

External Quality Assessment of Transporting Infectious Substances in Canada: A Follow-up StudyShelley M. Tiffin ART, BMLSc², Michael A. Noble MD, FRCPC, CMPT Chair¹¹Clinical Microbiology Proficiency Testing, Dept. Pathology and Laboratory Medicine, UBC, Vancouver, B. C.,²Laboratory Science Program, British Columbia Institute of Technology, Burnaby, B. C.

INTRODUCTION Transporting referral samples for analysis is an increasingly common practice in most medical laboratories. Because transport procedures have a direct impact on total costs, turn-around-time and quality of results, medical laboratories pay close attention to sample transportation. Canadian laboratory reforms have resulted in centralization of services and an overall increase in the number of samples transported for testing.

Laboratories must comply with Transport Canada's Transportation of Dangerous Goods (TDG) Regulations, which are in place to reduce potential health risks to the public. The regulations describe two transport packages called Type 1A and Type 1B. The 1A package is a standardized high containment package, while the 1B package is less stringent in design and labeling specifications^{1,2}. The choice to use 1A or 1B is in part dependent on the risk characterization of known infectious contents. Whether the package travels by air or ground and whether the sample is a culture or specimen may also influence the packaging decision. An alternate package option allows the sender greater choice in packaging but less protection from legal action should an accident occur^{3,4}. Packaging compliance of medical laboratory samples in transit is not well documented, indeed the only published studies were our original study published in 1998⁴ and one by Garner et al, now 15 years old⁵.

Our previous study found that while laboratory sample packaging in Canada was safe, packaging compliance was an issue. Since then, Transport Canada has fully implemented the Clear Language Version of the TDG Regulations. The Canadian packaging standard was also modified as of 1999.

Recent world events, commonly referred to as "the anthrax scare," may have influenced current packaging compliance. Confounding influences on transportation of infectious substances include continual laboratory reform, and increased rates of retirements and staff turn-over leading to loss of trained personnel⁶.

With these influencing factors in mind, this study seeks to gain a broad picture of practice of today's transportation of laboratory samples.

METHOD As most transported samples are for initial diagnostic testing or to confirm the presence of common infectious substances, we conducted an anonymous external quality assessment to determine the degree of compliance by clinical laboratories for the packaging and transporting of the common bacterium *Escherichia coli*, and human serum known to not contain HIV. The current method is consistent with the 1998 study for ease of comparison.

Phase 1 With the support and cooperation of the British Columbia Centre for Disease Control (BCCDC), routine sample packages arriving daily were examined. BCCDC is a provincial reference laboratory receiving human, animal, food and water samples from health units, laboratories, and environmental centres. Food and water samples were not included in this study. The packages were observed over a period of two weeks. Each package was described and recorded for outer package structure and integrity, safety marks present including shipping name, UN number, and package type, inner and secondary package water-tightness, and presence of absorbent material.

Phase 2 Canadian laboratories participating in the Clinical Microbiology Proficiency Testing (CMPT) clinical bacteriology programme were contacted for their voluntary participation in this study. CMPT laboratories are located in all provinces and territories other than Ontario and Quebec.

An information letter was sent to all laboratories assuring them of anonymity, followed by a written request to participate. Participants were randomly selected to submit either a live culture of *Escherichia coli* or serum sample for serology testing. Serum for HIV and hepatitis B virus were specifically excluded. All laboratories were sent another request after two weeks had passed in order to maximize the participation. Satellite laboratories that would normally forward all samples to another laboratory for final packaging were excluded from phase 2, but not phase 3.

Phase 3 A questionnaire was mailed out to each participant, requesting demographics, and details about their TDG training, certification, and resources. The questionnaire also used qualitative, open-ended questions to gather perceptions, and understandings.

RESULTS Phase 1 (See Table 1) Four hundred packages transported to BCCDC from hospital laboratories, private laboratories, health units, and clinics were observed. Of these 33 were known to contain HIV or Hepatitis B and were excluded. The 1998 results were based on data collected from 430 packages.

Phase 2 (See Table 1) Of the 173 samples requested from CMPT participants, 53 packages were received and described. Of the 120 laboratories that did not participate, 53 were satellite laboratories that would refer to a single central testing site. Thus, the true participation rate by laboratories that routinely transport materials was 44.2% (53 out of 120). Participation was substantially higher in 1998.

Phase 3 Of the 173 questionnaires requested from CMPT participants, 107 (61.9%) were returned and tabulated. Some respondents chose not to answer all questions. Tables 2 (a) through 2 (i) show the response breakdown per answered question (see page 3). Participation rates were higher in 1998; 171 (92.4%) out of 185 questionnaires requested were received from CMPT participants.

DISCUSSION This study was directed towards those laboratories that package single samples intended to go to a reference laboratory. It is important however to appreciate that over the 6 year interval, there have been major changes to the medical laboratory landscape. There are fewer laboratories with a far greater proportion transporting to a central laboratory. Samples may be transported several times daily, commonly by a facility courier. This study could not measure the packaging of samples involving this type of transport.

This study does indicate that Canadian medical laboratories continue to send microorganisms and serum safely packaged, but not necessarily in complete compliance with requirements. Inner

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packages are consistently watertight, and secure, and outer packages are firm and intact.

Examination of the results of the “not requested packages” indicate that over the interval, significantly more packages were sent within firm outer packages. Less than 5 percent of laboratories transported samples in shipping envelopes in 2004, as compared to almost 25 percent in 1998.

The study does, however, show some weak areas. Although there was substantial improvement between the 1998 study and the current one, too many packages still do not contain absorbent materials between the inner and secondary packaging. When multiple samples are sent in the same container, it is rare for individual tubes to be secured in a way to prevent bumping, and potential cracking. When using non-commercial packaging, they tend to be remiss in package designation.

