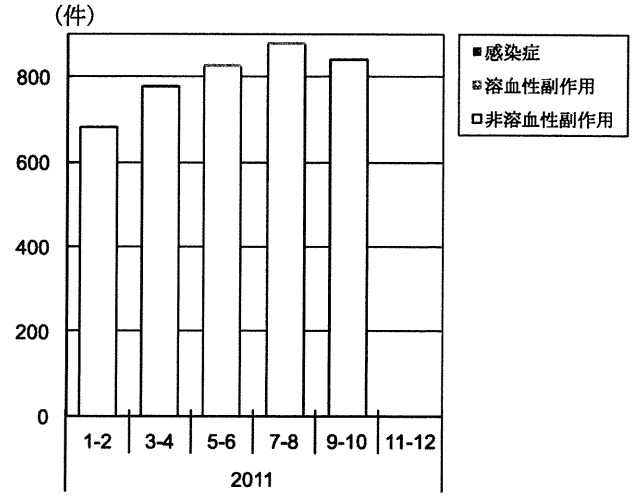
副作用報告件数

(件)

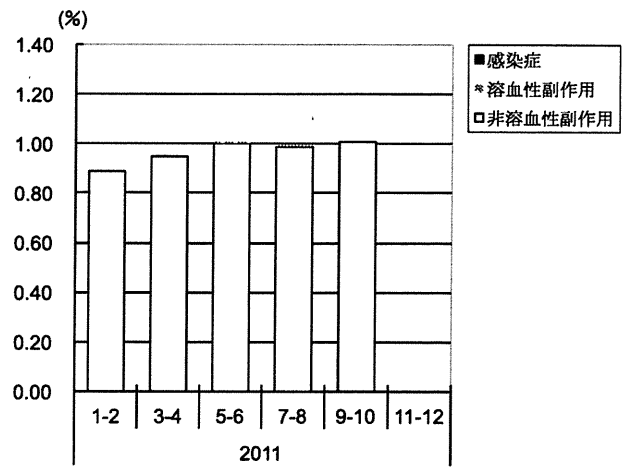
年	月	非溶血性副作用	溶血性副作用	感染症
2011	1-2	682	0	0
	3-4	778	0	0
	5-6	825	2	0
	7-8	878	1	0
	9-10	842	0	0
	11-12			
合計		4,005	3	0



副作用発生率

(%)

年	月	非溶血性副作用	溶血性副作用	感染症
2011	1-2	0.89	0	0
	3-4	0.95	0	0
	5-6	1.00	0.002	0
	7-8	0.99	0.001	0
	9-10	1.01	0	0
	11-12			
平均		0.97	0.0006	0.0000



(2) 製剤別副作用報告件数と副作用発生率

2 ヶ月ごとの製剤別副作用発生率は、赤血球製剤では　～　%、血小板製剤では　～　%、血漿製剤では　～　%であった。副作用の原因製剤を比較すると、血小板製剤が過半数以上を占めていた。

製剤別副作用報告件数

赤血球

年	月	副作用総件数	輸血総量(バッグ数)
2011	1-2	194	39,224
	3-4	167	42,858
	5-6	213	41,877
	7-8	217	43,016
	9-10	206	42,150
	11-12		
合計		997	209,125

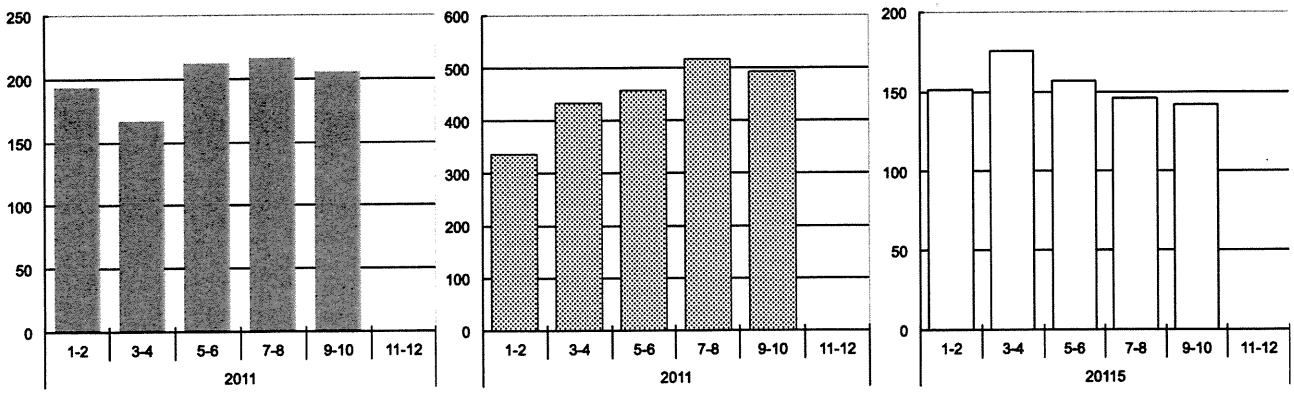
血小板

年	月	副作用総件数	輸血総量(バッグ数)
2011	1-2	337	17,430
	3-4	435	17,091
	5-6	457	18,029
	7-8	516	19,721
	9-10	494	18,076
	11-12		
合計		2,239	90,347

血漿

年	月	副作用総件数	輸血総量(バッグ数)
2011	1-2	151	19,662
	3-4	176	22,222
	5-6	157	23,018
	7-8	146	25,788
	9-10	142	22,974
	11-12		
合計		772	113,664

