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Efficacy of normogram using trans cutaneous bilirubin meter in reducing the number of serum bilirubin sampling in post natal ward of a tertiary care hospital in Pakistan.

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Keywords:	Audit, Jaundice, Neonatology

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Title: Efficacy of normogram using transcutaneous bilirubin meter in reducing the number of serum bilirubin sampling in post natal ward of a tertiary care hospital in Pakistan.

Introduction: Neonatal jaundice is the most common cause of concern in immediate newborn period for parents as well as for the care givers in healthy term and near term babies. Majority of the times it is a benign condition and resolves by itself but rarely it can lead to permanent neurological damage i.e. kernicterus even in good weight term or near term babies[1].

Traditionally babies with neonatal hyperbilirubinemia are identified with clinically visible jaundice by health care providers using Kramer's scale [2] and relying on their clinical judgment blood samples for Total Serum BiliRubin (TSBR) are sent for confirmation before starting treatment[3], clinical expertise varies from person to person and may lead to sending excessive blood sampling due to the fear of bilirubin encephalopathy[4,5]. Serum sampling is a painful procedure, it requires skilled health personnel and frequent sampling can expose baby to a risk of infection and iatrogenic anemia, moreover laboratory tests are costly and results can come late leading to waiting and unnecessary delays in commencing phototherapy and discharge from hospital[3].

Transcutaneous bilirubin (TcB) measurement devices use multiwavelength spectral reflectance from the skin surface and can be used to estimate total serum or plasma bilirubin (TB), and, thus, avoid blood sampling. It is being used for years as a noninvasive and rapid screening tool to identify babies with neonatal hyperbilirubinemia[6] and various studies have shown that it is safe, easy to use and its readings correlates well with TSBR level [7]and its use does not cause any delay in starting treatment for significant hyperbilirubinemia. TcBR test is a 'Point of Care' test (bed side test) that can be performed by physicians, nurses or any other health caregiver with in hospital or in community[8]. One RCT done in Netherlands showed significant reduction in serum sampling in TcBR group[9]. TcBR is an inexpensive test and can be done in well babies prior to discharge [10]. TcBR test performed at midsternum is better than forehead as forehead [11].TSBR test is still a gold standard test and TcBR does not completely substitute it[12]. Although TcBR is well established screening test but its use is still notuniversal, one telephonic survey done in developed world revealed only 27% ward using it as screening test.

Most studies on the use of TcBR are done to establish its accuracy, comparing TSB with TcBR levels. Implementation of TcB in hospital or community-screening program is associated with a reduction in the incidence of severe TB and readmission for phototherapy, and lower duration and rate of phototherapy [18]. Study done from our institute 25 years back showed a poor sensitivity and specificity of TcBR of 88% and 53% respectively[14]. Important to note was the small sample size and both term and preterm infants were enrolled. Similar study from Pakistan during the same era showed good sensitivity[15]. Technology has advanced significantly since then with newer and more sophisticated devices with good precision. Recent data from Pakistan have shown good correlation of TcBR with TSBR[16]. Although several transcutaneous bilirubin normograms have been evaluated, significant differences exists across populations based on

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ethnicity, race and bilirubin kinetics[17]. Up to the best of our knowledge no study has been performed using transcutaneous bilirubin normogram in Pakistan. Therefor our study is different because for the first time we will use a transcutaneous bilirubin normogram(Attached) to plot the readings of TcBR and only do serum TSBR sampling when the readings cross the TcBR line(Blue Line). A systematic review based upon four studies that constructed TcB nomograms from predominately Caucasian, Thai, or Hispanic populations reported TcBR nomogram values varied among the ethnic groups. Therfore it is imperative to know the normogram for our babies. We hypothesize that if our TcBR normogram is safe and effective this will reduce the number of serum sampling significantly and will be incorporated into the hospital phototherapy protocol.

Objectives: 1) We intend to implement a quality improvement program by introducing a normogram using transcutaneous bilirubin meter to reduce number of serum bilirubin sampling in term well babies.

Study Design: Pre and post analysis design.

Settings: Post natal ward of Aga khan university hospital Karachi.

Duration: 13 months (Pre implementation six months from 1-09-2016 to 28-02-2017, implementation phase one month 01-03-02017 and post implementation six months from 1-04-2017 to 30-09-2017)

Inclusion Criteria: All well babies admitted to AKU post natal ward from 1st September 2016-30th September 2017 with gestational age 37 weeks or more with birth weight more than 2500 grams having clinical jaundice after 24hrs of life till 7 days of life

Exclusion criteria: 1) Babies having clinical jaundice within 24 hours of life or after 7 days of life.

2) Babies at high risk for neonatal hyperbilirubinemia i.e. Preterm, Low birth weight, babies with positive maternal antibodies, babies with positive coombs test, babies requiring serum TSBR sampling within 24 hours of life, babies already on phototherapy, history of sibling with G6PD deficiency, history of sibling with kernicterus, history of sibling requiring exchange transfusion for neonatal hyperbilirubinemia.

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Operational definitions:

Clinical jaundice: Yellow discoloration of skin reaching up to abdomen assessed by trained health worker i.e. physician or nursing staff.

Term: Babies born at 37 to 42 weeks of gestation.

Preterm: Babies born before 37 weeks of gestation.

Low Birth Weight (LBW): Birth weight less than 2500 grams.

Methodology and Data Collection:

The study will be performed in two phases.

Phase 1: (pre implementation phase).

Duration: 6 months (1st sep 2016-28th feb 2017)

All neonates admitted in post natal ward will be identified using birth records. Babies full filling inclusion criteria will be selected and those who's TSBR are sent will be enrolled. Following data will be collected on a predesigned proforma.

Demographic data including gestational age, chronological age , gender and birth weight, mother's blood group, baby's blood group from the hospital database .TSBR data will be retrieved from the laboratory's online database and all babies who received phototherapy will be identified by reviewing medical records and cross-checked against nursery discharge data.

Implementation phase: (March 1st 2017 till March 31st 2017)

Two Dragger JM105 transcutaneous bilirubinometer will be recruited, one for each well baby nursery. Both devices will be regularly calibrated and serviced by our hospitals biomedical department. Using Bhutani[13] Neonatal bilirubin chart a new line will be drawn 2 mg/dl below the phototherapy line for low risk babies and will be named as TcBR line because literature review reveals a variation of ± 1 mg/dl in results of TcBR and TSBR.[19] For simplification the high and intermediate risk lines will be removed from the chart since those babies will not be the study population and their management will be done according to the hospitals jaundice protocol. The lines will be color coded. Phototherapy line will be of red color whereas TcBR line will be blue colored. Attached is the sample of modified Bhutani Chart for neonatal Hyperbilirubinemia.

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Prior to the implementation of transcutaneous bilirubinometer protocol, hands on training and competency certification of all neonatal staff and physicians will be done by senior neonatologist/nurse instructor regarding its proper use and all components of study protocol will be explained .Protocol flow chart and Modified Bhutani chart will given to all post natal nurses and physicians and also pasted at all post natal ward areas for reference.

The study will be approved by the hospitals ethical review committee.

