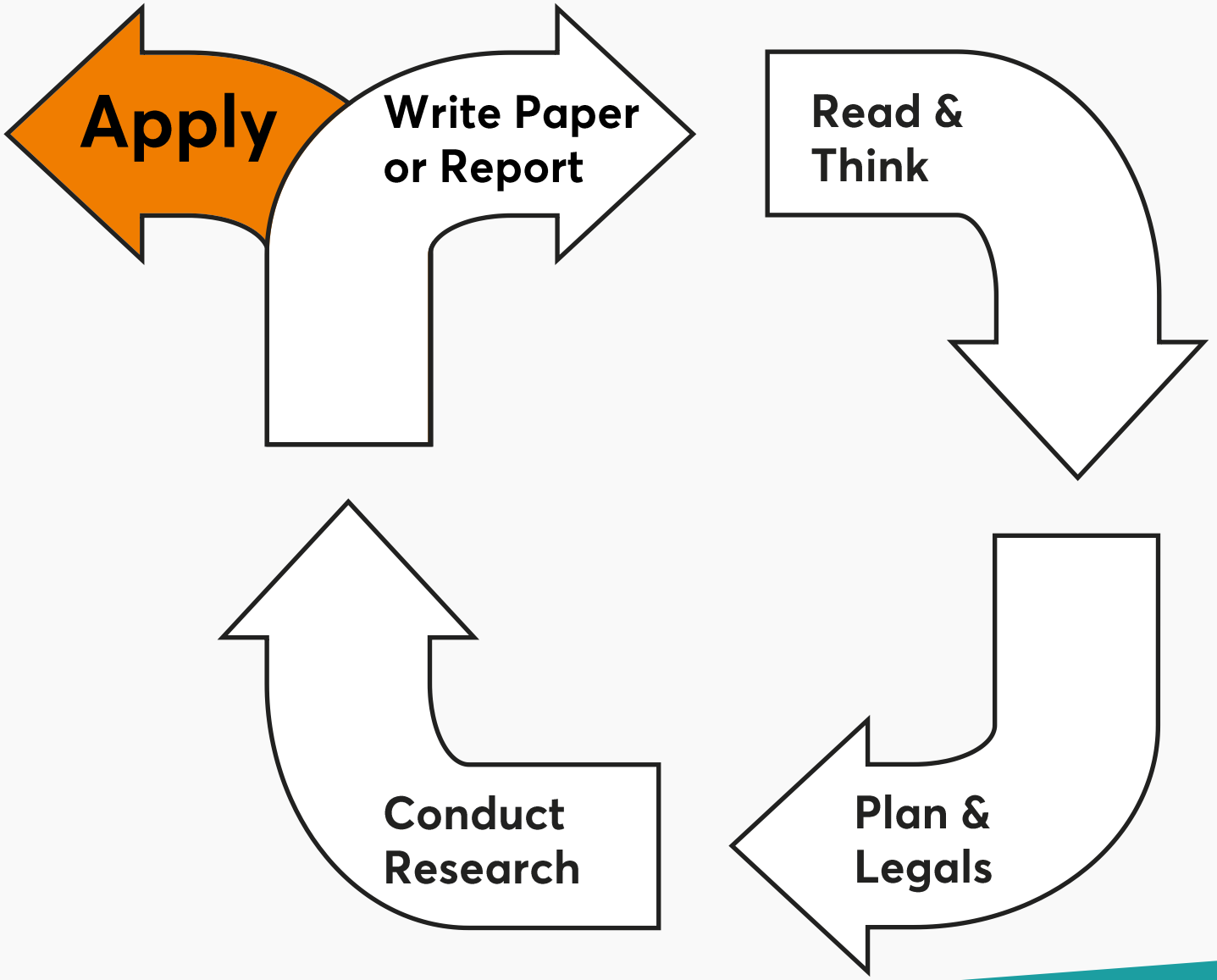
Seeing research Through Published papers

Pete Moore PhD



VoxSanguinis

ISBT International Society of Blood Transfusion

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REVIEW ARTICLE

Informed consent for whole blood donation

Brian Grainger & **Peter Flanagan**
New Zealand Blood Service, Epsom, Auckland, New Zealand

Background and objectives It is recognized that blood transfusion services have an ethical duty to obtain informed consent from their voluntary, non-remunerated donors. This right was most recently affirmed by the 2017 revision of the International Society of Blood Transfusion (ISBT) Code of Ethics. However, the constituent elements necessary to adequately inform such consent have not been definitively established.

Materials and methods This review evaluates the historical background to informed consent in medicine and as it has been applied to blood donation. The question of what information should be disclosed is then considered with regard to existing statutory requirements in both the United States and EU as well guidance from relevant international organizations. The emerging ethical issues around repurposing of donated blood for sale as recovered plasma and use in research are included in this analysis.