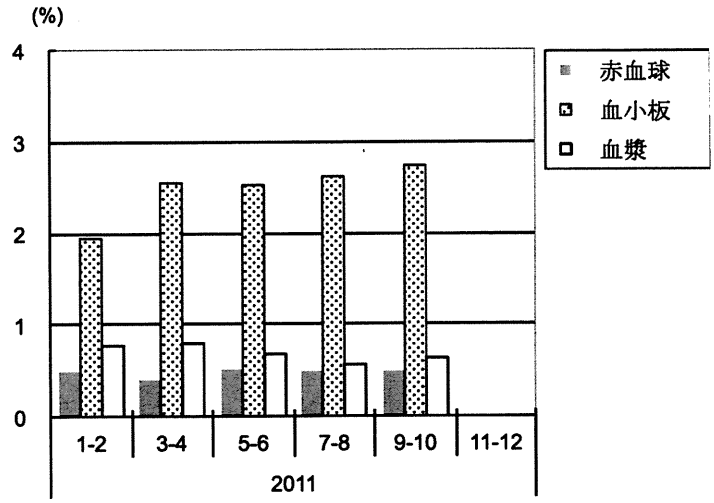
赤血球　　血小板　　血漿



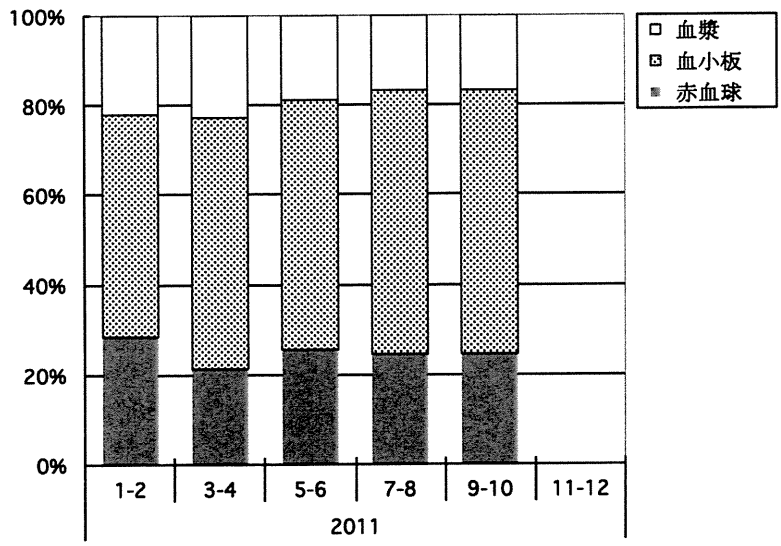
製剤別副作用発生率

(%)

年	月	赤血球	血小板	血漿
2011	1-2	0.49	1.93	0.77
	3-4	0.39	2.55	0.79
	5-6	0.51	2.53	0.68
	7-8	0.50	2.62	0.57
	9-10	0.49	2.73	0.62
	11-12			
平均		0.48	2.47	0.69



副作用 製剤別の内訳



4. 副作用症状別報告数

副作用の症状項目は平成 18 年度厚生労働科学研究費研究班「免疫学的輸血副作用の把握とその対応に関する研究」（主任研究者 愛知医科大学教授 高本 滋先生）から得られた知見をもとに 16 症状項目とした。1 製剤あたり複数の副作用症状が発生する可能性があるため、入力項目に関しては重複可能とし、該当しない症状は「その他」欄へ症状を記載した。

赤血球製剤では、発熱、発疹・蕁麻疹、掻痒感・かゆみの頻度が高く、これらの項目が約 50%を占めた。血圧の変動、 熱感・ほてり、発赤・顔面紅潮、悪寒・戦慄も多く見られた。 血小板製剤では、発疹・蕁麻疹、掻痒感・かゆみを併せてアレルギー症状がが 70%以上を占めた。血漿製剤でも同様に発疹・蕁麻疹、掻痒感・かゆみの症状が半数以上を占めていた。血小板製剤と血漿製剤ともにアレルギー症状に続いて、発熱、発赤・顔面紅潮、血圧の変動の副作用が比較的多く報告された。

(1) 赤血球

年	2011							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
副作用項目								
1) 発熱	64	49	71	62	64		310	23.0%
2) 悪寒・戦慄	8	18	13	15	22		76	5.6%
3) 熱感・ほてり	17	17	16	20	24		94	7.0%
4) 掻痒感・かゆみ	23	18	26	24	14		105	7.8%
5) 発赤・顔面紅潮	15	18	18	14	21		86	6.4%
6) 発疹・蕁麻疹	71	46	68	68	63		316	23.4%
7) 呼吸困難・呼吸障害	11	4	6	10	7		38	2.8%
8) 嘔気・嘔吐	9	9	12	6	13		49	3.6%
9) 胸痛・腹痛・腰背部痛	8	2	4	3	2		19	1.4%
10) 頭痛・頭重感	2	2	7	1	2		14	1.0%
11) 血圧低下	16	11	12	29	11		79	5.9%
12) 血圧上昇	14	10	22	19	18		83	6.2%
13) 動悸・頻脈	7	3	5	9	6		30	2.2%
14) 血管痛	3	4	5	4	8		24	1.8%
15) 意識障害	1	0	0	0	0		1	0.1%
16) 血尿（ヘモグロビン尿）	1	1	3	3	0		8	0.6%
17) その他								
圧迫感	1						1	0.1%
皮疹	1						1	0.1%
咳	1						1	0.1%
酸素飽和度低下	1	2					3	0.2%
目のかすみ		1					1	0.1%
体がむずむず		1					1	0.1%
眼瞼浮腫		1					1	0.1%
気道狭窄			1				1	0.1%
咽頭不快感			1				1	0.1%
溶血				1			1	0.1%
TRALIの疑い				1			1	0.1%
胸部違和感				1			1	0.1%
刺入部の疼痛				1			1	0.1%
不明	0	0	1	0	1		2	0.1%
報告数	274	217	291	291	276	0	1349	100%