Flow Chart for Neonatal Jaundice in term Well Babies (Pre implementation Phase)

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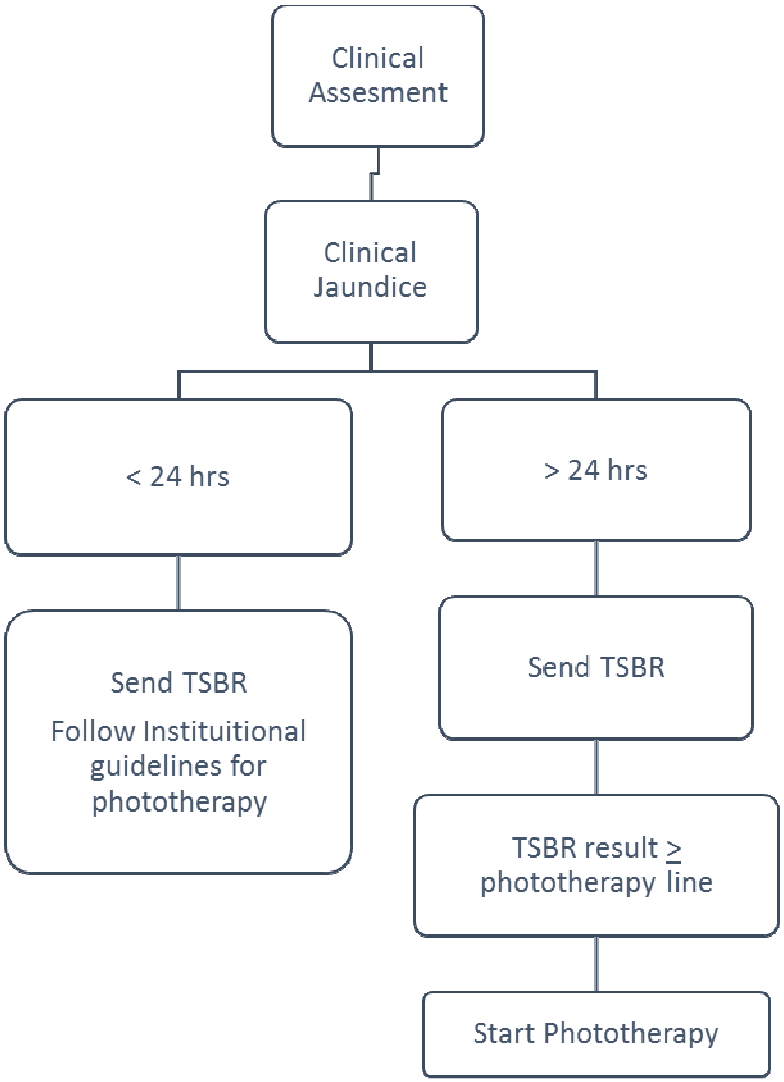

Phase 2: (Post Implementation Phase)

Duration: 6 months

All babies meeting inclusion criteria having clinical jaundice assessed by nursing staff/paeditric resident/neonatology fellow will be approached. Basic demographic and anthropometric data will be recorded. TcBR will be performed using dragger JM105. Three consecutive readings will be taken on the sternum and average result will be recorded on the proforma. If TcBR level falls on or over Red line(Phototherapy line), serum TSBR will be sent and phototherapy will be started. If TcBR level falls on or over Blue line(TcBR Line) then serum TSBR will be sent, and

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phototherapy will be started only if TSBR falls on or over Red Line (phototherapy line). All babies with TcBR or TSBR level below Blue line (TcBR line) will be followed with TcBR testing after every 8 hours untill resolution of clinical jaundice.

Protocol flow chart attached.

Flow Chart for Neonatal Jaundice in Term well Babies (Post implementation Phase)

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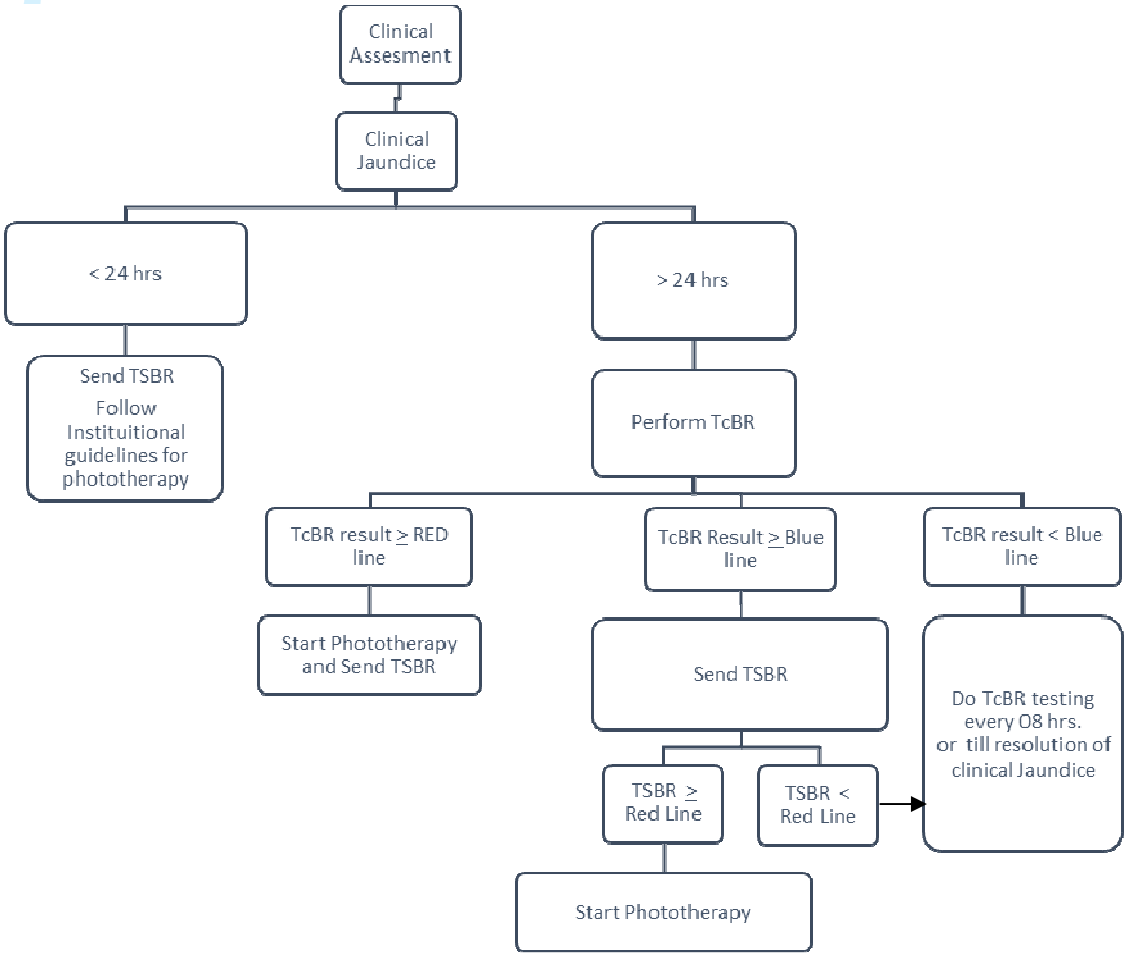

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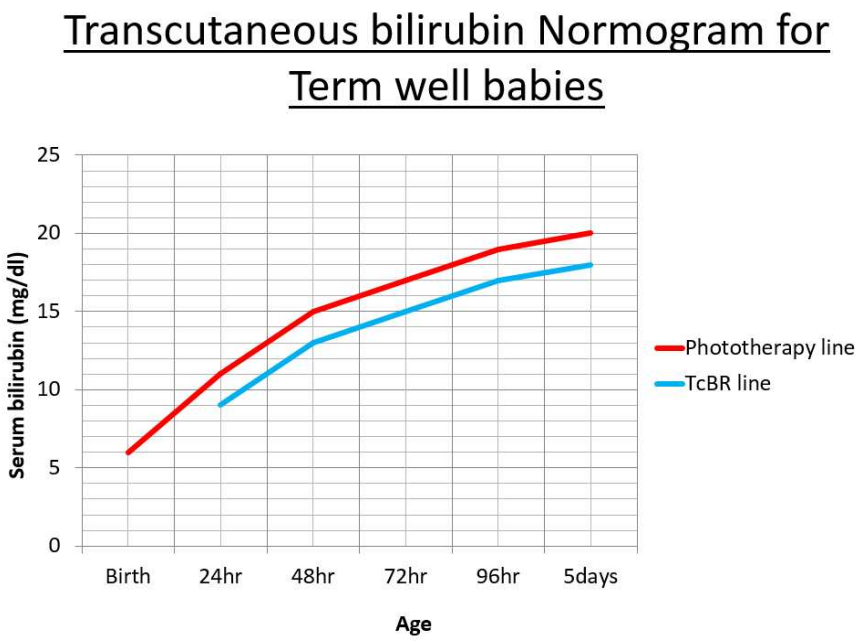

Outcome:

Primary outcome:

a. Reduction of serum sampling for TSBR.

