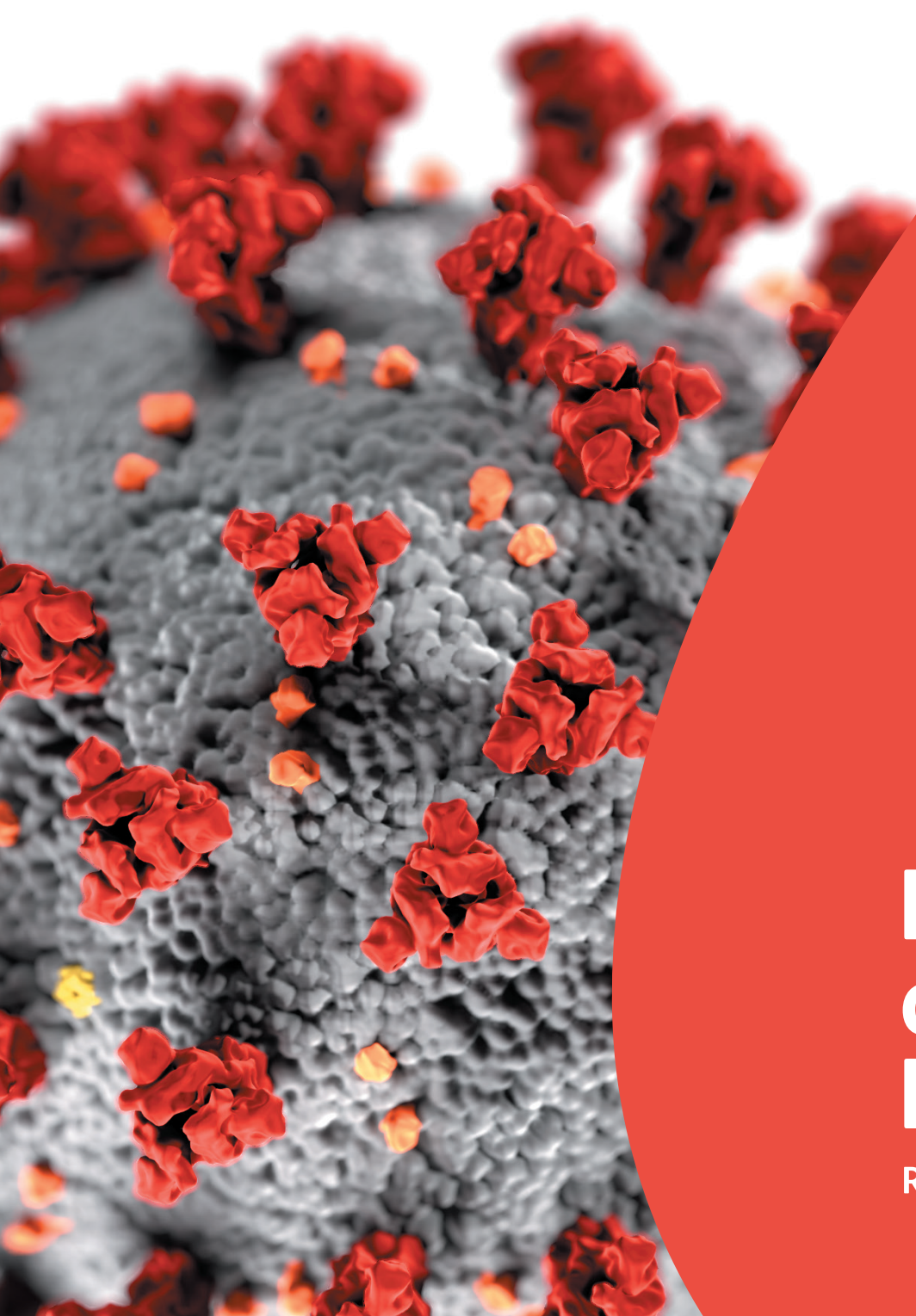
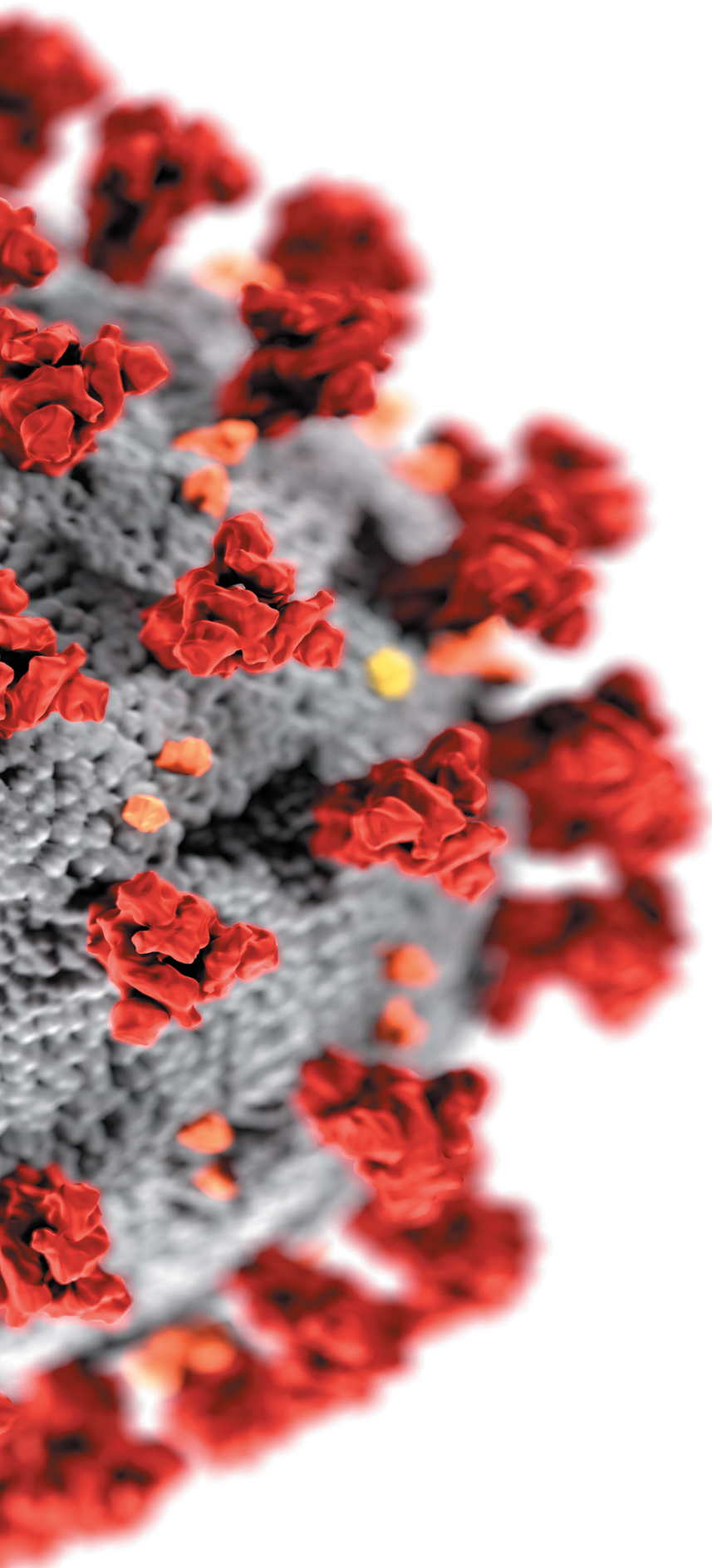