症状項目は重複可とした。

(2) 血小板

年	2011							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
副作用項目								
1) 発熱	37	33	28	27	42		167	5.1%
2) 悪寒・戦慄	18	20	11	15	20		84	2.5%
3) 熱感・ほてり	11	10	12	22	25		80	2.4%
4) 掻痒感・かゆみ	114	167	165	194	196		836	25.4%
5) 発赤・顔面紅潮	48	37	43	53	69		250	7.6%
6) 発疹・蕁麻疹	219	310	307	398	379		1613	49.0%
7) 呼吸困難・呼吸障害	13	19	15	13	4		64	1.9%
8) 嘔気・嘔吐	5	7	10	7	7		36	1.1%
9) 胸痛・腹痛・腰背部痛	3	4	4	1	3		15	0.5%
10) 頭痛・頭重感	0	1	2	3	2		8	0.2%
11) 血圧低下	16	8	14	14	12		64	1.9%
12) 血圧上昇	6	2	3	4	4		19	0.6%
13) 動悸・頻脈	6	7	2	5	7		27	0.8%
14) 血管痛	0	0	0	0	1		1	0.0%
15) 意識障害	1	0	0	2	2		5	0.2%
16) 血尿（ヘモグロビン尿）	0	0	0	0	0		0	0.0%
17) その他								
皮疹	2						2	0.1%
声がれ		1					1	0.03%
酸素飽和度低下		1					1	0.03%
浮腫		1		1			2	0.1%
咳		1	1	1			3	0.1%
気道狭窄			1				1	0.0%
咽頭違和感			1				1	0.03%
のどのしびれ			1				1	0.03%
呼吸苦			1				1	0.03%
眼瞼浮腫			1	2			3	0.09%
目眩				1			1	0.03%
浮腫				1			1	0.03%
鼻閉感				1			1	0.03%
TRALIの疑い				1			1	0.03%
のどの違和感					1		1	0.03%
手足のしびれ					1		1	0.03%
不明	0	0	1	1	2		4	0.1%
報告数	499	629	623	767	777	0	3295	100%

症状項目は重複可とした。

(3) 血漿

年	2011							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
副作用項目								
1) 発熱	7	4	14	7	14		46	3.7%
2) 悪寒・戦慄	2	1	7	5	3		18	1.4%
3) 熱感・ほてり	7	4	6	8	7		32	2.6%
4) 掻痒感・かゆみ	54	73	36	73	47		283	22.7%
5) 発赤・顔面紅潮	25	13	27	27	16		108	8.7%
6) 発疹・蕁麻疹	107	132	111	128	118		596	47.8%
7) 呼吸困難・呼吸障害	1	7	7	7	5		27	2.2%
8) 嘔気・嘔吐	1	11	8	3	0		23	1.8%
9) 胸痛・腹痛・腰背部痛	3	0	1	1	0		5	0.4%
10) 頭痛・頭重感	1	2	3	1	0		7	0.6%
11) 血圧低下	7	9	14	17	15		62	5.0%
12) 血圧上昇	3	2	4	1	5		15	1.2%
13) 動悸・頻脈	1	2	2	3	5		13	1.0%
14) 血管痛	0	0	0	0	0		0	0.0%
15) 意識障害	0	0	0	0	0		0	0.0%
16) 血尿（ヘモグロビン尿）	0	0	0	0	0		0	0.0%
17) その他								
顔面のしびれ	1						1	0.1%
浮腫		1					1	0.1%
紅斑		1					1	0.1%
舌の違和感		2					2	0.2%
不快感				2			2	0.2%
しびれ				3	1		4	0.3%
呼吸苦					1		1	0.1%
報告数	220	264	240	286	237	0	1247	100%

症状項目は重複可とした。

5. 副作用診断別報告数

非溶血性副作用診断については、重症アレルギー、輸血関連急性肺障害 (TRALI)、輸血関連循環過負荷 (TACO)、輸血後移植片対宿主病 (GVHD)、輸血後紫斑病 (PTP)の５項目に分類し、それらに該当しないすべての副作用を全て「その他」とした。

(1) 赤血球

年	2011							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
A) 非溶血性副作用								
重症アレルギー反応	2	0	4	3	1		10	1.0%
輸血関連急性肺障害 (TRALI)	0	0	0	1	0		1	0.1%
輸血関連循環過負荷 (TACO)	1	0	0	0	0		1	0.1%
輸血後移植片対宿主病 (GVHD)	0	0	0	0	0		0	0.0%
輸血後紫斑病 (PTP)	0	0	0	0	0		0	0.0%
その他	191	167	207	212	205		982	98.5%
発生件数	194	167	211	216	206	0	994	99.7%
B) 溶血性副作用								
急性溶血	0	0	2	1	0		3	0.3%
遅発性溶血	0	0	0	0	0		0	0.0%
発生件数	0	0	2	1	0	0	3	0.3%
C) 感染症								
HBV	0	0	0	0	0		0	0.0%
HCV	0	0	0	0	0		0	0.0%
HIV	0	0	0	0	0		0	0.0%
細菌	0	0	0	0	0		0	0.0%
その他	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
発生総数　A) ＋B) ＋C)	194	167	213	217	206	0	997	100%

(2) 血小板

年	2010							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
A) 非溶血性副作用								
重症アレルギー反応	4	0	5	3	3		15	0.7%
輸血関連急性肺障害 (TRALI)	1	0	0	1	0		2	0.1%
輸血関連循環過負荷 (TACO)	0	0	0	0	0		0	0.0%
輸血後移植片対宿主病 (GVHD)	0	0	0	0	0		0	0.0%
輸血後紫斑病 (PTP)	0	0	0	0	0		0	0.0%
その他	332	435	452	512	491		2222	99.2%
発生件数	337	435	457	516	494	0	2239	100%
B) 溶血性副作用								
急性溶血	0	0	0	0	0		0	0.0%
遅発性溶血	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
C) 感染症								
HBV	0	0	0	0	0		0	0.0%
HCV	0	0	0	0	0		0	0.0%
HIV	0	0	0	0	0		0	0.0%
細菌	0	0	0	0	0		0	0.0%
その他	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
発生総数 A) +B) +C)	337	435	457	516	494	0	2239	100%

(3) 血漿

年	2010							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
A) 非溶血性副作用								
重症アレルギー反応	0	3	9	4	4		20	2.6%
輸血関連急性肺障害 (TRALI)	0	0	0	0	0		0	0.0%
輸血関連循環過負荷 (TACO)	0	1	0	0	0		1	0.1%
輸血後移植片対宿主病 (GVHD)	0	0	0	0	0		0	0.0%
輸血後紫斑病 (PTP)	0	0	0	0	0		0	0.0%
その他	151	172	148	142	138		751	97.3%
発生件数	151	176	157	146	142	0	772	100%
B) 溶血性副作用								
急性溶血	0	0	0	0	0		0	0.0%
遅発性溶血	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
C) 感染症								
HBV	0	0	0	0	0		0	0.0%
HCV	0	0	0	0	0		0	0.0%
HIV	0	0	0	0	0		0	0.0%
細菌	0	0	0	0	0		0	0.0%
その他	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
発生総数 A) +B) +C)	151	176	157	146	142	0	772	100%

