consider possible variations in the availability of supply-side factors and their relative influence on childhood vaccination uptake.

We conducted a two-stage cluster and snowball sampling to estimate vaccination coverage and the factors associated with routine childhood vaccination uptake in rural and disadvantaged communities in Vellore. While both surveys employed non-probabilistic sampling, study II utilized a sampling strategy based on the standard EPI coverage survey methodology, entailing that the vaccination coverage estimates in studies II and III may not be comparable. Snowball sampling may have resulted in the participants being more inter-dependent and missing outlier families (Johnson, 2014). These reasons and the relatively small sample size may have impacted the accuracy and precision of the vaccination coverage estimates calculated in study III. We accounted for the clustering of children within the different communities surveyed and reported design-adjusted 95% confidence intervals to facilitate more robust comparisons (see Figure 3).

Although the household survey in study II followed the EPI cluster survey methodology (2005 guidelines), we could not implement the updated WHO vaccination coverage cluster survey guidelines released in July 2015 (World Health Organization, 2015). The specific updates we were unable to implement were the use of probability-based sampling (requiring maps or satellite images of the clusters), selection of households using survey coordinators or statisticians, conducting a weighted analysis (accounting for the probability of selection of children within the clusters), and visiting health facilities to verify vaccination records (World Health Organization, 2015). While the 2015 WHO cluster survey guidelines were designed to provide more robust vaccination coverage estimates and confidence intervals, they require an up-to-date and complete sampling frame constructed using census data in the various enumeration sites, unavailable for rural Vellore. Future independent surveys to estimate vaccination coverage can follow the latest WHO cluster survey guidelines to reduce the potential for selection biases, increase comparability of the survey estimates, and allow the reliable calculation of confidence intervals for the coverage point estimates (World Health Organization, 2015).

In addition, we only estimated routine vaccination coverage for children aged 12-23 months in rural and disadvantaged communities of Vellore due to logistic constraints. Thus, our estimates may not represent vaccination coverage in urban or suburban (including slums) regions of Vellore. Our study focused on rural communities in Vellore as the NFHS-4 estimated lower full vaccination coverage for rural (70%) than urban (78%) Vellore (IIPS, 2017). Another study reported full vaccination coverage of 78% for children from an urban slum in Vellore (Hoest et al., 2017). Therefore, our survey among disadvantaged communities focused on the other communities (migrant, tribal and hard-to-reach groups) targeted through the Mission Indradhanush campaign in Vellore. While we found high full vaccination coverage in the rural community (84 – 96%) and suboptimal coverage (65-77%) among the disadvantaged communities in Vellore, updated coverage estimates for urban Vellore are needed before conclusions on the impact of the MI campaign can be accurately drawn.

The observed associations between the parents' familiarity with and receipt of the information on the UIP schedule during antenatal visits and children's vaccination status in study II must be interpreted with caution. This is because we did not assess the parents' knowledge about the UIP schedule in greater detail or verify the information received by parents on childhood vaccinations during antenatal care visits. Therefore, while it is likely that parental awareness and receipt of the information on childhood vaccines was responsible for a higher uptake of routine vaccinations, the reverse may also be true. In addition, the multivariate analysis in study III may have been underpowered to detect statistical associations between the different parental characteristics and children's vaccination status due to the small sample size. Furthermore, all the data analyzed in this study (studies I, II, and III) were from cross-sectional surveys, limiting the ability to draw causal inferences from the observed statistical associations.

Finally, data saturation was not achieved in the FGDs with parents from the rural and disadvantaged communities in Vellore due to the limited number of meetings conducted. While it is difficult to comment on the range of responses that may have been obtained through conducting more meetings, we attempted to triangulate the findings from the household surveys and FGDs, as both data collection instruments had common sections based on the 5As taxonomy for determinants of vaccination uptake (Thomson et al., 2016). We also did not perform adequate cultural clarifications during the qualitative data analysis, which may introduce a reporting bias for the possible reasons for community-held perceptions, attitudes, or behaviors towards childhood vaccinations. Despite these limitations in the qualitative data collection and analysis, these data provided important insights into the barriers and facilitators of routine childhood vaccinations in Vellore that would have been missed if only household surveys had been conducted.

6.5 Conclusions and future research directions

6.5.1 Conclusions and public health implications of the research

This thesis aimed to assess vaccination coverage and the factors associated with routine childhood vaccination uptake among children aged 12-23 months, nationally and subnationally, in the district of Vellore, southern India.

Using pooled data from three rounds of the DLHS surveys, we found that the proportion of unvaccinated children decreased nationally during 1998-2008. However, the proportion of partially vaccinated children increased, suggesting increased vaccine dropouts over time. Data from the most recent national survey (NFHS-4, 2015-16) reported an even higher proportion of partially vaccinated children than in our study (56% versus 32%) (Srivastava et al., 2020). Furthermore, the ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has contributed to an increased number of both unvaccinated and partially vaccinated children nationally. The WUENIC data for India reveals that the number of children who did not receive the first dose of DPT/pentavalent vaccination increased from 1,404,000 in 2019 to 3,038,000 in 2020 (UNICEF, 2021). While it is likely that routine immunization coverage has improved since the early phase of the pandemic, our findings suggest a need to continue monitoring childhood vaccination coverage over time and identifying the children who are most at risk for missing some or all the primary vaccinations they are due using available data sources.

In the multivariate analysis for the national study, children's vaccination status was associated with a range of child, maternal, and household characteristics. While similar associations have previously been reported in many national-level studies, our study found these disparities in childhood vaccination uptake in pooled data spanning a decade (1998-2008). Thus, there is a need for culturally appropriate and targeted interventions, especially for children from Muslim, lower caste, and urban households in India.

Categorizing the mothers' responses to the question *"Why was your child not given any vaccination?"* during the DLHS surveys using the 5As taxonomy revealed gaps in awareness, acceptance, and affordability as the primary underlying reasons for non-vaccination among Indian children. The identified gaps related to parental awareness and acceptance highlight the potential for utilizing ongoing information, education, and communication campaigns to improve parental awareness and build trust in childhood vaccines, especially the newly introduced vaccines. In addition, the barriers related to affordability might suggest the need for national and regional immunization authorities to schedule routine vaccination sessions/campaigns based on the availability of target communities.

Our household surveys in Vellore, a district selected for intensified routine immunization through the MI campaign in 2015, found high childhood vaccination coverage in rural communities but suboptimal vaccination coverage among children in disadvantaged communities, including nomadic, tribal, and migrant groups. The lower vaccination coverage among the disadvantaged communities is concerning as children from these groups were targeted during the MI campaign (Ministry of Health and Family Welfare, 2016). Thus, our study provides preliminary evidence that the MI campaign may have increased full vaccination coverage in some but not all communities or regions within targeted districts.

No parental socio-demographic characteristics were associated with children's vaccination status in the multivariate analysis conducted on data from the rural community survey in Vellore. This finding suggests a uniform delivery and uptake of routine vaccinations nearly two years after the MI campaign in rural Vellore. However, in this analysis, parental familiarity with and receiving information on the UIP schedule during antenatal visits was positively associated with children's vaccination status. Therefore, pregnant women (and their families) need to continue being targeted with educational interventions to sustain the high coverage of routine childhood vaccinations in rural Vellore.

Maternal employment was negatively associated with children's vaccination status in the survey among the known disadvantaged communities in Vellore. While contrary to findings from previous Indian studies, this finding highlights the importance of conveniently timed sessions and the need for collaborative planning of immunization sessions based on the availability of parents from disadvantaged communities in Vellore. These collaboratively planned sessions will especially benefit parents from the Narikuravar and Irular communities, who are known to be away from their habitual residences for extended periods.

6.5.2 Future research directions

Our national study demonstrates the value of using secondary data sources such as the DLHS and NFHS surveys to assess the various demand-side disparities in childhood vaccination uptake. These findings can be used to develop subnational research (to investigate regional trends or variations in uptake) or guide more in-depth research (to understand better what the observed associations represent). For example, we investigated if the positive association between antenatal care participation and children's vaccination status in the national study was due to improved access to health facilities or information sharing (about the vaccination schedule) during these visits in the Vellore studies. More detailed investigations are needed to examine the causal pathways through which maternal characteristics (such as educational status and antenatal and postnatal participation) influence decision-making for childhood vaccinations in India.

The DLHS datasets also provided an invaluable opportunity to analyze the mothers' reasons for not vaccinating their children, and categorizing these data using the previously published 5As taxonomy provided insights into the root causes of non-vaccination in India. Since the DLHS is currently combined with the NFHS surveys, future NFHS questionnaires must include questions on why children may have missed some or all routine vaccinations if identified during the surveys (International Institute for Population Sciences (IIPS), 2016).

Our household surveys among rural and disadvantaged communities in the Vellore district provide the most recent childhood vaccination coverage estimates since the MI campaign was conducted between April 2015 and July 2017. These surveys are among the few independent studies conducted to evaluate India's Mission Indradhanush and subsequent Intensified Mission Indradhanush campaigns. Further assessments in the MI and IMI districts are needed to assess if vaccination gaps still exist and, if not, the specific components of these campaigns that may have contributed to increasing full vaccination coverage in these districts.

To better investigate the factors linked to childhood vaccination uptake in Vellore, we developed a questionnaire that investigated a broad range of socio-demographic and non-socio-demographic characteristics for the household surveys. As routine immunization services are improved through periodic campaigns such as MI and IMI, subnational coverage surveys must explore a broader range of parental characteristics than traditionally investigated to assess better the specific components of these campaigns that may have contributed to increasing childhood vaccination coverage. Future surveys could consider outlining the questions on the parents' non-socio-demographic characteristics using the 5As taxonomy domains (as employed in our household surveys) or include more detailed assessments of their attitudes towards childhood vaccines, such as provided by the "parental attitudes towards childhood vaccinations" (PACV) instrument (Opel, Taylor, et al., 2011; Thomson et al., 2016).

Finally, combining household surveys with in-depth interviews or focus group discussions can provide investigators with parental perspectives that may be missed if only surveys are conducted to evaluate the factors linked to childhood vaccination uptake. Triangulating the findings of quantitative and qualitative assessments can better inform targeted and contextual interventions to sustain or improve childhood vaccination uptake in different Indian communities.

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8 APPENDICES

Appendix 1. Survey questionnaire used in studies II and III

1

IMMUNIZATION COVERAGE AND THE FACTORS INFLUENCING CHILDHOOD VACCINATION UPTAKE IN VELLORE, SOUTHERN INDIA

PART 1: HOUSEHOLD SOCIO-DEMOGRAPHIC INFORMATION

(We will begin the interview by asking you a few details about your household)

1.1 Type of family: ☐ 1-Joint (*Parents, children, grandparents and aunts/uncle*) 2-Extended (*Parents, children and grandparents*) 3-Nuclear (*Only parents and their children*)

1.2 Head of the household:

1.2.1 D. No/St:

Place: Pin Code:

1.3 Respondent:

1.4 Religion: ☐ 1- Hindu 2-Christian 3- Muslim 4- Others 1.5 No. of members in the household: 1.6 Number of adults (≥18 yrs):

2.1 Marital status of the respondent: ☐ 1- Single 2- Married 3-Widowed 4- Divorced or Separated

2.2 Type of ration card owned: ☐ 1- Blue (Antyodaya) card 2- Yellow (BPL) card 3-Orange (APL) card

2.3 Caste of family: ☐ 1- Schedule caste 2- Scheduled Tribe 3- Other Backward Classes 4-Forward classes

2.3 Type of house: ☐ 1- Pukka 2-Mixed 3-Kutcha

2.4 No. of rooms in the house (excluding kitchen & bathroom):

(Next, we will collect basic information on the individuals in your household)

Parents of the child:

Mother

3.1.1 Name:

3.1.2 Date of birth (DD-MM-YYYY): 3.1.3 Occupation: ____________ 3.1.4 Education (in yrs):

Father

3.2.1 Name:

3.2.2 Date of birth (DD-MM-YYYY): 3.2.3 Occupation: ____________ 3.2.4 Education (in yrs):

Instruction to field worker:

The **index child** is a child aged **12 – 23 months** at the time of the survey.

2

If the parent has **more than one** child in the age g, **choose the child whose age is nearest to one year** as the index child.

The **index child** is the child for which all immunization and other information in this questionnaire will be collected.

 # Index child (aged 12 – 23 months):

3.3.1. Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

3.3.2. Date of birth (DD-MM-YYYY): ☐☐/☐☐ ☐☐☐☐

3.3.3. Gender:
M ☐
F ☐

3.3.4 Place of delivery: ☐ 1 = Government hospital or clinic 2 = Private hospital or clinic 3 = Home, 4 = Others, specify________________

Siblings (<5y) of index child in the household:

3.4.1. How many children have you had before birth of **#index child <insert name>**?: ☐☐

3.4.2. Number of children (≤ 5y): ☐☐

3.4.3. Number of children (> 5y): ☐☐

Instruction to field worker:

The section below only covers **routine immunizations**, i.e. vaccinations that are recommended by the government and which are generally available free of cost to parents at government facilities.

The routine vaccinations **currently recommended** for children include: **BCG** vaccine (against tuberculosis), **DPT** (against diphtheria, pertussis and whooping cough) or **pentavalent** vaccine (against diphtheria, pertussis, whooping cough, hepatitis B and Hib), OPV (oral polio vaccine), monovalent measles vaccines and Measles-Rubella (MR) vaccine (added in Feb 2017).

(Now, we would like to know about your # index child's <insert child's name> vaccination history)

PART 2: IMMUNIZATION HISTORY AND USAGE OF SERVICES

4. Has your child (NAME) ever received routine **vaccination**? ☐ 1-Yes 0-No 9 - Don't know

5. If **"No"** to Q4, why has your child (NAME) not been vaccinated? (*Skip to Part 3, after the response has been filled*)

____

____

____

6. If **"Yes"** to Q4, do you have your child's (NAME) **immunization card**? ☐ 1-Yes, presently with me 0-No, it is lost 9 – Don't know

Instruction to field worker: If parent responds **"No, it is lost"** to Q6, please skip this section to the questions in **Part 3**.

3

<u>For Q7:</u> Vaccines belonging to **category 1** are the routine vaccines that are to be used to calculate the immunization status of study children.

***Immunization status:** **Fully immunized** = all recommended vaccines in category 1 are taken, **under immunized** = at least one by not all vaccines in category 1 taken, **unimmunized** = no vaccines in category 1 taken

7. If the parent responds **"Yes, presently with me"** to Q6, please fill in the child's immunization history (*to be filled by field worker*):

Vaccine (Recommended age)	Date of administration (DD/MM/YYYY) Dose 1	Dose 2	Dose 3	Up-to-date (tick if all doses per vaccine taken)
BCG (Birth)				
Oral Polio Vaccine (OPV) (6w, 10w, 14w)				
DPT or Pentavalent (6w, 10w, 14w)				
Measles-Rubella (9-12m)				
Immunization status*				

<u>Instruction to field worker:</u> If the child is **not "fully immunized"** per the vaccines listed above, please enquire the reason(s) why the specific vaccine doses were missed. **Tick the appropriate reasons** for the missed doses in the table below.

8. Please tell us why your child (NAME) **did not receive** the following vaccine dose(s):

<u>Reasons for missed vaccine dose:</u>	--Category 1 vaccine doses-- BCG	DPT 1	DPT 2	DPT 3	OPV 1	OPV 2	OPV 3	Measles-Rubella
Not aware of vaccine or timing of vaccination								
Child sick after past vaccination								
Bad experience with health provider								
Financial difficulties								
Religious reasons								
Difficulty in accessing immunization facility								

Travel out of area								
Festival on day of vaccination								
Death in family or community								
Other reason								

9. Which is the **public health facility** did your child (NAME) receive most of his/her vaccines? (*please provide name and full address*)?

____

10. Did you have to **pay** for any or all routine vaccinations for your child (NAME)? ☐ 1-Yes 0-No 9 - Don't know

10.1 If No to Q10, would you be **willing to pay** for routine vaccinations for your child (NAME)? ☐ 1-Yes 0-No 9 - Don't know

11. What **mode of travel** did you generally use to travel to the health facility/Anganwadi for vaccinating your child (NAME)? ☐ 1 – Walking 2 – Own vehicle 3 – Public transport 9 – Don't know

12. Respond to the following statement: "The **timing of routine immunization** sessions or camps for your child (NAME) was generally convenient to you". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

13. Respond to the following statement: "I was generally satisfied with the **quality of routine immunization** services offered to me for my child (NAME)". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

PART 3: PARENTAL AWARNESS, ATTITUDES & CONCERNS REGARDING ROUTINE VACCINATIONS

(*The purpose of the next section is to understand your thoughts regarding routine vaccination for your index child <insert name>*)

Please respond to the following statements (Q 14 – 18) as directed:

14. "I think **immunization is important** to keep my children healthy". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

15. "I am **familiar with the recommended routine vaccinations** for my child (NAME), *i.e.* which vaccines are given when and for what". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

16. "I trust **all the information** I receive about vaccination for my children". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

5

17. "I am able to **openly discuss my concerns** about vaccinations for my child with the PHC/Anganwadi staff/Nurse/Doctor". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

18. "It is better for my child to develop **immunity by getting sick** than to get a vaccination". ☐ 1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

19. Overall, how **hesitant about childhood vaccinations** would you consider yourself to be? ☐ 1-Not at all hesitant 2 = Not too hesitant 3 = Not sure 4 = Somewhat hesitant 5 = Very hesitant

20. Has you heard about the vaccine that the government recently introduced against **Measles and Rubella** (MR vaccine in Feb 2017) for children aged 9 months– 15 years? ☐ 1-Yes 0-No 9-Don't know

20.1 If Yes to Q20, do you have any **concerns** about this new vaccine? ☐ 1 = Not at all concerned 2 = Not too concerned 3 = Not sure 4 = somewhat concerned 5 = Very concerned

20.2 If answer to Q20.1 is "4 or 5", Please specify the **major concern** you have about this vaccine:

____

____

PART 4: PEOPLE & SOURCES OF VACCINATION INFORMATION

(The purpose of this section is to obtain information about the people and sources who have provided advice or direction about your decision to vaccinate or not vaccinate your child)

21. Have any of the following people facilitated or motivated you to give vaccination to your child? (Record all mentioned)

Q.No	**Person**	**1-Yes, 0 – No, 9 – Don't know**
21.1	Doctor	
21.2	ANM/Health worker/Anganwadi worker	
21.3	ASHA	
21.4	NGO/Other organization	
21.5	Husband	
21.6	Mother-in-law or Mother	
21.7	Relatives/Friends	
21.8	Self	
21.9	Other person, specify	

22. During the first year of your child's (NAME) life, did an **ANM/ASHA/Anganwadi worker/community health worker** visit your home regarding routine immunization? ☐ 1-Yes 0-No 9-Don't know

22.1 If yes, how many **times** did the ANM/ASHA/Anganwadi worker/community health worker visit your home regarding routine immunizations? ☐ times

6

23. Have you consulted any of the following sources to decide about vaccinating your child?

Q.No	Source	1-Yes, 0 – No, 9 – Don't know
23.1	Radio	
23.2	Television	
23.3	Internet (computer or mobile)	
23.4	Mobile (SMS or phone call)	
23.5	Clinic/Hospital	
23.6	Government campaigns	
23.7	Posters/handouts	
23.8	Magazine/Newspaper	
23.9	Others, specify	

Willing to participate in focus group meeting? ☐ Yes ☐ No

Mobile phone number of parent: ______________________

Any other information regarding parent/child/survey?

