New National Strategies for Hospital Infection Control: A Critical Evaluation

by

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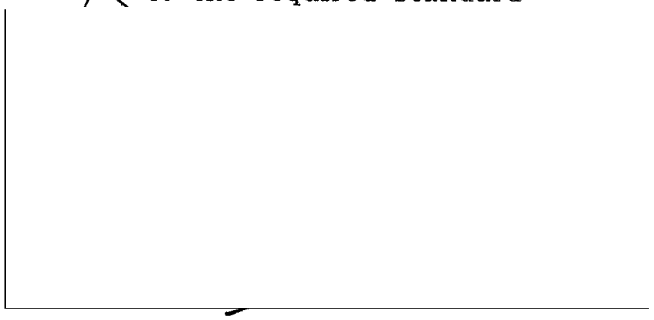

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Abstract:

Isolation of those ill with contagious disease has been a fundamental infection control concept for hundreds of years. However, recent studies suggest that fewer than 50% of health-care workers comply with their hospitals' isolation precaution policies and that efficacy of some of those policies is questionable. In response, two new systems, based upon fundamentally different goals, were promoted. The Centers for Disease Control, prompted by health-care workers' concerns about occupational risk of human immunodeficiency virus (HIV) from a growing number of patients with acquired immunodeficiency disease syndrome (AIDS), issued formal guidelines in 1987. This formed the basis for Universal Precautions (UP), a unifying strategy for precautions with all patients regardless of diagnosis intended to reduce risk to hospital staff members. Also in 1987, one hospital issued guidelines for Body Substance Isolation (BSI), hygienic precautions to be used with all patients based on recognition that colonized body substances are important reservoirs for cross-infection to both patients and staff members. These new strategies have been promoted widely, but there have been no formal assessments to reconcile controversies they raised nor to confirm their effectiveness. Further, necessary assessment tools have not been validated.

This thesis provides new tools and new information to address three vital questions: Have hospitals adopted Universal Precautions or Body Substance Isolation? Do their staff members use the new system of precautions in daily practice? Has reliable use of a new system led to decreased risk of infection?

A confidential mailed survey of all acute-care Canadian hospitals was conducted to measure rates of guideline receipt and adoption. It also obtained information on motivations for and perceived effectiveness of strategies adopted.

A self-selected group of responding hospitals subsequently participated in standardized covert observation of their nurses' infection control practices, then had the observed nurses complete a test examining their knowledge and beliefs. Employee health records were also examined to determine whether needlestick injury rates had changed since adoption of a new infection control strategy.

Most Canadian hospitals adopted and modified new strategies based upon reasonable but unproven extensions of logic to protect health-care workers from HIV. 74% claimed UP (65%) or BSI (9%) but only 5% of 359 claiming UP and 0 of 50 claiming BSI adopted all policies expected. Many hospitals had not received key guideline publications. Guideline source, hospital size, and other variables were significantly associated with receipt. Nurses in 35 hospitals were observed to wear gloves during only ≈60% of procedures in which gloving was expected; rates varied widely among hospitals. Direct examination of sharps disposal containers confirmed compliance with a policy to not recap used needles (taken as recapping rate of ≤25%) in only 47% of 32 hospitals. Paired analysis of needlestick injury rates in 11 hospitals during comparable 90-day periods before versus after implementing UP/BSI showed no significant difference. 489 nurses completing a written test achieved their highest scores and least discordance among questions regarding procedural issues established long before UP/BSI, and lower scores or greater discordance on UP/BSI concepts of philosophy, risk recognition and newer procedures. Positive correlation between knowledge and practice was not evident. UP and BSI now mean different things in different hospitals and have not been effective in harmonizing health-care workers' infection control practices. Carefully standardized assessment methods are needed to guide their evolution to cost-effectiveness.

Table of Contents:

Table of Contents (cont.):

List of Tables:

List of Tables: (cont.)

List of Figures:

Acknowledgement:

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Preface:

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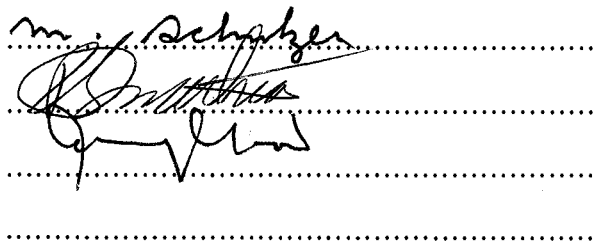
The research concepts, designs and execution were the original work of David Birnbaum; co-authors provided valuable constructive criticism, supervision of directed readings and logistical support.



I. Introduction:

Evolution of New Strategies for Infection Control

Universal Precautions and Body Substance Isolation

Segregation and isolation of those ill with contagious diseases has been a fundamental part of infection control for hundreds of years.[1] Over the last thirty years, a number of monographs and books from the American Public Health Association, American Hospital Association, the Centers for Disease Control (CDC) in Atlanta, and the Laboratory Centre for Disease Control (LCDC) in Ottawa codified specific isolation techniques for use in hospitals based upon this heritage and various extensions of logic. However, relatively few of today's hospital-acquired (nosocomial) infections are contagious or even communicable; most, in fact, are iatrogenic or endogenous (originating from treatments or a patient's own flora). Nevertheless, isolation of patients diagnosed or presumed as infectious rapidly became a mainstay of hospital infection control efforts in spite of an absence of proof that isolation per se reduces the risk of nosocomial infection.[2]

However, in light of persistent absence of proven effectiveness for various infection control measures, some experts began to question their continued use.[3] In response, the CDC initiated a project to review and revise infection control guidelines on the basis of expert consensus on interpretation of clinical or research studies. Notably, the revised CDC Guideline for Isolation Precautions in Hospitals "did not rank the recommendations by the degree to which they have been substantiated by scientific data or the strength of the working group's opinion on their effectiveness or practical value."[4] There were simply too few studies testing the efficacy or effectiveness of recommended measures. These revised guidelines offered hospitals a choice between the traditional

category-specific system and a potentially more user-flexible disease-specific system, and eliminated the traditional Protective Isolation category based upon proof that this time-honored isolation category was ineffective.[5]

In addition to an absence of studies demonstrating efficacy, a growing number of anecdotal reports and formal studies confirmed that compliance by health-care workers with their hospital's policies for isolation precautions frequently was poor.[6] Studies spanning the last ten years all suggest that fewer than 50% of staff complied with their hospitals' isolation precaution policies.[6] Over the last five years, two new systems were proposed based upon fundamentally different goals.

In 1987, CDC consolidated its 1982-1986 recommendations in response to health-care workers' concerns about acquiring human immunodeficiency virus (HIV) infection from patients with acquired immunodeficiency disease syndrome (AIDS).[7] This formed the basis of Universal Precautions (UP) for blood and body-fluids, a unifying strategy for precautions with all patients, regardless of diagnosis, intended to reduce risk to hospital staff members. It deals with blood-borne pathogens only, and is intended as a supplement to the CDC category- or disease-specific isolation system. Also in 1987, one hospital published its own recommendations for hygienic precautions to be used with all patients based on recognition that colonized body substances were important reservoirs for cross-infection to both other patients and staff members.[8] Body Substance Isolation (BSI), developed in response to bacterial cross-infection problems in critical care units, is intended to reduce cross-infection risk with all pathogens, not just blood-borne agents, for all patients and health-care workers. BSI replaces the CDC category- or disease-specific systems.

UP has been promoted widely by the CDC, LCDC, the Association of State

and Territorial Public Health Laboratory Directors and others. BSI was promoted in a videotape distributed to hospital administrators by the American Hospital Association. Endorsements by such influential agencies have not considered these new systems to be equivalent.[9] [10] Subsequent UP guideline revisions[11] have neither reduced this controversy nor received universal acceptance.[12]

Current Knowledge of Hospital Infection Control Practices

Although numerous guidelines have been published, only one descriptive study reports the extent of their receipt and adoption among hospitals in the United States.[13] Patterns of receipt among Canadian hospitals are unknown. Even though at least 80% of all US hospitals had received and adopted CDC guidelines, compliance rates by their staff members with these measures, as noted above, tended to be under 50%. Increasing concerns about the safety of treating AIDS patients in hospital, and increasing doubts about effectiveness of current isolation precautions have brought North American hospitals to a new crossroad.[14]

UP and BSI present new options and new controversies. The extent to which guidelines for these new systems have been reviewed by individual North American hospitals is unknown. Many infection control practitioners (ICP) believe that widespread variations in definitions and practices exist between hospitals, but the uniformity or quality of UP or BSI practice is also undocumented. Anecdotal reports suggest that UP and BSI have not succeeded as unifying strategies to improve compliance, but there have been no formal, multicenter studies. Standardized tools to survey these issues have not been validated. Therefore, expensive new strategies have been promoted widely for nearly five years in the absence of adequate tools or studies to document their implied effectiveness. Anecdotal reports, editorials and letters to editors reveal

controversy, confusion and need for formal evaluation. Further, unproven guidelines may be mandated in accreditation requirements and legislative regulations.[15] This presents an urgent need for applied research in hospital epidemiology to guide administrative and infection control decisions.

Scope and Limitations of Thesis Research

This thesis investigates the effectiveness of UP and BSI as currently adopted in acute-care Canadian hospitals. It validates new survey tools and applies survey sampling and multivariate statistical methods in multi-center research. The approach involves examination of three basic criteria in operational aspects of structure, process, output and outcome (Table 1).

Table 1: EVALUATION CRITERIA

CRITERION	STRUCTURE	PROCESS	OUTPUT	OUTCOME
1. Hospitals have received adequate information to make informed decisions;	All have received CDC/LCDC guideline for UP	All have reviewed CDC/LCDC guideline for UP	All know how UP and BSI differ	UP costs and benefits are identified in each hospital
Hospitals adopted appropriate policies consistent with the system adopted.			Coherent policy-set in place	
2. Hospital staff understand and accept UP or BSI	Hospitals mandate education	Education provided to staff	High staff scores on a test	Staff accept new system
3. Staff adhere to recommended UP or BSI guidelines in their daily work practices;	Hospitals provide gloves, gowns, eye protection and devices to discourage needle recapping	Hospitals monitor compliance and provide performance feed-back	Gloves worn for risk procedures Used needles not recapped	
Use of UP or BSI practices leads to reduced infection risk.				Fewer needlestick injuries after UP or BSI adopted

A number of important difficulties and limitations in this work must be noted. First, as implied earlier, UP and BSI are specific systems according to their respective published documentation, but are likely to mean different things as implemented in different hospitals. This research studies the effectiveness of UP and BSI as unifying strategies among all acute-care Canadian hospitals; it does not address efficacy nor superiority in reducing infection rates by some hospitals as opposed to others. Effectiveness is defined in terms of compliance, not reduction in nosocomial infection rates, for several reasons:

a) Given logistic restraints and the number of confounding variables associated with nosocomial infection risk, it was not feasible to study before-and-after rate differences. Further, it would not have been possible to randomize assignment of infection control systems to perform a true experiment.

b) Adequate microbiologic methods for tracking certain nosocomial pathogens are not available to support such epidemiologic investigation.[16] Part of this thesis research investigates the potential of a novel microbiologic method that may provide such support in the future.

c) As will be discussed later, the driving force motivating adoption of new systems has been a perceived occupational risk of HIV infection, not a desire to reduce risk of nosocomial infection in general.

d) Finally, since it is not yet documented whether UP or BSI have been adopted effectively, it is premature to focus evaluation on a long-term outcome (infection risk reduction) as opposed to short-term measures (improved compliance with reasonable policies).

Second, the representative nature of hospitals included in the study must be viewed with caution. UP or BSI were promoted widely before this research began. Individual hospitals' implementation costs and constraints, perceived needs and potential benefits are likely to vary widely as a function of hospital size and location. Infection control systems cannot be assigned in a randomized or blinded manner, and hospitals cannot be forced to participate. Likelihood, direction and extent of self-selection bias must be considered carefully. The study design must also achieve a balance between sample sizes large enough to generate convincing statistical power yet small enough to be practical.

Third, target events must be selected with regard to reliability of detection and clear importance in testing relevant hypotheses. Since validated survey tools pertinent to this research were not available, an important part of the work involved development and validation of standardized questionnaires and sampling plans. Further, since there is no criterion "gold" standard against which to validate these tools, methods to achieve face, consensual and content validity are emphasized.[17] Since opportunities to obtain repeated measurements in participating hospitals were very limited, other approaches to ensuring reliability are used.[18] [19]

Finally, this work cannot provide a definitive answer as to whether UP or BSI can succeed. Ideally, infection control guidelines evolve as a function of experience and evaluation. The nature of patients, pathogens and procedures in hospitals is dynamic; precautions that have been in force may fall from grace as new information and situations add to our knowledge. Inadequacies of traditional isolation systems became well-recognized. This led to a natural experiment: New isolation systems were promulgated. My work provides new tools and new information to indicate what the new systems have achieved.

The underlying null hypothesis being tested is that UP and BSI have not achieved a uniform standard of effective infection control practice among acute-care hospitals in order to protect health-care workers or their patients. This is examined in several ways through survey of administrative practices, covert observation of workers' practices, formal testing of workers' knowledge and beliefs, self-reported disease-exposure histories and review of employee health incident reports. These data are used to test a number of subordinate hypotheses relating to the elements listed in Table 1. Appendix 1 provides conceptual models for hospital infection control strategies. The following chapters discuss hypotheses, methods and results as well as provide descriptive information about participating hospitals, their policies and their staff.

II. Have Hospitals Accepted New Infection Control Strategies?

Receipt and Adoption of Guidelines by Canadian Hospitals

UP and BSI involve radical departure from long-standing reliance upon isolation precautions, and they imply potentially large cost increases, so it is important that hospital administrators understand their ramifications. UP and BSI both stipulate that all patients are to be treated alike, thus eliminating a need for traditional "biohazard" warning labels to prompt special isolation precautions, but they differ from each other in several important aspects. UP focuses on minimizing risk from blood-borne infections, primarily hepatitis B and HIV, while BSI focuses on minimizing cross-infection risk with all pathogens for both patients and staff. UP applies only to those body fluids associated with hepatitis B or HIV transmission while retaining traditional isolation categories to protect against transmission of other diagnosed or suspected infections. It is, in fact, universal application of the traditional CDC category "Blood/Body Fluid Precautions". BSI applies to all body substances and eliminates all other traditional isolation categories except that for infections spread by an airborne route. It promotes use of protective measures against risks identified on a procedure-specific rather than diagnosis-specific basis. BSI provides a detailed guide to patient placement based on evaluation of hygiene, cooperation, and disease susceptibility of patients and staff. BSI also originally emphasized gloving as an alternative rather than a supplement to handwashing, a view subsequently challenged[20] [21]

Rates of receipt and adoption for infection control guidelines by Canadian hospitals had not been reported previously. Therefore, a first step in examining the effectiveness of UP and BSI as unifying strategies was to determine whether Canadian hospitals received and reviewed appropriate publications that define

these new strategies. Next, beyond simply estimating the proportion of hospitals claiming adoption of UP or BSI, the specific published guideline statements adopted by each hospital were compared with their claimed adoption of UP or BSI to provide a measure of how well these new unifying strategies have harmonized hospital infection control policies. Specific objectives of this administrative survey were to determine, by size groups, hospitals' infection control information resources, current extent of adoption and evaluation of UP or BSI, motivation(s) for adopting a new strategy and knowledge of its cost implications.

Materials and Methods:

Sampling Frame and Questionnaire

Mailing addresses for all Canadian hospitals and size distribution for non-teaching non-specialty hospitals were obtained from the 1988 Canadian Hospital Association (CHA) Directory. Size distributions for teaching and for pediatric hospitals were obtained from the Association of Canadian Teaching Hospitals and the Canadian Association of Paediatric Hospitals membership lists respectively. No data were available regarding the size distribution of 153 specialty hospitals.

In March 1989, advance notice letters explaining the study's purpose and assurance of confidentiality were mailed to the administrator of each acute-care hospital listed in the 1988 CHA membership directory. Questionnaires with cover letter and prepaid return envelope were sent two weeks later. Instructions requested that administrators forward the questionnaire to their infection control program director. A prompt for reply was published in *Canada Diseases Weekly Report* (CDWR) (April 15, 1989). A second prompt, using identical forms, was mailed to non-responders in July, 1989.

The questionnaire, a 3-page self-report form, examines consideration and adoption of specific, major, referenced infection control guidelines and

recommendations. It had been pretested and modified for clarity before use, and was provided in English and French versions (see Appendix 2). A combination of open-text short responses and closed-response "check-off" boxes was used. Specific terms (i.e.: Universal Precautions, Body Substance Isolation) were purposely left undefined to test respondents' knowledge. Questions used to distinguish between UP, BSI and Traditional strategy related to types of body fluids perceived as potentially hazardous; to discontinuation of special "isolation" warning labels for soiled linen, specimens and waste; and to routine glove use and handwashing. The strategy claimed in open-text responses was compared with objective assignment to the UP, BSI or Traditional strategy, based upon the specific combinations of fundamental policy adoptions recorded in response to closed-response questions (Table 2).

TABLE 2: Policy Recommendation Versus Infection Control Strategy

POLICY RECOMMENDATION:	INFECTION CONTROL STRATEGY: UP	BSI	TRADITIONAL
1. No special warning labels on laboratory specimens, waste or soiled-linen bags	+	+	−
2. Gloves as alternative to handwashing	−	+	−
3. Private Room for staphylococcal pneumonia	±	−	±
4. Precautions limited to specific body fluids	+	−	−

The effect of not adopting a policy to train all staff was also examined. Responding and nonresponding hospitals were compared on the basis of size, location (province, setting), and accreditation status to assess the impact of self-selection bias.

Coding of Responses

Completed questionnaires were marked with unique sequential numbers upon receipt, and these data were stored on computer. Databases were maintained

with an interactive program written in FoxBASE+ (version 2.00, Fox Software, Perrysburg, Ohio); FoxDOC (Fox Software, Perrysburg, Ohio) was used in documenting and debugging the code. Replies with any one of the three pages left blank were not used. Missing responses were coded differently from negative responses to questions concerning guideline receipt and review; policy adoption was coded only if an explicit "yes" was indicated ("no" or non-response to the single items, or any indication that adoption was planned for a future date rather than actually achieved by the survey date were coded as not having adopted a guideline).

Grouping by number of beds was assigned using the same ranges as CHA and Statistics Canada: 1-24, 25-49, 50-99, 100-199, 200-299, 300+; and the latter further divided into 300-499 vs 500+ to facilitate comparison with a survey of US hospitals by Celentano and colleagues.[13] Total bed number may include long-term as well as acute beds; to be included in the sample, an institution must provide acute care service(s). Coding of claimed infection control strategy (UP, BSI, "Traditional") and rationale for that choice was based upon responses to open-text questions. If no indication was given of adopting one of the newer strategies, the response was coded as "Traditional". An indication of formal or informal use of UP or BSI was coded as adoption; indication of consideration rather than use per se was coded as "Traditional". Several Ontario hospitals indicated using "Body Substance *Precautions*" rather than "Body Substance *Isolation*"; if their response mentioned retaining category-specific isolation, then they were coded as UP, otherwise as BSI. Some hospitals indicated using both UP and BSI, which is self-contradictory; they appear to be using UP without accepting limitations upon which body fluids are considered "infectious" and were therefore coded as UP. Reasons given by each site for

adopting UP or BSI were coded under one or more of the following motives: 1) Staff Protection, 2) Patient Protection , 3) Compliance with a standard of practice expressed in expert guidelines, and 4) Miscellaneous.