Ⅲ．研究成果の刊行に関する一覧表

Ⅳ．研究成果の刊行物・別刷

研究成果の刊行に関する一覧表

（平成 21 年度）

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Fujii Y, Shibata Y, Miyata S, Inaba S, Asai T, Hoshi Y, Takamatsu J, Takahashi K, Ohto H, Juji T,Sagawa K.	Consecutive national surveys of ABO-incompatible blood transfusion in Japan.	Vox Sang.	97(3)	240-246	2009
藤井康彦	病院内の輸血副作用の監視体	Medical Technology	37(8)	865-868	2009

研究成果の刊行に関する一覧表

（平成22年度）

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
藤井康彦	輸血患者の観察	藤井康彦	輸血副作用対応ガイド	(-)	山口宇部	2011	1-58
下平滋隆	副作用の症状	高本　滋					
高本　滋	副作用への対応						
加藤栄史	ヘモビジランス						
浜口　功	用語の定義						
田崎哲典	副作用の重症度・起因性レベル						
石丸　健	副作用各論						
佐藤進一郎	1-1　急性溶血性輸血副作用						
百瀬俊也	1-2　遅発性溶血性輸血副作用						
松崎浩史	2-1　発熱性非溶血性輸血副作用						
岡崎　仁	2-2　アレルギー反応						
浅井隆善	2-3　輸血関連急性肺障害						
中島文明	2-4　輸血関連循環過負荷						
名雲英人	2-5　TAD						
松林圭二	2-6　低血圧性輸血副作用						
紀野修一	2-7　輸血後GVHD						
	2-8　輸血後紫斑病						
	2-9　輸血関連ヘモジデローシス						
	2-10　高カリウム血症						
	3-1　細菌感染症の疑い						
	3-2　輸血ウイルスおよび寄生虫感染症						
	遡及調査と輸血前後の感染症検査						

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
藤井康彦	不適合輸血：現状、予防と対処法	麻酔	60(1)	47-54	2011

研究成果の刊行に関する一覧表

（平成23年度）

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
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雑誌

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藤井康彦	免疫性副作用の原因・対応・リスク管理	Medical Technology	39 (13)	1578-83	2011
加藤栄史、高本滋、小高千加子、佐川公矯、星順隆、藤井康彦、米村雄士、岩尾憲明、田中朝志、岡崎仁、百瀬俊也、北澤淳一、森宏、松下明夫、野村久子、八十嶋仁、大日康史、岡田義昭、浜口功、山口一成	パイロット研究による輸血副作用の解析− 我国における包括的なヘモビジランスの構築に向けて−	日本輸血細胞治療学会誌	57 (3)	178-83	2011

The International Journal of Transfusion Medicine
Vox Sanguinis

Vox Sanguinis (2009) **97**, 240–246

DOI: 10.1111/j.1423-0410.2009.01199.x

ORIGINAL PAPER

Consecutive national surveys of ABO-incompatible blood transfusion in Japan

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Background and Objectives Morbidity and mortality from ABO-incompatible transfusion persist as consequences of human error. Even so, insufficient attention has been given to improving transfusion safety within the hospital.

Materials and Methods National surveys of ABO-incompatible blood transfusions were conducted by the Japanese Society of Blood Transfusion, with support from the Ministry of Health, Labor and Welfare. Surveys concluded in 2000 and 2005 analysed ABO-incompatible transfusion data from the previous 5 years (January 1995 to December 1999 and January 2000 to December 2004, respectively). The first survey targeted 777 hospitals and the second, 1355 hospitals. Data were collected through anonymous questionnaires.

Results The first survey achieved a 77·4% response rate (578 of 777 hospitals). The second survey collected data from 251 more hospitals, but with a lower response rate (61·2%, or 829 of 1355 hospitals). The first survey analysed 166 incidents from 578 hospitals, vs. 60 incidents from 829 hospitals in the second survey. The main cause of ABO-incompatible transfusion was identification error between patient and blood product: 55% (91 of 166) in the first survey and 45% (27 of 60) in the second. Patient outcomes included nine preventable deaths from 1995 to 1999, and eight preventable deaths from 2000 to 2004.

Conclusion Misidentification at the bedside persists as the main cause of ABO-incompatible transfusion.

Received: 12 January 2009, revised 27 April 2009, accepted 27 April 2009, published online 20 May 2009

Key words: non-infectious, transfusion complication, transfusion practices (adult), transfusion service operations.

A part of this research was supported by the Ministry of Health, Labor and Welfare, Japan. (Health and Labor Sciences Research Grants, Research on Regulatory Science of Pharmaceuticals and Medical Devices).

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Introduction

ABO-incompatible transfusion preceded Landsteiner's discovery of human blood groups, but persists more than 100 years later as an important cause of adverse events due to human error [1–3]. Haemovigilance systems in Europe and North America target ABO-incompatible blood transfusion [1,2,4]. In Japan, Red Cross blood centres collect haemovigilance data, but specifically target transfusion-transmitted virus infections and immune phenomena such as allergic reactions, transfusion-related acute lung injury, and transfusion-associated graft-vs.-host disease [5]. Therefore, the actual incidence of ABO-incompatible blood transfusion in our country has been uncertain. In order to investigate and guide methods of prevention, consecutive national surveys were initiated by the Japanese Society of Blood Transfusion (now the Japanese Society of Transfusion Medicine and Cell Therapy) [6,7].

Materials and methods

The Japan Society of Blood Transfusion developed anonymous questionnaires, targeting 777 hospitals from January 1995 to December 1999, and 1355 hospitals from January 2000 to December 2004. Data were analysed and reported in 2000 and in 2005. The first survey solicited cases arising from whole blood (WB), red cell concentrate (RCC) and fresh frozen plasma (FFP) transfusions at 777 hospitals, each having at least 300 beds. The scope of the second survey expanded to include cases arising from platelet concentrate transfusions, and targeted 1355 hospitals, including 777 of the same hospitals targeted in the first survey and 578 additional hospitals with fewer than 300 beds, where at least one transfusion specialist was working. Not only accidents but also incidents (errors without adverse reactions) were solicited. In regard to transfusion oversight, blood transfusion management systems and laboratory testing outside of core hours were investigated in first survey (Tables 1 and 2). To these, the second survey added utilization of electronic equipment for blood transfusion management and product testing (Tables 3 and 4).

