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Title page

Improvements in National Code Red Transfusion practice in Scotland after adoption of recommendations from the Scottish National Code Red 2015 review.

Authors: Matthew J Reed ^{1,2,3}, Claire Cooke ¹, Niall McMahon ^{4,5}, Katherine Hands ⁶, Susan Henderson ⁶, Eleanor Knight ⁶, Nicola Littlewood ^{4,7}, Munsoor Latif ⁷, Naomi Tod ⁷, Margaret McGarvey ⁸, Neil Hughes ^{4,9}, Michael Donald ^{4,10}, Megan Rowley ¹¹, Catherine Innes ¹¹, Symon Lockhart ¹¹ on behalf of the Scottish Transfusion and Laboratory Support in Trauma Group*.

Affiliations:

1. Department of Emergency Medicine, Royal Infirmary of Edinburgh, NHS Lothian, 51 Little France Crescent, Edinburgh, EH16 4SA, UK.
2. Emergency Medicine Research Group Edinburgh (EMERGE), Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh, EH16 4SA, UK.
3. Edinburgh Acute Care, Usher Institute of Population Health Sciences and Informatics, College of Medicine and Veterinary Medicine, University of Edinburgh, Edinburgh, UK.
4. Department of Emergency Medicine, Royal Alexandra Hospital, NHS Greater Glasgow and Clyde, Corsebar Rd, Paisley PA2 9PN, UK
5. EMRS, Emergency Medical Retrieval Service, ScotSTAR, Hangar B, 180 Abbotsinch Road, Paisley, PA3 2RY, UK
6. Department of Transfusion Medicine, Ninewells Hospital, Dundee DD2 1UB, UK
7. Department of Emergency Medicine, Queen Elizabeth University Hospital, NHS Greater Glasgow and Clyde, 1345 Govan Rd, Glasgow G51 4TF, UK
8. Department of Transfusion Medicine, Queen Elizabeth University Hospital, NHS Greater Glasgow and Clyde, 1345 Govan Rd, Glasgow G51 4TF, UK
9. Department of Emergency Medicine, Monklands Hospital, NHS Lanarkshire, Monks court Ave, Airdrie ML6 0JS, UK
10. Department of Emergency Medicine, Ninewells Hospital, Dundee DD2 1UB, UK
11. Department of Transfusion Medicine, Royal Infirmary of Edinburgh, NHS Lothian, 51 Little France Crescent, Edinburgh, EH16 4SA, UK.

Short title: National Code Red Transfusion practice 2015 review

Keywords: up to 10 keywords must be included.

* **Corresponding author;** E-mail address: matthew.reed@nhslothian.scot.nhs.uk

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Abstract (320 words)

Aims: The Scottish Transfusion and Laboratory Support in Trauma Group (TLSTG) previously reviewed all National Code Red activations between June 1st 2013 and October 31st 2015, generating a number of recommendations to be adopted to optimise the transfusion support given to patients following major trauma in Scotland. A repeat National survey was undertaken for all patients for whom Code Red was activated between 1st November 2015 and 31st December 2017.

Methods: A clinical and transfusion lead for each centre entered anonymised data onto a secure electronic database (REDCap).

Results: During the study period there were 66 activations (24 South-East of Scotland, 32 West, 10 East). Mean age was 45 years and 88% were male. Mean Injury Severity Score (ISS) was 28 with 75% blunt trauma. 93% (62/66) of Code Red patients received blood components with a 300% increase in pre-hospital transfusion (48 vs 16 patients; $p<0.001$). Median time from 999 call to Code Red activation reduced significantly to 37 minutes from 70 minutes ($p=0.01$) giving the hospital more time to prepare transfusion components. 78% patients received pre-hospital tranexamic acid (TXA; improved from 70%, $p=0.67$, ns). Concentrated Red Cell (CRC): Fresh Frozen Plasma (FFP) ratio was always less than 2:1 and below 1.4:1 at 90 minutes, compared to 2013-15 when CRC: FFP ratios did not drop to below 2:1 until 150 min after arrival in the ED. Mean time for Full Blood Count (FBC; 46 mins versus 81; $p=0.004$) and clotting (53 mins versus 119; $p<0.001$) result was reduced. Survival to hospital discharge was unchanged (66% versus 63%; $p=1.00$ ns).