Blood use in Europe: learning from the impact of COVID-19

A Blood and Beyond policy briefing

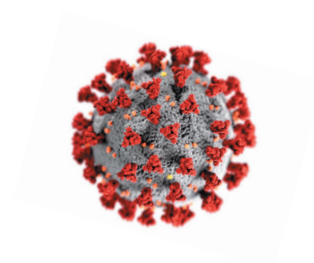


Blood 
and
Beyond.
Rethinking Blood Use



Inside:

- Impact of COVID-19 on blood donation and supplies
- Blood demand during COVID-19
- Rethinking blood use: updated and upgraded action needed
- Conclusion

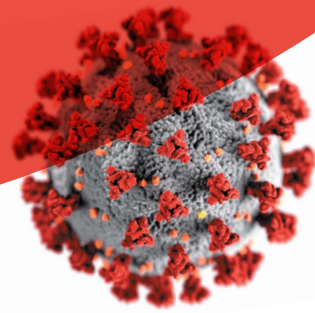


Blood and Beyond is a multi-stakeholder initiative developed and funded by Celgene, now part of Bristol Myers Squibb, involving experts from the fields of haematology and patient blood management, nursing, patient advocacy, health economics and hospital management. The aim of the initiative is to raise awareness of the impact of blood transfusion on patients, support networks, healthcare systems and society at large; with the overarching goal to help advance policies and practices that improve patient outcomes by optimising blood management and supporting innovation across Europe.

www.bloodandbeyond.com

May 2021

Introduction



The COVID-19 pandemic has caused considerable morbidity and mortality worldwide and has profoundly disrupted healthcare systems and society as a whole. The pandemic has had major implications for blood supply and demand, posing organisational and logistical challenges for transfusion services,^{1,2} which are essential for public health and healthcare systems and which are already under pressure. This impact varies within and between countries, depending on the epidemiology of COVID-19 and other factors, including the prevalence of transfusion-dependent chronic conditions. It warrants urgent attention by European Union (EU) and national policymakers at present, as policies and services continue to be adapted to cope with the pandemic, and during the subsequent recovery phase. This crisis also offers an opportunity for the development of sustainable, forward-thinking solutions to the longer-term challenges in blood use, including the preparedness for future pandemics.³

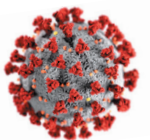
In many countries, the majority of red blood cell (RBC) transfusions are used in the supportive care of patients with chronic diseases.^{4–5} Indeed, RBC transfusions are currently seen as a cornerstone of care for the anaemia caused by various malignant and non-malignant blood diseases. In these settings they are often life-saving, and some patients are dependent on regular, life-long transfusions where currently no treatments for their chronic anaemia are available.⁶ In patients with solid cancers, chronic kidney disease, gastrointestinal disease and cardiovascular disease, the use of blood transfusions is still highly prevalent, although other treatment options to correct anaemia and its underlying conditions are gaining in importance.

Despite their benefits, transfusions can also have various negative effects for patients, healthcare systems and society at large, as the multistakeholder Blood and Beyond report highlighted in 2020.⁶ Frequent, regular transfusion therapy in hospital clinics can be debilitating for patients, and time-consuming and burdensome both for them and their caregivers and families – impairing their quality of life. Long-term transfusions also come with risks and complications, such as transfusion reactions and iron overload, and substantial costs to the healthcare system. Threats to the sustainability of blood supplies, especially with an ageing population and migration to Europe from areas where haemoglobinopathies such as β -thalassaemia are endemic, may also put the treatment of these patients at risk.

The Blood and Beyond report⁶ proposed a series of policy recommendations to help address these existing, well-recognised challenges in the blood ecosystem and in transfusion care for chronic diseases – with particular reference to the ongoing evaluation of the Blood, Tissue and Cells Directives (Directives 2002/98/EC and 2004/23/EC).⁷ Now, the COVID-19 pandemic has amplified these challenges and further reinforced the need to rethink blood use in Europe. This briefing paper aims to:

- *overview the impact of the COVID-19 pandemic on patients where transfusions are clinically indicated, particularly in the management of chronic conditions, and on the sustainability and competence of the blood supply at national level and across Europe*
- *revisit, extend and strengthen the recommendations already provided in the Blood and Beyond report, focusing in particular on the shift to optimised management of the patient's own blood, a concept known as patient blood management (PBM).*

In common with the Blood and Beyond report, this briefing paper was co-developed with experts from the fields of haematology and PBM, nursing and patient advocacy (see Contributors).



