

Impact of covid-19 pandemic era on prevalence of pregnant women sero-positivity for Syphilis, among women attending antenatal care in India and babies diagnosed with Congenital Syphilis: A cross-sectional research study

Abstract

Sexually Transmitted Infections (STIs) still continue to be a major public health problem globally, affecting the quality of life as well as causing serious morbidity and mortality. STIs have a direct and significant impact on reproductive and pregnant women-child health. They can directly cause infertility, cancers as well as pregnancy related complications, and indirectly affects individual/family economies. The information on the number of PW found to be sero positive for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis is collected from HMIS electronic records of MoHFW, Government of India with key objective to know about the impact of covid-19 era i.e. 2020 and 2021 on prevalence of syphilis by comparing it with the pre pandemic era of 2018 and 2019. I collected sero positivity data for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis across 36 states and union territories of India including all health facilities viz. public, private, rural, urban health facilities. The data is collected, observed and analyzed with Microsoft office software. The total number of pregnancies and deliveries have shown declining trend during pandemic years as compared to pre-pandemic era. Year-wise maximum number of syphilis positive pregnant women treated for syphilis were reported in 2021. The mean number of babies per month diagnosed with congenital syphilis increased in pandemic era whereas mean number of babies per month treated with congenital syphilis decreased in pandemic era. This research study revealed that there is an increasing trend of, number of PW tested using POC test for Syphilis, out of above, number of PW found sero positive for Syphilis, number of babies diagnosed with Congenital Syphilis and total pregnant women tested found sero positive for Syphilis by any test during pandemic years as compared to pre-pandemic years.

Keywords: Syphilis • COVID-19 • Sero-prevalence • Pregnant women • Antenatal care • New born

Abbreviation

STI: Sexually Transmitted Infections, PW: Pregnant Women, POC: Point of Care, COVID-19: Coronavirus Disease 2019, WHO: World Health Organization

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Introduction

Background/Rationale

Syphilis is among the one of the most common STI

(Sexually Transmitted Infections) globally, with about 6 million new cases per year. An infected pregnant woman if not diagnosed and treated early can transmit the infection to her foetus, known as

Piyush Kumar*

*Senior General Medical Officer, Health Department, Government of Bihar, India

*Author for correspondence:

drpiyush003@gmail.com

“congenital syphilis”. The global burden of mortality and morbidity due to congenital syphilis infection is high. The World Health Organization (WHO) reported in 2016 on global basis 661 000 total congenital syphilis cases, including:

- 143 000 early fetal deaths and stillbirths due to congenital syphilis[1]
- 61 000 neonatal deaths due to congenital syphilis[1]
- 41 000 preterm or low-birth weight births due to congenital syphilis[1]
- 109 000 infants found with a clinical diagnosis of congenital syphilis[1]

Of these adverse birth outcomes, 57 % occurred in pregnant women attending antenatal care but not screened for syphilis; 16 % occurred in mothers who were screened for syphilis but either did not receive treatment or received inadequate treatment. Congenital syphilis is also the second leading cause of preventable stillbirth globally, preceded only by malaria. Sexually Transmitted Infections (STIs) still continue to be a major public health problem globally, affecting the quality of life as well as causing serious morbidity and mortality. STIs have a direct and significant impact on reproductive and child health. They can directly cause infertility, cancers as well as pregnancy complications, and indirectly affects individual economies. On daily basis a million (10 lakh) STIs are acquired, in year 2012, 357 million new cases of curable STIs which includes gonorrhoea, chlamydia, syphilis and trichomoniasis occurred mainly among 15 years to 49 year old individuals globally, out of which 5.6 million cases were of syphilis [2]. Syphilis is a STI caused by bacterial infection of *Treponema pallidum*. It is usually transmitted during sexual contact with infectious lesions present on the mucous membranes or abraded epidermis, via blood transfusion, or vertical-transplacentally during pregnancy to the foetus. Vertical transmission of syphilis i.e. congenital syphilis is usually life-threatening to the fetus if maternal infection is not detected on time and treated early in the pregnancy. The work from home and lockdowns for covid-19 control can increase the prevalence and incidence of STI (hypothesis) as the chances for sexual relation is quite possibly increased due to availability and opportunity but this will be decided by multiple factors related to the transmission of infection. Discussing all the aspects, patho-physiology as well as clinical features etc., is not possible in this single article. Undertaking sero-sampling during the covid-19 pandemic is quite difficult when travel and household access are restricted by Covid control measures. Pregnant mothers and newborns continue to seek health services throughout the pandemic due to their special needs. Serological tests are simple to perform at ANC visits and POC test for Syphilis can be done with the residual blood volumes of samples

collected for routine ANC clinical screening for maternal infectious diseases and anaemia. Planning and provision of antenatal health care during pandemic like COVID-19 pose significant logistical and clinical challenges. In January 2020 first covid-19 case was documented in India [3]. Hence period from January 2020 onwards is counted as pandemic era which is still going on and period before January 2020 i.e. up to December 2019 is calculated as pre-pandemic era for this research study. Considering the significance of above mentioned facts the author cum researcher decided to do a research on the title mentioned question to assess the situation.