Conclusions: Code Red practice has improved in several ways since our last survey with earlier Code Red activation, more patients receiving pre-hospital transfusion and improved CRC:FFP ratios. Interventions such as earlier on scene Code Red activation, provision of pre-hospital TXA, Emergency Department (ED) resuscitation room pre-thawed FFP and point-of-care viscoelastic coagulation testing have all contributed to these improvements in transfusion practice in Scotland.

Highlights: *Please provide 3-5 highlights that clearly and succinctly convey the key messages of your paper. Each highlight should be no more than 125 characters (without spaces)*

- Interventions have improved Code Red transfusion practice in Scotland between 2013-15 and 2015-17
(86 characters)
- Pre-hospital clinicians are activating Code Red earlier giving the hospital more time to prepare transfusion components
(105 characters)
- 93% of Code Red patients received blood components with a 300% increase in pre-hospital transfusion (48 patients versus 16)
(100 characters)
- CRC:FFP ratios are now below 2:1, previously not achieved until 150 minutes helped by introducing pre-thawed FFP into the ED resuscitation room
(123 characters)
- Introduction of Point-of-Care viscoelastic coagulation testing has led to more patients receiving these tests (12 versus none in 2013-2015)
(122 characters)

Introduction

Since April 2014 three of Scotland's four pre-hospital trauma teams have used a unified national Code Red protocol that can be activated prior to a patient with major or massive haemorrhage arriving in the Emergency Department (ED) and which asks them to consider the following factors in order to decide whether to activate the National pre-hospital Code Red protocol; 1. Suspected or confirmed bleeding, 2. Systolic blood pressure <90 mmHg in an adult patient, and 3. Patient unresponsive to fluid boluses. The Code Red protocol allows sufficient blood components to be made available to the clinician on arrival of the patient to the ED.

An initial review of the implementation of the Code Red protocol between June 1st 2013 and October 31st 2015 (30 months) [1] conducted by the Scottish Transfusion and Laboratory Support in Trauma Group (TLSTG) studied 53 pre-hospital Code Red activations. Median Injury Severity Score (ISS) was 24 (IQR 14–37) and overall mortality 38%. 16 patients received pre-hospital blood. The pre-hospital Code Red activation criteria was found to be sensitive for predicting transfusion or haemorrhagic death (89%) but activation thresholds differed between regions. Only 71% of patients received pre-hospital tranexamic acid. Concentrated Red Cell (CRC): Fresh Frozen Plasma (FFP) ratios did not drop to below 2:1 until 150 min after arrival in the ED. 16 red cell units, 33 FFP and 6 platelets were discarded.

This study generated a number of recommendations to be adopted to optimise the transfusion support given to patients following major trauma in Scotland:

- Continued use of Code Red and the extension of the protocol to the North of Scotland.
- No change in current Code Red activation criteria.
- Continued local and national audit and feedback to clinicians in order to standardise Code Red activation thresholds between regions.
- Increased administration of Tranexamic Acid (TXA) where appropriate.
- Whilst there is a lack of quality evidence on the use of pre-hospital blood components, until studies such as RePHILL [2] report, a national approach should be adopted.
- Hospitals receiving major trauma should have in place a blood component transfusion guide for clinicians to enable them to better understand which blood components should be transfused and when.
- Hospitals receiving major trauma should consider ways to improve the time for universal FFP to be administered without this leading to a huge increase in discard rate. This should improve both the time to administration of FFP and CRC:FFP ratios, both of which could improve the time to correct ATC.
- Point-of-Care coagulation testing or Viscoelastic testing should be considered to improve the speed that coagulation information is available to the clinician.

A repeat review of the National Code Red Policy has been undertaken for all patients for whom a Code Red was activated between 1st November 2015 and 31st December 2017 (26 months). The main study aims were to establish

whether Code Red criteria predict need for in hospital transfusion, admission coagulation profile and treatment of any coagulation derangement, current CRC: FFP ratios and number of FFP and CRC discards.

Methods

A clinical and transfusion lead was identified for each centre. The standardised Case Report Form (CRF) used in the first study was replaced by a secure electronic database (Redcap; <http://www.project-redcap.org>) for anonymised data entry. [3,4] which was funded by the Scottish National Blood Transfusion Service (SNBTS). Prospectively recorded data was retrospectively obtained from hospital and blood transfusion Electronic Patient Records and entered into the secure electronic database.