Two survey questions were asked in relation to discouraging a contra-indicated practice of recapping of used needles. One asked whether the respondent felt that at least half of ward staffs still recap used needles regardless of policy. A second asked what type of disposal containers were provided and how needles were transported from the point of use. The extent to which Canadian hospitals have adopted practices and protective equipment that may be effective in reducing needlestick injury risk had not been reported previously. Responses to the second question were coded as either:

a) Bedside containers - "Point of Use" disposal, in container either mounted in each patient room or small special units hand-carried to each patient;

b) Carry unsheathed - used needles to be carried unsheathed by hand or on standard trays (e.g.: K-basin) to disposal containers located in utility areas and/or on medication carts;

c) Recap and carry - used needles recapped, emphasizing no particular technique, and carried by hand or tray to central disposal containers;

d) Safe Recapping - "Thimble Technique" or other one-handed method or provision of special recapping devices for recapping prior to transport;

e) Foam Stabbing Block - Used needle stabbed into small containers of rigid foam for transport (unsheathed) to central disposal containers;

f) Special Trays - Specially designed tray to support used needles safely during transport to central disposal containers;

g) Not Specified - Predominant system not evident from description provided.

If two systems were described in a given hospital, the system most immediate to

the point of use was coded (e.g.: safe recapping and carry unsheathed in K-basins would be coded as safe recapping; foam block and bedside (wall-mounted) containers coded as foam block; etc.).

Statistical Analysis

Point estimates and 95% confidence intervals for guideline receipt rates in the sample received were calculated using poststratification and normal approximation to the binomial distribution. Poststratification is a survey sampling technique that adjusts for the effect of applying stratification in the analysis rather than in the sampling step.[22] Stratification refers to division into subdomains (strata), in this case into hospital size groups by number of beds. The finite population correction factor was applied to variance calculations. Conservative correction for non-response was also applied to confidence intervals by assuming that all nonresponders had received guidelines.[22] This represents an extreme case correction. Approximated confidence intervals were also confirmed by exact probabilities computed with P-EXACT software (Kern International) using the hypergeometric distribution with both the classic and Miettinen's mid-p algorithm.[23] Unlike the classic algorithm, the mid-p algorithm adds only half of the probability associated with an observed distribution to the probabilities associated with all more extreme distributions.

Data extraction and simple descriptive statistics were executed with R&R Relational Report Writer (version 3)(Concentric Data Systems Inc., Westborough Massachusetts). Cross-tabulations of responses were analyzed by log-linear analysis, a multivariate technique that models the expected cell values in a multidimensional contingency table from information regarding a number of categorical variables and their interactions. Log-linear models were fitted and

evaluated by chi-square tests using SAS (version 6.03)(SAS Institute, Cary, North Carolina). SYSTAT (version 4.1) (Systat, Inc., Evanston, Illinois) was also used for table analysis with chi-square goodness of fit tests and for Spearman's correlation coefficients between guideline receipt or adoption rates and size. BMDP (BMDP Statistical Software, Los Angeles, California) was used for step-wise logistic regression in order to examine size as an interval as well as a categorical variable and to support inclusion of other variables as predictors of guideline receipt.

Hypotheses Tested

Null hypothesis #1: Canadian hospitals show no significant differences in rates for receipt of published guidelines defining UP and BSI in association with hospital size or location. The alternative hypotheses is that receipt rates differ by hospital size and/or location. A related objective was to measure Canadian hospitals' receipt rates for recent CDC or LCDC guidelines in comparison to American hospitals' receipt rates for previous CDC guidelines in order to determine whether all hospitals receive this fundamentally important information.

Null hypothesis #2: Canadian hospitals show no preference among infection control strategies (Traditional, UP or BSI). The alternative hypothesis is that a majority have adopted either a Traditional system or one of the new systems. A related objective was to compare each hospital's claim of system used against specific policies they adopted in order to determine whether hospitals implemented their infection control strategy coherently and completely.

Results

Response Rate in the Survey of Canadian Hospitals

A set of mailing labels for all Canadian hospitals was obtained from CHA. The population sampled consisted of 943 acute-care hospitals after 61 labels

were discarded for specialty hospitals listed as providing long-term care only or for duplicate addresses (i.e.: parent corporation as well as sites operated by the corporation). 454 responses were received after the first mailing (48% response rate), and another 125 from a second mailing for a total of 579 (61%). Among the 579, 10 indicated provision of long-term care only and these were excluded. Of the remaining 569 responses from acute-care hospitals, one site was not yet in operation and another 12 were excluded as insufficient completion of the forms. These exclusions occurred in the three least bed-size groups.

Table 3 summarizes the hospital sampling frame and distribution of responses by hospital size and province. The size distribution of responders approximates that of all Canadian hospitals. The composition expected versus received for the 1-49, 50-99, 100-199, 200-299, and ≥300 bed groups were 43% vs. 33%, 18% vs. 19%, 14% vs. 16%, 8% vs. 9% and 16% vs. 23% respectively. Mean response rate for urban centers was ≈80%, with 94% of the largest hospitals responding and lower response rates from smaller and rural hospitals.

Receipt of Published Guidelines by Canadian Hospitals

Correlations between rate of receipt for published guidelines and both the hospital size and type of publication are evident in Table 4. Receipt rates increased as a function of hospital size, but different publications' receipt rates were not equal. Federal publications were received more commonly than topical review or medical journals.

Two federal publications, CDWR and *Morbidity and Mortality Weekly Report* (MMWR), are key sources of information that provide primary documentation for UP protocols and timely updates of CDC or LCDC recommendations. Their receipt was dependent on hospital size ($p<0.001$, chi-square test). Log-linear analysis was used to examine the relation between receipt of CDWR or MMWR and hospital

Table 3:
Survey Response Frequency and Rate by Bed Size Group and Province for Non-Specialty Acute-Care Canadian Hospitals*

BED SIZE GROUP	ALBERTA (118)	BRITISH COLUMBIA (93)	MANITOBA (77)	NEW BRUNSWICK (32)	NEWFOUNDLAND/ LABRADOR (35)	NOVA SCOTIA (45)	NWT/ YUKON (7)	ONTARIO (189)	PRINCE EDWARD ISLAND (7)	QUEBEC (121)	SASKATCHEWAN (132)	ALL PROVINCES (856) †
1- 49	27	22	23	4	5	5	3	25	1	4	37	168
	42%	60%	40%	33%	25%	31%	50%	69%	33%	29%	35%	46%
50- 99	21	9	5	7	4	7	2	28	0	3	8	101
	63%	56%	71%	78%	80%	64%	100%	65%	0%	18%	79%	65%
100-199	12	13	5	2	2	13	0	23	1	10	6	88
	100%	100%	81%	50%	56%	100%	‡	67%	100%	33%	100%	75%
200-299	2	10	3	4	1	2	0	17	0	9	1	49
	83%	93%	100%	100%	56%	56%	‡	71%	‡	43%	28%	69%
300+	10	14	5	4	4	1	0	47	1	32	7	129
	100%	85%	91%	100%	100%	40%	‡	91%	100%	84%	100%	94%
ALL GROUPS	72	68	41	21	16	28	5	140	3	58	59	535
	61%	73%	53%	66%	46%	62%	71%	74%	43%	48%	45%	63%

NOTE:

* Table excludes 10 responses from chronic care sites, 1 from a site under construction, 12 incomplete responses from acute-care sites, and 21 responses from specialty hospitals.

† Total number of non-specialty hospitals listed for each province is shown in parentheses. Row totals include 24 responses from unknown provincial location.

‡ Indicates no hospitals in category.

TABLE 4:
Receipt of Guidelines by Source and Hospital Size

POLICY AREA AND SOURCE	BEDSIZE GROUP: <25	25-49	50-99	100-199	200-299	300-499	500+
Number of facilities:	80	103	105	89	50	79	50
ISOLATION ROOM REQUIREMENTS	25	40	50	61	36	62	45
CDC ISOLATION GUIDELINE	31%	39%	48%	69%	72%	78%	90%
ISOLATION ROOM REQUIREMENTS	23	46	65	58	36	53	47
LCDC ISOLATION GUIDELINE	29%	45%	62%	65%	72%	67%	94%
HAZARDOUS BODY FLUIDS LISTED	9	44	49	64	39	75	48
MMWR 1988;37:377	11%	43%	47%	72%	78%	95%	96%
WARNING LABELS - LABORATORY	25	48	69	69	43	73	48
CDWR 1987;13S3	31%	47%	66%	78%	86%	92%	96%
WARNING LABELS- HOUSEKEEPING	14	23	41	47	33	51	37
ASEPSIS 1986;8:2	18%	22%	39%	53%	66%	65%	74%
GLOVING VERSUS HANDWASHING	7	17	14	26	17	43	37
ANN INTERN MED 1987;107:243	9%	17%	13%	29%	34%	54%	74%
STAFF EDUCATION	17	36	35	41	28	51	42
N ENGL J MED 1986;315:1562	21%	35%	33%	46%	56%	65%	84%
CDC or *LCDC GUIDELINE* Rec'd	43%	56%	75%	82%	90%	87%	98%
Reviewed if Received	76%	84%	86%	92%	89%	96%	96%
CDWR or *MMWR* Received	34%	62%	76%	85%	90%	97%	98%
Reviewed if Received	89%	89%	88%	96%	96%	96%	96%

characteristics in addition to number of beds. Regional location and rural versus urban setting were not significant factors ($p>0.50$), but presence of an infection control practitioner (ICP) was associated with guideline receipt ($p<0.0001$). The vast majority of Canadian ICPs receiving a guideline reported reviewing it.

Backward step-wise multiple logistic regression was used to examine hospital size as an interval variable and to include more variables than could be accommodated in a log-linear model. Default probability limits to remove or enter terms were used (0.15 and 0.10 respectively). Regression models started with receipt of CDWR or MMWR as the dependent variable and size, presence of an ICP, presence of intern or resident teaching programs, provision of risk services (e.g.: dialysis, sexually-transmitted disease clinic, etc.) and interactions as independent variables. In decreasing order of significance, terms retained in all final models were size, presence of an ICP and presence of medical teaching programs. Provision of risk services was dropped as not significant in all models, and interaction terms dropped in all but two (ICP*size was retained when size was expressed as the logarithm of the group median; ICP*size and teaching*size were retained when size was expressed as an arbitrary 7-level categorical variable in an asymptotic but not in maximum likelihood regression).

One-third of hospitals under 200 beds had received neither MMWR nor CDWR (mean receipt rate 63%, 95% confidence interval with finite population correction 61% to 65%, and with very conservative correction for nonresponse 61% to 81%). An exact upper limit was within 1 percentage point of the approximation. In addition to this low receipt rate, these smaller hospitals were also the least likely to have their own full-time ICPs (Table 5).

Table 5:
Hospital Size vs ICP Staffing (as Full Time Equivalents)

Number of Beds	Number of Infection Control Practitioners: 0.0	<1.0	1.0	1.5	2.0	2.5	3.0	3.5	4.0
<25	65.0%	31.3%	3.8%	-	-	-	-	-	-
25- 49	32.0	58.3	9.7	-	-	-	-	-	-
50- 99	28.6	62.9	8.6	-	-	-	-	-	-
100-199	13.5	64.0	21.4	1.1	-	-	-	-	-
200-299	2.0	50.0	44.0	4.0	-	-	-	-	-
300-499	1.3	26.6	58.2	6.3	6.3	-	-	1.3	-
500+	2.0	6.0	36.0	10.0	26.0	2.0	14.0	2.0	2.0
All Sizes	23.4	46.2	22.8	2.3	3.2	0.2	1.3	0.4	0.2

Adoption of Guidelines for UP or BSI

The proportion of hospitals claiming adoption of UP or BSI rose progressively by size group (Table 6, $p<0.001$, chi-square test). Overall, 359

TABLE 6:
Percent Of Hospitals Claiming Adoption of New Strategies

NUMBER OF BEDS	STRATEGY CLAIMED: UP	BSI	Traditional
<25	43.6%	1.3%	55.1%
25- 49	62.1	6.8	31.1
50- 99	76.9	3.9	18.3
100-199	69.7	11.2	19.1
200-299	69.4	10.2	20.4
300-499	64.1	15.4	20.5
500+	61.2	22.5	16.3
TOTAL:	64.4	9.1	26.4

(64.4%) claimed UP and 50 (9.1%) BSI, ranging from 44.9% claiming UP or BSI in the <25-bed group to 83.7% in the ≥500-bed group.

Unlike receipt of guideline publications, a positive correlation between hospital size and affirmative response was not evident for adoption of individual policy guidelines (Table 7). Fundamental policy differences between UP, BSI and Traditional strategies, together with the percentage of hospitals giving an expected response for their claimed strategy, are shown in Table 8. Only 20 of 359 hospitals (5.6%) claiming UP had adopted the minimum set of policies expected under this strategy, and 0 of 50 claiming BSI had adopted all expected policies (Table 9). If a policy to educate staff was also required, then only 16 (4.5%) claiming UP adopted expected policies. If BSI was defined without the policy to relax handwashing when gloves were worn, then 11 of 50 (22%) met the requirements if an education policy was excluded but only 7 (14%) if education was required.

The majority of Canadian hospitals had not adopted guidelines suggesting gloving as a substitute for handwashing, nor limitation of Universal Precautions to visibly-bloody body fluids (Table 7). A minority of hospitals claiming UP or BSI had eliminated special warning labels for specimens (UP 29%, BSI 36%) and for trash and linen (UP 32%, BSI 52%); correlation between adoption of these two policies was weak ($r=0.10$, $p>0.50$). The proportion of hospitals claiming adoption of UP and claiming a policy to train <u>all</u> health-care workers to use UP with <u>all</u> patients ranged from just over 50% in the smallest to 90% in the largest facilities.

Table 7:
Adoption of Guidelines by Hospital Size

Policy Guideline	BEDSIZE GROUP: <25	25-49	50-99	100-199	200-299	300-499	500+
UP ends need for warning labels on specimens.	13 16%	20 19%	28 27%	26 29%	6 12%	26 33%	15 30%
Special labels & double bags not required for waste or soiled linen.	17 21%	30 29%	25 24%	26 29%	18 36%	29 37%	29 58%
Gloves replace handwashing unless hands visibly soiled.	3 4%	8 8%	9 9%	8 9%	1 2%	6 8%	2 4%
Private room required for Staph pneumonia.	25 31%	33 32%	37 35%	40 45%	23 46%	45 57%	26 52%†
Private room not required for Staph pneumonia.	14 18%	33 32%	40 38%	40 45%	20 40%	36 46%	25 50%†
UP does not apply to many body substances unless they contain visible blood.	8 10%	23 22%	33 31%	32 36%	23 46%	37 47%	24 48%
Train all health-care workers to use UP with all patients.	29 36%	59 57%	59 56%	52 58%	31 62%	53 67%	42 84%

† Note: Total may exceed 100% as some hospitals claimed adoption of both.

Table 8:
Percent (Number) of Hospitals Adopting Policies Expected under UP, BSI and Traditional Strategies

POLICY:	*EXPECTED RESPONSE UNDER:* UP	BSI	TRAD.
No Special Warning Labels:	ADOPT	ADOPT	REJECT
-for Specimens	29% (107)	36% (18)	94% (138)
-for Waste & Soiled Linen	32% (114)	56% (28)	78% (115)
Gloves as Alternative to Handwashing	REJECT 93% (333)	ADOPT 10% (5)	REJECT 96% (144)
Private Room for Staph Pneumonia	(n/a)	REJECT 44% (22)	(n/a)
Precautions Don't Apply to Many Non-Bloody Body Fluids	ADOPT 43% (154)	REJECT 90% (45)	REJECT 86% (126)

Note: CDC and LCDC guidelines are contradictory regarding Adoption or Rejection of requiring a private room for Staph pneumonia under UP or Traditional strategies. As such, this policy is not applicable to assignment of UP or TRAD based upon policies adopted.

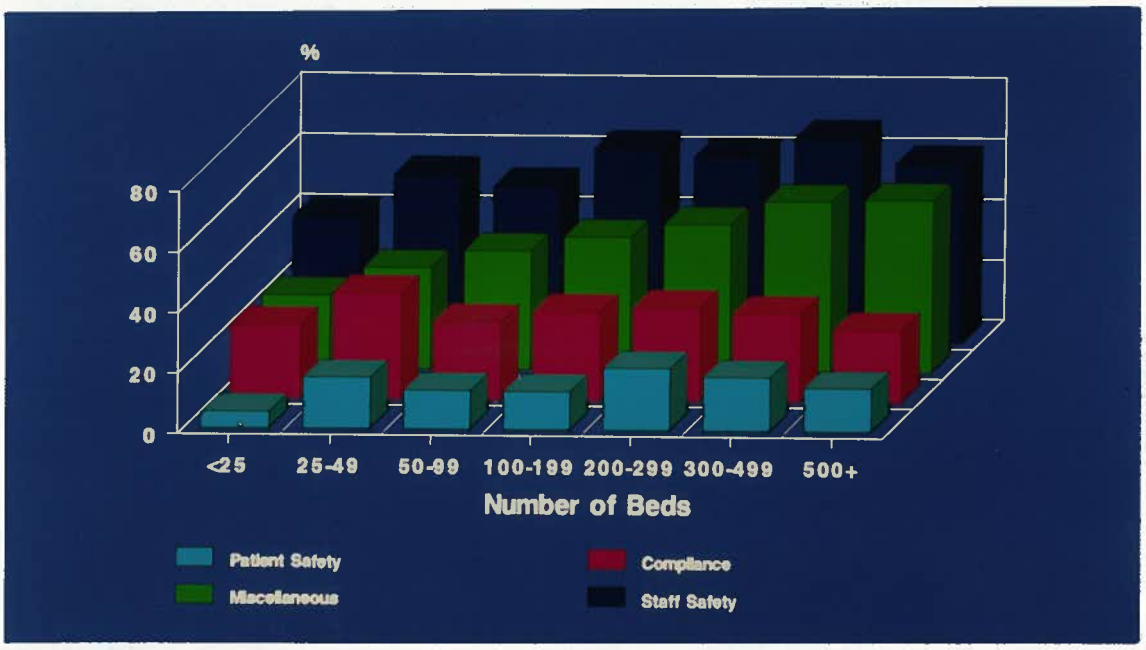
Table 9:
Infection Control Strategy Claimed versus Practiced

STRATEGY CLAIMED:	*STRATEGY PRACTICED:* UP	BSI	TRAD.	OTHER	TOTAL
UP	20 (5.6%)	1	119	219	359
BSI	0	0 (0.0%)	14	36	50
TRADITIONAL	1	0	96 (65%)	50	147
Total:	21	1	229	305	556

Rationale for Adopting a New Strategy

Hospitals explained their reason(s) in open text for adopting UP or BSI, and all reasons given were tabulated. These are summarized in Figure 1 as four categories. In all size groups, protection of staff was consistently the motivation most commonly claimed. Miscellaneous considerations (eg; "common-sense approach", "simpler change to introduce", "acceptance by staff", "want to keep isolation categories", "eliminate prejudice against labelled patients", etc.) and compliance with expert guidelines followed, with patient protection consistently the least common motivation.