Objectives

To assess and compare the trend in sero-prevalence of syphilis throughout the pandemic years i.e. 2020, 2021 and two previous years 2019, 2018 with key objective to find out the trends of disease occurrence in pregnant women and newborn by analysing sero positivity for Syphilis among pregnant women attending ANC clinic at different (public-private-rural-urban) health facilities in India and number of babies diagnosed with Congenital Syphilis.

Methods

Study design

This is a cross sectional retrospective mixed comparative research study. The data for this study was obtained from HMIS and forecasted by linear regression for necessary adjustments.

Setting

Locations: I collected sero positivity relevant data for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis across 36 states and union territories of India including all health facilities viz. public, private, rural, urban health facilities.

Relevant dates

The period of study is from 1st January 2018 to 31st December 2021 (forecasted with Microsoft excel software using data of pandemic year 2020 and available data of 2021).

Periods of study: The study started from 1st January 2018 and continued up to 31st December 2021. The author is still following the data and trends for future output of this research study.

Follow-up: The data is collected continuously and checked rigorously for specificity, measurability, availability, reproducibility and timeliness.

Data collection: The information on the number of PW found to be sero positive for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis is collected from HMIS electronic records of MoHFW, Government of India. The data is collected, observed and analyzed with Microsoft

office and stata software.

Participants: All pregnant women who are registered and tested for syphilis; treated for syphilis; babies diagnosed and treated for congenital syphilis during the study period as per electronic records of HMIS of MoHFW (Ministry of Health and Family Welfare), Government of India.

Eligibility criteria: Participants are eligible to be included in this research study if they are women with pregnancy registered on HMIS of MoHFW (Ministry of Health and Family Welfare), Government of India, tested for syphilis; treated for syphilis; babies diagnosed and treated for congenital syphilis during the study period as per electronic records of HMIS of MoHFW.

Sources and methods of selection of participants: The source for selection is data from HMIS and purposive sampling was done for selection of participants in order to find answer to research question mentioned above as title of the study.

Variables: The quantitative variables included in this research study are mentioned in Table 1 below (to reduce bias Total pregnancy and deliveries were also added-see Table 2)

Outcomes definition: Sero-positivity for syphilis by POC and other tests and treatment registered on HMIS. All reported and registered congenital syphilis diagnosed and treated as per HMIS. All pregnant women registered for ANC is taken as total number of pregnancy.

Exposures: The exposures are

- PW tested using POC or other test for Syphilis
- PW found sero positive for Syphilis
- Pregnant women treated for Syphilis
- Babies diagnosed with Congenital Syphilis and treated

Predictors: Sero-positivity, congenital syphilis and prevalence of syphilis

Diagnostic criteria: POC or other test for Syphilis and congenital syphilis

Data sources/Measurement

For all the variable of interest, sources of data were HMIS.

Methods of assessment (measurement)

The data is collected, observed, analysed and assessed with Microsoft office and stata software.

Comparability of assessment methods

The prevalence of syphilis during 02 pandemic years (2020 and 2021) is compared with 02 pre-pandemic years (2018 and 2019).

Data availability

The data for study is obtained from electronic records of HMIS of MoHFW (Ministry of Health and Family Welfare), Government of India.

Bias

The data on total number of pregnancy and delivery for study period is taken into account to reduce the bias and increase the sensitivity.

Efforts to address potential sources of bias

The prevalence of sero-positivity is calculated per 100000 pregnancy registered for each year. The congenital syphilis prevalence is calculated per 100000 deliveries for each year.

Study size

The actual study size was all registered and reported pregnancies and deliveries but the key consideration is given to variables mentioned in Table 1. The sizes of different variables are mentioned below in Table 2.

Explanations for the study size was arrived

This is a cross-sectional research study to assess the impacts of covid-19 pandemic era on Pregnant Women sero-positivity for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis as well as numbers of PW and children's treated for the same. Hence author have included the variables/indicators available at HMIS related to research question mentioned in the title of this research study and their numbers listed above in Table 2

Quantitative variables

All the quantitative variables are listed in Table 2 above.

Analysis

For each year under study total numbers of variables are taken for analysis and comparison. Since this study was exclusively done for assessing impacts of covid-19 pandemic era on Pregnant

Table 1. Variables included in this research study
Variables included
Number of PW tested using POC test for Syphilis
Out of above, number of PW found sero positive for Syphilis
Number of pregnant women tested for Syphilis by tests other than POC test
Number of pregnant women tested found sero positive for Syphilis by tests other than POC test
Number of syphilis positive pregnant women treated for Syphilis
Number of babies diagnosed with Congenital Syphilis
Number of babies treated for Congenital Syphilis

Table 2. Study size for each year.