The study was deemed a service evaluation by the South East Scotland Research Ethics committee (Ref: NR/1408AB11) and therefore did not require full ethics submission. The study was also registered with each hospital's clinical effectiveness/governance teams where available, and a favorable Caldicott opinion was obtained.

Statistical Analysis

Data was imported into Microsoft Excel for analysis. Non-parametric continuous data is presented as median with interquartile range (IQR) (25th to 75th percentile) and parametric continuous variables are presented as mean with 95% Confidence Interval (CI). Categorical variables are presented as simple frequencies, proportions and percentages. To assess CRC: FFP ratios, the mean cumulative ratio of blood components transfused was calculated at 30 min intervals from arrival to the ED. Clinician accuracy in declaring Code Red was defined as activation of the Code Red protocol in a patient who underwent in-hospital blood component transfusion (or had a haemorrhagic death). Massive Transfusion (MT) was defined as 10 or more CRCs in 24 hours. Changes in accuracy of clinicians declaring Code Red, number of patients receiving pre-hospital transfusion, number of patients receiving pre-hospital TXA and number of patients surviving to hospital discharge between 2013-15 and 2015-17 were assessed using a Chi-Squared test. Changes in time from 999 call to code red activation was assessed using a Mann-Whitney test. Time to first Full Blood Count (FBC) and laboratory clotting results were assessed using a Student t-test. A two-tailed significance level of 5% was chosen for all significance tests. Microsoft Excel (Microsoft TM) and SPSS (IBM) was used for statistical analysis.

Results

During the 26-month study period there were 66 Code Red activations. 24 activations were to the South-East of Scotland, 32 to the West and 10 to the East. The mean age of Code Red patients was 45 years and 88% patients were male, representing a slight increase in the number of male patients from the 2013-15 period (75%). Overall mean Injury Severity Score (ISS) was slightly higher in 2015-17 compared to 2013-17 (28 vs. 26), with the West region having the highest mean ISS score of 32. As in the 2013-15 period, blunt trauma was the most common mechanism

of injury at all sites (75%).

Slightly more patients survived for 24 hours after Code Red activation (81% in 2015-17 compared to 73% in 2013-2015) with 66% surviving to hospital discharge (63% in 2013-2015, $p=1.00$, ns). **Table 1** details characteristics of code red patients 2015-2017.

62 of 66 (93%) Code Red patients received blood components [**Figure 1**]. This compared to 47 of 53 in the previous study ($p=0.34$, ns). 4 patients received no pre-hospital or in hospital transfusion. Of the patients who received no pre- or in-hospital blood, all patients had a pre-hospital 1st systolic blood pressure of >90 mmHg.

More patients received pre-hospital blood in 2015-17 compared to 2013-15 (48 patients compared to 16 patients, $p<0.001$), likely related to the introduction of the pre-hospital Concentrated Red Cell (CRC) transfusion capability by Medic 1 in December 2015. Of those patients that did not received pre-hospital blood, 3 had a pre-hospital systolic blood pressure of <90 mmHg.

Blood component usage: Emergency CRC usage differed between sites although Emergency FFP usage was similar. The number of blood component units administered per patient who received transfusion, in the first 24 hours was similar across all regions. **Table 2** details use of red cells, FFP and platelets in code red patients 2015-2017. 5 (7.6%) patients underwent MT.

A key recommendation from the 2013-15 study was an increased administration of Tranexamic acid (TXA) where appropriate; TXA should be administered to 100% of bleeding trauma patients. 78% (49) of Code Red patients received pre-hospital TXA in 2015-17, compared to 70% (33) of Code Red patients in 2013-15 ($p=0.67$, ns).

The median time from arrival to transfusion of emergency O negative CRCs across all sites was 7.5 minutes longer in 2015-17 (16 minutes) and median time to Fresh Frozen Plasma (FFP) administration was 6 minutes longer (56 minutes) than in 2013-15.

The mean time for the treating clinician to receive the first Full Blood Count (FBC) result was reduced from 89 minutes in 2013-15 to 46 minutes in 2015-17 ($p=0.004$). Time to first laboratory clotting result was reduced from 125 minutes to 53 minutes ($p<0.001$). ROTEM or TEG was used in 12 patients (none in 2013-2015). Median arrival haemoglobin was 136 g/L (IQR 126-146), median arrival PT was 13 seconds (IQR 12-14.5), median arrival INR was 1.1 (IQR 1.0-1.2) and median arrival fibrinogen was 1.8 g/L (IQR 1.4-2.5). Median admission formal laboratory calcium was 2.15 mmol/L (IQR 2.05-2.24).

