COMMENTS

Walking blood banks: An immediate solution to rural India's blood drought

RACHITA SOOD, NAKUL RAYKAR, BRIAN TILL, HEMANT SHAH, NOBHOJIT ROY

Abstract

The current system of blood banks in India is such that rural patients are deprived of timely access to an adequate volume of life-saving blood, adding to preventable mortality. On the basis of an academic framework for a blood transfusion system, we describe an alternative approach in which rural practitioners utilise unbanked blood transfusions from a voluntary pool of pre-screened donors. This system would provide safe blood – as evidenced by international experience and limited projected increase in transfusion-transmissible infection in India – at a fraction of the financial cost imposed by the current system. Given the failing status quo and the undue burden placed on rural clinicians and patients to procure blood, it is imperative that policy-makers further explore the use of unbanked, direct blood transfusion for patients facing emergent, life-threatening haemorrhage.

Introduction

Each day, hundreds, if not thousands, of people die needlessly in rural India due to lack of safe, affordable blood products. Our team and other physicians have earlier described rural India's dependence on an often dilapidated, unsafe and inefficient blood banking system (1,2). Recently, issues related to the safety of and access to this life-saving treatment have returned to the public eye. According to the data released by the Indian National AIDS Control Organisation (NACO) in 2016, 2234 new cases of HIV were attributed to blood transfusions over 17 months (3). The report has led to increasing advocacy by individuals for an overhaul of blood transfusion regulations.

Here, we describe the existing framework for blood transfusion and discuss the deficiencies of this system in the context of surgical care in rural India. Next, we combine guidelines from NACO with a framework developed by Stainsby and colleagues (4) to detail an improved process for blood transfusion, especially in the setting of emergent, life-threatening haemorrhage (5). Finally, we discuss this transfusion practice in the context of both high and low-income settings and further our argument regarding its appropriateness in the context of rural India.

The current system

The existing framework depends on a functional blood bank, in close proximity to every hospital in the country, which can be rapidly accessed and has a large pre-screened pool of blood available at all hours of the day. There are several important reasons as to why this system fails to provide timely access to safe blood for patients in rural India.

First, India is a wide and vast country, with simply too few NACO-approved blood banks to cover all areas. This patchwork of private and public blood banks is largely concentrated in urban centres, leaving a large portion of rural India's patients and providers out of reach of the existing blood infrastructure (6). There are some 80 districts that have no access to any blood bank whatsoever (7). Second, the existing blood banks often lack a sufficient supply of blood products (8). These deficits lead to extraordinarily variable costs of blood, often leaving this essential treatment out of the reach of many patients and their families.

Third, despite the government regulations on the testing of blood for transfusion-transmittable infections (TTI), there are significant failures with regard to the testing, safety and quality of blood (9, 10). Finally, although non-voluntary and paid blood donations have been shown to be associated with a significantly higher incidence of TTI, both in India (11) and more broadly, in low- and middle-income countries (LMIC) (12), and in spite of a Supreme Court ruling outlawing non-volunteer donations, a significant portion of the blood available at NACO-supported blood banks continues to be procured from these illegal sources (13).

This fractured system often has disastrous consequences for those living in rural India. The system requires a family member of a patient in emergent need of blood transfusion to travel to

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the nearest blood bank, which is often hours away. If the blood bank has an insufficient supply of blood, the family members must furnish a willing, healthy replacement donor. They must then navigate the process of donating blood and obtaining proof of donation before travelling back to the hospital, blood in hand. This process is problematic for three important reasons. First, it results in extensive delays for patients urgently in need of blood products, leading to many unnecessary deaths. Second, the system is prohibitively expensive for many patients and their families, due to the high cost both of blood and travel, which again results in unnecessary deaths. Third, the system very often relies on non-volunteer replacement donors, thus increasing the overall risk of TTI within India's blood bank supply pool.

rather than on patients and their relatives. In addition, pre-screened donor pools are utilised by blood banks in urban India to ensure the availability of rare blood groups; thus, there should be no legal obstacle to employing the practice in rural India. Third, because the blood is directly transfused after appropriate testing, there is no need to rely on costly refrigeration systems and inconsistent power supplies (15) to ensure the quality of the blood.