Indicator	Grand Total Jan-Dec 2018	Grand Total Jan-Dec 2019	Grand Total Jan-Dec 2020	Grand Total Jan-Dec 2021 (forecast)
Total number of pregnant women registered for ANC	28715284	29239176	27331061	21891305
Total No. of Deliveries (HD+ID)	20842188	21571444	20375698	16864392
Number of PW tested using POC test for Syphilis	136377	639764	2106957	2580453.706
Out of above, number of PW found sero positive for Syphilis	4069	5032	10267	30241.23342
Number of pregnant women tested for Syphilis by tests other than POC test	7617933	9965701	8221419	8464474.626
Number of pregnant women tested found sero positive for Syphilis by tests other than POC test	45107	43058	40303	47883.13419
Number of syphilis positive pregnant women treated for Syphilis	15362	14911	13530	24282.75455
Number of babies diagnosed with Congenital Syphilis	3801	3372	4909	5816.366356
Number of babies treated for Congenital Syphilis	16029	4900	3674	3902.509419
Total pregnant women tested found sero positive for Syphilis by any test	49176	48090	50570	78124.36761

Women sero-positivity for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis as well as numbers of PW and children's treated for the same; different groupings related to these available on HMIS were chosen as listed in Table 1 and 2.

Statistical methods

Linear regression is used to forecast 2021 up to December to predict future values from available past values of 2021. Prevalence per 100000 and rate per 100 is calculated for total PW and deliveries as well as for the sample size to control for confounding. Missing data for 2021 is projected by linear regression with excel. Purposive sampling strategy was undertaken by author for prevalence analysis and comparison. For increasing sensitivity the total number of pregnancy and deliveries are analysed with specific variables of Table 1.

Result

Participants

Numbers of individuals at each stage of study:

The total number of pregnant women registered for ANC was considered as total number of pregnancy. The sum of all home and institutional deliveries is considered as total deliveries. The total numbers of pregnant women registered for ANC were 28715284, 29239176, 27331061, and 21891305 for years 2018-2019-2020-2021 respectively see Table 2. The Total No. of Deliveries (HD+ ID), were 20842188, 21571444, 20375698, 16864392 for years 2018-2019-2020-2021 respectively. The total number of PW tested using POC test for Syphilis were 136377, 639764, 2106957, and 2580453.706 for years 2018-2019-2020-2021 respectively. Out of above,

number of PW found sero positive for Syphilis were 4069, 5032, 10267, and 30241.23342 for years 2018-2019-2020-2021 respectively. The number of pregnant women tested for Syphilis by tests other than POC tests were 7617933, 9965701, 8221419 and 8464474.626, for years 2018-2019-2020-2021 respectively. The number of pregnant women tested found sero positive for Syphilis by tests other than POC test were 45107, 43058, 40303, and 47883.13419 for years 2018-2019-2020-2021 respectively. Regarding number of syphilis positive pregnant women treated for Syphilis it was 15362, 14911, 13530, and 24282.75455 for years 2018-2019-2020-2021 respectively. Considering the number of babies diagnosed with Congenital Syphilis it was 3801, 3372, 4909, and 5816.366356 for years 2018-2019-2020-2021 respectively whereas the number of babies treated for Congenital Syphilis were 16029, 4900, 3674, and 3902.509419 for years 2018-2019-2020-2021 respectively. The total pregnant women tested found sero positive for Syphilis by any test was 49176, 48090, 50570, and 78124.36761 for years 2018-2019-2020-2021 respectively. Why all pregnant women's were not tested for diagnosis of syphilis or they denied testing is not answerable as the data is from a secondary source but accredited source and same holds true for congenital syphilis.

This research study revealed that there is an increasing number trend of following in pandemic years as compared to pre-pandemic years:

- Number of PW tested using POC test for Syphilis
- Out of above, number of PW found sero positive for Syphilis
- Number of babies diagnosed with Congenital

Syphilis

- Total pregnant women tested found sero positive for Syphilis by any test
- Total pregnant women tested found sero positive for Syphilis by any test

The total number of pregnancies and deliveries have shown declining trend during pandemic years as compared to pre-pandemic era (figure-1, 2 and Table 2). To reduce the length of article author reduced texting more details and request readers to view Tables 1-4, and figures 1-4 for further information. Among 215037.8089, mean per month number of PW tested using POC test for Syphilis, 2520.102785, mean per month were sero positive for Syphilis giving a sero-prevalence of 1.26% in 2021(Forecasted up to December with available data of January to May 2021 see figure 4 and Table 3). Of 175579.75 mean per month number of PW tested using POC test for Syphilis, 855.58 mean per month were sero positive for Syphilis giving a sero-prevalence of 0.49% in 2020 (Jan to Dec). Of 53313.66 mean per month number of PW tested using POC test for Syphilis, 419.33 mean per month were sero positive for Syphilis giving a sero-prevalence of 0.79% in 2019 (Jan to Dec). Of 11364.75 mean per month number of PW tested using POC test for Syphilis, 339.08 mean per month were sero positive for Syphilis giving a sero-prevalence of 2.98 % in 2018 (Jan to Dec), (figure 4 and Table 3). This research study revealed that there is increase in mean per month number of PW tested using POC test for Syphilis and also there is increase in number of women mean per month sero positive for Syphilis during pandemic era using this test.

