たところ、EC から血液製剤を省くよう要請がなされ、これに対し、米国を中心とする血漿分画製剤の供給を行っている国からの反論があり、決着を見ていない。

また、2013 年 9 月にローマで開催された WHO 会議の結果、Roma Declaration が採択されたが、この Declaration にも多くの矛盾が存在する。

実態上は、自国の献血由来の血漿を原料とする血漿分画製剤の製造が「できない」、「必要量が確保できない」、「コストが高い」などの理由で、特に開発途上国や人口の少ない国では実現できておらず、多くの国で他国(主に米国)の原料血漿によって製造された血漿分画製剤を輸入し、使用しているのが現状であるにも関わらず、理想論あるいは原則論に終始している点である。

また、売血由来の原料血漿には品質上多くの問題があるとの指摘についても、何らの科学的実証がなされていないことも、本 Declaration の意義を弱めるものである。

血漿分画製剤を自国で製造できる国は限られており、多くの国が輸入の道を選択しているのが現実であり、この現状を変えていくのは事実上、難しいことを前提にした議論がなされるべきであると考える。

考察

現実は多くの国が自国での血漿分画製剤の製造を断念し、米国を中心とする供給国の安価な製剤の輸入を行っていることは厳然とした事実である。また、アジア諸国の例に見られるように確実に血漿分画製剤の使用は増えているのも事実である。

一方で WHO 決議に見られる自給を基本とする考えには世界各国の一定の理解がある。

WHO 内にも 2 分する大きな意見対立があり、問題の解決には様々な政治的な駆け引きも行われており、問題の解決には相当の時間が要すると考察される。

また、現実論と理想論の狭間で、現実的な落としどころも見えていない。

結論

アジア諸国においては、今後、益々、血漿分画製剤の使用が増えていくであろう。その増大していく血漿分画製剤を如何に確保していくのかについての明確な結論はない。

また、WHO という世界唯一の保健標準を策定する機関においても統一見解を見出せずにいる。

本研究の目的は、「わが国が有する安全で安心な技術・制度の普及を通じて、アジア諸国への貢献を行う方策についての調査研究を行い、わが国がアジア諸国に協力できる技術の選択ならびに同定を行うとともに、技術移転に伴う問題点を提示するという国際貢献を図

っていくこと」であるが、容易にその方向性を導き出せるとは言えない。

WHO 血液安全部が提唱する地域に供給基地国を作ると言う考えがある。例えば、アジア諸国であれば、既に製造を開始しているシンガポールやタイといった国に各国の余剰血漿を送り、血漿分画製剤の委託生産を行うというものであるが、そもそも、余剰血漿を現在供給できる国は、上記の国の他、ブルネイとマレーシアしか存在しない。マレーシアは既にオーストラリアでの委託生産をおこなっており、地域での供給基地を設けるべきとの考えには現実性がない。

WHO での議論を踏まえた国際的な統一見解が待たれるところと思量する。

Ｆ．健康危険情報

（総括研究報告書にまとめて記入）

Ｇ．研究発表

今年度はなし

Ｈ．知的財産権の出願・登録状況(予定を含む)

今年度はなし

資料１：

アジア諸国の血漿分画製剤に関する情報

資料２：

Roma Declaration

資料１：血漿分画製剤各国状況

国名	日本	Brunei	Cambodia	Indonesia	Laos	Malaysia
献血による血液自給率：成分製剤 Self-sufficiency rate of blood by donation: component preparation	100%	100%（全体）	24.5% （全体、2009年）	81.3% （全体、2009年）	96% （全体、2009年）	100%（全体）
献血による血液自給率：血漿分画製剤	80%					
献血による血液自給を実現するための法律の有無 National blood policy	有	策定中	有	2010年6月現在、策定され承認待ち	有	有
上記の法律の名称	＊献血の推進について（閣議決定）1964年8月21日。 ＊安全な血液製剤の安定供給の確保等に関する法律 2003年7月		National blood policy 2003年	National Blood Policy（仮）	National Blood Policy 国家血液事業政策法 1996年	National blood policy for BTS, April2008
血液事業を実施している機関名	日本赤十字社	the Blood Donation Centre at RIPAS Hospital	National Blood Transfusion Centre	Indonesian Red Cross Society (government assignment since 1950)	Lao Red Cross Society	National Blood Transfusion Centre

国名	Myanmar	Philippines	Singapore	Thailand	Viet Nam	India
献血による血液自給率：成分製剤 Self-sufficiency rate of blood by donation: component preparation	63% （全体、2009年）	45%（全体, 2011年） 58%（全体、2008年） 80%（全体、2009年）	100%（全体）	100%（全体）	93%（全体）	20%
献血による血液自給率：血漿分画製剤						
献血による血液自給を実現するための法律の有無 National blood policy	有	有	無	有	National blood policy is in draft form and under consideration by the MoH (2009)	有
上記の法律の名称	National Blood and Blood Product Law 2003年	National Blood Services Act (Republic Act No. 7719 in 1994)	National Blood Programme			National Blood Policy
血液事業を実施している機関名	ミャンマー赤十字協会, National Blood Center	National Council for Blood Services (chair) Philippine Red Cross Society (deputy chair)	Singapore Red Cross Society, Health Services Authority	Thai Red Cross Society	National Institute of Haematology and Blood Transfusion	National Blood Transfusion Council (NBTC)