Impact of COVID-19 on blood donation and supplies



Effects on donation

Blood is a finite resource gained from donors and delivered to patients via a complex, specialised system. In 2019, the European Commission (EC) Evaluation of the EU Blood Directive concluded that current EU provisions are insufficient to support an adequate and sustainable supply of blood.⁸

The COVID-19 pandemic caused a drop in the number of blood donations in most EU countries.⁹ According to data provided by the European Blood Alliance and reported by the European Centre for Disease Prevention and Control (ECDC),¹⁵ European national and regional blood services reported an average 9% (median, range 1–27%) decrease in blood and blood components collected in March and April 2020 compared with the respective period in 2019 (Figure 1).⁹ Consequently, there was an overall decrease reaching 12% in blood components distributed to hospitals (range 1–18%). Early in the pandemic, some centres reported reductions of 32% in Italy,¹⁰ 11–49% in Spain^{11,12} and 25–60% in Greece.¹³

Therefore, although supplies recovered partly or even fully during the year, overall reductions in supply levels have persisted and are still posing challenges in some countries. Across Italy, for example, the National Blood Centre reports that around 139,000 fewer RBC cell units were collected throughout 2020, compared with 2019 – a reduction of 5%.¹⁴

Several factors contributed to the reduction in blood donations,^{1,2,9,15,16} including:

- **Avoidance by donors**, owing to social distancing rules, travel restrictions, illness, self-isolation, need to care for family members, school closures, or fear of acquiring COVID-19 during donation
- **Cancellation of blood donation campaigns** in remote communities, owing to travel restrictions
- **Reduced capacity at donation centres** due to COVID-19 precautions, staff being on sick leave or self-quarantining due to COVID-19, or re-deployment of staff to other hospital areas or sections to meet high demand due to COVID-19

• **COVID-19 related diversion of blood and staff** to services related to the manufacture of convalescent plasma from patients who have recovered from COVID-19

• **COVID-19 related changes to donor selection criteria** employed to safeguard the safety of blood – although there is currently no evidence for coronavirus transfusion via donor blood and it is considered highly unlikely.^{2,9} However, since it cannot yet be totally excluded, donor selection and haemovigilance remain important tools to protect patients receiving donor blood^{2,9,15}

• **Blood processing and supply chain disruption** due to transport and trade restrictions, quarantine requirements, border control measures and production problems relating to critical materials and equipment.

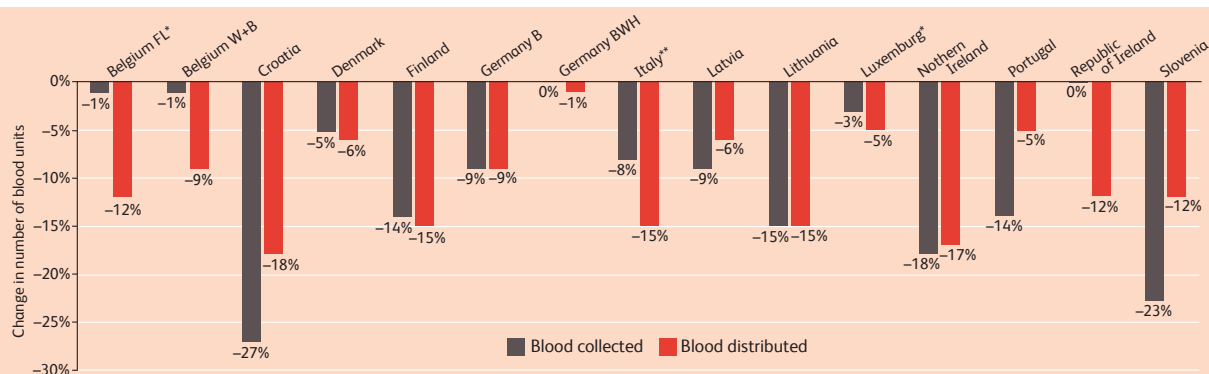
Notably, the reduction in blood donation has also affected blood exportation and importation between countries, an element which can be challenging for countries where the adequacy of blood supplies relies on such cross-border activities (e.g. exportation from Switzerland to Greece).

Supply mitigation measures

Blood establishments and other actors have worked hard to ensure the availability of safe blood products during the pandemic, both by maintaining supplies to reserves that are as safe as possible, and also by limiting demand (see below). Measures recommended to maintain supply have encompassed contingency planning, donation drives, donor selection procedures, safety precautions at donation centres, and adapted processing and storage measures.^{1,2,9}

For example, in Italy, Greece and Cyprus, the availability of blood transfusions has been maintained for transfusion-dependent patients through national networking, and some centres have reported stable (or even increased) outpatient use of blood¹⁷ despite the overall shortages experienced at national level. Successful national media campaigns were undertaken to boost donation in Cyprus, France, Greece, Italy and other countries.^{17–20}

Figure 1. Percentage changes in the number of units of blood and blood components collected and distributed to hospitals in 15 European member states/regions in March–April 2020, as compared with March–April 2019. Data provided by European Blood Alliance and reported by ECDC.⁹



*Plasma for fractionation excluded.

**Only whole blood and red blood cells.

Blood demand during COVID-19



The total use of blood has decreased during the pandemic owing to efforts to address the pandemic as a priority and public health emergency. This has largely, but not completely, compensated for the reduction in supply, particularly among patients with lifelong dependency on blood transfusion therapy.

The fall in demand for blood is primarily due to the widespread deferral of elective and non-urgent surgeries by health services across the world.^{1,2} In the UK, for example, there was an initial decrease of around 30% in the number of RBC units issued in March 2020, which levelled off to around 10% by May 2020.²¹ The demand for transfusions was also reduced by the delay or attenuation of cancer treatments^{22,23} and a reduction in trauma from traffic accidents, owing to restricted social mobility.

Of course, blood transfusions have still been necessary during the pandemic for various acute situations where they were clinically indicated, including trauma and emergency surgeries with concomitant massive haemorrhage, for severe anaemia caused by cancer chemotherapy, and for patients with chronic anaemia managed using long-term transfusions.^{1,2,16} However, in practice transfusions are often given when they are unnecessary or inappropriate.²⁴ Therefore the World Health Organization (WHO),² ECDC¹⁰ and many other experts^{1,17,25} have stressed the importance of good PBM as part of pandemic responses to reduce blood demand and safeguard stocks – as discussed further below. Strict adherence to transfusion guidelines is essential to ensure that transfusions are given only when clinically indicated. Some evidence at least in the USA has shown improved hospital-wide adherence to RBC transfusion guidelines during the pandemic.²⁶

Impact on transfusion care in chronic diseases

The disruption caused by the pandemic led to suboptimal haemotherapy in some transfusion-dependent patients with chronic diseases.²⁷

The capacity of some transfusion services has been reduced owing to COVID-19 safety precautions, staff shortages, and redeployment of resources to other hospital functions.¹⁶ This has resulted in the cancellation or postponement of transfusion appointments in some cases.