The sero-prevalence/POC test decreased in all years as compared to 2018. This research study revealed that in 2019 maximum mean per month number of PW

tested using other test for Syphilis whereas maximum numbers of women mean per month sero positive were found in 2021 for Syphilis using other test.

The annual sero-prevalence/test of syphilis in PW tested using other test for Syphilis decreased in all years as compared to 2018 see figure-3. Year-wise maximum number of syphilis positive pregnant women treated for syphilis were reported in 2021. Figure 4 shows that average number of babies per month diagnosed with congenital syphilis increased in pandemic era whereas Figure 4 shows that average number of babies per month treated with congenital syphilis decreased in pandemic era.

The Prevalence of sero-positivity for syphilis per 100000 PW was 171.2537477, 164.4711192, 185.0275772, 356.8739626 for 2018, 2019, 2020, and 2021 respectively. This novel research study revealed that there is significant increase in prevalence of sero-positivity for syphilis per 100000 PW during covid-19 pandemic years of 2020 and 2021(see figure-4, Table 4). The author would like to point out the fact that there is also a considerable increase in tests for detecting syphilis during pandemic years.

The Annual Prevalence of PW sero-positivity for syphilis- per 100 POC test was 2.9836409, 0.78654, 0.4872904, 1.1719347 for 2018, 2019, 2020, and 2021 respectively, whereas annual Prevalence of PW sero-positivity for syphilis- per 100 other tests were 0.592116, 0.4320619, 0.4902195, 0.5656953, for 2018, 2019, 2020, and 2021 respectively. The total annual prevalence/100 test of PW sero-positivity for all tests was 3.5757569, 1.218602, 0.9775099, 1.73763, for 2018, 2019, 2020, and 2021 respectively.

Regarding Annual Prevalence of congenital syphilis per 100000 deliveries it was 18.23704882, 15.6317769, 24.09242618, 34.48903676, for 2018,

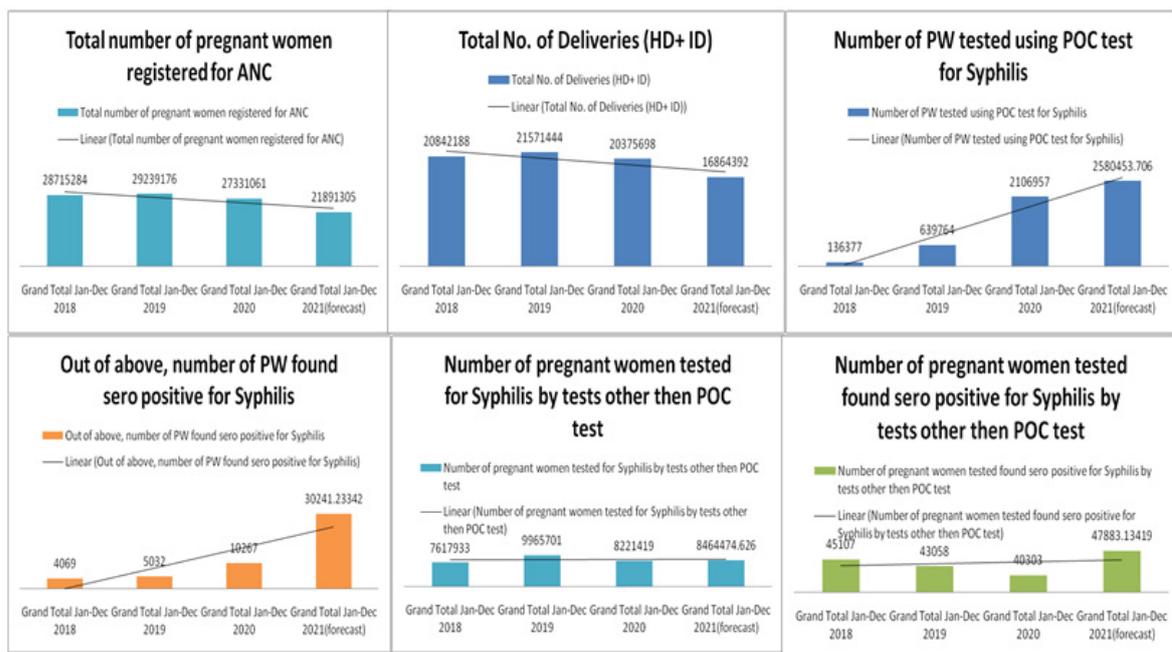


Figure 1: Chart showing comparison and trends of total numbers of different variables in different years