____

____

To be filled by the data entry personnel:

Data entered by: Date:

1. ________________________________ ☐☐/☐☐/☐☐☐☐

2. ________________________________ ☐☐/☐☐/☐☐☐☐

Appendix 2. Thematic guide for the focus group discussions in studies II and III

1. What are your **views on vaccination** for your child in general? (*Probes: Are vaccines necessary or can they be done without?)*
2. What do you see as the **benefits of vaccinating your child**? (*Are there any risks with government vaccination? What are your suggestions to reduce your concerns about vaccinations?*)
3. Who helps you with **making decisions for vaccination** for your child (*Who do you trust the most and why?*)
4. How is your **relationship with the healthcare provider** (Doctor/Nurse/ASHA/ANM) who generally provides vaccination for your children? (*Are you comfortable to clarify any issues you may have?*)
5. Are you satisfied with the **information on the benefits and risks** of particular government vaccines that your healthcare provider (Doctor/Nurse/ASHA/ANM) provides you before vaccination? (*Is there any way this information can be improved?*)
6. Are you aware of **any children from specific communities or households** who do not take all government vaccines or refuse certain vaccines in your area? (*What are some of the reasons why?*)
7. Are you satisfied with the **childhood vaccination services the government provides**? (*What are the benefits you have received? Are there any aspects that you would like improved?*)

PUBLICATION 1

Factors associated with routine childhood vaccine uptake and reasons for non-vaccination in India: 1998-2008

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Factors associated with routine childhood vaccine uptake and reasons for non-vaccination in India: 1998–2008

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ABSTRACT

Background: Despite almost three decades of the Universal Immunization Program in India, a little more than half the children aged 12–23 months receive the full schedule of routine vaccinations. We examined socio-demographic factors associated with partial-vaccination and non-vaccination and the reasons for non-vaccination among Indian children during 1998 and 2008.

Methods: Data from three consecutive, nationally-representative, District Level Household and Facility Surveys (1998–99, 2002–04 and 2007–08) were pooled. Multinomial logistic regression was used to identify individual and household level socio-demographic variables associated with the child's vaccination status. The mother's reported reasons for non-vaccination were analyzed qualitatively, adapting from a previously published framework.

Results: The pooled dataset contained information on 178,473 children 12–23 months of age; 53%, 32% and 15% were fully vaccinated, partially vaccinated and unvaccinated respectively. Compared with the 1998–1999 survey, children in the 2007–2008 survey were less likely to be unvaccinated (Adjusted Prevalence Odds Ratio (aPOR): 0.92, 95%CI = 0.86–0.98) but more likely to be partially vaccinated (aPOR: 1.58, 95%CI = 1.52–1.65). Vaccination status was inversely associated with female gender, Muslim religion, lower caste, urban residence and maternal characteristics such as lower educational attainment, non-institutional delivery, fewer antenatal care visits and non-receipt of maternal tetanus vaccination. The mother's reported reasons for non-vaccination indicated gaps in awareness, acceptance and affordability (nancial and non- nancial costs) related to routine vaccinations.

Conclusions: Persisting socio-demographic disparities related to partial-vaccination and non-vaccination were associated with important childhood, maternal and household characteristics. Further research investigating the causal pathways through which maternal and social characteristics influence decision-making for childhood vaccinations is needed to improve uptake of routine vaccination in India. Also, efforts to increase uptake should address parental fears related to vaccination to improve trust in government health services as part of ongoing social mobilization and communication strategies.

1. Introduction

Globally about one-third of the annual vaccine preventable child deaths or 500,000 deaths occur in India [1,2]. While most vaccine preventable deaths in India are due to pneumonia and diarrhea, complete immunization with existing routine vaccines against tuberculosis, diphtheria, pertussis and tetanus, polio,

Abbreviations: UIP, Universal Immunization Program; EPI, Expanded Program on Immunization; DLHS, District Level Household and Facility Survey; BCG, Bacillus Calmette-Guerin; DPT, Diphtheria-Pertussis-Tetanus; OPV, Oral Polio Vaccine; NFHS, National Family Health Survey; PSU, Primary Sampling Unit; ANM, Auxiliary Nurse Midwife.

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measles, hepatitis B and *H. influenzae* type b are essential to avert the associated mortality, morbidity and to prevent future outbreaks of these vaccine preventable diseases [3]. However, despite almost three decades of the UIP, the proportion of children aged 12–23 months receiving the full schedule of vaccinations in India is around 61% and for third dose DPT (DPT3) coverage is 72%, still below the global average of 86% [4]. The persisting low routine immunization coverage implies that one in three children born every year still do not receive complete protection against the diseases currently covered by the UIP, placing them at the highest risk of mortality and morbidity [2,5].

India's slow progress to achieving universal immunization for all children has generally been attributed to its sheer population size, high growth rate, geographic and cultural diversity and limited healthcare spending [6,7]. However, large inter-state and inter-district disparities in immunization coverage have helped uncover important supply and demand-side factors associated with uptake of routine vaccinations [7–9]. Supply-side factors generally include a lack of trained personnel to manage and deliver immunization services, poor relationship between health care workers and mothers, inconvenient timing or location of immunization services and even vaccine stock outs [6,8,10]. Demand-side factors associated with routine vaccination uptake however are complex and often multi-faceted. Previous research from India tends to highlight socio-demographic characteristics associated with uptake such as child's gender, order of birth, place of delivery, maternal age at childbirth, parental education, caste and religious preference, household wealth and location (urban or rural), [6–8,11,12]. Of late, non-socio-demographic demand-side issues such as awareness regarding the need for and timing of routine childhood vaccinations, fears regarding some or all routine vaccines and parental beliefs regarding false contraindications to routine vaccinations have been reported as reasons linked to partial-vaccination and non-vaccination of Indian children [4,12,13]. As, the Indian Government aims to boost full immunization coverage of UIP vaccines to 90% through the Mission Indradhanush initiative by 2020, it is important to track the various socio-demographic and non-socio-demographic factors influencing suboptimal vaccination over the years to identify key areas of intervention and further research.

We used pre-existing, nationally-representative datasets from three rounds of India's District Level Household and facility Survey's (DLHS) conducted from 1998 to 2008 to: (1) examine the socio-demographic factors associated with vaccination status of children aged 12–23 months at the time of survey (focusing on partial-vaccination and non-vaccination) and (2) categorize the reasons reported for non-vaccination by adapting the previously published "5A's Taxonomy for Determinants of Vaccine Uptake" [14], intended for non-socio-demographic factors.

2. Methods

2.1. Data source, sampling and survey questionnaire

The DLHS cross-sectional surveys are conducted periodically to monitor and assess reproductive and child health program indicators in every district of India. To date, four rounds of the DLHS have been completed (DLHS-1 in 1998–99, DLHS-2 in 2002–04, DLHS-3 in 2007–08 & DLHS-4 in 2012–13). Data from DLHS-4 were excluded because the survey was not nationally representative (DLHS-4 covered 336 of 640 Indian districts). Each DLHS round employed a similar systematic, multi-stage stratified sampling scheme. Additional detail on the survey design and calculation of sampling weights are available in the Appendix and elsewhere [15–18].

Interviews with currently married (or ever married) women and with any adult family member (aged 18 years and above) collected information for the "women's questionnaire" and "household questionnaire" respectively. We used information from the "women's questionnaire" containing relevant information on socio-demographic characteristics and childhood immunization information. The type and number of questions providing information on child, maternal and household characteristics and immunization histories were generally similar for the DLHS surveys, however, there were more questions about child and maternal health from DLHS-1 to DLHS-4 [19] (See Appendix for more details on questionnaire). In the DLHS, immunization histories for the last two surviving children were obtained from the vaccination card of the children. If the vaccination card was not available immunization data were based on maternal recall. The study sample comprised the most recently born children aged 12–23 months at the time of survey to limit the influence of poor maternal recall on immunization histories of older children. Also, for consistency and pooling we further restricted analysis to children of mothers who were currently married (*i.e.* ever-married mothers were excluded as they were only interviewed in DLHS-3) and aged 15–44 years at the time of survey (*i.e.* mothers aged >44 years from DLHS-3 were excluded).

2.2. Socio-demographic variables

Individual, household and regional characteristics having a previously reported association with children's vaccination status and with complete data available in the survey datasets were chosen for analysis. Individual characteristics included child-specific characteristics such as gender and age in months and maternal characteristics such as mother's age at childbirth, educational attainment, antenatal participation, place of delivery and maternal tetanus vaccination status [20–23]. In addition, caste and religious preference of the head of household were selected [22,24]. Household characteristics included urban or rural location and in the absence of a readily available wealth index measure (for DLHS-1), type of dwelling (Mud, semi-cemented or cemented) was used as a proxy measure of household wealth. And, geographical region of residence in India categorized as North, Central, North-East, West and South was used as the regional indicator for adjustment [7]. Further details on the variables are provided in the Appendix.

2.3. Outcome variable

The current Indian UIP schedule recommends one dose of BCG vaccine at birth (or as soon as possible), three doses of DPT, OPV and Hepatitis B (added in 2007) or pentavalent vaccine (available in some Indian states since 2011) provided at 6, 10 and 14 weeks of age and one dose of measles vaccine at 9 months of age. The main outcome of study was the vaccination status of children 12–23 months of age, defined using EPI recommendations which were in use during the surveys as follows [22,25]:

(1) <u>Fully vaccinated</u> – Children who received one dose of BCG, three doses of DPT, three doses of OPV (excluding the zero dose) and one dose of measles vaccine by 12 months of age.
(2) <u>Partially vaccinated</u> – Children who received at least one but not all the recommended vaccines by 12 months of age.
(3) <u>Unvaccinated</u> – Children who did not receive any of the recommended vaccines by 12 months of age.

2.4. Statistical analysis

Data from the three DLHS surveys were pooled to examine the socio-demographic factors associated with children's vaccination status over the ten-year period covered by the surveys. Similar pooling of data to assess trends and determine predictors of immunization coverage have been reported using the National Family Health Survey (India's Demographic & Health Survey) datasets [26]. Because of the complex, stratified sampling design, appropriate weighting of coverage proportions and regression estimates was done using the supplied national sampling weights for each survey. Univariate regression analysis was performed to examine associations between the socio-demographic variables and children's vaccination status for all surveys combined (see Appendix for technical details). All the socio-demographic variables which had a significant univariate association with vaccination status at the $p \leq 0.05$ level were included in the multivariate regression analysis to examine factors associated with partial-vaccination and non-vaccination compared with full vaccination for children aged 12–23 months as previously described [22]. Also, since the outcome of children's vaccination status had three levels, a pooled multinomial logistic regression adjusted for age of the child, type of dwelling, survey period and geographic region. Results of the multivariate regression modeling are presented as adjusted Prevalence Odds Ratio's (aPOR's) with 95% Confidence Interval's (CIs). The relative importance of each socio-demographic variable in the multivariate regression model was assessed using Wald Test *p*-values. We also performed secondary analyses restricting the analytical sample to the partially vaccinated children to explore differences in the socio-demographic factors associated with vaccination status based on whether children received "very few" vaccines (1–2 doses), "some" vaccines (3–5 doses) or "almost all" vaccines (6–7 doses). The survey analyses were performed using the "*svy*" package in STATA version 12 and figures made using Excel 2013.

Table 1
Definitions and contributing factors of the "5As Taxonomy for Determinants of Vaccine Uptake" [14].

Root causes	Definition
Access	The ability of individuals to be reached by, or to reach, recommended vaccines
Affordability	The ability of individuals to afford vaccination, both in terms of financial and non-financial costs (e.g. time)
Awareness	The degree to which individuals have knowledge of the need for, and availability of, recommended vaccines and their objective benefits and risks
Acceptance	The degree to which individuals accept, question or refuse vaccination
Activation	The degree to which individuals are nudged towards vaccination uptake

2.5. Categorization of reasons for non-vaccination

In the DLHS "women's questionnaire", mothers whose children had not received even a single dose of the recommended UIP vaccines were asked to choose either one important reason (DLHS-1 & DLHS-2) or one or more reasons (DLHS-3) from a list of pre-determined responses to the question "Why was your child not given any vaccination?". To organize the reported reasons for non-vaccination we used a semi-qualitative, framework-based methodology to categorize individual responses (separately for each survey) using the recently published "5A's Taxonomy for Determinants of Vaccine Uptake" to help identify the important underlying reasons for non-vaccination among Indian children [14]. The working definitions for each of the root causes in the 5As taxonomy are presented in Table 1.

3. Results

There were a total of 58,777 (31% of all surveyed children), 58,416 (30%), 61,280 (28%) and 178,473 (30%) eligible children aged 12–23 months in the DLHS-1, DLHS-2, DLHS-3 and the combined surveys respectively. Of these children, 74% lived in rural locations and 38% in mud households. Fifty-three percent of the children were male and 78% of the children were Hindu (Supplemental Table 1). Also, 50% of the children had mothers without any formal schooling and 59% of mothers had non-institutional deliveries.

Coverage of important UIP vaccine doses and children's vaccination status for the individual and combined surveys are presented in Table 2. Of the eligible children, 32% did not have a vaccination card and 30% reportedly had vaccination cards which could not be presented at the time of survey. Overall, coverage of BCG vaccination was highest (81%) and coverage of the third dose DPT (DPT3) vaccine was 62%, similar to third dose OPV (68%) and first dose measles

Table 2
Vaccination proportions for Indian children aged 12–23 months, DLHS1-3.

Category	Weighted percentages (95% CI)					
	DLHS-1 (1998–99)	DLHS-2 (2002–04)	DLHS-3 (2007–08)	Combined surveys (DLHS 1–3)	Relative change (%)*	P-value **
Vaccination card						
No	35.1 (34.5–35.6)	39.6 (38.9–40.5)	25.1 (24.6–25.7)	31.5 (31.1–31.9)	−28.4	<0.001
Yes (not seen)	30.8 (30.3–31.3)	29.0 (28.4–29.5)	31.0 (30.6–31.4)	30.4 (30.1–30.7)	0.6	
Yes (seen)	34.1 (33.6–34.7)	31.4 (30.7–32.1)	43.9 (43.3–44.4)	38.1 (31.1–31.9)	28.7	
BCG	73.9 (73.4–74.4)	75.4 (74.7–76.1)	87.4 (87.0–87.8)	80.7 (80.4–81.0)	18.3	<0.001
DPT3	65.9 (65.3–66.4)	58.6 (57.8–59.3)	60.8 (60.3–61.4)	62.2 (61.8–62.6)	−7.0	<0.001
OPV3	67.9 (67.3–68.4)	59.4 (58.6–60.2)	71.2 (71.4–72.4)	67.5 (67.1–67.9)	4.9	<0.001
Measles	60.0 (59.3–60.5)	56.8 (56.0–57.6)	73.9 (73.4–74.4)	65.7 (65.2–66.1)	23.2	<0.001
Fully vaccinated	54.3 (53.7–54.9)	47.9 (47.1–48.7)	56.0 (55.5–56.6)	53.4 (52.9–53.8)	3.1	
Partially vaccinated	27.4 (26.9–27.9)	32.1 (31.5–32.8)	34.6 (34.2–35.1)	32.1 (31.7–32.4)	26.3	
Very few (1 –2)	18.3 (17.5–19.2)	17.5 (16.1–18.8)	11.4 (10.9–11.8)	14.6 (14.0–15.2)	−37.7	<0.001
Some (3 –5)	32.8 (31.7–33.9)	35.5 (34.4–36.6)	35.8 (34.9–36.7)	35.0 (34.5–35.6)	9.1	
Almost all (6 –7)	48.9 (47.9–49.8)	47.0 (45.3–48.8)	52.8 (51.9–53.8)	50.4 (49.5–51.2)	7.9	
Unvaccinated	18.3 (17.9–18.8)	20.0 (19.4–20.6)	9.4 (9.0–9.7)	14.5 (14.3–14.9)	−48.6	

N = 58 777, 58 416 & 61 279 for DLHS-1, DLHS-2 & DLHS-3 respectively.
BCG: Bacillus Calmette – Guerin, DPT: Diptheria-Pertussis-Tetanus, OPV: Oral Polio Vaccine.
* Relative change calculated as ((DLHS1%/DLHS3%) − 1).
** P-value of trend from Chi-square using Rao-Scott design adjustment.