国名	日本	Brunei	Cambodia	Indonesia	Laos	Malaysia
血液事業を所管する省庁名	厚生労働省	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health
血漿分画製剤の自国製造の有無	有	無		無		自国で収集した血漿を委託契約によりオーストラリアのCSL Biotherapiesで分画している
製造業者名	日本赤十字社					CSL Biotherapies（オーストラリア）
血漿分画製剤の輸入の有無	有			有		有
血漿分画製剤年間使用量	36815リットル（アルブミン製剤）			345,500本（12.5g換算/アルブミン製剤/2009年）、21,500本（2.5g換算/IVIG製剤/2009年）		176,600本（12.5g換算/アルブミン製剤/2009年）、72,100本（2.5g換算/IVIG製剤/2009年）

国名	Myanmar	Philippines	Singapore	Thailand	Viet Nam	India
血液事業を所管する省庁名	Department of Health	Department of Health	Ministry of Health	Ministry of Public Health	Ministry of Health	Ministry of Health and Family Welfare
血漿分画製剤の自国製造の有無			有	有 (10 domestic fractionators)	無（良質の原料血漿を確保できないため分画施設計画を断念）	有 (one domestic fractionator)
製造業者名	National Blood Center		The Health Sciences Authority (2011年度 製造量: 899,064)	National Blood Center		Reliance Life Sciences（若干）※本格的な分画施設はまだない。2007年に15万L規模の分画施設をチェンナイにつくる計画が政府により承認されたが進捗していない。
血漿分画製剤の輸入の有無		有（韓国、インド等の外国企業から輸入）	有	有	有	有
血漿分画製剤年間使用量		97,600本（12.5g換算/アルブミン製剤/2009年）、19,000本（2.5g換算/IVIG製剤/2009年）	76,000本（12.5g換算/アルブミン製剤/2009年）、34,400本（2.5g換算/IVIG製剤/2009年）	334,000本（12.5g換算/アルブミン製剤/2009年）、73,000本（2.5g換算/IVIG製剤/2009年）	104,000本（12.5g換算/アルブミン製剤/2009年）、22,000本（2.5g換算/IVIG製剤/2009年）	841,000本（12.5g換算/アルブミン製剤/2009年）、482,000本（2.5g換算/IVIG製剤/2009年）

資料２

World Health Organization

The Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation

This declaration on 'Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation (VNRD)'[1] is founded on the policies articulated in numerous global and regional resolutions of the World Health Organization (WHO) (*1–7*) and other international organizations (*8–13*) which recommend voluntary non-remunerated donations as the foundation of a safe and adequate supply of blood and blood products and affirm the achievement of self-sufficiency in safe blood and blood products[2] based on VNRD as an important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products (blood components for transfusion and plasma-derived medicinal products) for patient care.

World Health Assembly resolution *WHA63.12: Availability, Safety and Quality of Blood Products* (2010) urges WHO Member States 'to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency'. Self-sufficiency in safe blood and blood products based on VNRD means that the national needs of patients for these products, as assessed within the framework of the national health system, are met in a timely manner, that patients have equitable access to transfusion services and blood products and that these products are obtained from voluntary non-remunerated donations of national, and where needed, of regional origin, such as from neighbouring countries (7).

We, being 153 representatives of ministries of health, national blood programmes, national blood transfusion services, national public health agencies, national regulatory bodies, national plasma fractionation institutes; representatives of international, intergovernmental and nongovernmental organizations, and experts in transfusion medicine from 51 countries from all WHO regions participated in the WHO High-level Policy Makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation, held on 8–9 October 2013 in Rome, Italy[3]. This Forum was organized jointly by the World Health Organization, the Ministry of Health, Italy, and the Ministry of Health, Labour and Welfare, Japan, in collaboration with the Council of Europe, European Commission, International Federation of Red Cross and Red Crescent Societies, International Society of Blood Transfusion, International Federation of Blood Donor Organizations and European Blood Alliance. At the Forum, we endorse the following:

> Recognizing that meeting the clinical needs of patients for safe blood and blood products is of paramount importance, and that it is the responsibility of national health authorities to meet these needs through moving towards self-sufficiency, based on VNRD;
>
> Affirming that measures to promote donor health and safety, equitable and timely access to safe blood and blood products of assured quality and efficacy from VNRD and the appropriate use of such products are essential for quality and safe health service provision and to meet the clinical needs of patients as part of universal health coverage;

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[1] Voluntary non-remunerated donation in this context includes the donation of blood, plasma and other blood components.

[2] Blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products.

[3] http://www.who.int/bloodsafety

Acknowledging that many countries face major challenges in making sufficient supplies of blood and blood products available, accessible and sustainable, while also ensuring the quality and safety of these products in the face of known and emerging threats to public health;

Recognizing that the commitment and support of national governments in developing and implementing policies for the achievement of self-sufficiency in safe blood and blood products based on VNRD, are prerequisites for well-organized, coordinated and sustainable national blood and plasma programmes that can ensure universal and timely access to safe blood and blood products;

Acknowledging that the achievement of self-sufficiency in safe blood and blood products based on VNRD requires a long-term perspective; this should be aligned to the state of development of the national health system and generally follows a step-wise development in scope, from whole blood to blood components for transfusion and further towards plasma fractionation for the provision of plasma-derived medicinal products (PDMP);

Recognizing that globally the most robust and safe national blood systems with sustainable access to sufficient supplies are based on the principle of VNRD; and that the continuity, sufficiency, sustainability and security of national supplies of safe blood and blood products require an adequate number of regular, voluntary, non-remunerated donors of blood and blood components;

Concerned that many countries currently depend to varying degrees on family/replacement donations (which have the potential for hidden payments) and also on paid donation;

Recognizing that payment for the donation of blood, plasma and other blood components not only threatens safety but also contravenes the Council of Europe's Oviedo Convention on Human Rights and Biomedicine of 1997 (*13*) which explicitly prohibits any financial gain from the human body and its parts, which erodes community solidarity and social cohesion that can be enhanced by the act of voluntary non-remunerated donation;

