

Witness Name: Professor Ian
Roberts

Statement No.: WITN7310001

Exhibits: 0

Dated: 6 October 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR IAN ROBERTS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 April 2021.

I, Professor Ian Roberts, will say as follows:

Section 1: Introduction

Name and address

Dr Ian Roberts

Home address:

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Work address:

London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E7HT

DOB: GRO-C 1962

Relevant qualifications

| | | | |
|------|---------------|---|------|
| MB | Medicine | University of Wales College of Medicine | 1985 |
| BCh | Surgery | University of Wales College of Medicine | 1985 |
| MRCP | Paediatrics | Royal College of Physicians | 1988 |
| PhD | Epidemiology | University of Auckland | 1994 |
| FFPH | Public Health | Faculty of Public Health | 2001 |
| FRCP | Medicine | Royal College of Physicians | 2009 |

Relevant memberships: The Joint Royal Colleges Tranexamic Acid in Surgery Implementation Group. We established this group in 2022, to improve the care of surgical patients and reduce unnecessary blood use in the NHS and world-wide.

Other inquiries: I have not provided evidence to any other relevant inquiry.

Section 2: Reducing surgical bleeding and the need for blood transfusion

1. Tranexamic acid is an inexpensive generic drug that reduces bleeding in surgery and trauma. It cuts surgical bleeding and the need for blood transfusion by about one third to one quarter and has an excellent safety profile. There is no evidence that tranexamic acid causes serious side effects. We can be reassured that over 100,000 patients have been included in randomised trials of tranexamic acid and when the results from these studies are combined, there is strong evidence of benefit and no evidence of any serious harms.

Evidence that tranexamic acid prevents surgical bleeding, reducing the need for a blood transfusion and for re-operation due to bleeding, has been available for over a decade but the recent publication [RLIT0001825] of the POISE-3 trial provides strong confirmation of the benefits and safety of tranexamic acid use in surgery. The POISE-3 trial randomly allocated 9,535 adults at risk of bleeding and cardiovascular complications undergoing noncardiac surgery to receive tranexamic acid or matching placebo. It found that tranexamic acid reduces major bleeding by about 25% and significantly reduces blood transfusion. The reduction in major bleeding was similar regardless of type of surgery, also in keeping with previous results. There was no evidence of any increased risk of unwanted thrombotic events in this large-scale trial.

Tranexamic acid was recommended in the NICE Guidelines for Blood Transfusion (2015) [RLIT0001793] and the NICE Quality Standard (2016) [RLIT0001794] that 'Adults who are having surgery and expected to have moderate blood loss (>500mL) are offered tranexamic acid'. However, a recent large national clinical audit shows that a large proportion (over 30%) of eligible surgery patients do not get it (NHS Blood & Transplant, 2021). We estimate that compliance with the NICE Guideline and Quality Standard would prevent over 15,000 major surgical bleeds, save 33,000 units of blood and save many millions of pounds for the NHS each year. It would reduce transfusion-related risks and surveys show that patients and healthcare providers would prefer to avoid bleeding and the need for blood transfusion.

To increase the use of tranexamic acid in surgery, we have established an implementation group with representation from the Royal College of Surgeons of England, the Royal College of Anaesthetists and the Royal College of Physicians. Our aim is to make sure that all surgeons and anaesthetists are aware of the benefits of tranexamic acid use in surgery and that 'consideration of tranexamic acid use' is included in the safe surgery checklist of all NHS hospitals. The Royal College of Surgeons (England) and the Royal College of Anaesthetists have highlighted the use of tranexamic acid in their member newsletters and through their social media outlets and further awareness raising activities (e.g., a webinar on tranexamic acid) are planned. However, we appreciate that these activities will not be sufficient to ensure compliance with the NICE Quality Standard for the use of tranexamic acid in surgical patients and that a system-wide approach is needed.