Secondary outcomes:

a. Assessment of accuracy of bilimeter in Pakistani population.

b. Reduction in cost of serum sampling of TSBR.

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Analysis plan and Results: Analysis will be done on SPSS v.19.

Means with standard deviations will be used for normally distributed data. Comparisons between the two groups will be made using equality of variances test and two independent t test for comparing means. The proportion of infants having a TSBR performed in both periods will be compared with the chi square test.
Sampling cost of TSBR will be obtained from laboratory and Cost comparison between two phases will be done to look for difference.
We will use SQUIRE v2.0. Guidelines for reporting our findings[20].

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A quality improvement project to reduce the number of serum sampling using transcutaneous bilirubin nomogram in post natal ward of a tertiary care hospital in Pakistan.

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Keywords:	Jaundice, Neonatology

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Title: A quality improvement project to reduce the number of serum sampling using transcutaneous bilirubin nomogram in post natal ward of a tertiary care hospital in Pakistan.

Key words: hyperbilirubinemia, Neonate, transcutaneous bilirubin meter

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Abstract:

Introduction: Neonatal jaundice is a common cause of concern in immediate newborn period for parents as well as for the care givers. Babies with visible jaundice are identified by the health care provider and blood samples are sent for confirmation. Clinical expertise varies from person to person and may lead to sending excessive blood sampling. Serum sampling is a painful procedure, it predisposes the baby to infections and requires skilled health personnel. Moreover laboratory tests are costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from hospital. Transcutaneous bilirubinometer has been in use for a long time as screening tool in post natal wards. With passage of time its accuracy and validity have improved tremendously. **Methodology:** We aim to implement a quality improvement initiative to reduce the number of serum sampling using transcutaneous bilirubin nomogram in full term, low risk babies who are born at our hospital and are admitted in post natal ward after birth. Using Pre and post analysis study design this study will be performed in two phases of 6 months each. Data regarding total number of admissions in post natal wards, demographics, serum bilirubin samplings (TSBR) and need for phototherapy will be recorded in both phases. TcBR will be done and recorded in post implementation phase. **Analysis and results:** Comparisons between the two groups will be made. Primary outcome will be reduction in serum sampling for TSBR after the implementation of TcBr protocol. The proportion of infants having TSBR performed in both periods will be compared. Crude Sampling cost of TSBR will be obtained from laboratory and cost comparison between two phases will be done to look for difference.

Summary Box:

What is already known about this subject:

- Neonatal jaundice is a common cause of concern both for care givers and parents.
- If left unrecognized it can lead to serious complications like bilirubin encephalopathy.
- Transcutaneous bilirubin meter has proven to be a good tool for screening of neonatal jaundice.

Whats New:

- We are presenting a quality improvement protocol to reduce the number of serum sampling for neonatal jaundice.
- We have introduced a TcBR nomogram for the first time in Pakistani population

How might it impact on clinical practice in the foreseeable future:

- If successful this can be used at a larger scale for improvement in quality and reduction in cost of care for babies with neonatal jaundice.
- If successful it can be used as a universal screening protocol for our babies.

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Title: A quality improvement project to reduce the number of serum sampling using transcutaneous bilirubin nomogram in post natal ward of a tertiary care hospital in Pakistan.

Introduction: Neonatal jaundice is a common cause of concern in the immediate newborn period for parents as well as for care givers. It occurs in many newborns, usually after the first 24 hours of life and spontaneously resolves over the next few days. If deep and prolonged jaundice remains unrecognized, it can lead to bilirubin encephalopathy and permanent neurological damage. [1]

Traditionally babies with neonatal hyperbilirubinemia are screened clinically using Kramer's scale or by using other modalities[2] .Serum sampling for total serum bilirubin (TSBR) is usually done to confirm and start treatment once jaundice is identified.[3] Serum TSBR sampling is a resource intense procedure. It requires skilled health personal and can also lead to nosocomial infections.[4] Moreover laboratory testing is costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from the hospital.[5]

Transcutaneous bilirubin (TcBR) measurement devices use multiwavelength spectral reflectance from the skin surface and can be used to estimate total serum or plasma bilirubin and thus avoid blood sampling. TcBR is a 'Point of Care' test (bed side test) that can be performed by physicians, nurses or any other health caregiver with in hospital or in community.[6] It is used as a noninvasive, rapid screening tool to identify babies with neonatal hyperbilirubinemia.[7] Various studies have shown its efficacy, safety and utility.[8-9] One randomized controlled trial (RCT) done in Netherlands showed significant reduction in serum sampling in TcBR group compared with non TcBR group.[9] TcBR is an inexpensive test,[10] and can be performed over forehead or mediastinum but studies suggest that measurements over mediastinum are better than forehead.[11] Despite its utility only 27 % of the hospital wards are using TcBR as a screening tool.[9]

Although TcBR is a good screening tool but TSBR is still the gold standard for diagnosing and commencing phototherapy.[12] Most studies on the use of TcBR are done to establish its accuracy, comparing TSBR with TcBR levels. Implementation of TcBR in hospital or community-screening program is associated with a reduction in the incidence of severe neonatal jaundice, readmission for phototherapy, and lower duration and rate of phototherapy .[13] Study done on TcBR from our institute 25 years back showed a poor sensitivity and specificity of 88% and 53% respectively.[14] Important to note was the small sample size and both term and preterm infants were enrolled. Similar study from Pakistan during the same era showed good sensitivity.[15] Technology has advanced significantly since then with the emergence of newer and more sophisticated devices with good precision. Recent data from Pakistan have shown good correlation of TcBR with TSBR.[16]

Although several transcutaneous bilirubin nomograms have been evaluated, significant differences exists across populations based on ethnicity, race and bilirubin kinetics.[17] A systematic review based on four studies that constructed TcBR nomograms from predominately Caucasian, Thai, or Hispanic populations reported TcBR nomogram values varied among the ethnic groups. Up to the best of our knowledge no study has been performed using transcutaneous bilirubin nomogram in Pakistan. Therefore it is imperative to know the nomogram for our babies. The Aim of our quality improvement initiative is to reduce the

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number of serum sampling by introducing a TcBR nomogram (Attached) to plot the readings of TcBR and only do serum TSBR sampling when the readings cross the TcBR line (Blue Line) We hypothesize that if our TcBR nomogram is safe and effective this will reduce the number of serum sampling significantly and will be incorporated into the hospital phototherapy protocol.

Objectives: 1) We intend to implement a quality improvement project to reduce the number of serum bilirubin sampling by introducing a transcutaneous bilirubin nomogram in term well babies admitted in the post natal ward of our hospital.

Study Design: Pre and post analysis design with preimplimentation phase being retrospective and post implementation phase as prospective cohort.

Settings: Post natal ward of Aga khan university hospital Karachi.

Duration: 13 months (Pre implementation six months from 1-09-2016 to 28-02-2017, implementation phase one month 01-03-02017 to 31-03-2017 and post implementation six months from 1-04-2017 to 30-09-2017).

Inclusion Criteria: All well babies admitted to AKU post natal ward from 1st September 2016-30th September 2017 with gestational age 37 weeks or more with birth weight more than 2500 grams having clinical jaundice after 24hrs of life but within 7 days of life.

Exclusion criteria: 1) Babies having clinical jaundice within 24 hours of life or after 7 days of life.

2) Babies at high risk for neonatal hyperbilirubinemia i.e. Preterm, Low birth weight, babies with positive maternal antibodies, babies with positive coombs test, babies requiring serum TSBR sampling within 24 hours of life, babies already on phototherapy, history of sibling with G6PD deficiency, history of sibling with kernicterus, history of sibling requiring exchange transfusion for neonatal hyperbilirubinemia.

Operational definitions:

Clinical jaundice: Yellow discoloration of skin reaching up to abdomen assessed by trained health worker i.e. physician or nursing staff.