Committed to the health and safety of donors and concerned that payment for the donation of blood, plasma and other blood components may exploit the poor and vulnerable by providing them with financial incentives to donate and that voluntary non-remunerated blood donor programmes may be compromised or undermined by the presence of parallel systems of paid donation;

Recognizing that, in the long term, it will not be feasible for a small number of countries to collect sufficient plasma to produce enough plasma-derived medicinal products to meet global needs;

Concerned that fragmented and poorly coordinated blood systems and services hinder efforts to ensure the accessibility and sufficiency of blood supplies and also contribute to the wastage of blood and blood products;

Aware that large volumes of plasma recovered from whole-blood donations based on VNRD, mainly in low- and middle-income countries, are currently discarded because of concerns that quality, logistical and budgetary requirements are not being met for plasma for fractionation for the manufacture of PDMP.

We declare that we:

Reaffirm self-sufficiency in safe blood and blood products based on VNRD as the policy direction to provide equitable access to safe blood and blood products to meet the clinical needs of patients as part of universal health coverage;

Recognize the strategic value of formulating and implementing national blood policies and legislation consistent with WHO resolutions and recommendations, and developing effective and sustainable national blood and plasma programmes to meet patients' needs for blood and blood products;

Commit to working towards the donation of blood, plasma and other blood components, in line with other therapeutic substances of human origin, only from VNRD, as appropriate in the national context, and ensuring that donations should remain in the public domain;

Commit to supporting, developing and implementing strategies for the stepwise progression from whole blood to blood components and PDMP consistent with the development of national health systems; and ensuring that recovered plasma can also be used for fractionation, thereby fully utilizing every donation;

Support the implementation of strategies for good clinical transfusion practices, including the appropriate use of blood and blood products, patient blood management, safe administration of blood and blood products, and haemovigilance;

Pledge to work in collaboration in international and regional efforts to promote self-sufficiency in safe blood and blood products, based on VNRD;

Pledge to promote and contribute to the establishment of global mechanisms for governance and monitoring to ensure transparency and accountability for the provision and use of blood and blood products at national and international levels.

We call on relevant national authorities to:

Incorporate the goal of self-sufficiency in safe blood and blood products, based on VNRD, into national health policies and to implement strategies to achieve this goal;

Introduce legislation to prohibit payment in cash or in kind for the donation of blood, plasma and other blood components and also, with specific timelines, to ensure VNRD as the source of labile blood components and PDMP as a means of moving towards self-sufficiency in safe blood and blood products;

Introduce labelling requirements to distinguish blood and blood products from PDMP of VNRD origin vs. paid donations, as well as the country of origin, to enable hospitals, clinicians and patients to make informed choices about the source of the products that they utilize;

Provide sufficient financial and other resources to move towards self-sufficiency, based on VNRD;

Establish a mechanism for the national coordination of the blood system, with the integration of blood and plasma programmes aimed at optimizing the use of recovered plasma for fractionation and minimizing wastage;

Put in place mechanisms and formal agreements between the blood system and fractionator(s) for the fractionation of surplus recovered plasma from VNRD to avoid the discard of recovered plasma and to contribute to national or regional self-sufficiency;

Incorporate measures to achieve self-sufficiency into the regulatory framework; to facilitate the supply of plasma, intermediate products and PDMP sourced from VNRD within regional or other collaborative self-sufficiency arrangements, including contract fractionation; and to phase out in a programmed manner, the use of blood components for transfusion, intermediates and PDMP obtained from paid or compensated donors and family/replacement donors;

Introduce specific measures, consistent with relevant international trade agreements, to protect the health of the public by ensuring the provision of sufficient, safe blood and blood products in the national health system through nationally, or where needed, regionally sourced VNRD (such as from neighbouring countries);

Establish mechanisms, such as an independent national transfusion committee, to identify actual clinical needs, to monitor trends in demand, patient needs and the clinical use of blood and blood products, to regularly evaluate and report on the level of sufficiency and to advise on priorities in the national supply;

Introduce strategies and measures to establish appropriate quality systems and standardized procedures in the national blood system for the collection, testing, processing, storage, distribution and use of blood and blood products;

Establish or strengthen existing mechanisms to collect, monitor and ensure the accuracy, transparency and traceability of all data on blood and blood product safety and reports from blood transfusion services and manufacturers of PDMP on national distributions, imports and exports of blood products and related intermediates, including the contribution of donations derived from VNRD;

Share key reports on blood and blood product safety and supply internationally to enable countries to make informed policy decisions for the safety and sufficiency of the supply of blood and blood products.

Note: This Declaration is an outcome of the WHO High-level Policy Makers Forum on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation, October 2013, Rome, Italy. It does not necessarily represent the decisions or policies of all governments and organizations represented, including the Australian Department of Health, and the Ministry of Health, Welfare and Sport, The Netherlands.

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資料３

World Health Organization

Concept Paper

High-level Policy Makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-remunerated Donation

Developing policies and strategies on donation, safety and self-sufficiency for universal access

8–9 October 2013, Rome, Italy

Issues and challenges

Universal and timely access to safe blood and blood products[1], which include blood components for transfusion and plasma-derived medicinal products (PDMP), and their appropriate use is an essential component of health-care provision. Governments are responsible for national health systems and therefore for the safety, availability and equitable distribution of these products. This responsibility encompasses the establishment of an effective national blood system that is integrated into the national health system, stewardship of donated blood and the blood products derived from it as a national resource, protecting the health of blood donors and recipients, and ensuring the safety, sufficiency, security and accessibility of supply. However, many countries are still facing challenges in making sufficient supplies of blood and blood products available and sustainable, while also ensuring their quality and safety from known and emerging threats to public health. Consequently, a large number of patients who require life-saving transfusion therapy still lack access to safe blood and blood products.