CRC:FFP ratios: 37% of patients receiving CRCs in the first 6 hours from ED arrival did not receive any FFP. In patients receiving both CRC and FFP the British Society for Haematology (BSH) target CRC:FFP ratio of 1:1 is never achieved by any centre, but the CRC:FFP ratios are much improved especially in the first 180 minutes in comparison to the 2013-15 study [Figure 2]. 55% of patients who received FFP did so within the first 60 minutes of ED arrival. **Table 2** details use of red cells, FFP and platelets in code red patients 2015-2017.

The median time from 999 call to Code Red activation was 37 minutes, compared to 70 minutes in 2013-15 ($p=0.01$). The median time from Code Red activation to the patient arriving in the ED was 33 minutes, representing a 9 minute increase from 2013-15. Overall mean time between 999 call to arrival in ED was 91 minutes, with regional differences likely due to geography and differential use of air and road transport.

CRC and FFP discards: For the whole Code Red population 9 units of CRCs were discarded, compared to 16 units in 2013-15. 14 units of FFP were discarded compared to 33 in 2013-15. 6 units of platelets were discarded.

Discussion

Between 2013-2015 and 2015-2017 our transfusion practice in Code Red patients has changed and improved in three key ways with earlier Code Red activation, more patients receiving pre-hospital transfusion and improved CRC:FFP ratios. The median time from 999 call to Code Red activation has halved in the 2015-17 period compared to 2013-15. Pre-hospital clinicians are activating Code Red earlier thereby giving the hospital more time to prepare transfusion components prior to the Code Red patient arriving. The long median time from 999 call to Code Red activation in 2013-15 was highlighted as a problem and training was fed back to individual centres to encourage early on scene Code Red activation.

93% of Code Red patients received blood components indicating a better accuracy of clinicians declaring Code Red since our previous study. The three fold increase in pre-hospital transfusion shows a change in the availability and use of pre-hospital red cell transfusion.

Whilst this review showed an improvement in the percentage of Code Red patients receiving pre-hospital TXA this was still only 78%. Our first Code Red review led to a change to practice in Scotland enabling TXA to be carried on ambulances and to be given by paramedics. The patients in our study represent the more seriously injured of those who should receive TXA and were all treated by a pre-hospital clinician service rather than by paramedics alone so it is disappointing that this figure was not closer to the target 100%.

A CRC:FFP ratio of 1:1 was never achieved by any centre but CRC:FFP ratios are now below 2:1, previously not achieved until 150 minutes. Time from arrival to transfusion of emergency O negative CRCs was longer across all

sites but this is likely to reflect the increased availability and use of pre-hospital red cell transfusion. Despite the reduction in median time from 999 call to Code Red activation and the improvement in CRC:FFP ratios, time to FFP administration was also longer in 2015-17. It is likely that this reflects changes in FFP availability in the ED. One of our recommendations from our previous study was to find ways to improve the availability of FFP in major Scottish EDs. During this study in response to growing evidence around early balanced blood component use, several centres introduced a system whereby 2 units of pre-thawed group A HT negative FFP were placed in a dedicated ED resuscitation room blood fridge. The unit could either be transfused within 120 hours; or was discarded and replaced. Units were available to be given immediately to any major haemorrhage or Code Red patient who the treating clinician determined needed emergency FFP [5]. ED clinical staff would not therefore be required to wait for the FFP to be sent down from the blood transfusion laboratory. This system may have led to inaccuracies in the recording of the time of FFP transfusion which is now more reliant on ED staff and not on blood transfusion laboratory staff.

Mean time for the treating clinician to receive the first FBC result and first laboratory clotting result were both reduced. These times however are still too long to enable on-line changes in clinical transfusion care. It was for this reason that the Scottish National Blood Transfusion Service (SNBTS) Better Blood Transfusion funded a ROTEM machine in two of the EDs during this study and 12 of the study patients underwent thromboelastometry testing. Viscoelastic testing such as ROTEM and TEG may be able to help clinicians here as they are able to rapidly diagnose ATC with a characteristic thromboelastometry profile within 5-10 minutes [6], better predict ATC than traditional coagulation tests [7], improve survival [8] and reduce blood product transfusion [8].

