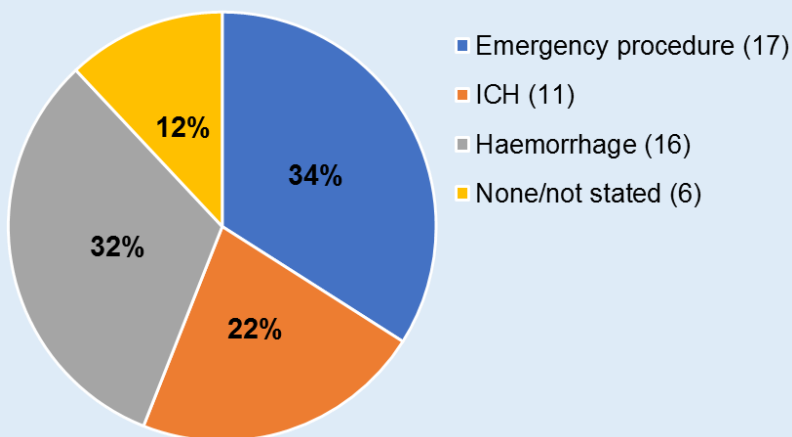


## Errors with Prothrombin Complex Concentrate

Prothrombin complex concentrates (PCC) are licenced for reversal of vitamin K antagonists (e.g. warfarin), with dosing based on patient body weight (kg) and INR (international normalised ratio) and can also be used to reverse the effects of some direct oral anticoagulants (DOAC). PCC products available in the UK are Beriplex (CSL Behring) and Octaplex (Octapharma). PCC is indicated in cases of life, sight, or limb threatening bleeds and needs to be administered as quickly as possible. PCC is also indicated for reversal of anticoagulant where emergency surgery is required (although intravenous vitamin K reduces the INR within a few hours). Any delays in administration, particularly in intracranial haemorrhage (ICH) can lead to patient death or serious morbidity. Reporting of events relating to PCC to SHOT is not mandatory but is encouraged and SHOT have been collating these since 2014.

## Trends in PCC SHOT reports

Review of reports received between 2014 and 2019 identified 50 cases relating to errors with PCC.

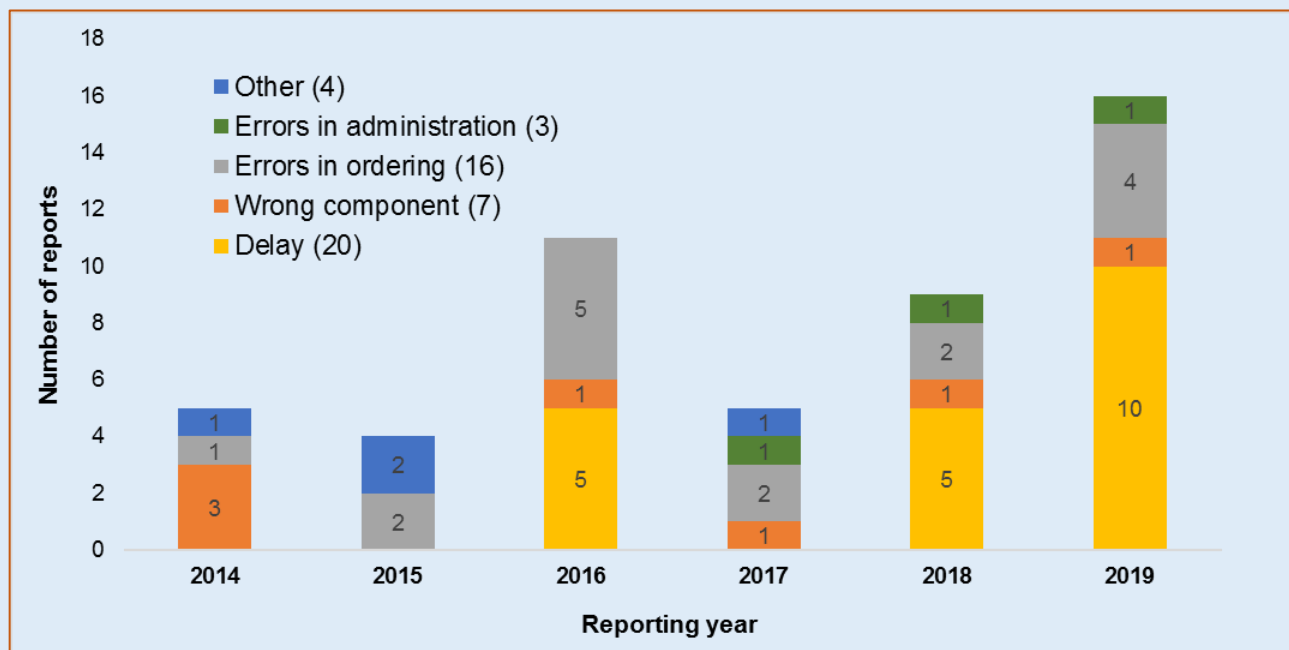


**Figure 1: Indication for PCC**

PCC was mainly indicated for emergency surgery, haemorrhage and ICH.

