Farooqui *et al. BMC Medicine* (2024) 22:453
https://doi.org/10.1186/s12916-024-03664-w

BMC Medicine

RESEARCH ARTICLE

Open Access

Potential impact of rotavirus vaccine introduction in India's Universal Immunisation Programme on private sector vaccine utilisation: an interrupted time series analysis

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Abstract

Background Despite free immunisation services through the Universal Immunisation Programme (UIP), around 14% of Indian households seek immunisation in the private sector. We examined the potential impact of rotavirus vaccine (RVV) introduction in the Universal Immunisation Programme (UIP) on private-sector rotavirus vaccine utilisation.

Methods We analysed nationally representative private-sector vaccine sales data. The intervention under consideration is RVV introduction in the UIP in selected Indian states. The outcome is the 'monthly RVV sales volume'—a proxy for vaccine utilisation. We performed a Poisson regression interrupted time series analysis to detect the pre-intervention trend, post-intervention level change and trend change relative to the pre-intervention for monthly rotavirus vaccine utilisation.

Results Poisson segmented regression analysis showed that immediately after RVV introduction in the UIP private-sector RVV sales showed a decline in Rajasthan by 37.4% (Incidence Risk Ratio (IRR): 0.626; 95% CI: 0.504–0.779), in Tamil Nadu by 26% (IRR: 0.740; 95% CI: 0.513–1.068), in Uttar Pradesh-East by 72.2% (IRR: 0.278; 95% CI: 0.178–0.436) and in Kerala by 3% (IRR: 0.970; 95% CI: 0.651–1.447). Rajasthan, Tamil Nadu and Kerala had sustained reduction in the postintervention trend relative to the preintervention trend by 20.1% (IRR: 0.799; 95% CI: 0.763–0.836), 6.4% (IRR: 0.936; 95% CI: 0.906–0.967) and 3.3% (IRR: 0.967; 95% CI: 0.926–0.960) per month, respectively. However, in Haryana and UP-west, in the first-month post-UIP introduction, the private-sector RVV sales increased by 101% and 3.8%, respectively which was followed by a sustained decrease of 14.2% (IRR: 0.858; 95% CI: 0.688–1.070) and 5.8% (IRR: 0.942; 95% CI: 0.926–0.960) per month, respectively. In terms of long-term impact, the private sector RVV sales post-UIP introduction decreased at a monthly rate of 4.4% (IRR: 0.956, 95% CI: 0.939–0.974) in Rajasthan but increased by 5.5% (IRR: 1.055; 95% CI: 1.040–1.070) in UP-east, 0.3% (IRR: 1.003, 95% CI: 0.976–1.031)) in Kerala and 0.2% (IRR: 1.002, 95% CI: 0.993–1.011) in Tamil Nadu whereas Haryana and UP-west had a reduction in RVV utilisation by 2.8% (IRR: 0.972; 95% CI: 0.955–0.990) and 1% (IRR: 0.990; 95% CI: 0.982–0.998), respectively.

Conclusions The study provides evidence that access to RVV through UIP leads to a reduction in private-sector RVV utilisation. We recommend strengthening UIP to expand the basket of new vaccines.

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Keywords India, Universal Immunisation Programme, Rotavirus vaccine, Interrupted time series

Background

In India, childhood diarrhoea is a major contributor to under-five mortality. As per the Global Burden of Disease Study 2015, the estimated number of diarrhoea-related deaths in children younger than 5 years was 104,643 (UI 89,526 to 122,376) [1]. Among all enteric pathogens, rotavirus was the most common cause of diarrhoea-related deaths, approximately 20.4% (UI 13.0 to 32.0) followed by shigella, campylobacter, adenovirus and other enteric pathogens [1]. As per the rotavirus surveillance network data, rotavirus was detected in 40% of cases in children hospitalised with diarrhoea [2]. Previous research suggests that around 11 million episodes of rotavirus gastroenteritis occur in children younger than 5 years, which leads to approximately 872,000 hospitalisations annually, [3] resulting in a substantial financial burden on the households. Furthermore, the total direct costs of hospitalisations due to rotavirus gastroenteritis at the country level were approximately Indian Rupee (INR) 10.4 billion per year [3].

The rotavirus vaccine (RVV) remains the most effective [4] and cost-effective intervention [5] to prevent rotavirus infections in children. The World Health Organization (WHO) recommended the inclusion of rotavirus vaccines into the Universal Immunisation Programme (UIP) in 2013 [6]. In 2014, India's National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of rotavirus vaccines in the Indian Universal Immunisation Programme (UIP) [7]. However, in India, two live attenuated rotavirus vaccines (Rotarix: GSK Biologicals and RotaTeq: Merck and Co,) have been available in the private sector retail market since 2008 and 2011, respectively [8, 9]. Other indigenously developed oral rotavirus vaccines (Rotavac: Bharat Biotec and Rotasill: Serum Institute of India)) were introduced in the market in 2015 and 2017, respectively. Based on the surveillance studies and the clinical trial data, [10] indigenously developed oral rotavirus vaccines were selected for introduction in the UIP [11].