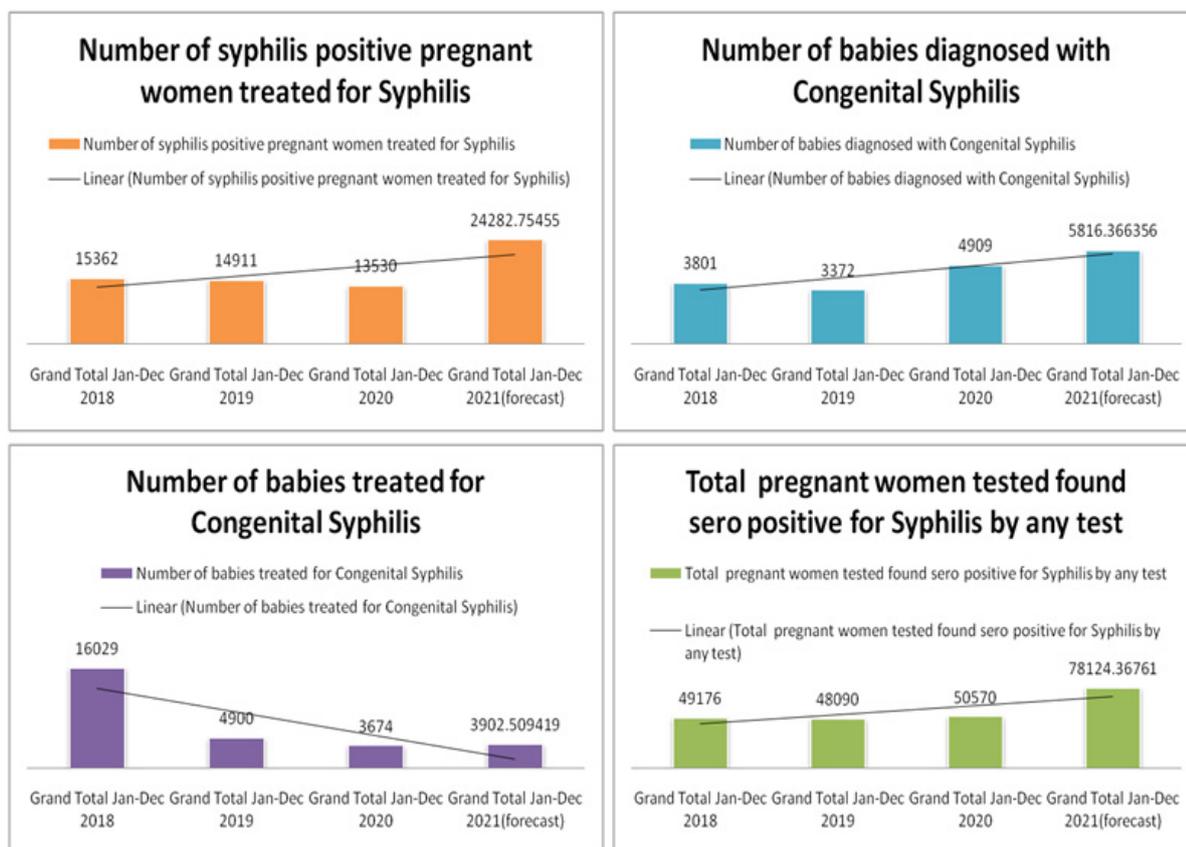


Figure 2: Chart showing comparison and trends of total numbers of different variables in different years

Table 3. Mean/month comparison of different variables in different years.

Indicator	Mean per month Jan-Dec 2018	Mean per month Jan-Dec 2019	Mean per month Jan-Dec 2020	Mean per month Jan-Dec 2021 (forecast)
Mean Total number of pregnant women registered for ANC/month	2392940.333	2436598	2277588.417	1824275.417
Mean Total No. of Deliveries (HD+ ID)/month	1736849	1797620.333	1697974.833	1405366
Mean Number of PW tested using POC test for Syphilis/month	11364.75	53313.66667	175579.75	215037.8089
Mean Out of above, number of PW found sero positive for Syphilis/month	339.0833333	419.3333333	855.5833333	2520.102785
Mean Number of pregnant women tested for Syphilis by tests other than POC test/month	634827.75	830475.0833	685118.25	705372.8855
Mean Number of pregnant women tested found sero positive for Syphilis by tests other than POC test/month	3758.916667	3588.166667	3358.583333	3990.261183
Mean Number of syphilis positive pregnant women treated for Syphilis/month	1280.166667	1242.583333	1127.5	2023.562879
Mean Number of babies diagnosed with Congenital Syphilis/month	316.75	281	409.0833333	484.6971964
Mean Number of babies treated for Congenital Syphilis/month	1335.75	408.3333333	306.1666667	325.2091183
Mean Total pregnant women tested found sero positive for Syphilis by any test/month	4098	4007.5	4214.166667	6510.363968