Some patients may have also postponed their own transfusion clinic appointments due to fears of acquiring COVID-19.^{15,21,27,28} Indeed, transfusion-dependent patients with chronic diseases are likely to be at elevated risk from COVID-19 – although this has not been well-studied.^{15,28,29}

Some transfusion-dependent patients have experienced blood supply shortages. For example, in a survey of 378 haematology and oncology physicians in France, Germany, Italy, Spain, and the UK:³⁰

- 65.6% of physicians reported having transfusion-dependent patients with myelodysplastic syndrome (MDS) who had encountered delays in transfusion due to blood supply shortages (range 54.7% in France to 73.7% in the UK)
- 17.2% of physicians reported that delays due to shortages affected at least a quarter of these patients (range 9.3% in Spain to 31.6% in Italy)
- Overall, 9.0% of these patients were affected (6.6% in Spain to 14.1% in Italy).

Similarly, in an international survey on the effects of the pandemic in the treatment of paediatric patients with cancer, the majority of participants reported decrease of availability of blood products. This observation was more pronounced in low and lower middle-income countries, compared with upper middle and high-income countries (62%, 74%, 56% and 46% of respondents, respectively).³¹

In some cases, limited blood supplies have necessitated more frequent, smaller transfusions and hence more clinic visits. This has exacerbated the logistical burden that patients and carers already face in their dependence on regular transfusion clinic visits,⁶ as well as increasing their risk of contracting COVID-19 and increasing the workload of clinics. In one survey, almost 17% of transfusion-dependent patients were estimated to need additional healthcare practitioner visits when transfusion was delayed due to blood supply shortages.³⁰

In addition, the uncertainty of blood availability and the disruption of essential transfusion care may have contributed to increased fear, anxiety, depression and stress in some patients.^{32,33}

Other potential problems have included:

- *Challenges with essential iron chelation therapy among some transfusion-dependent patients, including interruptions or shortages.*²⁷ *Effective iron chelation therapy is essential to avoid the serious complication of iron-overload that can occur in chronically transfused patients.*
- *Delays in seeking care for health problems associated with long-term anaemia, or difficulty in accessing primary care services.*^{21,34} *Disruptions to care pathways may have resulted in underdiagnosis of diseases requiring long-term blood transfusion, or delays in referral for transfusion. This may be expected to cause collateral damage in the coming years. As an example, one UK haematology centre reported a 71% fall in the number of full blood count tests performed from primary care in the first 4 weeks of the initial lockdown, and a 57% reduction in the number of e-referrals of patients for specialist haematology review. Overall, diagnoses of new blood cancers were reduced by 54%.³⁴ This may lead to a rise in cases after the pandemic, and potentially more patients presenting with advanced disease owing to the delay. This*

centre also reported a 20% reduction in RBC transfusions in the first month of lockdown, along with reductions in chemotherapy and supportive care.³⁴

- Many chronic disease patients have also been affected by postponement of other non-transfusion consultations, assessments and procedures.

The pandemic has triggered various important changes in the delivery of care by haematology and transfusion services.^{1,23,29,34} These include:

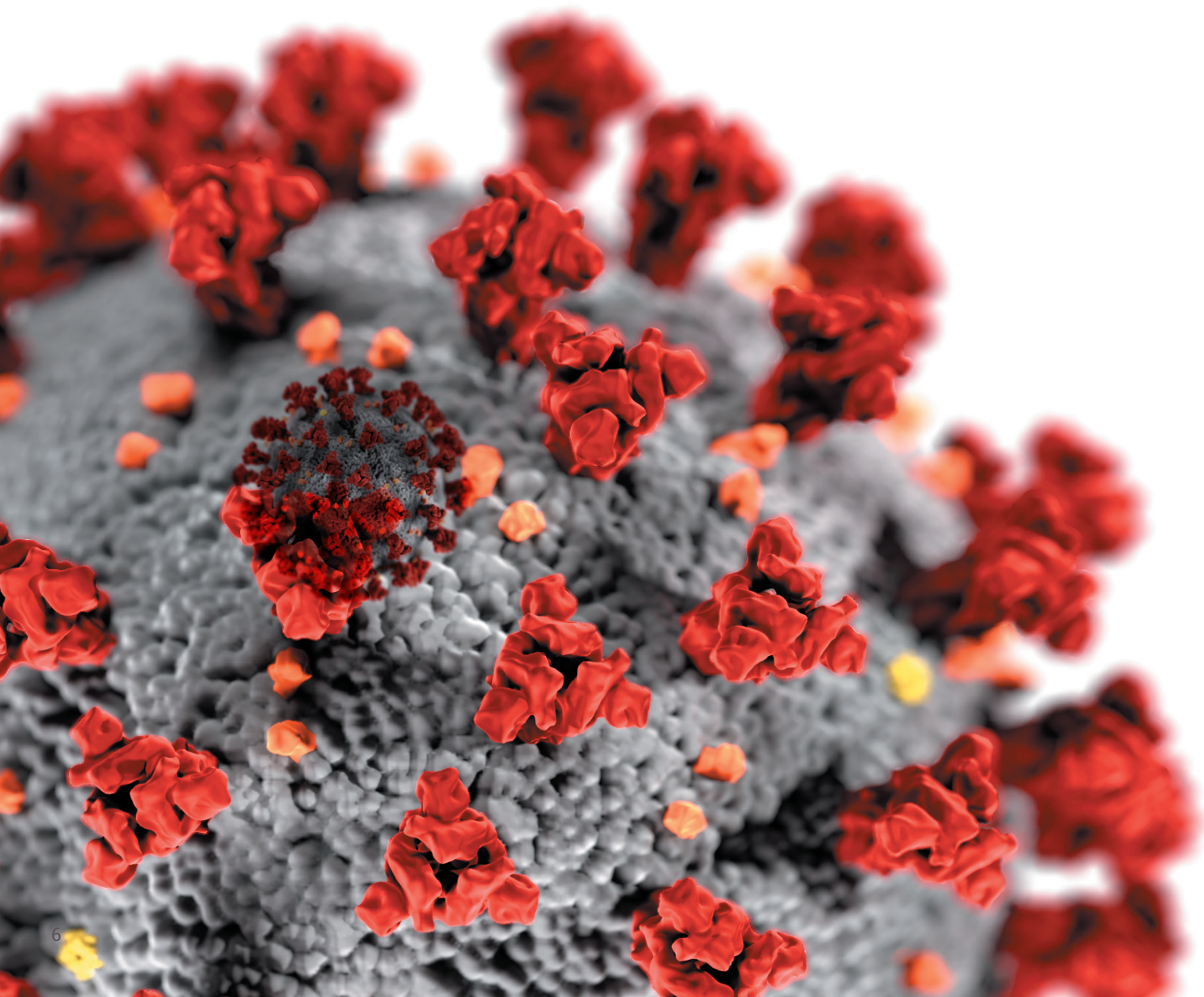
- Clinic organisation measures, including extended clinic hours, increased staffing and COVID-19 safe procedures
- Approaches to reduce transfusion use, e.g. by adjusting thresholds for transfusion²³