The actual introduction of the rotavirus vaccine in the Universal Immunisation Programme was conducted in a phased manner. The vaccine was first introduced in Andhra Pradesh, Haryana, Himachal Pradesh, and Odisha in April 2016. These states accounted for around 9% of the Indian birth cohort. By September 2017, the vaccine was further expanded to an additional five states (Rajasthan, Madhya Pradesh, Assam, Tripura, Tamil Nadu) which accounted for around 26% of the country's birth cohort [7]. In the third phase, the vaccine was expanded to Uttar Pradesh and by the year 2019, RVV had been scaled across 29 states and 8 union territories covering around 26.7 million children [12].

As per the WHO/UNICEF Estimates of National Immunization Coverage, 2022 the estimated coverage for 3 doses of rotavirus vaccine was 92% in 2020 [13]. Furthermore, as per the National Family Health Survey-5 (NFHS-5) around 4.2% (urban—11.1%, rural—1.6%) of households accessed immunisation services in the private sector [14]. It may be noted that a small proportion (3.2%) of the birth cohort was already immunised for rotavirus through private-sector immunisation services before the vaccine was introduced in the Universal Immunisation Programme [15]. Previous research has indicated that private-sector immunisation coverage is driven by urban areas, prescribing practices of the private-sector paediatricians and the purchasing capacity of households [16]. Private sector plays an important role in immunisation services in India and are important access point for not only traditional UIP vaccines but also newer vaccines such as rotavirus, pneumococcal conjugate vaccine, typhoid vaccine and others [15]. However, to access immunisation services in the private sector, households are required to bear vaccination costs and service charges at the point of care resulting in out-of-pocket expenditures (OOPE) [17]. In addition, other hidden costs associated with vaccination include loss of wages and expenditure on travel to reach immunisation facilities [17].

Ideally, vaccines should be free at the point of care as they are a public good. A public good is non-excludable (i.e. it is not possible to prevent others from getting the benefits) and non-rivalrous (i.e. its use doesn't reduce the amount for others) [18]. Hence, public financing and provisioning of vaccines through UIP in the public sector is essential. Several studies have demonstrated that public investments in vaccination provide significant public health benefits that translate into a return on investment through reduced healthcare expenditure and increased productivity gains at the household level [19, 20]. Furthermore, access to free immunisation services through a UIP could theoretically reduce the out-of-pocket payments for immunisation services by households to zero.

We hypothesised that rotavirus vaccine introduction in the UIP should increase access to the rotavirus vaccine at the population level because of its wider geographical reach (across rural, urban and migrant populations) and free vaccine and vaccination services at the point of care. Furthermore, given a fixed cohort of eligible children population for rotavirus vaccination, increased utilisation of rotavirus vaccination in the public sector should be reflected in reduced rotavirus vaccine utilisation in the private sector. Recent research has estimated and reported the impact of rotavirus vaccine introduction on the reduction of the rotavirus disease burden. Dhalaria et al. reported that the prevalence of diarrhoea in India decreased significantly after introduction of rotavirus vaccine [21]. Another modelling study has reported rotavirus vaccine introduction has a broader economic impact by aiding poverty reduction and equity benefits [22]. However, evidence on the impact of new vaccine introduction in the UIP on efficiency and equity gains at the population level in terms of reduction in demand for immunisation services in the private sector has not been explored. We examined the potential impact of rotavirus vaccine introduction in the UIP on utilisation of rotavirus in the private-sector as a proxy for demand for rotavirus vaccination in the private sector.

Methods

Data

We analysed the Indian pharmaceutical sales data—PharmaTrac, which is collected from a panel of around 18,000 stockists in the private sector spread across 23 regions in India by a market research company All-Indian Origin Chemists and Distributors Limited (AIOCD). After conducting a census to identify the total number of pharmaceutical companies in the state, those stockists who account for at least 25% of pharmaceutical companies' turnover are selected in the panel. Then using a software program, pharmaceutical utilisation data are compiled and extracted every month from the selected stockists. Finally, the data are extrapolated to reflect the overall pharmaceutical utilisation (value and volume) in the private-sector retail market. The data organises the pharmaceutical products using the Anatomical Therapeutic Chemical (ATC) classification of the European Pharmaceutical Market Research Association (EphMRA). This classification was employed to identify the value and volumes of retail sales of rotavirus vaccines (RVV) in select Indian states (Haryana, Tamil Nadu, Rajasthan, Uttar Pradesh and Kerala). The selection of states was constrained by data availability and the time period under consideration to implement an interrupted time-series analysis.

Study period

The study period was from January 2015 to December 2020.

