		管理システムへの理解、導入状況、方法、改善案の提示	
		指摘された問題点への対応方法と組織内協力の獲得方法	
19	リスクコミュニケーションのバイオリスク管理における役割	バイオリスク管理プログラムとしてのリスクコミュニケーション計画	0.5
		緊急対応、事故対応に必要なコミュニケーション技術、各部署との連携と協力関係の設立	
		情報収集と広報活動	
20	バイオリスク管理とICAO 区分 6.2 危険物の輸送の関係	関連法規、指針、マニュアルと所管官庁	2
		包装時と輸送中のバイオリスクの評価と対応	
		荷送人責任、訓練の必要性、訓練記録の保持	
		包装容器の選定、包装、マーキング、ラベル添付、オーバーパック	
		手続き、届出、書類	
		演習	0.5
合計時間数			30.45

選択可能な上級編研修内容

1	動物を使う実験 1（小型動物、ABSL）
2	動物を使う実験 2（大型動物,ABSL）
3	ヒト以外の哺乳類を用いた実験
4	植物を使う実験
5	その他の生物学的材料を使う実験（節足動物、プリオン）
6	大規模生産（プラント、セキュリティ管理、品質管理、GMP（適正製造規範））
7	空中生物学（気流制御）
8	教育プログラムの作成（教育プログラムのデザインと評価方法の選定）
9	感染性物質の輸送（資料５を参照）
10	リスクコミュニケーション訓練（情報の提供方法、表現、効果の分析方法）
11	GMT（基準微生物実験技術）
12	微生物学基礎（病原性、感染成立に必要な病原体量、感染経路等）
13	感染制御（感染経路、感染機序、免疫、感染予防手法、隔離、封じ込め等）
14	実験室機器の選定、バリデーション、検定と運用

15	目的に合わせた実験室デザイン、設計
16	高度封じ込め実験室（封じ込めレベル3と4の実験室）の運用
17	組換えDNA実験

モデル２：
研究者および研究支援者　初期研修のプログラム案①（講義1日、演習0.5日分、1日7時間）
感染症に関する基礎知識がある場合

項目		内容	研究者	支援
1時限	導入：バイオリスク管理の全体像把握	実験室内感染と健康監視	●	●
		バイオリスク管理の用語の定義	●	●
		バイオセーフティとバイオセキュリティの違いと関係	●	●
		バイオリスク管理の目的と基本的アプローチ	●	●
2時限	バイオリスク管理プログラム	バイオリスク管理システム、役割と責任（IBC 等の委員会を含む機関内の構造）	●	●
		バイオリスク管理プログラムの原理と運用、効果評価	●	○
		訓練、研修の必要性	●	●
3時限	関連法規	国際法規、指針など	●	○
		国内法規、指針等	●	●
4時限	バイオリスク管理の基礎	AMP モデル	●	●
		ハザード分析（病原体、エアロゾル発生手技）	●	●
		リスクアセスメント	●	●
5時限	バイオリスク管理の手法	封じ込めの原理、BSC、PPE	●	●
		施設、機器によるリスク緩和	●	●
		管理方法によるリスク緩和	●	●
		実践・運用によるリスク緩和	●	○
		演習（PPE 着脱、BSC 利用方法）	○	－
6時限	消毒、滅菌、除染方法	除染、消毒、滅菌の基礎知識	●	●
		除染、消毒、滅菌の実践とリスク	●	○
7時限	廃棄物と事故・緊急時対応	緊急時対応計画の作成	●	○
		廃棄物取扱い時のリスク	●	●
		事故・緊急時の対応手順、報告、記録	●	●
		バイオ／ケミカルスピルの除染	●	●
		演習（スピル対応）	○	－
8時限	ICAO 区分 6.2 危険物の輸送	容器、包装、輸送方法、関連法規、演習	○	－

注：●は基本選択、○はオプション、－は不要項目

研究者および研究支援者　初期研修のプログラム案②（講義1.5日、演習0.5日分、1日7時間）
感染症に関する基礎知識が無い場合

	項目	内容	研究者	支援
1時限	導入：バイオリスク管理の全体像把握	実験室内感染と健康監視	●	●
		感染を起こす病原体	●	●
		曝露と感染の違い	●	●
		感染経路	●	●
		バイオリスク管理の用語の定義	●	●
		バイオセーフティとバイオセキュリティの違いと関係	●	○
		バイオリスク管理の目的と基本的アプローチ	●	●
2時限	バイオリスク管理プログラム	バイオリスク管理システム、報告事項と体系	●	●
		バイオリスク管理プログラムの原理と遵守事項	●	○
		訓練、研修の必要性	●	●
3時限	関連法規	国際法規、指針など	●	○
		国内法規、指針等	●	●
4時限	バイオリスク管理の基礎	AMP モデル	●	●
		ハザード分析（病原体、エアロゾル発生手技）	●	○
		リスクアセスメント	●	●
5時限	バイオリスク管理の手法	封じ込めの原理、BSC、PPE	●	●
		施設、機器によるリスク緩和	●	●
		管理方法によるリスク緩和	●	●
		実践・運用によるリスク緩和	●	○
		演習（PPE 着脱、BSC 利用方法）	○	－
6時限	消毒、滅菌、除染方法	除染、消毒、滅菌の基礎知識	●	●
		実験室で使用する一般的消毒薬とその使用方法	●	○
		除染、消毒、滅菌の実践とリスク	●	○
7時限	廃棄物と事故・緊急時対応	緊急時対応計画の作成	●	○
		廃棄物取扱い時のリスク	●	●
		事故・緊急時の対応手順、報告、記録	●	●
		バイオ／ケミカルスピルの除染	○	○
		演習（スピル対応）	○	－