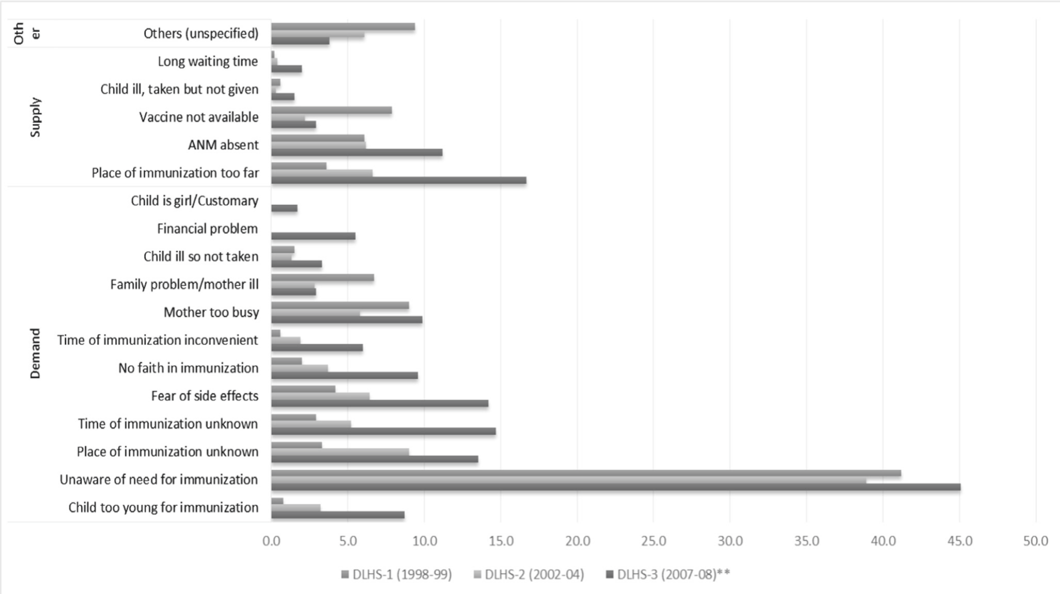
(66%) vaccines. Coverage of BCG and measles vaccination increased from 74% to 87% and 60% to 74% respectively from 1998–1999 (DLHS-1) to 2007–2008 (DLHS-3). However, DPT3 coverage decreased from 66% to 61% for the same period. Fifty-three percent of the eligible children were fully vaccinated, with 32% and 15% partially vaccinated and unvaccinated respectively. The proportion of unvaccinated children was reduced from 18% to 9% and the proportion of partially vaccinated children increased from 27% to 35% from the 1998–1999 (DLHS-1) period to the 2007–2008 (DLHS-3) period.

Results of the pooled multivariate analysis are presented in Table 3. Children in the 2007–2008 (DLHS-3) period were less likely to be unvaccinated (aPOR: 0.92, 95%CI = 0.86–0.98) and more likely to be partially vaccinated compared to the 1998–1999 period (DLHS-1) (aPOR: 1.58, 95% CI = 1.52–1.65). After adjusting for age of the child, type of dwelling, survey period and geographic region, female children were more likely to be unvaccinated than males (aPOR: 1.16, 95%CI = 1.10–1.21). Children living in urban households (compared with rural households) were more likely to be unvaccinated (aPOR: 1.37, 95% CI = 1.26–1.49). Compared to Hindu children, Muslim children were more likely to be unvaccinated (aPOR: 2.03, 95% CI = 1.89–2.18) and partially vaccinated (aPOR: 1.44, 95%CI = 1.37–1.51). And, relative to children belonging to the general class, those belonging to scheduled caste and other backward classes were more likely to be unvaccinated. Lower maternal education, fewer antenatal care visits, non-institutional delivery, non-receipt of maternal tetanus vaccination and non-retention of children's vaccination cards were similarly associated with increased odds of children being unvaccinated and partially

Table 3
Results of multivariate regression modeling for pooled DLHS datasets.

Covariates	Weighted proportions (95%CI)*			Adjusted prevalence odds ratio (95% CI)**	
	Fully-vaccinated	Partially-vaccinated	Unvaccinated	Unvaccinated versus full vaccination	Partial versus full vaccination
Survey period					
1998–1999	54.3 (53.7–54.9)	27.4 (26.9–27.9)	18.3 (17.9–18.8)	Ref	
2002–2004	47.9 (47.1–48.7)	32.1 (31.5–32.8)	20.0 (19.4–20.6)	1.57 (1.47–1.67)	1.51 (1.44–1.58)
2007–2008	56.0 (55.5–56.6)	34.6 (34.2–35.1)	9.4 (9.0–9.7)	0.92 (0.86–0.98)	1.58 (1.52–1.65)
Location					
Rural	49.4 (48.6–50.2)	32.3 (32.0–32.7)	18.3 (17.7–18.9)	Ref	
Urban	65.2 (63.8–66.6)	25.1 (24.0–26.2)	9.7 (9.2–10.3)	1.37 (1.26–1.49)	1.03 (0.98–1.07)
Religion					
Hindu	54.3 (52.9–55.7)	30.7 (30.1–31.2)	15.0 (14.1–15.9)	Ref	
Muslim	43.9 (42.4–45.4)	31.7 (30.9–32.5)	24.4 (23.2–25.6)	2.03 (1.89–2.18)	1.44 (1.37–1.51)
Christian	58.8 (56.5–61.1)	29.0 (27.6–30.5)	12.2 (10.8–13.5)	0.90 (0.76–1.07)	1.01 (0.92–1.12)
Other***	70.5 (69.0–72.0)	21.6 (20.2–22.9)	7.9 (7.1–8.8)	0.58 (0.50–0.69)	0.62 (0.56–0.67)
Social class					
General class	50.6 (49.5–51.7)	31.6 (30.9–32.3)	17.8 (16.8–18.7)	Ref	
Scheduled caste	47.1 (45.4–48.7)	35.7 (34.8–36.7)	17.2 (16.2–18.2)	1.29 (1.20–1.39)	1.11 (1.06–1.16)
Scheduled tribe	51.1 (49.8–52.4)	30.9 (30.3–31.6)	18.0 (17.0–18.9)	1.09 (0.99–1.19)	1.04 (0.98–1.11)
Other backward classes	61.7 (60.5–62.9)	26.5 (25.8–27.2)	11.8 (11.1–12.5)	1.42 (1.34–1.52)	1.16 (1.12–1.21)
Mother's age at birth of eligible child					
≤18	48.2 (46.7–49.8)	34.5 (33.5–35.4)	17.3 (16.1–18.5)	1.21 (1.12–1.32)	1.23 (1.17–1.30)
19–25	56.8 (55.7–57.9)	30.2 (29.7–30.7)	13.0 (12.3–13.7)	Ref	
26–35	51.2 (49.6–52.9)	29.6 (28.8–30.4)	19.2 (18.1–20.2)	1.05 (0.99–1.10)	0.95 (0.92–0.98)
>35	37.8 (35.8–39.8)	31.0 (29.7–32.4)	31.1 (29.4–32.9)	1.19 (1.08–1.32)	0.95 (0.88–1.03)
Mother's education					
High school and above (9 years & above)	76.9 (76.2–77.5)	20.3 (19.7–20.8)	2.8 (2.6–3.1)	Ref	
Middle (6–8 years of schooling)	65.1 (64.3–66.0)	28.2 (27.4–28.9)	6.7 (6.3–7.1)	1.17 (1.03–1.33)	1.19 (1.13–1.26)
Primary (1–5 years of schooling)	56.2 (55.4–56.9)	32.6 (31.8–33.3)	11.2 (10.7–11.8)	1.50 (1.32–1.70)	1.33 (1.27–1.41)
No schooling	37.4 (36.5–38.1)	35.8 (35.5–36.2)	26.8 (26.1–27.6)	2.61 (2.33–2.93)	1.77 (1.68–1.86)
Number of antenatal care visits					
≥7	78.5 (77.5–79.5)	18.6 (17.7–19.5)	2.9 (2.6–3.2)	Ref	
3–6	68.7 (68.1–69.3)	26.3 (25.8–26.8)	5.0 (4.7–5.3)	0.68 (0.58–0.80)	1.13 (1.06–1.20)
1–2	50.4 (49.6–51.1)	37.1 (36.5–37.7)	12.5 (12.1–13.0)	1.09 (0.92–1.28)	1.60 (1.50–1.70)
None	29.1 (28.3–30.1)	35.1 (34.6–35.6)	35.8 (34.9–36.7)	1.75 (1.50–2.06)	1.92 (1.78–2.07)
Maternal tetanus vaccination					
Yes	61.7 (60.7–62.7)	29.1 (28.5–29.7)	9.2 (8.7–9.7)	Ref	
No	26.2 (25.2–27.1)	35.1 (34.5–35.6)	38.7 (37.6–39.9)	2.82 (2.64–3.01)	1.35 (1.29–1.42)
Gender of eligible child					
Male	54.4 (53.1–55.7)	30.4 (29.8–31.1)	15.2 (14.4–16.0)	Ref	
Female	52.4 (51.1–53.4)	30.5 (29.9–31.0)	17.1 (16.2–18.0)	1.16 (1.10–1.21)	1.03 (1.00–1.06)
Place of delivery					
Institutional government	69.9 (69.2–70.6)	25.3 (24.6–25.9)	4.8 (4.6–5.1)	Ref	
Institutional private	71.7 (70.7–72.7)	23.1 (22.4–23.9)	5.2 (4.7–5.6)	1.11 (0.98–1.26)	1.07 (1.02–1.13)
Non-institutional	41.0 (40.2–41.8)	34.9 (34.6–35.3)	24.1 (23.4–24.8)	1.53 (1.41–1.67)	1.22 (1.17–1.27)
Vaccination card					
Yes (seen)	75.7 (75.0–76.4)	23.4 (22.7–24.1)	0.9 (0.7–1.0)	Ref	
Yes (not seen)	57.5 (56.8–58.2)	37.8 (37.1–38.3)	4.7 (4.5–5.1)	6.53 (5.51–7.75)	1.90 (1.83–1.97)
No	22.4 (21.6–23.1)	32.0 (31.4–32.5)	45.6 (44.8–46.4)	118.0 (100.24–138.83)	3.57 (3.43–3.72)

* Coverage proportions presented for combined DLHS surveys and are calculated using the total weighted sample of children in each covariate category as the denominator.
** Adjusted for type of dwelling, age of child in months and geographical region.
*** Other religions include Sikh, Buddhism, Jainism, Judaism and Atheism.



Footnote:
1) N = 10 679, 11 751, 5 471 responses for DLHS - 1, DLHS - 2, DLHS - 3 respectively
2) DLHS-1 and DLHS-2 allowed only single responses, DLHS-3 allowed multiple responses
3) Demand and supply categorization of reported reasons based on standard operational practice
4) Reported reasons under the "others" category were unspecified and kept as such

Fig. 1. Reported reasons for non-vaccination among children aged 12–23 months of India: 1998–2008. (1) DLHS-1 and DLHS-2 allowed only single responses, DLHS-3 allowed multiple responses. (2) Demand and supply categorization of reported reasons based on standard operational practice [4]. (3) Reported reasons under the "others" category were unspeci ed and kept as such).

vaccinated. The ndings of the secondary analysis restricting the analytical sample to the partially vaccinated children were generally consistent with those of the primary analysis (see supplemental Table 2).

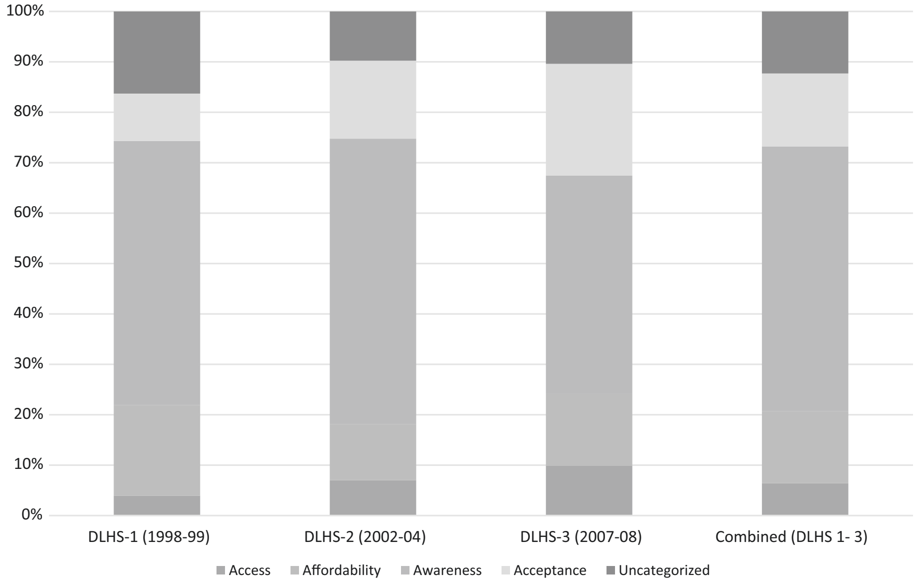
Across the three surveys, the most frequently occurring reason for non-vaccination was that mothers were "unaware of the need for immunization" (Fig. 1). Other noteworthy reasons were not knowing the place for and timing of vaccinations, fear of side-effects following vaccination, access to immunization facilities ("place of immunization too far") and the absence of health workers ("ANM absent"). Most reported reasons for non-vaccination could be categorized as issues of awareness, acceptance or affordability. The categorization of reported reasons for non-vaccination using the 5As taxonomy is available in Table 4. Four of the 17 reported reasons, mainly involving supply-side issues such as absence of health workers, vaccine stock outs and missed opportunities for vaccination could not be classi ed using the 5As taxonomy domains. Over the ten years spanning the surveys, issues of poor parental awareness (regarding the need for, place and timing of immunizations), acceptance of vaccines (including fear of side effects, lack of trust and false contraindications) and affordability (nancial and non- nancial costs) were the most important underlying reasons for non-vaccination among children aged 12–23 months in India (Fig. 2).

Table 4
Categorizing the reported reasons for non-vaccination among Indian children using the 5As taxonomy for Determinants of Vaccine Uptake [adapted from reference 14].

5A's taxonomy domains	Reported reason for non-vaccination
Access	Place of immunization too far
Affordability	Time of immunization inconvenient, Mother too busy, Financial problem, Family problem or mother ill
Awareness	Unaware of need for immunization, place of immunization unknown, time of immunization unknown
Acceptance	Child too young for immunization, Fear of side effects, No faith in immunization, child ill so not taken, child is a girl or customary
Activation	–
Uncategorized	ANM absent, vaccine not available, child ill, taken but not given, long waiting time

4. Discussion

India has the largest number of unvaccinated children globally. Our research indicates that the proportion of unvaccinated children decreased between 1998 and 2008; however the proportion of partially vaccinated children increased slightly for the same period, concurring with previous reports from India [27,28]. The increase in partially vaccinated children, while suboptimal, possibly implies that greater numbers of children are receiving at least some of the recommended UIP vaccines compared with earlier years. Persisting socio-demographic disparities in children's vaccination status were found to be associated with individual characteristics such as the child's gender, mother's education, maternal antenatal participation, receipt of maternal tetanus vaccination, place of delivery, religious preference and caste. Most reported reasons for non-vaccination could be categorized as issues of



Footnote:
1) N = 9 669, 11 081, 4 963, 25713 responses for DLHS - 1, DLHS - 2, DLHS - 3 & Combined surveys (DLHS 1 - 3) respectively
2) The 5As of the taxonomy are access, affordability, awareness, acceptance and activation [14].
3) None of the reported reasons could be categorized under activation.
4) Uncategorized reasons were mainly "supply-side" issues such as absence of health workers, missed opportunities for vaccination and vaccine stock outs.

Fig. 2. Reported reasons for non-vaccination among children 12–23 months of India categorized by the 5As taxonomy for Determinants of Vaccine uptake: 1998–2008. (1) The 5As of the taxonomy are access, affordability, awareness, acceptance and activation [14]. (2) None of the reported reasons could be categorized under activation. (3) Uncategorized reasons were mainly "supply-side" issues such as absence of health workers, missed opportunities for vaccination and vaccine stock outs.

awareness, acceptance and affordability related to routine childhood vaccinations.

Of the many potential demand-side factors, social determinants are known to have a significant impact on routine immunization programs in countries regardless of their income level [29]. They are also considered indicators of inequalities in access to immunization services or uptake of vaccinations among different populations [29,30]. In this study, children were more likely to be partially vaccinated in urban areas compared with rural areas, similar to the findings of a recent study using data from DLHS-3 [22]. An important reason for this might be the presence of underserved populations living in urban slums with limited access to primary health infrastructure and consequently routine immunization services compared with non-slum urban and rural dwellers [21,22]. Additionally, female children were more likely to be unvaccinated than males, potentially highlighting the chronic issue of gender discrimination for preventive health care within some Indian households [11,20].

Lower maternal education and antenatal participation, non-institutional delivery and non-receipt of maternal tetanus vaccination were found to be associated with higher odds of children being partially vaccinated and unvaccinated. The pathways through which maternal characteristics may influence immunization decisions for children are complex [31]. For example, previous research from India highlights the role of health knowledge and the ability to communicate in mediating the effect of maternal education on childhood immunization decisions [31]. Interventions to improve utilization of maternal health services, may help improve childhood immunization outcomes [22]. It is unclear if the associations between religion and caste with children's vaccination status represent differential access to routine immunization services or perceived barriers, health beliefs and lack of awareness regarding vaccinations in general [22,30]. Further research disentangling the role of supply-side and demand-side barriers to immunization and investigating the causal pathways through which important maternal and social characteristics influence decision-making for childhood vaccinations is needed to inform governmental interventions to improve uptake of routine vaccination in India.

Since socio-demographic characteristics are often difficult to interpret and modify, we also organized the mother's reported reasons for not vaccinating their children by adapting the "5As Taxonomy for Determinants of Vaccine Uptake", intended for non-socio-demographic determinants [14]. In addition to gaps in awareness, the categorization helped identify issues of acceptance and affordability as other important underlying reasons for non-vaccination among Indian children. These findings suggest that communication strategies to increase immunization coverage focusing on improving parental knowledge alone may not be sufficient to change vaccination behavior as previously indicated [32]. Although models elucidating parental decision-making for childhood vaccinations are available, studies examining the applicability of the existing theoretical frameworks in India are not available and the complex interplay of several social, cultural, political, economic and religious influences on parental decision-making for childhood vaccinations in India make the use of existing frameworks difficult. Therefore, contextual research investigating these factors in India is needed to develop interventions to improve vaccination acceptance rates [33–35]. Past and recent reports of vaccine refusal related to the OPV and DPT vaccines from different parts of the country and clustering of vaccine-refusing households can provide some insights on other dynamics affecting vaccine decisions. [36–38]. Expanding and leveraging the successful Social Mobilization Network (SMNet) approach used in the National Polio Eradication Programme, incorporating the use of local religious leaders and community influencers may improve trust between parents and health providers [39]. The Indian UIP may also consider parental time constraints through the organization of regular catch-up sessions for missed vaccinations and the wider use of mobile immunization reminder services such as the "vRemind" and "IAP-ImmunizeIndia" to help reduce India's immunization gap [40,41].