Intervention under study

The rotavirus vaccine (RVV) introduction in the Universal Immunisation Programme (UIP) in the Indian states of Haryana, Tamil Nadu, Rajasthan, Uttar Pradesh and Kerala in a phased manner as per the recommendation of the National Technical Advisory Group on Immunisation (NTAGI) [23].

Outcome

The main outcome of interest was 'rotavirus vaccine sales volume per month'—a proxy for the utilisation of rotavirus vaccines in the private sector. The dataset provides information on the vaccine sales volume in terms of number of vaccine units/packs sold per month for each Indian state. We stratified the outcome data by Indian states under consideration (Haryana, Tamil Nadu, Rajasthan, Uttar Pradesh and Kerala) for the study.

Research design

We used a quasi-experimental research design and conducted an interrupted time series (ITS) [22, 24] analysis to estimate the potential impact of the introduction of rotavirus vaccine (RVV) in the Universal Immunisation Programme (UIP) on private-sector rotavirus vaccine sales.

Statistical analysis

We used descriptive statistics to summarise rotavirus vaccine sales per month in the private sector before and after the rotavirus vaccine introduction in the UIP.

We used the segmented Poisson regression model to evaluate the impact of the Rotavirus vaccine (RVV) introduction in the Universal Immunisation Programme on private-sector rotavirus vaccine sales. We used Newey–West standard errors [25] to account for autocorrelation and heteroskedasticity.

The Poisson regression model included a 'time' variable, a dummy 'intervention' variable indicating pre-RVV introduction and post-RVV introduction period, and an interaction term 'time after intervention' variable. This analytical approach takes account of pre-UIP introduction trends and allows estimation of the effect of RVV introduction in the UIP at various timepoints by centring time at that timepoint.

$$Y_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time\ after\ intervention_t + \varepsilon_t \quad (1)$$

where Y_t is the 'sales volume' of rotavirus vaccines per month at time t, β_0 measures the *base level* of the outcome in the pre-intervention segment; β_1: estimates the *base trend*; β_2: estimates the *change in level* in the post-intervention segment; and β_3: estimates the *change in trend* in the post-intervention segment. Variable 'time' is a continuous variable and is the time since the start of the series, 'intervention' is a dummy variable for intervention that occurred at time t and is coded 0 for pre-intervention and 1 for the postintervention period, 'time after intervention' is the interaction term (time t is coded 0 pre-intervention and is time − timepoint when the intervention occurred), and e_t is the error term.

The potential impact of the intervention (RVV introduction in UIP) was estimated as the immediate impact (level change) and long-term impact (post-UIP introduction trend change and post-UIP introduction trend). The 'level change' (β_2) represents the difference in rotavirus vaccine utilisation between the specified post-intervention time point and the pre-intervention regression line that is extrapolated to that same time point (i.e. counterfactual). The 'post-UIP introduction trend change' (β_3) represents an increase or decrease in the slope of a post-intervention regression line compared with the pre-intervention regression line. The 'post-UIP introduction trend' was estimated by adding together the coefficients associated with time and the time-intervention interaction.

As the vaccine was introduced in a phased manner across the Indian states, the pre-intervention period for Haryana was from January 2015 to April 2016, for Rajasthan and Tamil Nadu it was from January 2015 to September 2017, for Uttar Pradesh it was from January 2015 to September 2018, and for Kerala it was from January 2015 to September 2019. The post-intervention period for each state was from the month of vaccine introduction to December 2020.

We analysed rotavirus vaccine sales per month in the private sector before and after the RVV introduction and presented the pre-RVV introduction trend, post-RVV introduction level change, post-RVV introduction trend change and post-RVV introduction trend as incidence rate ratios. For example, the level change ($\beta_{2)}$ is interpreted as the percentage change in the RVV sales volume in the private sector in a selected state post-RVV introduction in the Universal Immunisation Programme as compared to pre-RVV introduction.

Autocorrelation (ac) and partial autocorrelation (pac) estimates and plots of the residuals were used to test for autocorrelation. Model diagnostics based on autocorrelation (ac) and partial autocorrelation (pac) plots are provided in the additional file (Additional file 1: Figs. S2–S7). STATA version 18 was used to conduct statistical analysis.

Results

We observed that at least three different brands of licensed rotavirus vaccines (RVV) were available in the private sector in India—RotaTeq, RotaVac, and Rotasiil. Among the three brands, RotaTeq contributed the highest average monthly sales of 138,613.3 packs followed by RotaVac (3695.52) and Rotasiil (3544.72) during the study period from January 2015 to December 2020. (Additional file 1: Fig. S1 and Table S1).

Descriptive analysis suggests that across selected states (Haryana, Rajasthan, Tamil Nadu, Uttar Pradesh and Kerala), both mean and median monthly rotavirus vaccine sales in the private sector were lower in the pre-intervention period (rotavirus vaccine (RVV) introduction in UIP compared to the post-intervention period except for Uttar Pradesh-East (Table 1 and Fig. 1).