8時限	ICAO 区分 6.2 危険物の輸送	容器、包装、輸送方法、関連法規、演習	○	－

注：●は基本選択、○はオプション、－は不要項目

モデル３：

病原体および感染性が疑われるか、患者情報の無い臨床検体の輸送に関する研修プログラム

	項目	内容	想定時間（分）				IATA 荷送人研修で求められている項目
			初・完全版	初・簡易版	継・実務者	継・管理者	
1	プレ試験	択一問題10問程度の事前知識を図るもの	15	10	10	10	
2	概要説明	講習内容	5	5	5	5	
		目的と到達点	5	5	5	5	
3	関連法規	国内法規、指針、関連通知の内容と適用	30	30	15	25	●
		国際法規、指針の内容と影響範囲	30	20	15	15	●
4	荷送人責任	荷物の送手の責任	15	10	5	10	●
5	輸送品の分類	危険物の分類方法の基本、定義	60	30	5	25	●
		分類による取扱の違い	25	—	—	10	●
6	基本包装	感染性物質の三重梱包	20	20	5	20	●
7	カテゴリＡ	選択可能な輸送方法	5	40	10	15	●
		輸送容器	20				●
		梱包方法	30				●
		マーキング（記載事項）	20				●
		ラベルの選定と添付	30				●
		準備する書類と保管	40	20	20	15	●
		手続きと届け出	40				●
		具体例	40	—	10	20	
8	カテゴリＢ	選択可能な輸送方法	5	40	10	15	●
		輸送容器	10				●
		梱包方法	10				●
		マーキング（記載事項）	20				●
		ラベルの選定と添付	20				●
		準備する書類と保管	20	15	10	10	●
		手続き	20				●
		具体例	40	—	10	10	
9	少量危険物	カテゴリＡ及びＢとの違い	30	—			●
10	例外(適用免除)とされる患者試料	選択可能な輸送方法	10	15	5	—	
		輸送容器	10				
		梱包方法	10				
		マーキング（記載事項）	20				

		ラベルの選定と添付	10				
		準備する書類と保管	5				
		具体例	20		5	5	
11	適用除外(特定品目)	カテゴリA及びBとの違い	10	5	—	—	
12	遺伝子組み換え生物	カテゴリA及びBとの違い	10		—	5	●
13	冷却材	ドライアイス、液体窒素の危険物としての取扱い	30	10	5	5	●
14	保存剤	ホルマリンなどの扱い	10	—	—	5	
15	緩衝材	材質、使い方	10	—	—	—	
16	吸収材	材質、使い方	20	—	—	—	
17	オーバーパック	材質	20	10	5	5	
		梱包方法	20				●
		マーキング（記載事項）	20				
		ラベルの選定と添付	20				
		具体例	20				
18	事故・緊急時対応	輸送途中の事故、荷崩れ、破損、紛失、書類不備などの対応と責任	30	10	10	5	
		梱包中の事故	10				●
		到着物の破損、開封時の事故への対応	20				
19	演習	危険物の分類演習	45	30	—	—	
		梱包演習：包装容器の選定、包装、マーキング、ラベル添付、オーバーパック	90				
		文書作成演習：添付文書、届け出、危険物申告書	90				
20	終了試験	実例について全行程と必要事項について解答し、包装物を作る。	45	15 (前半部分のみ試験)	10 (前半部分のみ試験)	—	●
	合計時間		1210 (約3日)	340 (約6時間)	175 (約3時間)	240 (約4時間)	

注１：但し、法規、梱包方法、輸送方法に大きな変更が生じた場合には、随時追加講習を必要とする。また、安全な輸送は基礎原理の理解に基づくことから、継続講習は最低各年での実施が望ましい。仮に人員数が多く全員への講習が難しいときにも、国際輸送のルールの改訂に合わせて、最低3年に一度は全員が再受講できるような工夫が必要である。オンライン試験などを毎年実施し、その結果により、補充の講習を検討する方法も考えられる。

注２：毒素は、分類、包装等級の判定基準、混合毒物、農薬について約2時間の追加が必要。

Ⅱ．研究成果の刊行に関する一覧表

別紙４

研究成果の刊行に関する一覧表

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
安藤秀二、佐多徹太郎、重松美加	感染性物質の輸送規則に関するガイダンス 2013-2014（WHO出版物翻訳）	国立感染症研究所（翻訳監修）	感染性物質の輸送規則に関するガイダンス 2013-2014	国立感染症研究所		平成25年	1-42
重松美加	６　身体的健康	吉川肇子、杉浦淳吉、西田公昭	大学生のリスク・マネジメント	ナカニシヤ出版	東京	平成25年	81-104
安藤秀二、佐多徹太郎、重松美加、杉山和良、中嶋建介	感染性物質の輸送規則に関するガイダンス 2011-2012（WHO出版物翻訳）	国立感染症研究所（翻訳監修）	感染性物質の輸送規則に関するガイダンス 2011-2012	国立感染症研究所		平成24年	1-42
安藤秀二	第25章 リケッチア	平松啓一監修、中込治、神谷茂編集	標準微生物学	医学書院	東京	平成24年	
杉山和良	実験室におけるバイオハザード	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	39-45
杉山和良	リスク評価	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	50-54
杉山和良	病原微生物のリスク分類	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	54-58
杉山和良	組織管理と健康管理	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	73-85
安藤秀二	病原体等の保存・保管と輸送	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	112-121
伊木繁雄	バイオセーフティレベル（BSL）と実験	バイオメディカルサイエンス研究会	バイオセーフティの原理と実際	みみずく舎	東京	平成23年	58-67

重松美加 （国名のみ表記）	（全体を共著）		CEN Workshop Agreement (CWA) 15793: 2011 – Laboratory biorisk manage-ment	European Committee for Standardi-zation		2011	
重松美加 （国名のみ表記）	（全体を共著）		CEN Workshop Agreement (CWA) 16335: 2011 – Biosafety professional competence	European Committee for Standardi-zation		2011	