We will recommend to *NHS England* that 'consideration of tranexamic acid use' is included in the safe surgery checklist of all NHS hospitals. The safe surgery checklist is a patient safety communication tool used by operating room professionals (nurses, surgeons, anesthesiologists, and others) to discuss important details about each case. Because the checklist is considered at the precise time that tranexamic acid should be given (if indicated), namely just prior to incision, we think this is an opportune moment to remind operating room staff about the use of tranexamic acid. We will also recommend to *NHS England* and *NHS Improvement* that tranexamic acid use is considered for inclusion as one of the CQUIN (Commissioning for Quality and Improvement) quality indicators. Under the CQUIN system NHS Trusts are offered a financial incentive to implement effective patient care. Given the strong evidence of patient benefits and safety, we believe that tranexamic acid use in surgery would be suitable as a quality indicator within this system. Audit and feedback are considered to be among the most effective ways to change clinical practice. Therefore, we will recommend to *NHS England* that the use (or lack of use) of tranexamic acid is documented in the medical record in a way that facilitates audit and feedback, which can also be

analyzed by the Care Quality Commission (CQC) in its inspection of NHS Trusts.

Changing practice in the NHS is hard, especially so in this case because tranexamic acid is a cheap generic drug and there is no profit motive for pharmaceutical companies to promote and implement it. Nevertheless, the wider use of tranexamic acid in surgery is a strongly evidence-based strategy to reduce transfusion and thus the risk of its complications. We hope that you will draw attention to this in your report.

2. Throughout the NHS, too little attention is given to strategies to reduce the need for blood transfusion. Blood transfusion is a 'liquid organ transplant,' and like any organ transplant, should not be done without good reason. There are several ways to avoid unnecessary blood transfusion but tranexamic acid is the most effective and has the strongest supporting evidence. In my opinion, the low use of tranexamic acid in the NHS is a market failure. Tranexamic acid was invented in the early 1960s. It was initially marketed for use in heavy menstrual bleeding and to prevent bleeding after dental procedures in people with haemophilia. The beneficial effects of tranexamic acid in patients with bleeding due to surgery, trauma and childbirth were not recognised until my research group at LSHTM started conducting large scale clinical trials and systematic reviews of clinical trials. By that time, tranexamic acid had long lost patent protection and was an inexpensive generic drug. Because no pharmaceutical companies were making large profits from selling tranexamic acid there was little incentive to promote it. Although NICE Guidelines recommend the use of tranexamic acid in surgery and trauma, compliance with the guidelines is poor and there are no sanctions for non-use. Patients experience worse outcomes and are unnecessarily exposed to the risks of blood transfusion but there are no consequences for doctors or hospitals that fail to provide recommended care. Over the past two decades years I have written many times to UK Ministers of Health, Chief Medical Officers, the Care Quality Commission, UNAIDS, the WHO and many others, attempting to draw attention to the role of tranexamic acid to reduce bleeding and the need for transfusion but there has been no action in response. Only in the past few months, after NHSBT declared a national blood shortage have the relevant authorities shown any interest.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed

GRO-C

Dated 6 October 2022

Table of exhibits:

| Date | Notes/ Description | Exhibit number |
|-------------|--|-----------------------|
| April 2022 | Devereaux PJ, Marcucci M, Painter TW, Conen D, Lomivorotov V, Sessler DI, et al. Tranexamic Acid in Patients Undergoing Noncardiac Surgery. N Engl J Med. 2022 Apr 2. doi: 10.1056/NEJMoa2201171. | RLIT0001825 |
| 01/01/2015 | National Clinical Guideline Centre 2015 'Transfusion, Patient information; 20.1 Review question: What is the information and support patients under consideration for a blood transfusion and their family members or carers would value and how would they prefer to receive it?' | RLIT0001793 |
| 15/12/2016 | NICE, National Institute for Health | RLIT0001794 |

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| | and Care Excellence, 2016 publication titled 'Blood Transfusion' Quality statements. | |
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|------------------|--|-------------|
| December 2021 | NHS Blood & Transplant National Audit of NICE Quality Standard QS138 | RLIT0001824 |
| 05/07/2022 | 'Tranexamic acid for safer surgery: the time is now' article | RLIT0001792 |