Table 1 ABO-incompatible blood transfusion questionnaire form 1 of the first survey (1 January 1995 to 31 December 1999)

I. Did the ABO-incompatible blood transfusion occur in the past 5 years (1 January 1995 to 31 December 1999)?
(The targets are whole blood, red cell concentrates, and fresh frozen plasma; and platelets concentrates should be excluded.)
(1) Yes (Please give details using investigation form 2 on the next page.)
(2) No

II. Questions on system of blood transfusion management

1. Number of hospital beds: Select from the following:
   (1) 300 to less than 400 beds
   (2) 400 to less than 500 beds
   (3) 500 to less than 600 beds
   (4) 600 to less than 700 beds
   (5) 700 to less than 800 beds
   (6) 800 to less than 900 beds
   (7) 900 to less than 1000 beds
   (8) More than 1000 beds
2. Amount of transfused blood components during the last fiscal year: Select from the following:
   (1) 3000 to less than 10 000 units
   (2) 10 000 to less than 20 000 units
   (3) 20 000 to less than 30 000 units
   (4) 30 000 to less than 40 000 units
   (5) 40 000 to less than 50 000 units
   (6) More than 50 000 units
3. Section that manages blood supply:
   (1) Blood transfusion service
   (2) Laboratory
   (3) Pharmacy
   (4) Others
4. Pretransfusion testing out of core hours:
   (1) Duty by laboratory technician
   (2) The doctor takes charge
   (3) Laboratory technician's system of on call
   (4) Others
5. Doctor accredited by the Japan Society of Blood Transfusion:
   (1) Yes
   (2) No
6. Laboratory specialist accredited by the Japan Society of Blood Transfusion:
   (1) Yes
   (2) No
7. Hospital transfusion therapy committee:
   (1) Yes
   (2) No
8. Please describe any special method to prevent of ABO-incompatible blood transfusion in your hospital.

Results

A 74·4% response rate was achieved in the 1995–99 survey, corresponding to 578 of 777 hospitals. A 61·2% response rate was achieved in the 2000–04 survey, corresponding to 829 of 1355 hospitals. From 578 participating hospitals in the first survey came 166 case reports, vs. only 60 case reports from the 829 hospitals participating in the second survey including six cases reported from hospitals with fewer 300 beds (Table 5). These cases include those without adverse reactions. Nevertheless, the number of fatalities reported in each survey was nearly equal: nine in the first survey and eight in the second. In the second survey, the mean number of transfused blood components reported from 540 hospitals during survey period was 14 855 bags, but in first survey the exact number of transfused blood components was not

Table 2 ABO-incompatible blood transfusion questionnaires form 2 (case report) of the first survey (1 January 1995 to 31 December 1999)

1. Content of case:

(Please describe details and the reason for the discovery of ABO-incompatible blood transfusion.)

2. Persons concerned who made a mistake:
   (1) Doctor
   (2) Nurse
   (3) Laboratory technician
   (4) Others ( )
3. Time period:
   (1) Regular (daylight) hours
   (2) Out of core hours
4. Was it an urgent blood transfusion?
   (1) Yes
   (2) No
5. Site of blood transfusion:
   (1) Ward
   (2) Operation room
   (3) ICU
   (4) Emergency room
   (5) Others
6. Blood product:
   (1) Whole blood
   (2) Red cell concentrates
   (3) Fresh frozen plasma
7. ABO type:
   Blood type of blood preparation
   Patient's blood type
8. Amount of blood transfusion (ml):
9. How long did it take you to become aware of ABO-incompatible blood transfusion from the beginning of transfusion?
10. Did you explain the situation to the patient and family?
    (1) Yes
    (2) No
    (3) Uncertain
11. Was there any symptom of shock?
    (1) Yes
    (2) No
    (3) Unknown
12. Was there any sign of haemolysis?
    (1) Yes
    (2) No
    (3) Unknown
13. Was there any sign of disseminated intravascular coagulation?
    (1) Yes
    (2) No
    (3) Unknown
14. Was there any sign of renal insufficiency?
    (1) Yes
    (2) No
    (3) Unknown
15. What kind of treatment was performed?
16. Outcome:
    (1) Death
    (2) Survival with adverse effects
    (3) Survival without adverse effects
17. Improvement plan concerning ABO-incompatible blood transfusion prevention adopted after the case occurred:
18. Others

(If you think there is anything else pertinent to this case, please describe the details.)

Table 3 ABO-incompatible blood transfusion questionnaire form 1 of the second survey (1 January 2000 to 31 December 2004)

I. Did the ABO-incompatible blood transfusion occur in the past 5 years (1 January 2000 to 31 December 2004)?
(The targets are whole blood, red cell concentrates, fresh frozen plasma, and platelet concentrates.)
(1) Yes (Please give details using investigation form 2.)
(2) No

II. Questions on system of blood transfusion management

1. How many beds does your hospital have?
( ) beds
2. How many units of total blood transfusion products were administered over 5 years 1 January 2000 to 31 December 2004?

