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Original Research Article

Standard operating procedure for prevention and initial management of COVID-19 in pregnancy at a secondary level hospital in rural South India: a quality improvement project

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ABSTRACT

Background: During the COVID-19 pandemic there was an influx of antenatal patients presenting with symptoms while still requiring essential obstetric care. We needed to follow a standard operating procedure (SOP) at this rural maternity hospital for the prevention and initial management of COVID-19 in pregnancy.
Methods: An SOP was formulated using national and international guidelines that were tailored to a resource-constrained setting. Healthcare workers were trained to implement the SOP. Sequential Plan-Do-Study-Act (PDSA) cycles enabled fine contouring of the prevention and initial management steps. Data was collected using an observational checklist at the end of each PDSA cycle and compared statistically to the baseline assessments using chi-square test.
Results: Patients wearing face mask appropriately increased from 60% to 82.4% (P=0.0007). Patients using hand sanitizer provided at the hospital improved from 50% to 84.8% (P=0.0004). Proportion of patients screened for covid-19 symptoms rose from 74% to 94.4% (P=0.0002). Patients counselled for COVID-19 vaccination increased from 42% to 87.2% (P<0.0001). Proportion of patients triaged at the OPD using the SOP improved from 66.6% to 87.2% (P=0.004). All improvements were statistically significant.
Conclusions: The SOP for prevention and the initial management of COVID-19 symptoms in pregnancy was successfully implemented followed by PDSA cycles and can be used in similar health-care settings.

Keywords: Quality improvement, Standard operating procedure, COVID-19 in pregnancy

INTRODUCTION

The world health organization (WHO) on March 11th, 2020 declared the Novel Coronavirus (COVID-19) outbreak as a global pandemic.[1] In mid-2020, the first wave of the COVID-19 pandemic in India was largely confined to the cities. The second wave of the COVID-19 pandemic hit India hard. In mid-April of 2021, the number of cases climbed higher than ever before, with over 4,00,000 new cases per day in mid-May.[2] Test positivity rates during the peak of the second wave were as high as 25%. The infection spread like wild-fire to small towns and rural areas, raging out of control.[3] Snehalaya Hospital at Solur village is a secondary level hospital, located in Ramnagara district of Karnataka in the south of India, 50 km from Bangalore city. It is primarily a maternity hospital that also provides general medical and pediatric services. The hospital comprises an outpatient department (OPD), 50 in-patient beds, laboratory facilities, labour room, operation theatre and newborn care facilities. This busy hospital sees over 150 patients on outpatient clinic days and 5-6 deliveries a day. Maternity services being essential and vital, Snehalaya Hospital continued to provide health care throughout the

pandemic. The challenges faced by the hospital staff included an increase in number of pregnant patients presenting with symptoms of COVID-19 such as cough, cold, fever, headache, body pain and fatigue. Given the backdrop of the pandemic, pregnant patients coming to the centre with symptoms of COVID-19 posed a therapeutic challenge due to high rates of transmission. Patients needed to be referred to the nearby government Primary Health Centre for COVID-19 testing and those who tested positive would need further management at a higher centre. During the pandemic, the hospital staff faced challenges of poor adherence of the patients and their attendants (persons who accompany patients to the hospital) to the general COVID-19 protocols of social distancing and wearing face masks. COVID-19 vaccine hesitancy was prevalent among the antenatal population and this issue also needed to be addressed. As the omicron variant became the dominant strain in the third wave, and more evidence in medical literature became available, a standard operating procedure (SOP) for COVID-19 screening and initial management among antenatal women needed to be drawn up.[4] It was felt that repeated training of staff with consequent plan-do-study-act (PDSA) cycles would be needed to conduct this quality improvement project (QIP). An SOP tailored to the context of a rural maternity hospital, would therefore be beneficial to both patients and the hospital staff at the hospital to address challenges during the pandemic in care of pregnant women.

Objectives

Objectives of the current study were to develop a SOP for prevention and initial management of COVID-19 symptoms in pregnancy, based on available international and national guidelines and to conduct this QIP using sequential PDSA cycles.

METHODS

Study design and duration

Current study was a cross-sectional study (quality improvement program) carried out during January to May 2022 which included one baseline survey and three PDSA cycles of one month duration each.

Inclusion criteria

All consenting pregnant women availing antenatal care at Snehalaya Hospital, Solur were included in the study.

Baseline assessment

Before establishing the guidelines, the current situation and practices were assessed with inputs from the senior doctor in-charge of the hospital, interns, nurses and auxiliary nurse and midwives (ANM) working at the hospital. A random sample of 5 patients on 10 successive OPD days in January 2022 were observed and practices related to COVID-19 precautions and initial management of COVID-19 symptoms were observed.

