Decommissioning of the Red Cell Dosage Calculator: Resources to assist an alternative manual process

Background

The Red Cell Dosage Calculator (RCDC) [https://rcd.boltonft.nhs.uk/] was developed by Bolton NHSFT and Technical Solutions Worldwide Ltd primarily for local use. It has been shared free of charge to other NHS organisations on a trial basis. It was originally registered with the MHRA as a Class 1 Medical Device (decision support software) in 2016 and UKCA marked. Due to a change in Medical Devices legislation known as rule 11, the app now needs to be re-classified as a class IIa medical device. This means the app is no longer eligible for Declaration of Conformity self-certification, as devices above class I must be assessed by a MHRA approved body.

Problem

While these requirements are appropriate for higher-risk medical devices, they represent a significant increase in complexity, cost, and ongoing regulatory burden compared to the original Class I framework. Need for independent assessment and certification by an approved body introduces substantial financial and administrative overhead.

Implications for Continued Use

Given the nature of the RCD Calculator as a relatively simple clinical tool, it is no longer proportionate or feasible to maintain the application under these enhanced regulatory requirements. Regrettably the app will need to be de-commissioned and de-registered as a medical device with the MHRA. **The agreed date for this will be 1st June 2026**.

Resources to Support an Alternative Manual Process

The app covers two processes:

1. The cause of anaemia which informs the indication for transfusion and target Hb. This is based on guidance which can be found in the NBTC indication codes document [https://nationalbloodtransfusion.co.uk/sites/default/files/documents/2024-10/NBTC-indication-codes-V3-2024.pdf] – see R2 and R3 codes for acute anaemia in the table and associated supporting text

2. The dose calculation is based on the target Hb and dosing guidance as per guidance in the document above which states: Dose: in non-bleeding patients 4 ml/kg raises haemoglobin concentration by approximately 10 g/l.1 Use the minimum number of units (or weight-adjusted volume) to achieve the clinical target. This is especially important for patients who are at risk of transfusion-associated circulatory overload (TACO), have low body weight or have severe chronic anaemia. The average volume of an adult unit is 290 ml.

Dose Formula

Volume red cells (ml) = (Target Hb g/L* – Pre transfusion Hb g/L) x (0.4 x weight in kg)

***R2 Acute anaemia** (e.g. following bleeding/ surgery/ critical illness) – haemodynamically stable patient and Hb ≤ 70 g/l5,6 Consider a haemoglobin threshold of 70 g/l and a target haemoglobin of 70-90 g/l to guide red cell transfusion.

***R3 Acute Anaemia** – haemodynamically stable patient **with acute coronary syndrome** (excluding stable ischaemic heart disease) and Hb ≤ 80 g/l5,6,7 Consider a haemoglobin threshold of 80 g/l and a target haemoglobin of 80-100 g/l. Caution giving multiple units in patients with chronic anaemia (see R7). A higher haemoglobin target might be considered where there is ongoing myocardial ischaemia, balanced against risk of exacerbating heart failure.

Note that patients with severe chronic anaemia (NBTC indication code R7) e.g. due to haematinic deficiency, or anaemia of chronic disorder there is no universal transfusion trigger or target; physiological compensation means transfusion is unlikely to be required if haemoglobin > 70 g/l and most patients with lower haemoglobins **will not need transfusion. Transfuse a single unit if necessary to** prevent acute complications of severe anaemia while the underlying cause is investigated and treated.

Future Development

Re-commissioning of the app may be possible if a funding source is identified for ‘Approved Body’ assessment and associated ongoing associated support requirements.