Term: Babies born at 37 to 42 weeks of gestation.

Preterm: Babies born before 37 weeks of gestation.

Low Birth Weight (LBW): Birth weight less than 2500 grams.

Methodology and Data Collection:

The study will be performed in three phases.

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Phase 1: (pre implementation phase).

Duration: 6 months (1st September 2016-28th February 2017)

Data regarding all neonates admitted in post natal ward will be extracted retrospectively using medical records. Babies full filling the study criteria will be enrolled. Following data will be collected on a predesigned proforma.

Demographic data including gestational age, chronological age , gender and birth weight etc , will be extracted from the hospital database .TSBR data will be retrieved from the laboratory's online database and all babies who received phototherapy will be identified by reviewing medical records and cross-checked against nursery discharge data.[Figure 1]

Implementation phase: (March 1st 2017 till March 31st 2017)

Two Dragger JM105 transcutaneous bilirubin meter will be used, one for each well baby nursery. Both devices will be regularly calibrated and serviced by our hospitals biomedical department.

TcBR nomogram: TcBR nomogram will be made using American Academy of Pediatrics (AAP) guidelines for phototherapy threshold. A new line will be drawn 2 mg/dl below the phototherapy line for low risk babies and will be named as TcBR line because literature review reveals a variation of ± 1 mg/dl in results of TcBR and TSBR.[18] For simplification the high and intermediate risk lines will be removed from the chart since those babies will not be the study population and their management will be done according to the hospitals jaundice protocol. The lines will be color coded. Phototherapy line will be of red color whereas TcBR line will be blue colored. This modification in the AAP nomogram will be called TcBR nomogram. Attached is the sample of our TcBR nomogram. [Figure 2]

Prior to the implementation, hands on training and competency certification of all neonatal staff and physicians will be done by senior neonatologist/nurse instructor regarding its proper use and all components of study protocol will be explained .Protocol flow chart and TcBR nomogram will handed over to all post natal nurses and physicians and also pasted at all post natal ward areas for reference.

The study is approved by the hospitals ethical review committee.

Phase 2: **(Post Implementation Phase)**

Duration: 6 months (01-04-2017 till 30-09-2017)

All babies meeting inclusion criteria having clinical jaundice assessed by nursing staff/paeditric resident/neonatology fellow will be approached. Basic demographic and anthropometric data will be recorded. TcBR will be performed using dragger JM105Three consecutive readings will be taken on the sternum and average result will be recorded on the proforma. If TcBR level falls on or over red line (phototherapy line), serum TSBR will be sent and phototherapy will be started. If TcBR level falls on or over blue line(TcBR Line) then serum TSBR will be sent, and phototherapy will be started only if TSBR falls on or over red line (phototherapy line). All babies with TcBR or TSBR level below blue line (TcBR line) will be followed with TcBR testing after every 8 hours until resolution of clinical jaundice. [Figure3]

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Figure 3: post implementation phase protocol flow diagram.

Outcome:

Primary outcome:

a. Reduction of serum sampling for TSBR.

Secondary outcomes:

a. Assessment of accuracy of bilimeter in Pakistani population.

b. Reduction in cost of serum sampling of TSBR.

Analysis plan and Results: Analysis will be done on SPSS v.19.
Means with standard deviations will be used for normally distributed data. Comparisons between the two groups will be made using equality of variances test and two independent t test for comparing means. The proportion of infants having a TSBR performed in both periods will be compared with the chi square test.
Assessment of accuracy of bilirubin meter will be assessed by performing comparative analysis between TcBR and TSBR only on those babies in whom both are done.
Sampling cost of TSBR will be obtained from laboratory and Cost comparison between two phases will be done to look for difference.
We will use SQUIRE v2.0. Guidelines for reporting our findings.[19]

Discussion:

NICE guidelines 2016 for the management of neonatal hyperbilirubinemia recommends the use of TcBR for the screening of babies who are >24 hours old and more than 35weeks.[20] We aim to improve the quality of care given to our neonates by reducing the number of serum sampling using transcutaneous bilirubin nomogram on babies who are low risk and are more than 24 hours old. We believe that this will be decrease the requirement of serum sampling for TSBR and also reduce cost, infections, pain and delay in discharge from hospital. If the results are suggestive and favorable, this protocol will be incorporated into our hospitals phototherapy protocol. Furthermore it can also be used for our high risk population (with some modifications) once this study has been successfully completed. On a larger perspective this protocol can be used by other hospitals/settings throughout the developing world specifically the subcontinent.

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Figure Legends:

Figure 1: pre implementation phase flow diagram

Figure 2: Transcutaneous Bilirubin Nomogram

Figure 3: post implementation phase protocol flow diagram

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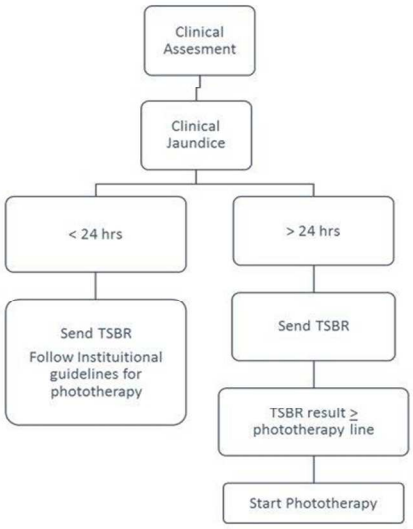
Figure 1: pre implementation phase flow diagram



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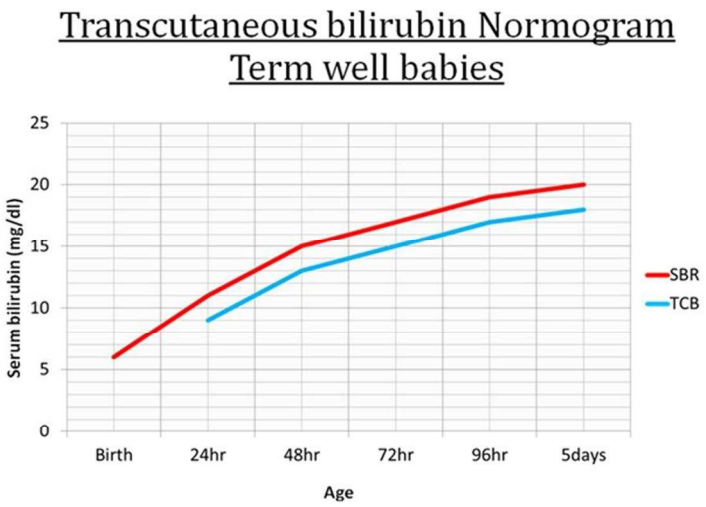

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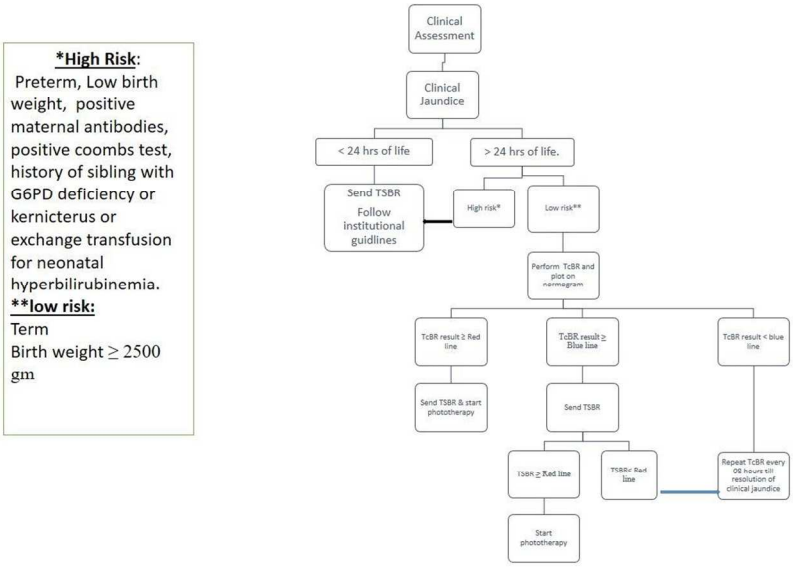

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BMJ Paediatrics Open

Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan

Journal:	*BMJ Paediatrics Open*
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Date Submitted by the Author:	06-Jul-2017
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Keywords:	Jaundice, Neonatology

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Title: Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan.