Figure 1:
Hospitals' Motivations for Adopting UP or BSI



Other Perceptions - Disposal of Sharps

With regard to sharps disposal, only 13 of 556 hospitals (2.3%) described the use of cardboard disposal containers. All other descriptions referred to durable plastic (or, rarely, metal or glass) containers which were either obtained commercially or recycled from discarded solution containers. However, ICP's in over half of the facilities claiming adoption of UP or BSI still felt that at least 50% of their staff members continued to recap used needles. While many reported advocating "safe" (one-handed or thimble) techniques when recapping cannot be avoided, several questioned whether these techniques were used in practice and none claimed any measurement of staff compliance. Table 10 summarizes how needles were transported from their point of use to disposal containers. In 46% of the hospitals, no special provisions were identified for needle recapping and transportation to disposal containers on medication carts or in utility rooms: nurses carried presumably unsheathed needles on any available tray or by hand (36.3%), or they recapped needles at the bedside (9.9%). 40% of the hospitals did advocate safety procedures or devices: 17.8% provided bedside containers to discourage recapping and 21.7% used special devices to improve the safety of recapping and/or transportation. Table 11 summarizes respondents' perception of recapping practices in hospitals promoting strategies to discourage recapping: The alternative most commonly used was perceived to be the least effective.

Overall, 318 respondents (57%) felt that at least half of their hospital's staff recap used needles. Of these, 242 specified a strategy other than bedside containers to discourage unsafe recapping en route to disposal containers. 50 (21%) promoted recapping safety devices or one-handed technique, and, as noted in Table 11, 10 (4%) provided foam stabbing blocks and 9 (4%) provided special

Table 10:
Predominant Method for Transporting Used Needles from the Point of Use to the Point of Disposal, by Hospital Size According to Number of Beds

PREDOMINANT METHOD	NUMBER OF BEDS: <25	25-49	50-99	100-199	200-299	300-499	≥500	TOTAL
Bedside Container	13.8*	13.6	12.4	15.7	26.0	25.3	28.0	17.8%
Carry Unsheathed	36.3	50.5	40.0	41.6	32.0	13.9	30.0	36.3%
Recap & Carry	23.8	9.7	10.5	9.0	2.0	6.3	2.0	9.9%
Safe Recapping	5.0	4.9	11.4	18.0	18.0	15.2	14.0	11.7%
Foam Stabbing Block	2.5	3.9	4.8	3.4	4.0	12.7	4.0	5.0%
Special Trays	0.0	5.8	2.9	5.6	10.0	6.3	8.0	5.0%
Not Specified	18.8	11.7	18.1	6.7	8.0	20.3	14.0	14.2%

* Percent of size group using method indicated.

Table 11:
Perceived Effectiveness of Strategies To Avoid Recapping of Used Needles

PREDOMINANT STRATEGY:	NUMBER (%) OF HOSPITALS CLAIMING ≥50% OF STAFF: DO NOT RECAP	DO RECAP
Bedside Containers	61 (61.6%)	38 (38.4%)
Carry unsheathed	83 (41.1)	119 (58.9)
Foam Stabbing Block	18 (64.3)	10 (35.7)
Special Trays	19 (67.9)	9 (32.1)

PEARSON CHI-SQUARE = 17.550, 3 d.f., $p < 0.001$

trays. Thus, only 29% of hospitals where the majority were perceived to recap had promoted point-of-use safety devices and procedures to reduce risk of needlestick injury.

Other Perceptions - Knowledge of Costs and Benefits

While this survey did not ask for detailed economic evaluations, only 19% of hospitals claiming UP or BSI indicated knowledge of cost implications in their institution. These were primarily gross estimates rather than sophisticated examination of marginal costs. Less than half a dozen sites indicated that they were planning or conducting comprehensive reviews. Measurement of compliance with infection control policies by health-care workers, and of benefits achieved under UP or BSI as practiced in Canadian hospitals, largely unknown at this time, were identified as priorities for further research. 57% of respondents indicated a desire to participate in the next part of this research: multicenter evaluation of compliance and effectiveness by standardized covert observations and questionnaires from health-care workers themselves.

Summary of Major Findings

1. Three-quarters of Canadian acute-care hospitals reported use of UP or BSI.
2. Guidelines defining UP or BSI were not received by all of these hospitals: one-third of facilities under 200 beds (those most likely to need external help) had not received them.
3. While 65% of hospitals claiming a Traditional isolation program adopted all policies expected, <6% claiming UP or BSI adopted all expected policies. Inconsistency in the application of policy to different departments was noted, and numerous names other than UP or BSI were substituted.
4. Distinctions between UP and BSI, and the costs or benefits of either, were not well-known.

III. Have Hospital Staff Members Accepted the New Strategies?

Infection Control Practices of Critical Care Nurses.

The major emphasis in guidelines for UP or BSI focuses on appropriate use of gloves, handwashing and handling of sharps. Handwashing is a necessary[24] but perhaps insufficient measure to protect patients and staff from nosocomial infection; UP and BSI guidelines therefore propose gloving as an adjunct. Frequent failure to wash hands, and the over-estimation of one's own handwashing compliance, remain common findings throughout studies spanning the last fifteen years.[25 - 30] Failure to wear gloves for direct contact with blood or other body substances during nursing care is associated with transmission of herpes simplex[31] and hepatitis A[32] viruses as well as a wide variety of bacteria,[33 - 38] and, rarely, hepatitis B[39] and human immunodeficiency virus.[40 41] Gloving, however, is not a panacea. Gloves contaminated after[42] or even before use[43] may spread contamination and infection.[44] Some guidelines permit reuse of gloves between patients after effective washing, but washed gloves soon become sticky[45] and even new gloves do not provide an absolute barrier to virus penetration.[46] Bacterial contamination of hands has been demonstrated after dressing wounds even when gloves were worn.[47] This could result from nasal carriage with subsequent transfer to hands, or from direct contamination of hands upon glove removal.[48] Latex gloves may cause allergic reactions,[49] and detrimental environmental byproducts are also generated in glove disposal.[50] Current guidelines allow some individual discretion in choosing between no-touch technique and gloving with several of the patient-care practices selected for observation in this study. However, it is reasonable to conclude from current knowledge that universal use of gloves during all of the procedures selected might help to

prevent nosocomial infection of patients or staff. It is also reasonable to conclude from recent studies that glove use in many hospitals is far from universal.

Needlestick injury is the foremost occupational exposure leading to hepatitis B infection among health-care workers. In the United States, it is estimated that 500 to 600 health-care workers will be hospitalized and over 200 will die from associated fulminant hepatitis, cirrhosis or liver cancer every year.[15] A very small but real occupational risk of becoming infected by HIV also exists, and 70-90% of occupational exposures to this fatal infection have consistently involved needlestick injuries.[41, 51 - 61] Although it may be necessary to redesign invasive equipment in order to reduce this risk, UP and BSI infection control guidelines focus on admonishing health-care workers to handle needles carefully and especially to not recap them. This, however, is not new advice and there is little evidence to suggest that such warnings about safe handling of sharps have been effective.[62]

The few publications reporting understanding, compliance and/or effectiveness of UP or BSI in individual hospitals present contradictory findings. Programs may fail to achieve their objectives if they are based upon faulty theoretical models or if workers fail to comply with program policies. As described earlier, the majority of Canadian hospitals introduced myriad modifications in adopting UP or BSI, to a point where these names no longer have any specific meaning in practice. Further, the sharps disposal system most commonly provided to Canadian health-care workers was found to be the least effective in discouraging their recapping of used needles. It is not clear whether new infection control strategies have induced consistent use of gloves as expected, or whether safer sharps-handling practices have resulted.

Therefore, the next step in examining the effectiveness of UP and BSI as unifying strategies was to determine the extent to which health-care workers actually adhere to these precautions in daily practice.

Materials and Methods:

Recruitment and Participation Requirements

All acute-care Canadian hospitals had received questionnaires during the administrative survey described in the previous chapter. In January and March 1990, letters inviting participation in this study were sent to administrators of hospitals that indicated in their response to the administrative survey a desire to take part in subsequent research. Participation requirements were explained as: (1) submission of hospital policies regarding gloving, sharps disposal, hepatitis B immunization and in-service education; (2) agreement to conduct 60 covert observations of nursing care in their critical care unit; (3) inspection of 10 filled sharps-disposal containers to estimate the extent of recapping; (4) review of staff needlestick incident reports; and (5) distribution of test questionnaires (described in the next chapter) to critical care nurses.

ICPs in each participating site were asked to conduct 60 covert observations of specific nursing procedures in their intensive care unit (ICU). The quota of 60 observations requested from each site reflects a balance between a number low enough to be feasible yet high enough to provide precision and power. Sixty observations of nursing care would provide ≈99% power to detect ≥50% improvement over random (50%) compliance with approved procedures.[63] Specific procedures monitored include intravascular therapy, wound care, oral care, and perineal care (Table 12). ICPs were instructed to record specific observations on a check-list every week over a period of several months, and each recorded observation was dated. ICPs also examined the

contents of 10 filled sharps disposal containers from the critical care unit, estimating the proportion of recapped needles as 0, 1-10%, 11-25%, 26-50%, or >50%. ≤10% and ≤25% were taken as two limits for tolerable policy compliance.

Statistical Analysis and Hypothesis Testing

Four observation scores were calculated for each hospital as the simple proportion of glove use in each of the four categories of procedures observed. These scores relate to hospitals, not individual nurses, as the sampling unit. Notch plots were used to examine the distribution of hospitals' scores.[64] Normality of score distributions was confirmed by the Kolmogorov-Smirnov test.[65] SYSTAT (ver. 4.1) was used to perform these analyses.

A null hypotheses (#3) that ICU nurses do not recap used needles was tested at two levels of compliance. Five or more containers with more than 10% of the needles recapped formed one critical region for rejecting the null hypothesis (α=0.0015, β=0.0001 against an alternative hypothesis of ≥90% recapping). Six or more containers with more than 25% recapped formed the critical region for a second test (α=0.0197, β=0.0781 against an alternative of ≥75% recapping).

Table 12:
Nursing Care Procedures Observed

INTRAVASCULAR	ORAL
Start new IV site	Mouth care
Change IV line	Suction airway
Use IV stopcock	Retape endotracheal tube
WOUND CARE	**PERINEAL**
Dress dry wound	Perineal care
Dress draining wound	Remove bedpan
Empty hemovac	Empty foley bag

Note: Form supplied to ICPs had 5 lines for recording observations of "Start new IV site", 5 for "Change IV line", etc., so that the 60 total observations would be composed of equal numbers from each of the four categories and that none of the procedures would be observed more than 5 times.

Results

Response Rate

57% of over 500 hospitals participating in the administrative survey expressed interest in participating in this second phase, but only 72 actually enrolled. Half withdrew before completing covert observations and nurses' tests, for the same stated reason that so few enrolled: workload conflicts of their ICP. The 35 hospitals completing this study were primarily large community-hospitals from urban centers across Canada. Approximately 3% of western, mid-western and central but 10% of eastern hospitals participated. Smaller facilities tended to be excluded by the requirement to make observations in a critical care unit, and very few university-affiliated hospitals elected to participate.

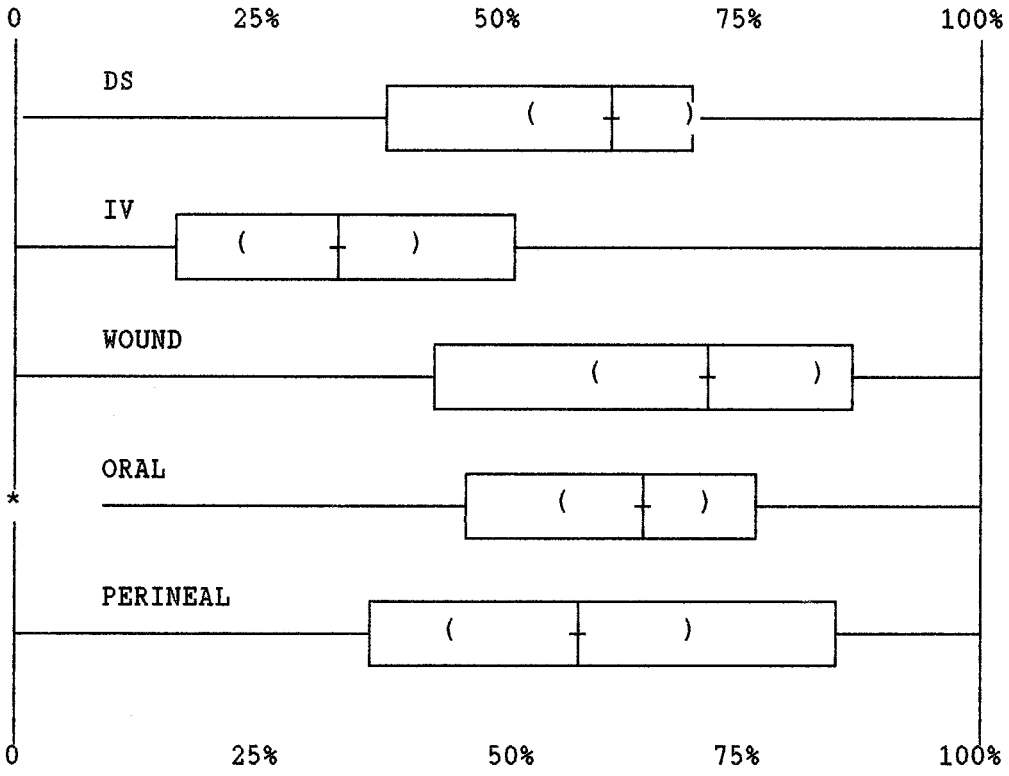
Use of Gloves

There was considerable variation from hospital to hospital in the frequency of glove use observed during various types of nursing care procedures: Figure 2 shows ranges of 0-100% in all of the categories observed. Distributions of overall hospital scores for glove use during IV and Perineal care procedures were approximately normal ($p=0.679$ and 0.272, respectively, Kolmogorov-Smirnov test). Oral and Wound care scores were skewed slightly more by relatively high numbers of hospitals observing frequent use, but were still reasonably normal in their distribution ($p=0.095$ and 0.073 respectively). There were large positive correlations between several of these four categories of practice.

Since the composition of observations from sites providing fewer than 60 observations varied, simple overall means would be confounded by the mix of procedures observed and therefore not be suitable for direct comparison. Direct standardization,[66] applying the four category-specific rates to a "standard population" composed of 15 observations from each of the four categories, yields

uniformly-biased overall scores suitable for comparison (Figure 2).

Figure 2:
Frequency of Observed Glove Use During Types of Nursing Care



Note: Scale represents the percentage of observations in which gloves were worn. ┼ indicates the median among all 35 hospitals, () indicates a 95% confidence interval for the median, boxed areas extend from the 25th to the 75th percentile, * indicates an extreme value. "DS" is a uniformly-biased directly-standardized overall rate (see text).

Handling of Used Disposable Needles

As predicted in the administrative survey, nurses frequently did not comply with national guidelines for safe needle disposal. Table 13 summarizes the frequency with which sharps disposal containers held various proportions of recapped needles. Recommended disposal practices were followed ≥90% of the time in 9 of 32 hospitals (28%) and ≥75% of the time in 15 (47%).

Table 13:
Frequency of Recapped Needles in Disposal Containers

	PERCENTAGE OF RECAPPED NEEDLES IN EACH CONTAINER					
	0%	1-10%	11-25%	26-50%	51-100%	TOTAL
CONTAINERS:	32	65	56	63	104	320
% OF TOTAL:	10.0	20.3	17.5	19.7	32.5	100%

Summary of Major Findings

1. All surveyed hospitals had policies in place mandating use of protective apparel, but few were prepared to monitor policy compliance and provide feed-back on performance to their staffs.
2. On the average, gloves were worn about 60% of the time expected, with wide variation ranging from 0-100% among the hospitals. Fewer than half of the hospitals achieved minimally-acceptable compliance (≥75% usage).
3. Fewer than half of the hospitals achieved minimally-acceptable compliance (≤25% recapping) with policies to not recap used disposable needles.

Knowledge and Beliefs of Critical Care Nurses

Programs may fail to achieve their objectives if they are based upon faulty theoretical models or if workers fail to comply with program policies. Direct observation of critical care nurses at work found frequent noncompliance with infection control policies. This could result from failure to know, to understand or to accept hospital policies. Unless pressures of the workplace interfere, strong correlation between knowledge and practice might be expected. However, industrial safety experience often shows discrepancies between knowledge and practice. In order to test the knowledge and beliefs of nurses whose work practices had been observed in the 35 hospitals described above, questionnaires were distributed to those nurses after completion of the covert observations.

Materials and Methods:

Test Forms

Test statements covered knowledge and belief concerning risk recognition, risk control and infection control policy with respect to four knowledge areas: (1) hepatitis B and AIDS in the workplace, (2) safe handling of sharps, (3) use of gloves under UP or BSI, and (4) general aspects of infection control. Concepts and answers were taken from published infection control guidelines. Wording was modified after review of draft statements and their intended purpose by nurses experienced in infection control and patient care but not employed in the hospitals where the test would be applied. The test consisted of 32 statements, and responses were recorded on a 5-point scale of degree of (dis)agreement with each statement (a Likert scale). Some of the statements ask about personal history (e.g.: if the subject has suffered a needlestick injury in the preceding 30 days, if they had difficulty understanding the questionnaire or using an optional computer program provided). Each statement, an expected

answer consistent with corresponding referenced publication(s) and the pertinent reference(s) are listed in Appendix 3.

Participating hospitals were offered printed forms or a computer program to conduct the tests. Statements were presented with identical wording on both the forms and computer screen. All critical care nurses in participating hospitals were invited by their own ICP to complete a standardized test anonymously at their own convenience; forms were collected a few days after mass distribution to minimize opportunities for collaboration. The interactive computer program, written in FoxBASE+ (version 2.00), does not ask for identity of individual nurses, but does automatically identify the hospital, type of computer, and test completion time. The encrypted and compiled program confirms integrity of stored coded responses before each subsequent use, and does not permit decoding by individual sites. Printed questionnaires, also anonymous, were returned in sealed envelopes. Upon receipt, they were marked with unique sequential numbers and transcribed using duplicate data entry via FoxBASE+ programs for automated error-checking and scoring.

Statistical Analysis

Four section scores (one for each of the knowledge areas tested) and an overall score were computed for each nurse as the percentage of statements answered as expected. Hospital scores were derived as the means of their nurses' scores. The distribution of these scores was examined in several ways. Normality of nurses' and hospitals' overall and section score distributions were confirmed by the Kolmogorov-Smirnov test.[65] Notch plots[64] and ANOVA of nurses' overall test scores (using site and claimed difficulty as independent variables) were used to determine whether nurses' overall scores differed significantly between hospitals or in association with other variables. A bar

graph of the four section scores, grouped by site, was used to look for any nation-wide trends in relative performance among the different knowledge areas.

Each concept on the questionnaire was tested by two statements which appear at variable distances apart from each other. Appendix 3 lists the pairings to which each statement was assigned (0 indicates unscored items). The influence of the order in which statements were presented was not studied; however, potential for learning bias as well as further examination of relative performance were explored by comparing scores on the first versus second statement in each pair using Tukey's sum-difference graph.[67]

Correlation coefficients were also computed. A null hypothesis (#4) that there is not a strong positive correlation ($r \geq 0.5$) between infection control knowledge and daily practice scores was tested in three ways: correlation coefficients between individual knowledge and practice component section scores, between unweighted overall test and observed-practice summary scores, and also with weightings derived from canonical correlation using the four knowledge sections of the test and four care categories of the observations. Canonical correlation is a multivariate technique to produce linear combinations attaining the maximum correlation possible.[68] SYSTAT (ver. 4.1) and SAS (ver. 6.03, PROC GLM) were used for these analyses.