Results A reasonable basis is found in the literature to advocate that valid informed consent of blood donors should encompass: the donation process itself and potential adverse effects, the need for pre-donation transfusion-transmissible infection (TTI) screening, potential non-transfusion uses of derived products, requirements to obtain and store personal information, the consequences that non-disclosure of such information may have for both the donor and the recipient and reassurance as to the confidentiality of this information.

Conclusion Informed consent is a key component of the duty of care between a blood service and its donor. We identify essential elements that should be present for such consent to be considered valid.

Received: 20 June 2019,
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published online 13 November 2019

Key words: donors, donor health, blood collection.

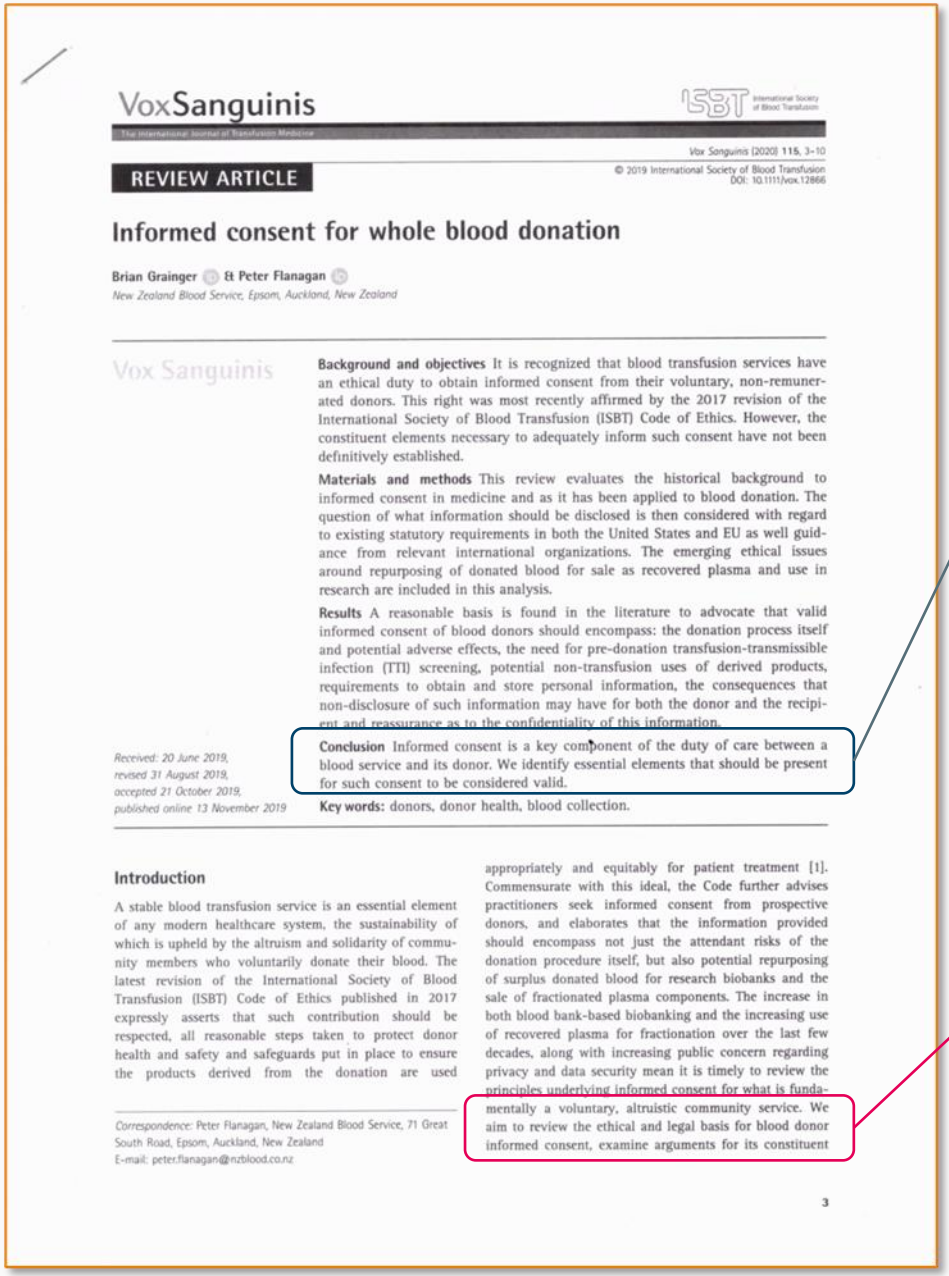
Introduction

A stable blood transfusion service is an essential element of any modern healthcare system, the sustainability of which is upheld by the altruism and solidarity of community members who voluntarily donate their blood. The latest revision of the International Society of Blood Transfusion (ISBT) Code of Ethics published in 2017 expressly asserts that such contribution should be respected, all reasonable steps taken to protect donor health and safeguards put in place to ensure the products derived from the donation are used appropriately and equitably for patient treatment [1]. Commensurate with this ideal, the Code further advises practitioners seek informed consent from prospective donors, and elaborates that the information provided should encompass not just the attendant risks of the donation procedure itself, but also potential repurposing of surplus donated blood for research biobanks and the sale of fractionated plasma components. The increase in both blood bank-based biobanking and the increasing use of recovered plasma for fractionation over the last few decades, along with increasing public concern regarding privacy and data security mean it is timely to review the principles underlying informed consent for what is fundamentally a voluntary, altruistic community service. We aim to review the ethical and legal basis for blood donor informed consent, examine arguments for its constituent