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
Shimizu H [分担執筆]	Country Progress Report on Maintaining Polio-free Status, Japan	WHO annual report, 2011-2013			2013
Hovi T, Paananen A, Blomqvist S, Savolainen-Kopra C, Al-Hello H, Smura T, Shimizu H, Nadova K, Sobotova Z, Gavrilin E, Roivainen M	Characteristics of an Environmentally Monitored Prolonged Type 2 Vaccine Derived Poliovirus Shedding Episode that Stopped without Intervention	PLoS One	8(7)	e66849	2013

Burns CC, Shaw J, Jorba J, Bukbuk D, Adu F, Gumede N, Pate MA, Abanida EA, Gasasira A, Iber J, Chen Q, Vincent A, Chenoweth P, Henderson E, Wannemuehler K, Naeem A, Umami RN, Nishimura Y, Shimizu H, Baba M, Adeniji A, Williams AJ, Kilpatrick DR, Oberste MS, Wassilak SG, Tomori O, Pallansch MA Kew O	Multiple Independent Emergences of Type 2 Vaccine-Derived Polioviruses during a Large Outbreak in northern Nigeria	J Virol	87	4907-4922	2013
杉山和良	研究室・検査室での活動とWHO「実験室バイオセーフティ指針」	バムサジャーナル	第25巻 第4号	3-7	平成25年
伊木繁雄	バイオセーフティとバイオセキュリティ	獣医畜産新報	第66巻 第4号	249-251	平成25年
杉山和良	臨床分離株の取り扱いと菌株保存	皮膚病診療	第35巻第11号	1010-1015	平成25年
清水博之	102. わが国のポリオ流行とポリオワクチンの歴史	小児内科	増刊号「予防接種Q&A 改訂第３版」		平成25年
清水博之	103. わが国と世界のポリオの現状と問題点	小児内科	増刊号「予防接種Q&A 改訂第３版」		平成25年
清水博之	106. 生ワクチンの存続	小児内科	増刊号「予防接種Q&A 改訂第３版」		平成25年
清水博之	不活化ポリオワクチンの現状	ファルマシア	49	211-216	平成25年
清水博之	不活化ポリオワクチン導入の現状と今後の課題	Bio Clinica	28	19-24	平成25年

清水博之	ポリオ流行のリスクとポリオワクチン	モダンメディア	54	85-92	平成 25 年
Iki S, Horiguchi I, Shigematsu M, Sata T, Sugiyama K	Qualitative analysis by focus group interviews of the image and acceptability among housewives of pathogen transport	Jpn. J. Infect. Dis.	65	403-409	2012
伊木繁雄	バイオセーフティの原理と考え方	バムサジャーナル	第24巻 第3号	19-27	平成24年
伊木繁雄	我が国における病原体輸送の課題と対策	モダンメディア	第58巻	329-336	平成24年
清水博之	ポリオウイルスの病原体管理	JBSA Newsletter	2	11-14	平成 24 年
清水博之	ポリオの病態とポリオワクチン	小児科臨床	65	2281-2287	平成 24 年
清水博之	不活化ポリオワクチンの導入と今後の課題	日本医事新報	4613	70-75	平成 24 年
清水博之	感染症担当者が知っておきたい不活化ポリオワクチンの最新状況	INFECTION CONTROL	21	1	平成 24 年
清水博之	不活化ポリオワクチン(IPV)と経口生ポリオワクチン(OPV)	小児内科	44	1234-1237	平成 24 年
清水博之	ポリオウイルスワクチン	ウイルス	62	57-66	平成 24 年
清水博之	不活化ポリオワクチン導入の現状と移行期の問題点	愛知県小児科医会会報	95	14-17	平成 24 年
清水博之	世界ポリオ根絶計画とポリオの疫学	バムサジャーナル	24	32-36	平成 24 年
染谷雄一、清水博之	ポリオウイルスワクチンの品質管理	臨床とウイルス	40	306-313	平成 24 年
Arita M, Iwai M, Wakita T, Shimizu H	Development of a poliovirus neutralizing test with poliovirus pseudovirus for measurement of neutralizing antibody titer in human serum	Clin Vaccine Immunol	18	1889-1894	平成23年
Arita M, Masujima S, Wakita T, Shimizu H	Particle agglutination method for poliovirus identification	Journal of Visualized Experiments.	50	ID=2824, doi: 10.3791/2824	2011

Ⅲ. 研究成果の刊行物・別刷

感染性物質の輸送規則に関するガイダンス
2013-2014 版

2013 年 1 月 1 日より適用

日本語版 翻訳・監修　　国立感染症研究所

目次

訳注：以下に本文中に用いている輸送関係機関および規則の略語を示す。

UNCETDG： United Nations Committee of Experts the Transport of Dangerous Goods
（国連危険物輸送専門家委員会）

ICAO： International Civil Aviation Organization
（国際民間航空機関）

IATA： International Air Transport Association
（国際航空運送協会）

DGR： Dangerous Goods Regulations
（危険物規則書）

RID： International Carriage of Dangerous Goods by Rail
（欧州 危険物国際鉄道輸送規則）

ADR： European Agreement concerning the International Carriage of Dangerous Goods by Road
（欧州危険物国際道路輸送協定）

SOLAS： International Convention for the Safety of Life at Sea
（国際海上人命安全条約）

IMO： International Maritime Organization
（国際海事機関）

IMDG Code： International Maritime Dangerous Goods Code
（国際海上危険物規程）

UPU： Universal Postal Union
（万国郵便連合）

序文

感染性物質は多種多様な理由から国内および国際的に輸送される。輸送する物資を損なわず、目的地への適時の到着を促すためにも、荷送人（荷物の送り主）には、輸送物の梱包や輸送条件が法的要件を遵守していることを確認する責任がある。