This study has some limitations. The Electronic Patient Record was used to determine the time of the laboratory result appearing to the clinician. The laboratory may have phoned the clinical area to verbally report results to the treating clinician which was generally not recorded making this timing inaccurate. Whilst this study only looked at 66 patients, it does represent the Code Red experience of almost the whole country (extension of the protocol to the North of Scotland was not achieved until 2019) and has allowed the impact of interventions since the last survey to be accurately and rapidly assessed.

Conclusions:

Code Red practice has improved in several ways since our last survey with earlier Code Red activation, more patients receiving pre-hospital transfusion and improved CRC:FFP ratios. Interventions such as reducing late on scene Code Red activation, introducing pre-thawed group A HT negative FFP into the ED resuscitation room, introducing TXA into pre-hospital services, introducing a blood component transfusion guide for clinicians to enable them to better understand which blood components should be transfused and when, and introducing a Point-of-Care viscoelastic coagulation testing service have all contributed to these improvements in transfusion practice in Scotland. There are

still improvements to be made in TXA administration and time to blood products. There is very little published data on Code Red experience to compare our practice to [9] and even less looking at the effects of implementing improvement measures. It is therefore vital that a transfusion dedicated group such as our Scottish Transfusion and Laboratory Support in Trauma Group exists, and is able to independently continually review, improve and measure practice in this area.

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Competing interests: The authors declare that they have no competing interests

Table and Figure legends:

Table 1: Characteristics of code red patients 2015-2017

Table 2: Use of red cells, FFP and platelets in code red patients 2015-2017

Figure 1: Flow chart showing transfusion events and outcomes of Code Red patients

Figure 2: Ratio of the mean number of CRC and FFP transfused to Code Red patients at 30 minute intervals

Table 1:

	All data (n=66)
Age, years *	45 (18) (n=64)
Male, %	88 (n=58)
ISS *	28 (14) (n=56)
Method of transport (air/road/other)	19/43/2
Mechanism of Injury	
Blunt trauma, %	75 (n=50)
Penetrating trauma, %	20 (n=13)
Other, % (n)	5 (n=3)
Pre-hospital	
Time from 999 call to activation of Code Red, minutes +	37 (34-72) (n=59)
First SBP, mmHg *	103 (31)
First DBP, mmHg *	58 (30)
Volume of clear fluid given, mls +	285 (449) (n=57)
Received pre-hospital tranexamic acid, % (n/total)	78 (n=49/63)
Emergency Department	
Time from Code Red activation to arrival in ED, minutes +	30 (15-45) (n=59)
First SBP (mmHg) *	104 (28)
First DBP (mmHg) *	60 (26)
First ED Base Excess, mmol/L *	-6 (6) (n=43)
Volume of clear fluid given (ml) +	0 (0-1000) (n=53)
Patient time in ED, minutes +	122 (92-213)
Patient's immediate destination	
ITU, %	39 (n=25)
Theatre, %	38 (n=24)
HDU, %	3 (n=2)
CT/Radiology, %	5 (n=3)
Ward, %	2 (n=1)
Discharged, %	1 (n=1)
Other, %	10 (n=7)
Outcome	
Survived 24hrs after Code Red, %	81 (n=52)
Survived to Discharge, %	66 (n=42)
Died in ED, %	20 (n=11)
Died in hospital, %	19 (n=12)

Values are * mean (SD) or + median (IQR)

Table 2:

	All Data (n=66)
Pre-hospital	
Received CRCs, %	73 (n=48)
Total number of units transfused	112
CRC units per patient receiving CRCs	2.5
Emergency Department	
Received O negative CRCs, %	75 (n=49)
O negative units per patient receiving O negative	3.5
Received universal FFP, %	42 (n=28)
Universal FFP units per patient receiving universal FFP	3
Received universal platelets, %	28 (n=19)
Universal platelet units per patient receiving universal platelets	1
In hospital (within first 24 hours)	
Received O negative CRCs, %	94 (n=62)
O negative units per patient receiving O negative	5
Received universal FFP, %	59 (n=39)
Universal FFP units per patient receiving universal FFP	4
Received universal platelets, %	36 (n=24)
Universal platelet units per patient receiving universal platelets	1.5

Values are * mean (SD) or + median (IQR)

Figure 1:

Figure 2:

* Based on available data from 38 patients receiving CRC and FFP

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