Results

Response Rates

None of the sites used the interactive software. Seventy-two of 489 questionnaires received from 35 sites had one or more questions left unanswered; eight of these (from eight different sites) left an entire page blank and were excluded as incomplete. Table 14 summarizes characteristics of participating hospitals completing this part of the study.

Table 14:
Characteristics of Participating Hospitals

Site #	Approx. Number of Beds	Region of Canada	Questionnaire Response Fraction
61	200	West	7/10 (70%)
125	200	West	15/16 (94%)
123	300	West	5/16 (31%)
9	350	West	7/17 (41%)
417	450	West	9/14 (64%)
257	>500	West	8/27 (30%)
258	>500	West	30/67 (45%)
19	250	Mid-West	6/30 (20%)
103	400	Mid-West	11/29 (38%)
225	400	Mid-West	11/50 (22%)
420	400	Mid-West	13/22 (59%)
527	>500	Mid-West	47/65 (72%)
131	50	Central	3/ 6 (50%)
78	100	Central	7/10 (70%)
192	100	Central	6/12 (50%)
95	235	Central	10/15 (67%)
165	250	Central	13/20 (65%)
408	400	Central	20/30 (67%)
481	400	Central	23/50 (46%)
541	400	Central	21/61 (34%)
81	>500	Central	22/59 (37%)
104	>500	Central	29/60 (48%)
179	>500	Central	19/40 (48%)
67	100	East	5/ 6 (83%)
378	100	East	10/25 (40%)
296	100	East	6/14 (43%)
6	200	East	13/24 (54%)
59	200	East	9/18 (50%)
189	200	East	14/16 (88%)
363	200	East	15/15 (100%)
418	250	East	13/25 (52%)
285	300	East	15/17 (88%)
284	400	East	10/15 (67%)
558	450	East	15/40 (38%)
452	>500	East	19/29 (66%)

Note: Response fractions are the number of ICU nurses returning a completed questionnaire divided by the number of ICU nurses in each hospital.

Nurses' Knowledge and Belief Scores

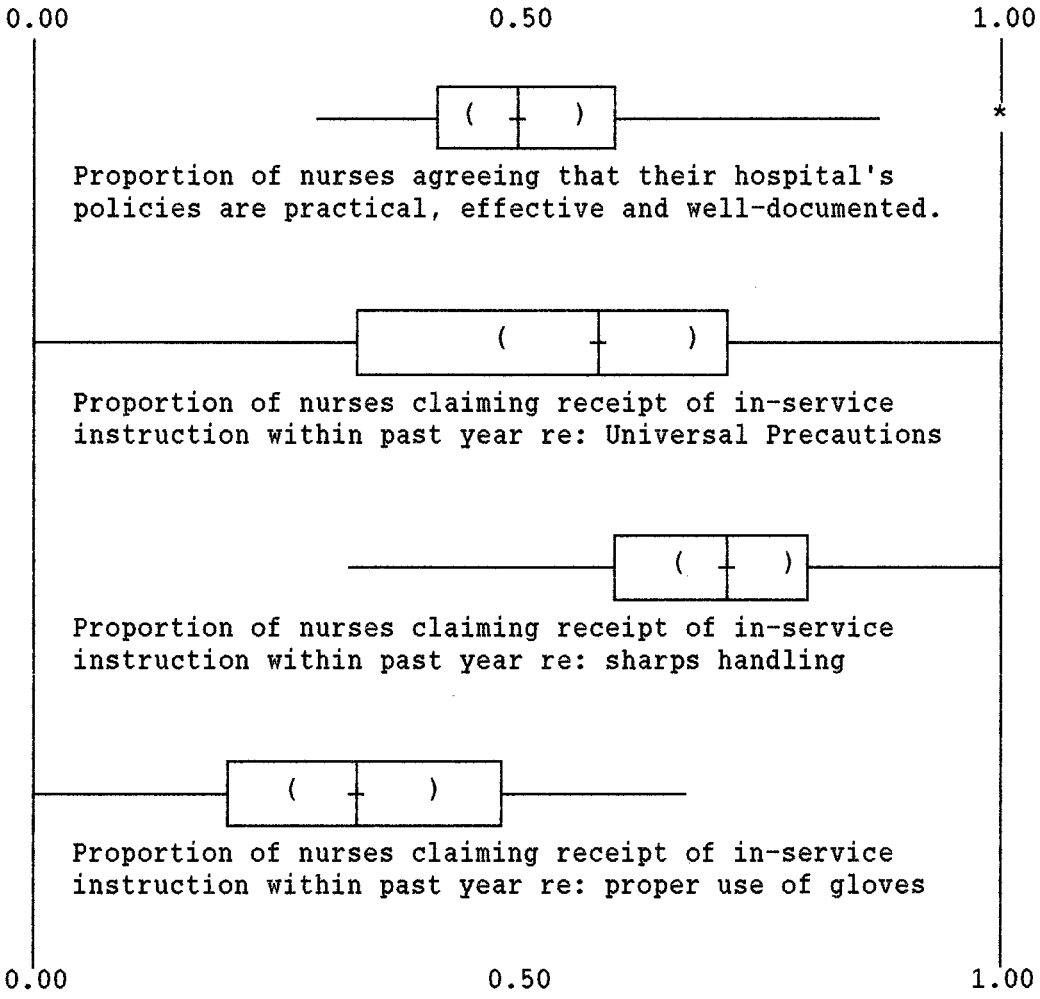
Test scores by section tended to range from highest to lowest for sharps handling, gloving, AIDS or hepatitis, and general aspects of infection control, respectively (Table 15). The proportion of nurses in each hospital agreeing that their hospital's infection control measures were practical, effective and well-documented is shown in Figure 3, as well as the proportion claiming receipt of instruction in these policies. There was a statistically significant association between nurses agreeing with their hospital's policies and claiming receipt of instruction ($p<0.001$, chi-square test; Pearson correlation coefficient ≈ 0.2) but no such association between the proportion of nurses in agreement with policies or receipt of instruction and higher overall hospital test or observed-practice scores. Inservice education provided to these nurses appeared to stress sharps handling more frequently than gloving or general aspects of UP/BSI.

Table 15:
Relative Ranking of Knowledge Test Section Scores

	Number of Hospitals in Which Section Score Was Ranked As:			
Test Section	Highest	2nd	3rd	Lowest
SHARPS	24	9	2	0
GLOVES	11	24	0	0
AIDS/HEPATITIS	0	2	29	4
GENERAL	0	0	4	31

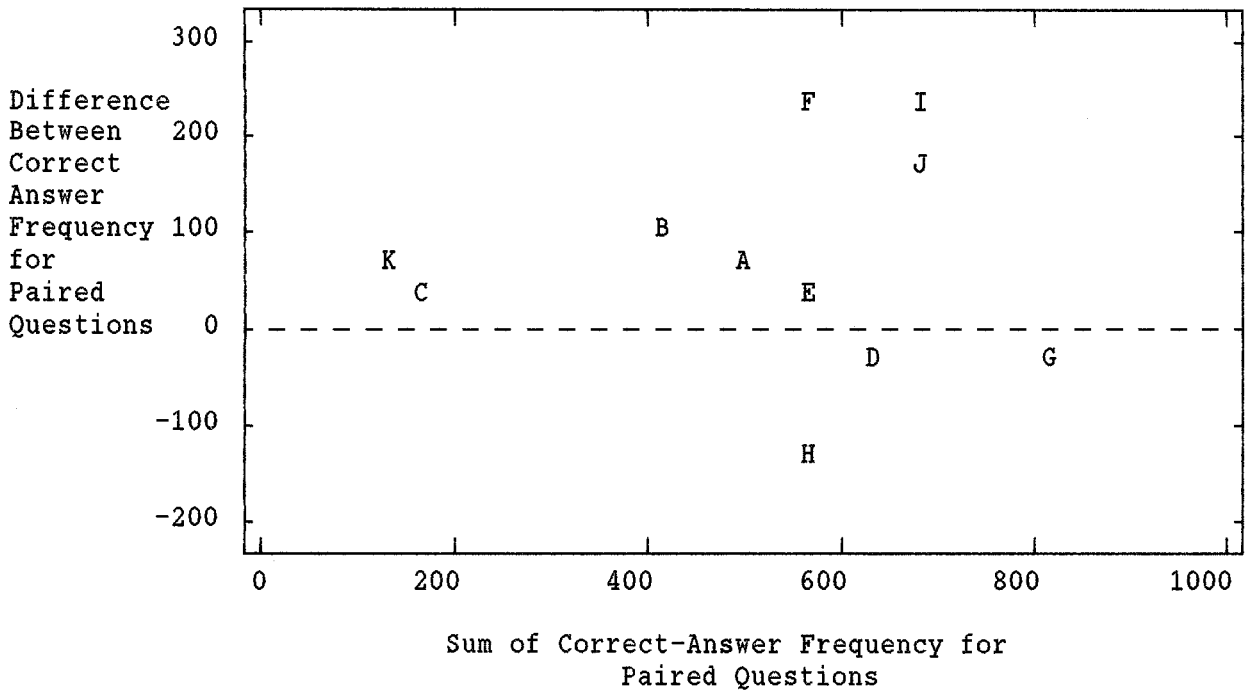
Nurses' scores did not improve as a function of exposure to test questions. Figure 4 depicts the distribution of scores for question-pairs horizontally, and for discordance within pairs vertically. The frequency of correct answers to a second member in each pair of questions exceeded that for the first member in only three of eleven pairs. 42-52% of answer-pairs were discordant (one correct, the other incorrect) for all pairs except those regarding philosophic

Figure 3:
Effectiveness of Hospitals' In-Service Program



Note: Scale represents the proportion of nurses in each hospital responded affirmatively. + indicates the median among all 35 hospitals, () indicates a 95% confidence interval for the median, the boxed area extends from the 25th to the 75th percentile, * indicates an extreme value.

Figure 4:
Tukey Sum-Difference Graph of Correct Response Frequencies



LEGEND: Net discordance in paired-item scores is indicated by distance above or below the dashed horizontal line; pairs with higher scores appear to the right and with lower scores to the left on this graph. Questions were paired on the basis of testing related concepts:

A = infectivity of HIV and hepatitis B virus	(questions 1 & 5)
B = need for screening and warning labels	(questions 2 & 26)
C = purpose and philosophic differences of UP/BSI	(questions 4 & 30)
D = immunity to infectious disease	(questions 6 & 24)
E = operational definitions with UP and BSI	(questions 8 & 18)
F = frequency and severity of needlestick injury	(questions 9 & 12)
G = recapping and needlestick risk	(questions 10 & 13)
H = protection afforded by gloves	(questions 15 & 19)
I = frequency of handwashing	(questions 16 & 23)
J = proper use of gloves	(questions 20 & 22)
K = definition and disposal of infectious waste	(questions 27 & 28)

differences of UP and BSI (C, 29%), recapping and needlestick risk (G, 23%) and infectious waste (K, 22%). Scores were lowest on questions regarding infectious waste, those pertaining to quantification of risk (F), and purpose or philosophy of specific control measures. Highest scores were achieved on information recognized well before the advent of new infection control strategies (D,G,I,J).

There were statistically significant differences between scores achieved by nurses in individual hospitals as well as by those claiming difficulty versus no difficulty understanding the test (2-way ANOVA):

SOURCE	DEGREES OF FREEDOM	TYPE III SUM OF SQUARES	MEAN SQUARE	F RATIO	p
Hospital	34	12763.08693	375.3849	2.85	0.0001
Difficulty	1	688.93145	688.93145	5.22	0.0228

Neither region nor hospital size were significant in explaining this variation about a total mean score of 54%, and very few sites (e.g.: site #6) had a distinctly different median score (Figure 5). The 141 nurses (29%) claiming difficulty with the test itself achieved a slightly lower median score than those not claiming difficulty (Figure 6). Similarly, those claiming receipt of in-service education or agreeing that their hospital's infection control measures were practical, effective and well-documented achieved only slightly higher scores than those not. Overall scores achieved by nurses approximated a normal distribution ($p \geq 0.05$, Kolmogorov-Smirnov test) in 30 of the 35 hospitals.

The hospitals' overall knowledge test scores were normally distributed ($p=0.316$, Kolmogorov-Smirnov test), but their directly standardized overall practice scores less so ($p=0.046$). Weighted arcsine transformation of these scores [$\sqrt{n_i}$*arcsine($\sqrt{p_i}$)] adjusted the raw scores (p_i) for differing numbers of tests or observations submitted by each hospital (n_i) as well as modifying the distribution shape of overall test and practice scores ($p=0.114$ and 0.185 respectively, Kolmogorov-Smirnov test). The Pearson correlation coefficient

Figure 5:
Nurses' Overall Test Score, by Site (Ordered by Region and Size)

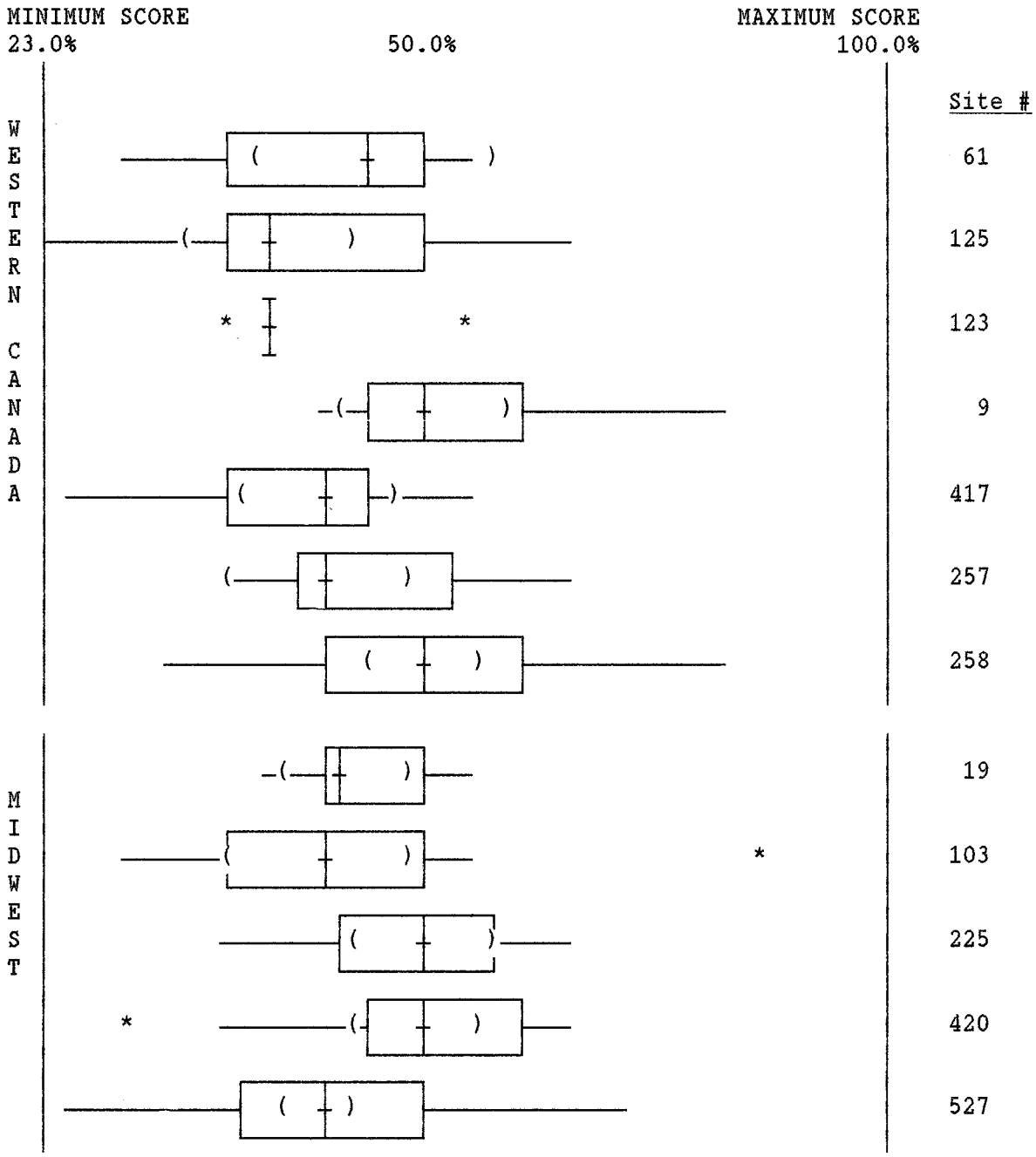


Figure 5 (cont.):