Development of the SOP

The SOP was formulated after an extensive review of literature of existing guidelines of management of COVID-19 in pregnancy; international guidelines from the international federation of gynecology and obstetrics (FIGO), Royal college of obstetricians and gynaecologists (RCOG) and American college of obstetricians and gynecologists (ACOG) as well as Indian guidelines from the federation of obstetric and gynaecological societies of India (FOGSI) and Indian council of medical research (ICMR).[5-9] The health care staff of the hospital were trained on how to follow the SOP.

PDSA cycles

The SOP was implemented for a month in each cycle. Data was collected by observing a random sample of 5 patients on each OPD day (24 OPD days in February, 27 days in March and 25 days in April of 2022). This was done during the middle of the OPD hours, when the patient load was maximum. Observations were made to check if the SOP was being followed for each patient, using a checklist. This data was analysed and the gaps in implementation of the SOP were then discussed with the health care team during the feedback session at the end of each cycle. Based on feedback, minor adjustments were made in the protocol, and the next PDSA cycle was initiated (Figure 1).

Statistical analysis

The data was collected on Google forms, exported to Microsoft Excel and analysed using IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, N.Y., USA). Chi-square test was performed to look at the difference in proportions of the selected SOP-implementation indicators between PDSA cycles. A p value of <0.05 was considered significant.

RESULTS

The SOP focussed on four areas: prevention of transmission of COVID-19 among pregnant patients and their attendants, screening for COVID-19 and triaging of antenatal patients, initial management of symptomatic patients and addressing vaccine hesitancy among antenatal patients (Figure 2-3).

PDSA cycle 1 (one month)

The objective of this cycle was to familiarize the pregnant patients and their attendants to COVID-19 preventive measures and to familiarize the health care staff at the hospital with the SOP for the screening and initial management of COVID-19 symptoms in pregnancy.

Table 1: SOP implementation over 3 PDSA cycles.

Indicator	Baseline N=50	PDSA 1 N=120	PDSA 2 N=135	PDSA 3 N=125	P value
Pregnant patients wearing face mask which covers both nose and mouth	30 (60.0)	75 (62.5)	103 (76.3)	103 (82.4)	0.0007
Attendants wearing face mask which covers both nose and mouth	16 (32.0)	44 (36.6)	58 (42.9)	71 (56.8)	0.003
Pregnant patients using hand sanitizer provided at the hospital	25 (50.0)	70 (58.3)	88 (65.2)	106 (84.8)	0.0004
Pregnant patients screened for covid-19 symptoms	37 (74.0)	90 (75.0)	108 (80.0)	118 (94.4)	0.0002
Pregnant patients triaged at the OPD using the SOP	Nil *	88 (73.3)	105 (77.7)	112 (89.6)	0.004
Pregnant patients counselled for COVID-19 vaccination	21 (42.0)	80 (66.6)	101 (74.8)	109 (87.2)	<0.0001

*SOP was implemented after the baseline assessment was done, during the first PDSA cycle

This was done by displaying signages across the OPD regarding wearing of face masks, sanitising hands and maintaining social distancing. The SOP was shared with the health care staff at the hospital. Six key indicators were chosen to assess the implementation of the SOP. These were: Proportion of pregnant patients wearing face mask which covers both nose and mouth, proportion of pregnant patients' attendants wearing face mask covering both nose and mouth, proportion of pregnant patients using hand sanitizer provided at the hospital, proportion of pregnant patients screened for COVID-19 symptoms, proportion of pregnant patients triaged at the OPD using the SOP, proportion of pregnant patients counselled for COVID-19 vaccination. These indicators were assessed by observation. At the end of the first cycle, there was marginal improvement across the first five indicators and a larger improvement in the proportion of pregnant patients counselled for COVID-19 vaccination.