Large-scale, periodic surveys providing data on health indicators in India such as the DLHS and National Family Health Survey (NFHS) have typically focused on capturing a wide range of maternal and child health outcomes, including details on recommended vaccinations for the most recently born children [19]. As the DLHS survey is currently combined with the National Family Health Survey, it is important for future NFHS "women's questionnaires" to include questions on why children missed some or all vaccinations [17]. As demonstrated in this study, it is possible to categorize mother's reported reasons using an analytical framework such as the 5As Taxonomy to aid identification of the possible root causes for suboptimal vaccination among Indian children. To better capture issues of parental "acceptance" of childhood vaccination, the Parent Attitudes about Childhood Vaccination (PACV) short scale could be adapted for use in the NFHS surveys [42]. Also, since supply-side issues were consistently reported as important reasons for non-vaccination by mothers across the surveys, it may be valuable to include an additional dimension (a sixth "A") such as the "availability" of vaccinators, vaccines and timely vaccination services to the 5As Taxonomy, especially for use in developing countries such as India. Comparison of the 5As taxonomy categorization to standard categories (supply or demand-side) and the "Classification of Factors Affecting Receipt of Vaccines" are presented in Supplemental Table 3 [43].

Among the limitations of this study, the first is the use of relatively old datasets for analysis. The analysis was restricted to the first three DLHS rounds since the fourth round (DLHS-4) was not nationally representative. Furthermore, the NFHS datasets could not be utilized for analysis as its fourth round is currently underway and it does not include mother's reasons for not vaccinating their children. Even still, the use of the first three rounds of the DLHS datasets allowed pooling for the study sample, increasing analytical power and facilitating investigation of the various socio-demographic factors associated with suboptimal vaccination which are unlikely to change substantially over time. Second, the vaccination status of children was categorized using maternal recall in addition to vaccination card information. Because of differential recall, estimates of vaccine coverage and vaccination status may have been under or overestimated (Supplemental Table 4). Many earlier studies from India have conducted similar analyses combining immunization information based on maternal recall and vaccination cards and in our study, a vast majority of the unvaccinated children (89%) would have been excluded if the analyses were restricted to information from vaccination cards alone [7,12,22,23,26,28,44,45]. Third, a recent study observed age misreporting and likely underreporting of recent pregnancies among female respondents, highlighting potential selection and information biases in large scale surveys such as the DLHS [46]. Fourth, the DLHS surveys were cross-sectional in design, limiting the ability to draw causal inference from the observed associations. Fifth, the association of important characteristics such as parental employment, birth order and household size with vaccination status could not be assessed as those data was incomplete. Sixth, the wealth index for households in the first DLHS survey (DLHS-1) was not available, therefore type of dwelling was used as an "absolute" measure of household wealth to help quantify the level of poverty of survey households as opposed to wealth indices which are "relative" measures of wealth generally created using Demographic and Health Survey data [47].

5. Conclusions

This study utilized mixed methods to examine the socio-demographic and non-socio-demographic factors influencing sub-optimal routine vaccination among Indian children. Persisting socio-demographic disparities in children's vaccination status were found to be associated with important childhood, maternal and household characteristics. This analysis found that gaps in awareness, acceptance and affordability (financial and non-financial costs) were the most important underlying reasons for non-vaccination among Indian children, but further research investigating the causal pathways through which important maternal and social characteristics influence decision-making for childhood vaccinations is needed to improve uptake of routine vaccination in India. Efforts to increase vaccine uptake should address parental fears related to vaccination to improve trust in government health services as part of ongoing social mobilization and programmatic communication strategies.

Authors' contribution

Study concept and design: MRF, JPN; Acquisition of data: MRF; Analysis and interpretation of data: MRF, JPN; Drafting of the manuscript: MRF, JPN; Critical revision of the manuscript for important intellectual content: All authors; Statistical analysis: MRF; Obtained funding: JPN; Study supervision: JPN; Final approval: All authors.

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Conflict of interest

The LSHTM (to which HL belongs) have received funding from Novartis for maternal immunization acceptance research; funding from GSK for advising on vaccine hesitancy issues; and funding from both GSK and Merck to convene research symposiums. HJL served on the Merck Vaccines Strategic Advisory Board. None of the funders had any role in the preparation of this paper and none of the other authors declare any competing interests.

Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2017.08.026.

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PUBLICATION 2

Vaccination coverage and factors associated with routine childhood vaccination uptake in rural Vellore, southern India, 2017

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Vaccination coverage and factors associated with routine childhood vaccination uptake in rural Vellore, southern India, 2017

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A B S T R A C T

Background: Vellore district in southern India was selected for intensified immunization efforts through India's Mission Indradhanush campaign based on 74% coverage in the National Family Health Survey in 2015. As rural households rely almost entirely on the Universal Immunization Program (UIP), we assessed routine immunization coverage and factors associated with vaccination status of children in rural Vellore.
Methods: We conducted a cross-sectional household survey among parents or primary caretakers of children aged 12–23 months during August–September 2017 using two-stage, EPI cluster sampling. We verified vaccination histories from vaccination cards and collected data on sociodemographic and non-socio-demographic characteristics by using mobile data capture. Associations with vaccination status were examined with univariate and multivariate logistic regression models.
Results: A total of 643 children were included. Coverage of BCG, third dose pentavalent/DPT, measles/MR vaccines and full vaccination (BCG, three doses of polio and pentavalent/DPT and measles/MR vaccines) among children with vaccination cards (n = 606) was 94%, 96%, 93% and 84%, respectively. Of children with vaccination cards, 70.8% had received all recommended doses according to the UIP schedule. No socio-demographic differences were identified, but parents' familiarity with the schedule (Adjusted Prevalence Odds Ratio (aPOR): 2.06, 95%CI = 1.26–3.38) and receiving information on recommended vaccinations during antenatal visits (aPOR: 2.16, 95% CI = 1.13–4.12) were significantly associated with full vaccination status of the children.
Conclusions: We found higher UIP antigen coverage and proportion of fully vaccinated children than previously reported from rural Vellore. However, adherence to the recommended schedule was still not optimal. Our study highlights the potential of improving parental awareness of vaccination schedule and targeting health education interventions at pregnant women during antenatal visits to sustain and improve routine immunization coverage.

1. Introduction

India's Universal Immunization Program (UIP) is one of the largest public health initiatives in the world in terms of the quantity of vaccines delivered, number of beneficiaries reached and the geographic diversity of regions covered [1]. The UIP provides free vaccines against tuberculosis (BCG), poliomyelitis (OPV and IPV), diphtheria, pertussis, tetanus, *H. influenzae* type b, hepatitis B (pentavalent), measles, Japanese Encephalitis (in endemic districts)

Abbreviations: MI, Mission Indradhanush; NFHS, National Family Health Survey; EPI, Expanded Program on Immunization; UIP, Universal Immunization Program; BCG, Bacillus Calmette-Guerin; DPT, Diphtheria-Pertussis-Tetanus; OPV, Oral Polio Vaccine; IPV, Inactivated Polio Vaccine; MR, Measles-Rubella vaccine; PCV, Pneumococcal conjugate vaccine; PSU, Primary Sampling Unit.

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and recently Rubella (MR), rotavirus diarrhea and pneumococcal diseases (PCV) in some Indian states [2,3]. Perhaps the greatest achievement of the Indian UIP is the eradication of polio, with India certified "polio-free" in 2014 [4]. Despite nearly three decades of the UIP, an estimated 500,000 children still die annually of vaccine preventable diseases and only 62% of children receive the full schedule of UIP vaccines during their first year of life according to a report by the National Family and Health Survey (NFHS-4) conducted during 2015–16 [5,6]. The suboptimal coverage of UIP vaccines suggests that nearly 10 million of the 26 million children born every year in India might be partially-vaccinated or completely unvaccinated [7,8].

The Indian government launched the Mission Indradhanush (MI) campaign in 2015 aiming to increase the coverage of recommended UIP vaccines during the first year of life to 90% by 2020 [1,9].The campaign is conducted in four phases and targets districts with the lowest immunization coverage across the country [1,9]. Strategies to improve routine immunization coverage include special immunization sessions, enhanced community engagement and mobilization, intensive training of health workers and increased accountability at all levels of program implementation [9]. Recent administrative reports suggest that full immunization coverage among children aged 12–23 months has increased by 5–7% after the first two phases of Mission Indradhanush [10]. However, aggregated coverage estimates often conceal important regional disparities [11]. For example, NFHS-4 reports full immunization coverage above 80% for states such as Kerala, Punjab, Goa and Sikkim, whereas states like Arunachal Pradesh and Assam have a coverage of 38% and 47% respectively [6]. Even Tamil Nadu, the only Indian state with conditional cash transfer to economically-disadvantaged mothers whose children have completed the primary vaccination series (until the third dose of pentavalent vaccine) has significant district-level differences in immunization coverage [6,12,13].

The district of Vellore in Tamil Nadu was selected as one of 201 "high-focus" districts for intensified routine immunization as part of the MI campaign in 2015 [14]. The NFHS-4, however, reported full immunization coverage of 74% for Vellore, with important urban-rural difference (78% vs. 69% respectively) [6]. Since rural households are almost entirely dependent on immunization services provided by the UIP, it is important to investigate the reasons for the suboptimal coverage and identify potential disparities in the uptake of routine childhood vaccination that may be addressed by targeted interventions [15]. The objective of our study was to assess routine immunization coverage and the factors associated with the vaccination status of children aged 12–23 months in rural Vellore. As a secondary objective, we also describe and evaluate the factors associated with adherence to the UIP schedule, which are generally not reported by administrative and national health surveys in India.

2. Methods

2.1. Study setting

The study was conducted in Thimiri, a rural administrative block comprising 67 villages in Vellore district in Tamil Nadu, India. Thimiri is one of the larger blocks of the Vellore district with a population of 105,691, with 11,242 children aged six years or younger and literacy of approximately 65% (2011 census). Thimiri was selected as it is easily accessible by road and expected to be representative of the routine immunization services available to the other blocks of the district. Routine immunization is provided in primary health centers, childcare centers (Anganwadis) or the government district hospital at no cost to parents. A Measles-Rubella (MR) vaccination campaign was held during February-March 2017 to provide a single dose of the vaccine to all children aged 9 months to 15 years before formal introduction into the UIP schedule, replacing the monovalent measles vaccine. Numerous private clinics and hospitals around Thimiri and other parts of Vellore also provide UIP and non-UIP vaccinations for a fee, and generally use the Indian Academy of Pediatrician (IAP) immunization schedule [16].

2.2. Survey procedure and sample size

A household survey of children aged 12–23 months (henceforth called "eligible children") was conducted during August and September 2017, using two-stage cluster sampling based on the Expanded Program on Immunization (EPI) coverage survey methodology [17]. First, 30 clusters were selected with probability proportional to size (PPS), with a cluster defined as a village or a group of congruent villages with a population of ≥2000 individuals (or 400–500 households). At the second stage, from the geographic center of each cluster, a direction for survey and the starting household were selected randomly using EPI guidelines [18]. The next nearest households were based on proximity to the prior household; sampling continued until the required number of children were surveyed in each cluster or until the last household with an eligible child in a given cluster was reached. If multiple children in the eligible age group were present in a household, only the youngest child was included.

The proportion of fully vaccinated children (children who received one dose of BCG and measles and three doses each of DPT & OPV vaccines) according to the NFHS-4 for rural Vellore was 70% [19]. Using this estimate with an absolute precision of ±5%, anticipated design effect (deff) of 2 and inflating the effective sample size by 15% for potential non-response during the surveys, a total sample of 750 children aged 12–23 months or 30 clusters of 25 children each was planned.

2.3. Data collection & management

We used a structured, interviewer-administered questionnaire to collect information from parents or primary caretakers of eligible children from whom written informed consent was obtained. A primary caretaker had to be a relative involved in caring for the child and knowledgeable of their immunization history. The questionnaire was translated to Tamil and programmed using the "KoBo Toolbox", an open-source application for mobile data collection [20]. Both the translated paper and electronic versions of the questionnaire were pre-tested among parents of children aged 12–23 months in a non-study village. Range checks, skip patterns and pictures of children's vaccination cards were programmed into the interface to minimize data-entry errors. All the field staff had a three-day training session prior to survey commencement. 10% validation was independently done for randomly selected children. The study protocol received ethical clearance from the Institutional Review Board (IRB) of the Christian Medical College, Vellore (*IRB no. 10691, dated 21.06.2017*).

2.4. Study variables

The independent variables included socio-demographic characteristics such as parent age, education and occupation and household type, number of members, caste and religion and child characteristics like age at survey, birth order and places of birth and vaccination. Non-socio-demographic characteristics of the parents were outlined using the "5A's taxonomy for determinants of vaccine uptake" [21]. Information on issues of Access – mode of

Table 1
Definitions of vaccination status and schedule-appropriate vaccination status of children aged 12–23 months in rural Vellore, southern India.

Outcome	Definition
Primary: Vaccination status [49]	**Fully vaccinated:** Children who received one dose of BCG, three doses of pentavalent (containing antigens against diphtheria, pertussis, tetanus, hepatitis B and *Haemophilus influenzae* B) or DPT, three doses of OPV (excluding the zero dose) and one dose of measles containing vaccine (monovalent measles or Measles-Rubella), irrespective of age at receipt of individual doses; **Undervaccinated:** Children who missed one or more recommended doses or those who received none of the recommended doses
Secondary: Schedule-appropriate vaccination status [31]	**Schedule-appropriate**: Children who were vaccinated at the right age and interval as per the UIP schedule, i.e. those who received (1) BCG at birth or as early as possible until one year of age, (2) pentavalent/DPT & OPV vaccines - first dose 6 weeks after birth and subsequent doses with at least four week (28 day) intervals and receipt of all three doses before the first birthday (3) Measles containing vaccine (monovalent measles or Measles-Rubella) administered after completion of 9 months of age, but before their first birthday; **Not schedule-appropriate:** Children who either missed one or more recommended doses or did not receive one or more doses at the recommended age and interval as per the UIP schedule during the first year of life (according to the definition above)

Table 2
Socio-demographic characteristics of children aged 12–23 months and their parents in rural Vellore, southern India (N = 643).

Characteristic	Category	Frequency	Percentage (%)
Child characteristics			
Child's age (months)	12–17	308	47.9
	18–23	335	52.1
Child's gender	Female	305	47.4
	Male	338	52.6
Child's birth order	1	275	42.8
	2	279	43.4
	≥3	89	13.8
Place of birth	Public facility	518	80.6
	Private facility	119	18.5
	Home/Others	6	0.9
Place of vaccination	Public facility	605	94.2
	Private facility	38	5.8
Parental characteristics			
Respondent	Mother	611	95.0
	Father	17	2.6
	Others	15	2.4
Age of mother at birth of child (years)	<20	74	11.5
	20–30	526	81.8
	>30	43	6.7
Marital status of respondent	Single	3	0.5
	Married	627	97.5
	Divorced/Widowed	13	2.0
Mother's education	Illiterate	17	2.6
	Up to 12th standard	527	82.0
	Diploma/Degree	99	15.4
Father's education	Illiterate	31	4.8
	Up to 12th standard	522	81.2
	Diploma/Degree	90	14.0
Mothers occupation	Homemaker	561	87.2
	Wage earner	68	10.5
	Salary earner/business	14	2.2
Fathers occupation (n = 638)	Unemployed	16	2.5
	Wage earner	457	71.6
	Salary earner/business	165	25.9
Household characteristics			
Religion	Hindu	623	96.9
	Others	20	3.1
Household size	< 5	217	33.7
	5–10	418	65.0
	> 10	8	1.3
Type of dwelling	Mud	19	2.9
	Semi-cemented	32	5.0
	Cemented	592	92.1
Social group	SC*	164	25.5
	ST	68	10.6
	OBC/general	411	63.9
Ration card ownership	Yes	595	92.5
	No	48	7.5

*SC: Scheduled castes, ST: Scheduled tribes, OBC: Other Backward classes (for more detail see supplemental material).

travel to the most frequented vaccination center, Affordability – timing of immunization services (a proxy for opportunity costs such as lost earnings or time), Awareness – familiarity with UIP schedule for children and the recently introduced MR vaccine, Acceptance – trust in information provided by health care providers, reported hesitancy about childhood vaccines and Activation

Table 3
Non-socio-demographic characteristics of survey participants in rural Vellore, southern India (N = 643).

Characteristic	Categories	Frequency	Percentage (%)
Access			
Travel to immunization facility (proxy for distance to facility)	Walking	420	65.3
	Private/Public transport	223	34.7
Awareness			
Heard about recently introduced Measles-Rubella vaccine	No	523	81.3
	Yes	120	18.7
I think immunization is important to keep my child healthy	Don't agree (N*)	4	0.7
	Agree (SA,A)	639	99.3
I am familiar with the immunization schedule (individual vaccines & timing of doses)	Don't agree (N,DA, SDA)	180	28.0
	Agree (SA,A)	463	72.0
Affordability			
The timing of immunization sessions was convenient for me	Don't agree (N, DA)	45	7.0
	Agree (SA, A)	598	93.0
Acceptance			
Self-reported hesitancy with one or more childhood vaccines	Hesitant (N,SH,VH**)	365	56.8
	Not hesitant (NH,NTH)	278	43.2
I trust the information provided by the health workers on immunizations	Don't agree (N)	12	1.9
	Agree (SA,A)	631	98.1
Activation			
Health worker home visits	No/Not sure	139	21.6
	Yes	504	78.4
Information about recommended vaccines provided during antenatal visits	No/Not sure	65	10.1
	Yes	578	89.9
Received incentive for completing pentavalent/DPT series (n = 641)	No	208	32.4
	Yes	433	67.6

*SA: Strongly agree, A: Agree, N: Neutral, DA: Disagree, SDA: Strongly disagree.
** SH: Strongly hesitant, VH: Very hesitant, N: Neutral, NH: Not hesitant, NTH: Not too hesitant.

– receipt of monetary incentive for completion of the pentavalent/DPT series, health-worker home visits and provision of information on the UIP schedule during antenatal visits was collected.

Data on routine childhood vaccinations administered during the first year of life were collected from the vaccination cards of eligible children (including doses and dates of vaccination) as well as parental report. If a vaccination card was not available, data were based on parental recall. Children without recorded dates for vaccination were assumed to have missed those doses and were asked for reasons for the missed doses [22,23]. The categorization of the primary and secondary outcomes are found in Table 1.

2.5. Statistical analysis

Data were entered real-time on the KoBo Toolbox interface using Android™ devices. Data were uploaded to the KoBo server and downloaded for cleaning. Data cleaning included reviewing the completeness and validity of the variables collected and verification of the dates of birth and vaccination using the pictures of children's vaccination cards. Data were managed and analyzed using STATA (version 14, StataCorp LP, College Station, TX, USA).