Key words: hyperbilirubinemia, Neonate, transcutaneous bilirubin meter

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Abstract:

Introduction: Neonatal jaundice is a common cause of concern in immediate newborn period for parents as well as for the care givers. Babies with visible jaundice are identified by the health care provider and blood samples are sent for confirmation. Clinical expertise varies from person to person and may lead to sending excessive blood sampling. Obtaining blood bilirubin samples is a painful procedure, it predisposes the baby to infections and requires skilled health personnel. Moreover laboratory tests are costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from hospital. Transcutaneous bilirubinometer has been in use for a long time as screening tool in post natal wards. With passage of time its accuracy and validity have improved tremendously. **Methodology:** We aim to implement a quality improvement initiative to reduce the number of blood bilirubin samples using transcutaneous bilirubin nomogram in full term, low risk babies who are born at our hospital and are admitted in post natal ward after birth. Using Pre and post analysis study design this study will be performed in two phases of 6 months each. Data regarding total number of admissions in post natal wards, demographics, serum bilirubin samplings (TSBR) and need for phototherapy will be recorded in both phases. TcBR will be done and recorded in post implementation phase. **Analysis and results:** Comparisons between the two groups will be made. Primary outcome will be reduction in blood bilirubin samples for TSBR after the implementation of TcBr protocol. The proportion of infants having TSBR performed in both periods will be compared. Crude Sampling cost of TSBR will be obtained from laboratory and cost comparison between two phases will be done to look for difference.

Summary Box:

What is already known about this subject:

- Neonatal jaundice is a common cause of concern both for care givers and parents.
- If left unrecognized it can lead to serious complications like bilirubin encephalopathy.
- Transcutaneous bilirubin meter has proven to be a good tool for screening of neonatal jaundice.

Whats New:

- We are presenting a quality improvement protocol to reduce the number of blood bilirubin samples for neonatal jaundice.
- We have introduced a TcBR nomogram for the first time in Pakistani population
- If successful this can be used at a larger scale for improvement in quality and reduction in cost of care for babies with neonatal jaundice.

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Title: Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan.

Introduction: Neonatal jaundice is a common cause of concern in the immediate newborn period for parents as well as for care givers. It occurs in many newborns, usually after the first 24 hours of life and spontaneously resolves over the next few days. If deep and prolonged jaundice remains unrecognized, it can lead to bilirubin encephalopathy and permanent neurological damage. [1]

Traditionally babies with neonatal hyperbilirubinemia are screened clinically using Kramer's scale or by using other modalities[2] .Blood bilirubin samples for total serum bilirubin (TSBR) is usually done to confirm and start treatment once jaundice is identified.[3] Serum TSBR sampling is a resource intense procedure. It requires skilled health personal and can also lead to nosocomial infections.[4] Moreover laboratory testing is costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from the hospital.[5]

Transcutaneous bilirubin (TcBR) measurement devices use multiwavelength spectral reflectance from the skin surface and can be used to estimate total serum or plasma bilirubin and thus avoid blood sampling. TcBR is a 'Point of Care' test (bed side test) that can be performed by physicians, nurses or any other health caregiver with in hospital or in community.[6] It is used as a noninvasive, rapid screening tool to identify babies with neonatal hyperbilirubinemia.[7] Various studies have shown its efficacy, safety and utility.[8-9] One randomized controlled trial (RCT) done in Netherlands showed significant reduction in blood bilirubin samples in TcBR group compared with non TcBR group.[9] TcBR is an inexpensive test,[10] and can be performed over forehead or mediastinum but studies suggest that measurements over mediastinum are better than forehead.[11] Despite its utility only 27 % of the hospital wards are using TcBR as a screening tool.[9]

Although TcBR is a good screening tool but TSBR is still the gold standard for diagnosing and commencing phototherapy.[12] Most studies on the use of TcBR are done to establish its accuracy, comparing TSBR with TcBR levels. Implementation of TcBR in hospital or community-screening program is associated with a reduction in the incidence of severe neonatal jaundice, readmission for phototherapy, and lower duration and rate of phototherapy .[13] Study done on TcBR from our institute 25 years back showed a poor sensitivity and specificity of 88% and 53% respectively.[14] Important to note was the small sample size and both term and preterm infants were enrolled. Similar study from Pakistan during the same era showed good sensitivity.[15] Technology has advanced significantly since then with the emergence of newer and more sophisticated devices with good precision. Recent data from Pakistan have shown good correlation of TcBR with TSBR.[16]

Although several transcutaneous bilirubin nomograms have been evaluated, significant differences exists across populations based on ethnicity, race and bilirubin kinetics.[17] A systematic review based on four studies that constructed TcBR nomograms from predominately Caucasian, Thai, or Hispanic populations reported TcBR nomogram values varied among the ethnic groups. Up to the best of our knowledge no study has been performed using transcutaneous bilirubin nomogram in Pakistan. Therefore it is imperative to know the nomogram for our babies. The aim of our quality improvement initiative is to reduce the

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number of blood bilirubin samples by introducing a TcBR nomogram (Attached) to plot the readings of TcBR and only do serum TSBR sampling when the readings cross the TcBR line (Blue Line). We hypothesize that if our TcBR nomogram is safe and effective this will reduce the number of blood bilirubin samples significantly and will be incorporated into the hospital phototherapy protocol.

Objectives: 1) We intend to implement a quality improvement project to reduce the number of blood bilirubin samples by introducing a transcutaneous bilirubin nomogram in term well babies admitted in the post natal ward of our hospital.

Study Design: Pre and post analysis design with preimplimentation phase being retrospective and post implementation phase as prospective cohort.

Settings: Post natal ward of Aga khan university hospital Karachi.

Duration: 13 months

Inclusion Criteria: All well babies admitted to AKU post natal ward from 1st September 2016-30th September 2017 with gestational age 37 weeks or more with birth weight more than 2500 grams having clinical jaundice after 24hrs of life but within 7 days of life.

Exclusion criteria: 1) Babies having clinical jaundice within 24 hours of life or after 7 days of life.

2) Babies at high risk for neonatal hyperbilirubinemia i.e. Preterm, Low birth weight, babies with positive maternal antibodies, babies with positive coombs test, babies requiring serum TSBR sampling within 24 hours of life, babies already on phototherapy, history of sibling with G6PD deficiency, history of sibling with kernicterus, history of sibling requiring exchange transfusion for neonatal hyperbilirubinemia.

Operational definitions:

Clinical jaundice: Yellow discoloration of skin reaching up to abdomen assessed by trained health worker i.e. physician or nursing staff.

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Methodology and Data Collection:

The study will be performed in three phases.

Phase 1: (pre implementation phase).

Duration: 6 months (1st September 2016-28th February 2017)

Data regarding all neonates admitted in post natal ward will be extracted retrospectively using medical records. Following data will be collected for all eligible cases..

Demographic data including gestational age, chronological age , gender and birth weight etc , will be extracted from the hospital database .TSBR data will be retrieved from the laboratory's online database and all babies who received phototherapy will be identified by reviewing medical records and cross-checked against nursery discharge data.[Figure 1]

Implementation phase: (March 1st 2017 till March 31st 2017)

Two Dragger JM105 transcutaneous bilirubin meters are being used, one for each well baby nursery. Both devices are being regularly calibrated and serviced by our hospitals biomedical department.