2019, 2020, and 2021 respectively. This novel research study revealed that there is significant increase in Annual Prevalence of congenital syphilis per 100000 deliveries. The Annual Prevalence of PW treated for syphilis per 1000 sero-positivity was 312.3881568, 310.0644625, 267.5499308, 310.8217742, for 2018, 2019, 2020, and 2021 respectively. Regarding

Annual Prevalence of PW treated for syphilis per 100000 PW it was 53.49764258, 50.99664915, 49.50411548, 110.9241982, for 2018, 2019, 2020, and 2021 respectively. The Annual Prevalence of babies treated for syphilis per 100000 deliveries was found to be 76.90651289, 22.71521554, 18.03128413, 23.14052839, for 2018, 2019, 2020,

Table 4. Prevalence comparison of different variables in different years.

Indicator	Jan-Dec 2018	Jan-Dec 2019	Jan-Dec 2020	Jan-Dec 2021 (forecast)
Annual Prevalence of sero-positivity for syphilis per 100000 PW	171.2537477	164.4711192	185.0275772	356.8739626
Annual Prevalence of PW sero-positivity for syphilis- per 100 POC test	2.983641	0.78654	0.48729	1.171935
Annual Prevalence of PW sero-positivity for syphilis- per 100 other test	0.592116	0.432062	0.49022	0.565695
Total annual prevalence per 100 test of PW sero-positivity- all tests	3.575757	1.218602	0.97751	1.73763
Annual Prevalence of congenital syphilis per 100000 delivery	18.23704882	15.6317769	24.09242618	34.48903676
Annual Prevalence of PW treated for syphilis per 1000 sero-positivity	312.3881568	310.0644625	267.5499308	310.8217742
Annual Prevalence of PW treated for syphilis per 100000 PW	53.49764258	50.99664915	49.50411548	110.9241982
Annual Prevalence of babies treated for syphilis per 100000 delivery	76.90651289	22.71521554	18.03128413	23.14052839