Global concerns

Concerns about global blood safety and availability were first raised in 1975 when, in resolution WHA28.72, the World Health Assembly (WHA) urged Member States to promote the development of national blood services based on voluntary non-remunerated donation (VNRD)[2] and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products. Resolution WHA58.13, resolutions of WHO Regional Committees and *The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components* (2009) further defined guiding principles and essential elements in the development of sustainable national blood systems that could ensure access to safe blood and blood products as part of universal health coverage.

In 2010, the World Health Assembly deliberated on challenges to the availability, safety and quality of blood products and defined self-sufficiency in the supply of safe blood and blood products based on voluntary non-remunerated donation, and the security of that supply, as important national goals to prevent blood shortages and meet the transfusion requirements of the patient population. Resolution WHA63.12 urged Member States "to take all necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency". In this context, self-sufficiency means that the national needs of patients for safe blood and blood products, as assessed within the framework of the national health system, are met in a timely manner and that patients have equitable access to transfusion services and blood products.

Despite some successes, in many countries self-sufficiency is not yet a reality. Although it has been recognised that the most robust and safe blood system is based on VNRD, it is a reality that family/replacement donation is still practiced in some regions due to the lack of development of

[1] Blood products are defined as "any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products"

[2] Voluntary non-remunerated donation in this context includes the donation of blood, plasma and cellular blood components

programmes for VNRD. The weakness of a family/replacement donation system is that it puts the responsibility for the provision of blood on individuals rather than on the national health system, and therefore may lead to coercion and hidden payment which often cause undue risks to patients and harm to the donors. In the long term, family/replacement donation systems will be unable to provide safe, sufficient and sustainable national blood supplies to ensure equitable access for all patients. Such systems will inevitably act as a barrier to enabling national blood systems to develop appropriately alongside countries' overall health systems.

Most middle- and low-income countries rely on the import of commercial PDMP and the supply tends to be proportional to the country's level of economic development. The introduction of blood component production invariably leads to a surplus of recovered plasma, much of which is currently discarded. Fractionation of this plasma can provide significant benefits to the national health-care system although it requires improved quality systems, including Good Manufacturing Practices, and access to a plasma fractionation facility. The development of national capacity for the collection of sufficient plasma for fractionation, and the establishment of national or regional fractionation facilities, can be pursued in parallel with the importation of commercial PDMP with the aim of complementing and progressively replacing (even partially) commercial purchasing, wherever possible.

With increasing global needs for blood and blood products including plasma-derived medicinal products, the complex nature of systems to obtain and supply these products and the inability of many national health systems to meet these urgent needs, there has been a growing trend towards the expansion of international commercial activities in relation to the collection of blood, plasma and cellular donations. Blood, plasma, cellular blood components and other therapeutic substances derived from the human body, should not be considered as mere "commodities". The act of voluntary blood donation is an honourable expression of community and citizen participation in the health system, and blood and its components donated voluntarily by healthy and socially committed people is a precious national resource that is, and will remain, limited by nature. In contrast, the commercial collection of blood, plasma and cellular blood components may exploit the poor and vulnerable by providing them with financial incentives to donate, with the potential for undue risks to patients and harm to donors.

The Charter of the United Nations (1945) clearly reaffirms faith in the dignity and worth of the human person and the Oviedo Convention on Human Rights and Biomedicine of 1997 explicitly prohibits any financial gain from the human body and its parts. In 2000, this was echoed in the Charter of Fundamental Rights of the European Union, in which article 3, 'Right to the Integrity of the Person' states that "In the fields of medicine and biology, the following must be respected in particular: the prohibition on making the human body and its parts as such a source of financial gain". There are also serious concerns that sufficient safe donations and sustainable supplies of blood and blood products based on VNRD may be compromised by the presence of parallel systems involving payment for collection of blood and/or plasma. Further expansion of commercial plasma/blood collection centres may represent potential competition for health-care professionals as well as blood donors with voluntary non-remunerated donation programmes in the same communities. The lack of an effective global mechanism to ensure self-sufficient and sustainable supplies of blood and blood products in the long term constitutes a grave challenge to public health.

Towards self-sufficiency in safe blood and blood products

The implementation of a policy for self-sufficiency in blood and blood products generally follows a stepwise progression, from whole blood to blood components for transfusion and further to PDMP produced by plasma fractionation. Countries may set different timelines in achieving the goals of self-sufficiency in the supply of blood and blood products from VNRD and ensuring the security of that supply, depending on the state of development of their national health systems. Countries that have already established policies and systems to achieve self-sufficiency can serve as models by demonstrating the effectiveness of policies, strategies and mechanisms that should be supported and implemented in other countries.

To support countries in implementing resolution WHA63.12, WHO has launched a new initiative on self-sufficiency in safe blood and blood products, based on VNRD. In 2011, WHO organized an expert consultation to analyse factors influencing the global implementation of self-sufficiency, including safety, ethics, security and sustainability of supply, trade and its potential impact on public health, and availability and access for patients. The consultation also provided policy guidance on strategies and mechanisms for achieving self-sufficiency and made recommendations to national health authorities and WHO. These were published in an *Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products based on voluntary non-remunerated blood donation*.

