



**Patient Costs and Outcomes Before and After the Institution
of a Preeclampsia Quality Improvement Initiative in a
Southwestern Tertiary Facility**

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3 **Patient Costs and Outcomes Before and After the Institution of a Preeclampsia Quality**
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5 **Improvement Initiative in a Southwestern Tertiary Facility**
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10 **Running head:** Costs and Outcomes of a Pre-eclampsia Quality Improvement Initiative
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For Peer Review Only

Abstract

The study objective was to evaluate the effect of the California Maternal Quality Care Collaborative (CMQCC) initiative, as implemented in a southwestern U.S. tertiary hospital, on associated patient costs and outcomes. Using a quasi-experimental study design, we collected existing data (cost and patient outcomes) comparing two six-month periods at the baseline and one-year follow-up. Following descriptive statistics, Chi-square tests and t-tests were used to compare categorical and continuous variables, respectively. One hundred and eighty-nine women met the inclusion criteria for the study (93 and 96 women in the baseline and follow-up period, respectively). There was no significant difference in maternal health outcomes between both periods. However, there was a significant difference for newborns with almost 90% (95%CI=0.06–0.92; $p=0.027$) reduction in stillbirths in the follow-up period. There was also a significant reduction in the days between discharge and follow-up appointments ($p<0.01$). Importantly, the initiative bears no additional financial burden on patients, as hospitalisation cost was unchanged.

Impact statement

- **What is already known on this subject?** In 2013, the California Maternal Quality Care Collaborative (CMQCC) set up a task force to develop guidelines for managing patients with preeclampsia based on global best practices. A previous study showed that despite system-level implementation challenges, the initiative led to significant increase in blood pressure treatments within one-hour and reduced severe maternal morbidity.
- **What do the results of this study add?** This study follows patients from admission, beyond the one-hour post-treatment and into the post-partum phase, to understand if outcomes of the initiative extend beyond the admission. While the study findings do not show any statistically significant difference in readmission before and after the initiative, nor any marked difference in maternal outcomes, it shows a significant difference in the prevalence of stillbirths at no additional cost to the patient.
- **What are the implications of these findings for clinical practice and/or further research?** Based on these findings, there is a case for scaling-up the initiative as in addition to its evidenced improvements in maternal outcomes; it is effective in improving newborn health outcomes at no additional cost. Further research, using larger sample size and exploring different care levels would be useful to verify these findings.

Key words: Pre-eclampsia; hypertension; pregnancy; safety; quality collaborative; quality improvement

Introduction

Globally, preeclampsia is one of the leading causes of pregnancy-related morbidity and mortality (Say *et al.* 2014). The condition is associated with increased risks of preterm delivery, intra-uterine growth restriction, placental abruption and perinatal mortality (Conde-Agudelo *et al.* 2000; Zhang *et al.* 2000; Goldenberg *et al.* 2008; Ananth and Basso 2010). Some authors have described pre-eclampsia as a “sentinel marker” for women who will develop chronic cardiovascular conditions following delivery (Irgens *et al.* 2001). Women with pre-eclampsia have an increased risk of future hypertension, ischemic heart disease and stroke (Bramham *et al.* 2013). In the United States, with an estimated prevalence of 3.8% in 2010 (Ananth *et al.* 2013), pre-eclampsia is responsible for 17% of all maternal deaths that occur. However, 50% – 70% of such deaths are deemed preventable (MCAH 2012).

In 2013, the California Maternal Quality Care Collaborative (CMQCC) set up a task force made up of a multi-disciplinary team of experts, working in both high and low-volume obstetric units. They were tasked to develop tools and guidelines for managing patients with preeclampsia based on global best practices in diagnosis and management of preeclampsia (CMQCC 2013). The quality improvement initiative required early detection of preeclampsia with blood pressure (BP) confirmation within 15 – 20 minutes, if BP > 160/110 mmHg, provider notification, the institution of treatment (based on evidence-based algorithms) within one-hour of BP confirmation including seizure prophylaxis with Magnesium Sulphate (Figure 1). Further recommendations include a follow-up appointment within 3 – 7 days if anti-hypertensive medication was used during labour and delivery or postpartum or within 7 – 14 days if no anti-hypertensive medication was used. The initiative also requires standardised patient education (CMQCC 2013).