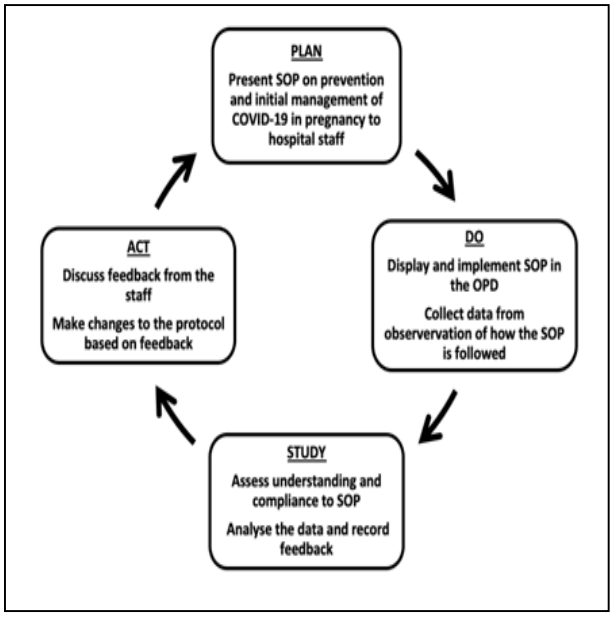

Figure 1: Diagrammatic representation of the PDSA cycle followed in the implementation of the SOP.

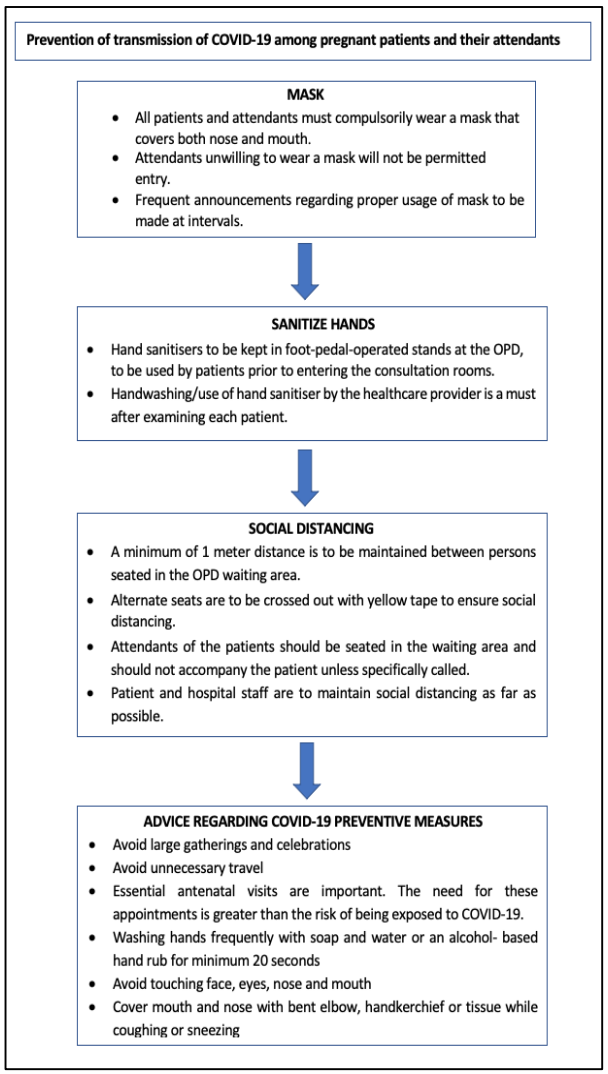

Figure 2: Prevention of transmission of COVID-19 among pregnant patients and their attendants.

A discussion with the health care staff at the feedback session revealed the need for further re-enforcement of the SOP among patients and possible reasons for their non-

compliance being illiteracy and therefore inability to read signages.