TcBR nomogram: TcBR nomogram is made using American Academy of Pediatrics (AAP) guidelines for phototherapy threshold. A new line is drawn 2 mg/dl (34.2 umol/l) below the phototherapy line for low risk babies and is named as TcBR line because literature review reveals a variation of ± 1 mg/dl(17.1 umol/l) in results of TcBR and TSBR.[18] For simplification the high and intermediate risk lines are removed from the chart since those babies are not the study population and their management is being done according to the hospitals jaundice protocol. The lines are color coded. Phototherapy line is of red color whereas TcBR line is blue colored. This modification in the AAP nomogram is called as TcBR nomogram. Attached is the sample of our TcBR nomogram. [Figure 2]

Prior to the implementation of the project , hands on training and competency certification of all neonatal health care providers has been undertaken by senior neonatologist/nurse instructor in which all components of study protocol were explained .Protocol flow chart and TcBR nomogram were handed over to all post natal nurses and physicians and also pasted at all post natal ward areas for reference.

The study is approved by the hospitals ethical review committee. Ref # 4742-PED-ERC-17

Phase 2: **(Post Implementation Phase)**

Duration: 6 months (01-04-2017 till 30-09-2017)

All babies meeting inclusion criteria having clinical jaundice assessed by nursing staff/pediatric resident/neonatology fellow will be approached. Basic demographic and anthropometric data will be recorded. TcBR will be performed using dragger JM105.Three consecutive readings will be taken on the sternum and mean result will be recorded on the proforma. If TcBR level falls on or over red line (phototherapy line), serum TSBR will be sent and phototherapy will be started. If TcBR level falls on or over blue line(TcBR Line) then serum TSBR will be sent, and

phototherapy will be started only if TSBR falls on or over red line (phototherapy line). All babies with TcBR or TSBR level below blue line (TcBR line) will be followed with TcBR testing after every 8 hours until resolution of clinical jaundice. [Figure3]. Figure 3: post implementation phase protocol flow diagram.

Sample size: As we have an average of 4000-5000 admissions in post natal wards per year out of which approx. 500-1000 are high risk babies, we anticipate a sample size of around 1500 eligible babies in each phase.

Outcome:

Primary outcome:

a. Reduction in the number of blood bilirubin samples for TSBR.

Secondary outcomes:

a. Assessment of accuracy of bilimeter in Pakistani population.

b. Reduction in the cost of blood bilirubin sampling between the two phases..

Analysis plan and Results: Analysis will be done on SPSS v.19.
Means with standard deviations will be used for normally distributed data. Comparisons between the two groups will be made using equality of variances test and two independent t test for comparing means. The proportion of infants having a TSBR performed in both periods will be compared with the chi square test.
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We will use SQUIRE v2.0. Guidelines for reporting our findings.[19]

Discussion:

NICE guidelines 2016 for the management of neonatal hyperbilirubinemia recommends the use of TcBR for the screening of babies who are >24 hours old and more than 35weeks.[20] We aim to improve the quality of care given to our neonates by reducing the number of blood bilirubin samples using transcutaneous bilirubin nomogram on babies who are low risk and are more than 24 hours old. We believe that this will be decrease the requirement of blood bilirubin samples for TSBR and also reduce cost, infections, pain and delay in discharge from hospital. If the results are suggestive and favorable, this protocol will be incorporated into our hospitals phototherapy protocol.

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Figure Legends:

Figure 1: pre implementation phase flow diagram

Figure 2: Transcutaneous Bilirubin Nomogram

Figure 3: post implementation phase protocol flow diagram

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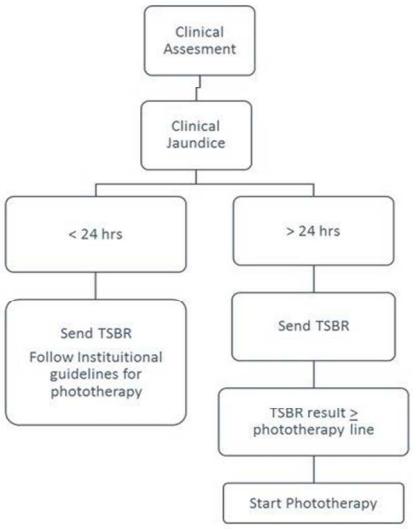
Figure 1: pre implementation phase flow diagram



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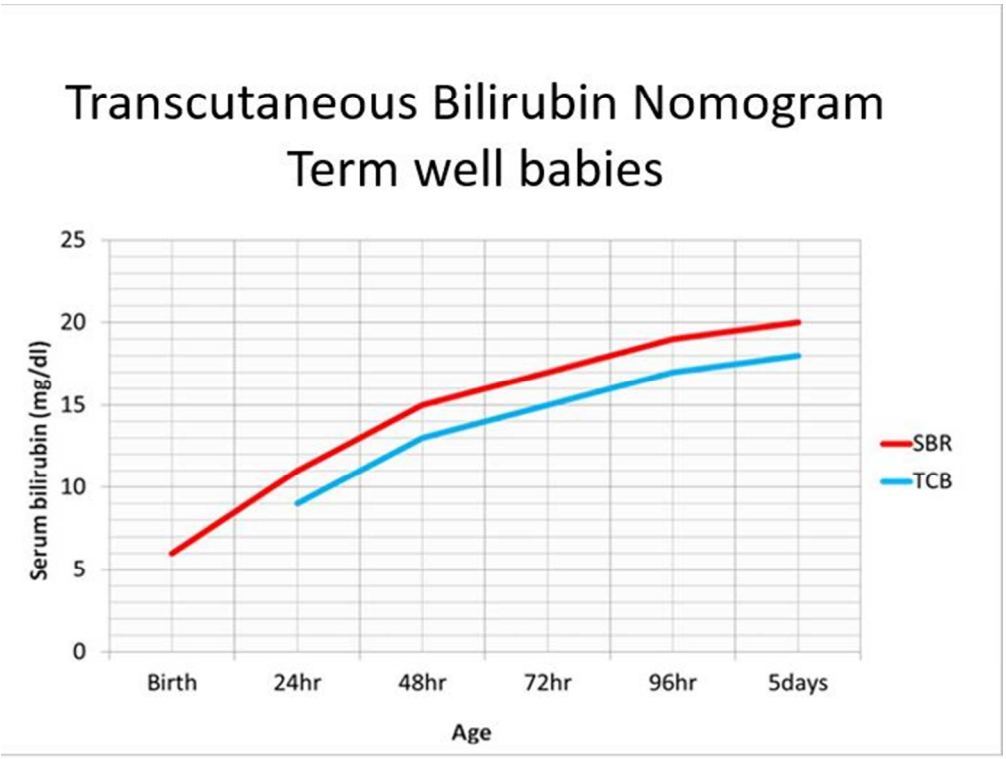

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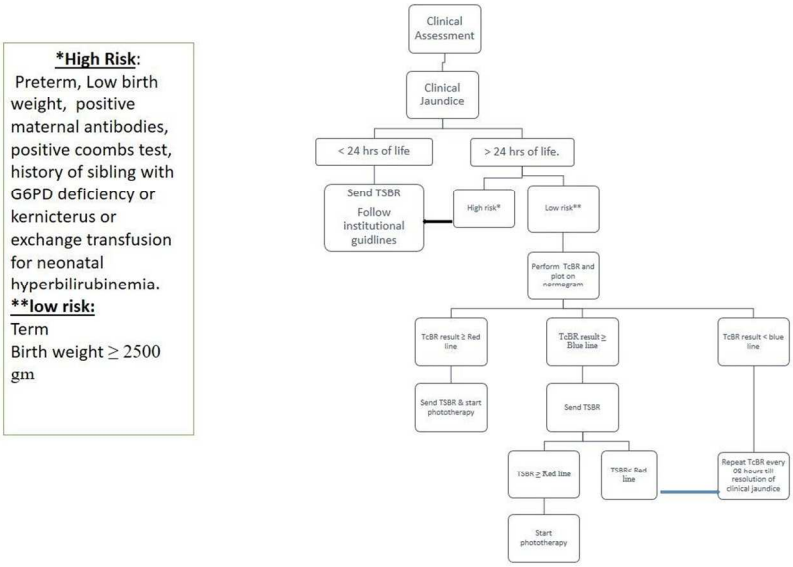

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BMJ Paediatrics Open

Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan

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Title: Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan.

