

# Reducing Outpatient Infant Blood Draws with Transcutaneous Measurement of Bilirubin

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## Abstract

**Introduction:** Newborn jaundice is a common outpatient problem. Transcutaneous bilirubin (TcB) measurements correlate well with total serum bilirubin (SB) measurements below 15 mg/dl and are efficient and noninvasive. Some concern exists that TcB measurement may subsequently lead to an increase in the number of SB measurements performed in the outpatient setting. We aimed to implement the use of a TcB device in an outpatient clinic. By doing so, we sought to increase the number of newborns screened solely by TcB as opposed to SB, by 30%, within 12 months. **Methods:** We conducted plan-do-study-act cycles with targeted interventions to promote the use of TcB in an outpatient clinic for eligible newborns older than 35 weeks gestational age, aged 1–20 days, and without a history of transfusion, phototherapy, extensive bruising, or risk of hemolysis. We used statistical process control methods to measure proportions of newborns evaluated with TcB (run chart) and patients-between SB measurements (G-chart) over time in the outpatient clinic. **Results:** We collected preintervention data for 18-months and intervention data for 12 months. For newborns attending the outpatient clinic, the proportion of TcB measurements increased after implementation of the use of TcB measurement. There was an increase in patients-between SB measurements. At project inception, SB was drawn for every 8 eligible patients. By the end of the project, there were 98 eligible newborns between instances of SB testing. **Conclusion:** Implementation of a quality-improvement initiative to measure TcB in the outpatient clinic was feasible and reduced the number of SB tests. (*Pediatr Qual Saf* 2020;4:e335; doi: 10.1097/pq9.000000000000335; Published online 7 July, 2020.)

## INTRODUCTION

Bilirubin level measurement in newborns occurs by visual assessment, total serum bilirubin (SB), and, more recently, transcutaneous bilirubinometry (TcB). Measuring SB requires a heel stick or a venous blood draw, resulting in one or more painful procedures, iatrogenic blood loss, increased waiting time, and laboratory costs. In inpatient newborns, TcB reduces the need for blood draws by more than one third,<sup>1,2</sup> and in this population, it also reduces cost and

painful procedures.<sup>3</sup> TcB correlates well with SB in the immediate newborn period,<sup>4,5</sup> at least at TcB levels <15 mg/dl, and possibly above this.<sup>6</sup> Outpatient use of TcB is not extensively evaluated. TcB used for outpatient follow-up reduces the incidence of blood draws for bilirubin in some studies.<sup>7,8</sup> Transcutaneous bilirubinometry used in the outpatient setting has been shown to reduce the incidence of very high bilirubin values (>25 mg/dl), reduce the age at admission for phototherapy, and reduce the duration of phototherapy.<sup>7</sup>

Despite these benefits, concern persists that TcB may not be a reliable<sup>9</sup> or efficient<sup>10</sup> substitute for SB in the clinic. These concerns may contribute to an increase in SB blood draws in the outpatient setting,<sup>11</sup> due to ease of use of TcB, if providers must verify elevated TcB levels with serum measurements. This concern is related to device limitations requiring verification of levels >15 mg/dl or within close range of the phototherapy threshold on the American Academy of Pediatrics (AAP) phototherapy nomogram, based on local protocol. TcB ease of use comes from device availability in the clinic as a noninvasive test performed by scanning a newborn's forehead or chest. It is a similar technique to using a temporal thermometer. The device provides results in less than 1 minute.

This quality improvement project implemented a TcB measurement device and aimed to increase the number

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of low-risk newborns older than 35 weeks gestational age screened by TcB as opposed to SB. We measured the desired outcome as an increase in newborn visits between each patient tested by SB, to increase this number by 30% over 12 months of implementation.