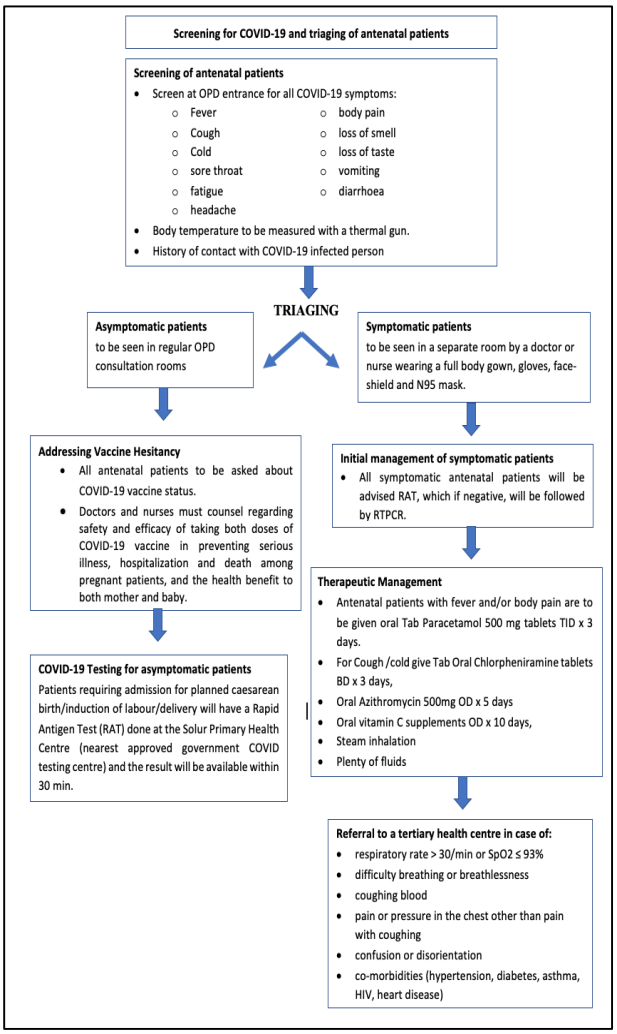

Figure 3: Screening, triaging, and initial management of COVID-19 in pregnancy.

PDSA cycle 2 (one month)

The objective of this cycle was to re-enforce the SOP by improving understanding and identify possible reasons for non-compliance with preventive measures. To improve compliance regarding wearing of face masks and sanitizing hands, especially for the benefit of illiterate patients and their attendants, repeated announcements were made regarding these preventive measures in the local language. To strengthen the implementation of the SOP, this was displayed in the screening and triage area of the OPD. At the end of the second cycle there were improvements in all six indicators. During the feedback session with health care staff, it was felt that patients attendants were not maintaining mask etiquette and pulling down their face mask to expose their nose. It was decided to initiate stricter action and not permit entry to those without a face mask and to ask those who do not cover both nose and mouth with face mask to leave the OPD.

PDSA cycle 3 (one month)

The objective of this cycle was to strengthen the implementation of the SOP. Those without a face mask were not permitted entry to the OPD and were asked to procure one and then enter. Those who did not maintain proper mask etiquette (who did not cover both nose and mouth with face mask) were asked to wear the face mask properly or else leave the OPD and wait outside the building. Those health care staff who were not fluent in English were re-trained in the local language in the use of the SOP for screening and triaging and initial management of COVID-19 symptoms in pregnancy. At the end of the third cycle there were once again improvements in all six indicators. At the feedback session with the health care staff, the importance of further continuance of the SOP was discussed.

Comparison of key indicators across the PDSA cycles

The proportions were compared at baseline and across the three PDSA cycles. Patients wearing face mask which covers both nose and mouth increased from 60% at baseline in January to 82.4% in April at the end of the third PDSA cycle (p=0.0007). However, the proportion of patients' attendants wearing face mask covering both nose and mouth was low to begin with (32%) and increased to just 56.8% at the end of the study (p=0.003). Patients using hand sanitizer provided at the hospital started at 50% and increased to 84.8% (p=0.0004). Similar improvements were found among the proportion of patients screened for covid-19 symptoms (74% to 94.4%, p=0.0002), and patients counselled for COVID-19 vaccination (42% to 87.2%, p<0.0001). The proportion of patients triaged at the OPD using the SOP increased from 66.6% at the first PDSA to 87.2% at the end of the study (p=0.004). The improvements in all six indicators were statistically significant (Table 1).

DISCUSSION

This QIP was undertaken to implement an SOP for prevention and initial management of COVID-19 in pregnancy at a secondary level hospital. The SOP was prepared based on international and national guidelines. While pregnant women do not appear more likely to contract the infection than the general population, pregnancy itself alters the body's immune system and response to viral infections in general, which can occasionally be related to more severe symptoms of COVID-19.[9] As pregnancy is a physiological prothrombotic state and COVID-19 produces a hyper-coagulable state, pregnant women with COVID-19 may be at increased risk of developing coagulopathic and/or thromboembolic complications. This was confirmed in a systematic review of 69 studies and 1063 women by Servante et al.[10] Therefore, early diagnosis of COVID-19 is important. Since this study setting did not have the

facility for COVID-19 diagnosis, referral for COVID-19 testing to the nearest government approved testing centre was included in the SOP.

Preventive measures to avoid COVID-19 infection in pregnancy have been detailed by FOGSI. Social distancing is to be maintained by keeping a distance of at least one metre in various necessary interactions and activities, avoiding non-essential travel and avoid gatherings and celebrations. Maintenance of hygiene is advocated to reduce transmission of COVID-19: washing hands frequently with soap and water or an alcohol- based hand rub for minimum 20 seconds, avoiding the touching of face, eyes, nose and mouth with hands, covering mouth and nose with bent elbow, handkerchief or tissue while coughing or sneezing.[8] However, in this study we faced challenges in the maintenance of COVID-19 prevention measures that we overcame by regular announcements in the local language for illiterate patients and their attendants.