Before the RVV introduction in the UIP, there was a positive trend for monthly RVV utilisation in the private sector across Indian states considered in the study, ranging from 1.0% (IRR: 1.010; 95% CI: 0.994–1.027) for Uttar Pradesh (UP)-East to 19.6% (IRR: 1.196; 95% CI: 1.155–1.239) for Rajasthan (Table 2). Poisson segmented regression analysis showed that immediately after the introduction of RVV in the UIP (i.e. first-month post-UIP introduction) private-sector RVV sales showed a decline in Rajasthan by 37.4% (IRR: 0.626; 95% CI: 0.504–0.779), in Tamil Nadu by 26% (IRR: 0.740; 95% CI: 0.513–1.068), in Uttar Pradesh-East by 72.2% (IRR: 0.278; 95% CI: 0.178–0.436) and in Kerala by 3% (IRR: 0.970; 95% CI: 0.651–1.447). Furthermore, Rajasthan, Tamil Nadu and Kerala reported a sustained decrease in the postintervention trend relative to the preintervention trend by 20.1% (IRR: 0.799; 95% CI: 0.763–0.836), 6.4% (IRR: 0.936; 95% CI: 0.906–0.967) and 3.3% (IRR: 0.967; 95% CI: 0.926–0.960) per month, respectively suggesting a sustained impact on RVV sales in the post-intervention period. In terms of long-term impact, the private sector RVV sales decreased at a monthly rate of 4.4% (IRR: 0.956, 95% CI: 0.939–0.974) in Rajasthan but increased at a monthly rate of 5.5% (IRR: 1.055; 95% CI: 1.040–1.070) in UP-east, 0.3% (IRR: 1.003, 95% CI: 0.976–1.031)) in Kerala and 0.2% (IRR: 1.002, 95% CI: 0.993–1.011) in Tamil Nadu by the end of the study period (Fig. 2 provides a visual display of these results).

However, in Haryana and UP-west, in the first-month post-UIP introduction, the private-sector RVV sales increased by 101% and 3.8%, respectively,

Table 1 Summary statistics of private-sector RVV sales before and after RVV introduction in UIP in selected Indian states, January 2015–December 2020

States	RVV introduction timeline	Number of observations (72)	Pre-UIP introduction (RVV sales per month, median (IQR)	Pre-UIP introduction (RVV sales per month, mean (SD)	Post- UIP introduction (RVV sales per month, median (IQR)	Post-UIP introduction (RVV sales per month, mean (SD)
Haryana	April 2016	Pre-intervention: 15 and post-intervention: 57	700 (570–2360)	2377.46 (4096.77)	1430 (286–12,334)	5725.91 (6849.76)
Rajasthan	September 2017	Pre-intervention: 32 and post-intervention: 40	3821.5 (1144.5–9930)	18,717.72 (37,970.04)	32,555 (19,208–43,629)	39,603.28 (36,338.56)
Tamil Nadu	September 2017	Pre-intervention: 32 and post-intervention: 40	4332.5 (3149–7685)	8962.219 (12,495.57)	22,849.5 (17,968.5–30,398.5)	24,579 (8859.87)
[a]Uttar Pradesh-East	September 2018	Pre-intervention: 44 and post-intervention: 28	89,214.5 (66,264–119,679)	92,662.77 (47,633.67)	63,568.5 (45,477.5 -98,678.5)	73,316.57 (36,635.23)
[a]Uttar Pradesh-West	September 2018	Pre-intervention: 44 and post-intervention: 28	2657 (1569.5–4889.5)	4032.47 (3559.70)	10,601.5 (9454.5–12,568)	11,224.71 (2674.19)
Kerala	September 2019	Pre-intervention: 56 and post-intervention: 16	184 (61–570.5)	479 (668.86)	2436 (1834–2819.5)	2362.438 (623.23)

IQR interquartile range

[a] Reporting for Uttar Pradesh as UP - east and UP - west is driven by data collection and reporting system adopted in the PharmaTrac dataset. UP -west also includes data from Uttarakhand