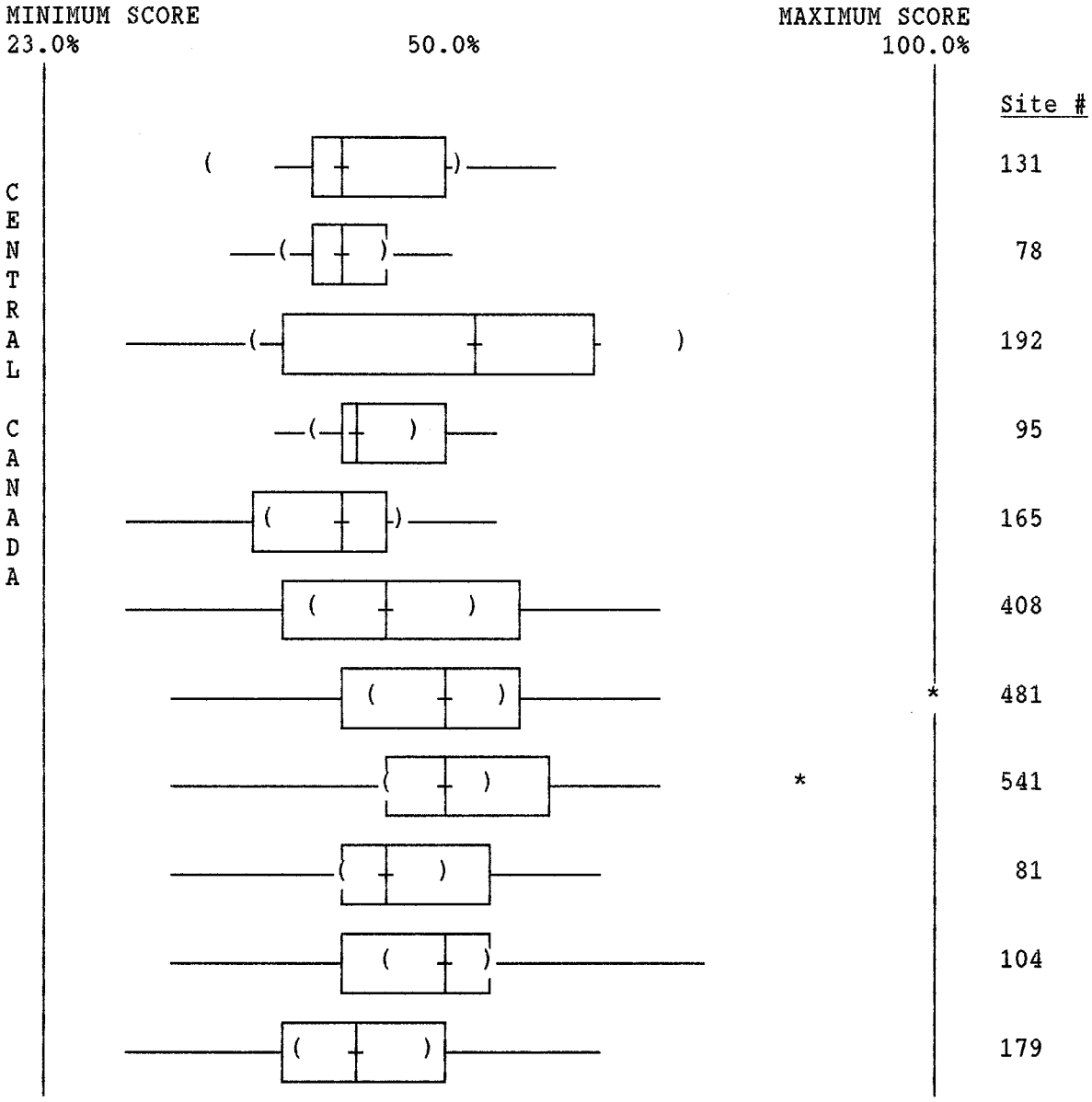
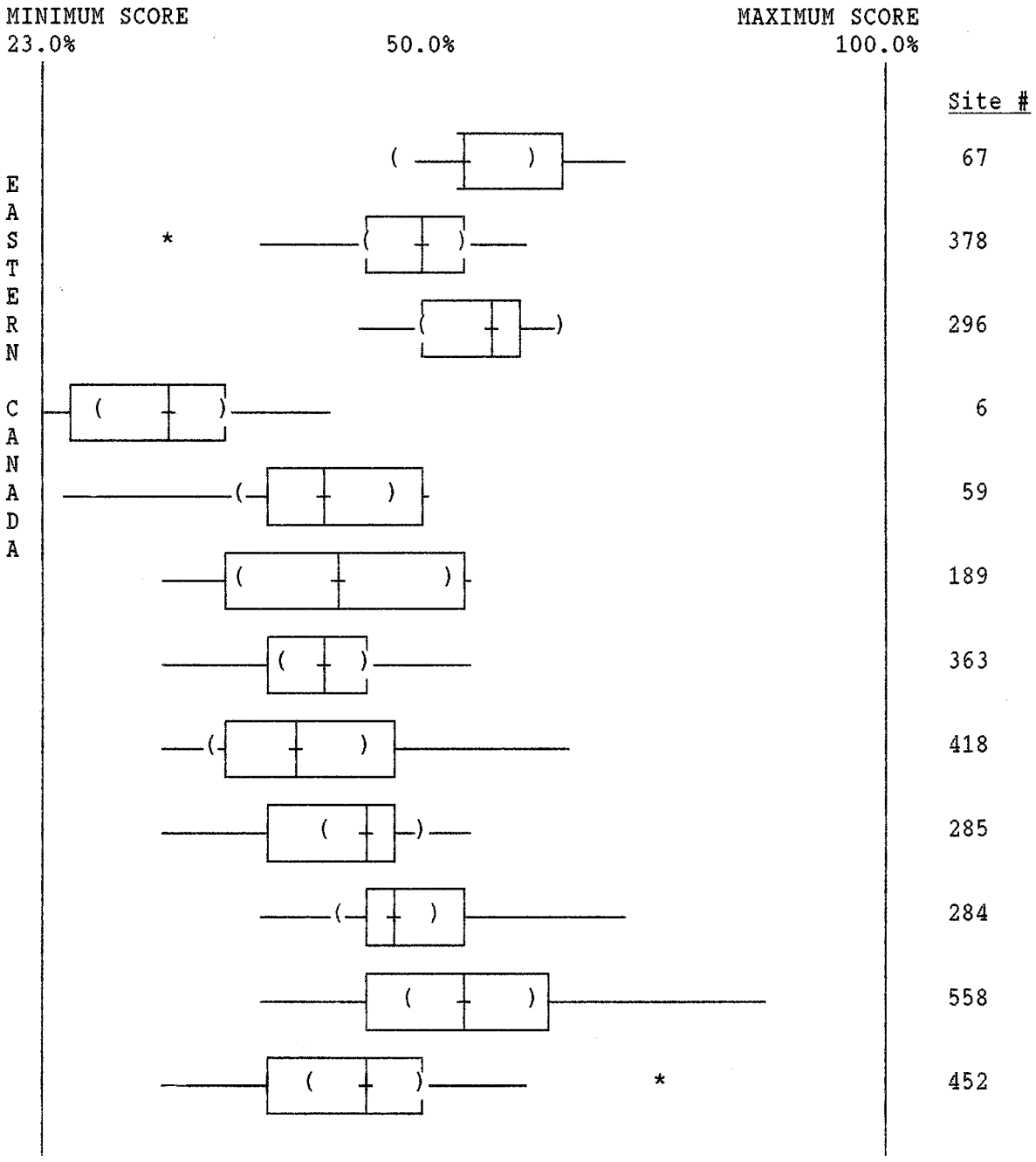
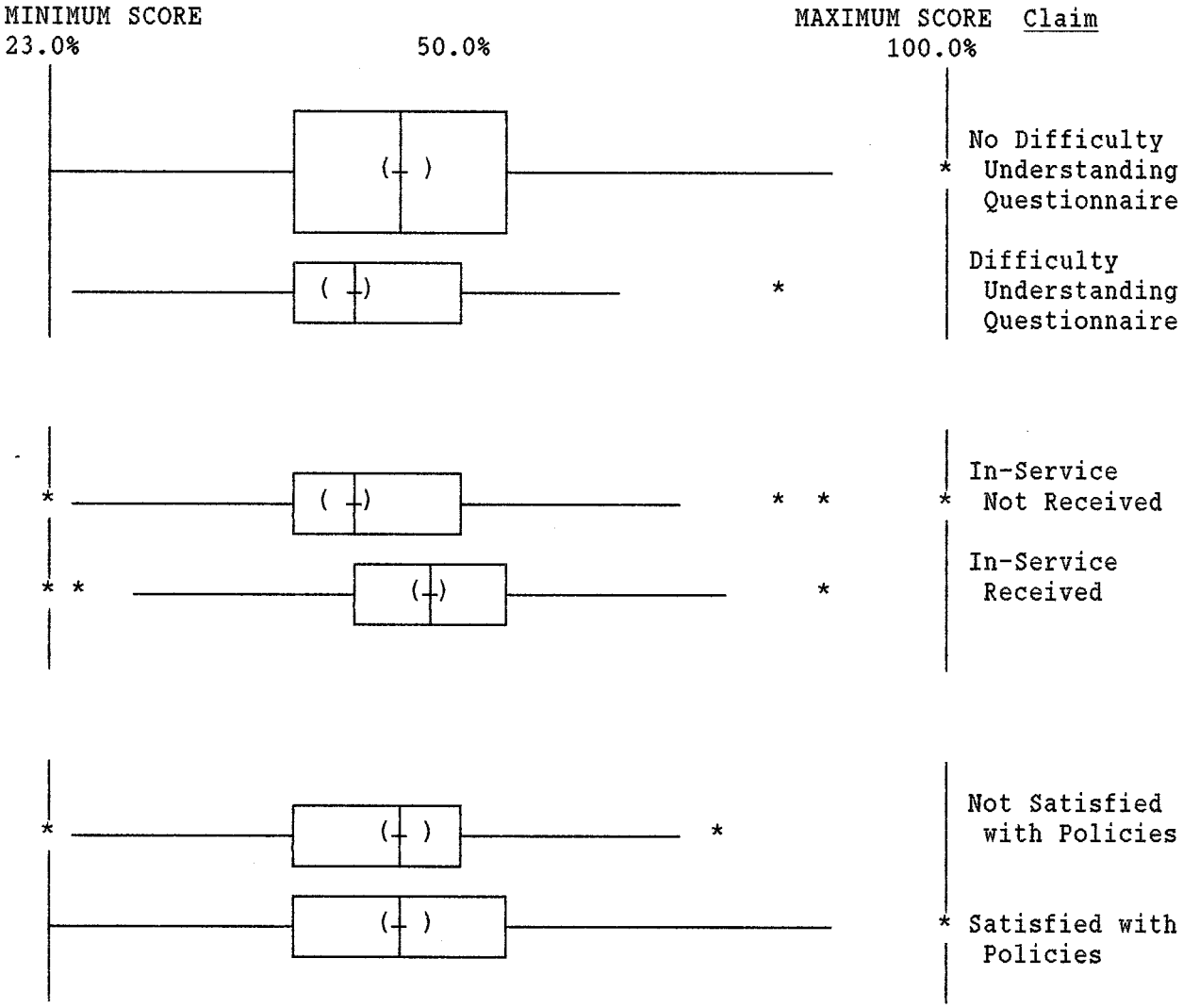


Figure 5 (cont.):



Legend: ┼ indicates medians, () indicates 95% confidence intervals, and * indicates extreme values. Median scores differ significantly if their confidence intervals do not overlap.

Figure 6:
Nurses' Overall Test Score, by Personal History Claims



Legend: ┼ indicates median score for all nurses regardless of hospital, () indicates 95% confidence intervals, and * indicates extreme values. Median scores differ significantly if their confidence intervals do not overlap. Box width is proportional to the square root of the group size.

between these summary scores was only moderately strong (≈0.35) and just achieved statistical significance (p≈0.04). Spearman's correlation coefficients among test section and care category scores were not statistically significant (Table 16). Table 16A treats all hospitals as equals; 16B (the transformed data) gives greater weight to those with larger nursing staffs (as implied by larger numbers of tests returned). The number of multiple comparisons possible in Table 16 inflates the probability that a spurious association may be found as statistically significant; Bonferroni adjustment reduces the chances of this.

Relationship Between Knowledge and Practice

Correlation between directly-standardized overall practice and knowledge scores was not statistically significant (Table 16), nor were any of the larger correlations achievable through reweighting by coefficients derived from canonical correlation analysis (Table 17). Further, if the analysis is restricted to those sites coming closest to the number of observations requested, a persistent negative trend in the correlation coefficient is evident (Figure 7). At the extreme of this sensitivity analysis, data from the four sites providing all 60 observations requested yield a correlation coefficient of −0.8. This effect is also evident in the difference between test-practice correlation coefficients on Tables 16A and 16B: weighted-arcsine transformed data provides a correction for this confounding and yields a smaller correlation coefficient.

Summary of Major Findings

1. In half of the hospitals, no more than 50% of participating nurses agreed that their policies were practical, effective and well-documented.
2. Many nurses held divergent opinions, did not understand or did not agree with tenets fundamental to UP and BSI. Test scores averaged 54% correct.
3. A positive correlation between knowledge and practice was not found.

Table 16:
Spearman Correlation Coefficients Between Test and Practice Scores

Table 16A: Correlation Coefficients, Raw Data

	TEST	OVERALL PRACTICE	AIDS/HEP	SHARPS	GLOVES	OTHER	IV	WOUND	ORAL	PERINEAL
Overall										
TEST	1.000									
PRACTICE	0.310	1.000								
Test Section										
AIDS/HEP	**0.783**	0.275	1.000							
SHARPS	0.438	-0.061	0.231	1.000						
GLOVES	**0.709**	0.246	0.401	0.142	1.000					
OTHER	**0.586**	0.363	0.277	0.002	0.332	1.000				
Care Category										
IV	0.432	**0.688**	0.298	0.008	0.341	0.503	1.000			
WOUND	0.267	**0.757**	0.191	0.089	0.075	0.370	0.501	1.000		
ORAL	0.145	**0.665**	0.184	-0.263	0.308	0.087	0.245	0.315	1.000	
PERINEAL	0.192	**0.800**	0.201	0.077	0.072	0.172	0.420	0.492	0.500	1.000

Table 16B: Correlation Coefficients, Weighted Arcsine Transformed Data

	TEST	OVERALL PRACTICE	AIDS/HEP	SHARPS	GLOVES	OTHER	IV	WOUND	ORAL	PERINEAL
TEST	1.000									
PRACTICE	0.287	1.000								
AIDS/HEP	**0.932**	0.236	1.000							
SHARPS	**0.908**	0.250	**0.811**	1.000						
GLOVES	**0.980**	0.259	**0.901**	**0.872**	1.000					
OTHER	**0.967**	0.309	**0.879**	**0.860**	**0.938**	1.000				
IV	0.259	**0.756**	0.245	0.187	0.237	0.310	1.000			
WOUND	0.207	**0.913**	0.154	0.206	0.168	0.254	**0.682**	1.000		
ORAL	0.280	**0.674**	0.256	0.147	0.301	0.272	0.317	**0.575**	1.000	
PERINEAL	0.166	**0.857**	0.168	0.157	0.131	0.180	0.557	**0.731**	**0.622**	1.000

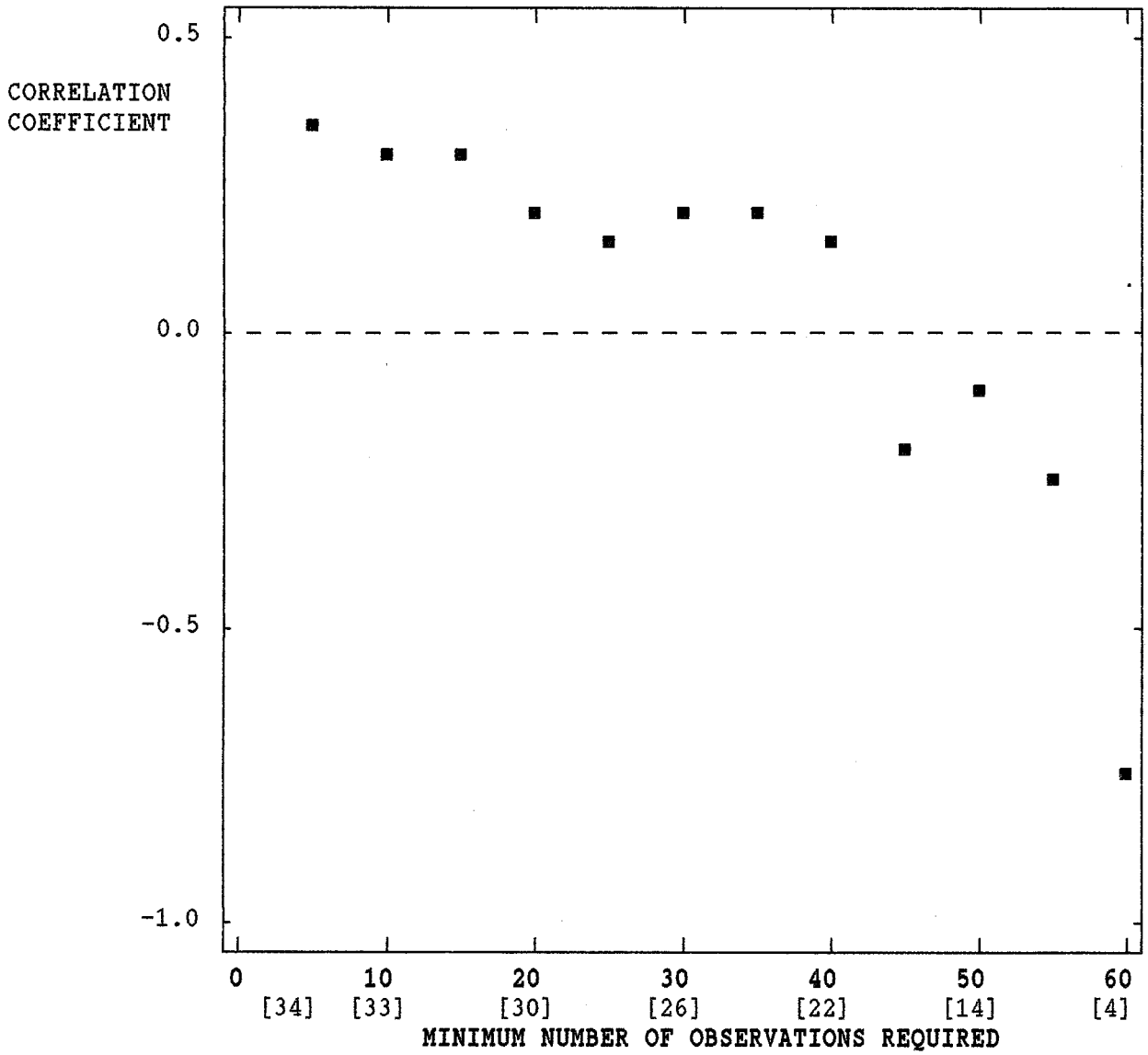
Note: Values ≥0.341 are statistically significant (p≤0.05, 2-sided) without Bonferroni adjustment; values ≥0.573 achieve statistical significance with Bonferroni adjustment.[69] The latter are shown **boldface.**

Table 17:
Canonical Variate Coefficients and Correlations

KNOWLEDGE TEST SECTION SCORES: AIDS/HEP	SHARPS	GLOVES	OTHER	r_1*	OBSERVED PRACTICE SCORES: IV	WOUND	ORAL	PERINEAL
0.124	-0.577	0.535	0.519	0.593	-0.703	0.147	-0.804	0.398
0.122	0.597	-0.453	0.738	0.409	0.254	0.804	-0.664	0.245

*Note: None of the canonical correlations are statistically significant (p>0.3)

Figure 7:
Spearman's Correlation Coefficient (of Knowledge and Practice Scores) vs. Minumum Number of Practice Observations Required for Inclusion in Analysis



Note: Numbers in brackets indicate number of sites included.

IV. Have New Infection Control Strategies Reduced Infection Risks?

Although reduced infection risk for patients will undoubtedly provide the major economic benefit from an effective infection control strategy, reduced risk for health-care workers was the major focus of this research for two reasons. First, Canadian hospitals indicated that protection of staff, specifically from HIV, was their primary motivation for adopting new strategies. This can be evaluated indirectly by measuring needlestick injury rates, since the majority of occupational HIV and hepatitis B infections involve needlesticks. Second, there were too many interacting variables associated with most types of nosocomial infections suffered by patients, too many endogenous and exogenous sources of pathogens and too many inadequacies in current microbiologic typing methods to make a study of patients' risk practicable. The impact of nurses' gloving practices on intravascular-associated nosocomial infections was considered for study, since this problem involves relatively few confounding variables. However, an adequate typing method was not available for the nosocomial pathogens most commonly associated with intravascular cannulae, coagulase-negative staphylococci.[16]

Epidemiologic Assessment of Risk to Hospital Staff- Needlestick Injuries

Needlestick injury is a well-recognized occupational hazard for health-care workers. Published guidelines discourage recapping of used needles as an unsafe and unnecessary practice. However, the strategy most commonly employed by Canadian hospitals appeared to be the least effective in discouraging recapping of used needles (Tables 10 and 11). Subsequent observation of nursing practice confirmed the opinion that many nurses still recap used needles in spite of policies discouraging this habit. A test of knowledge among these same nurses confirmed that most agree that used needles should not be recapped. However,

these were cross-sectional surveys, not before-and-after studies. Therefore, the next step in this research was refinement to see if adoption of UP or BSI resulted in decreased needle recapping or injury rates. Needlestick injury incidence rates were estimated from data before and after adoption of new infection control strategies, and incidence density rates were calculated (essentially, number of injuries divided by number of hours worked) on paired before-and-after data. Incidence density is more meaningful than other attack rates which are often published (e.g.: injuries per number of employees, per number of full-time equivalent employees, or per number of hospital beds) because it takes the duration of risk-exposure into account.[70]

Materials and Methods:

The nursing test questionnaire described above asked whether respondents had suffered one or more needlestick injuries in the preceding thirty-day period. ICPs reviewed the hospital's employee health records after nurses completed the questionnaires, looking for needlestick injury reports from critical care nurses during three consecutive preceding thirty-day periods and during corresponding thirty-day periods prior to adoption of their new infection control strategy.