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3 Previous studies that assessed the effectiveness of the initiative in reducing severe maternal
4 morbidity (SMM) were based on a process indicator of time to institute treatment and
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6 immediate outcome indicator of the persistence of severe maternal morbidity one-hour after the
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8 institution of treatment (Shields *et al.* 2015; 2017). However, no study had explored the effect
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10 of the initiative on the cost of care and outcomes that occur beyond this one-hour post-
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12 treatment phase, despite the known fact that complications of preeclampsia can extend even
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14 beyond delivery and into the six-week post-partum period (Matthys *et al.* 2004). Our study
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16 objective was to evaluate the effectiveness of the CMQCC initiative as implemented in a
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18 tertiary hospital on associated patient costs and outcomes during the intrapartum and post-
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20 partum periods.
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28 **Materials and methods**

29
30 A quasi-experimental design was used for this study. This design has been selected because it
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32 was not logistically feasible and unethical to conduct a randomised controlled trial, which is
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34 generally regarded as the “gold standard” of causal research design (Morgan *et al.* 2000; Harris *et*
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36 *al.* 2006), since women with preeclampsia cannot be denied of care they require upon
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38 presentation.
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45 ***Study setting***

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47 This study was conducted in St. Joseph’s Hospital and Medical Centre (SJHMC) hospital,
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49 which is managed by a non-profit organisation, Dignity Health. In 2014, the organisation
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51 embedded the CMQCC pre-eclampsia initiative as practice across all its hospitals including
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53 SJHMC, where about 5,000 births occur annually.
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58 ***Data collection***

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3 Existing secondary data was mined for this research with coded data from a six-month pre-
4 collaborative baseline period compared to prospectively reported outcomes of a six-month
5 follow-up period, one-year after the CMQCC implementation. The coded intrapartum data was
6 mined from the patient database (Midas®) and additional post-partum data collected from patient
7 records (as this could not be mined in Midas®). Microsoft Excel (Microsoft Corporation,
8 Redmond, California, USA) was used as a repository for the secondary data, collating the data
9 in such a way it was easily retrievable.
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21 All women, 18 years and above, who had conditions that could be classed under the relevant
22 International Classification of Diseases (ICD)-10 codes for pre-eclampsia as recommended by
23 experts (Callaghan *et al.* 2014) and captured on the Midas platform (Supplemental file 1) and
24 who presented in the hospital within either study phase (baseline and follow-up) were included
25 in the study.
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35 Data on the pregnancy characteristics and relevant pre-existing conditions, intrapartum care and
36 outcomes as well as outcomes reported during the post-partum period was collected. Using a
37 unique patient medical record number (anonymised), we gathered pregnancy-related data
38 focused on gestational age on admission (term vs. pre-term), number of foetuses (singleton vs.
39 multiple gestation), delivery method, admission date, delivery date and discharge date (the
40 latter three variables were used to estimate admission to delivery and admission to discharge
41 period).
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52 Also, we collected data on pre-existing conditions such as obesity and chronic hypertension.

53 Intrapartum care data included data on the course of treatment, including the time and date for
54 the initial episode of BP trigger (>160/100mmHg) and treatment regimen given to the patients.
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3 The data on any complications of pre-eclampsia which had been reported during the
4 hospitalisation, included eclampsia, stroke, post-partum haemorrhage, pulmonary oedema,
5 renal insufficiency (Creatinine >1.1mg/dL or double in a woman with already high creatinine)
6 and liver injury (Twice normal high of Aspartate transaminase [AST]=68IU/L and Alanine
7 transaminase [ALT]=110 IU/L) were also collected. In addition, we collected data on the cost
8 of intrapartum care (only direct hospitalisation costs that included hospitalisation stay,
9 medicines, and provider costs were included) and the payer for the care received
10 (Self/Commercial/Medicaid/Medicare/Others). Post-partum period data captured included data
11 on follow-up appointment time frame, BP after delivery, readmission history in the hospital for
12 post-partum pre-eclampsia.
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29 We used a comprehensive standardised operating procedure manual and ethical guidelines to
30 support data collection. To quality-assure the data collection process, the investigators were
31 competent in quantitative research with previous experience and significant training as well as
32 trained in good clinical practice and data management, which was recently updated. Also, data
33 was rechecked for completeness, accuracy and to avoid any errors which could bias analysis.
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43 ***Data analysis***