- Wider use of localised, drive-through or home-care services for transfusion care, where suitable, blood tests or other types of anaemia care,^{23,29,35} as well as medicines collection or delivery systems³⁴

- Embracing telehealth (i.e. telephone or video consultations) to maintain patient care and contact^{29,34}

- Enhanced communication and information sharing between patients and healthcare professionals.^{15,16}

Also of great importance is the increased communication that has occurred between central blood establishments, hospitals, transfusion teams, healthcare professional organisations, patients and patient organisations, and the public, including via online and digital platforms and social media.^{21,27}



Rethinking blood use: updated and upgraded action is needed at EU and national levels



The COVID-19 pandemic has multiplied the existing challenges in blood supply and use in Europe, and created additional ones. Ongoing coping strategies have helped to maintain supplies during the present crisis but are not viable options in the long run.

The pandemic has underscored the pressing need for a co-ordinated EU vision on the future of blood use. This must include new ideas, tools and policies not only on blood and its use, but also on the means to better manage and preserve the patients' own blood. In particular, Europe urgently needs strengthened public health programmes and innovative approaches to support the health system-wide implementation of PBM and the sustainability of supplies. Long-term solutions must be achieved in each country. The revisiting of EU directives and regulations – to be subsequently transposed into national laws – offers opportunities for change, and should be followed by proper national implementation.

In view of the importance of the blood ecosystem, lessons learnt to improve the resilience and sustainability of national blood systems must be embedded into post-COVID-19 recovery plans for the healthcare sector. This includes EU-level development of crisis strategies, protocols to manage future threats, and the sharing of best practices – including insights into how some countries better managed the impact of COVID-19.

It is a challenge to keep legislation up-to-date in a dynamic sector with changing risks, such as the blood sector. This field is characterised by the following features, many of which have been acknowledged during the evaluation of the EU legislation on blood, tissues and cells:³⁶

- Significant technological, epidemiological and social changes, coupled with increased innovation and strengthened patient engagement in decision-taking.
- Gaps in the scope of the legislation regarding blood, which have led to widely divergent applications and interpretations

of relevant quality standards, and weaknesses in surveillance and monitoring activities. This is coupled with limited or absent central EU coordination, and lack of robust oversight and support of some of the crucial components of securing and safeguarding the quality and adequacy of blood.

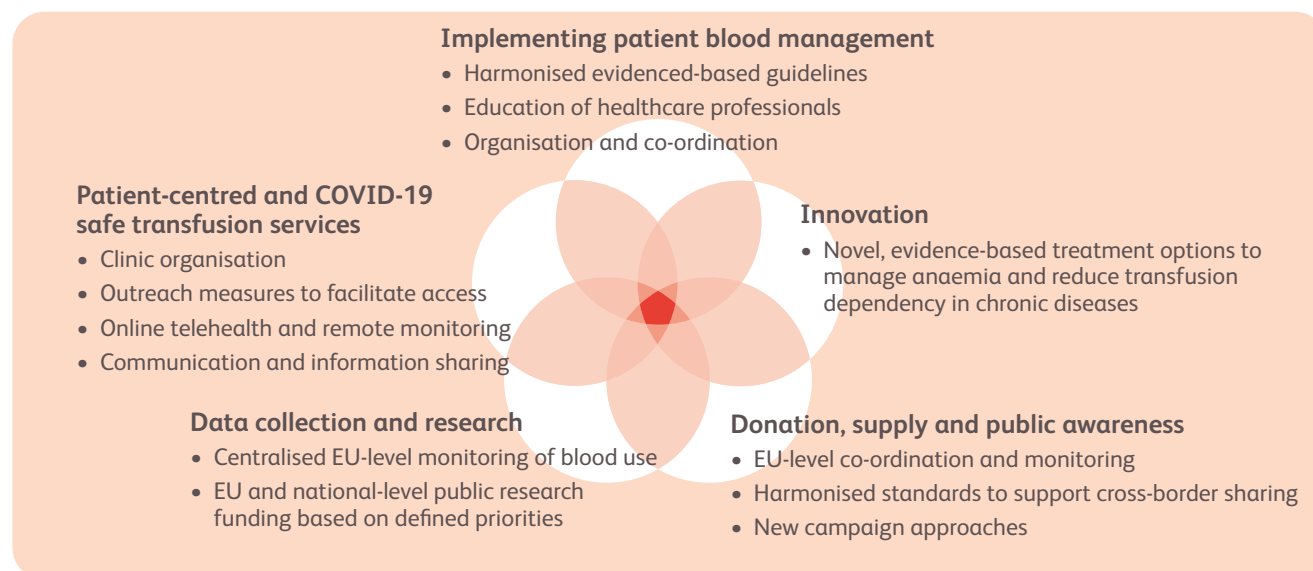
- Existing current policies and legislation at national and EU levels do not facilitate innovation in the blood sector for patient benefit, and do not include sufficient provisions for proof of effectiveness in patients. Indeed, there has been a high level of innovation achieved in the blood sector in recent years, including measures to reduce or eliminate transfusion dependency.

The Blood and Beyond report made policy-level recommendations to optimise PBM to help improve outcomes for patients with chronic diseases, reduce the potential risks from transfusions, avoid blood wastage, and safeguard blood supplies for patients who need them.⁶ COVID-19 has underscored the importance of these recommendations, and warrants additional, urgent considerations (Figure 2).