In India, due to resource constraints, the service providers are guided by the ICMR to assess the feasibility of patient home isolation or else admit in hospital or quarantine facility. Most of these women will not require hospital admission.[9] Still, as per FOGSI guidelines, women with tachypnoea (respiratory rate > 30/min), hypoxia ($SpO2 \leq 93\%$) and > 50% lung involvement on imaging must get admitted in a critical care unit.[8] Pregnant women with COVID-19 are more likely to need invasive ventilation than non-pregnant women of reproductive age. Pre-existing comorbidities, non-white ethnicity, chronic hypertension, pre-existing diabetes, high maternal age, and high body mass index are risk factors for severe COVID-19 in pregnancy. Pregnant women with COVID-19 versus without COVID-19 are more likely to deliver preterm and could have an increased risk of maternal death and of being admitted to the intensive care unit.[11] Since intensive care facilities are not available at a secondary-level hospital, it was decided to refer pregnant patients to a tertiary care centre with ICU in the case of respiratory rate > 30/min or $SpO2 \leq 93\%$, difficulty breathing or breathlessness, confusion or disorientation or with co-morbidities (hypertension, diabetes, asthma, HIV, heart disease), and hence the same was included in the SOP. All guidelines advise screening at the entrance to hospital. FIGO further guides that screen positive patients should have minimum waiting period, evaluated for the presence of severity of symptoms and tested according to local protocols.[5] ACOG guidelines further provide an algorithm to help classify based on severity of symptoms where clinical symptoms such as difficulty in breathing/gasping/cough/chest-pain/ dysphagia/confusion point toward an elevated risk.[7] The QIP therefore includes both screening for common symptoms of COVID-19 as well as documenting severe symptoms.

The minimum in-person OPD visits suggested by FIGO are six in number, at 12 weeks, 20 weeks, 28 weeks, 32 weeks, 36 weeks and 37-41 weeks. All other visits to be by tele or videoconferencing which must be made available as a duty, by the obstetricians. Specific stress must be laid on the need to come alone or only one accompanying person.[5] While it is possible to restrict the number of accompanying attendants, tele or video conferencing was not an option in the rural setting of this hospital. Pregnant individuals are at increased risk for severe disease; therefore, it is extremely important that pregnant individuals in high COVID-19 community level areas continue to use face masks. Even in low COVID-19 community level areas, pregnant individuals may wish to continue wearing face masks and should be supported if they decide to do so. There are currently no known risks related to face mask use during pregnancy.[12] RCOG guidelines state that women with mild symptoms can be sent home after proper advice of home monitoring of symptoms while those with moderate or severe symptoms need to be admitted after detailed assessment.[6] FOGSI recommends Tab. Azithromycin (500 mg OD) for 10 days for treatment of COVID-19 infection in pregnancy in addition to supportive treatment (Paracetamol, oxygen). In high-risk women with uncontrolled diabetes, immunosuppression or chronic diseases, antiviral therapy (Lopinavir+ Ritonavir Or Oseltamavir) may be used.[8] Anti-viral therapy was not included in the SOP as women who were high-risk were referred to a tertiary care centre for further management. An attender or care partner may be a relative, partner, friend or anyone the patient chooses to have at their side during care. Visitor guidelines for patient care partners during COVID-19 at Johns Hopkins Medicine facilities insist that care partners must follow all of the following safety precautions, even if vaccinated against COVID-19. Face masks are required to enter any of Johns Hopkins care facilities and expected to be worn at all times over the nose and mouth. Care partners who do not comply with these guidelines will be asked to leave.[13] This was similarly done in our QIP when we realised that compliance with appropriate mask etiquette needed to be enhanced. COVID-19 vaccination is strongly recommended at any stage of pregnancy. Receiving two doses of the vaccine and the booster dose is the safest and most effective way of protecting mother and baby from COVID-19 infection. COVID-19 vaccination in pregnancy has been found to prevent severe illness, hospitalisation and death due to COVID-19.[14] Pregnant women are a priority group for the booster vaccination. United Kingdom obstetric surveillance system (UKOSS) showed that no woman receiving both vaccine doses required admission for COVID. 99% of the pregnant women admitted with COVID-19 complications were unvaccinated.[15] Therefore emphasis was placed on counselling pregnant women to take free vaccination provided by the Government.

CONCLUSION

The protocol for prevention and the initial management of COVID-19 symptoms among pregnant patients in the pandemic scenario was successfully implemented across

three PDSA cycles and can be used in similar resource-constrained settings.

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