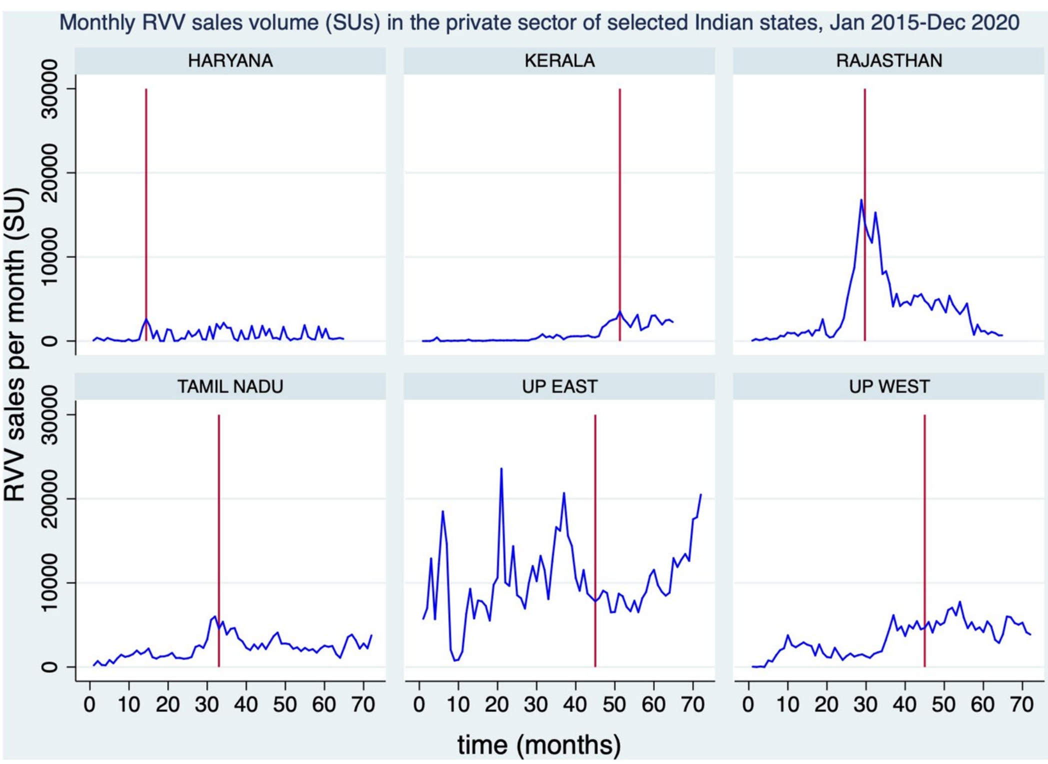

Fig. 1 Private-sector monthly RVV sales trend in selected Indian states (Haryana, Kerala, Rajasthan, Tamil Nadu and Uttar Pradesh (UP)—east and west), before and after RVV introduction in UIP, January 2015–December 2020. Note: The vertical line on the *x*-axis represents RVV introduction time in UIP in each state

Table 2 Poisson segmented regression models of the impact of RVV introduction in UIP on private-sector vaccine sales in selected Indian states, Jan 2015–Dec 2020

States	Pre-UIP introduction trend[a]	Post-UIP introduction level change	Post-UIP introduction trend change[a]	Post-UIP introduction trend[a]
Haryana	1.132 (1.049–1.222)	2.016 (1.185–3.429)	0.858 (0.795–0.927)	0.972 (0.966–0.978)
Kerala[b]	1.036 (0.998–1.076)	0.970 (0.651–1.447)	0 0.967 (0.920–1.018)	1.003 (0.976–1.031)
Rajasthan[b]	1.196 (1.155–1.239)	0.626 (0.504–0.779)	0.799 (0.763–0.836)	0.956 (0.939–0.974)
Tamil Nadu[b]	1.070 (1.038–1.104)	0.740 (0.513–1.068)	0.936 (0.906–0.967)	1.002 (0.993–1.011)
Uttar Pradesh-east	1.010 (0.994–1.027)	0.278 (0.178–0.436)	1.044 (1.022–1.066)	1.055 (1.040–1.070)
Uttar Pradesh-west[b]	1.050 (1.034–1.065)	1.038 (0.793–1.360)	0.942 (0.926–0.960)	0.990 (0.982–0.998)

Data are incidence rate ratio (95% CI) or trend (95% CI)

[a] Slope change per month

[b] model adjusted for heteroskedasticity

followed by a sustained decrease in the post-intervention trend relative to the pre-intervention trend by 14.2% (IRR: 0.858; 95% CI: 0.688–1.070) and 5.8% (IRR: 0.942; 95% CI: 0.926–0.960) per month, respectively (Fig. 2). In terms of long-term impact, the private sector RVV utilisation in Haryana decreased at a monthly rate of 2.8% (IRR: 0.972; 95% CI: 0.955–0.990), and in UP-west at a monthly rate of 1% (IRR: 0.990; 95% CI: 0.982–0.998).

Discussion

India has one of the largest Universal Immunisation Programmes (UIP) that covers a cohort of 26.7 million children every year. The UIP provides free vaccines and