Implementing patient blood management

The pandemic has emphasised the vital importance of PBM implementation across Europe. PBM is an evidence-based care bundle recommended to optimise outcomes in both acute and chronic care settings by the clinical management and preservation of the patient's own blood, thereby conserving donor blood supplies for patients in whom it is clinically indicated, according to peer-reviewed guidelines. While PBM primarily aims to improve patient outcomes, it can also significantly reduce the use of blood products and save healthcare costs.³⁷ Endorsed by the WHO,³⁸ its effective implementation is a strategic objective of the WHO Action Framework on Blood Products for 2020–2023.³⁹

Figure 2. Revisiting the Blood and Beyond recommendations: priorities to optimise patient blood management and transfusion for patients with chronic diseases post-COVID-19.



As well as being an essential part of pandemic responses, PBM will become even more important in the longer term, as demand for blood is expected to rise sharply when hospitals resume elective surgery and non-COVID-19 admissions rise – especially to cope with a backlog of postponed interventions.^{1,16} Indeed, in some cases, disease may have progressed during the postponement of elective surgeries, necessitating more complex or urgent surgery, and hence greater blood use.¹⁶ This expected increase could once again put blood supplies under pressure, especially if donations are still lower than usual owing to COVID-19.

Accordingly, the EU Blood Directive and other available means should be employed to drive and monitor PBM implementation broadly and uniformly across the EU. Key actions include:

Development of harmonised, evidence-based PBM guidelines:

The Blood and Beyond report highlighted the pressing need for multidisciplinary European-level guidelines for PBM, including improved anaemia treatment concepts for acute and chronic diseases, to address the gaps and heterogeneity in existing guidelines.

Education of healthcare professionals: Standardised, continuous, up-to-date education on PBM and optimal blood use is essential to ensure uniform patient-centric practice and levels of expertise in the EU and address gaps and variations across countries.

- *This should be provided to all relevant staff (e.g. specialist and non-specialist physicians and nurses), and at under-graduate and post-graduate levels (i.e. across medical and surgical specialties and during internal hospital staff training).*
- *Training should include PBM, optimal blood transfusion use, management of transfusion reactions, limiting risks, and specific issues in managing the impact and complications of long-term transfusions in chronic disease patients.*
- *Communication resources should also be developed within the hospital community to increase awareness of PBM and the improved use of blood products.*

EU-level medical societies and blood establishments have a key role to play in fostering continuous medical education on PBM and optimal blood use. The European Commission should take this into consideration in the context of the Directive on the recognition of professional qualifications⁴⁰ and allow for a flexible system to enable rapid continuous professional education in times of crises.

Organisation and co-ordination: For these measures to be effective and adopted appropriately at the country level, robust central EU coordination, harmonisation and monitoring elements must be included in the revised EU blood legislation. Multi-stakeholder EU- and national-level committees are required to oversee patient information, data collection and analysis, policy guidance, guidelines and education.

Patient-centred and COVID-19 safe transfusion services

The Blood and Beyond report made recommendations to help improve the patient-centredness of transfusion services for patients who are currently dependent on long-term regular transfusions, and to help reduce the negative impact of care on patients and caregivers. It is essential now to ensure that the additional impact of COVID-19 is minimised, learning from examples of good practice. These aspects would generally apply to any outpatient services for chronically ill patients.

These include:

- *clinic organisation measures, including staffing, scheduling, social distancing, strict COVID-19 screening measures, and suitable facilities and procedures to isolate and care for COVID-19-infected patients^{9,15}*
- *wider use of outreach measures to facilitate patients' access to transfusion services (e.g. via homecare and mobile units)*
- *exploiting the experience gained during the pandemic on the potential roles of online telehealth consultations and remote monitoring*
- *enhanced communication and information sharing between patients and healthcare professionals.*

Observed variations in transfusion care could be addressed by the EU Blood Directive revision, for example via changes to EU-wide oversight of quality.

Notably, transfusion-dependent patients with chronic diseases should be considered among high-priority groups for COVID-19 vaccination, given their elevated risk.^{15,28}

Innovation

There are few alternative options to treat severe chronic anaemia in patients who require transfusions. Even where alternative treatments exist, they may be underutilised.⁴¹ Accordingly, many experts and stakeholders have already drawn attention to the unmet need for the development and implementation of alternatives to blood transfusion for the treatment of anaemia in chronic diseases.⁶

COVID-19 has now underscored the urgency for innovative approaches to improve patient outcomes and optimise transfusion use and PBM in chronic diseases. These approaches include novel, evidence-based, approved treatment options to manage anaemia and reduce transfusion dependency in chronic diseases, alternatives to blood (such as synthetic oxygen carriers), and gene therapies for inherited diseases.⁶ In reducing blood demands, such approaches are vital to help improve the resilience of the blood system in the event of future pandemic threats, as well as to release patients from transfusion-dependency and thus improve their quality of life and their social integration.

Future EU legislation on blood should be designed and harmonised to help foster innovation and its uptake – a core objective of the EU Blood Directive revision.⁸

Data collection and research

Data collection systems

Systems to collect accurate and comparable data are essential to facilitate monitoring and evaluation of the blood system.³⁹ The EU has a key role to play in improving the co-ordination of data collection and sharing at all levels across Europe. The COVID-19 pandemic has underscored the need for a centralised EU-wide mechanism to monitor the national blood supply levels. This would allow concerted EU-level action to support countries that fall below a minimum level of adequacy, including in times of crisis. Indeed, policy options considered by the European Commission in the revision of the EU Blood Directive include an EU monitoring system on blood use – such a system should be based on accurate, comparable data and should encompass types of use, indications, observance of PBM guidelines and guidance by the WHO and the European Directorate for the

Quality of Medicines. Comprehensive recommendations for the stepwise implementation of mandatory monitoring of patient-level indicators have already been published.⁴²

In addition, systematic data on disease burden relating to high transfusion demand, and the costs of transfusion services are important. These data would help national policymakers to better assess the need for change and to anticipate future blood demands, taking into account the ageing of both the general and the transfusion-dependent populations, and migratory patterns relevant to blood use. These data could help define or strengthen patient management and haemovigilance programmes, and inform decision-making about patients' access to alternative treatments.

These issues should be taken into consideration during the shaping of the European Health Data Space.

Research needs

Blood services have played an important role in research initiatives related to COVID-19.⁴³ However, COVID-19 has significantly disrupted many research activities.