WHO High-level Policy Makers Forum

In October 2013, WHO plans to convene a Policy Makers Forum on Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-remunerated Donation, to share experiences in gaps and challenges and introduce strategies and mechanisms for self-sufficiency to senior government policy makers who are accountable for the safety and sufficiency of their national blood supplies. The Forum will take place in Rome, Italy. The two-day High-level Policy Makers Forum is being jointly organized by WHO, the Ministry of Health, Italy, the National Blood Centre and the Ministry of Health, Labour and Welfare, Japan. It will bring together the most senior officials in policy and decision-making positions from the Ministries of Health and key organizations, agencies and institutions in national blood systems from about 50 countries, both developed and developing, representing all WHO regions. Key international organizations with shared and common objectives will be invited as co-organizers. Invitations will also be extended to other United Nations agencies and intergovernmental organizations including the African Union, Association of Southeast Asian Nations, Council of Europe, European Commission, International Federation of Red Cross and Red Crescent Societies, Organization for Economic Cooperation & Development and the World Bank. Simultaneous translation will be available in English, French, Italian and Spanish.

Objectives of the Forum

1 To share national and international experiences on different strategies and mechanisms for working towards self-sufficiency in safe blood and blood products based on VNRD.

2 To review evidence, gaps, challenges and trends in donation, safety, self-sufficiency and access to blood and blood products

3 To underscore the need for policy development and priority actions at national, regional and global levels to achieve the goal of self-sufficiency.

4 To reach a high-level consensus on the role of governments and international organizations in working towards self-sufficiency based on VNRD to ensure availability and access to secure supplies of safe and quality blood and blood products.

Expected outcomes of the Forum

1 Recognition of the roles and responsibilities of national health authorities and national partners in achieving self-sufficiency in safe blood and blood products as part of universal health coverage.

2 Enhanced elaboration of national policies, systems, strategies, mechanisms and identification of resources that can contribute to the achievement of self-sufficiency in safe blood and blood products based on VNRD.

3 Declaration expressing the consensus, commitment and support of national health authorities and international organizations for policies and actions to be taken by countries and at regional and global levels.

平成 25 年度厚生労働科学研究費補助金(地球規模保健課題推進研究事業)
研究分担報告書 （3）

アジア地域の血漿分画事業の現状と将来

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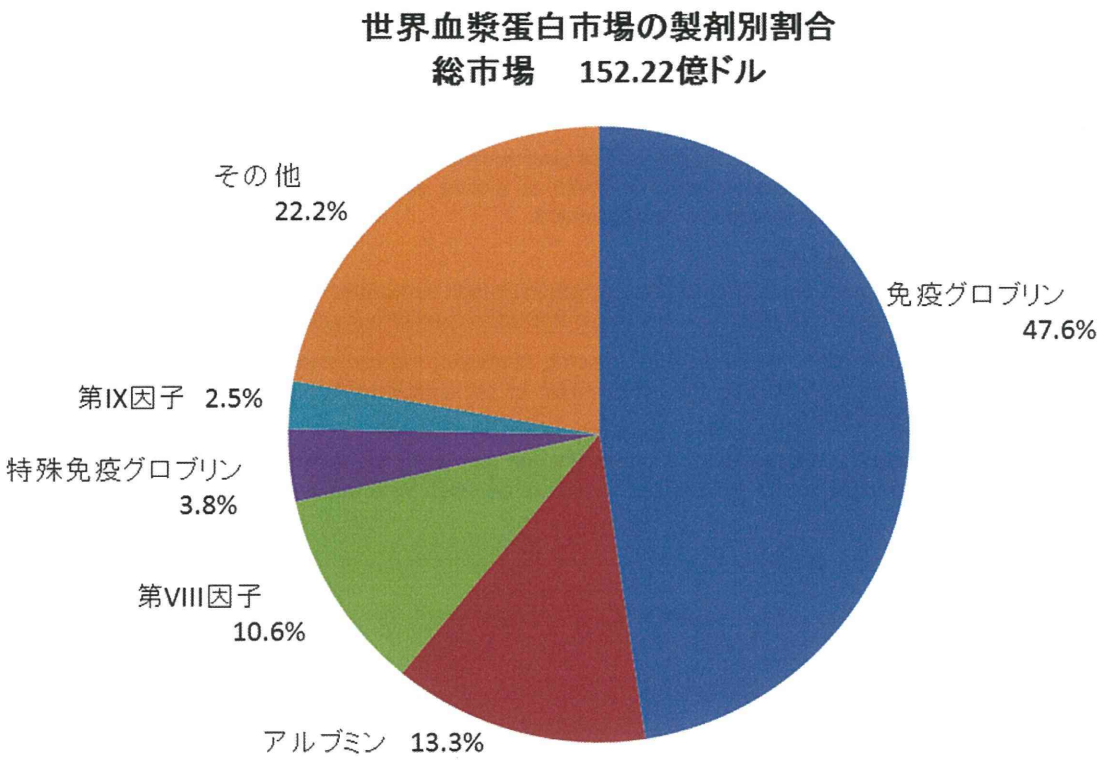
◆血漿蛋白市場の最近の動向と今後の方向

MRB では世界各地域の血漿蛋白市場の動向を定期的にとりまとめている。アジア太平洋地域については 3 年ごとに情報収集を行っており、2009 年の状況が 2011 年にまとめられている。また、本年には"The Worldwide Plasma Proteins Market－2012"がまとめられた。

2012 年の世界血漿蛋白市場(遺伝子組換え製剤を除く)は 152 億ドルであり、製剤別の割合では免疫グロブリン 47.6%と約 5 割を占め、アルブミン 13.3%、第 VIII 因子 10.6%と続く。(グラフ 1)

グラフ 1



出典：Bioplasma World Asia 2013

地域別の割合では、北米 43.2%、欧州 30.8%、アジア太平洋地域 14.2%となっている。(表1) 2012 年における世界の人口のうちアジア太平洋地域の人口は 57.8%であるが、同年の世界血漿蛋白市場（遺伝子組換え製剤を除く。）152 億ドルに占めるアジア太平洋地域の血漿蛋白市場の割合は 14.2%に過ぎない。