The analyses accounted for the cluster sampling design using a cluster identifier as the primary sampling unit for survey specification in the "svy" package of STATA. Proportions of children aged 12–23 months receiving each of the recommended UIP doses and 95% confidence intervals (CIs) were calculated using information based on (1) vaccination cards or parental recall and (2) vaccination cards alone. We also calculated the sensitivity and specificity of parental recall and vaccination card information to categorize children's vaccination status using the "diagt" package for STATA. The age of children at receipt of individual UIP doses was calculated by subtracting their birthdate from the dates of vaccination. All independent variables were analyzed categorically (see supplemental material). Univariate analysis to examine associations between the socio-demographic and non-socio-demographic variables with vaccination status used logistic regression. All independent variables with a significant univariate association at the $p \leq 0.20$ level were included in the multivariate regression models. The univariate and multivariate analyses were restricted to children with vaccination cards, however supplementary analyses were performed for all the surveyed children, *i.e.* irrespective of the source of vaccination history. Associations between the independent variables and full and schedule-appropriate vaccination status of children are presented as crude and adjusted Prevalence Odds Ratios (aPORs) with 95% CIs derived from design-adjusted standard errors. As sensitivity analysis, we examined the factors associated with full and schedule-appropriate vaccination status after restriction to children exclusively vaccinated at public health facilities.

3. Results

3.1. Participant characteristics

A total of 643 children aged 12–23 months were included (one family declined to participate; survey response proportion = 99.8%) in the survey. Mean (SD) age of children was 18.2 (3.6) months, 52.6% were boys and 42.8% were firstborn. Of the children, 92.1% lived in cemented houses and 623 (96.9%) belonged to Hindu families. Most children (94.2%) received vaccination at public facilities. The characteristics of children and parents are presented in Tables 2 and 3, respectively.

4. Vaccination coverage and adherence to the UIP schedule

The coverage of important UIP doses and children's vaccination status are presented in Table 4. Of the children included, 606 (94.3%) had a vaccination card and the rest reportedly had a vaccination card that could not be produced at the time of survey. There were no significant differences in the socio-demographic characteristics of children with and without vaccination cards (Supplemental Table 1). Vaccination coverage using information from

Table 4
Coverage and vaccination status of children aged 12–23 months in rural Vellore, southern India.

Vaccine antigen	Recommended age	Vaccination status, Card or parental recall (N = 643)		Vaccination status, Card only (N = 606)		Schedule-appropriate vaccination status* (N = 606)	
		Number vaccinated	Coverage, % (95% CI)	Number vaccinated	Coverage, % (95% CI)	Number vaccinated	Coverage, % 95% CI
BCG	Birth	642	100.0 (–)	572	94.4 (91.8–96.2)	567	93.5 (91.2–95.9)
Pentavalent/DPT-1	6 weeks	640	99.8 (98.8–99.9)	590	97.4 (95.1–98.6)	572	94.4 (92.2–96.5)
Pentavalent/DPT-2	10 weeks	636	99.5 (97.9–99.8)	590	97.4 (95.3–98.5)	571	94.2 (92.0–95.8)
Pentavalent/DPT-3	14 weeks	632	99.2 (97.1–99.7)	580	95.7 (93.2–97.2)	567	93.6 (91.3–95.3)
OPV-1	6 weeks	641	99.8 (98.8–99.9)	593	97.9 (96.6–98.7)	575	94.9 (93.0–96.7)
OPV-2	10 weeks	636	99.3 (97.9–99.8)	589	97.2 (94.7–98.5)	570	94.0 (91.9–95.7)
OPV-3	14 weeks	635	99.2 (97.1–99.7)	579	95.5 (92.8–97.3)	565	93.2 (90.9–95.0)
Measles or MR	9–12 months	630	98.1 (95.3–99.3)	563	92.9 (89.7–95.2)	517	85.3 (81.7–88.3)
Fully vaccinated children	12–23 months	619	96.4 (93.4–98.1)	509	84.0 (79.0–87.9)	–	–
Schedule-appropriately vaccinated children**	By 12 months of age	–	–	–	–	429	70.8 (65.6–75.5)

*Children with a vaccination card who received individual doses according to the UIP prescribed ages and before 1 year of age (BCG: Birth to 1 year; Pentavalent/DPT1 & OPV1: After 6 weeks of age, Pentavalent/DPT2 & OPV2: $\geq$ 28 days after first dose, Pentavalent/DPT3 & OPV3: $\geq$ 28 days after second dose; Measles: 9–12 months).
**Children who received (1) BCG before one year of age (2) Pentavalent/DPT & OPV vaccines - first dose after 6 weeks of birth and two subsequent doses at 28-day intervals, all before the first birthday and (3) Measles after 9 months and before the first birthday

vaccination cards or parental recall (n = 643) was 100% for BCG, and 99.2% and 98.1% for the third dose of pentavalent/DPT and measles/MR vaccination. The coverage of BCG, third dose of pentavalent/DPT and measles/MR vaccine among children with a vaccination card (n = 606) was 94.4%, 95.7%, 92.9% respectively. Coverage of the pentavalent/DPT and OPV doses was similar as these doses were mainly (>98%) co-administered.

The proportion of fully vaccinated children was 96.4% and 84% for information based on parental recall or vaccination cards and vaccination cards alone, respectively. The sensitivity and specificity of parental recall to classify children's vaccination status using vaccination card information as the gold standard for children with a card (n = 606) was 95% and 21% respectively (Supplemental Table 2). Among the children with a vaccination card, 97 (16%) were undervaccinated and only one of these children was completely unvaccinated. A majority (72.2%, n = 70) of the undervaccinated children missed 1–2 recommended UIP doses (Supplemental Table 3). The most frequently missed doses were measles/MR (22.4% of all missed doses), BCG (17.7%) and third dose of OPV or pentavalent/DPT vaccination (14.1% & 13.6% respectively).

Of the 606 children with a vaccination card, 429 (70.8%) had received all the recommended doses at the prescribed age and interval according to the UIP schedule, 80 (13.2%) received all the recommended doses but at least one dose was not given according to schedule and 97 (16%) missed one or more recommended doses. Failure to adhere to the UIP schedule among the 80 children who had received all the recommended doses by their first birthday was mainly due to the first dose of pentavalent/DPT given before 42 days (n = 18 (17.8% of missed doses), mean (SD) age at vaccination = 37.9 (6.1) days) (Supplemental Table 4) or the interval between pentavalent/DPT doses being less than 28 days (n = 32 (31.7%), mean (SD) interval between doses = 24.2 (5.2) days) or measles/MR vaccine given before 9 months of age (n = 32 (31.7%), mean (SD) age at vaccination = 262.5 (6.7) days).

5. Reasons for missed vaccination doses

The most frequent reason for missed UIP doses reported by parents was a failure of health workers to record dates despite the child being vaccinated (n = 137/192 reasons for missed doses, 71%). Other important reasons included travel out of the village on the due date of vaccination (n = 24, 12.4%), misplaced vaccination cards (n = 20, 10.4%) and a lack of awareness of the recommended schedule (n = 5, 2.6%) (Supplemental Table 5).

5.1. Factors associated with vaccination status and adherence to the UIP schedule

Results of the univariate and multivariate analyses of factors associated with the vaccination status of children aged 12–23 months with a vaccination card at the time of survey are presented in Table 5. In the univariate analysis, children vaccinated in private facilities had a lower odds of full vaccination compared with those receiving vaccination in public facilities (POR: 0.40, 95% CI = 0.17–0.97). Children whose parents agreed (strongly agreed or agreed) that they were familiar with the recommended UIP schedule were more likely to be fully vaccinated compared with those who did not agree (neutral, disagreed or strongly disagreed) to being familiar with the schedule (POR: 2.02, 95% CI = 1.23–3.33). In addition, children whose parents had reported receiving information about the recommended UIP schedule during antenatal visits were more likely to be fully vaccinated than those who reportedly did not receive this information during the visits (POR: 2.53, 95%CI = 1.25–5.11).

In the multivariate analysis, self-reported familiarity with the UIP schedule (aPOR: 2.06, 95%CI = 1.26–3.38), and receipt of information on recommended vaccinations during antenatal visits (aPOR: 2.16, 95%CI = 1.13–4.12) were significantly associated with full vaccination status of children. Familiarity with the UIP schedule and receipt of information on recommended vaccinations during antenatal visits remained associated with full vaccination status in the supplementary analyses including all children regardless of source of vaccination history (n = 643) (Supplemental Table 6). However, children belonging to the other backward classes or the general category were more likely to be fully vaccinated compared with children from the scheduled castes in this analysis (aPOR: 6.02, 95% CI = 1.82–19.90). As sensitivity analysis, we also examined the factors associated with children's vaccination status after recategorizing the doses for which there were missing dates on vaccination cards and for which parents reported a failure in primary recording of the dates as "vaccinated". Familiarity with the UIP schedule and belonging to other backward classes or the general category (vs. scheduled castes) were associated with increased odds of full vaccination (Supplemental Table 7). The positive association between receiving information on the schedule during antenatal visits and full vaccination status remained, but was not statistically significant (aPOR: 2.05, 95% CI = 0.78–5.43). The results of the multivariate analysis restricting the sample to children who were exclusively vaccinated at public

Table 5
Participant characteristics and their association with vaccination status of children aged 12–23 months in rural Vellore, southern India (N = 606).

Characteristic	Categories	Proportions, n (%)		Prevalence Odds Ratio (95% CI)	
		Fully vaccinated	Undervaccinated	Unadjusted	Adjusted
Socio-demographic					
Child's age (months)	12–17	236 (46.4)	56 (57.7)	**Ref**	**Ref**
	18–23	273 (53.6)	41 (42.3)	1.58 (0.94–2.65)*	1.64 (0.99–2.70)*
Child's gender	Male	257 (50.5)	62 (63.9)	**Ref**	**Ref**
	Female	252 (49.5)	35 (36.1)	1.74 (0.97–3.01)*	1.70 (0.92–3.11)*
Child's birth order	1	210 (41.2)	49 (50.5)	**Ref**	**Ref**
	2	230 (45.2)	37 (38.2)	1.45 (1.01–1.95)**	1.24 (0.86–1.79)
	$\geq$3	69 (13.6)	11 (11.3)	1.46 (0.70–3.09)	1.77 (0.77–4.10)
Place of vaccination	Public facility	484 (95.1)	86 (88.7)	**Ref**	**Ref**
	Private facility	25 (4.9)	11 (11.3)	0.40 (0.17–0.97)**	0.62 (0.20–1.92)
Mother's age at birth of child (years)	< 20	60 (11.8)	9 (9.3)	**Ref**	–
	20–30	417 (81.9)	81 (83.5)	0.77 (0.34–1.73)	–
	> 30	32 (6.3)	7 (7.2)	0.69 (0.20–2.39)	–
Mother's education	Illiterate	11 (2.2)	5 (5.2)	**Ref**	–
	Upto 12th standard	424 (83.3)	73 (75.3)	2.64 (0.54–13.02)	–
	Diploma/Degree	74 (14.5)	19 (19.5)	1.77 (0.34–9.09)	–
Father's education	Illiterate	23 (4.5)	4 (4.1)	**Ref**	–
	Upto 12th standard	417 (81.9)	76 (78.4)	0.95 (0.16–5.52)	–
	Diploma/Degree	69 (13.6)	17 (17.5)	0.71 (0.11–4.56)	–
Mother's occupation	Homemaker	448 (88.0)	80 (82.5)	**Ref**	–
	Wage earner	51 (10.0)	14 (14.4)	0.65 (0.32–1.31)	–
	Salary earner/business	10 (2.0)	3 (3.1)	0.60 (0.17–2.06)	–
Father's occupation***	Unemployed	12 (2.4)	4 (4.1)	**Ref**	**Ref**
	Wage earner	365 (72.4)	63 (65.0)	1.93 (0.73–5.13)*	1.51 (0.61–3.79)
	Salary earner/business	127 (25.2)	30 (30.9)	1.41 (0.43–4.64)	1.22 (0.42–3.60)
Religion	Hindu	495 (97.3)	94 (96.9)	**Ref**	–
	Others	14 (2.7)	3 (3.1)	0.89 (0.16–4.81)	–
Household size	< 5	171 (33.6)	34 (35.1)	**Ref**	–
	5–10	331 (65.0)	62 (63.9)	1.06 (0.71–1.58)	–
	> 10	7 (1.4)	1 (1.0)	1.39 (0.14–13.84)	–
Social group	Scheduled caste	127 (24.9)	23 (23.7)	**Ref**	**Ref**
	Scheduled tribe	47 (9.2)	18 (18.6)	0.47 (0.17–1.29)*	0.50 (0.18–1.35)
	Other backward classes/General	335 (65.9)	56 (57.7)	1.08 (0.57–2.04)	1.50 (0.80–2.84)
Type of dwelling	Mud/Semi-cemented	44 (8.6)	3 (3.1)	**Ref**	**–**
	Cemented	465 (91.4)	94 (96.9)	0.33 (0.05–2.44)	–
Non-socio-demographic					
Travel to immunization facility	Walking	337 (66.2)	61 (62.9)	**Ref**	–
	Private/Public transport	172 (33.8)	36 (37.1)	0.86 (0.49–1.53)	–
I think immunization is important to keep my child healthy	Don't agree (N)	2 (0.4)	1 (1.0)	**Ref**	–
	Agree (SA,A)	507 (99.6)	96 (99.0)	2.64 (0.21–32.81)	–
I am familiar with the immunization schedule (individual vaccines & timing of doses)	Don't agree (N,DA, SDA)****	127 (25.0)	39 (40.2)	**Ref**	**Ref**
	Agree (SA,A)	382 (75.0)	58 (59.8)	2.02 (1.23–3.33)**	2.06 (1.26–3.38)**
The timing of immunization sessions was convenient for me	Don't agree (N, DA)	262 (51.5)	58 (59.8)	**Ref**	–
	Agree (SA,A)	247 (48.5)	39 (40.2)	1.40 (0.80–2.45)	–
Self-reported hesitancy with one or more childhood vaccines	Hesitant (SH, VH, N)*****	302 (59.3)	52 (53.6)	**Ref**	–
	Not hesitant (NTH, NH)	207 (40.7)	45 (46.4)	0.79 (0.49–1.28)	–
Health-worker home visits	No/Not sure	107 (21.0)	22 (22.7)	**Ref**	–
	Yes	402 (79.0)	75 (77.3)	1.12 (0.57–2.12)	–
Information about recommended vaccines provided during ANC visits	No/Not sure	42 (8.2)	18 (18.6)	**Ref**	**Ref**
	Yes	467 (91.8)	79 (81.4)	2.53 (1.25–5.11)**	2.16 (1.13–4.12)**
Received incentive for completing pentavalent/DPT series	No	157 (30.9)	38 (39.2)	**Ref**	**Ref**
	Yes	351 (69.1)	59 (60.8)	1.44 (0.91–2.29)	1.48 (0.83–2.58)

* $p < 0.10$; ** $p < 0.05$, *** n = 5 missing observations for father's occupation, N = 601 for multivariate model, **** SA: Strongly agree, A: Agree, N: Neutral, DA: Disagree, SDA: Strongly disagree, ***** SH: Strongly Hesitant, VH: Very hesitant, N: Neutral, NTH: Not too hesitant, NH: Not hesitant

health facilities (n = 570) were similar to the unrestricted sample (Supplemental Table 8). Birth order, social group, self-reported familiarity with and receipt of information on the UIP schedule during antenatal visits and receiving an incentive for completing the pentavalent/DPT series had a univariate association with the schedule-appropriate vaccination status of children at the $p \leq 0.20$ level (Table 6). In the multivariate analysis, children belonging to families of the other backward classes or the general category were more likely to be vaccinated according to schedule compared to those belonging to the scheduled castes (aPOR: 1.69, 95% CI = 1.04–2.73). The findings of the multivariate analysis restricted to children receiving only public facility vaccination were similar to the model with all children included (Supplemental Table 9).

6. Discussion

The proportion of children aged 12–23 months who were fully vaccinated in rural Vellore was 96.4% and 84% using information from vaccination cards or parental recall and vaccination cards alone, respectively. The coverage estimate based on vaccination card information may be more reliable since the specificity of parental recall (to classify children's vaccination status) in our survey was low (21%). The low specificity indicates that the use of parental recall possibly overestimates vaccination coverage, concurring with previous reports from India and elsewhere [24,25]. Full vaccination coverage in our survey however, differs considerably from the NFHS-4 estimates of 69.7% for children aged 12–23 months in rural Vellore and 74% for the Vellore district overall, which are

Table 6
Participant characteristics and their association with schedule-appropriate vaccination status of children aged 12–23 months in rural Vellore, southern India (N = 606).