Whole blood	( ) units, ( ) bags
Red cell concentrates	( ) units, ( ) bags
Fresh frozen plasma	( ) units, ( ) bags
Platelets concentrates	( ) units, ( ) bags

3–8. Same as those of the first survey
9. Do you electronically verify patients and blood products before transfusion at bedside?
(1) Yes
(2) No
(3) Only in a part of the ward
10. Is a computer-based ordering system used to request the blood supply?
(1) Yes
(2) No
(3) Its introduction is scheduled
11. Is the ordering computer system used to request the pretransfusion testing?
(1) Yes
(2) No
(3) Its introduction is scheduled
12. Is a computer-based system used for the stock-taking and managing the delivery of the blood products?
(1) Yes
(2) No
(3) Its introduction is scheduled
13. Is an automatic blood transfusion testing machine used?
(1) Yes
(2) No
(3) Its introduction is scheduled

Table 4 ABO-incompatible blood transfusion questionnaire form 2 (case report) of the second survey (1 January 2000 to 31 December 2004)

1–18. Same as those of the first survey
19. Did it occur before introducing the portable digital assistant to blood transfusion confirmation at the bed side?
(1) Yes
(2) No

Table 5 Analysed data

	First survey	Second survey	
Survey period	1 January 1995 to 31 December 1999	1 January 2000 to 31 December 2004	
Target hospital	777	1355	
> 300 beds	777	777[a]	
< 300 beds	0	578	
Response (%)	578 (74·4)	829 (61·2)	
> 300 beds	578 (74·4)	502 (64·2)	
< 300 beds		327 (55·7)	
Reported cases[b]			
	WB + RCC + FFP[c]	RCC + FFP[d]	PC[e]
> 300 beds	166	48	6
< 300 beds	0	4	2
Total	166	52	8

[a]777 hospitals the same as those targeted in the first survey.
[b]Reported cases including those without adverse reactions.
[c]Cases arising from whole blood (WB), red cell concentrate (RCC), and fresh frozen plasma (FFP), including those arising from unknown components.
[d]Cases arising from RCC and FFP, including those arising from unknown components.
[e]Cases arising from platelet concentrate.

Table 6 Number of reports according to the type of blood product

	First survey[a]	Second survey[b]
Whole blood major mismatch	3	0
Whole blood minor mismatch	2	0
Red cell concentrate major mismatch	48	22
Red cell concentrate minor mismatch	38	9
Fresh frozen plasma	71	19
Platelet concentrate	Not reported	8
Unknown	4	2
Total	166	60

[a]1 January 1995 to 31 December 1999.
[b]1 January 2000 to 31 December 2004.

collected. The number of reported cases of ABO-incompatible blood transfusion according to the number of hospital beds is shown in Fig. 1. A decrease in the number of reported cases was recognized in large hospitals, defined as having more than 700 beds. Table 6 shows the numbers of reported cases according to the type of blood product. A decrease of RCC minor mismatch and FFP was more remarkable than that of RCC major mismatch. Outcomes in patients receiving RCC major mismatch included nine deaths in the first survey and eight in the second. The cause of death includes the possibility of underlying disease in nine of 17 cases according to the contents of cases in questionnaire form 2. In six of the remaining eight deaths, unambiguously due to ABO-incompatible transfusion, the patients were of group O blood type. Data from the second survey suggest a risk of ABO-incompatible

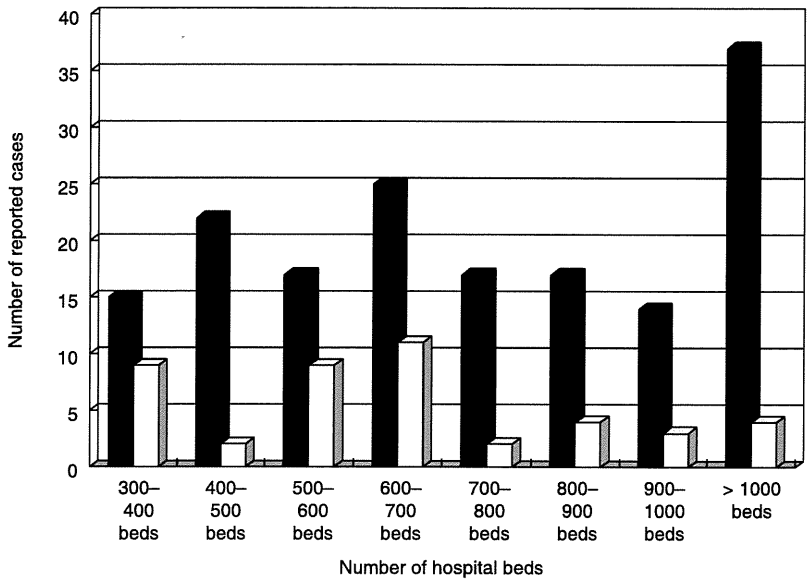


Fig. 1 Number of reported cases of accidental ABO-incompatible blood transfusion of red cell concentrate and fresh frozen plasma according to the number of hospital beds.
■: Number of reported cases of ABO-incompatible blood transfusion of whole blood, red cell concentrates, and fresh frozen plasma in the first survey (1 January 1995 to 31 December 1999).
□: Number of reported cases of ABO-incompatible blood transfusion from red cell concentrates and fresh frozen plasma reported only from hospitals having at least 300 beds in the second survey (1 January 2000 to 31 December 2004).

Table 7 Pretransfusion testing out of core hours

	Number of hospitals		
	First survey[a]		Second survey[b]
	> 300 beds (%)	> 300 beds (%)	< 300 beds (%)
Duty of laboratory specialist	347 (60·35)	476 (75·1)	26 (13·9)
Laboratory specialist on call	163 (28·35)	147 (23·2)	157 (83·9)
The doctor takes charge	43 (7·5)	4 (0·6)	2 (1·1)
Others	22 (3·8)	7 (1·1)	2 (1·1)
Total	575 (100)	634 (100)	187 (100)

[a]1 January 1995 to 31 December 1999.
[b]1 January 2000 to 31 December 2004.

transfusion as 1 : 200 000 and a risk of the death as 1 : 3 000 000. The status of pretransfusion testing out of core hours is shown in Table 7. Electronic correlation of patients and blood products seems to have had limited implementation in 1999, when the first survey was executed, but was reported in 8·8% of facilities in 2004 when the second survey was executed.

Main causes of transfusion error

Identification error between patient and blood product

The main cause of transfusion error was misidentification between patient and blood product: 55% of cases (91 of 166) in the first survey, and 45% (27 of 60) in the second (Table 8). RCC major mismatch comprised 36 cases in the first survey and 14 cases in the second survey. Among the reported cases, no technology-based identification systems were in place.

Phlebotomy error

Phlebotomy errors were reported in 2% of cases (four of 166) in the first survey, and 3% (two of 60) in the second. All phlebotomy errors were emergency situations where the blood typing and cross-matching were performed on the same specimen.