## METHODS

### *Context*

The General Academic Pediatric outpatient clinic at Children's Hospital at Dartmouth-Hitchcock (CHaD) implemented the project. CHaD is a tertiary hospital and academic center with approximately 1200 annual deliveries in 2016–2018. The population is primarily rural and Caucasian. Interns, residents, advanced practice providers, and attending pediatricians see newborns and children at the CHaD clinic. Newborns are admitted to the CHaD newborn nursery if they are greater than or equal to 35 weeks gestational age and do not require central monitoring or continuous intravenous infusions. In the nursery, predischarge TcB is obtained universally to screen all newborns; however, the device was not used in the CHaD clinic before this study. Newborns are seen in the CHaD clinic for an initial newborn follow-up visit 24–72 hours after nursery discharge and at 2 weeks of age per AAP recommendations, with additional visits as needed. Before the implementation of the transcutaneous bilirubinometer, providers decided to test SB based on clinical discretion. Concurrent with clinic device implementation, we developed and disseminated a local clinic guideline so that clinicians could readily distinguish between TcB eligible and noneligible newborns (detailed in Implementation).

### *Method Selection*

We used plan-do-study-act (PDSA) cycles, within the Institute for Healthcare Improvement Model for Improvement framework, to introduce TcB measurement as an alternative to SB levels in the outpatient setting. The use of PDSA cycles allowed for the evaluation of changes before a further adjustment and additional cycles.

### *Implementation*

In January 2018, TcB measurement was introduced in the CHaD clinic as an alternative to SB levels. A newly developed clinical policy guided the use of the transcutaneous bilirubinometer and included newborn eligibility criteria. We made TcB available in the clinic, at provider discretion as an alternative to SB. The implementation of the device included strict criteria to obtain SB for any TcB result of >15 mg/dl, or if the TcB result was within 2 points of the phototherapy threshold on the AAP phototherapy nomogram. Eligible newborns included those greater than or equal to 35 weeks gestational age and 1–20 days old who were born at CHaD and presented for newborn follow-up to the hospital-based primary care pediatric clinic. Noneligible newborns included those with

excessive bruising of the forehead or chest precluding use of the device, history of transfusion, history of inpatient phototherapy, or high risk of hemolysis, as evidenced by a positive direct antibody test. The clinic staff developed and disseminated policies and procedures on the use of TcB to all providers. TcB use was not a universal screener in the outpatient clinic but used at provider discretion as an alternative to serum lab draw for the patient with concern for hyperbilirubinemia. All infants received universal screening for hyperbilirubinemia before discharge from the CHaD newborn nursery.

### *Interventions*

A team of health care providers, including pediatric residents, general pediatric attending physicians, clinic nurses, medical assistants, and a pediatric hospitalist, met and planned to institute a new transcutaneous bilirubinometer in the outpatient clinic.

We used academic detailing to ensure standardized implementation through 4 PDSA cycles. Pediatric residents involved in the project determined the next step intervention for each PDSA cycle. The first PDSA cycle consisted of the arrival of the transcutaneous bilirubinometer and the first draft of the TcB clinic policy proposal. PDSA cycle 2 included a TcB reminder message in the clinic workroom that provided information on the new transcutaneous bilirubinometer available for use in the clinic by all staff and providers. PDSA cycle 3 consisted of a clinic staff meeting and a resident conference to promote TcB use, including indications for TcB use in the clinic. PDSA cycle 4 involved further academic detailing with an additional resident discussion. Figure 1 contains annotations of the timeline of PDSA cycles.

### *Study of the Interventions*

We performed a retrospective chart review and collected preintervention data from June 9, 2016, to December 31, 2018, and postintervention data from January 1, 2018, to December 8, 2018. The primary data evaluated included the first TcB or SB per newborn tested in the outpatient clinic; we reported subsequent test results separately. This approach allowed for a count of individual newborns who experienced clinic bilirubin testing, not the total number of tests. We collected data on subsequent TcB and SB tests to determine if TcB testing contributed to additional SB testing.

### *Measures*

We evaluated the use of TcB and SB during newborn follow-up visits for eligible patients, with increases in TcB as the process measure and decreases in SB as the outcome measure. We assessed the proportion of patients with bilirubin measurements done by TcB versus SB during the PDSA cycle over a total of 31 months. We evaluated the number of repeat tests for bilirubin as well as the number of newborns who required admission for inpatient phototherapy treatment after testing as balancing measures.