The use of such systems for unbanked, direct blood transfusion (UDBT) has been widely adopted in military settings. During the NATO conflicts in Iraq and Afghanistan, thousands of whole blood transfusions were performed safely and effectively, using a similar pre-tested donor pool and rapid diagnostic testing at the time of transfusion (16). Moreover, the practice has proven so successful that efforts are under way to adopt similar whole

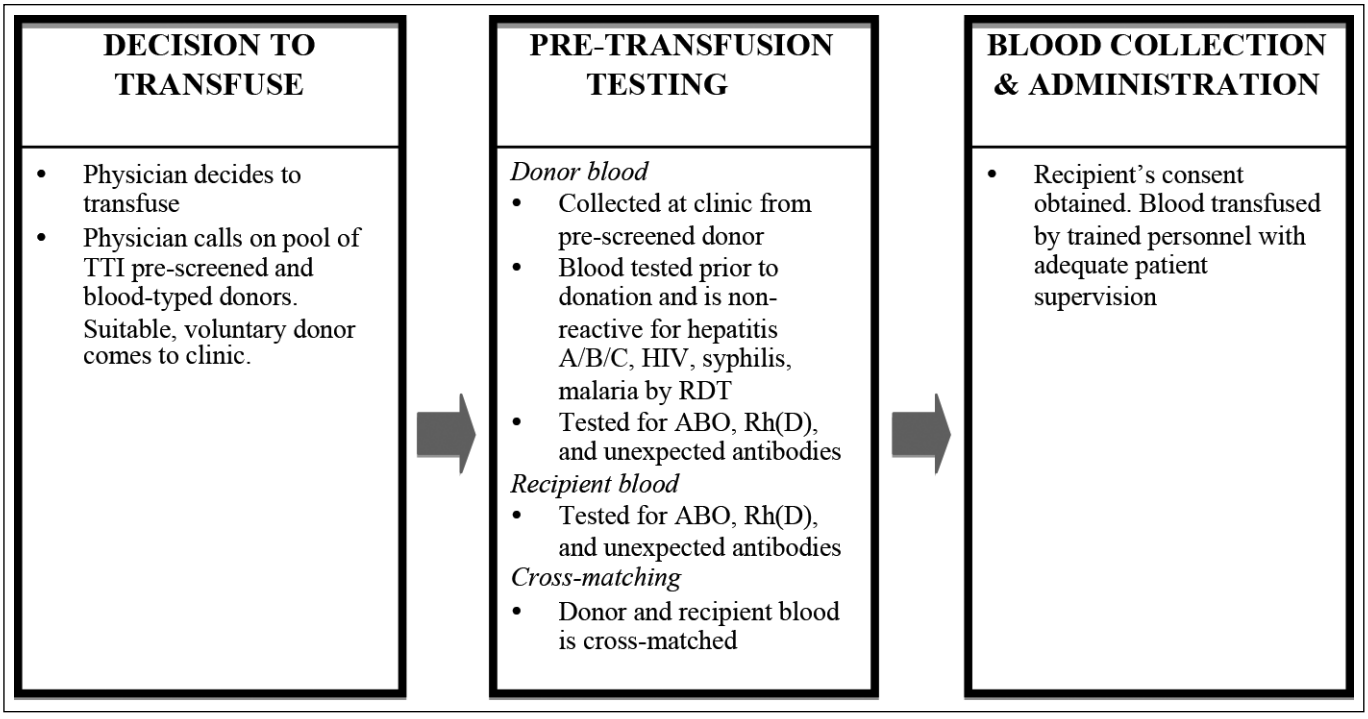

Figure 1. Process map for unbanked-direct blood transfusion (UDBT) in rural areas, based on Stainsby and colleagues' (2005) framework.

Toward an effective, viable alternative

Our proposed framework (Fig 1) places a safe, reliable blood supply within the reach of each hospital, with the costs being a fraction of those that would be involved in operating a full blood bank. First, donated blood is procured and used for treatment in the local hospital. This greatly improves the likelihood of timely access, and also significantly reduces the cost incurred by patients and their families. A prospective trial in Malawi found that such a system reduced the cost per unit of blood by more than 67%, even without taking any travel costs into account (14). Second, blood is collected from a pool of voluntary, pre-tested donors that is organised by physicians, thus limiting the reliance on unsafe replacement donors. This system has the added benefit of placing the responsibility for procuring blood on the treating physician, blood-based treatments for acute haemorrhage in US civilian settings (17–19). Among the LMIC, a similar system has proved to be effective in a large trial at a district-level hospital in Ghana (20).

The safety of walking blood banks

The proposed UDBT process map would rely on the rapid diagnostic test (RDT) for HIV, hepatitis B and hepatitis C, rather than the more sensitive and specific ELISA tests. A major criticism of UDBT is that the process is unsafe due to inadequate pre-transfusion testing of donated blood using RDTs, rather than the ELISA. However, the numbers do not support this criticism in the context of the rural Indian hospital. The prevalence of HIV among voluntary blood donors in India ranged from 0.0017–0.0022 from 2010 to 2013 (11).

Using the upper bound, this would mean that there would be an estimated 220 infected units per 100,000 transfusions. The WHO reports that the HIV RDT has a sensitivity of 0.976 and the ELISA of 1.0. This means that the RDT would correctly detect 215 out of 220 units of infected blood (hence missing 5 units) (21,22). Is the consideration of the theoretical risk of five additional HIV infections per 100,000 blood transfusions a rational choice when many more experience morbidity or mortality due to the lack of blood at rural Indian hospitals every day?