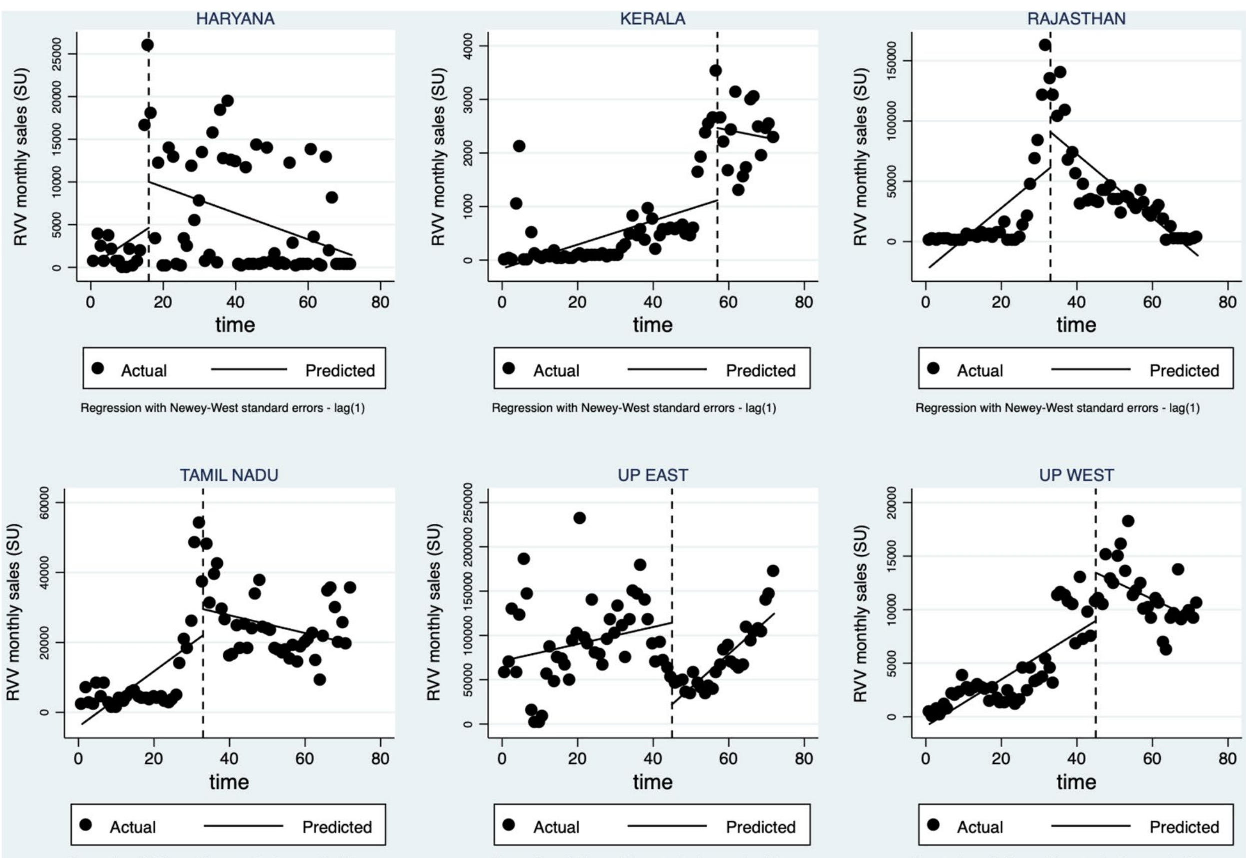

Fig. 2 Poisson segmented regression analyses of private-sector RVV vaccine sales in selected Indian states (Haryana, Kerala, Rajasthan, Tamil Nadu, Uttar Pradesh—east and west), before and after RVV introduction in UIP

immunisation services to the eligible population through a large network of public health facilities and outreach sessions across the country. However, several factors hindered universal coverage of basic vaccines in the recent past such as hard-to-reach and mobile populations, poor demand from uninformed and uneducated populations, and fear of side effects [26, 27]. To target underserved, and inaccessible populations and improve coverage rates in hard-to-reach areas, the Mission Indradhanush (MI) programme was implemented. Later Intensified Mission Indradhanush (IMI)—a kind of periodic intensification of routine immunisation was initiated between April 2015 and July 2017 to reach 90% full immunisation coverage in districts with persistently low levels [28]. The IMI also introduced rotavirus vaccine (RVV) and pneumococcal conjugate (PCV) across the country in a phased manner. The impact of Mission Indradhanush and Intensified Mission Indradhanush on the improvement of coverage rates of standard UIP vaccines in the implementation districts has been documented [29, 30]. However, the impact of the introduction of the rotavirus vaccine (RVV) on access to immunisation services and private-sector vaccine utilisation has not been studied.

To our knowledge, ours is the first study to evaluate the potential impact of RVV introduction in the UIP on private-sector rotavirus vaccine utilisation in India—a proxy for demand for rotavirus vaccination in the private sector. We found that public financing and provisioning of the RVV through its introduction in UIP resulted in a heterogeneous impact on private-sector rotavirus vaccine utilisation across Indian states selected for the research. Post-UIP introduction of RVV, Rajasthan, private sector RVV utilisation in Tamil Nadu and Kerala had an immediate drop in level and a decline in the postintervention trend relative to the preintervention trend, but the long-term impact was sustained only in Rajasthan and not in Kerala and Tamil Nadu as by the end of the study period, both states reported a marginal increase in RVV utilisation. However, Haryana and UP-west reported an immediate increase in RVV utilisation in the first month post-UIP introduction but had a positive long-term impact as reflected in a decline in the post-intervention trend relative to the pre-intervention trend and a reduction in monthly utilisation rate by the end of the study period. UP-East had an increase in post-intervention trend relative to the pre-intervention trend and also increased monthly utilisation towards the end of the study period suggesting no impact.