44 Following data collation in Microsoft Excel, the completed data sheet was exported to STATA
45 13.0 SE (Stata-Corp., College Station, Texas, USA), for analysis. Cost and outcome in a six-
46 month pre-collaborative baseline were compared to the prospectively reported outcomes of the
47 six-month follow-up period, one year after implementation of the initiative. The rationale for the
48 choice of this one-year gap between the baseline and follow-up in the research is based on the
49 85% uptake of the protocol at this point. We argued that such a high percentage uptake would
50 make outcome attributed to the initiative more sensible.
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6 Descriptive statistics with percentages were used to describe the demographic characteristics of
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8 the women included in the study. Chi-square test was used in comparing the proportion of
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10 outcomes at baseline with the one-year follow-up period, as this was categorical data. For cost,
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12 which is a continuous variable, the Student t-test comparison of two means was used for the
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14 analysis. Results were presented in tables with odds ratio, confidence intervals and *p*-values. A
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16 significance level of $p < 0.05$ was used to confirm if there were any statistically significant
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18 differences in costs and outcomes between the baseline and follow-up periods.
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24 We followed the most up-to-date SQUIRE (Standards for Quality Improvement Reporting
25
26 Excellence) publication guidelines (Version 2.0) in reporting our study (Ogrinc *et al.* 2015).
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30 ***Ethical considerations***

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33 The four key moral principles in conducting ethically sound research - autonomy, beneficence,
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35 non-maleficence, and justice (Beauchamp and Childress 2008), formed the ethical foundations
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37 of this study. All efforts to uphold the dignity of participants, to preserve their anonymity,
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39 confidentiality and protection against psychological harm were implemented through data
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41 collection, management and storage. Permission to access the database containing patient
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43 information was approved by the institutional review board (IRB) of the Dignity Health System
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45 (Ref #: 010764). The data within Midas was already de-identified. However, for data that
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47 needed to be collected outside Midas, only the principal researcher had access to patient names.
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51 The combined database created did not include any attributable data to the included patients.
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54 The data was secured on the researchers' computers, was password protected and was not
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56 stored in any online/cloud storage.
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Results

One hundred and eighty-nine women met the inclusion criteria for this study, with 93 women included in the baseline period (before the initiative) and 96 women included in the follow-up period. Of the 93 women in the baseline group, 70 (75%) had been classified as obese while 63 (66%) of the 96 women in the follow-up group had been classed obese ($p=0.15$) (Table I).

Fifteen (16%) and 21 (22%) women in the baseline and follow-up group respectively had pre-existing chronic hypertension by the time of hospitalisation ($p=0.32$) (Table I).

Regarding the pregnancy, 2 (2%) and 5 (5%) in the baseline and follow-up group respectively were pregnant with more than one foetus ($p=0.27$) (Table I). While 43 (46%) in the baseline and 50 (52%) in the follow-up group were term (37 weeks 0, as defined by the American College of Obstetrics and Gynaecology (ACOG Committee on Obstetric Practice Society of Maternal-Fetal Medicine 2013)) at the time of admission ($p=0.42$) (Table I). At delivery, 52 (56%) and 59 (62%) were delivered by Caesarean in the baseline and follow-up arm of the study, respectively ($p=0.44$) (Table I).

There was no significant difference in the pre-eclampsia complications between the baseline and follow-up, except for stillbirth ($p=0.027$) (Table II). In a multivariate analysis, there was an 87% (95%CI 0.06–0.92; $p=0.027$) decrease in the odds of having a stillbirth in the follow-up phase compared to the baseline (Table III). When adjusted for obesity, the adjusted odds ratio was estimated at 0.11 (95%CI 0.13–0.88; $p=0.027$) (Table III).

For the continuous variables, though the mean cost of hospitalisation was about \$14 higher, this was not statistically significant (Table IV). Similarly, there was no statistically significant difference in admission-delivery and admission-discharge periods (Table IV). However, there

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3 was a significant difference in duration of follow-up appointment following discharge ($p<0.01$),
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5 with mean days being estimated as approximately 13 and 7 days respectively for baseline and
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7 follow-up periods (Table IV).
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10 11 12 **Discussion**