In addition, WHO recommends the use of a highly sensitive and specific RDT in remote, rural laboratories, where the number of samples tested, staff training and the reliability of power supply may prove to be hurdles in ELISA testing (23). NACO also allows the practice, and many rural blood banks in India already employ RDT for the transfusion of banked blood. Thus the practical, population-level impact of our proposed UDBT framework on TTI rates would be even less than that presented here.

More broadly, there is a significant amount of data demonstrating that testing for TTI in LMIC remains substandard. These studies examine centres employing both the RDT and ELISA tests (24, 25). The evidence suggests that operator error and poor storage of instruments play a significant role in impeding safe blood transfusions. Proper training and context-specific test validation remain critical to maintaining a safe blood supply, both in high- and low-income settings, and careful training must be the cornerstone of any effort to improve the safety and quality of blood. The implementation of the framework we have proposed should be accompanied by a robust training and certification process on the use and validation of RDT.

Conclusions

There is credible evidence from both high and low-income settings that direct unbanked whole blood transfusion can be performed safely and effectively. There is also significant evidence that RDTs can be used effectively in both types of settings to limit TTI events to nearly zero. In the context of many LMIC, India included, it is likely that a robust system for UDBT, based on the framework we have proposed, will significantly reduce TTI events.

It is clear that the current system in India is resulting in a premature end to innumerable lives due to delays and the prohibitive expense of blood products. Building thousands of functional, staffed blood banks with robust blood collection and safety protocols, as well as the ability to immediately separate blood into its components, would be both prohibitively expensive and logistically unfeasible. Such investment in blood bank infrastructure and technology in rural settings should remain a future goal for the government of India. In the interim period, the price paid by rural patients is too high, and we make a plea for UDBT to be investigated further as a safe and effective immediate alternative to the failing status quo.

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Placing the "radar" under the radar: Ethics of public health surveillance

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Abstract

Public health surveillance (PHS) is an essential public health activity, which entails collecting data on diseases and disease-related states in a timely manner to aid in international health regulations and in local health planning. Opinions differ sharply on whether it is a research or non-research activity. In recent years, most low- and middle-income countries (LMICs) have been establishing their own PHS systems, with or without support from external donors, to comply with the stipulations of international health regulations. With the expansion of the scope and role of PHS in ensuring the health security of countries, it is important to understand the ethical principles of PHS and the specific ethical issues involved in it, as well as the need for ethical oversight of PHS. This paper deals with these aspects of PHS, and highlights the need for specific ethical guidance and oversight mechanisms in LMICs that are setting up their own PHS systems.

Introduction

Public health surveillance (PHS), also referred to as the "radar" of public health, can be defined as the ongoing, systematic collection, collation, analysis, interpretation and dissemination of health-related data in a timely manner to those who need to know, so as to effectively plan, implement and evaluate public health activities (1). The National Institute of Communicable Diseases, South Africa defines it as "continuous analysis, interpretation and feedback of systematically collected data, generally using methods distinguished by their practicability, uniformity and rapidity" (2). According to an older definition, PHS is "a system of close observation of all aspects of the occurrence and distribution of a given disease through the systematic collection, tabulation, analysis and dissemination of all relevant data pertaining to that disease" (3). This activity is essential for the proper planning and delivery of public health interventions. Originally, the term PHS was used to refer to infectious disease surveillance, but now it encompasses a wide array of targets that are under scrutiny. These are chronic diseases, chronic disease risk factors, and environmental exposures. Several modalities of surveillance of health-related states and events have been in use. The most common and time-tested modality is the reporting of diseases by health providers, health facilities and laboratories. Of late, non-surveillance data are being used for PHS. Vital registrations, health information systems, disease registries, demographic and health survey data, law enforcement records, etc are all used as sources of data for PHS (4–6). The social media and Internet-based data are also used for PHS (7). Given this expansion of the role and scope of PHS in recent years, the ethical considerations in the practice of PHS are now a matter of global concern. Several important ethical issues are involved in the practice of PHS. These are as follows.

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Ethical imperative to perform PHS

Conducting PHS is necessary to ensure local and global health security. Health security has been defined in several ways. Health security includes protection against threats such as poverty, hunger, disease, pandemics and bio-terrorism; the provision of medical aid and humanitarian assistance during conflict; and the involvement of military and political interests to prevent the cross-border spread of diseases (8). The International Health Regulations, which were modified in 2005 and came into force in 2007, have been ratified by 196 countries. They aim to "prevent, protect against, control and provide a public health response to the international spread of disease" (9). The recent Ebola epidemic in West Africa created awareness of the collective threat to health security