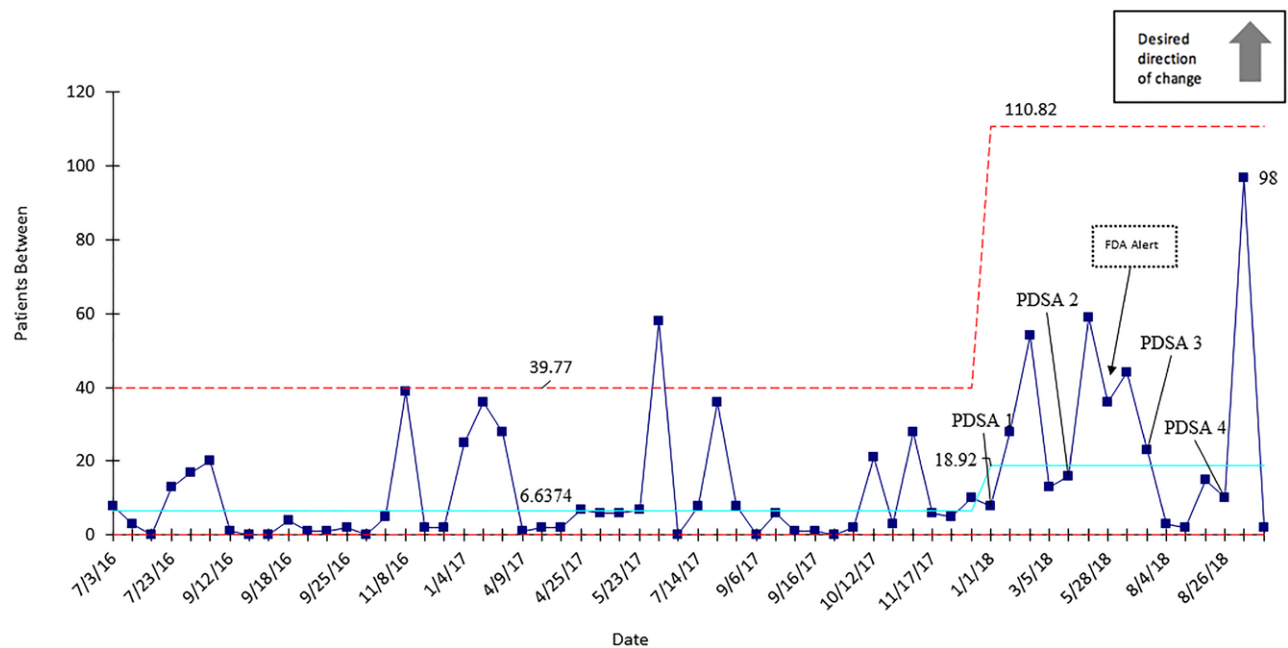


Fig. 1. G-chart of patient between blood draws for serum bilirubin.

Two individuals (K.C.K. and E.J.M.) independently reviewed the data for quality assurance.

### Analysis

We used statistical process control methods for quantitative analysis. The primary outcome was eligible newborn patients seen in the clinic between blood draws for SB, as plotted on a G-chart. The G-chart is used because bilirubin testing is a relatively rare event in the outpatient clinic, even at newborn follow-up visits. The desired direction of change was an increase in the patients-between SB blood draws. Multiple monthly data collection periods had a numerator of zero, indicating no SB drawn for an entire month. The G-chart allowed evaluation of process control stability before and after implementation of the SB device and how the change affected blood draws for SB. A run chart tracked the use of the TcB measurement device, with the proportion of newborns who had TcB measured, to determine if implementation had indeed been successful in promoting usage. A run chart tracks the number of SB done without previous measurement of TcB to evaluate testing not done as verification of elevated TcB.

### Ethical Considerations

The project was submitted to the internal review board and deemed exempt from the institutional review due to the nature of quality improvement, not meeting the definition of human subjects research.

## RESULTS

There were 903 newborns included who met eligibility criteria in this QI initiative; we excluded 8 newborns.