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14 In this quasi-experimental study, we evaluated the effectiveness of the CMQCC preeclampsia
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16 treatment initiative on patient costs and outcomes. Our findings showed that in a tertiary
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18 hospital setting, there was no significant difference in maternal health outcomes. However,
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20 there was a significant difference in newborn health outcomes with almost 90% reduction in
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22 odds of babies being born as stillbirths following the uptake of the initiative compared with
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24 baseline. There was also a significant reduction in the number of days between discharge and
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26 follow-up appointments. Regarding the care costs, similarly, there was no significant change in
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28 cost after the initiative was implemented. As in other collaborative assessments (Main *et al.*
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30 2017), the groups used in this study for the baseline and follow-up periods were comparable as
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32 there was no significant difference in pregnancy characteristics and pre-existing conditions.
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40 In a previous evaluation of the initiative, the authors found that compliance with utilisation of
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42 intravenous blood pressure medication increased by 33.2% ($p<0.01$) and utilisation of
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44 Magnesium Sulphate increased by 10.8% ($p<0.01$) during the six months of monitoring
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46 following the implementation of the initiative. In addition, incidence of eclampsia and total
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48 severe maternal morbidity (SMM) decreased by 42.6% ($p<0.01$) and 1.7% ($p<0.01$)
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50 respectfully (Shields *et al.* 2017). The former outcome change is a 'process' outcome, while the
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52 latter is a clinical outcome. While process outcomes demonstrate the evidence-based best
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54 practices that represent a health system's efforts to systematise its improvement efforts, clinical
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56 outcomes represent the changes that patient's experience (Mant 2001; Rademakers *et al.* 2011).
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3 Both have their value, however, indicators for tracking clinical outcome can be particularly
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5 useful in standardised data collection methods and when the occurrence of the outcome is
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7 sufficiently common that the outcome indicator will have the power to detect real differences in
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9 quality (Mant 2001). While standardised data collection procedures were instituted in this
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11 study, the outcome did not occur sufficiently enough to allow our analyses to pick the “real”
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13 differences. For example, we found no statistically significant differences in maternal outcomes
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15 that occurred before and after the initiative. While this may be due to the high standard of care
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17 expected in a tertiary hospital such as the one evaluated in this study, it could also be because
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19 of the relatively small sample size, especially as an earlier study conducted on a larger scale
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21 showed significant differences in SMM before and after the initiative was implemented
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23 (Shields *et al.* 2017). As such, the null difference finding in our study needs to be interpreted
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25 with caution. However, our study clearly showed that the initiative had been fully embedded in
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27 the hospital with a highly significant reduction in the number of days between discharge and
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29 follow-up visits comparing the number of days women had to wait for follow-up appointments
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31 before and after the initiative ($p<0.01$). This is a process indicator that demonstrates uptake of
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33 the initiative within the facility.
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42 One of the findings that had not been previously reported in the literature was a significant
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44 reduction in stillbirths in the follow-up period compared with the baseline. This significant
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46 reduction remained even after controlling for obesity. Pre-eclampsia is firmly associated with
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48 stillbirth (Conde-Agudelo *et al.* 2000; Ananth and Basso 2010; Smith 2015) and as evidenced
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50 in this study, clear guidelines in treating patients with the condition help to reduce associated
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52 mortalities with the unborn child.
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3 One other key finding the absence of a cost difference between the baseline and follow-up
4 periods. As such, the benefits of the initiative are not coming at a significant cost to the
5 patients. In our study, we estimated costs at \$1,589.23 at baseline and \$1,607.36 during the
6 Follow-up. A previous estimate of the short-term costs associated with pre-eclampsia per birth
7 at 36 weeks of gestational age were at \$1,311.00 (Stevens *et al.* 2017). As the study was based
8 on data from 2012 (Stevens *et al.* 2017) and our study was based on data from the 2015 – 2016
9 period, it is possible to attribute the observed difference to inflation.
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21 One of the key strengths of this study was that it leveraged a robust electronic health system
22 that had standardised obstetric data definitions (Menard *et al.* 2014). While this study offers
23 unique insight regarding the effectiveness of the CMQCC quality initiative, it is important to
24 recognise the limitations that we have identified. We did not collect race/ethnicity data,
25 especially as the impact of race/ethnicity on hypertensive diseases of pregnancy (Fridman *et al.*
26 2014). Furthermore, this study was based in a tertiary hospital. While facility based
27 assessments like this provide some unique insight for quality improvement (Callaghan *et al.*
28 2014), there may be different explanations as to why there are observed variations in obstetric
29 services in different levels of care (Main 2015). With the singular facility assessed, there was
30 also a limit to the sample size that could be achieved in the study. There is certainly a case for
31 conducting this research on a larger scale while capturing more facilities including different
32 levels of care facilities. This would allow for more study power to assess effect of confounders.
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51 **Conclusion**

52 Scaling-up the uptake of the CMQCC quality improvement initiative in health facilities is a
53 worthwhile venture, as along with its already evidenced effect on improving maternal health
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3 outcomes in larger scale studies, we found that it contributes to reduction in stillbirths. These
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5 outcomes are achieved at no increase in hospitalisation cost for women with preeclampsia.
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Table I. Characteristics of pregnancy and pre-existing conditions