In order to control for the confounding influence of differing durations of exposure to a risk of needlestick injury, incidence density was calculated by dividing the number of needlestick injuries reported among critical care nurses by the number of hours those nurses worked in each thirty-day period. Paired analysis of before versus after UP/BSI rates was used to control for differing baseline rates among the hospitals. The Sign Test for persistence of a trend of any magnitude, and Wilcoxon's Signed Ranks Test for a trend of significant magnitude were used.[71] SYSTAT (ver. 4.1) was used for these tests. The frequency of reported injuries was compared to the number of questionnaire-

respondents claiming needlestick injury in order to assess the extent of injury under-reporting.

Results

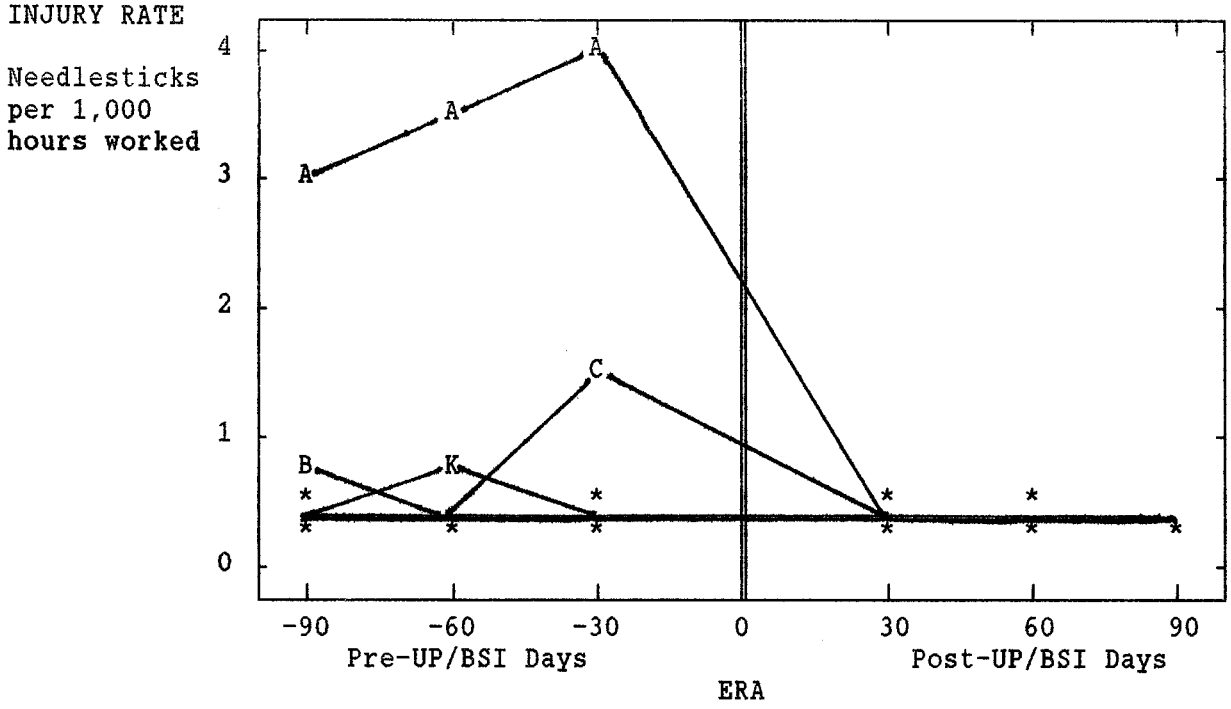
Eleven hospitals provided complete data (number of needlesticks reported and hours worked among critical care nurses for three 30-day periods after and three corresponding periods before adoption of UP or BSI). Thirty-three hospitals provided partial data. Eleven of 312 staff (3.5%) who returned questionnaires in hospitals providing complete data claimed one or more needlestick injuries during a preceding thirty day period; only four needlestick injuries were documented in incident reports. This rate is higher than the 2.3% (21 injuries among 929 staff in a 30-day period) documented in employee health records of all responding hospitals.

Monthly incidence density rates in the eleven hospitals providing complete data ranged from a minimum of 0 per 1000 hours worked to maximums of 3.94 before and 0.41 after UP/BSI adoption. Although the latter numbers suggest lower risk after each hospital adopted a new infection control strategy, paired data did not show a statistically significant trend based upon persistence of differences of any size ($p=0.332$, Sign Test). If the magnitude as well as direction of before- versus after-UP/BSI differences were considered, borderline statistical significance was attained ($p=0.076$, Wilcoxon Signed Ranks Test). Much of the latter effect was attributable to one hospital with a before-UP/BSI incidence rate at least one order of magnitude higher than any of the other hospitals (Figure 8).

The proportion of discarded needles that were recapped had also been assessed in ten of these eleven hospitals. Only four showed evidence of ≤25% recapping frequency, and decreasing needlestick incidence rates were found in

only one of these. Conversely, four of six hospitals where recapping was still widespread reported decreased post-UP/BSI incidence rates.

Figure 8:
Needlestick Injury Rates in 11 Hospitals Providing Paired Data



Note: Hospital "A" had pre-UP/BSI rates one order of magnitude higher than the other ten hospitals. Distinct data points are labelled by hospital (A,B,C,K); * indicates overlapping data points from two or more hospitals in this time-series analysis.

Summary of Major Findings

1. Employee health records documented fewer nurses suffering needlestick injury during a 30-day period (2.3% of 929 nurses in 33 hospitals) than was found by surveying nurses directly (3.5% of 312 nurses in 11 hospitals).
2. Only 1 of 11 hospitals indicated appreciable risk reduction after UP started.
3. An association between reduced needle-recapping and reduced needlestick injury risk was not evident.

Epidemiologic Assessment of Risk to Hospital Patients–
Tracing the Sources of Infection by Microbiologic Methods

The marginal cost of UP in excess of existing infection control costs is appreciable,[72] and its cost per case of occupational HIV seroconversion prevented has been estimated at over $8–million.[73] While patients and staff members have a right to a safe hospital environment, and hospitals, in turn, have both legal and ethical obligations to provide this, it is unlikely that economic benefits from UP will exceed its costs. Accurate cost–effectiveness comparison of UP, BSI and other strategies will undoubtedly require assessment of their impact on the costs associated with patients' nosocomial infections. If treatment costs can be averted by preventive measures, this would motivate implementation and support of those measures. However, in order to classify patients into case or referent study groups for such epidemiologic and economic research, better microbiologic typing methods are needed.

Microbiologic methods to determine whether isolates are epidemiologically related exploit the diversity within taxonomic relationships. If one or more differences can be found, this implies that isolates may be unrelated in spite of their common genus–species name. Typing to a subspecies level supports epidemiologic investigation by determining whether microbes isolated from two sources may have an epidemiologic relationship (e.g.: from different patients, suggesting cross–infection; from patients and an environmental reservoir, suggesting common–source transmission; from different sites of a patient, such as blood and an intravascular cannula, suggesting routes of transmission, etc.). However, the problem of proving epidemiologic relatedness by microbiologic typing is often analogous to hitting a moving target with tools of undefined precision, accuracy and reliability.[16]

The extent of diversity within a species must be documented and sufficient to generate enough typing categories for adequate discriminatory power. The typing method itself must be sufficiently precise, accurate, reliable and practical to generate useful results. Methods that have been or could be applied to typing coagulase-negative staphylococci were reviewed[16] (Table 18). The MIDI system for semi-automated fatty acid analysis (Microbial ID, Inc. Newark Delaware) was felt to show promise, and an evaluation project was initiated. That research is still in progress (see Appendix 4).

Table 18:
Typing Methods for Coagulase-Negative Staphylococci

	CONVENTIONAL METHODS			MOLECULAR METHODS					NOVEL METHODS	
	Biotype and/or	Phage	Serology	Plasmid Profile			Chromosomal		Multilocus	Fatty
CRITERION	Antibiogram			Elect.	REA	RFLP	REA	RFLP	Enzyme Elect.	Acids
1. CAN IT DO THE JOB?										
Discriminatory Power	±	-	-	±	+	+	+	+	?	?
Species Diversity Documented	+	-	-	-	-	-	-	-	-	?
2. DOES IT DO THE JOB?										
Accuracy and Reliability	±	±	-	+	+	+	+	+	?	?
Availability	+	-	-	±	-	-	-	-	-	?

KEY: + = Good
± = Problematic, but possible
- = Inadequate
Elect. = Electrophoresis
REA = Restriction Endonuclease Analysis
RFLP = Restriction Fragment-Length Polymorphism
Fatty Acids = Fatty Acid Profile

V. Discussion:

Validity, Reliability, Power and Generalization of This Research

This research produced a considerable amount of data to address three basic questions: Have Canadian acute-care hospitals adopted Universal Precautions or Body Substance Isolation; do their staff members use the new system of precautions in daily practice; and has reliable use of a new system led to decreased risk of infection? In order to answer these questions and understand the limits to interpretation in those answers, a basic procedure for appraisal of data is important. Abramson suggests that this involves three steps.[74] First, what are the facts, how were they obtained and what is the likelihood that bias has distorted the true facts? Second, what are the possible explanations (i.e.: a fluke of random chance, confounding or a true relationship)? Third, what additional information is required to confirm the possible relationship(s)? This chapter reviews the methods and data presented earlier in order to appraise the information derived from them.

Administrative Survey

In the administrative-level survey, most Canadian acute-care hospitals reported adopting Universal Precautions or Body Substance isolation. As in all evaluative research, validity and reliability are critical issues. Face and content validity of survey questionnaires were high in that questions concerning discrete, objective key variables related to stated survey objectives. Consensual validity was established by pretesting survey forms at ten geographically diverse pilot sites and discussing these preliminary results with an expert research supervisory committee. Reliability was supported by using an objective mailed survey (allowing respondents to check institutional records before answering, and reducing a risk of interviewer bias); including redundant

questions to ensure consistency of response; automating error-checking on data entry; and random checks of questionnaire data against corresponding computer-stored transcripts. Other than redundant questions, there was no way to confirm responses in this phase of the research. However, given the anonymous nature of the survey, there was no obvious motive for respondents to misrepresent their hospital's position and the nature of responses does not suggest that unduly favorable pictures were provided. Further, copies of policies received from hospitals participating in the second phase of the research confirmed their administrative survey claims. The nature of responses received both in the pretest and main survey were clear and did not suggest misunderstanding of questions themselves. The questionnaire was created in English, then translated into French by one native-speaker, checked by a second, and my translation of completed French forms was double-checked by a third person whose native language was French. Neither misrepresentations nor misunderstandings in completing or interpreting the questionnaires were likely to have distorted the conclusions drawn.

Non-response and self-selection bias weaken the survey's external validity; however, use of a sampling frame and separate analysis of responders to a second mailing indicated that non-responders were primarily small, rural hospitals with guideline receipt rates lower than responders. Highly conservative correction for nonresponse was therefore unwarranted. Given the direction of bias, survey results were unlikely to have under-estimated guideline receipt or adoption rates.

The first two null hypotheses tested were rejected: statistically significant associations were found between hospital size, preferred infection control system and receipt of pertinent guidelines. Rejection of a null hypothesis carries the

risk of α-error, a chance that aberrant findings resulted from a quirk of random chance. However, corroborating evidence reduces this possibility here. Beyond the level of statistical significance achieved, parallel trends were observed, for example, in adoption rates for both UP and BSI as opposed to a Traditional system, and in receipt rates for a variety of different publications. The stratified and multivariate analyses performed explored any influence of the most likely confounding variables which might have distorted true relationships. Other variables examined were ICP-to-bed ratio, provision of risk services (e.g.: dialysis, drug abuse or sexually transmitted disease clinic), hospital location, and size as an interval variable using number of beds, group median or log of group median. Hospital size remained the most significant determinant of information receipt in models that considered all of these variables simultaneously.

Objective comparison of the specific policies adopted versus the system claimed provided important additional information about the infection control systems of these hospitals. Increasing hospital size and presence of ICPs or medical teaching programs may indicate a more cosmopolitan outlook, and thus greater emphasis on staying informed. It is unlikely that smaller hospitals simply felt that UP or BSI and the underlying problem of HIV were not relevant to them: nearly half of the smallest hospitals claimed to have adopted UP, stated motivations for adoption were the same in hospitals from all size ranges, provision of risk-services was not found to be a significant variable, and trends related to size were evident throughout the entire range of hospital size groups. Some hospitals undoubtedly accepted the UP or BSI system but rejected certain guideline recommendations selectively after careful review, but this does not explain all of the deviation from expected policies found. The proportion of

hospitals that had not received guidelines defining the system they claimed, the low correlation between use of "biohazard" labels for housekeeping versus laboratory materials, the few sites commenting upon a major discrepancy (a typographical error) between two guidelines, and the comments received suggest other explanations for this deviation.

Covert Observation of Nursing Practice

In the study of nurses' daily practices, covert observation found significant variation in staff members' adherence to their hospital's system of precautions. Validation of observation accuracy and inter-observer agreement for different hospitals' ICPs could not be evaluated. These are weaknesses in the internal validity of this research. ICPs, however, routinely observe and evaluate aseptic practices as one of their own job responsibilities. Observations required in this study were objective: gloves were worn or not, and needles were capped or not. The open layout of most ICU's promotes relatively unrestricted view of any nursing procedures being observed. These factors hopefully reduced observer biases. ICPs were recruited for the study because they are trained observers of aseptic practice who regularly visit all nursing units, and therefore may not raise nurses' suspicion or prompt major changes in work practices simply by their presence. ICPs were instructed as to what kinds of practices to observe, and to spread their observations of glove use over several months in order to obtain results representative of nursing unit practices. Extended duration of studies may introduce problems (e.g.: drop-outs, consistency of performance, temporal effects), but in this case an observation period of several months was necessary. When ICPs evaluated the frequency of needle-recapping, no effort was made to distinguish between needles used solely to draw up medications versus those exposed to patients' blood.

In addition to self-evident descriptive data on glove use, a third null hypothesis regarding the unsafe practice of needle recapping was rejected in 53% of these highly-motivated hospitals. The probability that significantly worse compliance with needle disposal policies really existed but was not found (β-error) was low, ≈0.08 in each site at a sample size of 10 units (Table 19).

Table 19:
Magnitude of α- and β-error for Hypothesis #3

Action	Number of Containers With >25% of Needles Recapped	Probability if True Recapping Rate Is ≤25%	Probability if True Recapping Rate Is ≥75%	Magnitude of α	Magnitude of β
Accept Null Hypothesis	0	0.0563	0.0000		0.0000
	1	0.1877	0.0000		0.0000
	2	0.2816	0.0004		0.0004
	3	0.2503	0.0031		0.0035
	4	0.1460	0.0162		0.0197
	5	0.0584	0.0584		0.0781
Reject Null Hypothesis	6	0.0162	0.1460	0.0197	
	7	0.0031	0.2503	0.0035	
	8	0.0004	0.2816	0.0004	
	9	0.0000	0.1877	0.0000	
	10	0.0000	0.0563	0.0000	

Staff members' use of prescribed infection control precautions in daily practice was far from universal, and this trend was evident in many hospitals with both gloving for various types of care as well as needle disposal practices. This is consistent with reports in the recent literature and the historic reports of noncompliance under traditional programs which prompted development of new infection control strategies in the first place.

Test of Nurses' Infection Control Knowledge and Beliefs

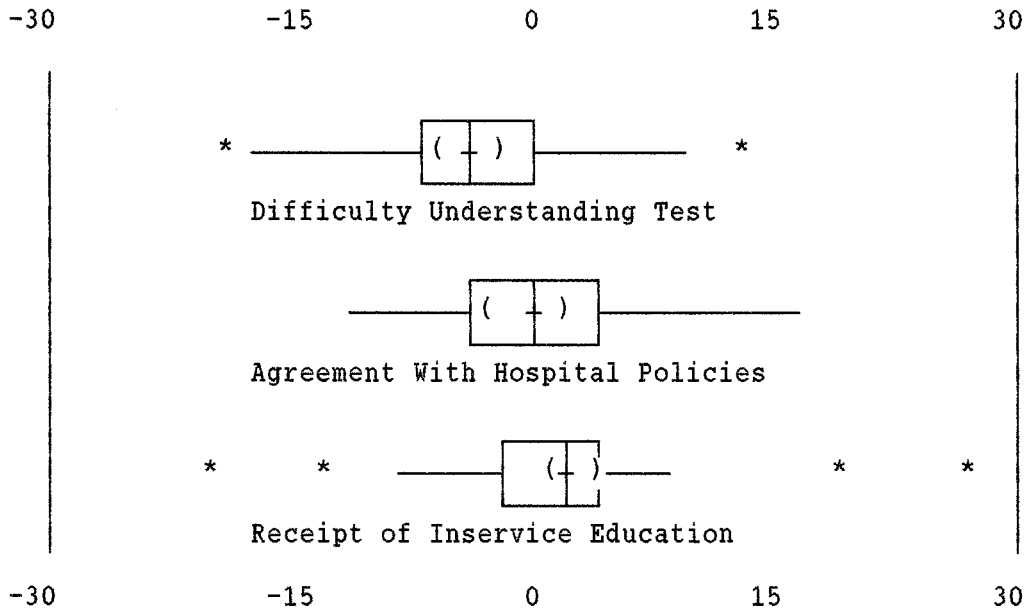
A test of knowledge and belief found that many nurses in all parts of the country held views divergent from published information. Efforts to safeguard internal validity in the knowledge and belief test phase of this research were

similar to efforts in the administrative survey. Face and content validity of questionnaires were high in that questions related to stated objectives and were derived from key publications. Consensual validity was established by pretesting question statements and discussing their intent with an independent panel of experts in infection control and nursing practice as well as with an expert research supervisory committee. Two questions were selected for each concept tested. Again, the questionnaire was created in English, then translated into French by one native-speaker and checked independently by a second. Finally, the 35 ICPs acting as liaison to their hospital were invited to comment on any concerns about ambiguity or validity. Automated error-checking on data entry, automated scoring and random comparisons of questionnaire data with corresponding computer-stored transcripts again were used to guard against introducing transcription errors in data handling.

Few sites produced significantly different mean test scores (Figure 5). Confounding of mean scores by attitude toward policies, receipt of instruction or difficulty with the test (Figure 6) was not significant (Figure 9). Score distributions tended to approximate a normal distribution. The Kolmogorov-Smirnov test used is relatively powerful for detecting non-normality in small samples.[75] The few deviations that it detected were not severe (Figure 10). Two-way ANOVA indicated site and claimed difficulty as determinants of test score; significance of differences found was confirmed by nonparametric methods.