The preintervention period included 492 eligible newborns, of which 490 (99.5%) met inclusion criteria. The postintervention period included 419 eligible newborns, of which 413 (98.5%) met inclusion criteria. The 2 newborns excluded in the preintervention period and the 6 newborns excluded in the postintervention group met exclusion criteria due to direct antiglobulin test-positive status. Late preterm infants from 35 weeks to 36 weeks 7 days made up 4.8% of the preintervention newborns and 4.5% of the postintervention group. There were no significant differences in demographic data for the preintervention and postintervention groups (Table 1).

During the implementation period, we saw the use of the TcB measurement device in eligible newborns, with a rise in use after PDSA cycles and a decline in use after the Food and Drug Administration (FDA) released a warning regarding TcB measurement devices<sup>12</sup> (Fig. 2). This warning highlighted a possible misinterpretation, as the device displayed “-0-” when levels were too high to read. This result led to concern for incorrect interpretation of this as zero. Subsequently, the clinic disseminated this information to all staff to prevent misinterpretation. During this study, no data existed on newborns with recorded TcB of 0mg/dl or reading of -0-. Figure 1 is a G-chart of the number of patients-between SB blood draws. The G-chart is used to track rare events and was the chosen control chart because blood draws for SB exist as a relatively rare event in our population. As demonstrated in Figure 1, in the preintervention period, a high degree of instability occurred in patients-between blood draws for SB with no points crossing the control limit. In the postintervention period, there are no points above the control limit. Still, there is a trend toward increasing

**Table 1. Demographic Data for Preintervention and Postintervention Groups**

	Preimplementation (n = 490)	Postimplementation (n = 413)	P
Percent female (%)	45.7	50.6	0.14
Median birth weight (g)	3,365	3,338	0.62
Median gestational age	39wk 0 d	39wk 0 d	0.74

patients-between blood draws for SB with a peak of 98 patients-between blood draws, a percent change of 1125% at the peak from initiation. However, there was a subsequent decline in patients-between blood draws following this peak.

The balancing measure was the number of repeat tests for bilirubin measurement. In the preintervention period, there were a total of 4 (0.08%) newborns who returned to the clinic for a second bilirubin measurement, all of which were SB in this group. In the postintervention period, there were 7 (0.02%) newborns who returned for a second bilirubin measurement, 5 of which were TcB, and 2 infants had a clinic visit with TcB followed by verification with SB. There were 2 (0.004%) newborns who returned for a third bilirubin measurement, of which all were SB. Figure 3 demonstrates the number of newborns who had SB measurements done without a prior TcB. In the preintervention period, 2 newborns were admitted for phototherapy (0.4% of total eligible newborns), one of which was a late preterm infant, and 4 newborns were admitted in the postintervention period for phototherapy (0.9%), 3 of which were late preterm infants. No newborns were admitted for exchange transfusion throughout the project, and no newborns required readmission for a second treatment with phototherapy.