These results must be put into the context of the questionnaire information. In both the 1998 and the current study, most laboratories employ technologists who have been trained and certified as competent for packaging. Most use in-house personnel to train others.

The results of this study may reflect upon the knowledge and status of adult learning for medical laboratory personnel. Adult learners tend to be goal-oriented, relevancy-oriented and practical, doing best when learning information is applicable to their work and focuses on the aspects most useful to them^{7,8}. The aspects that motivate the adult learner include personal advancement, interest, and external expectations. If these principles are applied to acquiring the information necessary and relevant to packaging requirements for infectious agents, it might suggest that for many adult learners, external markings may seem less relevant and less practical than the requirements for physical structure of the package. If this is a fair interpretation, it suggests that all courses that lead to certification may

need to evaluate how they convey the importance of markings to people working in medical laboratories. Changing behaviors requires application of both positive and negative reinforcement.

The samples and questionnaires were received from all provinces that participate in CMPT programs, and thus can be predicted to generalize packaging throughout Canada. It could be argued that the examination of the not requested packages at the single site may be less reflective of wide-spread packaging practices, the strong similarity in performances between the two parts suggests, that general conclusions can be drawn from both sets.

CONCLUSION This follow-up study on sample transporting practices in Canada demonstrates packaging improvements have been made over the past six years. More laboratories are routinely adding absorbent to the inner packages. Packages are safe, but few routine packages comply with the packaging standard for TC 125 1B packages. Transport Canada accepts an alternate packaging type providing that the consignor understands the onus to prove their package construction meets with the spirit of the regulations. Most packages would fully comply at no additional cost to the consignor, by the addition of a few safety marks applied to the outer package: TC 125 1B and the name of the person who constructed the package. The main reason for non-compliance is differences in interpretation of the TDG regulations. The findings from this study have implications for future policy development at Transport Canada.

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Table 1. Comparison between Phase 1 and Phase 2 packages.

Phase/Year/Number	Phase 1 Not requested packages		Phase 2 Requested packages	
	2004 n = 367	1998 n = 430	2004 n = 53	1998 n = 138
Outer Package a) Intact	367 (100%)	500 (100%)	53 (100%)	138 (100%)
b) Firm	355 (96.7%)	384 (76.8%)	52 (98.1%)	132 (95.7%)
c) Package Designation	85 (23.2%)	61 (12.2%)	25 (47.2%)	50 (36.2%)
d) Name/Symbol	7 (1.9%)	71 (14.2%)	12 (22.6%)	56 (40.6%)
Inner Package a) Watertight primary	367 (100%)	495 (99.0%)	52 (98.1%)	137 (99.3%)
b) Watertight secondary	357 (97.3%)	423 (84.6%)	51 (96.2%)	135 (97.8%)
c) Absorbent	161 (43.7%)	178 (35.6%)	45 (84.9%)	96 (69.6%)
d) Multiple Tubes Secure	rarely	84 (16.8%)	NA	NA
TC Package Types a) 1A	0	7 (1.4%)	4 (7.6%)	12 (8.7%)
b) Close to 1A	0	10 (2.0%)	6 (11.3%)	7 (5.1%)
c) 1B	0	12 (2.4%)	5 (9.4%)	15 (10.9%)
d) Close to 1B	166 (45.2%)	143 (28.6%)	22 (41.5%)	66 (47.8%)
e) Alternate	177 (48.2%)	137 (27.4%)	9 (17.0%)	32 (23.2%)
f) Inconsistent with TDG package types	21 (5.7%)	121 (24.2%)	1 (1.9%)	6 (4.3%)
g) Known to contain HIV or Hepatitis B	33	6	NA	NA

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Table 2 (a). Number of specimens or samples received.

Survey Year	<1000	1001-10,000	10,001-50,000	50,001-100,000	100,001-500,000	>500,000
2004	19	15	27	7	25	17
1998	15	43	33	21	37	14

Table 2 (b). Number of specimens or samples sent.

Survey Year	<100	101-500	501-1000	1001-5000	5001-10,000	>10,000
2004	0	3	5	18	36	43
1998	5	8	7	58	52	36

Table 2 (c). Type of laboratory receiving the majority of specimens or samples.

Survey Year	Central processing	Provincial or another Reference Laboratory	Special Research	Other
2004	29	82	1	2
1998	25	143	0	0

Table 2 (d). Total number of personnel (including technologists and assistants) employed by laboratory.

Survey Year	1-5	6-10	11-25	26-50	51-100	>100
2004	24	14	24	16	10	17
1998	55	28	36	25	15	11

Table 2 (e). Number of specimen packers employed by laboratory.

Survey Year	None	1-5	6-10	>10
2004	2	60	17	28
1998	2	106	21	28

Table 2 (f). Training in transport requirements for Canada was/were done by (all that apply).

	Survey Year	2004	1998
Previously trained in-house packer		42	62
In-house transport specialist		28	44
Private company		28	44
University/community college course		3	8
other		13	33

Table 2 (g) Number of certified packers.

	Survey Year	2004	1998
Not certified		10	26
Not certified, but aware of certification		5	6
Certified		96	144
Recertified		84	144
Frequency of recertification: 1 year		5	7
2 years		30	23
3 years		57	71

Table 2 (h). Packers certification (all that apply).

Survey Year	2004	1998
No formal certification after training	11	14
Certification included in the course	42	72
In-house transport specialist	22	33
Head of the department	25	27
other	4	9

Table 2 (i). TDG resources available in the laboratory (all that apply).

Survey Year	Formal copy of regulations	Notes from training course	Journal articles describing regulations	Other	None available
2004	64	44	5	11	3
1998	104	70	19	28	3