In the states with a sustained positive impact, this could be a reflection of more people accessing rotavirus immunisation in public sector health facilities indicating improved access. Given the fact that around 11.2% of urban households [14] in India were accessing immunisation services in the private sector, the introduction of RVV in the Universal Immunisation Programme which provides access to RVV free of cost in public health facilities could have resulted in households switching to the public sector from the private sector for immunisation services. However, an increase in private sector RVV sales just before and after the vaccine introduction in the UIP could be an outcome of increased population-level awareness about the disease and the vaccination as a result of mass media campaigns that usually follow new vaccine introduction. Recent research has indicated that to ensure a high level of RVV coverage a holistic strategy comprising public–private partnership, health systems strengthening, vaccine-specific training and capacity building complemented with strong communications systems and media involvement was implemented for RVV introduction in India [7, 12]. The communication and media advocacy strategy also involved discussion with the Indian Academy of Pediatrics—the biggest association of private-sector paediatricians—on the vaccine rollout [7].

Though all states under consideration reported a consistent and sustained decrease in the post-intervention trend change relative to the preintervention trend for private sector RVV utilisation except for UP-East, the impact was not sustained by the end of the study period in UP-East, Tamil Nadu and Kerala. The sustained effect of RVV introduction on the reduction in private-sector RVV sales in Haryana, Rajasthan and UP-west, may be explained by the success of periodic intensification of routine immunisation activities under the Intensified Mission Indradhanush (IMI) campaign in these states. Clarke-Deelde et al. reported that IMI activities improved access to thirteen UIP vaccines by 10.6% (95% CI 5.1–16.5%). However, there was no sustained effect after implementation ended [30]. A coverage evaluation survey [31] reported that all districts in Haryana covered under Intensified Mission Indradhanush achieved more than 20% increase in full immunisation coverage. Similarly, Uttar Pradesh and Rajasthan achieved an overall 15.2% and 11.6% increase in full immunisation coverage (FIC) after Intensified Mission Indradhanush activities [31].

The increase in the private sector RVV sales in the UP-east could be explained by poor immunisation coverage rates [14] due to poor health system performance [32] resulting in continued reliance of households on the private sector for rotavirus vaccination services. A recent study has also reported that districts of eastern Uttar Pradesh are less developed compared to the western in terms of overall composite health index and indices of availability, amenities, and affordability of healthcare services [33]. Tamil Nadu and Kerala are the best-performing states in terms of governance and health outcomes [32] suggesting that households may have switched to the public sector for rotavirus vaccination from the private sector resulting in a decline in private sector RVV sales post-UIP introduction. It may be noted that the percentage of 12–23-month-old children receiving the majority of their vaccinations in the private sector is more than 10% in Tamil Nadu and Kerala [14], hence, the higher likelihood and proportion of households switching to the public sector when a vaccine become available in the public sector through the UIP.

The declining trend in the private-sector RVV sales post-UIP introduction is also indicative of potential reductions in household out-of-pocket expenditure (OOPE) on immunisation services in the private sector. Previous research reported that the average out-of-pocket expenditure for immunisation was USD 0.74 (95% CI 0.56–0.91) in the public sector where the immunisation services are free at the point of care [17]. This indicates that in the private sector, immunisation services are certainly more expensive than in the public sector as the households not only bear the cost of the vaccine but also pay for consultation charges and travel expenses. Recent research has reported that expenditure on immunisation was high among children from rich wealth quintiles and those who got immunised in a private facility [34]. Still, several households seek immunisation services in the private sector as newer vaccines such as rotavirus and pneumococcal vaccines have an aspirational value for parents and the cost of a vaccine is not an inhibitory factor [35].

Furthermore, increased access to rotavirus immunisation through UIP would result in higher vaccine coverage rates leading to a reduction in rotavirus diarrhoea episodes and associated hospitalisations and hospitalisation costs. Recent research has indicated that around 69.2% and 57.4% of diarrhoea-related outpatient consultations and hospitalisations in India, are treated in the private sector [36] and out-of-pocket expenditure on these episodes is around 7.1% and 4.5% of a household's monthly per capita consumption expenditure, respectively [37]. Thus increased access to RVV through UIP has the potential to not only reduce out-of-pocket expenditure on immunisation but also on treatment and care at the household level.