The Blood and Beyond report called for additional EU and national-level public funding of research and proposed a priority research agenda, to which must now be added the following:

- *Risk of COVID-19 and associated morbidity/mortality in transfusion-dependent patients*
- *Impact of shortages on transfusion-dependent patients and accessibility of care/treatment*
- *Evaluation of innovative transfusion service models (e.g. homecare)*
- *PBM approaches during the pandemic and beyond*
- *New models to predict the impact of pandemic threats on the blood supply/demand balance to inform future preparedness planning*
- *Development and use of disease-specific patient databases and registries to provide appropriate data to inform policy, as well as patient care*
- *Collateral damage of COVID-19 disruption on underdiagnosis of diseases associated with chronic anaemia and transfusion dependency.*

These topics should be considered within the annual work programmes of EU4Health and Horizon Europe.

A common EU-wide model to help member states ascertain the cost of providing blood services is essential. This would allow competent authorities to recognise the value of promoting policies, programmes, research activities and innovation to (1) minimise the unnecessary use of blood and its components, (2) maintain sufficient blood supplies for patients in whom they are clinically indicated, and (3) save human and financial resources – thereby allowing for optimised resource allocation to improve the overall public health status. The Thalassaemia International Federation (TIF) has recently completed a disease-specific cost-of-illness model, recognising the importance of determining the costs involved in lifelong blood transfusion and other treatments so that competent authorities can tailor their policies and services accordingly. This model has a generic character to enable its application by any competent authority wishing to assess the cost of the services provided to patients. With minor alterations, the model could be used to assess the wider cost of transfusion services in general within a population.⁴⁴

Donation, supply and public awareness

Implementing PBM and harnessing innovation are key to rethinking blood use and should substantially reduce blood demands. Nevertheless, during the transition to these approaches and until alternatives exist, patients in whom transfusions are clinically indicated will continue to need safe, adequate and sustainable supplies.

Centralised EU coordination is vital to achieve this over and above all efforts and programmes exercised by member states.

The EU should support the sharing of good practices and recommendations to ensure the preparedness, resilience and COVID-19 safety of blood donation systems in alignment with WHO,² ECDC⁹ and others.^{1,15,28}

Systems to ensure that national authorities are rapidly notified of sudden blood shortages are of the utmost importance, together with contingency planning for severe epidemiological outbreaks and central EU-level monitoring of blood reserves. Cross-border sharing of blood products during emergencies can prove life-saving for patients, particularly for transfusion-dependent patients. This cross-border collaboration requires harmonised, equal quality standards at every step of the process – the central upgrading and monitoring of these is needed to ensure high levels of public health protection across the EU.

Effective public awareness campaigns should be continuous, as recommended by WHO and others,^{2,28} stressing the importance of maintaining an adequate national blood supply, the need for donors, and the safety of the donation process.

Specific considerations include the following:

- *New approaches to encourage blood donations at national level, encompassing all stakeholders, should be conceptualised immediately to prevent shortages.*
- *Awareness raising within the general public of the role of donation/blood in the life-saving care of patients with some chronic diseases. Awareness-raising should start from a young age in school settings, giving to the word “blood” a positive connotation.*

Authorities should also consider public information and patient education campaigns regarding evidence-based treatment options that exist to correct anaemia and to reduce bleeding risks, particularly prior to surgery.

Unmet blood demand – an illustration

Some EU member states (e.g. Cyprus and Greece) with a high prevalence of haemoglobin disorders that cause transfusion dependency, such as thalassaemia, use around 20–30% of their blood supplies annually to meet the needs of these patients. However, this is not sufficient for their needs given other current demands on blood supplies; family replacement practices provide more than 30% of donated blood and for many years Greece has imported blood to manage thalassaemia patients. Transfusion services, healthcare professionals and patients aim to abolish the burden of these practices.⁴⁴

Conclusion

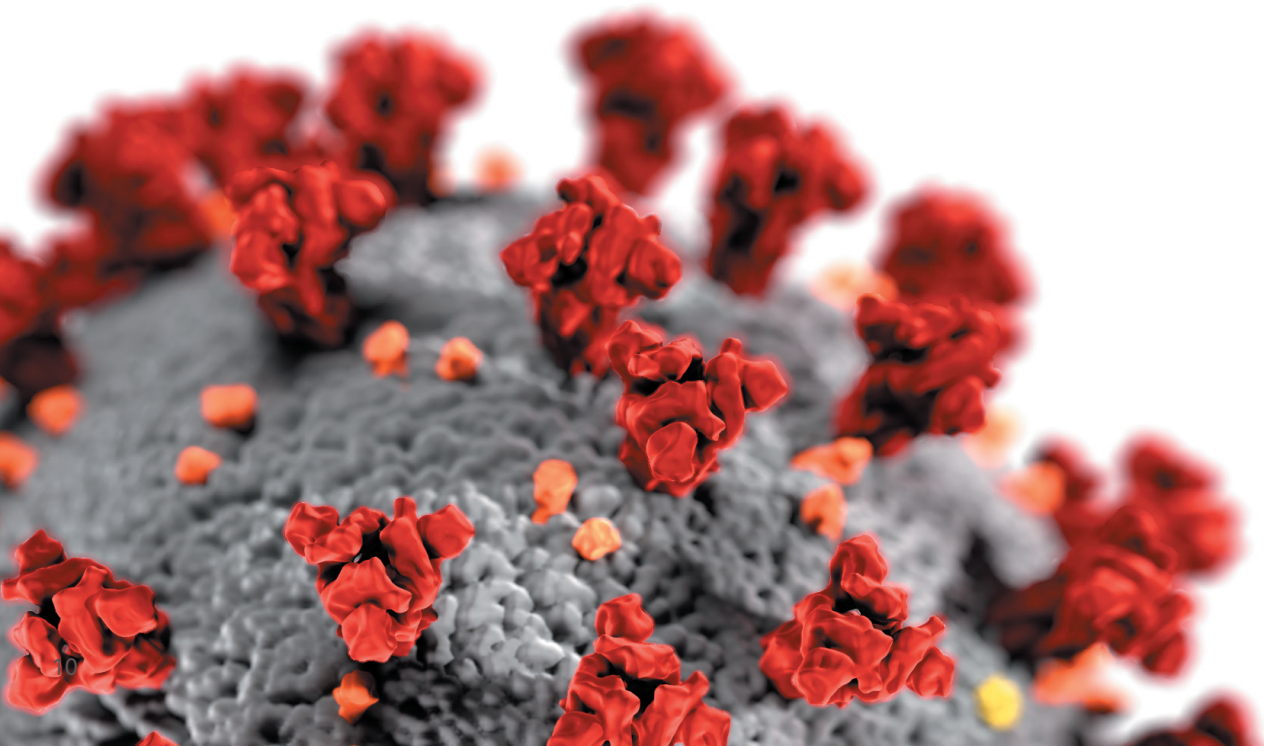
● The COVID-19 pandemic has clearly demonstrated the vulnerability and instability of the blood supply system in Europe, and elsewhere. We urge EU and national decision-makers and other stakeholders to act on our recommendations.