世界血漿蛋白市場の地域別割合　　表 1

地域	市場の割合 %	人口の割合 %
北米	43.2	4.8
欧州	30.8	10.7
アジア太平洋地域	14.2	57.8
南米	5.5	8.6
中東	3.3	17.9
アフリカ	1.1	
オセアニア	1.9	0.2

出典：Bioplasma World Asia 2013

人口 1,000 人あたりの血漿蛋白製剤の支出額（2009 年、遺伝子組換え製剤を除く。）は平均 0.64 ドルである。調査対象とした 17 か国の比較ではオーストラリアの 9.34 ドルからパキスタンの 0.04 ドルまで大きな開きがある。(表 2)

人口 1,000 人あたりの血漿蛋白製剤支出額 2009 年(遺伝子組換え製剤を除く) 表 2

	支出額　ドル		支出額　ドル
オーストラリア	9.34	中国	0.56
日本	6.40	タイ	0.37
ニュージーランド	4.31	スリランカ	0.10
韓国	2.31	インドネシア	0.09
台湾	2.31	フィリピン	0.08
香港	2.16	ベトナム	0.08
シンガポール	1.91	パキスタン	0.04
マレーシア	0.85		

出典：Bioplasma World Asia 2013

製剤ごとの全世界に占めるアジア太平洋地域のシェアは、アルブミンで 41%、静注用免疫グロブリン(IVIG)で 16%、第Ⅷ因子製剤で 11%（2009 年、遺伝子組換え製剤を含む。）である。アルブミンのシェアが突出して大きい。(表３)

地域・製剤別の血漿蛋白製剤のシェア（%） 2012　　表３

	アルブミン*1	IVIG*2	第 VIII 因子*3	第 VIII 因子*4
北米	23	48	10	29
欧州	21	25	44	43
アジア太平洋地域	41	16	13	11
その他の地域	15	11	33	17