In a small number of historic cases the reason for PCC was not evident in the report. In one case the PCC was labelled for one patient but administered to another patient. In two cases PCC was given but the patient was not bleeding or requiring

**Figure 2: SHOT reporting category in PCC 2014-2019**



*Note: category 'other' includes label transposition, failure to administer and excess dose*

Reports relating to errors with PCC have increased over the reporting years with the majority relating to delays. Delay in administration during this period (2014-2019) resulted in the death of one patient and contributed to the death of another patient.

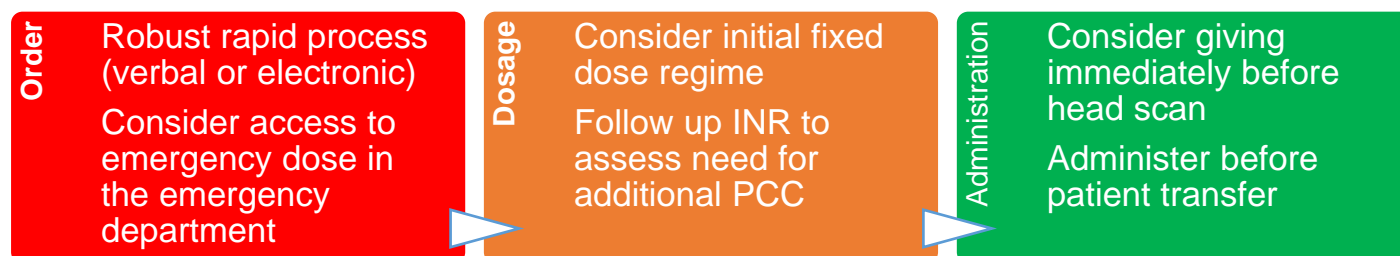
# SHOT Bite No. 16: Errors with Prothrombin Complex Concentrate

**SHOT****Serious Hazards  
of Transfusion**


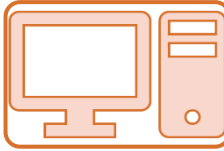

## Common features of delays in PCC administration

|                          |   |
|--------------------------|---|
| Ordering and prescribing | <ul style="list-style-type: none"><li>•Lack of knowledge in clinical teams how to order/prescribe</li><li>•Challenges with obtaining INR and patient weight</li></ul>     |
| Approval                 | <ul style="list-style-type: none"><li>•Unnecessary referral to consultant haematologist</li><li>•Difficulties/reluctance to contact consultant haematologist</li></ul>    |
| Laboratory release       | <ul style="list-style-type: none"><li>•Insufficient stock in low-use laboratories</li><li>•Dose calculation using INR and weight</li></ul>                                |
| Administration           | <ul style="list-style-type: none"><li>•Lack of understanding of the importance of rapid administration</li><li>•Difficulties with reconstitution of the product</li></ul> |

## Reducing delays



## Key messages

-  Every second counts - delays in administration of PCC costs lives. Approval for use by a consultant haematologist should not delay provision in appropriate situations. Rapid access to emergency stock and fixed dosing should be considered to reduce delays in collection of this product. PCC must be given before patient transfer.
-  Clear communication is key - processes for ordering PCC from the laboratory must be clear and should not contribute to delays. Ordering on electronic systems must include a call to the laboratory. Prescriptions must clearly state the dose to be administered. Vitamin K must be given in conjunction with PCC for warfarin reversal and the INR monitored.
-  Appropriate transfusion support – Fresh frozen plasma is never appropriate for reversal of warfarin, particularly in cases of life, sight, or limb threatening bleeds. Monitor INR following PCC use for warfarin reversal. Ensure PCC use, ordering and administration is covered in local policies and training. Training is also available from the PCC suppliers.



### Further resources

NICE guideline on transfusion 2015  
<https://www.nice.org.uk/guidance/ng24/chapter/Recommendations#prothrombin-complex-concentrate-2>

Oxford University Hospitals  
<https://www.ouh.nhs.uk/services/referrals/specialist-medicine/documents/anticoagulant-protocols.pdf>

BSH guideline for anticoagulant reversal

SmPC for PCC  
<https://www.medicines.org.uk/emc/product/6354/smpc> and  
<https://www.medicines.org.uk/emc/product/6566/smpc>