Key words: hyperbilirubinemia, Neonate, transcutaneous bilirubin meter

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Abstract:

Introduction: Neonatal jaundice is a common cause of concern in immediate newborn period for parents as well as for the care givers. Babies with visible jaundice are identified by the health care provider and blood samples are sent for confirmation. Clinical expertise varies from person to person and may lead to sending excessive blood sampling. Obtaining blood bilirubin samples is a painful procedure, it predisposes the baby to infections and requires skilled health personnel. Moreover laboratory tests are costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from hospital. Transcutaneous bilirubinometer has been in use for a long time as screening tool in post natal wards. With passage of time its accuracy and validity have improved tremendously. **Methodology:** We aim to implement a quality improvement initiative to reduce the number of blood bilirubin samples using transcutaneous bilirubin nomogram in full term, low risk babies who are born at our hospital and are admitted in post natal ward after birth. Using Pre and post analysis study design this study will be performed in two phases of 6 months each. Data regarding total number of admissions in post natal wards, demographics, serum bilirubin samplings (TSBR) and need for phototherapy will be recorded in both phases. TcBR will be done and recorded in post implementation phase. **Analysis and results:** Comparisons between the two groups will be made. Primary outcome will be reduction in blood bilirubin samples for TSBR after the implementation of TcBr protocol. The proportion of infants having TSBR performed in both periods will be compared. Crude Sampling cost of TSBR will be obtained from laboratory and cost comparison between two phases will be done to look for difference.

Summary Box:

What is already known about this subject:

- Neonatal jaundice is a common cause of concern both for care givers and parents.
- If left unrecognized it can lead to serious complications like bilirubin encephalopathy.
- Transcutaneous bilirubin meter has proven to be a good tool for screening of neonatal jaundice.

Whats New:

- We are presenting a quality improvement protocol to reduce the number of blood bilirubin samples for neonatal jaundice.
- We have introduced a TcBR nomogram for the first time in Pakistani population
- If successful this can be used at a larger scale for improvement in quality and reduction in cost of care for babies with neonatal jaundice.

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Title: Effectiveness of transcutaneous bilirubin measurement in managing neonatal jaundice in post natal ward of a tertiary care hospital in Pakistan.

Introduction: Neonatal jaundice is a common cause of concern in the immediate newborn period for parents as well as for care givers. It occurs in many newborns, usually after the first 24 hours of life and spontaneously resolves over the next few days. If deep and prolonged jaundice remains unrecognized, it can lead to bilirubin encephalopathy and permanent neurological damage. [1]

Traditionally babies with neonatal hyperbilirubinemia are screened clinically using Kramer's scale or by using other modalities[2] .Blood bilirubin samples for total serum bilirubin (TSBR) is usually done to confirm and start treatment once jaundice is identified.[3] Serum TSBR sampling is a resource intense procedure. It requires skilled health personal and can also lead to nosocomial infections.[4] Moreover laboratory testing is costly and time consuming leading to unnecessary delays in commencing phototherapy and discharge from the hospital.[5]

Transcutaneous bilirubin (TcBR) measurement devices use multiwavelength spectral reflectance from the skin surface and can be used to estimate total serum or plasma bilirubin and thus avoid blood sampling. TcBR is a 'Point of Care' test (bed side test) that can be performed by physicians, nurses or any other health caregiver with in hospital or in community.[6] It is used as a noninvasive, rapid screening tool to identify babies with neonatal hyperbilirubinemia.[7] Various studies have shown its efficacy, safety and utility.[8-9] One randomized controlled trial (RCT) done in Netherlands showed significant reduction in blood bilirubin samples in TcBR group compared with non TcBR group.[9] TcBR is an inexpensive test,[10] and can be performed over forehead or mediastinum but studies suggest that measurements over mediastinum are better than forehead.[11] Despite its utility only 27 % of the hospital wards are using TcBR as a screening tool.[9]

Although TcBR is a good screening tool but TSBR is still the gold standard for diagnosing and commencing phototherapy.[12] Most studies on the use of TcBR are done to establish its accuracy, comparing TSBR with TcBR levels. Implementation of TcBR in hospital or community-screening program is associated with a reduction in the incidence of severe neonatal jaundice, readmission for phototherapy, and lower duration and rate of phototherapy .[13] Study done on TcBR from our institute 25 years back showed a poor sensitivity and specificity of 88% and 53% respectively.[14] Important to note was the small sample size and both term and preterm infants were enrolled. Similar study from Pakistan during the same era showed good sensitivity.[15] Technology has advanced significantly since then with the emergence of newer and more sophisticated devices with good precision. Recent data from Pakistan have shown good correlation of TcBR with TSBR.[16]

Although several transcutaneous bilirubin nomograms have been evaluated, significant differences exists across populations based on ethnicity, race and bilirubin kinetics.[17] A systematic review based on four studies that constructed TcBR nomograms from predominately Caucasian, Thai, or Hispanic populations reported TcBR nomogram values varied among the ethnic groups. Up to the best of our knowledge no study has been performed using transcutaneous bilirubin nomogram in Pakistan. Therefore it is imperative to know the nomogram for our babies. The aim of our quality improvement initiative is to reduce the

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number of blood bilirubin samples by introducing a TcBR nomogram (Attached) to plot the readings of TcBR and only do serum TSBR sampling when the readings cross the TcBR line (Blue Line). We hypothesize that if our TcBR nomogram is safe and effective this will reduce the number of blood bilirubin samples significantly and will be incorporated into the hospital phototherapy protocol.

Objectives: 1) We intend to implement a quality improvement project to reduce the number of blood bilirubin samples by introducing a transcutaneous bilirubin nomogram in term well babies admitted in the post natal ward of our hospital.

Study Design: Pre and post analysis design with preimplimentation phase being retrospective and post implementation phase as prospective cohort.

Settings: Post natal ward of Aga khan university hospital Karachi.

Duration: 13 months

Inclusion Criteria: (Eligibility criteria) All babies admitted to AKU post natal ward from 1st September 2016-30th September 2017 with gestational age 37 weeks or more with birth weight more than 2500 grams having clinical jaundice after 24hrs of life but within 7 days of life.

Exclusion criteria: 1) Babies having clinical jaundice within 24 hours of life or after 7 days of life.

2) Babies at high risk for neonatal hyperbilirubinemia i.e. Preterm, Low birth weight, babies with positive maternal antibodies, babies with positive coombs test, babies requiring serum TSBR sampling within 24 hours of life, babies already on phototherapy, history of sibling with G6PD deficiency, history of sibling with kernicterus, history of sibling requiring exchange transfusion for neonatal hyperbilirubinemia.

Operational definitions:

Clinical jaundice: Yellow discoloration of skin reaching up to abdomen assessed by trained health worker i.e. physician or nursing staff.

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Methodology and Data Collection:

The study will be performed in three phases.

Phase 1: (pre implementation phase).

Duration: 6 months (1st September 2016-28th February 2017)

Data regarding all neonates admitted in post natal ward will be extracted retrospectively using medical records. Following data will be collected for all eligible cases.

Demographic data including gestational age, chronological age , gender and birth weight etc , will be extracted from the hospital database .TSBR data will be retrieved from the laboratory's online database and all babies who received phototherapy will be identified by reviewing medical records and cross-checked against nursery discharge data.[Figure 1]

Implementation phase: (March 1st 2017 till March 31st 2017)

Two Dragger JM105 transcutaneous bilirubin meters are being used, one for each well baby nursery. Both devices are being regularly calibrated and serviced by our hospitals biomedical department.