出典 ：Bioplasma World Asia 2013

*1：ボリュームにおける割合　　総市場量　665 トン

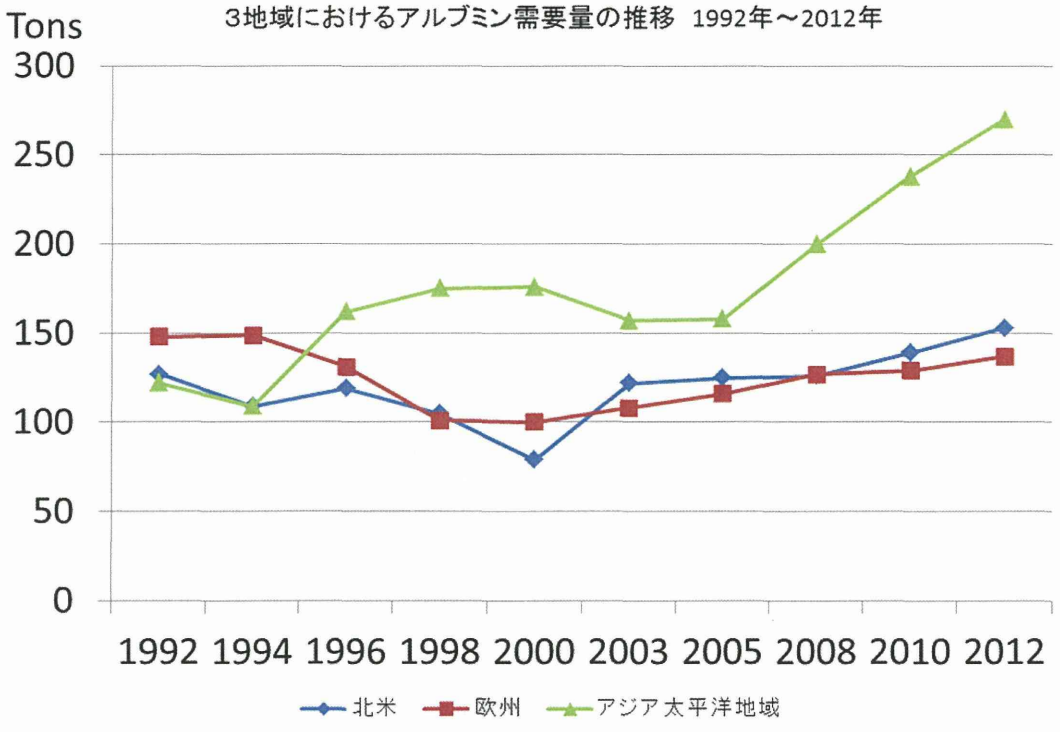
*2：ボリュームにおける割合　　総市場量　115.4 トン

*3：血漿由来製剤のみ　　総市場量　35.7 億 IU

*4：血漿由来+リンコンビナント 総市場量　89.5 億 IU

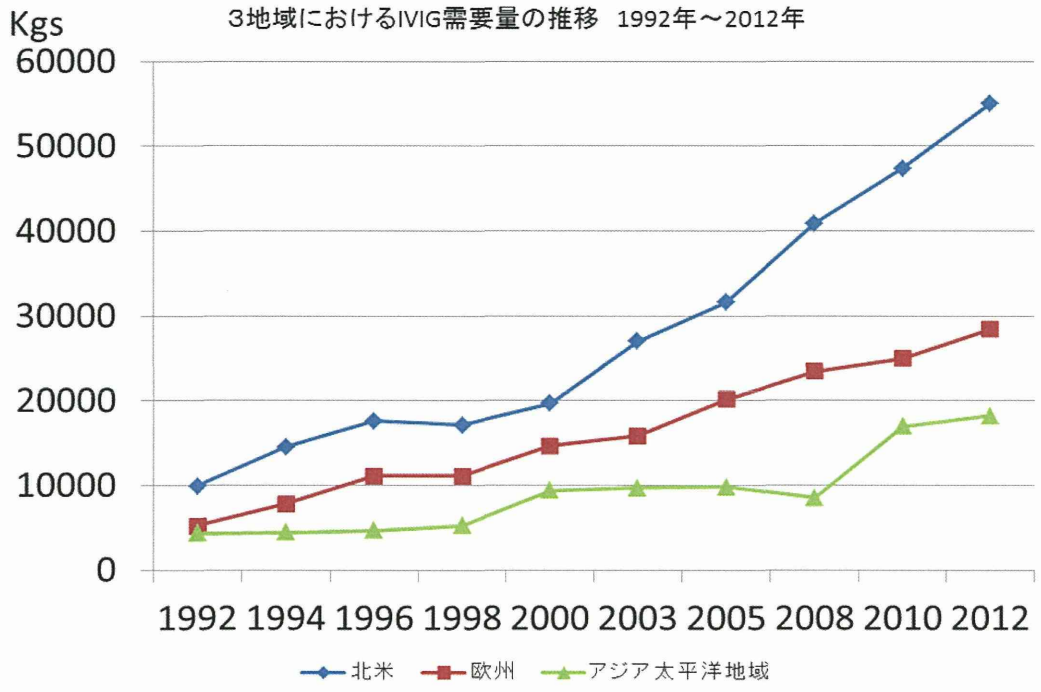
アルブミン、IVIG、第 VIII 因子の北米、欧州、アジア太平洋地域における需要量の推移は表４、５、６であった。アルブミンは 1990 年代後半に需要量が減少したが、2000 年代に入り再び増加しており、すべてが増加傾向にある。

グラフ２



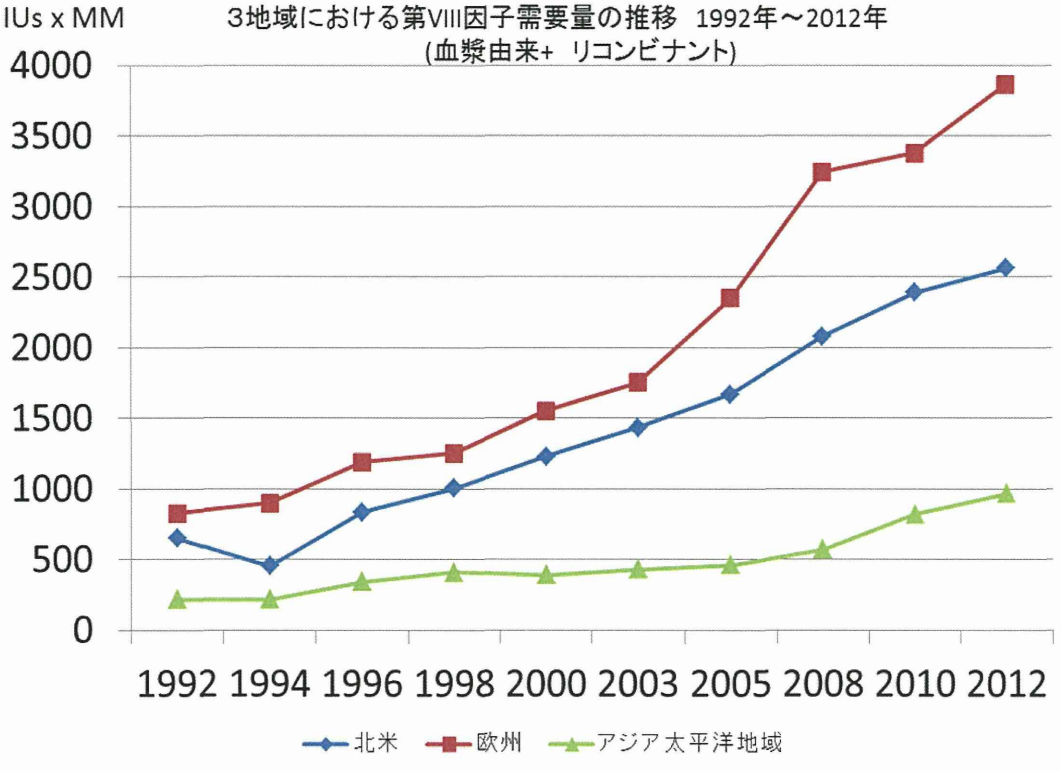
出典 ：Bioplasma World Asia 2013

グラフ３



出典：Bioplasma World Asia 2013

グラフ４



出典：Bioplasma World Asia 2013

将来的に血漿の需要は増加すると見込まれる。IVIG と皮下注用免疫グロブリン（SCIG）では、より多くの患者が診断され、新しい適応が承認され、財源がより多くなるので、先進国においても新興国においても増加し続けるであろう。アジアにおける近年のアルブミンの需要は他の地域と比較して増加率が高く、今後はさらに増加し、年平均成長率は欧米の 2.5~3%を大幅に上回る 8%と見ている。これに対して IVIG は欧米が 7~10%の伸びが見込まれるのに比べて 3%とあまり増加しない見込みである。第Ⅷ因子製剤は今後の世界の伸び率（年平均 3.8%）を上回る 5%を見込んでいる。

分画用に収集される血漿量は全世界では 3,227 万リットル、アジアでは計 521 万リットルである（2010 年推計）。2018 年にはそれぞれ 4,777 万リットル、569 万リットルと予測しており、需要増加に対応するためには大量の血漿を収集する必要があると見積もられている。