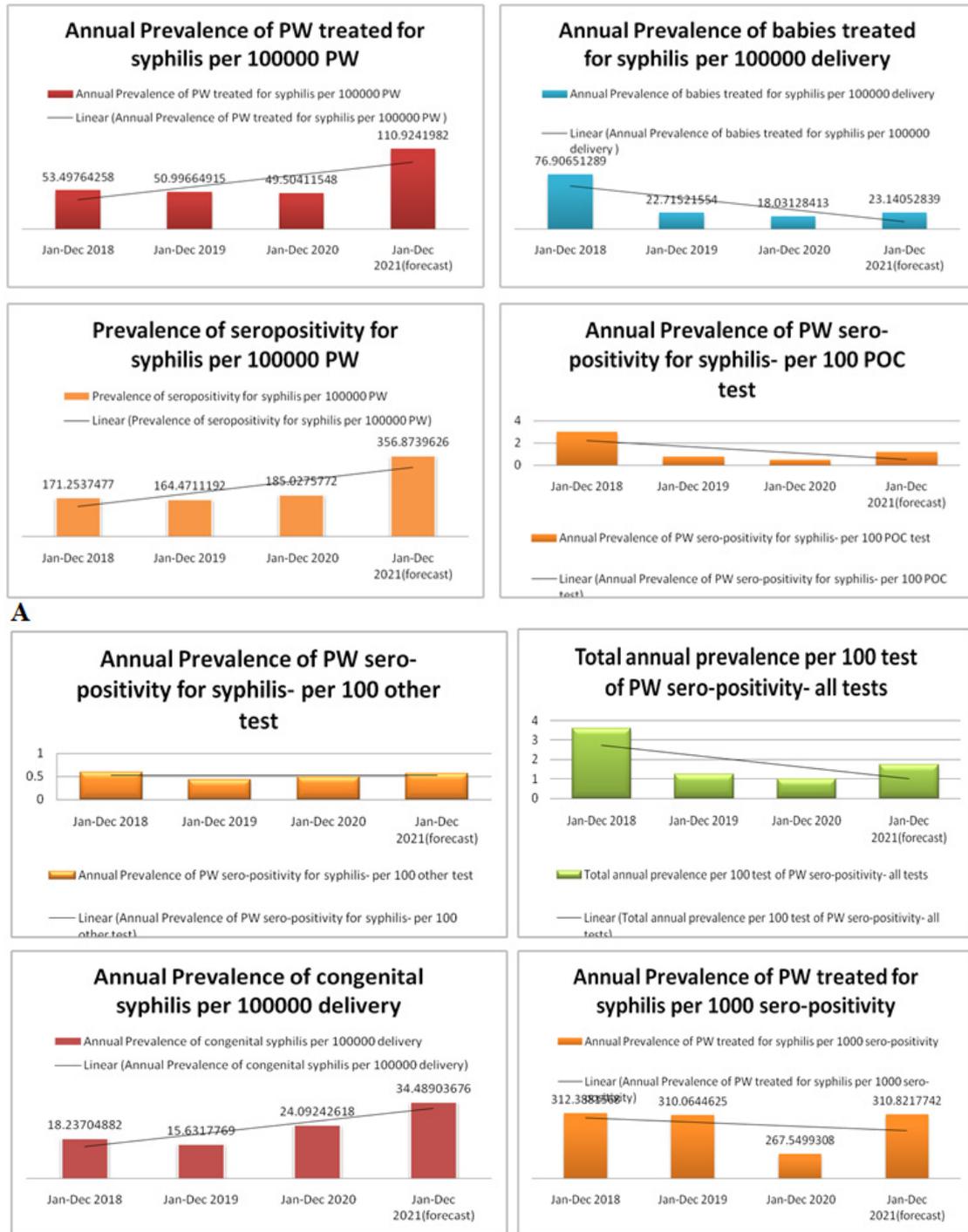


Figure 3 (A, B): Chart showing Prevalence comparison and trends of different variables in different years.

and 2021 respectively which shows that treatment prevalence decreased in spite of increase in cases of congenital syphilis during pandemic-era (see Table 4 and Figure 4).

Descriptive data

Characteristics of study participants (e.g. demographic, clinical, social) and information on

exposures and potential confounders. This study include all public-private-rural-urban health facilities across 36 states and union territories of India whose data are registered on HMIS-MoHFW, Govt. of India. The total number of pregnant women registered for ANC was considered as total number of pregnancy. The sum of all home and institutional deliveries is considered as total deliveries. This