郵便、航空会社、その他の輸送業に携わる人々は、容器の破損、漏れ、または不適切な梱包により洩れ出した感染性微生物への曝露によって、感染する可能性を懸念している。したがって、感染性物質の輸送容器は、輸送中に破損する可能性を最小限に留めるように設計されていなければならない。さらにまた、確実に検体を無傷に保ち、そして時宜にかなった的確な処理を行えるような容器でなければならない。

以下のガイドラインには、輸送のための感染性物質の分類に関する情報を提供し、その安全な包装を確実なものとする。本書では、これら感染性物質の安全で速やかな輸送を図るために、関係者（発送人、輸送業者、受取人）間で業務遂行上の協力関係を築くことの重要性が強調されている。

❖ このガイドラインは、国内輸送および国際輸送において、あらゆる輸送手段による感染性物質と患者検体の輸送に関する、適切な国際規則を守ることを促すための実践的な要領を示す。これには 2013 年 1 月 1 日から適用される変更も含まれている。本書は 2011 年に世界保健機関（WHO）から発行されたガイドライン（WHO/CDS/IHR/2010.8）に代わるものであるが、各国の輸送規則や国際的な輸送規則の代用となるものではない。

今日では、無数の感染性物質の試料を送る必要があり、実際に世界中で毎日発送されている。疾患の検査、臨床試験、サーベイランス研究、ドーピング検査、日常的な分析など、様々な理由からヒトおよび動物の検体が採取され、発送されている。定期的に発送している人や、時折発送する人によって、毎日のように感染性物質が発送される。これらの中には、製薬業界、医療機関、診断や研究のための実験施設、医療従事者、そして個々の患者も含まれている。

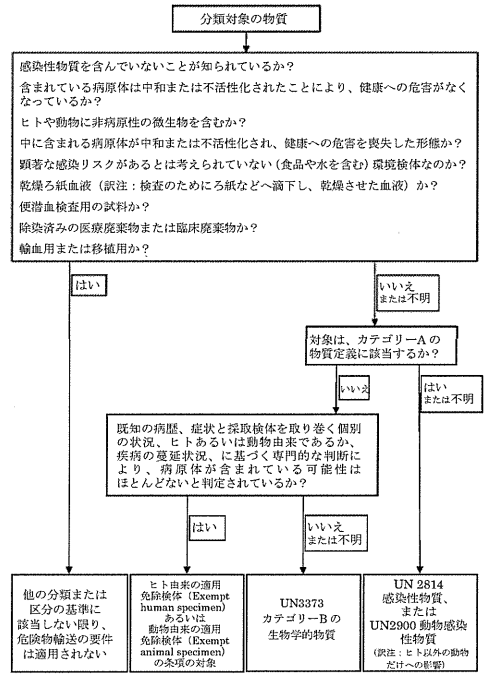
世界の公衆衛生を維持するには、ヒトや動物の検体が、採取された場所から分析される場所へと、安全に、適時に効率よく、合法的に輸送されなくてはならない。輸送に係る人たちを感染の

別添５　感染性物質の輸送に関わる危険物のリスト

								旅客機および貨物にて輸送				貨物機専用としての輸送	
								少量危険物					
正式輸送品名目	国連番号	分類または区分	副次危険性	危険性ラベル	政府例外規定 (States variation)	特別規定 (Special provisions)	包装等級	包装基準	1包装当たりの最大正味量	包装基準	1包装当たりの最大正味量	包装基準	1包装当たりの最大正味量
1	2	3	4	5	6	7	8	9	10	11	12	13	14
航空輸送規制を受ける液体類 (Aviation regulated liquid,n.o.s*)	3334	9		その他の有害物質		A27		Y964	30 kgG	964	制限なし	964	制限なし
カテゴリーBの生物学的物質 (Biological substance, category B)	3373	6.2		なし	GB 5					650 を参照		650 を参照	
(生物) 医療廃棄物 (Bio)medical waste	3291	6.2		感染性物質		A117	II			622	制限なし	622	制限なし
固形二酸化炭素、ドライアイス (Carbon dioxide, solid dry ice)	1845	9		その他の有害物質		A48 A151				954	200 kg	954	200 kg
非特定の臨床廃棄物 (Clinical waste, unspecified,n.o.s.)	3291	6.2		感染性物質		A117	II			622	制限なし	622	制限なし
エタノール エタノール溶液 エチルアルコール エチルアルコール溶液	1170	3		引火性液体		A3 A58	II	Y341	1 L	353	5 L	364	60 L
						A180	III	Y344	10 L	355	60 L	366	220 L
25%以上のホルムアルデヒドを含むホルムアルデヒド溶液	2209	8		腐食性物質	US 4		III	Y841	1 L	852	5 L	856	60 L
引火性ホルムアルデヒド溶液	1198	3	8	引火性液体&腐食性物質		A180	III	Y342	1 L	354	5 L	365	60 L
遺伝子組換え微生物 遺伝子組換え生物	3245	9		その他の有害物質		A47				959	制限なし	959	制限なし
動物感染性物質	2900	6.2		感染性物質	AU 3 CA 5 CA 10 GB 5 VU 2	A81 A140				620	50 ml または 50 g	620	4 L または 4 kg
感染性物質	2814	6.2		感染性物質	AU 3 CA 5 CA 11 GB 5 VU2	A81 A140				620	50 ml または 50 g	620	4 L または 4 kg
医療廃棄物 (Medical waste, n.o.s)	3291	6.2		感染性物質		A117	II			622	制限なし	622	制限なし
メタノール	1230	3	6.1	引火性液体		A164 A113	II	Y341	1 L	352	1 L	364	60 L
深冷液化窒素	1977	2.2		非引火性ガス		A152				202	50 kg	202	500 kg
規制医療廃棄物 (Regulated medical waste, n.o.s.)	3291	6.2		感染性物質		A117	II			622	制限なし	622	制限なし