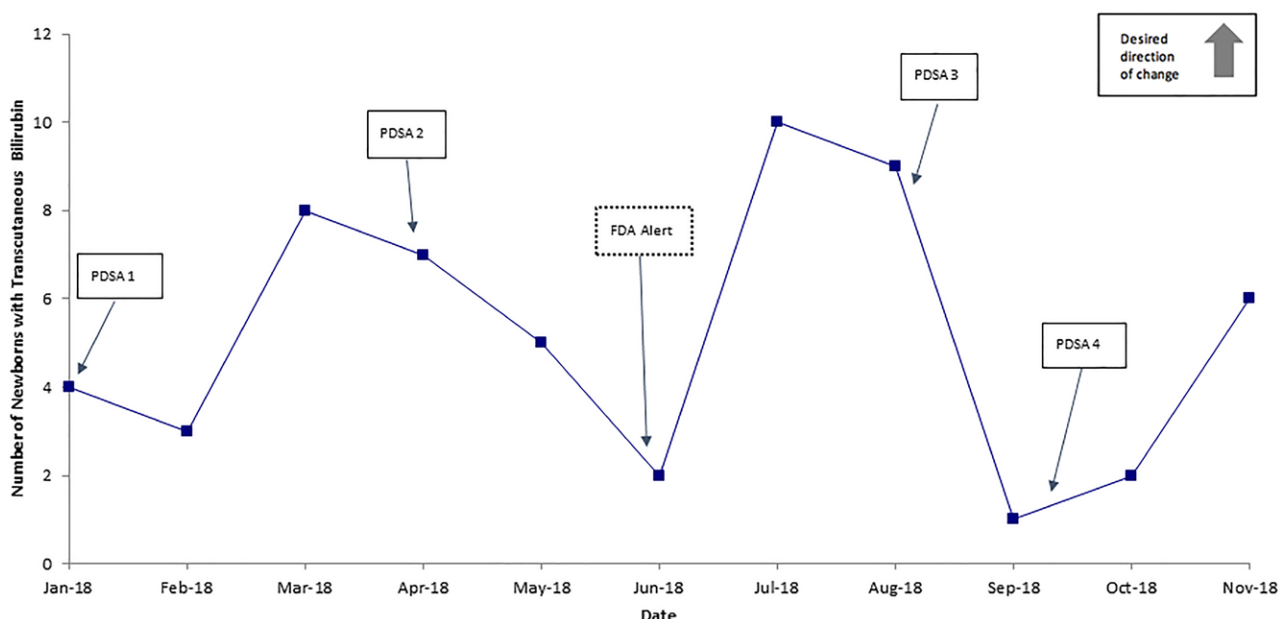
## DISCUSSION

We completed a quality improvement project that evaluated the implementation of a transcutaneous bilirubinometer in an outpatient clinic, which successfully promoted the use of the device without increasing SB testing.

The introduction of the bilirubinometer required multiple interventions to promote usage. Academic detailing included educational conferences, feedback, signage, and email reminders. The FDA issued an alert in June 2018<sup>12</sup> for error potential with the type of device used in the study clinic. The device would display “-0-” when levels were too high to read, with concern for incorrect interpretation as a value of 0.0mg/dl. Following the FDA warning, no increase in serum blood draws resulted. Instead, an increase in patients-between blood draws occurred.

Before the interventions, there was a repeated pattern of special cause with a persistently low number of patients-between demonstrating a pattern of frequent SB testing. In the preintervention period during June 2017, there was also a significant increase in patients-between blood draws, with this point above the UCL. This finding may be related to intern-level providers having increased comfort levels with visual assessment by the end of their first year of training. However, this pattern was not present in 2016. Additionally, the period from May 2017 to August 2017 shows variability with points alternating across both sides of the centerline.

With the introduction of the interventions, there was the detection of special cause variation; therefore, the control limits were recalculated to reflect process change. There was initially a significant concern that the ease of use of the transcutaneous bilirubinometer would lead providers to obtain bilirubin measurements that they would not have obtained in the past when bilirubin measurement