TcBR nomogram: TcBR nomogram is made using American Academy of Pediatrics (AAP) guidelines for phototherapy threshold. A new line is drawn 2 mg/dl (34.2 umol/l) below the phototherapy line for low risk babies and is named as TcBR line because literature review reveals a variation of ± 1 mg/dl(17.1 umol/l) in results of TcBR and TSBR.[18] For simplification the high and intermediate risk lines are removed from the chart since those babies are not the study population and their management is being done according to the hospitals jaundice protocol. The lines are color coded. Phototherapy line is of red color whereas TcBR line is blue colored. This modification in the AAP nomogram is called as TcBR nomogram. Attached is the sample of our TcBR nomogram. [Figure 2]

Prior to the implementation of the project , hands on training and competency certification of all neonatal health care providers has been undertaken by senior neonatologist/nurse instructor in which all components of study protocol were explained .Protocol flow chart and TcBR nomogram were handed over to all post natal nurses and physicians and also pasted at all post natal ward areas for reference.

The study is approved by the hospitals ethical review committee. Ref # 4742-PED-ERC-17

Phase 2: **(Post Implementation Phase)**

Duration: 6 months (01-04-2017 till 30-09-2017)

All babies meeting eligibility criteria having clinical jaundice assessed by nursing staff/pediatric resident/neonatology fellow will be approached. Basic demographic and anthropometric data will be recorded. TcBR will be performed using dragger JM105.Three consecutive readings will be taken on the sternum and mean result will be recorded on the proforma. If TcBR level falls on or over red line (phototherapy line), serum TSBR will be sent and phototherapy will be started. If TcBR level falls on or over blue line(TcBR Line) then serum TSBR will be sent, and

phototherapy will be started only if TSBR falls on or over red line (phototherapy line). All babies with TcBR or TSBR level below blue line (TcBR line) will be followed with TcBR testing after every 8 hours until resolution of clinical jaundice. [Figure3]. Figure 3: post implementation phase protocol flow diagram.

Sample size: As we have an average of 4000-5000 admissions in post natal wards per year out of which approximately. 500-1000 are high risk babies, we anticipate a sample size of around 1500 eligible babies in each phase.

Outcome:

Primary outcome:

a. Reduction in the number of blood bilirubin samples for TSBR.

Secondary outcomes:

a. Assessment of accuracy of bilimeter in Pakistani population.

b. Reduction in the cost of blood bilirubin sampling between the two phases..

Analysis plan and Results: Analysis will be done on SPSS v.19.
Means with standard deviations will be used for normally distributed data. Comparisons between the two groups will be made using equality of variances test and two independent t test for comparing means. The proportion of infants having a TSBR performed in both periods will be compared with the chi square test.
Assessment of accuracy of bilirubin meter will be assessed by performing comparative analysis between TcBR and TSBR only on those babies in whom both are done.
Sampling cost of TSBR will be obtained from laboratory and Cost comparison between two phases will be done to look for difference.
We will use SQUIRE v2.0. Guidelines for reporting our findings.[19]

Discussion:

NICE guidelines 2016 for the management of neonatal hyperbilirubinemia recommends the use of TcBR for the screening of babies who are >24 hours old and more than 35weeks.[20] We aim to improve the quality of care given to our neonates by reducing the number of blood bilirubin samples using transcutaneous bilirubin nomogram on babies who are low risk and are more than 24 hours old. We believe that this will be decrease the requirement of blood bilirubin samples for TSBR and also reduce cost, infections, pain and delay in discharge from hospital. If the results are suggestive and favorable, this protocol will be incorporated into our hospitals phototherapy protocol.

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Figure 3: post implementation phase protocol flow diagram

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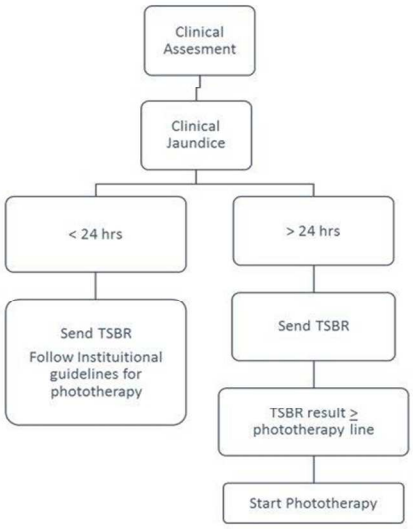
Figure 1: pre implementation phase flow diagram



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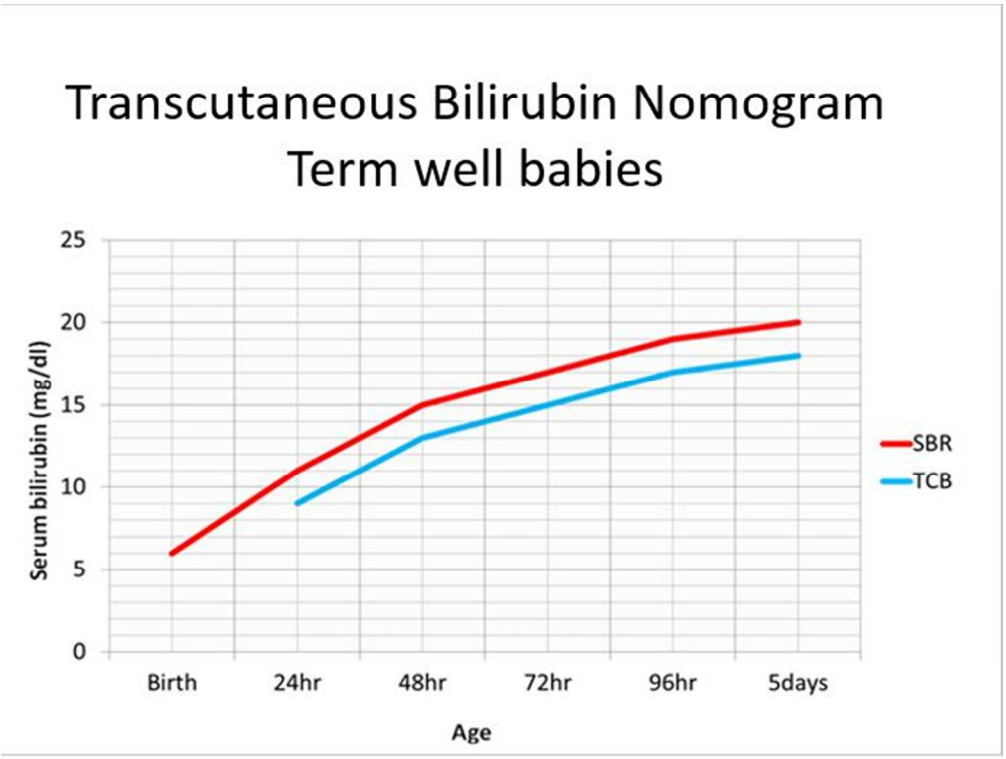

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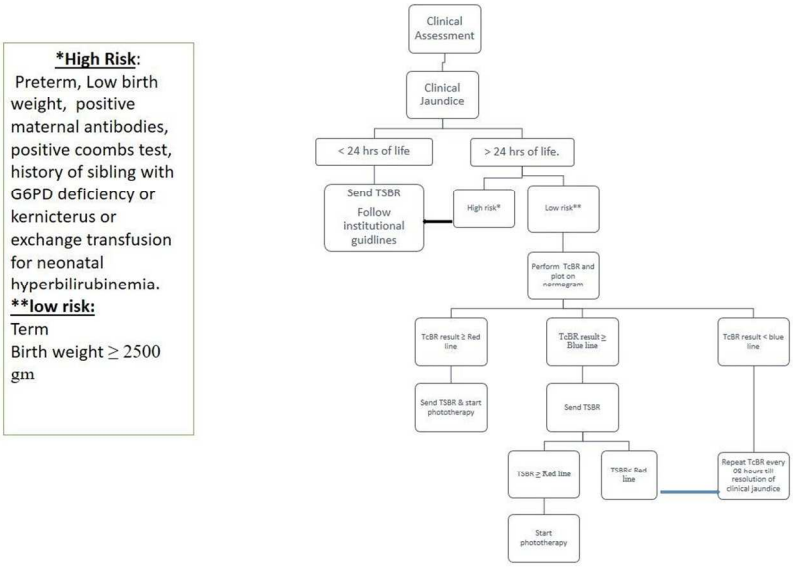

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