	Baseline (n=93)	Follow-up (n=96)	<i>p</i> value
Obesity	70 (75.3%)	63 (65.6%)	0.15
Chronic hypertension	15 (16.1%)	21 (21.9%)	0.32
Multiple gestation	2 (2.2%)	5. (5.2%)	0.27
Term pregnancy	43 (46.2%)	50 (52.1%)	0.42
Caesarean delivery	52 (56.0%)	59 (61.5%)	0.44

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Table II. Bivariate analysis of categorical outcome data

Outcome	Total (N=189)	Before	After	p value
Readmission				
Yes	13	6 (6.5%)	7 (7.3%)	0.820
No	176	87 (93.5%)	89 (92.7%)	
Eclampsia				
Present	3	2 (2.2%)	1 (1.0%)	0.542
Not present	186	91 (97.8%)	95 (99.0%)	
Cerebro-vascular accident				
Present	1	0 (0.0%)	1 (1.0%)	0.324
Not present	188	93 (100.0%)	95 (99.0%)	
Post-partum haemorrhage				
Present	23	11 (11.8%)	12 (12.5%)	0.888
Not present	166	82 (88.2%)	84 (87.5%)	
Acute kidney injury				
Present	7	2 (2.2%)	5 (5.2%)	0.266
Not present	182	91 (97.8%)	91 (94.8%)	
Liver injury				
Present	27	13 (13.9%)	14 (14.6%)	0.905
Not present	162	80 (86.0%)	82 (85.4%)	
Birth status				
Still birth*	8	7 (7.5%)	1 (1.0%)	0.027
Live birth	181	86 (92.5%)	95 (99.0%)	

*Significant variable $p < 0.05$

Table III. Logistic regression analysis

Outcome	Crude odds ratio with 95% CI	p value	Adjusted odds ratio with 95% CI	p value
Readmission				
Yes	-	-	-	-
No	-	-	-	-
Eclampsia				
Present	-	-	-	-
Not present	-	-	-	-
Cerebro-vascular accident				
Present	-	-	-	-
Not present	-	-	-	-
Post-partum haemorrhage				
Present	-	-	-	-
Not present	-	-	-	-
Acute kidney injury				
Present	-	-	-	-
Not present	-	-	-	-
Liver injury				
Present	-	-	-	-
Not present	-	-	-	-
Birth status				
Still birth	0.13 (0.06–0.92)	0.03	0.11 (0.13–0.88)	0.04
Live birth	1.00		1.00	

Table IV. Two-sample t test with equal variances for continuous variables

Variable	Group	Mean	Std. Error	Std. Dev	[95% Conf. Interval]		p value
Hospitalisation cost	Baseline	1,589.23	68.36	659.22	1453.47	1724.99	0.8323
	Follow-up	1,607.36	51.91	508.60	1504.31	1710.41	
Admission to delivery period differentials	Baseline	3.14	0.14	1.37	2.86	3.42	0.3142
	Follow-up	3.34	0.14	1.41	3.05	3.63	
Admission to discharge period differentials	Baseline	4.66	0.25	2.43	4.15	5.16	0.3542
	Follow-up	4.99	0.26	2.5	4.48	5.59	
Follow-up appointment from discharge differentials*	Baseline	13.19	1.16	11.17	10.89	15.49	0.0000
	Follow-up	6.84	0.38	3.72	6.09	7.59	

Cost in US\$. All women included in the analysis (93 at baseline and 96 at follow-up).

**Significant variable $p < 0.05$*

Supplemental material 1. ICD-10 codes included in analysis

Codes	Description of condition
11.1	Pre-existing hypertension with pre-eclampsia, first trimester
11.2	Pre-existing hypertension with pre-eclampsia, second trimester
11.3	Pre-existing hypertension with pre-eclampsia, third trimester
11.9	Pre-existing hypertension with pre-eclampsia, unspecified trimester
14.1	Severe pre-eclampsia, unspecified trimester
14.12	Severe pre-eclampsia, second trimester
14.13	Severe pre-eclampsia, third trimester
14.2	HELLP syndrome, unspecified trimester
14.22	HELLP syndrome, second trimester
14.23	HELLP syndrome, third trimester
15	Eclampsia in pregnancy, unspecified trimester
15.02	Eclampsia in pregnancy, second trimester
15.03	Eclampsia in pregnancy, third trimester
15.1	Eclampsia in labour
15.2	Eclampsia, in the puerperium
15.9	Eclampsia, unspecified as to time period