**Fig. 2.** Run chart of eligible newborns with transcutaneous bilirubin measurement.



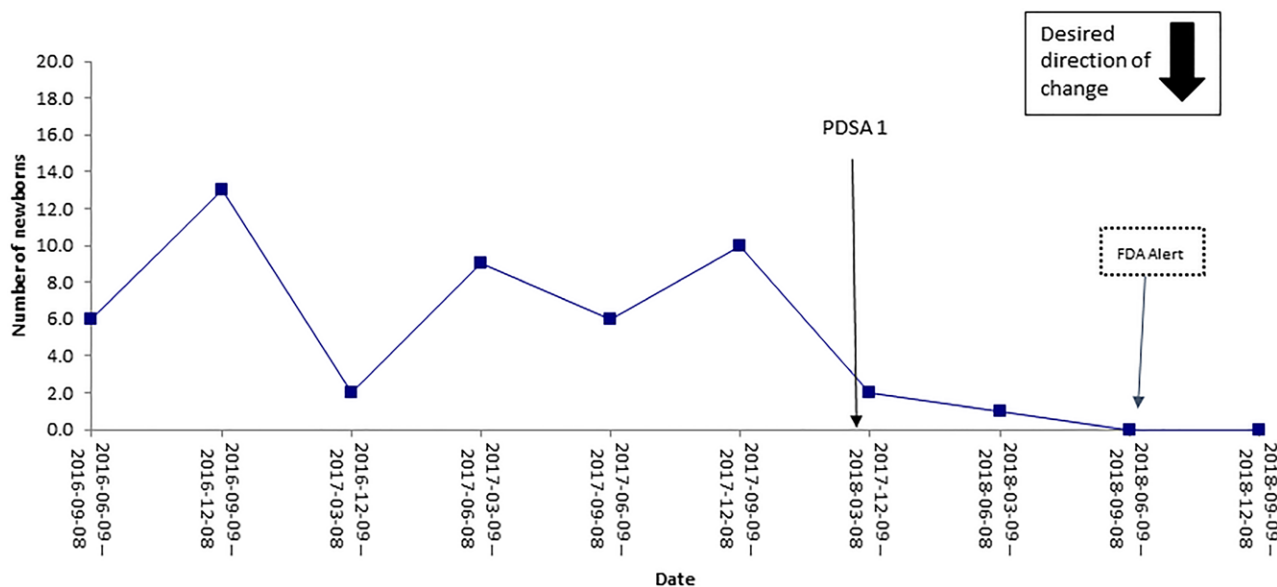


Fig. 3. Run chart of the number of serum bilirubin measurements without previous transcutaneous bilirubin.

always required a blood draw. There was further concern that this could cause an increase in SB draws for newborns with measurements over 15 mg/dl or within 2 points of the AAP phototherapy threshold. This concern is due to TcB being less reliable at these levels. This consequence did not happen: as the rate of TcB measurements increased, there was a trend toward an increase in patients-between SB to a peak of 98 patients-between. The number of patients who had SB obtained as a first test, as opposed to as a verifier of TcB, decreased over time, as seen in Figure 3.

The use of TcB may reduce the overall cost of testing for hyperbilirubinemia in this patient population, as the device has a one-time cost as opposed to the ongoing costs of laboratory testing. The estimated cost per TcB screen in hospital and community (urban and rural) settings was \$3.54 and \$3.76, respectively. The estimated cost per SB screen in hospital and urban and rural community settings was \$15.82, \$50.21, and \$65.03, respectively. In addition to anticipated cost-saving of the actual test, the bilirubinometer also saves time for providers and families as results are immediately available. There was also concern that the use of TcB may also result in additional testing and, therefore, further clinic visits, which would increase costs. We used repeat clinic visits for subsequent bilirubin testing as the balancing measure. There was a more significant proportion of infants in the pre-intervention period who returned for subsequent testing compared with the postintervention period.

This improvement project was the first of its kind performed in the outpatient clinic setting, despite a robust literature on inpatient newborn testing for TcB. It remains unknown if the use of TcB increases the total number of bilirubin tests ordered, as ease of use may result in repeated TcB testing even if not clinically indicated. We evaluated the use of the transcutaneous bilirubinometer as an alternative

to serum testing in newborns at low risk for hyperbilirubinemia. Those with risk factors may be amenable to initial testing with TcB, but this requires further evaluation. This project is limited by taking place at a single center with a single TcB measurement device, and by our local clinic policy which excluded infants who were direct antiglobulin test positive. The population is primarily Caucasian, and a diverse population would likely impact use frequency due to increased limitations of TcB use in newborns with different skin tones, as previous studies have demonstrated an increased range of error in these newborns.<sup>13</sup> Due to the instituted local policy on transcutaneous bilirubinometer use, and training of providers and ancillary staff in the use of the device, we expect sustained use of the device.

Future directions for the evaluation of hyperbilirubinemia in low-risk newborns in the outpatient setting would include a more substantial, diversified population over a longer timeframe. A project examining caregiver and provider comfort with the safety of TcB testing and satisfaction of using the transcutaneous bilirubinometer would provide additional information.

## CONCLUSIONS

A quality-improvement initiative to screen for treatable hyperbilirubinemia by transcutaneous bilirubinometry in the outpatient setting appeared to reduce the number of blood draws for total SB. The ease of use of transcutaneous bilirubinometry did not have the untoward effect of increasing follow-up SB measurements.

## DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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