Prescription error

Prescription errors were reported in 11% of cases (19 of 166) in the first survey, and 13% (eight of 60) in the second. In these cases, blood component orders of an incorrect ABO blood group were sent to the laboratory. Fresh frozen plasma

Table 8 Main causes of transfusion error

	First survey[a]	Second survey[b]
Identification error	91	27
Phlebotomy error	4	2
Prescription error[c]	19	8
Testing error by doctor	21	10
Laboratory error outside of core hours	12	6
Laboratory error during core hours	5	4
Other	14	3
Total	166	60

[a]1 January 1995 to 31 December 1999.
[b]1 January 2000 to 31 December 2004.
[c]Blood components orders of incorrect ABO blood group.

or platelet concentrate orders of an incorrect ABO blood group sent to the laboratory were undetected by laboratory methods due to the omission of the minor cross-match. No reported prescription error was associated with an RCC major mismatch.

Testing error by doctors

Testing errors by doctors were reported in 13% of cases (21 of 166) in the first survey, and 17% (10 of 60) in the second. In hospitals where these errors arose, laboratory services for blood transfusion were not available.

Laboratory error outside of core hours

Laboratory errors outside of core hours were reported in 7% of cases (12 of 166) in the first survey, and 10% (six of 60) in the second. These errors included technical testing errors in 10 cases, issuance of the wrong units in four cases, and use of the wrong patient sample for testing in one case, and, in four cases the details of errors were not reported.

Laboratory error during regular (daylight) hours

Laboratory errors during regular (daylight) hours were reported in 3% of cases (five of 166) in the first survey, and 7% (four of 60) in the second. These errors included technical testing errors in three cases, clerical error in transcription in one case, issuance of the wrong units in two cases, and use of the wrong patient sample in three cases.

Other errors

In the first survey: a wrong blood type was displayed at the bedside in one case; 11 cases had no reports about the main cause; and in two cases, a main cause could not be clearly discerned. In the second survey, two ABO-incompatible bone marrow transplant recipients received the wrong blood, and in one other case, incompatible FFP was taken from an operating room refrigerator.

Discussion

Based on data from the second survey, the risk of ABO-incompatible transfusion and that of death is about half of those reported by Serious Hazards of Transfusion (SHOT) [1]. In Japan, at least 8000 hospitals transfuse blood, perhaps more if the smallest hospitals are counted, but this investigation focused on the hospitals responsible for about 80% of the blood products transfused in Japan. The Japanese Red Cross (JRC) is the only supplier of allogeneic blood components used in Japan. The collection of allogeneic blood by a hospital transfusion service is rare and permitted in emergency cases if the JRC has failed to supply the blood products to hospitals. The total amount of all blood components supplied by the JRC corresponded to the total amount of blood components transfused in Japan. In the fiscal year of 2004, when the second survey was done, the total amount of blood components supplied by the JRC Blood Center was 16 668 784 units, and the total amount of blood components transfused in the 829 hospitals which responded to the second survey was 7 962 317 units, with about 47·8% of blood components supplied by the blood centre.

ABO-incompatible blood transfusion arises from human error [8]. Eighty per cent of ABO-incompatible blood transfusions were reported from the clinical setting of a ward or operating room and 20% were reported from a laboratory. No reported errors were associated with blood banking procedures of the JRC. There were no mislabelling of units or, weak A or B antigens typed as O. This underscores the value of an incident reporting system that collects data from hospitals, and provides analytical feedback to each facility [9–11]. Identification errors between patients and blood products provoke most RCC major mismatch transfusions. Preventive efforts are important because these errors are eminently preventable. Many hospitals had their own transfusion procedural manual, including the final identification between patients and blood products in the clinical area. In many cases, procedural deviations occurred, including half of the hospitals that maintained their own procedures. Following the first survey, a standardized blood transfusion procedure manual emphasizing the final identification between patients and blood products was developed by the Japanese Society of Blood Transfusion, and this procedure has been widely propagated through distributing a poster showing the procedural manual by the Japanese Society of Blood Transfusion and JRC [6]. The second survey collected only about 30% as many identification errors as were reported in the first survey, even with the participation of an additional 251 hospitals. It may be that the dissemination of a standard procedure contributed to a decrease in identification error. This was the main intervention undertaken to reduce the incidence of ABO-incompatible transfusion after the first survey. However, incorrect blood recipient identification at

the patient's bedside persists as the main cause of ABO-incompatible transfusion. Education programmes may be helpful to the extent that they reach all staff involved in transfusion. This is challenging under the best of circumstances, and more so where staff turnover is high. It thus behooves us to monitor employment trends in the healthcare sector. Technological interventions also have the potential to interdict human error, provided that the technology is not bypassed for reasons of expediency or lack of understanding [12–15]. The introduction of electronic correlation of patients and blood products has progressed in large-scale hospitals. Pretransfusion testing out of core hours is another problem. In 7·5% of hospitals in the first survey, laboratory services for blood transfusion out of core hours were not available, thus forcing clinicians into the role of laboratory professionals. The number of facilities where a doctor performs pretransfusion testing outside of core hours decreased from the first survey, and the number of facilities where laboratory staff perform all testing increased. Even so, laboratory staff who do not routinely perform transfusion-related testing are likely to be more error prone than those who are devoted to the blood bank or transfusion service. These were the main differences between the two surveys.

The second national survey of ABO-incompatible blood transfusion was completed 5 years after first survey. Ideally, investigative data should be collected continuously and reported at least annually, as occurs in other countries with formal haemovigilance systems [1,2]. We aspire to blend the Japanese experience described herein with international best practices described elsewhere, with the ultimate goal of mitigating the needless morbidity and mortality arising from human error.

A part of this research was supported by the Ministry of Health, Labor and Welfare.