There are two aspects to reliability in psychometric testing: internal consistency and stability. Internal consistency, that is, cohesiveness among test items themselves, is best measured by Kuder-Richardson's formula KR20 or KR21[76] which are special cases of Cronbach's alpha coefficient. Stability provides an indication of the degree to which achieved scores on a test measure

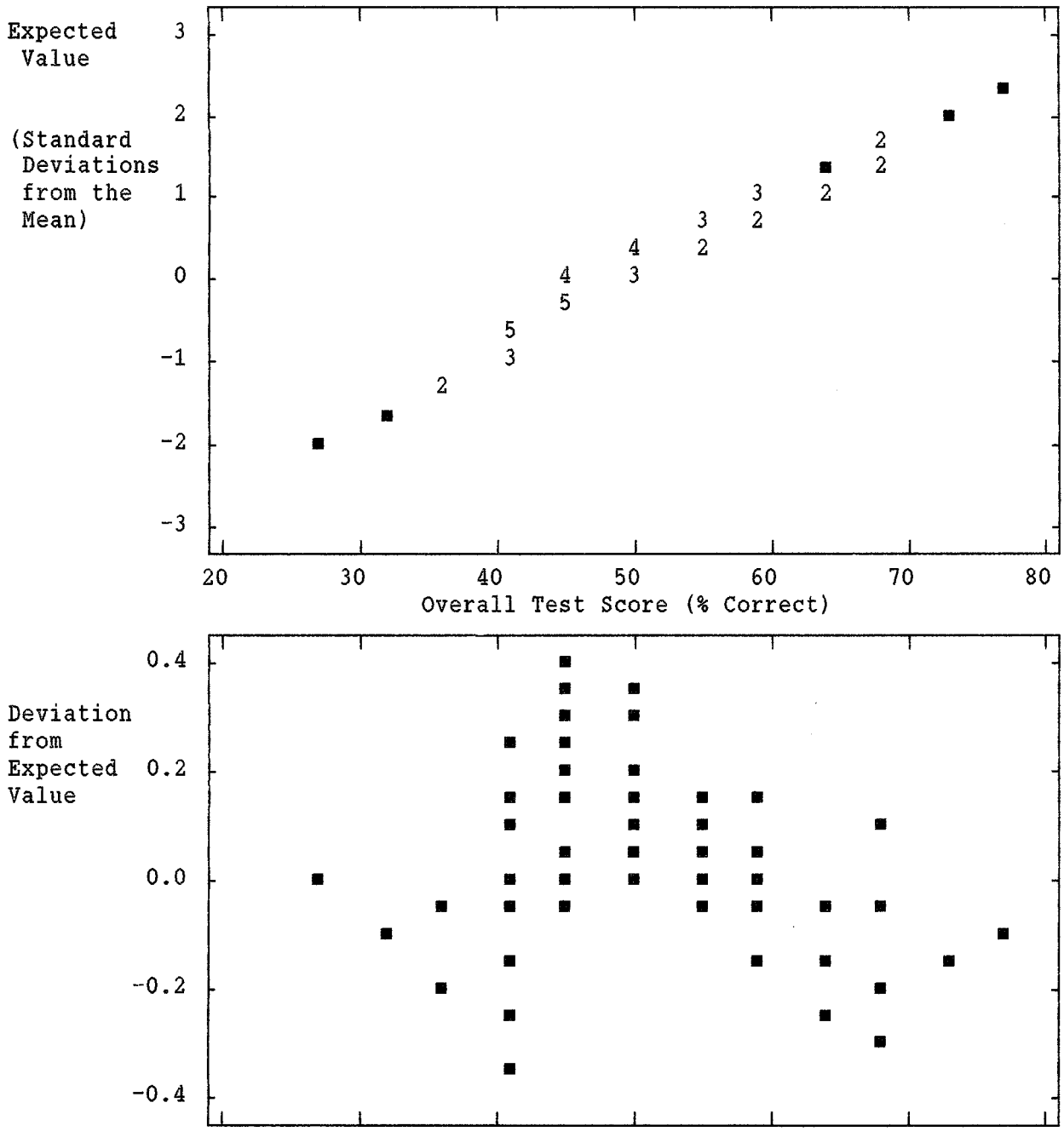
Figure 9:
Magnitude of Confounding in Nurses' Test Scores



Note: Scale represents the difference (in percentage points) between mean scores for nurses in each hospital who claimed or did not claim each factor. ┼ represents median differences among the 35 hospitals. () represents 95% confidence intervals for medians. * represents extreme values. These values are corrected for differences in individual hospital's scores.

individuals' "true" scores. It may be assessed by giving the same test to each subject twice (test-retest method) or using another, equivalent second test (parallel forms), or by correlating scores achieved on each of several equivalent parts of a single test given once to each subject (split-half method). Internal consistency among the diverse items in a nurses' knowledge and beliefs test developed for this research was expected to be low, and therefore was of little interest. Stability of the new test, as an indication that similar scores would be achieved if nurses were tested repeatedly, was difficult to measure but of greater interest.

Figure 10:
Normal Probability Plot- Distribution Rejected by the Kolmogorov-Smirnov Test



Note: Normality of the distribution of these 47 nurses' test scores from site #527 was rejected by the Kolmogorov-Smirnov test (p=0.008). Of fifty-five distributions tested, this was one of the more extreme p-values among nine rejected. There were more scores near the middle of the distribution than expected, but the extent of this deviation was not severe.

Each ICU nurse could not be tested on two occasions for a test-retest or parallel-forms assessment, a simple split-half single-test method would require too many randomizations to provide statistically valid results,[76] and a standard method to assess stability would be difficult to establish for tests consisting of nonequivalent items. Therefore, reliability of the nurses' knowledge test was assessed in the following manner. Phi coefficients[77] (a correlation coefficient for two dichotomous variables) were computed for each of the eleven pairs of questions for each site returning at least ten completed tests (Figure 11). Questions had been paired on the basis of similar concept. Appendix 3 lists the questions and their pairings; 0 indicates unscored items. The median of each site's eleven phi values then was taken as an index for that site. Median phi values were corrected for test length with the Spearman-Brown formula[77] ("stepped-up reliability"). These stepped-up medians then were used in meta-analysis[78] to determine whether a statistically-significant positive correlation was characteristic of all of the sites. That consistency would suggest a degree of reliability, indicating that the new test may provide a reproducible measurement.

Meta-analysis of phi coefficients reexpressed by Fisher's z-transformation failed to find significant differences among the sites ($p>0.99$, chi-square test for heterogeneity). This suggested that all sites shared a common correlation value, estimated as $r\approx0.14$, 95% confidence interval $\approx0.03-0.25$. This weak but statistically significant positive correlation between paired-responses provides weak evidence of test reliability. That conclusion was supported by finding correlations among the four knowledge section scores all to be positive (Table 16). The frequency of discordance found in responses to question pairs suggests that many of the paired questions were not of equivalent difficulty. This limits the ability to explore test reliability from these data. Paired questions appear

Figure 11:
Distribution of Phi Coefficients for 11 Paired Responses, by Site, in 22 Sites Returning ≥10 Tests

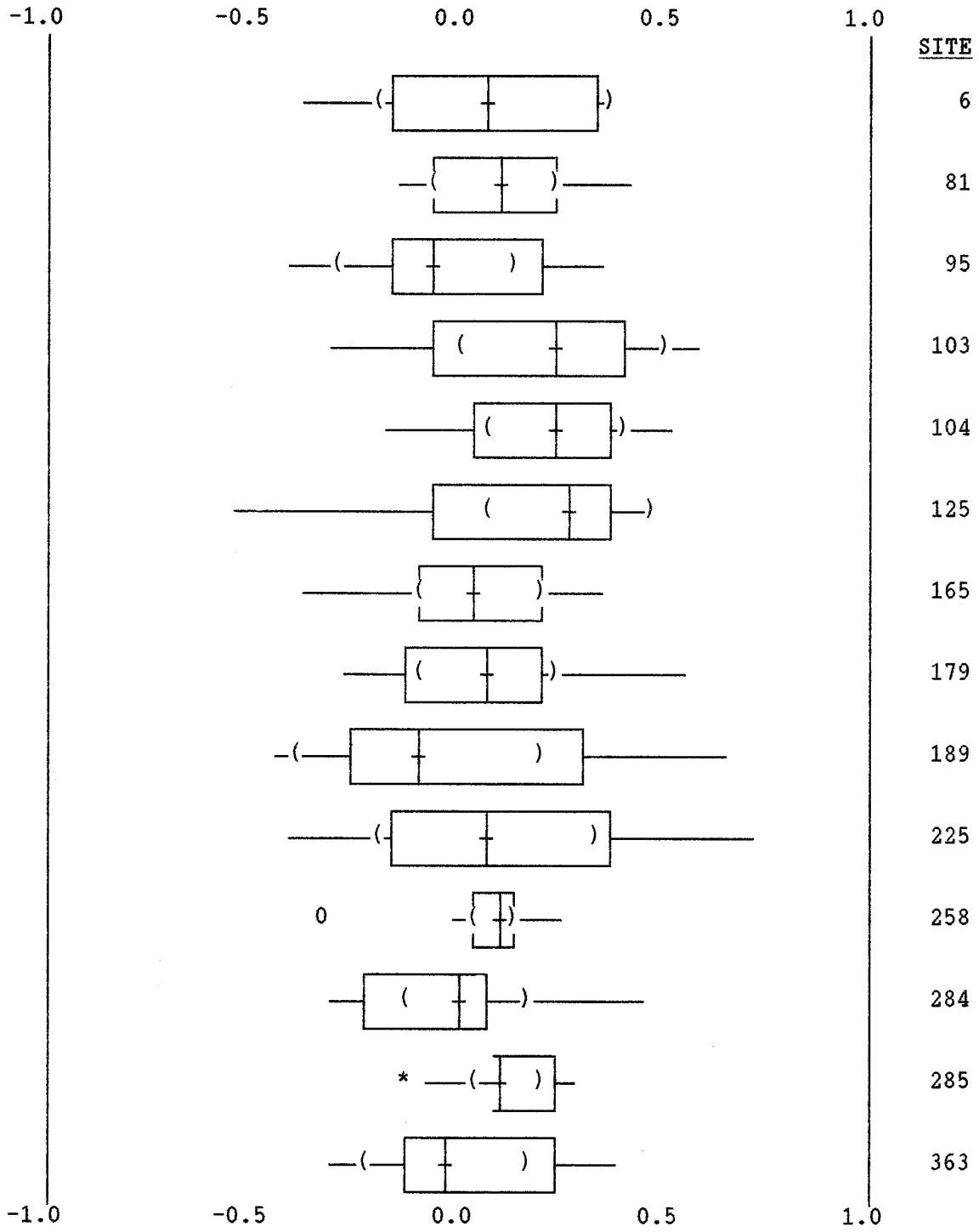
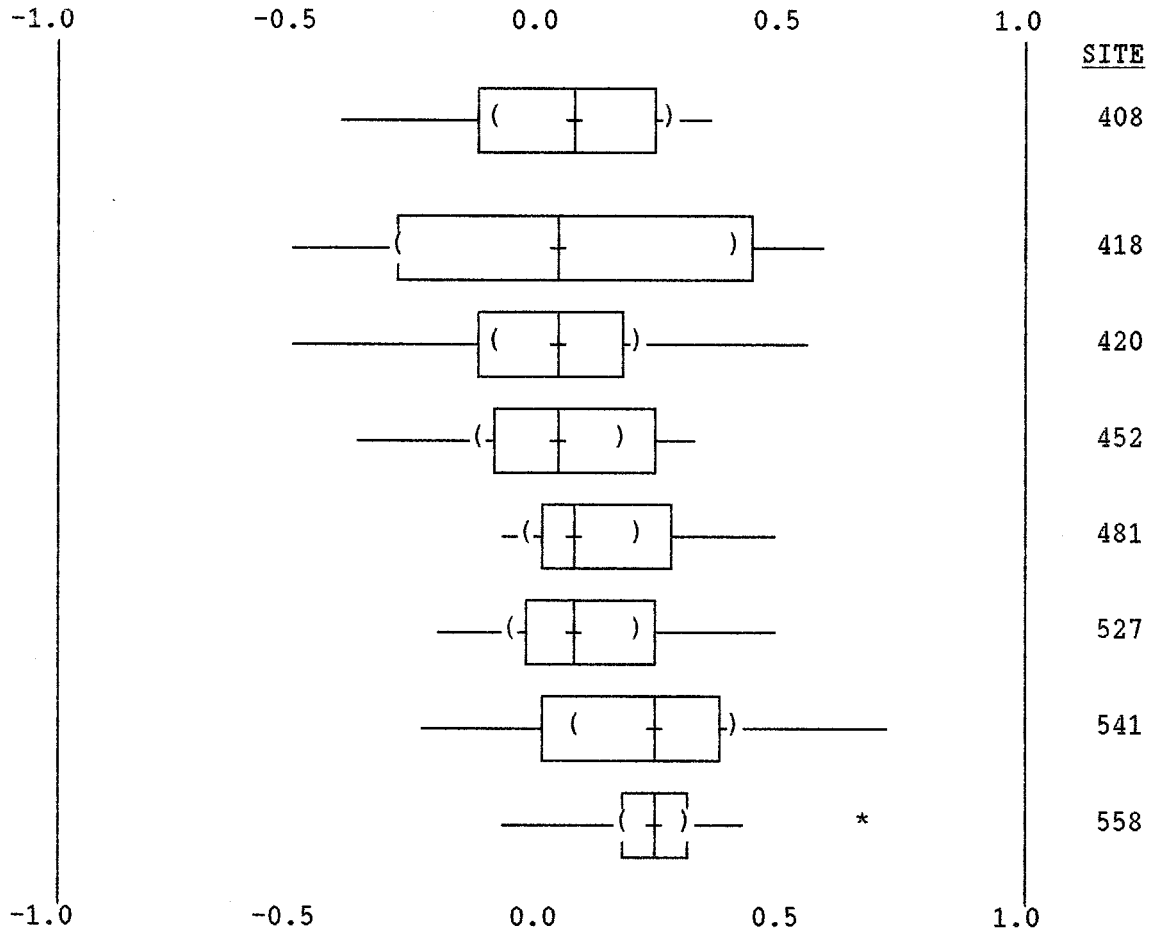


Figure 11 (cont.):



at variable distances apart from each other on the test and the influence of the order in which questions were presented was not studied experimentally. However, gross evidence of learning bias was not evident in a comparison of differences in scores on a first versus second question of each pair (Figure 4).

Relationship Between Infection Control Knowledge and Practice

In examining the relationship between knowledge and practice, this work failed to find a strong positive correlation. Since null hypothesis #4 was not rejected, one must consider the possibilities of insufficient statistical power to detect a true relationship, and of distortion by other variables (confounding).

Sixty observations provide ≈99% power to detect change in a hospital from random (50%) to minimally acceptable (at least 75%) compliance with gloving policy; a sample of 35 hospitals provides ≈93% power to detect strong positive correlations ($r \geq 0.5$). Thus, sample sizes appear to have been sufficient. However, knowledge and practice scores of individual nurses could not be linked because of logistical constraints and requirements of anonymity. Comparison of mean knowledge and practice scores for each hospital was a feasible but less refined approach. Pearson's correlation coefficient provides greater statistical power to find statistically significant linear associations between normally-distributed variables than the Spearman coefficient; however, the latter is more robust to non-normal distribution and more powerful at finding nonlinear associations. The former was used on data that were normally distributed (or transformed into a normal distribution), and the latter when normality could not be assured. Since both coefficients were of similar magnitude and thus led to the same conclusions with these data, these conclusions are more likely to reflect true facts than to be artifacts of a particular statistical model.

Univariate correlations between knowledge and practice scores approached a moderately strong positive level (Table 16), but this appears to have resulted from confounding (Figure 7). When analyses corrected for differing numbers and compositions of observations from the various hospitals, progressive improvement in quality of the data was associated with a negative trend in the correlation. Correlations found between knowledge and practice were not significant when each component of knowledge and practice scores was given equal weight (Table 16). Canonical correlation analysis suggested that stronger correlations might be achievable by contrasting various aspects of knowledge and practice rather than giving each aspect equal weight (Table 17). Failure to achieve statistical

significance in these multivariate models may be due to a small sample size (35 hospitals relative to 8 variables), since an accepted rule of thumb for multivariate analyses calls for at least ten observations per variable.[79] However, more importantly, the models suggested are not readily interpretable by any logic concerning what is known about the importance of these component aspects of knowledge and practice.

Bias in Knowledge, Practice and Injury Measurements

The 35 hospitals providing covert observations, knowledge tests and needlestick rate data comprised a highly-motivated, non-random, self-selected sample. They were primarily large community-hospitals from urban centers all across Canada, but are not representative of all hospitals in size or type. Approximately 3% of western, mid-western and central but 10% of eastern hospitals participated. Smaller facilities tended to be excluded by the requirement to make observations in a critical care unit, and very few university-affiliated hospitals elected to participate. Further, nurses tested within these hospitals were also volunteers. As a consequence of volunteer bias,[80] these results might therefore be considered to represent maximal rather than mean values if extrapolated to all hospitals. Given the anonymous nature of the covert observations and nurses' tests, it was not possible to make any objective assessment as to the direction or degree of bias. Self-selection bias must therefore be considered an important limit to external validity. Selective reporting bias (e.g.: not reporting injuries from "clean" needles) and recall bias must also be kept in mind with regard to the needlestick injury data.[80]

Have Universal Precautions or Body Substance Isolation Been Effective as Harmonizing Strategies for Hospital Infection Control?

Historically, numerous anecdotal reports and studies show poor compliance

as a common problem under traditional isolation approaches. Indeed, UP/BSI could be considered behavior modification strategies to achieve better compliance. However, most of the few studies documenting performance under these new strategies find poor compliance with infection control precautions under UP. Clements et al., in a covert "before and after" study, found higher rates of colonization and lower compliance with appropriate glove or gown use after implementing UP.[81] Conversely, Klein et al., in a randomized prospective study, found fewer infections and longer infection-free durations among pediatric ICU patients under a protocol similar to BSI as compared to standard care.[82] Baroff et al.'s covert observation of a small number of emergency department procedures and subsequent staff interviews report results consistent with less than 50% compliance, poor exposure-risk knowledge, disagreement with gloving as providing protection during phlebotomy, and complaint that required protective eyewear was not readily available.[83] This is consistent with Kelen et al.'s findings.[84] Hammond et al. similarly found poor compliance during trauma care even if patients were already identified or suspected of HIV.[85] Kaczmarek et al. found average glove-use rates of 92% (drawing arterial blood gas) to 71% (phlebotomy) with significant differences between states with high versus low AIDS incidence rates. They conclude that "glove utilization by health-care workers during procedures in which they may contact patient body fluids is substantial, but not universal."[86] Lynch et al. described improvement in knowledge and compliance on some but not all wards after an intense and comprehensive inservice effort.[87] Wong et al. reported increased use of barrier garments (from 54% to 73%) associated with a decrease in exposure incidents following adoption of UP.[88] However, unlike this thesis research which found composition of observations to be an important confounding variable, these

studies relied upon convenience samples rather than standardized covert observations. Further, completion of daily self-report forms in studies, such as that of Wong et al., may itself prompt behaviour changes artificially. Other self-report surveys that rely upon memory of past events are subject to well-recognized biases. Single-center studies might be considered as hypothesis-generating whereas multicenter research with standardized covert observations provides stronger evidence for or against universal trends.

Hospitals have been motivated to adopt either UP or BSI to quell staff fears of occupationally-acquired HIV infection. Protection of staff against HIV has been the prime motivation for change in Canadian hospitals. This was evident in the administrative survey from reasons stated for adopting UP or BSI. It was also reflected in the finding that receipt of a staff education guideline published in HIV-related literature was more common in every size group than receipt of the BSI handwashing guideline that would not be found in HIV-related literature searches.

This research confirms that, in practice, UP and BSI now mean different things in different hospitals. At the extremes, one site claiming to have implemented UP had eliminated specimen warning labels and all isolation categories other than "Respiratory": this is essentially BSI. Two others claimed adoption of BSI, one specifically recommending against UP, yet retained all of the original isolation categories: this is essentially UP. In many hospitals claiming UP, glove use policy was more in line with BSI. A recommendation to limit UP primarily to visibly-bloody fluids was rejected by approximately half of the hospitals in each size group claiming both adoption of UP and receipt of this guideline. Further, additional terms were introduced by some respondents ("Routine Infection Control Precautions", "Hygienic Precautions", "General

Precautions", "Basic Precautions", "Routine Precautions", "Body Substance Precautions", "Universal Barrier Precautions", "Infection Control Precautions"). Some were synonyms for UP with precautions for all rather than just bloody body fluids; others were synonyms for BSI with more emphasis on handwashing.