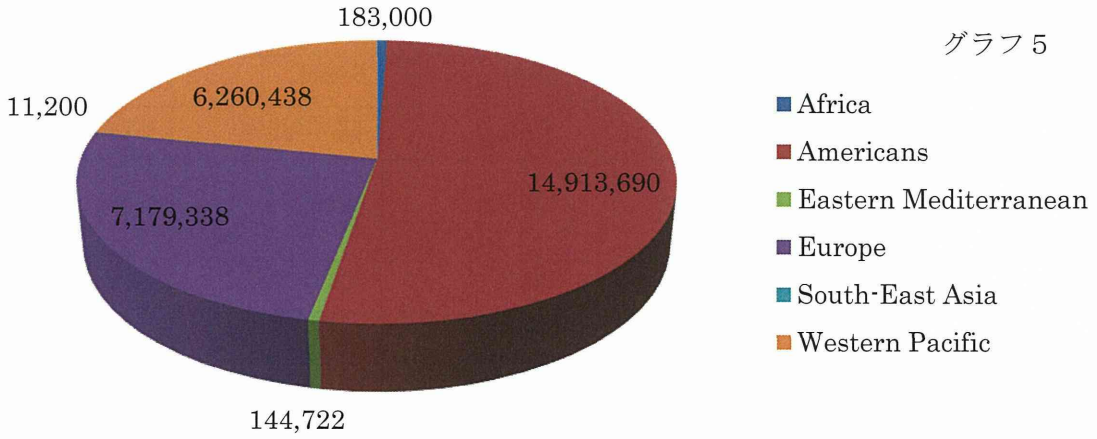
しかしながら、現在採血されている血液から得られる血漿がすべて輸血用あるいは分画製剤原料として利用されてはいない。特に特定の地域、中低所得国では多量の血漿が減却、廃棄されリカバード血漿の浪費が起きているといわれている。

◆血漿由来医薬品供給のための VNRD からの血漿

WHO Global Database on Blood Safety (GDBS)に報告された 51 か国のデータの集計では 2011 年に採血された VRND に基づく分画用血漿量は 2,870 万リットルであった。分画用血漿のほとんどは WHO Region（後述）の区分で、アメリカ region、ヨーロッパ region、西太平洋 region で採血されている。

また、高所得国の 10 か国、米国、中国、ドイツ、日本、フランス、韓国、イタリア、英国、オーストラリア、オランダで世界全体の分画用血漿量の 90%を採血しているが米国が圧倒的に多い。

WHO Region 別　分画用原料血漿量 (L)　2011

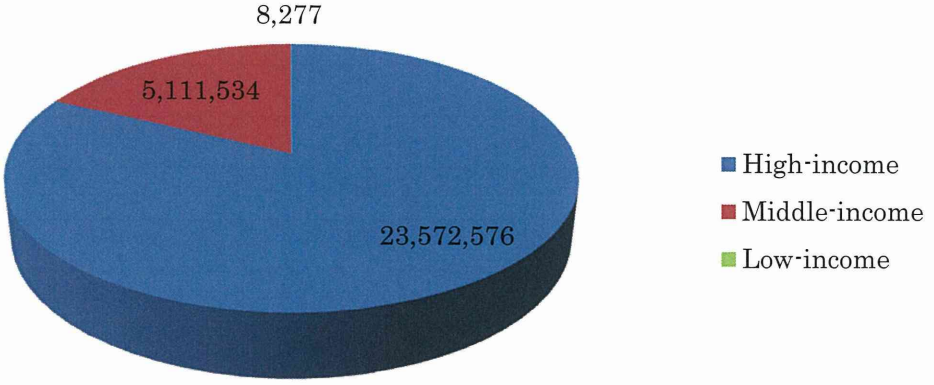


グラフ 5

出典 Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated
Donation　,Global Status 2013, WHO

グラフ 6

Income 別　分画用原料血漿量 (L)　2011



出典 Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Donation　,Global Status 2013, WHO

血漿由来医薬品供給のための VNRD からの血漿の採取方法について region 別、income 別のデータは次のとおりである。

表4

WHO Region	Recovered Plasma		Source (apheresis) plasma	
	Volume (L)	%	Volume	%
Africa (n=1)	180,000	98%	3,000	2%
Americas (n=5)	2,516,954	17%	12,022,247	83%
Eastern Mediterranean (n=2)	144,293	99.7%	429	0.3%
Europe (n=29)	3595903	52%	3,223,521	48%
South-East Asia (n=1)	10,000	89%	1200	11%
Western Pacific (n=7)	941,430	15%	5,319,009	85%
Total (n=45)	7,388,580	26%	20,569,405	74%

出典 Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Donation ,Global Status 2013, WHO

表5

Countries	Recovered Plasma		Source (apheresis) plasma	
	Volume (L)	%	Volume(L)	%
High-income (n=27)	6,618,444	28%	16,667,755	72%
Middle-income (n=17)	761,859	16%	3,901,650	84%
Low-income (n=1)	8,277	100%	-	
Total (n=45)	7,388,580	26%	20,569,405	74%

出典 Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Donation ,Global Status 2013, WHO

153 か国から血漿分画の状況と血漿由来医薬品の供給ついて報告された。

42 か国(High-income：21, Middle-income：19, Low income：2) は、国内で供給する血漿由来医薬品のすべてあるいは一部を国内で採血された血液から国内施設あるいはまた分画製造業者に製造委託していた。42 か国のうち 33 か国で血漿分画が国内で行われ、9 か国、カナダ、チリ、チェコ、デンマーク、エストニア、インド(2008)、マレーシア、ニュージーランド、シンガポールはすべての血漿を他国に送り分画製造を委託していた。

残りの 111 か国は血漿由来医薬品については完全に完成品の輸入品のみに頼っていた。