References

1 Stainsby D: ABO incompatible transfusions – Experience from the UK Serious Hazards of Transfusion (SHOT) scheme Transfusions ABO incompatible. *Transfus Clin Biol* 2005; 12:385–388

2 Stainsby D, Russell J, Cohen H, Lilleyman J: Reducing adverse events in blood transfusion. *Br J Haematol* 2005; 131:8–12

3 Linden JV, Wagner K, Voytovich AE, Sheehan J: Transfusion errors in New York State. An analysis of 10 years' experience. *Transfusion* 2000; 40:1207–1213

4 Andreu G, Morel P, Forestier F, Debier J, Rebibo D, Janvier G, Herve P: Hemovigilance network in France: organization and analysis of immediate transfusion incident reports from 1994 to 1998. *Transfusion* 2002; 42:1356–1364

5 Takahashi K, Juji T, Miyamoto M, Uchida S, Akaza T, Tadokoro K, Shibata Y, Ino T, Hidano A: Analysis of risk factors for post-transfusion graft-versus-host disease in Japan. Japanese Red Cross PT-GVHD Study Group. *Lancet* 1994; 343:700–702

6 Sibata Y, Inaba R, Uchikawa M, Osada K, Kurata Y, Sakamoto H, Sagawa K, Tadokoro K, Handa M, Yoshioka H, Juji T: Results of the survey on the present state of ABO-incompatible blood transfusion in Japan. *Jap J Transfusion Med* 2000; 46:545–564

7 Fujii Y, Matsuzaki M, Miyata S, Higashitani T, Inaba S, Asai T, Hoshi Y, Inada E, Kawahara K, Takamatsu J, Takahashi K, Sagawa K: Analysis of the causes of ABO-incompatible transfusions in Japan. *Jap J Transfusion Cell Therapy* 2007; 52:112–132

8 Myhre BA, McRuer D: Human error – a significant cause of transfusion mortality. *Transfusion* 2000; 40:879–885

9 Callum JL, Kaplan HS, Merkley LL, Pinkerton PH, Rabin Fastman B, Romans RA, Coovadia AS, Reis MD: Reporting of near-miss events for transfusion medicine: improving transfusion safety. *Transfusion* 2001; 41:1204–1211

10 Ibojie J, Urbaniak SJ: Comparing near misses with actual mis-transfusion events: a more accurate reflection of transfusion errors. *Br J Haematol* 2000; 108:458–460

11 Galloway M, Woods R, Whitehead S, Gedling P: Providing feedback to users on unacceptable practice in the delivery of a hospital transfusion service – a pilot study. *Transfus Med* 2002; 12:129–132

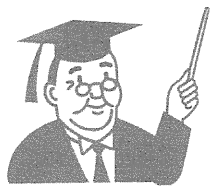
12 Pagliaro1 P, Rebulla P: Transfusion recipient identification. *Vox Sang* 2006; 91:97–111

13 Miyata S, Kawai T, Yamamoto S, Takada M, Iwatani Y, Uchida O, Imanaka H, Sase K, Yagihara T, Kuro M: Network computer-assisted transfusion – management system for accurate blood component-recipient identification at the bedside. *Transfusion* 2004; 44:364–372

14 Murphy MF, Casbard AC, Ballard S, Shulman IA, Heddle N, Aubuchon JP, Wendel S, Thomson A, Hervig T, Downes K, Carey PM, Dzik WH: Prevention of bedside errors in transfusion medicine (PROBE-TM) study: a cluster-randomized, matched-paired clinical areas trial of a simple intervention to reduce errors in the pretransfusion bedside check. *Transfusion* 2007; 47:771–780

15 Sandler SG, Langeberg A, DeBandi L, Gibble J, Wilson C, Feldman CL: Radiofrequency identification technology can standardize and document blood collections and transfusions. *Transfusion* 2007; 47:763–770

MT Seminar



病院内の輸血副作用の監視体制

●今月の講師　藤井康彦

はじめに

輸血の安全性についてさまざまな議論がなされているが，これらは各病院から赤十字血液センター，厚生労働省に報告された副作用・輸血過誤のデータをもとにしている．

これまでの輸血に関連した学会によるアンケート調査では，各病院から赤十字血液センターへ報告された副作用報告数には大きな差があった[1]．また，都道府県単位で見ても，その人口当りの副作用報告件数には大きな違いがある[1]．つまり，現状は，不完全なデータに基づいた議論が行われており，新たな安全性向上のための対策が実施されても，その効果の評価も不完全なデータに基づいて判定されることになる．

このため，各病院の医療スタッフは，個々の病院の副作用報告が国政レベルの輸血の安全性対策に影響を与える可能性があることを自覚する必要がある．

輸血医療の体制整備

輸血副作用の監視体制の前提となるのは，輸血療法委員会を中心とした輸血医療全体の体制整備である．各病院では，輸血療法委員会の監督下に，病棟・外来で発生した副作用を輸血部門が収集し，赤十字血液センターへ報告することが期待されている．このような輸血療法委員会の役割について，厚生労働省「輸血療法の実施に関する指針」に規定されているが，具体的な方法論についての記載が少ない．各病院の輸血療法委員会のレベルアップを図るため，厚生労働省では，都道府県単位の合同輸血療法委員会の設置を推進しているが，設置されていない県もある．

輸血療法の安全性の観点からは，輸血医療に関する体制整備は不可欠である．しかし，輸血実施施設において必要とされる検査技師の人数・知識・能力，検査・血液製剤保管のための機器，臨床部門での実施体制，ITシステムなどについて具体的な規定がない．さらに，体制整備を中心となって推進する役割が期待される輸血責任医師についても，知識・経験，職責遂行のために必要な権限，業務に必要な時間などの規定がない．輸血責任医師については，輸血医療に関して不都合な事例が発生した場合に「責任をとる医師」と解釈され，病院長などが兼務している場合があり，実質的な体制整備が進まない施設が散見される．

表 1　輸血実施施設の必要要件[2]

日本輸血・細胞治療学会 I & A 認証基準 ・ABO，Rh（D），不規則抗体スクリーニング検査，交差適合試験ができる ・輸血検査，製剤管理が一元化され，24 時間体制である ・輸血療法委員会が開催され，責任医師が明確である ・輸血副作用調査，原因検索，報告体制が確立している
義務的必須項目： インフォームド・コンセントの実施，輸血手順書の整備，輸血記録の 20 年間保管 望ましい項目： 専任輸血検査技師の配置，輸血部門の設置，自己血輸血の実施，試薬・機器の精度管理の保証