As a priority, policymakers, public health authorities and healthcare providers urgently need to change their focus towards patient-centric PBM. This will help to address the impact of COVID-19 on transfusion-dependent patients, ensure the resilience of the blood ecosystem against future pandemics, and protect its sustainability. Moreover, PBM improves the overall population health status by improving patient outcomes, reducing morbidity and mortality, improving patient safety, and reducing the risks and health system costs associated with anaemia, blood loss and transfusions.

The ongoing revision of the EU Blood Directive now offers a vital and timely opportunity for EU-level action.⁷ The European Commission has already concluded that further measures are needed to ensure sufficiency and sustainability in blood supplies, that the existing legislation is outdated, and that gaps and divergences exist at national level.⁸ Importantly, the revision aims to support innovation, as well as to optimise access to blood, to avoid shortages, and to ensure the framework is future-proof – and now it can apply lessons learnt from the pandemic. An EU Action Plan (across all EU countries) is urgently needed to further strengthen member states' co-operation and sharing of best practices in PBM and optimal blood use.

The proposed EU legislation on Cross-Border Health Threats,⁴⁵ the upcoming evaluation of the Cross-border Healthcare Directive⁴⁶ and the proposed expansion of the European Reference Networks (ERN) model⁴⁷ also provide potential vehicles, opportunities or tools to help improve standards of transfusion care and PBM uniformly across Europe.

Patients themselves are central to the achievement of these aims. Patients should be educated and empowered to have an active, informed and meaningful involvement in every decision taken with regard to PBM and blood within their own care, and in policies regarding the adequacy, safety, and quality of blood, the introduction and integration of innovation, and research activities.



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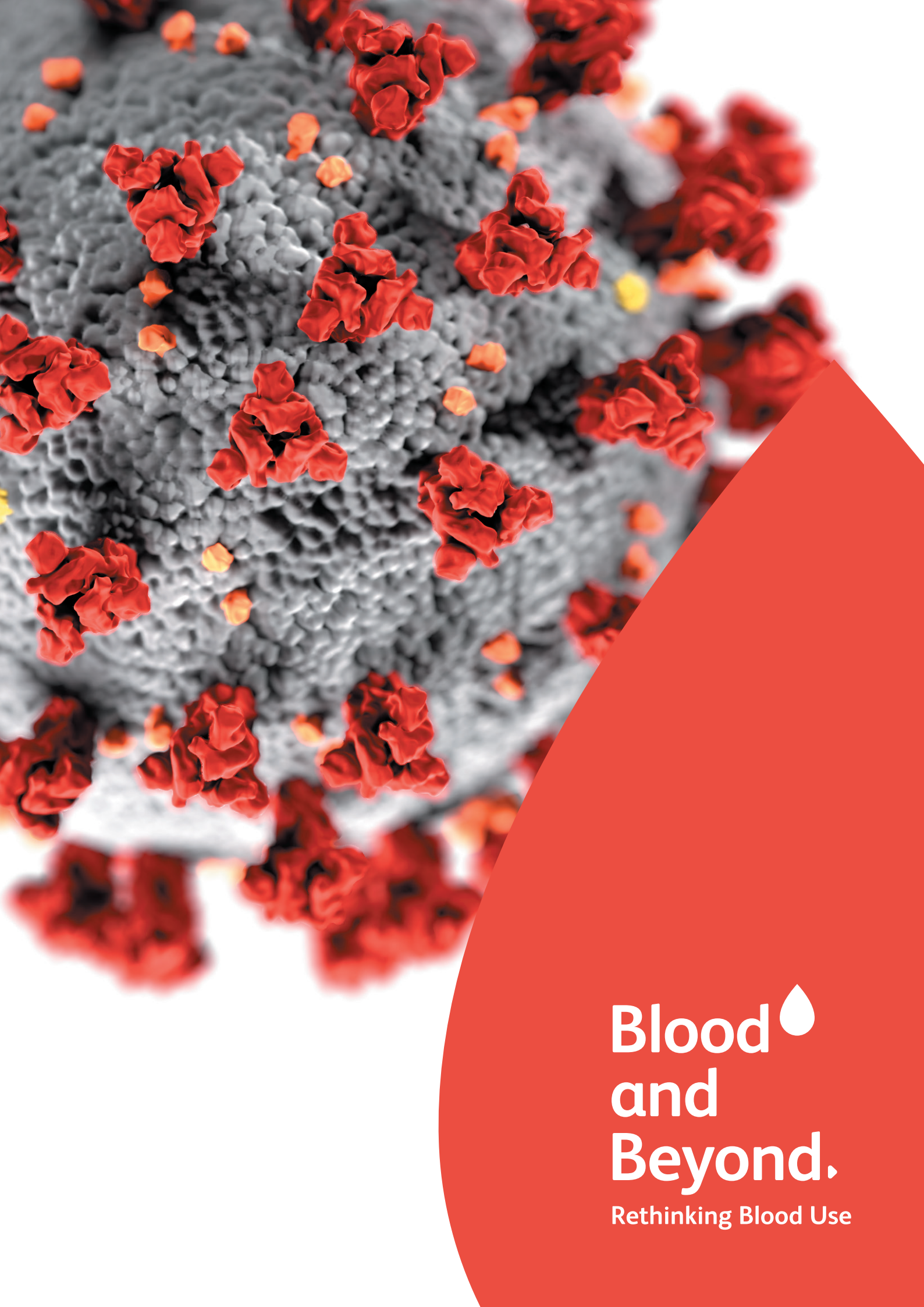
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