From the country's perspective, the national government is the major financing agent, however, households still bear a significant cost of immunisation as reflected in spending on immunisation in low-income and middle-income countries [38]. Chatterjee et al. reported that the incremental economic cost per Intensive Mission Indradhanush dose delivered was higher than the routine immunisation dose indicating the need for additional resources to reach unvaccinated children in hard-to-reach locations [39]. Given the high return on investment from spending on immunisation, we recommend an increased allocation of financial resources and a sustainable financing mechanism should be implemented to strengthen the UIP to ensure improved access and wider coverage of existing and newer vaccines at the population level.

This study has some limitations. First, though the PharmaTrac data is nationally representative, the available vaccine utilisation data was aggregated at the state level as a result we could not report district-level variation. Second, our data analysis includes the COVID-19 lockdown period which resulted in the immunisation services disruption both in the public and private sector. This could have negatively affected private-sector RVV sales even in the absence of the RVV introduction of the UIP. We conducted a sensitivity analysis by excluding the COVID-19 period and found that the direction and magnitude of impact did not markedly change for any of the States under consideration (Additional file 1: Table S2). Third, the vaccine utilisation data does not capture the actual use of the vaccine at the prescriber level, hence age and gender-specific outcomes or reduction in rotavirus disease burden could not be estimated. Finally, the scope of this research was limited to measuring the change in the private sector vaccine utilisation, hence we did not evaluate the impact of rotavirus vaccine introduction on the improvement in vaccine coverage rates at the population level.

Conclusions

In conclusion, our findings on the impact of rotavirus vaccine introduction in the Universal Immunisation Programme on private-sector rotavirus vaccine utilisation show the important role that it plays in ensuring universal access to life-saving vaccines. It is essential to ensure enhanced financial commitment to the program to strengthen the immunisation services delivery and expand the basket of childhood vaccines.

Abbreviations

AICOD	All-Indian Origin Chemists and Distributors Limited
ATC	Anatomical Therapeutic Chemical
COVID-19	Coronavirus disease 2019
EphMRA	European Pharmaceutical Market Research Association
FIC	Full immunisation coverage
INR	Indian National Rupee
IMI	Intensified Mission Indradhanush
ITS	Interrupted time series
IQR	Interquartile range
MI	Mission Indradhanush
NFHS-5	National Family Health Survey-5
NTAGI	National Technical Advisory Group on Immunisation
OOPE	Out-of-pocket expenditure
PCV	Pneumococcal Conjugate Vaccine

RVV	Rotavirus vaccine
UIP	Universal Immunisation Programme
USD	United States Dollar
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12916-024-03664-w.

Additional file 1: Figure S1. Private-sector monthly rotavirus vaccinesales trend across different brands, January 2015–December 2020. Figure S2a. Autocorrelation of residuals, Haryana. Figure S2b. Partial autocorrelation of residuals, Haryana. Figure S2c. Distribution of residuals, Haryana. Figure S3a. Autocorrelation of residuals, Rajasthan. Figure S3b. Partial autocorrelation of residuals, Rajasthan. Figure S3c. Distribution of residuals, Rajasthan. Figure S4a. Autocorrelation of residuals, Tamil Nadu. Figure S4b. Partial autocorrelation of residuals, Tamil Nadu. Figure S4c. Distribution of residuals, Tamil Nadu. Figure S5a. Autocorrelation of residuals, UP East. Figure S5b. Partial autocorrelation of residuals, UP East. Figure S5c. Distribution of residuals, UP East. Figure S6a. Autocorrelation of residuals, UP West. Figure S6b. Partial autocorrelation of residuals, UP West. Figure S6c. Distribution of residuals, UP West. Figure S7a. Autocorrelation of residuals, Kerala. Figure S7b. Partial autocorrelation of residuals, Kerala. Figure S7c. Distribution of residuals, Kerala. Table S1. Summary statistics of private-sector monthly rotavirus vaccinesales across different brands, January 2015–December 2020. Table S2. Poisson segmented regression models of the impact of RVV introduction in UIP on private-sector vaccine sales in selected Indian states, Jan 2015-Dec 2019

Acknowledgements
Not applicable.

Authors' contributions
HHF and AK contributed to the study's conceptualization, methodology and validation. HHF, AK, and AM conducted data curation and formal analysis. HHF, AK, and AM conducted the literature review and drafted the manuscript. GRB and OVS did supervision, visualisation and validation. HHF, AK, AM, GRB and OVS critically revised the manuscript for intellectual content. All authors read and approved the final version of the manuscript.

Funding
Open Access funding is provided by the Qatar University College of Medicine.

Availability of data and materials
The data that support the findings of this study are available from PharmaTrac but restrictions apply to the availability of these data. (https://www.aiocdawacs.com/(S(closk2ozinyrosjywwc21yxf))/ProductDetail.aspx).

Declarations

Ethics approval and consent to participate
Ethical approval for this study was not needed. The study only used anonymized data from secondary sources.

Consent for publication
Not applicable.

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

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Received: 4 February 2024 Accepted: 26 September 2024
Published online: 11 October 2024

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