Characteristic	Categories	Proportions, n (%)		Prevalence odds ratio (95% CI)	
		Schedule-appropriate	Not schedule-appropriate	Unadjusted	Adjusted
Socio-demographic					
Child's age (months)	12–17	206 (48.0)	86 (48.6)	**Ref**	–
	18–23	223 (52.0)	91 (51.4)	1.02 (0.74–1.43)	–
Child's gender	Male	217 (50.6)	102 (57.6)	**Ref**	–
	Female	212 (49.4)	75 (42.4)	1.32 (0.83–2.14)	–
Child's birth order	1	174 (40.6)	85 (48.0)	**Ref**	**Ref**
	2	198 (46.2)	69 (39.0)	1.40 (1.04–1.88)**	1.36 (0.98–1.88)
	≥3	57 (13.2)	23 (13.0)	1.21 (0.75–1.95)	1.64 (0.84–3.19)
Place of vaccination	Public facility	407 (94.9)	163 (92.1)	**Ref**	–
	Private facility	22 (5.1)	14 (7.9)	0.62 (0.30–1.30)	–
Mother's age at birth of child (years)	< 20	46 (10.7)	23 (13.0)	**Ref**	–
	20–30	354 (82.5)	144 (81.4)	1.22 (0.69–2.19)	–
	> 30	29 (6.8)	10 (5.6)	1.45 (0.58–3.64)	–
Mother's education	Illiterate	10 (2.3)	6 (3.4)	**Ref**	–
	Upto 12th standard	357 (83.2)	140 (79.1)	1.53 (0.36–6.58)	–
	Diploma/Degree	62 (14.5)	31 (17.5)	1.20 (0.29–4.99)	–
Father's education***	Illiterate	19 (4.4)	8 (4.5)	**Ref**	–
	Upto 12th standard	353 (82.3)	140 (79.1)	1.06 (0.37–3.08)	–
	Diploma/Degree	57 (13.3)	29 (16.4)	0.83 (0.27–2.49)	–
Mother's occupation	Homemaker	378 (88.1)	150 (84.8)	**Ref**	–
	Wage earner	42 (9.8)	23 (13.0)	0.72 (0.33–1.49)	–
	Salary earner/business	9 (2.1)	4 (2.2)	0.89 (0.28–2.82)	–
Father's occupation	Unemployed	10 (2.4)	6 (3.4)	**Ref**	–
	Wage earner	311 (73.3)	117 (66.1)	1.59 (0.58–4.38)	–
	Salary earner/business	103 (24.3)	54 (30.5)	1.14 (0.39–3.33)	–
Religion	Hindu	419 (97.7)	170 (96.0)	**Ref**	–
	Others	10 (2.3)	7 (4.0)	0.58 (0.17–1.92)	–
Household size	< 5	147 (34.3)	58 (32.8)	**Ref**	–
	5–10	276 (64.3)	117 (66.1)	0.93 (0.65–1.33)	–
	> 10	6 (1.4)	2 (1.1)	1.18 (0.21–6.62)	–
Social group	Scheduled caste	101 (23.5)	49 (27.7)	**Ref**	**Ref**
	Scheduled tribe	39 (9.1)	26 (14.7)	0.73 (0.34–1.54)	0.73 (0.34–1.57)
	Other backward classes/General	289 (67.4)	102 (57.6)	1.37 (0.84–2.24)	1.69 (1.04–2.73)**
Type of dwelling	Mud/Semi-cemented	36 (8.4)	11 (6.2)	**Ref**	–
	Cemented	393 (91.6)	166 (93.8)	0.72 (0.25–2.09)	–
Non-socio-demographic					
Travel to immunization facility	Walking	285 (66.4)	113 (63.8)	**Ref**	–
	Private/Public transport	144 (33.6)	64 (36.2)	0.89 (0.55–1.44)	–
I think immunization is important to keep my child healthy	Don't agree (N)	2 (0.5)	1 (0.6)	**Ref**	–
	Agree (SA,A)****	427 (99.5)	176 (99.4)	1.21 (0.1–15.1)	–
I am familiar with the immunization schedule (individual vaccines & timing of doses)	Don't agree (N,DA, SDA)	108 (25.2)	58 (32.8)	**Ref**	**Ref**
	Agree (SA,A)	321 (74.8)	119 (67.2)	1.44 (0.91–2.30)	1.42 (0.90–2.22)
The timing of immunization sessions was convenient for me	Don't agree (N, DA)	31 (7.2)	12 (6.8)	**Ref**	–
	Agree (SA,A)	398 (92.8)	165 (93.2)	0.93 (0.44–1.99)	–
Self-reported hesitancy with one or more childhood vaccines	Hesitant (SH, VH, N)*****	259 (60.4)	95 (53.7)	**Ref**	–
	Not hesitant (NTH, NH)	170 (39.6)	82 (46.3)	0.76 (0.54–1.07)	–
Health-worker home visits	No/Not sure	88 (20.5)	41 (23.2)	**Ref**	–
	Yes	341 (79.5)	136 (76.8)	1.16 (0.68–2.00)	–
Information about recommended vaccines provided during ANC visits	No/Not sure	36 (8.4)	24 (13.6)	**Ref**	**Ref**
	Yes	393 (91.6)	153 (86.4)	1.71 (0.97–3.01)*	1.42 (0.90–2.22)
Received incentive for completing pentavalent/DPT series	No	130 (30.3)	65 (36.9)	**Ref**	**Ref**
	Yes	299 (69.7)	111 (63.1)	1.35 (0.98–1.86)*	1.55 (0.82–2.94)

* p < 0.10; ** p < 0.05, *** n = 5 missing observations for father's occupation, N = 605 for multivariate model, **** SA: Strongly agree, A: Agree, N: Neutral, DA: Disagree, SDA: Strongly disagree, ***** SH: Strongly Hesitant, VH: Very hesitant, N: Neutral, NTH: Not too hesitant, NH: Not hesitant.

based on information from vaccination cards or parental recall [19]. One possible reason for the different estimates may be that immunization coverage was estimated for different birth cohorts in the NFHS-4 (2013–14) and our survey (2015–16). Since Vellore was selected as a high-focus district in 2015, the coverage of individual UIP antigens and fully vaccinated children may have increased between the two surveys. Another potential explanation from an independent audit of the NFHS-3 data is the significant difference in full vaccination coverage between children whose vaccination card was seen and those whose card was not seen during the survey [25]. The proportions of fully vaccinated children for these two categories was similar in our study (data not shown).

Many (∼40%) undervaccinated children had missed doses of BCG or Measles. The UIP recommends that BCG is administered at birth or as early as possible until one year of age [2]. Nearly 73% (n = 25) of children with missed BCG doses were born in public facilities and since children may potentially have up to four immunization visits (at 6, 10, 14 weeks & 9–12 months) between birth and one year of age, the missed doses represent missed opportunities for routine immunization at birth or during later visits. If the opportunities to vaccinate these children were utilized, the coverage of BCG would have increased from 94.5% to 99.5%. The first dose of measles is recommended during 9–12 months of age, children who are not vaccinated during the first year only have opportunity to catch up when returning for the booster doses of OPV and DPT at 16–24 months, when the second dose of measles is due [2]. Timely reminders to parents through health worker home visits or mobile-phone reminders may help improve uptake of measles vaccination during the first year of life [26,27].

While many studies from India have reported socio-demographic disparities in vaccination coverage among young children, we found none in our study, suggesting a uniform delivery and uptake of routine immunization services in rural Vellore [28–33]. The observed disparity in full vaccination coverage by social group in the supplementary and sensitivity analyses may represent differences in parental beliefs and practices regarding childhood immunization or access to routine immunization services, which needs further investigation [28]. Of the non-socio-demographic factors assessed, parents' familiarity with the recommended UIP schedule and receiving information on the UIP schedule during antenatal visits were associated with increased odds of full vaccination. Nearly one-third of parents in our survey reported not being familiar with the UIP schedule for their children and a majority (>80%) had not heard of the recently introduced Measles-Rubella vaccine. With the recent addition of the rotavirus and pneumococcal conjugate vaccines to the UIP in some Indian states and planned nationwide introduction, health education interventions must aim to improve parental awareness of currently available and newly introduced UIP vaccines. The positive association between the reported receipt of information on the UIP schedule during antenatal visits and children's vaccination status highlights the importance of nudging parents towards vaccine uptake [21]. This finding is compatible with previous research from India which suggests that a higher number of antenatal visits (three or more) is associated with an increased likelihood of children completing the recommended immunization schedule [34]. Pregnant women are an important group for targeted educational intervention to sustain and improve uptake of routine childhood vaccination.

We also analyzed children based on if they had received all the recommended vaccine doses during the first year of life according to the UIP schedule or not [31]. Many previous studies have reported the need to measure adherence to immunization schedules in addition to the traditionally used coverage metrics to evaluate the performance of routine immunization programs [35–38]. Despite the high proportion (84%) of fully vaccinated children in our study, 13% of these children had one or more doses not given according to schedule (mainly due to less than optimal spacing of the multiple dose vaccines or early measles vaccination). Improper spacing of the pentavalent, DPT or OPV doses may lead to suboptimal immune response and according to current UIP guidelines, measles doses administered before 9 months of age are considered invalid and must be repeated [2,39]. These findings concur with various national, state and community-level evaluations which recommend the need for periodic assessment and improvement of age-appropriate immunization coverage among young children in India [31,33,40–42].

Our study had some limitations that should be considered when interpreting the findings: First, the exclusion of children without a vaccination card could have introduced a selection bias; however, we found no significant differences in the socio-demographic characteristics of children with and without vaccination cards (Supplemental Table 1). The results of the multivariate analysis were also similar whether restricted to children with a vaccination card or including all children irrespective of the source of vaccination history. Second, most parents (>70%) reported a failure of the health worker to record vaccination dates as the main reason for missed UIP doses and we were unable to verify these inconsistencies with provider-maintained records due to logistic constraints. It is possible that children received the doses for which the dates were not recorded and since the accuracy of coverage estimates largely depend on the quality of vaccination documentation, there is a need to improve primary data recording [43]. However, it is also likely that there was a degree of "social desirability" in parents' reasons for missed vaccinations for their children as the questionnaires were interviewer-administered [43]. In addition, some overlapping of the reasons for missed vaccination may have occurred; for example, the reported failure in primary data recording could have been due to misplaced cards during vaccination sessions. Third, we were unable to validate parents' knowledge of the vaccination schedule, which may have helped identify knowledge gaps to be addressed by government educational interventions. Fourth, it was also not possible to verify if the participating women had actually received information on the UIP schedule during antenatal visits. The observed association between receiving information on the schedule during antenatal visits with children's vaccination status may in part be due to a recall bias. We did not find any differences in reporting by place of delivery (public vs. private facility). Fifth, a degree of bias in the recording of study exposures may have occurred since the interviewers were not blinded to the children's vaccination records. However, information bias is expected to be minimal as the interviewers were unaware of the study outcomes during data collection. And lastly, as self-reported measures of household income are generally considered unreliable, we used the "type of dwelling" of eligible children as a relative measure of household wealth as previously reported [29,44].

The limitations notwithstanding, this survey is the most recent independent assessment of routine immunization coverage among young children in Vellore, a Mission Indradhanush high-focus district. Our study was characterized by high vaccination card availability (>94%), improving the accuracy of the coverage estimates reported. In contrast, other independent household surveys from India have reported a vaccination card availability of 60–80% [30,31,45,46]. We used standard EPI coverage survey methodology and recorded information using KoBo Toolbox, a free, open-source application for field data collection [20]. Mobile data collection is known to improve real-time supervision of data collectors, reduce the duration and cost of interviewing participants and decrease the possibility of data-entry errors at the point of collection [47,48]. In addition, the "5As taxonomy" aided identification of the possible role of "awareness" regarding the UIP schedule and "activation" through health education to pregnant women in the uptake of routine childhood vaccinations in rural Vellore and can be used for similar evaluations in other parts of India.

7. Conclusions

Periodic, region-specific evaluations of childhood immunization coverage are important to monitor progress and identify barriers to the achievement of national immunization program targets. We found higher coverage of the individual UIP antigens and full vaccination among children in rural Vellore than previously reported. Despite the high coverage, however, adherence to recommended schedule was not optimal. Self-reported familiarity with the UIP recommended schedule and receipt of information regarding childhood vaccinations during antenatal visits were associated with increased odds of full vaccination. Our study highlights the need to improve parental awareness of the currently available and newly introduced UIP vaccines. Health education interventions to improve coverage of routine vaccinations may benefit if targeted at pregnant women during antenatal visits.

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Authors' contributions

Study concept and design: MRF, JPN, GK, VB, VRM; Analysis and interpretation of data: MRF, JPN, GK, VRM; Drafting of the manuscript: MRF; Critical revision of the manuscript for important intellectual content: All authors; Statistical analysis: MRF; Obtained funding: JPN, GK; Study supervision: JPN, GK, VRM; Final approval: All authors.

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Conflict of interest

HL's research group has received funds from GSK and Merck to convene research symposium and holds a grant from GSK to support research on maternal vaccination. HL has served on the Merck Vaccines Strategic Advisory Board 2014-2016. None of the other authors have conflicts of interest to declare.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2019.04.058.

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Vaccination coverage and the factors influencing routine childhood vaccination uptake among communities experiencing disadvantage in Vellore, southern India: a mixed-methods study

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Abstract

Background: In 2015, the Vellore district in southern India was selected for intensified routine immunization, targeting children from communities experiencing disadvantage such as migrant, tribal, and other hard-to-reach groups. This mixed-methods study was conducted to assess routine immunization coverage and the factors influencing childhood vaccination uptake among these communities in Vellore.

Methods: We conducted a cross-sectional household survey ($n = 100$) and six focus group discussions ($n = 43$) among parents of children aged 12–23 months from the known communities experiencing disadvantage in Vellore during 2017 and 2018. Multivariate logistic regression was conducted to examine associations between the parental characteristics and children's vaccination status in the household survey data; the qualitative discussions were analyzed by using the (previously published) "5As" taxonomy for the determinants of vaccine uptake.

Results: In the household survey, the proportions of fully vaccinated children were 65% (95% CI: 53–76%) and 77% (95% CI: 58–88%) based on information from vaccination cards or parental recall and vaccination cards alone, respectively. Children whose mothers were wage earners [Adjusted prevalence odds ratio (aPOR): 0.21, 95% CI = 0.07–0.64], or salaried/small business owners [aPOR: 0.18, 95% CI = 0.04–0.73] were less likely to be fully vaccinated than children who had homemakers mothers. In the focus group discussions, parents identified difficulties in accessing routine immunization when travelling for work and showed knowledge gaps regarding the benefits and risks of vaccination, and fears surrounding certain vaccines due to negative news reports and common side-effects following childhood vaccination.

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Conclusions: Vaccination coverage among children from the surveyed communities in Vellore was suboptimal. Our findings suggest the need to target children from Narikuravar families and conduct periodic community-based health education campaigns to improve parental awareness about and trust in childhood vaccines among the communities experiencing disadvantage in Vellore.

Keywords: Mission Indradhanush, Communities experiencing disadvantage, Parental perceptions, Childhood vaccination, Vellore, India

Background

The Indian Universal Immunization Program (UIP) is the largest public health initiative of its kind, tasked with vaccinating nearly 27 million children every year [1]. The UIP currently provides free vaccines against tuberculosis (BCG), poliomyelitis (OPV and IPV), diphtheria, pertussis, tetanus, *H. influenzae* type b, hepatitis B (pentavalent), measles-rubella (MR), rotavirus diarrhea, Japanese Encephalitis (in endemic districts) and pneumococcal diseases (in some Indian states) [2]. India was certified polio-free in 2014 as a result of a decade-long intensification of polio immunization activities [3]. Following this successful polio eradication campaign, the Indian Government launched the Mission Indradhanush (MI) campaign in 2015 to increase full immunization coverage (children aged 12–23 months who receive one dose each of BCG and measles vaccines and three doses of pentavalent and OPV) in the poorest performing districts to 90% by 2020 [4]. While administrative reports suggested improved full immunization coverage after the first two phases of MI, the recently concluded National Family Health Survey (NFHS-4, 2015–16) reports increased immunization coverage for all Indian states except Haryana, Himachal Pradesh, Uttarakhand, Maharashtra, and Tamil Nadu which warrants further investigation [5, 6].

Tamil Nadu has traditionally had high full immunization coverage and is the only Indian state which provides a financial incentive to economically disadvantaged mothers whose children have received three pentavalent doses [7]. The NFHS-4 estimates full immunization coverage at 70% for Tamil Nadu during 2015–16, compared with 81% during 2005–06 (NFHS-3) [8]. Eight out of thirty-eight districts in Tamil Nadu were selected for intensified routine immunization (including the organization of special immunization sessions, enhanced community engagement and mobilization, and increased accountability at all levels of program implementation) through the MI campaign in 2015 [9]. Vellore was one of the eight "MI districts" in Tamil Nadu, and NFHS-4 reported full immunization coverage of 74% for Vellore with an important urban-rural difference in coverage (78% versus 69%, respectively) [9, 10]. However, a recent survey among young children in rural Vellore reports a full immunization coverage of 84%, close to the prescribed MI target of 90% [11]. An important MI objective involved targeting children from disadvantaged communities such as migrant, tribal, and other hard-to-reach groups [9]. While there is no similar data from Vellore for comparison, a recent review of studies from other parts of India suggests that full immunization coverage among children in communities experiencing disadvantage varies widely from 31 to 89% [12].

Timely and region-specific estimates of routine immunization coverage among children from disadvantaged communities can identify potential inequities in service delivery or uptake and inform targeted interventions to tackle the barriers to vaccination uptake in such settings. With this mixed-methods study, we aimed to assess routine immunization coverage and the factors influencing childhood vaccination uptake among communities experiencing disadvantage in Vellore.

Methods

Study setting and communities

This mixed-methods study was conducted in the Vellore district of Tamil Nadu, southern India. The district has a population of approximately 4 million, of which 43% of residents live in urban, and 57% live in rural areas (2011 Census). There are nearly half a million children under six years of age and literacy is approximately 80% (2011 Census). Routine immunization is generally provided to children in primary health centers, childcare centers (Anganwadis), or the government district hospital at no cost to parents. There are private clinics and hospitals in Vellore that provide vaccinations for a fee, generally using the Indian Academy of Pediatrician (IAP) immunization schedule [13].

Parents or primary caretakers (adults involved in caring for children and knowledgeable of their immunization history) of children under two years of age from the known communities experiencing disadvantage in Vellore such as Narikuravar, Irular, stone quarry, and brick kiln worker communities participated in our study. The Narikuravar are a semi-nomadic tribe of Tamil Nadu similar in origin to the Romani or Roma communities of Europe [14]. This community has low literacy, poor access to public welfare services such as health care, and limited sources of income [15]. The

Irular are a large tribal group of Tamil Nadu characterized by low literacy, extreme poverty, and facing a degree of cultural and geographic isolation [16, 17]. Brick kiln and stone quarry workers are generally migrants from adjoining districts in Tamil Nadu or the neighboring Indian States and reside in suboptimal conditions, have poorer health than the general population, and limited or no access to public welfare services [18, 19].

Cross-sectional survey

The methods of the cross-sectional survey are organized in accordance with the STROBE guidelines for observational studies (Supplemental Table 1).

Study participants

Parents of children aged 12–23 months (henceforth called eligible children) were eligible to participate in the cross-sectional household survey conducted to assess routine immunization coverage and the factors associated with childhood vaccination uptake during December 2017 and January 2018. The age range of eligible children (12–23 months) was set to assess the coverage of vaccines during their first year of life, following expanded programme on immunization (EPI) and UIP guidelines [9, 20]. The vaccination status of children aged 12–23 months is an important indicator widely used to evaluate national and regional immunization programs in India and other developing countries [1, 20–22].

Sample size

Since estimates of the proportions of fully vaccinated children (children who received one dose of BCG and measles and three doses each of pentavalent and OPV vaccines) were not available for the different disadvantaged communities in southern India, we used an anticipated proportion of 50% fully vaccinated children with absolute precision of ±10% and inflating for 15% non-response, to estimate that 110 children needed to be surveyed.

Recruitment

Due to the lack of a pre-existing sampling frame, we surveyed all households with eligible children using an adaptation of traditional snowball sampling, where contacted respondents typically refer one or more respondents to the study [23]. This approach was used to identify additional communities once initial contact with at least one of each community type was made since Narikuravar and Irular settlements are especially difficult to locate and recruit for research [15–17]. Twelve Narikuravar, 16 Irular, 3 brick kiln, and 3 stone quarry settlements in Vellore were covered in the cross-sectional survey.