*訳注：“・・, n.o.s.” とは、not otherwise specified の略で、「不特定のあるいは一般的総称としての」という意味である。

別添７　感染性物質と患者検体の分類に関するフローチャート



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Original Article

Qualitative Analysis of the Perception and Acceptability of Pathogen Transport among Housewives Using Focus Group Interviews

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SUMMARY: We conducted focus group interviews to understand how residents of Japan feel about the transport of pathogens. Twelve randomly selected housewives, who had no special knowledge regarding the topic before the interview, expressed their opinions in 2 separate meetings regarding pathogen transport. The results of the interviews were analyzed by the KJ method. The analysis found that although the transport of pathogens is universally recognized to be necessary, there is not clear consensus on the exact methods of transport, the positive and/or negative value of such information, and how clearly and/or uniquely to label containers, packages, compartments, vehicles, and conditions used for such transportation. Further studies to improve the skills of both the providers and receivers of such information (a technique of risk communication) are necessary.

INTRODUCTION

Pathogens should be studied to prevent and/or minimize the effect of disease outbreaks, and this requires the isolation of these pathogens to confirm or disprove doctors' diagnoses. Local hospitals, however, often do not have the facilities that are required for such testing. Therefore, it is often necessary to transport pathogens to facilities such as the National Institute of Infectious Diseases (NIID), universities, research institutes, and vaccine manufacturers that have the technology necessary for the identification and treatment of the pathogens.

When transporting pathogens or clinical samples, hermetically sealed containers are used to ensure biosafety during transport and to prevent the contamination of the contents by other microbes. The World Health Organization publishes guidance for the transport of pathogens (1), which we follow for domestic transport. The International Air Transport Association Dangerous Goods Regulations also allows the international transport of pathogens by air, as long as dedicated containers are used and regulations are observed (2). However, the transport of pathogens and clinical samples is provided by very few courier services in Japan and there is no clear commitment that these providers will continue their services because of the negative image attached to the term "pathogen." It is urgent that a reliable pathogen transport system be established because of the threat of pandemics caused by new infectious diseases such as severe acute respiratory syndrome or influenza.

Whether a courier service transports pathogens or not depends on the policy of the company. Moreover, this policy is influenced by public opinion. However, to our knowledge, there have been no reports of research or structured surveys concerning how the public views pathogen transport.

The purpose of this research is to understand the views of the public regarding the transport of pathogens and to help in improving these views in the future. Our research used focus group interviews (FGI) to qualitatively survey and analyze the public's understandings of pathogen transport. FGI has been a very popular research tool for studying marketing or business trends for more than 30 years. The FGI is an informal discussion undertaken by a group of 6–12 individuals who are selected for a specified topic in relation to a specific situation; it helps in inducing emotions and revealing the attitudes and values of the interviewees (3–5). The FGI can explain the behavior and motivation of the group as well as improve or change their opinion regarding a specified topic (6).

MATERIALS AND METHODS

We adopted the FGI method for this qualitative survey. Interviews were carried out in Tokyo under the theme "transport of clinical samples as a part of the countermeasures against infectious diseases."

The interviewees comprised housewives in their 30s–50s, who were registered as monitors for a research company and lived in Tokyo or its surrounding prefectures. We recruited 12 housewives, and divided them into 2 groups consisting of 6 members each. Attributes of the interviewees are listed in Table 1.

The interviews were conducted in line with the interview guidelines that had been prepared in advance. First, a short explanation regarding pathogen transport

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Table 1. Attributes of interviewees enrolled in the group interviews

Group A			Group B		
Age	Prefecture	No. of speaking[1)]	Age	Prefecture	No. of speaking[1)]
37	Tokyo	13 (4)	32	Kanagawa	3 (1)
39	Tokyo	33 (7)	33	Tokyo	65 (14)
42	Kanagawa	77 (14)	43	Kanagawa	60 (2)
44	Tokyo	18 (2)	45	Tokyo	44 (2)
52	Tokyo	14 (6)	51	Tokyo	84 (17)
59	Saitama	47 (12)	54	Kanagawa	4 (2)

[1)]: The parenthesis indicate the number of questions.
The interviewees are comprised from housewives in their 30s to 50s, who were registered as a monitor of a research company and lives in Tokyo and surrounding prefectures. They spoke each other without reserve, and did not speak specific members who have special knowledge. The number of speaking includes the opinions, the ideas, and the questions.

was provided by a panel of biosafety experts who responded to questions as the housewives had no special knowledge of the topic. This provided the minimum necessary information before the discussion. Then, they were interviewed as a group. The 2 main questions in the interview were "Did you know that pathogens must be transported to multiple institutions for repeated testing for pathogen surveillance as a part of infectious disease prevention?" and "What do you think of the present pathogen transport methods?" Then, the interviewees were given the opportunity to handle real pathogen transport containers and to hear explanations on pathogens and clinical sample packaging and specifications as set by the United Nations. The interviewing time was set at approximately 1.5 h for each group.

We analyzed the results by the KJ method (7,8). Digitally recorded interviews were transcribed word for word, and each transcription was itemized using 1 statement for 1 item. We then reconfirmed the content through comparison with the recorded interviews. After removing the comments by the facilitator and questions from participants, the remaining remarks were extracted, cut into strips concerning each item, and labeled. Subsequently, the labeled strips were grouped according to similarity of concepts as indicated by the phrases, and a schematic diagram was formulated for analysis. The analysis was performed with extreme care to exclude any subjective prejudices or assumptions on the part of the analysts. These operations were performed by a collaboration of researchers of infectious disease and social scientists.

RESULTS

In the analysis of FGI by the KJ method, 49 of the extracted items were chosen. The content of each item contained comments of the interviewees regarding present pathogen transport, the measures used to continue pathogen transport smoothly, and the reasons why pathogen transport is needed. Consequently, we classified these items into 3 categories as "Present status," "Future measures," and "Necessity of pathogen transport."