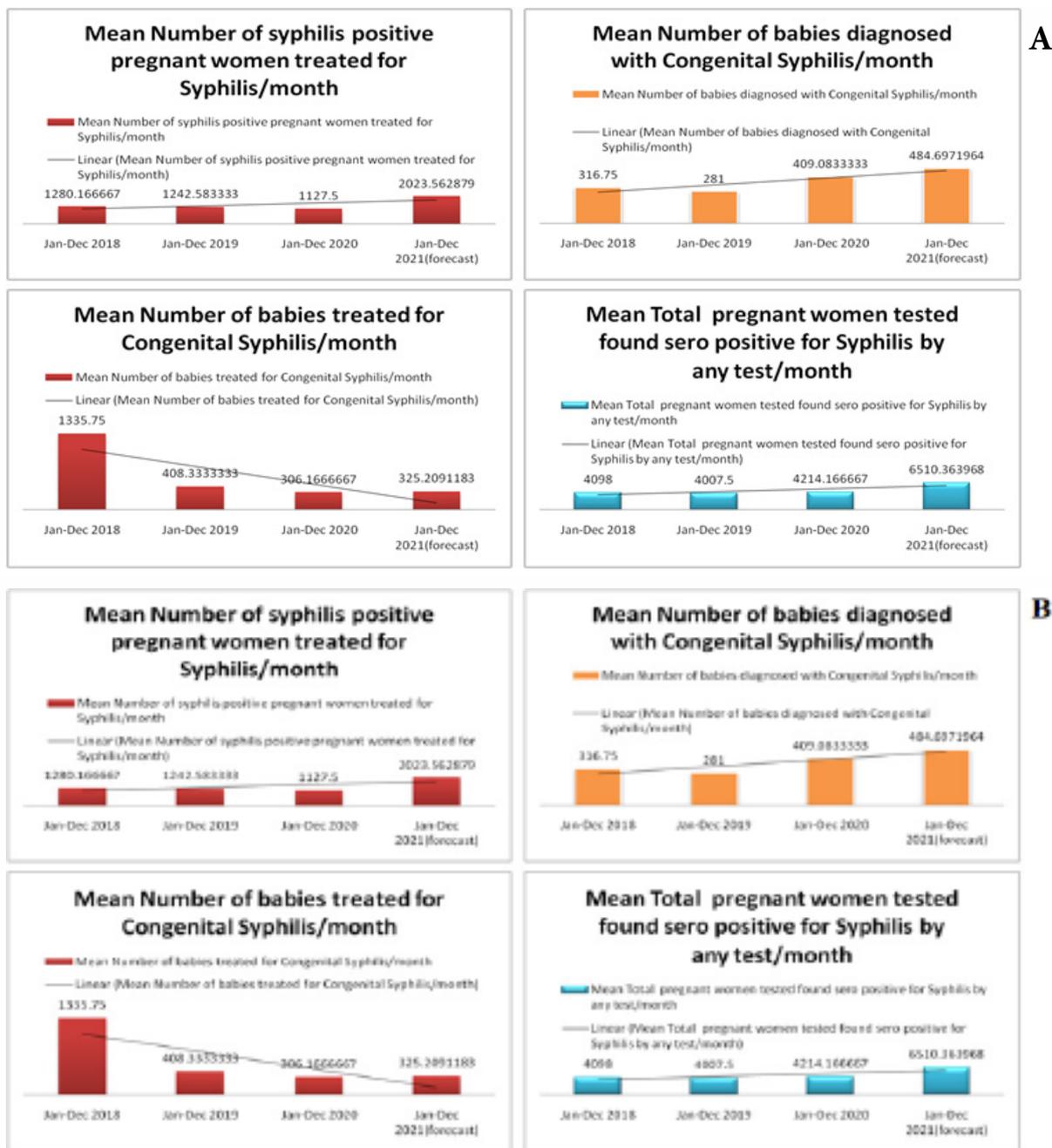


Figure 4 (A, B): Chart showing mean/month comparison and trends of different variables in different years

is a cross-sectional research study to assess the Impacts of covid-19 pandemic era on Pregnant Women sero-positivity for Syphilis among women attending antenatal care in India and number of babies diagnosed with Congenital Syphilis as well as numbers of PW and children's treated for the same. Hence author have included the variables/indicators available at HMIS related to research question mentioned in the title of this research study and their numbers listed above in Table 2.

Number of participants with missing data for each variable of interest. The missing data for each variable for 2021 were projected with Microsoft excels by linear regression. There may be under-reporting etc. which are excluded in this study.

Discussion

The average number of PW tested per month using POC test for Syphilis increased gradually from year 2018 continuously see figure 1 and Table 1. There is also an increase in average number of PW found sero positive for Syphilis which indicates that increasing number of tests have detected more syphilis cases as well as less number of testing may have left several cases. It is frequently asked that which test is most diagnostic for syphilis. The Direct fluorescent antibody test for T pallidum is considered as the most specific test for the diagnosis of syphilis when lesions are present. This test utilize fluorescein isothiocyanate-labelled antibody which is specific to pathogenic Treponema [4]. Very simple rapid tests for detection of syphilis are also commercially available. These are popularly known as point of care (POC) tests which can be performed without laboratory setting and with minimal training as well as no special equipment is required. POC are done using a small amount of whole blood collected by a finger prick [5].

Study Strength and Limitation

This is a cross-sectional retrospective research study based on secondary data which was one of the main limitations of this research study. Another limitation is availability of data from any other accredited and established source recognized worldwide is not available. The main strength is that the whole study is based on real time based accredited government data sources and this kind of research study is unique and not available for the context of India as found by the researcher of this novel study.

Conclusion and Recommendation

During pandemic era Women and infants affected by syphilis is increasing in India. The antenatal care services utilization is also affected significantly in India at different rural-urban-public-private health facilities across 36 states and union territories of

India [6]. This may be due to covid-19 induced restrictions to stay at home (by increasing opportunity for sexual-intercourse due to lockdown etc), unsafe sexual intercourse. It is crucial to screen all pregnant women with early screening tests and treatment as early as possible with high-quality antenatal care [7]. The health systems and government led programmes need to ensure that all PW and infants diagnosed with syphilis, are effectively treated as well as their sexual partners are tested and treated timely/properly [8]. India and global nations can also reduce syphilis prevalence by ensuring that testing, treatment and partner reached for the infection should be implemented, beyond ANC (antenatal care). The author endorse WHO recommendation for screening of all pregnant women for syphilis at first antenatal care visit [2,9]. In pregnant women with early syphilis, the WHO STI guideline recommends benzathine penicillin G 2.4 million units once intramuscularly over no treatment [10].

Declarations

This version of paper has not been previously published in any peer reviewed journal and is not currently under consideration by any journal. The document is Microsoft word with English (United States) language & 4001 words excluding reference and declaration (4983 words Total including all).

Ethics approval and consent to participate

Not applicable. This study has not involved any human or animals in real or for experiments. The submitted work does not contain any identifiable patient/participant information.

Consent for publication

The author provides consent for publication.

Availability of data and materials

Electronic records from HMIS (health management information system) of MoHFW (ministry of health and family welfare), Government of India.

Conflicts of Interest/Competing Interest

There are no conflicts/competing of interest.

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Authors' contributions

The whole work is done by the Author - Dr Piyush Kumar, M.B.B.S., E.M.O.C., P.G.D.P.H.M., -Senior General Medical Officer- Bihar Health Services-Health Department- Government of Bihar, India.

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