Data collection

Data for the cross-sectional survey were collected by trained field workers using a pre-tested, interviewer-administered questionnaire after obtaining written informed consent from the parents of eligible children. The questionnaire consisted of three major sections that captured information on child and parents' socio-demographic characteristics, children's immunization history and the reasons for non-vaccination, and parental awareness, attitudes, and concerns regarding routine vaccination (See supplemental material for the survey questionnaire). We collected information on socio-demographic characteristics such as parents' age, education, occupation, household type, caste and religion, and child characteristics such as age, gender, and place of birth. The section collecting children's immunization history was adapted from the EPI cluster survey questionnaire [20]; Information on childhood vaccinations was recorded from vaccination cards, if available, or through parental recall when vaccination records were unavailable. We outlined the section on parents' awareness, attitudes, and concerns regarding routine vaccines using the "5As" taxonomy for the determinants of vaccine uptake - a published framework developed to provide a practical nomenclature to organize the possible root causes of vaccination coverage gaps in diverse settings [24]. This section included questions on "Access" – mode of travel to vaccination centers (a proxy for distance to vaccination centers), "Affordability" – the timing of immunization services (an opportunity cost, since routine vaccines, are provided free of cost), "Awareness" – familiarity with the UIP immunization schedule, "Acceptance" – reported hesitancy about childhood vaccines, and "Activation" – receipt of the information on the UIP schedule during antenatal visits, and a monetary incentive for completing the pentavalent vaccination series. The definitions of the 5As are presented in Table 1. The questionnaire was translated to local vernacular (Tamil) and programmed using the KoBo Toolbox suite, an open-source application for mobile data collection [25].

Statistical analysis

Data from the cross-sectional survey were entered real-time on the "KoBoCollect" application for Android™ devices [26]. Range checks, skip patterns, and pictures of children's vaccination cards were programmed into the interface to minimize data-entry errors. These data were reviewed for completeness, and birth dates and vaccinations were verified using photos of children's vaccination cards. Descriptive analyses were conducted to summarize the distribution of the study variables using frequencies, percentages, means, and standard

Table 1 Definitions of the "5As" taxonomy for the determinants of vaccine uptake domains [21]

"5As" domains	Definition
Access	The ability of individuals to be reached by, or to reach, recommended vaccines
Affordability	The ability of individuals to afford vaccination, both in terms of financial and non-financial costs (e.g. time)
Awareness	The degree to which individuals have knowledge of the need for, and availability of, recommended vaccines and their objective benefits and risks
Acceptance	The degree to which individuals accept, question or refuse vaccination
Activation	The degree to which individuals are nudged towards vaccination uptake

deviations where appropriate. Next, the proportions of children aged 12–23 months vaccinated with the recommended UIP doses were estimated using information from 1) vaccination cards or parental recall and 2) vaccination cards alone, following EPI recommendations. Although estimates from documented sources such as vaccination cards or health-facility records are preferable, combining vaccination cards and parental recall information provides a "crude" estimate of vaccination coverage, which is useful in settings where immunization cards are not commonly available [20]. We also calculated the sensitivity and specificity of parental recall and vaccination card information to classify children's vaccination status for the subset of children with a vaccination card available during the survey. Univariate associations between the independent variables, including socio-demographic and non-socio-demographic characteristics (parents' awareness, attitudes, and concerns regarding routine vaccines) and children's vaccination status (based on parental recall or vaccination cards), were assessed using Chi-square or Fisher's exact tests. Children's vaccination status was categorized as "fully vaccinated" or "under-vaccinated," based on EPI and UIP recommendations; A fully vaccinated child was one who had received one dose of BCG and measles-containing vaccine (monovalent measles or Measles-Rubella) and three doses each of pentavalent and OPV vaccines by 12 months of age [2, 20].

The independent variables associated with children's vaccination status at the $p < 0.05$ level in the univariate analyses were included in a multivariate logistic regression model. Multicollinearity between independent variables in the multivariate model was assessed by estimating the variance inflation factor (VIF) [27]. Since none of the VIF values reached 10 and the mean VIF of the multivariate model was 3.28, there was no evidence of multicollinearity between variables [27]. Hosmer and Lemeshow's goodness-of-fit test was used to evaluate the fit of the multivariate regression model [28]. The multivariate analysis findings are presented as adjusted Prevalence Odds Ratios (aPORs) with 95% CIs derived from design-adjusted standard errors. We considered multivariate associations with a $p < 0.05$ as statistically significant. All analyses accounted for the clustering of children in the individual settlements (34 in total), using the "*svy*" package in STATA (version 14, StataCorp LP, College Station, TX, USA).

Focus group discussions

Study participants

Parents of children aged 12–23 months who participated in the cross-sectional survey were eligible to join the focus group discussions conducted to investigate the barriers and facilitators of childhood vaccination uptake among these populations.

Sample size

The focus group discussions were conducted to assess community norms and parental perceptions surrounding vaccinations for their children. Due to logistical constraints, we determined a priori that two FGDs with 8–10 parents per meeting would be conducted in the Narikuravar, Irular, and stone quarry communities for this qualitative investigation (6 FGDs in total).

Recruitment

Purposive sampling was used to recruit parents for the focus group discussions conducted in December 2017. Only parents who participated in the cross-sectional survey and indicated their willingness to join follow-up discussions were contacted by the trained field workers.

Data collection

A pre-tested thematic guide containing open-ended questions exploring aspects such as perceptions on childhood vaccination and immunization safety, parent–healthcare worker interactions, and suggestions for improving routine immunization services was used for the FGDs. The thematic guide was developed in English, translated to local vernacular (Tamil), and modified using feedback from a pilot FGD conducted in a community that was not part of the survey (see supplemental material for the FGD guide). The FGDs were conducted in Tamil by a field supervisor with extensive experience in community engagement and fieldwork in the study region. Separate FGDs were held with mothers and fathers to ensure their free participation. The FGDs were audio-recorded after obtaining verbal consent from the participating parents. The lead investigator (MRF) was present as a facilitator during all the meetings and recorded written observations relevant to the qualitative analysis. Important responses to the different FGD topics were clarified during each meeting by the field supervisor and lead investigator to better understand them within the sociocultural contexts of the participating communities.

Data analysis

Anonymized audio transcripts from the FGDs were translated into English, and the responses were entered in Microsoft Word for initial analysis. Data were reduced using open coding, and common categories (sub-themes) were identified for each question inductively by the first author (MRF). The sub-themes and associated responses were then mapped to the "5As" taxonomy domains to triangulate the findings of the focus group discussions with those from the household survey [24]. The mapping of sub-themes to the "5As" domains is presented in Table 2. A co-author (KLS) checked the consistency and relevance of the mapped sub-themes and responses. Quotes from participants have been used to support the findings where appropriate and additional text for clarification placed within square brackets, as necessary. The mapping and organization of sub-themes and associated responses to the "5As" domains was performed using Microsoft Excel.

Results

Cross-sectional survey

A total of 100 children aged 12–23 months were included in the household surveys (two families declined to participate, response proportion = 98%). The mean (SD) age of children was 18.7 (3.4) months; 53% of children belonged to Narikuravar communities and 47% to Irular, stone quarry, and brick kiln communities (Table 3). Most participants (89%) were mothers, 46% of all mothers had no formal education, and 51% were homemakers. Almost all parents (95%) agreed that immunization was important to keep their children healthy, and a little more than half (56%) reported that they were familiar with the recommended immunization schedule for their children.

Of the children included, 51% had a vaccination card, and the rest reportedly had a vaccination card that could not be produced during the survey. Vaccination coverage using information from vaccination cards or parental recall (n = 100) was 97% (95% CI: 92–99%) for BCG, and 81% (95% CI: 70–89%) and 75% (95% CI: 65–83%) for the third dose of pentavalent and measles vaccination respectively (Table 4). Among children with a vaccination card (n = 51), coverage of BCG, third dose of pentavalent and measles vaccination was 94% (95% CI: 85–98%), 90% (95% CI:76–96%), 90% (95% CI:77–96%) respectively. The proportions of fully vaccinated children were 65% (95% CI: 53–76%) and 77% (95% CI: 58–88%) for information based on either vaccination cards or parental recall and vaccination cards alone, respectively (Table 4). The sensitivity and specificity of parental recall (to classify their child's vaccination status) using vaccination card information as the gold standard for children with a card (n = 51) was 100 and 58%, respectively.

In the univariate analysis, children who had a vaccination card were more likely to be fully vaccinated compared to those without a vaccination card available during the survey (77% versus 53%, p = 0.006, Table 3). Children from non-Narikuravar communities (Irular, brick kiln, and stone quarries) were more likely to be fully vaccinated than children from Narikuravar communities (81% versus 51%, p = 0.022). Children from non-Narikuravar communities especially had a higher coverage of pentavalent and measles vaccination compared to children from the Narikuravar communities (Fig. 1). Children with educated mothers (primary schooling or higher versus no formal education) and with mothers who were homemakers (compared to daily wage or salaried employees) or fathers who were daily wage laborers (compared to salaried employees) were also more likely to be fully vaccinated (Table 3). In addition, parents'

Table 2 Mapping of sub-themes from the focus group discussions to the "5As" taxonomy domains [21]

"5As" domains	Sub-themes (from open-coding)
Access	Good access to vaccines, travel out of town as reason for missed or delayed doses, time of travel out of town
Affordability	Convenient timing of immunization sessions, free vaccination provided by the government a benefit
Awareness	Benefits of vaccination, names of vaccines (or diseases prevented), knowledge sharing by health care workers, other sources of vaccination information, limited awareness of benefits/risks of vaccination, more information requested
Acceptance	Positive view of vaccines in general, vaccination as a social responsibility, influence of health care worker on parents, family or peer influence on attitudes, impact of negative news on parental attitudes, experiences with vaccination, fear of vaccine side-effects
Activation	Government ads and campaigns, prompts and reminders by health care workers, provisions for delayed doses, financial incentives for vaccination
Uncategorized	Choice of vaccination centers

Table 3 Characteristics of the study participants in the household survey and their association with the vaccination status of children among communities experiencing disadvantage in Vellore, southern India ($N = 100$)

Characteristic	Categories	*N* (%)	Fully vaccinated, *n* (%)	Under vaccinated, *n* (%)	*p*-value*
Socio-demographic					
Child's gender	Male	53 (53.0)	35 (66.0)	18 (34.0)	0.805
	Female	47 (47.0)	30 (63.8)	17 (36.2)	
Place of birth	Public facility	78 (78.0)	52 (66.7)	26 (33.3)	0.198[†]
	Private facility	12 (12.0)	9 (75.0)	3 (25.0)	
	Home	10 (10.0)	4 (40.0)	6 (60.0)	
Mother's education	No formal education	46 (46.0)	23 (50.0)	23 (50.0)	**0.029**
	Primary school or higher	54 (54.0)	42 (77.8)	12 (22.2)	
Father's education	No formal education	39 (39.0)	20 (51.3)	19 (48.7)	0.097
	Primary school or higher	61 (61.0)	45 (73.8)	16 (26.2)	
Mother's occupation	Homemaker	51 (51.0)	43 (84.3)	8 (15.7)	**< 0.001**
	Wage earner	17 (17.0)	10 (58.8)	7 (41.2)	
	Salary earner/small business owners	32 (32.0)	12 (37.5)	20 (62.5)	
Father's occupation	Unemployed/wage earner[a]	62 (60.0)	47 (76.7)	15 (23.3)	**0.005**
	Salary earner/small business owners	38 (38.0)	18 (47.4)	20 (52.6)	
Religion	Hindu	83 (83.0)	57 (68.7)	26 (31.3)	0.130
	Others	17 (17.0)	8 (47.1)	9 (52.9)	
Community type	Narikuravar	53 (53.0)	27 (50.9)	26 (49.1)	**0.022**
	Other communities[b]	47 (47.0)	38 (80.9)	9 (19.1)	
Type of dwelling	Mud/semi-cemented	45 (45.0)	28 (62.2)	17 (37.8)	0.503
	Cemented	55 (55.0)	37 (67.3)	18 (32.7)	
Vaccination card	Not available	49 (49.0)	26 (53.1)	23 (46.9)	**0.006**
	Yes	51 (51.0)	39 (76.5)	12 (23.5)	
Non-socio-demographic					
Mode of travel to immunization facility (proxy for distance to facility)	Walking	54 (54.0)	32 (59.3)	22 (40.7)	0.200
	Private or public transport	46 (46.0)	33 (71.7)	13 (28.3)	
I think immunization is important to keep my child healthy	Not agree (N)	5 (5.0)	1 (20.0)	4 (80.0)	0.075[†]
	Agree (SA,A)[c]	95 (95.0)	64 (67.4)	31 (32.6)	
I am familiar with the recommended immunization schedule for children	Not agree (N,DA, SDA)	44 (44.0)	22 (50.0)	22 (50.0)	**0.035**
	Agree (SA,A)	56 (56.0)	43 (76.8)	13 (23.2)	
Reported hesitancy about one or more childhood vaccines	Hesitant (N,SH,VH)	22 (22.0)	14 (63.6)	8 (36.4)	0.869
	Not hesitant (NH,NTH)[d]	78 (78.0)	51 (65.4)	27 (34.6)	
Received information about the recommended immunization schedule during antenatal visits	No or not sure	9 (9.0)	2 (22.2)	7 (77.8)	**0.007**
	Yes	91 (91.0)	63 (69.2)	28 (30.8)	
Incentive for receiving three doses of pentavalent vaccine	No or not sure	51 (51.0)	27 (52.9)	24 (47.1)	**0.015**
	Yes	49 (49.0)	38 (77.6)	11 (22.4)	

* The *p*-values account for clustering among surveyed children; Boldface indicates $p < 0.05$

[†] *P*-value from Fisher's exact test due to the low cell counts

[a] $n = 2$ fathers were unemployed during the survey

[b] Other communities include the Irular, brick kiln, and stone quarry worker communities

[c] *SA* Strongly agree, *A* Agree, *N* Neutral, *DA* Disagree, *SDA* Strongly disagree

[d] *SH* Strongly hesitant, *VH* Very hesitant, *N* Neutral, *NH* Not hesitant, *NTH* Not too hesitant

Table 4 Coverage and vaccination status of children aged 12–23 months among communities experiencing disadvantage in Vellore, southern India

Vaccine antigen	Card or parental recall (n = 100)		Card only (n = 51)	
	Number vaccinated	Proportion (95% CI)[b]	Number vaccinated	Proportion (95% CI)
BCG	97	97.0 (92.4–98.8)	48	94.1 (84.8–97.9)
Pentavalent- 1	90	90.0 (83.0–94.3)	48	94.1 (85.2–97.8)
Pentavalent- 2	86	86.0 (78.3–91.3)	50	98.0 (89.7–99.7)
Pentavalent- 3	81	81.0 (70.2–88.5)	46	90.2 (76.0–96.4)
OPV- 1	92	92.0 (84.6–96.0)	50	98.0 (89.7–99.7)
OPV- 2	86	86.0 (78.3–91.3)	50	98.0 (89.7–99.7)
OPV- 3	80	80.0 (68.9–87.8)	45	88.2 (74.8–95.0)
Measles or MR	75	75.0 (65.3–82.7)	46	90.2 (76.9–96.2)
Fully vaccinated[a]	65	65.0 (52.5–75.8)	39	76.5 (58.2–88.4)

[a] Children who received one dose of BCG, three doses each of OPV and pentavalent and one dose of measles or MR by 12 months of age
[b] 95% Confidence Intervals (CIs) account for clustering among surveyed children

familiarity with the recommended immunization schedule for their children, receiving information about the immunization schedule during antenatal visits, and receiving a financial incentive for up-to-date vaccination (with three pentavalent doses) were positively associated with children's vaccination status (Table 3).

On multivariate analysis, children whose mothers were wage earners (adjusted Prevalence Odds Ratio (aPOR): 0.21, 95% CI = 0.07–0.64), or salaried/small business owners (aPOR: 0.18, 95% CI = 0.04–0.73) were significantly less likely to be fully vaccinated than children who had homemaker mothers (Table 5). The positive association between parental familiarity with the recommended childhood immunization schedule and children's vaccination status remained in the multivariate analysis but was no longer statistically significant (aPOR: 2.89, 95% CI = 0.90–9.28). In addition, while children from Narikuravar communities had less than half the odds of being fully vaccinated compared to children from the other surveyed communities, this finding was not statistically significant (aPOR: 0.33. 95% CI = 0.06–1.91). Hosmer and Lemeshow's goodness-of-fit test

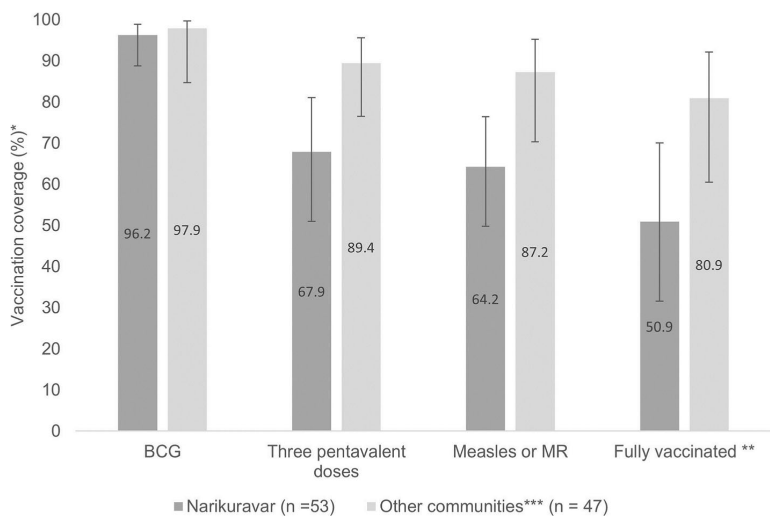

Fig. 1 Coverage and vaccination status of children aged 12–23 months by community type in Vellore, southern India (N = 100). Presents comparisons in the proportions of children vaccinated with the different antigens between the Narikuravar and non-Narikuravar communities. Legend: * Coverage proportions based on vaccination card or parental recall information. ** Children who received one dose of BCG, three doses each of OPV and pentavalent vaccination and one dose of measles or MR by 12 months of age*** Other communities include the Irulars, brick-kiln and stone quarry worker communities

Table 5 Multivariate analysis of the parental characteristics associated with children's vaccination status among communities experiencing disadvantage in Vellore, southern India ($N = 100$)

Characteristic	Categories	*N* (%)	Prevalence Odds Ratio (95% CI)	
			Unadjusted	Adjusted
Mother's education	No formal education	46 (46.0)	**Ref**	**Ref**
	Primary school or higher	54 (54.0)	3.50 (1.15–10.64)**	0.99 (0.20–4.94)
Mother's occupation	Home maker	51 (51.0)	**Ref**	**Ref**
	Wage earner	17 (17.0)	0.27 (0.09–0.82)**	0.21 (0.07–0.64)**
	Salary earner/small business owners	32 (32.0)	0.11 (0.04–0.31)**	0.18 (0.04–0.73)**
Father's occupation	Unemployed/wage earner	62 (62.0)	**Ref**	**Ref**
	Salary earner/small business owners	38 (38.0)	0.29 (0.12–0.68)**	1.30 (0.40–4.22)
Community type	Other communities[a]	47 (47.0)	**Ref**	**Ref**
	Narikuravar	53 (53.0)	0.25 (0.08–0.81)**	0.33 (0.06–1.91)
Vaccination card	Not available	49 (49.0)	**Ref**	**Ref**
	Yes	51 (51.0)	2.88 (1.38–5.99)**	1.59 (0.61–4.19)
I am familiar with the recommended immunization schedule for children	Not agree (N,DA, SDA)[b]	44 (44.0)	**Ref**	**Ref**
	Agree (SA,A)	56 (56.0)	3.31 (1.09–10.02)**	2.89 (0.90–9.28)*
Received information about the recommended immunization schedule during antenatal visits	No or not sure	9 (9.0)	**Ref**	**Ref**
	Yes	91 (91.0)	7.89 (1.86–33.28)**	4.55 (0.58–35.38)
Incentive for receiving three doses of pentavalent vaccine	No or not sure	51 (51.0)	**Ref**	**Ref**
	Yes	49 (49.0)	3.07 (1.26–7.49)**	1.18 (0.26–5.28)

* $p < 0.10$
** $p < 0.05$
[a] Other communities include the Irular, brick kiln, and stone quarry worker communities
[b] *SA* Strongly agree, *A* Agree, *N* Neutral, *DA* Disagree, *SDA* Strongly disagree

yielded a p-value = 0.226, indicating that the multivariate logistic regression model fit the data well.