As shown in Table 2A, 6 extracted items were classified in the category "Present status." Two items indicated that pathogen transport was not known to interviewees and the other 4 items indicated their perception regarding such transport. Accordingly, we divided the category "Present status" into 2 subcategories as "Lack of information about pathogen transport" and "The matter of image of pathogens."

Forty-one of the extracted items revealed ways to continue pathogen transport smoothly in the future, and they were classified into the category "Future measures." This category was divided into 2 subcategories as "To load together or separately" and "To disclose or not to disclose information" based on the substance of the extracted items (Table 2B).

Some extracted items in the category "Future measures" were related to each other, and we connected these items by arrows as indicated in Fig. 1.

The former subcategory includes 2 middle categories "Adopt mixed loading" and "Do not adopt mixed loading" as shown in Table 2B. Figure 1A shows the relationship of extracted items in the former middle category. The focus of this middle category is the extracted item "I am not concerned about mixed loading if appropriate measures are taken," and the other 3 items "Place a dedicated container in the vehicle," "Transport by specially trained operators only," and "Select reliable carriers" are the requirements for grouping items together. An extracted item "Place a dedicated container in the vehicle" is also related to another item "Providing a dedicated container costly." Because these items conflict with each other, the arrow is drawn by a dotted line. Although there were 4 extracted items revealing the ideas on transport method except for mixed loading in the latter middle category, 1 extracted item "Transport by motorbike messengers" was not connected to any item and the other 3 extracted items were connected to items of opposed relationship (Fig. 1B).

The latter subcategory "To disclose or not to disclose information" was divided into 3 middle categories "Disclose information," "Do not disclose information," and "Not sure about disclosing information" as shown in Table 2B. Only the middle category "Disclose information" had 2 bottom categories "Disclose that pathogens are being transported" and "Appeal proactively." This is because the extracted items in this middle category can be divided into 2 more categories of disclosing information of being transported and of how to appeal to the public. As shown in Fig. 1C, there are 2 extracted items indicating the methods of disclosure "Attach a visual symbol to the vehicle" and "Sound a siren" and an extracted item "It is more reassuring to know that pathogens are being transported" is connected to these items in a former bottom category. This is because the latter item explains the reasons for the other 2 items. Furthermore, an extracted item "Attach a visual symbol to the vehicle" was referred to the other 4 items indicating the assumed results for this measure. Although an extracted item of these 4 items conflict with this measure, the other 3 items received the contents of this item affirmatively.

The bottom category "Appeal proactively" is the category that included the most extracted items. These items could be divided into clusters by their make-up, and we supported this bottom category by adding 3

Table 2. Schematic diagram of each category of the focus group interviews using the KJ method

A

Category	Subcategory	Extracted item
Present status	Lack of information about pathogen transport	I was surprised to hear the explanation. I did not know that it contributes to our life.
	The matter of image of pathogens	I feel reassured when information on containers is provided. I am concerned about mixed loading. It is a matter of image not fact that mixed loading is actually unfavorable. It can never be completely safe because humans are involved.

B

Category	Subcategory	Middle category	Bottom category	Extracted item
Future measures	To load together or separately	Adopt mixed loading		See Fig. 1A
		Do not adopt mixed loading		See Fig. 1B
	To disclose or not to disclose information	Disclose information	Disclose that pathogens are being transported	See Fig. 1C
			Appeal proactively	See Fig. 1D
		Do not disclose information		It is also misleading to have only some knowledge. There are people who would abuse such information.
		Not sure about disclosing information		I do not think all people are well-intentioned. People would feel more at ease without knowledge about pathogen transport, but it could lead to a panic in the case of an emergency.
				Conduct an opinion survey.

C

Category	Extracted item
Necessity of pathogen transport	Pathogen transport is definitely required. Pathogen transport must not be discontinued.

The diagram of the KJ method process explains stepwise approach from grouping labeled extracted items of interviews with the contents of the given phrase to the bottom categories and then to the subcategories with the addition of relevant item slips, and finally to three large categories of "Present status," "Future measure," and "Necessity of pathogen transport."
(A) The category "Present status" includes 2 contents. One is that the participants did not know about pathogen transport. Another is a matter of image of pathogens that land courier service offered by only a limited number of door-to-door service providers. These indicate the participants realized the necessity of pathogen transport.
(B) The category "Future measures" includes the largest number of extracted items and is divided into 2 subcategories and 1 extracted item. Moreover, these subcategories divided into 2 or 3 middle categories. Even though the antagonistic middle categories each other, all of middle categories are constructed from the extracted items on the assumption that pathogen transport must be continued.
(C) The extracted items included in the category "Necessity of pathogen transport" are the most important contents in the focus group interviews (FGI). This category indicates the emotions and value of the participants for pathogen transport that the purpose of the FGI.

minimum clusters "Who," "What," and "How" as shown in Fig. 1D. In the minimum cluster "Who," 2 extracted items "Carriers' appeal" and "National and/or local governments' appeal" were connected to the same extracted item "If public relations activity is successful, other carriers may follow suit" finally. In the other 2 minimum clusters "What" and "How," 2–4 extracted items were connected to 1 extracted item, respectively.