Correspondence: Peter Flanagan, New Zealand Blood Service, 71 Great South Road, Epsom, Auckland, New Zealand
E-mail: peter.flanagan@nzblood.co.nz

Five basic types

1. Standard science form (IMRaD)
   Intro / Methods / Results / Discussion.
2. ‘Essay’
   Intro / Sections…./Discussion
3. Review
4. Systematic review
5. Short communications or Letters.



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E-mail: peter.flanagan@nzblood.co.nz

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provided during the consent process. Both the relevant EU Directive [18] and US FDA CFR [17] require prospective donors to sign a declaration attesting to the truth of personal information they have provided to the blood service regarding their medical history and behavioural risk profile. As such, it is beholden on the service to inform the donor of the consequences of their failure to disclose such information, so that the individual can take the required responsibility for their informed decision to donate. The ISBT Code of Ethics accordingly asserts that donors must be made aware of this responsibility as part of the informed consent process. Moreover, an accurate individualized appraisal of the material risk the donation process may pose to a donor themselves is also dependent on that donor providing an honest disclosure of the relevant parts of their own past medical and medication history. Indeed, such honest disclosure of information by patients has previously been argued as requisite for the process of informed consent to occur in the context of providing medical treatment [64]. Social science experiments have demonstrated that an individual's honesty can be favourably manipulated through appealing to their commitment to maintain a certain standard of conduct [65]. This suggests that requiring donors to expressly declare the information they have provided is true and that they are aware of the potential consequences dishonesty could have for a recipient may in itself improve the accuracy of information disclosed.

Proposed framework for information disclosure

Commensurate with the guidance set out in the ISBT Code of Ethics, echoed in the 2018 version of the AABB's Standards and WHO's Donor Counselling Guidelines, as well as the statutory requirements set out within the US CFR Title 21 and EU Commission Directive 2004/33/EC [1,17,18,23], we summarily propose that information provided to support valid informed consent for blood donation should encompass:

(1) The donation process itself and potential adverse effects. Common reactions (which could be defined as those with a incidence of greater than one per cent by Newman et al. [21]) should be routinely disclosed to all donors; specifically localized bruising, post-cannulation arm discomfort, vasovagal reactions, nausea and vomiting and arm haematoma. The risk of post-donation iron deficiency should also be discussed specifically, along with the associated deferral process. There is arguably scope for the exercising of discretion regarding disclosure reactions known to be less frequent, including death, in accordance with a donor's desire of information, their temperament and overall health, as guided by the judgement of *Rogers v Whitaker* [10].
(2) The need for pre-donation TTI screening, the means by which any positive test results will be communicated to the donor, any need for mandatory public health notification as per the relevant jurisdiction and the process referral for further clinical management as appropriate.
(3) Potential non-transfusion uses of derived products of the donation, including specifically for both research and commercialization. The donor should be aware of the circumstances, if any, by which decisions will be made on the use of their donation in research.
(4) Requirements pertaining the storage of donor personal information by the blood service, including minimum periods of such storage for the purposes of TTI tracing.
(5) Reassurance as to the confidentiality of all personal information pertaining to the donor held or obtained by the blood service, including screening test results.
(6) The consequences that non-disclosure of relevant personal information by the donor may have for both their health and that of the recipient.

Provision of written consent forms may improve donor understanding, as reported comprehension in the Pennsylvania donor survey reported earlier [19] was higher for topics and risks that had been presented multiple times using various methods of communication as part of the consent process.

Conclusion

The ethical codes and regulatory framework of both the transfusion medicine community and several legal jurisdictions have long established that a duty of care exists between a blood service and its voluntary, non-remunerated donors. Informed consent for donation is accepted as an explicit, essential element of such duty. A review of the published literature, however, reveals deficiencies in how such consent is obtained in practice, with consequential limitations in donor understanding that may influence the likelihood of repeat donation.

In accordance with the ISBT Code of Ethics and other contemporary international guidelines, we propose a framework to guide informed consent of blood donors incorporating the donation process itself and potential adverse effects, the need for pre-donation transfusion-transmissible infection (TTI) screening. Donors also have a right to be informed of the potential for repurposing of their donation beyond mainstream transfusion

In accordance with…
we propose a framework…

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- conduct the specific study
- send the paper to a specific journal
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- What do you need to do now?
- What small step deadlines could you set for yourself?

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