Focus group discussions

Forty-three parents (22 mothers and 21 fathers) participated in the FGDs conducted in Narikuravar, Irular, and stone quarry worker communities. Each focus group had 7–8 parents, and the FGDs lasted between 25 and 40 min with a mean duration of 31 min. All the "5As" domains were discussed organically by parents in the FGDs, and these findings are summarized below.

Access

Parents did not report issues with accessing routine immunization services in their regular places of residence; however, parents from Narikuravar and Irular communities expressed difficulties getting their children vaccinated when travelling "out of town". Parents from Irular communities discussed that this is an important reason for missed or delayed vaccination doses for children.

My child has missed vaccines. We were out of town for a long time while she was younger. As far as I know, she only received two vaccines.
(Father, Irular community)

There are parents [in the community] who delay vaccines by a month or two, may be because they travel out of the town […].
(Mother, Irular community)

Parents from the Narikuravar settlement provided greater detail on the specific time of the year they were likely to travel out of town.

After new year we go out (January-March), during Pongal [a southern Indian harvest festival] we stay out for 20 to 25 days.
(Father, Narikuravar community)

Affordability

Parents from Irular and stone quarry communities discussed the benefit of receiving routine childhood vaccines for free, at times comparing it to vaccines available in private clinics or hospitals, which they felt were for the more affluent.

The government is giving vaccination free, if we had to get those vaccines in private clinics it would cost us 1000 or 2000 INR [15 – 30 USD], we cannot afford that, so we take the vaccines given by the government.
(Father, Irular community)

The convenient timing (*a non-financial cost described in the 5As taxonomy*) of routine vaccination sessions was discussed as a facilitator of childhood vaccination uptake, especially by mothers in the Narikuravar community.

This time [10 – 12 am] is the best for us, if we leave the house by 10, we are able to get the vaccine by 11 and return home.
(Mother, Narikuravar community)

Awareness

There was widespread understanding of the general benefits of childhood vaccination, with parents describing the utility of vaccines to prevent diseases and keep their children healthy. A mother described the benefits of vaccination in general and specific terms, referring to the protection her child had received against measles.

If we vaccinate our children, they are healthy and well, no problems will come to them. Many other children get measles, but my child does not have it because she has been vaccinated.
(Mother, Narikuravar community)

Fathers from the Irular and quarry worker communities, however, commonly expressed their desire for more information on how diseases occur, how vaccines work, and if there were any other benefits or risks from vaccination that they needed to know.

We want to know more about the diseases, how they come and how vaccines help reduce them, this advice would be very helpful to us. […] We want to keep our children safe and healthy, that is very important to us.
(Father, Irular community)

The problem in villages like ours is that fathers generally go for work 6 days a week, we are free on Sundays only. So we don't get a chance to go for vaccination sessions. Most people don't have much awareness about vaccines.
(Father, Quarry worker community)

Parents generally referred to vaccines (in the routine immunization schedule) in terms of the diseases vaccines protect their children against. A few parents highlighted the role of village health nurses (VHNs) in disseminating vaccination-related information.

The nurse sometimes seats a few of us parents and explains why the vaccine is being given and when the next vaccine is due. They tell us where the vaccine must be given also [site of administration].
(Mother, Quarry worker community)

A few parents across the communities highlighted the need for more detailed information on the routine immunization schedule and the need for regular knowledge-sharing sessions at a convenient time for their community.

Before they [VHN/doctor] vaccinate our children, they do not give us enough information. For example, they say, this is the 1.5-month vaccine, they do not tell us the name or what it is for, similarly with the 2.5- and 3.5-month vaccines [the mother is referring to the pentavalent vaccine].
(Mother, Quarry worker community)

Parents from the Narikuravar community also discussed their lack of awareness about getting their children vaccinated when travelling out of town for work.

We do not know anything there, it is a new place. We do not know where to get it done [vaccinations]. We wait till we return back home, and get our child vaccinated then.
(Mother, Narikuravar community)

Acceptance

Parents across the communities were largely accepting of vaccinations for their children. Many mothers revealed being the primary decision-makers for vaccinating their children and appeared proactive in following up with vaccinations for both their child and other children in the neighborhood. A Narikuravar mother described the need for vaccinating all children, seemingly assuming the role of a "vaccination advocate" in her community.

If there is anyone [an unvaccinated child] like that, we tell them to vaccinate their child. It is good for the child. There are 12 months in a year and 24 hours in a day, what if anything happens to the child at that time? It is important to vaccinate children to keep them protected at all times.
(Mother, Narikuravar community)

Parents from the Narikuravar and Irular communities at times expressed fears due to negative news reports about specific childhood vaccines in the media or from potential side-effects following vaccination as reasons for children not being vaccinated.

Many parents got scared because of that [the news], some did not want to give their children polio drops. People saw some news on TV and some video, and got afraid, will anything like this happen to our children?
(Mother, Narikuravar community)

There are many parents who are afraid that their child may get fever after vaccination, or that their child may have some defects.
(Mother, Irular community)

Activation

The importance of prompts and reminders for childhood vaccinations was discussed by a small number of Narikuravar and Irular parents. Telephonic reminders and house visits by the VHNs were discussed as facilitating childhood vaccination uptake.

[…] *Even if we miss immunization sessions in the Anganwadi [public childcare centers], she [the VHN] comes in search of the specific houses with such children and organizes special sessions to get them vaccinated the following day.*
(Father, Irular community)

Discussion

This study found that full immunization coverage among young children from the communities experiencing disadvantage in Vellore was 65% and 77% using information based on vaccination cards or parental recall and vaccination cards alone, respectively. These coverage estimates are similar to recent studies among migrant (67%), tribal (78%), and slum (72%) populations in other parts of India, but lower than the prescribed Mission Indradhanush target of 90% [9, 29–31]. Previous studies from India predominantly report coverage estimates combining vaccination cards and parental recall information [12, 22, 29, 32–35]. We calculated vaccination coverage estimates using information from vaccination cards or parental recall and for vaccination cards alone following EPI guidelines and due to the low proportion of children with vaccination cards available during the survey (~ 50%). Our study found higher vaccination coverage for children with vaccination cards (n = 51) than the entire sample (n = 100), which was contrary to expectation as combining vaccination cards and parental recall generally provides the highest estimate of vaccination coverage [20]. A large study covering all districts in the state of Tamil Nadu also found lower full vaccination coverage (among children aged 12–23 months) when combining vaccination card and parental recall information than for vaccination cards alone in rural (78.6% versus 80%) and urban (73% versus 73.4%) regions in five districts (including Vellore) [36]. The accuracy of parental recall is often reduced by parents forgetting the number or types of vaccination given to their children, providing socially desirable responses, or receiving incorrect information on the immunization schedule from health workers [37]. Therefore, there is a need to improve vaccination card retention and explore alternate sources of vaccination histories such as provider-maintained records to improve the accuracy of vaccination coverage estimates for children from disadvantaged communities in Vellore.

We observed an important difference in full vaccination coverage between children from the Narikuravar and Irular, brick kiln, and stone quarry worker communities (51% vs. 81%, respectively). The coverage of pentavalent and measles doses was especially lower among Narikuravar children than children in the other communities (Fig. 1), which is concerning considering reports of measles, rubella, and diphtheria outbreaks in other parts of the country [38, 39]. Most Narikuravar parents in our study reported that their children were born in public facilities (75%, n = 40) and that they possessed vaccination cards for their children (81%, n = 43), indicating sufficient access to public health services. Another study among Narikuravar women in Chennai, Tamil Nadu, revealed that women had no issues accessing vaccination for their children [15]. However, parents from the Narikuravar and Irular communities revealed difficulties in accessing routine immunization services when travelling out of town for work. This finding is similar to a study among Gypsy and Irish Traveller communities in the United Kingdom, where some parents discussed difficulty getting appointments for children's vaccinations when away from their usual residence [40]. Parents in this UK study also discussed that scheduling childhood vaccinations around travel commitments, receiving reminders about due vaccines through short message service (SMS) text messages or healthcare workers, and having access to walk-in clinics (not requiring prior appointments) helped them catch up on missed vaccinations for their children [40]. While our study was not designed to compare vaccination coverage estimates between the individual communities, these preliminary findings suggest the need for improving awareness on how and where the Narikuravar (and Irular) communities can access routine vaccinations when away from their regular residence and scheduling catch-up appointments for due vaccination doses.

Children whose mothers were wage earners, or salaried/small business owners were significantly less likely to be fully vaccinated than children who had homemaker mothers in the multivariate analysis. This negative association between maternal employment and children's vaccination status appears counterintuitive as studies among disadvantaged communities and the general population from India and other countries report higher vaccination rates for children with working mothers [35, 41, 42]. Maternal employment is hypothesized to improve uptake by removing financial obstacles to vaccination but may also contribute to missed vaccination appointments due to work commitments [35, 42]. Parents from Roma communities in the United Kingdom reported missing immunization appointments for their children due to long working hours [43]. This may have been true for the children with working mothers (49%, $n = 49$) in our study; mothers from the Narikuravar communities discussed conveniently timed sessions as facilitating childhood vaccination uptake in the focus groups. Having flexible immunization appointments (within 1–2 days of the original appointment) and widespread use of SMS text-based and face-to-face reminders were reported to improve childhood vaccination uptake among communities experiencing disadvantage in the United Kingdom [43]. The district health authorities in Vellore could collaboratively plan immunization sessions based on the availability of parents, and ongoing telephonic or face-to-face reminders by village health nurses (and other health workers) are important to ensure timely childhood vaccinations in these communities.

Just over half (56%) of the parents strongly agreed or agreed that they were familiar with the recommended vaccination schedule for their children in the household survey. We also found a positive but non-significant association between parental familiarity with the vaccination schedule and children's vaccination status in the multivariate analysis. Many previous studies among migrant, tribal, and slum-dwelling communities in India report a lack of parental awareness about the vaccination schedule, place of vaccination, and the need for vaccination frequently as reasons for children being partially vaccinated or unvaccinated [12, 29, 31, 35, 44]. Parents who participated in the FGDs in our study were generally aware of the benefits of vaccination and could list a few vaccines from the routine immunization schedule. However, many parents were dissatisfied with the depth of vaccination-related information provided by health workers (village health nurses and doctors). Fathers, in particular, requested more information on the benefits and risks of vaccination and the specific vaccines available in the routine immunization schedule for their children. Community-based health education through village meetings or home visits has been shown to improve the coverage of DTP3 vaccination among children in a Cochrane review [45]. While mothers generally receive information on childhood vaccines during antenatal visits [46], periodic community-based health education campaigns could educate better and engage the fathers of disadvantaged communities in Vellore.

Around a fifth (22%) of the parents were hesitant (strongly hesitant, hesitant, or neutral) towards childhood vaccines in the household survey. Although parental vaccine hesitancy was not linked to childhood vaccination uptake in the multivariate analysis, it is an important barrier to children being fully vaccinated in migrant and slum-dwelling communities in India [12, 30, 47]. Fear of vaccine side-effects is a frequently cited reason for children from Roma and Traveller communities in Europe being under-vaccinated [48]. A few parents from the Narikuravar and Irular communities expressed fears due to negative news reports about certain vaccines (one parent mentioned the polio vaccine) and common side-effects following vaccination such as fever or body pain. Parents (in the FGDs) could not remember any details of these news reports but were probably referring to a report about two deaths among children in the Theni and Dindigul districts of Tamil Nadu, wrongly linked to the oral polio vaccine in 2014 [49]. These deaths were due to suffocation and aspiration resulting from children being overfed post-vaccination [49]. Community-based health education campaigns can also build confidence in vaccines by combating the prevalent rumors and misconceptions regarding childhood vaccines and educating parents on managing the common side effects following immunization.

Our study had a few limitations that are important to consider. The findings from the household survey must be interpreted in the light of its non-probabilistic design and small sample size, which limits generalizability to the other disadvantaged communities in southern India. The use of snowball sampling may have resulted in participants being more inter-dependent and missing outlier families, further impacting the accuracy of our survey estimates and the generalizability of the survey findings [23]. We accounted for the clustering of children within the individual communities to provide design-adjusted standard errors (and 95% CIs) for the proportions and estimates presented in this study. The multivariate analysis may also have been underpowered to detect statistically significant associations between the different parental characteristics and children's vaccination status due to the small sample size. Next, there were fewer brick kiln and stone quarry communities than expected in Vellore, possibly due to changes in government regulations toward quarry workers and bonded labor at brick kilns [50, 51]. As a result, we could not estimate vaccination coverage for each community due to the low number of eligible children. Data saturation could not be achieved in the focus groups due to the limited number of meetings conducted with parents in the different communities. While we are unable to comment on the range of responses that may have been obtained by conducting more meetings, we attempted to triangulate the findings from the focus groups and the household survey using the "5As" taxonomy domains and only use the qualitative findings to elaborate on those from the household survey. Finally, although the important responses from participants were clarified during the focus groups, we did not perform adequate cultural clarifications (during the analysis of the survey and FGD data) from the members of each community due to logistical and time constraints. This may introduce a reporting bias while discussing the possible reasons for community-held perceptions, attitudes, or behavior towards childhood vaccinations.

The limitations notwithstanding, our survey provides the most recent estimate of routine vaccination coverage for children from the Narikuravar, Irular, and migrant communities in Vellore. Despite the individual limitations of our household survey and focus group discussions, using a mixed-methods approach helped identify and describe the important parental characteristics linked to childhood vaccination uptake among disadvantaged communities in Vellore. The survey data were collected using the KoBo Toolbox, an open-source application for Android™ devices, which helped decrease the possibility of data-entry errors with pre-programmed range checks and skip patterns for the electronic questionnaire. Furthermore, using the "5As" taxonomy to outline study questions and map responses from the FGDs helped identify important barriers and facilitators of routine childhood vaccination, informing targeted and contextual interventions to improve vaccination uptake in these communities.

Conclusions

Recent estimates of routine immunization coverage among young children from communities experiencing disadvantage in India are lacking. We found lower full vaccination coverage (65–77%) among children aged 12–23 months in Vellore than the prescribed Mission Indradhanush target of 90%. Children whose mothers were wage earners, or salaried/small business earners were less likely to be fully vaccinated than children with homemakers mothers in the household survey. In the focus groups, parents identified difficulties in accessing routine immunization when travelling for work (reported by the Narikuravar and Irular communities), showed important knowledge gaps regarding the benefits and risks of vaccination, and fears due to negative media reports and common-side effects following vaccination. While larger studies are needed to validate our findings, our study findings suggest the need for targeted and contextual interventions to improve routine immunization uptake among children from the communities experiencing disadvantage in Vellore.

Abbreviations

UIP: Universal Immunization Program; MI: Mission Indradhanush; NFHS: National Family Health Survey; IRB: Institutional Review Board; BCG: Bacillus Calmette-Guerin; OPV: Oral Polio Vaccine; MR: Measles-Rubella; SD: Standard Deviation; FGD: Focus Group Discussion; VHN: Village Health Nurse

Supplementary Information

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Additional file 1.

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Authors' contributions

V.B., G.K. and V.R.M. conceived the study. M.R.F. wrote the study protocol with input from J.P.N., R.Z.K., V.B., G.K. and V.R.M.. M.R.F. led the data collection for the study. M.R.F. and K.L-S. analyzed the qualitative data and M.R.F. and J.P.N. analyzed the quantitative data. M.R.F. and J.P.N. wrote the first draft of the manuscript. All authors participated in manuscript revisions and approved the final manuscript.

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Availability of data and materials

The data that support the findings of this study are available from the Christian Medical College, Vellore, Tamil Nadu, India, but restrictions apply to the availability of these data due to the sensitive nature of the study topic and populations interviewed, and thus are not publicly available. Data may be made available by the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol received ethical clearance from the Institutional Review Board (IRB) of the Christian Medical College, Vellore, Tamil Nadu, India (*IRB no. 10691, dated 21.06.2017*). Data for the cross-sectional survey were collected by trained field workers using a pre-tested, interviewer-administered questionnaire after obtaining written informed consent from the parents of eligible children. Participants with lower literacy provided a thumbprint in place of their signature on the informed consent form in the presence of a literate witness during the cross-sectional surveys. Group verbal consent for participating in and audio-recording the FGDs was obtained by trained field workers prior to the commencement of each meeting. Only those participants who consented to participate in the study were enrolled. All study methods and procedures were conducted in accordance with the ethical principles of the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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