Incidentally, 3 middle categories "Disclose information," "Do not disclose information," and "Not sure about disclosing information," were grouped into the category "Future measures," which was connected to the middle category "Adopt mixed loading," because these 3 middle categories consisted of the opinions on the assumption of mixed loading. Although the directions of these middle categories are different, the extracted item "Conduct an opinion survey" is thought to be the measuring method that decides the direction. Consequently, these 3 middle categories are connected

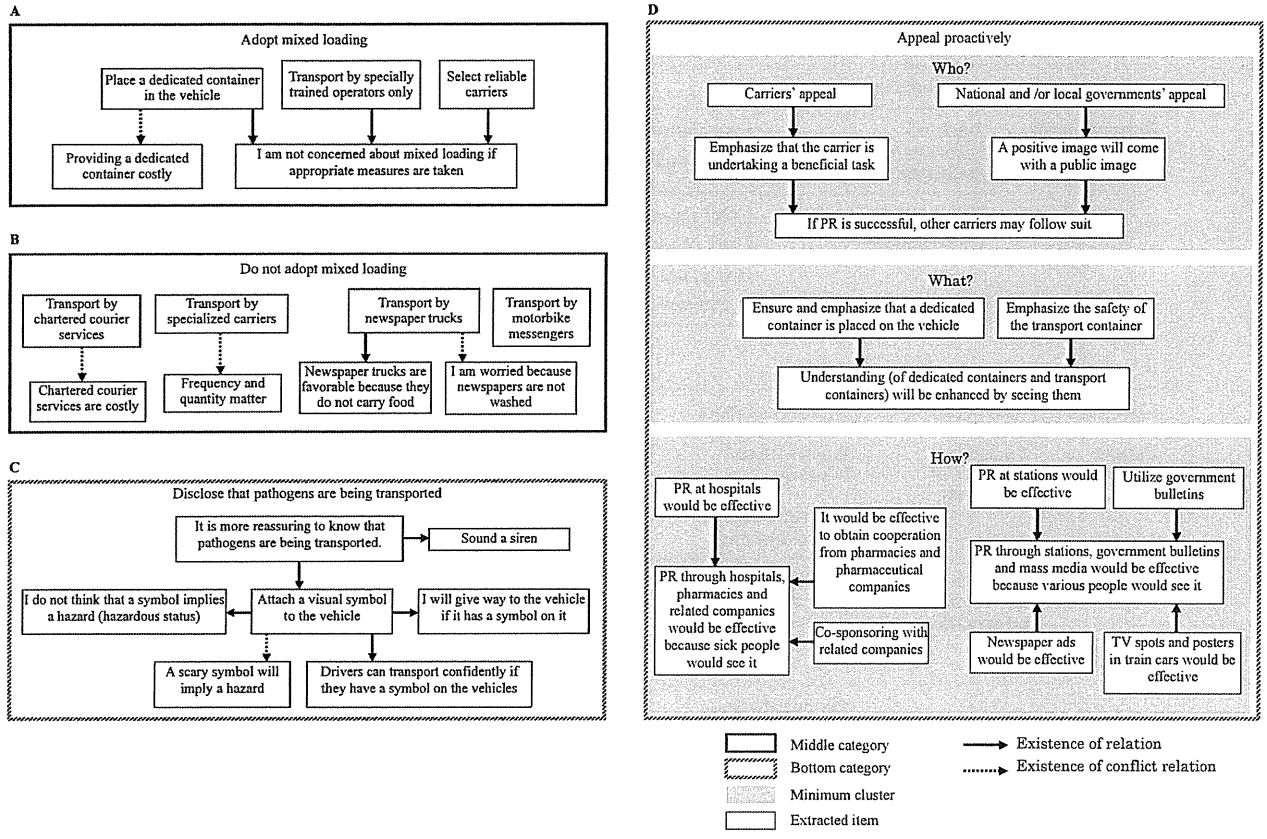

Fig. 1. Relations of extracted items in subcategories "To load together or separately" and "To disclose or not to disclose information" of the schematic diagram of focus group interviews using the KJ method. Categorized items were boxed in to squares of several sizes and the relations of the categories are shown by arrows. (A) Three extracted items of the ideas of measuring methods about mixed loading connected to a common extracted item. Each item indicates affirmation of mixed loading, although we can appreciate appropriate measures are needed. (B) Three extracted items of the other measuring methods replacing mixed loading connected to different 3 items indicate denying of these ideas, respectively. (C) An extracted item of the idea of disclosing that pathogens are being transported connected to 4 extracted items indicate participants' emotions. Three of these items affirm to attach a visual symbol to the vehicle. (D) This bottom category explains the methods of appeal about pathogen transport and it is divided into 3 minimum clusters according to the content. Two to 4 extracted items of appeal method connect to 1 item expressing the reason or the predictable result in each minimum cluster.

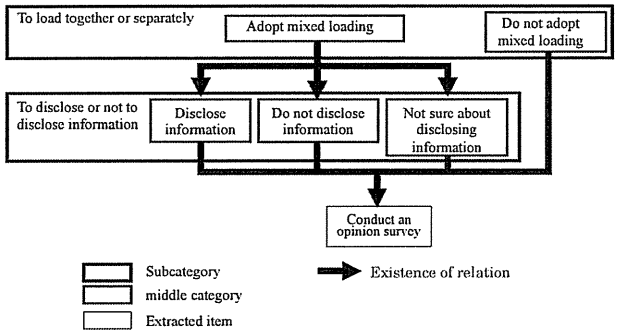

Fig. 2. Relations of each subcategories, middle categories or extracted item in category "Future measures" of the schematic diagram of focus group interviews using the KJ method. A subcategory "Adopt mixed loading" connects to the other 3 subcategories and 1 extracted item except for the subcategory "Do not adopt mixed loading" in the category "Future measures". The relation indicates that the existence of some measuring methods about mixed loading information is appeared.

