Application of POCT Hemoscreen for FBC in less than 2 months old Neonates: A Pilot Study

Healthcare Science Innovation Fellowship Project; Cohort 3

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Introduction

Performing a full blood count (FBC) is a common clinical practice in neonatal care. Samples reported as "clotted" are not able to be analysed for FBC and require a redraw leading to a delay in reporting results. A perceived "high" clotting rate elicits frustration among clinical team members and has negative effects on patient flow and patient satisfaction. The overall % rejection rate of neonatal FBC samples due to the presence of clots is significant and has been estimated at 20-30% by the neighbouring neonatal units in large teaching hospitals in the region. The literature confirms clotting rejection rate of 30% *(McCoy et al, 2016*). Published data on this is limited but it is well recognised in routine clinical practice as a challenge.

Capillary blood is the main technique used to collect blood from neonates. Typically, platelet activation is triggered when there is a break in the vascular endothelium (heel prick). There are studies that indicate that capillary blood sampling collection increases the risk of clotting *(McCoy et al, 2016*). There is preliminary evidence show that venous samples have a lower clotting rate but the latter is not an option except in few PICU cases. There are few postulated mechanisms for the cause of clotting in neonates such as the sample transfer time to the laboratory, the blood collection technique, prematurity, neonate weight or coexisting maternal or neonate's clinical conditions. A recent study demonstrated that a child's increasing body weight reduced the risk of pre-analytical errors, including risk of clotting (*Hjelmgren et al, 2021).* Therefore, the clotting rate is not a large pre-analytical problem in neonates older than 3 months old. However, to date, there are no studies to elucidate the main reason for the high clotting rate in neonates.

Proposal

The Pixcell Hemoscreen is a small footprint Point of Care Testing (POCT) device which analyses 40uL of capillary/venous blood to generate a 5 part differential Full Blood Count (FBC) result. The blood sample is drawn into a sampler coated with lithium heparin which is then clipped into the reagent cartridge and processed by the analyser. It is very easy to use and requires minimal training. The device uses cutting edge viscoelastic focussing (VEF) technology and takes 5 minutes to generate a result. The device has been CE marked for use in patients >2 months of age and has FDA approval for >2 years of age.

Prior to this project 15 samples from the laboratory from patients< 2months of age were analysed on the device (post laboratory analysis, not requiring ethical approval) to ascertain how well the device compares against the laboratory method. The results showed that the performance was favourable when compared to the Laboratory Sysmex XN1000 for FBC.

Whilst reassuring, this did not assess how the device would perform when used in clinical practice in the way in which it is intended.

This project aimed to assess the Hemoscreen analyser performance when it was placed on the Special Care Baby Unit (at the point of clinical care) and the samples from neonates < 2 months of age were processed **prior** to laboratory analysis. If a FBC is required for the clinical care of the neonate then 400uL was drawn into the EDTA tube as per routine practice. Before the sample was sent to the laboratory for processing, 40uL of this sample was analysed on the Hemoscreen by SCBU staff. The results between the Hemoscreen and the laboratory Sysmex XN1000 were compared and a statistical assessment of comparability was performed. Favourable opinion from REC (ethical approval via IRAS) was obtained for this study.

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Method

A minimum of 15 patients are to be recruited to make a library of a minimum of 30 samples (max. 2 samples per single patient) is recommended by Altman and Bland graphical method as described in the Lancet 1986[37]. This sample size would give a 95% Confidence Interval (CI) of about +/- 0.34S, where S is the standard deviation of the difference of the two methods used in this study (HemoScreen and Sysmex).

Results

The results to date (not the full 30 as data still being collected) show acceptable correlation with the Sysmex XN1000; 4 key parameters are shown below:

Findings

The next steps are to gather the data available on the performance of this device, including submissions to the FDA and CE marking, IVDR approval. The results from this project will be published in a peer approved scientific journal which can then be used as evidence to support off label use of the device. It is unclear whether the laboratory Sysmex XN1000 has CE approval for use in neonates but it is in routine laboratory service use internationally so we need to identify how this was approved for service use and what evidence was presented.

There is a real opportunity to improve outcomes for neonates by continuing the evaluation work on this medical device and pursuing the route to routine service implementation. The initial results by themselves are not sufficient enough to demonstrate that the performance of the Hemoscreen is equivocal to the laboratory Sysmex XN1000 due to the low sample numbers. They do show strong correlation and demonstrate there is huge potential and value in continuing this work, extending to additional centres and increasing the number of patients tested, growing the evidence base.

What is lacking is clear direction from the regulatory bodies about the body of evidence that is needed and who will approve the device for routine service use in neonates. There is a clearly identified and universally recognised clinical need for this device, early method comparison results are promising and this the potential to improve patient outcomes considerably.

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