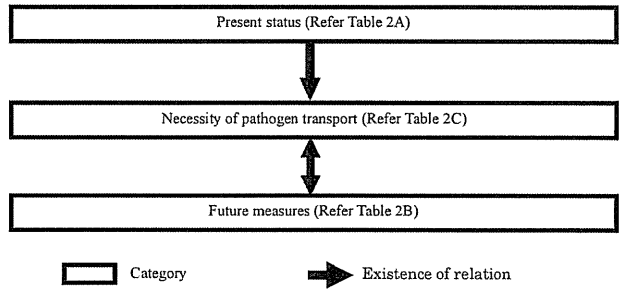

Fig. 3. Relations of each categories of the schematic diagram of focus group interviews using the KJ method. This figure shows the conclusion of the analysis. The categories "Present status" and "Future measures" connect to a category "Necessity of pathogen transport." The connection of latter 2 categories is mutual each other.

to this extracted item as shown in Fig. 2.

In the results, 40 of the extracted items in the category "Future measures" could be applied to each of 2 subcategories. Only 1 extracted item "Conduct an opinion survey" did not belong to a group because the meaning of this item discorded with any subcategories and all contents in these 2 subcategories connected to this item finally (Table 2B and Fig. 2).

Two extracted items shown in Table 2C have a common meaning (i.e., why pathogen transport is needed). Accordingly, these items are classified into a new cate-

gory "Necessity of pathogen transport" without a subcategory or a bottom category.

There is no extracted item denying pathogen transport. Furthermore, all items in both categories of "Present status" and "Future measures" are connected to the category "Necessity of pathogen transport."

This is because these 2 categories are based on continuing pathogen transport without exceptions. Moreover, the category "Necessity of pathogen transport" is influenced by the category "Future measures," for example, "Pathogen transport is necessary and future measures are also necessary." Consequently, we drew a 2 directional arrow between these categories. These results were indicated in Fig. 3.

DISCUSSION

Method of survey: The degree of public understanding of pathogen transport in Japan is unclear; hence, we decided to adopt a qualitative research method to elucidate the baseline level of public perception. There are various methods for qualitative research, such as the participative observation, individual interview, group interview, life history analysis, and the FGI (9–12). The FGI is defined as "informal discussion undertaken by some individuals, who are selected under a specified topic in relation to a specific situation" (6). The FGI is performed "to evaluate the reasons behind interviewees' perception, their attitudes and emotions, and perceived solutions" (3). During the FGI, participants may be stimulated by each other's opinions and further develop their discussion into themes that had not been predicted by the researchers, which is beneficial in identifying grounds for new hypothesis and findings (13). From this perspective, it was considered appropriate that various emotions and views of individuals should be extracted.

Interviewees: When the FGI is carried out, 1 or 2 focus groups comprising of 6–12 individuals with common backgrounds are sufficient for investigative research (6). However if 1 or more specialists are included in the group, it becomes difficult for other members to give their opinions. Moreover, the others cannot speak freely if the specialist dominates (6).

Two groups of 6 housewives were selected as interviewees for this survey, assuming an absence of knowledge on the present status of pathogen transport and related experience for this survey. We prepared and used dedicated interview rooms instead of the NIID building. Accordingly, an intellectual did not speak and all members were allowed to voice their honest opinions in this interview (Table 1).

Method of analysis: The KJ method was invented by Jiro Kawakita. It is in order to systemize the results of heterogeneous brainstorming results by discuss with experts (14). The KJ method is a tool for generating ideas and resolving problems by collecting a variety of information on various facets of the proposed issue and interrelating and classifying the collected information. This method is adopted for analyzing qualitative research in diverse fields (14–18) and is often used for analysis of questionnaire records (14–17). The KJ method is unique because it does not distinguishes the thoughts of individuals from those of the group, both in principle and in practice (7). In this research, this is considered the most effective method to investigate and identify the relationship and overview of how people recognize pathogen transport after the relevant information has been provided. Means are considered to have been taken to prevent prejudice and assumptions by the inclusion of individuals who are not specialized in infectious disease and pathogen transport in the analytical team.

Results of interview extraction analysis: Based on the analysis using the KJ method, the subcategory "Lack of information about pathogen transport" was made (Table 2A). Accordingly, it was confirmed that none of the interviewees had knowledge regarding pathogen transport, and many questions were given by the interviewees, as shown in Table 1.

Because some questions were based on the efficiency of containers for pathogen transport, we provided information on the quality of the containers during the interviews. As a result, an extracted item "I feel reassured when information on containers is provided" was added as seen in Table 2A. This was thought to result in the removal of anxiety about pathogen transport by providing information on the container because "panic can be prevented by providing information" (19). On the other hand, an extracted item "I am concerned about mixed loading" was made in the same subcategory. This is thought to reflect that "no matter how much people are guaranteed safety by specialists, they do not necessarily feel reassured" (20) as shown in an extracted item in Table 2A "It is a matter of image not fact that mixed loading is actually unfavorable." It supposed that these extracted items came from the idea that "recognition of risk by people is grounded on the statistical sensitivity that no matter how low the probability is, as long as the probability is not zero, it signifies 'it does occur' to the involved people" (21) as shown in the extracted items in Table 2A "It can never be completely safe because humans are involved." Therefore, this suggests that the images of pathogen transport among the interviewees include the problem of safety based on scientific grounds.

From these considerations, it is necessary to seek a method to settle these problems, considering that there is a gap between risk assessment based on scientific grounds and the risk recognition of the public.

Three extracted items to solve this problem by avoiding mixed loading were shown in Fig. 1B. These extracted items connect to the different negative extracted items. On the other hand, 3 extracted items concerning measures about the assumptions of mixed loading connect to a common affirmative extracted item (Fig. 1A). These results indicate that the measures compiled by the public are possibly led by the calm consideration and judgment based on the adequate information.

As a concrete example of these measures, 2 bottom categories were made. First, 2 extracted items showing the methods of disclosing how pathogens are being transported "Attach a visual symbol to the vehicle" and "Sound a siren" were picked in the bottom category "Disclose that pathogens are being transported" as shown in Fig. 1C. Next, another bottom category "Appeal proactively" indicates the method of appeal (Fig. 1D). The reason for these proposals is indicated in the