Several survey responses suggested confusion between the recently-proposed BSI protocol and CDC's existing "Blood/Body Fluids Precautions" isolation category. This may be due to inadequate receipt of information: two reports by BSI's originators have not been received by a high proportion of Canadian ICP's. Among respondents in the larger size groups claiming adoption of BSI, 36-60% and 18-40% reported not receiving the ANNALS OF INTERNAL MEDICINE and ASEPSIS issues cited. This confusion was also evident among nurses' test responses: uniformly low scores were achieved on paired questions regarding fundamental differences between UP and BSI, and a number of nurses added written comments about being unfamiliar with the term BSI.

A main finding of the administrative survey is that number of beds was the most significant determinant of guideline receipt. Fully one-third of hospitals under 200 beds had not received either CDWR or MMWR guidelines. This is in contrast to the reported American rates of ≥80% receiving and ≥50% reviewing CDC Isolation guidelines.[13] All size groups received federal guidelines more commonly than those published in topical review or medical journals. Although CDWR and the LCDC Guidelines series were distributed without charge to Canadian hospitals, neither was sent unless specifically requested. The original CDC Guidelines series issued in 1981 was mailed, unsolicited, to all U.S. acute-care hospitals. Presence of an ICP and of medical teaching programs were found to be additional significant determinants for receipt independent of bedsize, but interpretation of interaction terms (ICP*size and teaching*size) as

significant determinants of guideline receipt will require further study.

Conflicting guideline statements regarding staphylococcal pneumonia provided an opportunity to consider the depth of review applied by hospitals. A CDC Guideline[4] specifies a private room (as well as staff use of masks and gowns) for staphylococcal pneumonia or draining lung abscess. This is intended to control the extent of environmental contamination by virulent bacteria known for their ability to survive drying. An LCDC Guideline,[89] derived from the CDC document, recommends neither private room nor masks, and specifies gowns for pneumonia but not lung abscess. Only two of the responding sites specifically commented on this discrepancy between CDC and LCDC documents, one stating that they had not previously noted it.

The majority of Canadian hospitals adopting UP, BSI, or "Body Substance Precautions" have not eliminated special warning labels for recognized "infectious" cases, especially with regard to laboratory specimens. This may invite a double-standard. It is difficult to find evidence supporting a belief that such warning labels are effective prompts to take due caution.[90] Over half of ward staff in one confidential survey admitted to routinely using inadequate infection control precautions in the care of patients known or suspected to have HIV infection.[91] Limited accuracy of such labeling was documented by Handsfield et al., who found that only 67% of HIV and 28% of HBsAg seropositive specimens were labelled.[92] However, respondents commented that eliminating specimen warning labels is a controversial proposal. Similarly, Miller and Farr have reported that while 86% of hospital epidemologists agreed with UP and 69% of 121 US hospitals established UP as policy, 74% retained special signs to mark rooms of patients with HIV or hepatitis B.[93]

Only two collaborative efforts between neighboring hospitals were evident

in the administrative survey. Development of common guidelines and educational packages by an Ontario city's Task Force for Implementation of Body Substance Precautions (BSP) (essentially BSI with greater emphasis on handwashing) was the most extensive. One Alberta hospital had initiated comprehensive studies and acted as a regional resource; while adopting "Universal Precautions", their program retains only Respiratory Isolation, eliminates specimen warning labels, and rejects the limitation of UP to bloody fluids (thus, comparable to Ontario's BSP).

This lack of consistency between hospitals was reflected in observed staff practices. Failure to wear gloves at appropriate times has been associated with transmission of viral hepatitis and HIV.[32 39 40 41 94] Addition of single- or double-gloving usually, but not invariably,[95] has been associated with resolution in anecdotal hepatitis outbreak reports. While routine use of gloves as a universal precaution is a reasonable extension of logic, it remains to be demonstrated that the strategy is effective when scaled up. Whether such demonstration would improve staff compliance also remains to be shown, especially since a strong correlation between knowledge and practice was not found in this and another[96] study.

The optimal type and number of gloves to wear have also been points of controversy. Case reports and, more significantly, outbreak investigations using case-control and molecular-typing methods have implicated failure to wear any gloves during direct contact with blood or other body substances in the transmission of various nosocomial pathogens. While the potential severity of such infections is self-evident from these reports, the exact magnitude of this infection risk and of its reduction through routine use of gloves are not known. Handwashing, "no-touch technique" and selective use of gloves were considered

adequate in guidelines prior to the AIDS epidemic. However, in responding to fears triggered by AIDS, UP changed the focus of infection control from protecting patients to protecting healthcare workers. An historic emphasis on handwashing and no-touch technique changed to an emphasis on routine use of gloves. Blood contact with skin can be prevented by gloving.[97] Double-gloving has been shown to reduce the extent of blood exposure during surgery;[98] single- or double-gloving may be equally effective in reducing the volume of blood transferred from a needlestick by 50%.[99]

BSI also stressed routine use of gloves, but for a different reason: handwashing and no-touch technique alone were not proving effective in resolving bacterial cross-infection problems. These new mandates to expand the use of gloves were based solely on extensions of logic. Logically, the next step would be to confirm assumptions of effectiveness. Unfortunately, attention quickly turned from epidemiologic study of glove effectiveness to laboratory study of glove function. "Leakage rates were reported in several papers during Session 55 (Protecting Health Care Personnel) at the October 1988 Interscience Conference on Antimicrobial Agents and Chemotherapy. While discussion stressed the epidemiologic fact that no excess risk has been demonstrable given a seemingly adequate though less-than-perfect barrier, Dr. Frank Young, Commissioner of Food & Drugs, reported to the Third National Forum on AIDS and Hepatitis B last November [1988] that leakage levels are 'alarmingly high' and that FDA plans to use 'a more stringent and sensitive test for gloves than that used for screening condoms.'"[100] It remains to be demonstrated whether routine use of single- or double-gloves can reduce infection risk and whether any such effect is jeopardized by "alarmingly high" leakage rates.

Further evidence against the effectiveness of new infection control

strategies adopted by Canadian acute-care hospitals was found in needlestick injury rates. In order to compare results of studies with varying durations of exposure time, annual risk of one or more needlestick injuries can be estimated as $[1-(1-r)^t]$ where "r" equals a measured risk during shorter time intervals and "t" equals the number of such intervals in one year. The monthly risk of ≈2.3-3.5% found in this research equates to an annual risk of ≈245-350 injuries per 1000 critical care nurses. The former figure is similar to an annual 273.4 injuries per 1000 registered nurses reported recently by McCormick et al.[101] and higher than the 153-194 per 1000 nurses in a five-year study by Linnemann et al.[102] The latter figure is similar to a recent survey of midwives in which 24% claimed one or more needlestick injuries in a preceding six-month period (≈422 per 1000 nurses annually).[103] Hamory, correcting for 40% under-reporting, found an annual incidence rate of 611 per 1000 nurses and cautioned against reliance upon employee health records to assess changes in injury rates.[104] Correction for under-reporting in the 2.3% health record based rate found in this research suggests a figure similar to that reported by Hamory. The level of risk found among Canadian critical care nurses is commensurate with previous reports and remains cause for concern. Beyond a potential for transmission of hepatitis B and HIV, the direct costs of sharps injury postexposure investigation and treatment are appreciable.[105] [106]

The perception that needle-handling practices have not improved, the confirmation that discarded needles are still recapped frequently, a finding of injury rates commensurate with rates reported prior to adoption of UP and BSI guidelines, demonstration of only borderline statistical significance in rate reduction trends and no evidence of a relationship between rates of needle recapping and needlestick injury in this multicenter hospital study reinforce a

suggestion that UP and BSI have missed the point on needlesticks.[62] Needlestick injury is the predominant occupational exposure to HIV, and preventing occupational HIV exposure was expressed as Canadian hospitals' primary motivation for adopting new infection control strategies.

In conclusion, returning to Table 1's list of assessment criteria, these results provide little reason to believe that infection control practices have become uniform between or even within facilities under UP or BSI (Table 20). Guidelines defining these strategies were not received by all hospitals, especially those smaller facilities most in need of expert guidance, and the degree to which those receiving guidelines reviewed their content may not be adequate. There were inconsistencies in policies between nearby hospitals as well as within hospitals (e.g.: the low correlation between warning label use for housekeeping versus the laboratory). Appreciable proportions of nurses had not received inservice education and held divergent views. Appreciable proportions of nurses were observed to disregard their hospital's policies on glove use and needle recapping in spite of expressed agreement with those policies. This research also failed to produce convincing evidence linking reduced needle recapping with reduced needlestick injury rates. The low level of effectiveness discovered for strategies which may cost as much as $10-million per case of HIV seroconversion prevented is disappointing.

Recommendations for Improving the Research Tools

Survey forms and questionnaires were designed, pretested and validated because established tools were not available. These new tools may be of value in future research studies and hospital quality assurance projects.

The forms developed for the administrative survey could be useful for similar cross-sectional surveys in other countries, or for repeated surveys to

Table 20:
Status of UP/BSI in Canadian Acute-Care Hospitals, 1990

EVALUATION CRITERION	FINDINGS WITH REGARD TO: STRUCTURE	PROCESS	OUTPUT	OUTCOME
1. Hospitals have received adequate information to make informed decisions;	≈37% of smaller hospitals didn't receive guidelines	<1% of all hospitals noted major conflict in CDC vs LCDC guidelines	Few knew how UP and BSI differ	≤19% could identify their UP/BSI-related costs
Hospitals adopted appropriate policies consistent with the system selected.			≈75% claim UP or BSI; ≤5% adopted all policies expected	
2. Hospital staff understand and accept UP or BSI	Most sites mandated education for all staff	Many nurses did not receive education re: UP/BSI	Mean staff score ≈54% on test of knowledge	Many nurses held divergent opinions and disagreed with new policies
3. Staff adhere to recommended UP or BSI guidelines in their daily work practices;	All sites providing policies mandated protective apparel.	Hospitals rarely monitored compliance or provided feed-back to staff	Glove-use compliance ≈60% but ranged widely among hospitals ≈50% of hospitals reported ≤25% needle recapping	
Use of UP or BSI practices leads to reduced infection risk.				Needlestick injury rates comparable before and after UP/BSI

study changes over time. This 1989 survey provided a picture of hospital operation at one point in time. It would be interesting to learn, for example, if guideline receipt patterns change or if more becomes known about costs and benefits of evolving new infection control strategies in the future.

Two changes might make the questionnaires even more useful. First, since the types of "isolation" used (e.g.: "Strict", "Respiratory", etc.) are intrinsic to defining which strategy or system was adopted by each hospital, this area should be made more explicit. Sufficient information was volunteered in open-text replies, but more explicit interrogation on this point would be prudent. Second, since the marginal costs of UP and BSI are poorly detailed and their benefits are even more obscure, a series of questions dealing with economic aspects should be added. A careful cost-effectiveness study of alternative infection control strategies would provide important information.

The forms used to record covert observations of daily practice could be useful in hospitals' on-going quality assurance audits. Substantial agreement among different ICPs' independent observations of nursing practices was not confirmed in this research, but has been reported in a small study by others.[107] Observer accuracy and agreement, essential to validity and reliability of infection control research studies, deserve further study. The composition of observations sampled was not evaluated as a potential confounding variable in previous studies, but was found as an important source of distortion in this research. Future studies should establish observation quotas and schedules, as was done in this research, rather than rely on convenience samples. It was not feasible to evaluate observers' performance, for example in watching a videotape of specific nursing practices, but this could be considered in future studies.

The knowledge and beliefs test validated in this study should be useful for

hospitals' educational needs assessments and evaluation of in-service education programs. With minor modification, it would provide a practical, valid and sufficiently reliable means to measure knowledge of infection risks and control measures in nursing practice under UP/BSI. Such assessment is important in developing and promoting effective infection control programs. Use of this test in additional hospital studies is encouraged.

This study used photocopied, double-sided forms with sequentially-numbered questions. Individual-history questions #7 and #32 (unscored items) and, collectively, questions #9-21 (the entire second page) were left blank with disproportionate frequency. While only ≈1.6% of returned tests were spoiled by missing answers, this might be improved by better typeset quality or use of single-sided forms.

Interactive response to a computerized "interview", unlike use of forms, would allow direct control of quality (no missing answers, out-of-range responses, transcription errors, etc.) and encryption of data (supporting confidentiality for participating staff). The software provided required neither computing nor typing expertise to install or operate. However, results are in agreement with unpublished data suggesting that fewer than one-third of North American ICPs have computer support and nurses' access to other computers is limited (market survey, Applied Epidemiology, Sidney, British Columbia). Computer-based survey of hospitals, whether by modem or mailed disks, is not yet a viable option for hospital epidemiology research.

No serious ambiguity or validity concerns were expressed by ICPs after receiving tabulated summaries of test results. Inclusion of test statements better answered by "yes" or "no" rather than on a Likert scale was identified as a source of difficulty in specific comments written on tests by critical care

nurses. Answers to such questions were penned in the margin rather than indicated on the Likert scale of several tests. Several test items regarding local policy were phrased as requiring or prohibiting certain practices; in retrospect, it would be preferable to substitute "encouraging" or "discouraging" since alternatives were allowed in some policies (e.g.: discouraging needle recapping but offering a preferred method if recapping were deemed necessary). Potentially ambiguous test items specific to knowledge of local policy were therefore not scored. There is no "gold standard" against which to establish criterion validity for this test. Satisfactory review by 35 ICPs is therefore important confirmation of test validity achieved through appropriate test content and expert consensus, but the test could be improved by rewording its local policy questions and substituting "yes/no" boxes for personal history responses. Further refinement and assessment of test reliability would also be desirable.

The database management software written for this research is as important as the forms themselves. Without it, the task of accurately extracting data from the forms would be insurmountable. Designing, programming, debugging and documenting the code required a formidable number of hours. The existing database management system could be refined by adding user-level help or documentation; additional index files and options to search for hospitals by name, region, size, etc., rather than solely by site number; and by creating more standard output report formats now that the methods of analysis are defined. Speed of operation and size of files could also be improved by upgrading to a product release more recent than the version of FoxBASE used.

VI. Conclusions and Recommendations

Health policy is influenced by political, cultural, economic and technological factors as well as by epidemiologic information. The latter is not always compelling and sometimes frankly ignored. Some hospital epidemiologists and infection control practitioners also have lacked sufficient status, authority, autonomy or support to shape hospital infection control policies efficiently.[108] Hospitals adopt procedures believed effective to prevent infection and periodically modify their strategies when epidemiologic evaluations fail to document effectiveness. Universal Precautions and Body Substance Isolation are the most recent modifications, and these new national strategies were evaluated in this multi-center research.

Table 20 indicates failures at all levels of structure, process, output and short-term outcome. The long-term outcome of reduced risk to hospital patients and health-care workers remains a noble goal. In order to achieve this, improvements are needed in the forces acting upon hospital practice (structure), the measures taken within hospitals themselves (process) and measurement of what actually is done as daily practice (output). A conceptual model of goals, objectives and related assumptions fundamental to all hospital infection control programs is shown in Appendix 1. Within this context, the following conclusions and recommendations are made. Beyond these, the relatively small number of hospitals completing all phases of this research underscores workload conflicts as a limiting factor. ICP staffing, supervision, computer support and priorities are related issues that cannot be addressed directly here. Alternatives to a traditional infection control program structure should be considered so that applied research may be supported more extensively in hospital epidemiology.[109]

Recommendations for Improving New Infection Control Strategies

1. UP and BSI cannot be cost-effective solely in terms of protecting health care workers from blood-borne infection, the motivation for their adoption claimed most frequently in this research. UP and BSI are costly, their focus is on gloves and gowns whereas 70-90% of health care workers' hepatitis B and HIV nosocomial infections derive from sharps injuries and the incidence of such infections is already low. We need to refocus infection control on protecting patients as well as staff and visitors. BSI may be cost-effective in this broader context, but research to explore this must receive greater priority.

2. Sharps injuries pose a much greater risk of blood-borne infection for health care workers than does skin contact. However, this research found a relatively low proportion of hospitals using promising new protective devices in comparison to the larger proportion accepting increased costs for gloves and gowns. As noted by McCormick et al.,[105] there should be commensurate spending to purchase and evaluate novel devices which could reduce sharps injuries.

3. UP and BSI are influential new initiatives, but have lost any specific meaning in practice. Three-quarters of Canadian hospitals adopted the names, but not all of the policies recommended in published guidelines for these strategies. Confusion over the meaning of UP and BSI was evident in survey responses. Fewer than half of the nurses in half of the hospitals surveyed felt that their hospital's policies were practical, effective and well-documented. ICPs, hospital epidemiologists and other staff members in their hospitals should discuss the implications of these different strategies at the working level. UP and BSI need to be redefined from the perspective of health care workers, not consultants who are distant from provision of care itself.

4. Expert interpretation of research studies and consensus on recommended

practices is potentially beneficial to all hospitals and health-care agencies. Those with their own resources can use these guidelines as starting points. Those without in-house or networked expertise could accept such guidelines as a basis for responsible policies, but were found to be the least likely to have received published guidelines. This presents two problems: How many different expert working groups need to produce guidelines independently; how can current guidelines best be provided to hospitals? Better coordination should be a priority to reduce duplication of effort as well as opportunities to introduce contradictions and typographical errors which may mislead unwary end users. A plethora of guidelines and revisions for UP has been issued over the past few years from federal, state, provincial, regulatory and professional associations with but limited opportunity for widespread review of preliminary drafts by interested parties. Since these guideline updates and revisions are published at irregular intervals, are advertised in publications to which only some hospitals subscribe, and are not received unless specifically requested, a means for placing standing orders or otherwise improving distribution would help to assure that appropriate parties always have current versions of recommended practices.

5. Administrators need to ensure that a comprehensive, practical system emerges which is consistent with a guiding philosophy and capable of achieving clearly stated, realistic goals. Further, administrators need to ensure that policies in all departments throughout their hospital become consistent with the system selected as quickly as possible. Piecemeal implementation, poor knowledge of costs and inconsistency in policies were evident in this research.

6. The prospect of regulatory or accreditation agencies stifling applied research by mandating one set of unproven guidelines as the only acceptable

approach is cause for concern. The prospect of guidelines being accepted without careful review by qualified individuals in health-care institutions is equally distressing. This research failed to produce convincing evidence linking UP, BSI and avoidance of needle recapping with widespread improvement in rates of needlestick injury, the only quantifiable risk for occupational HIV transmission. As Gerberding recommends, "Until additional research clarifies the value of current infection control policies, standards should maximize institutional autonomy to develop rational strategies consistent with local practice and perceived needs."[90] Hospitals need tools now, not rules.

7. Higher priorities should be placed on having ICPs and hospital epidemiologists carefully assess implications of changes proposed in new guidelines, discuss new recommendations with other health-care workers so as to provide liaison with those who must actually live with proposed measures, and assist in establishing institutional process review audit mechanisms. Few hospitals were prepared to undertake such audits. This research documented widespread deficiencies in knowledge and policy compliance as well as lack of correlation between knowledge and practice. Validated audit tools are needed.

8. Noncompliance again was found to be a primary impediment to the effectiveness of infection control strategies. Innovative approaches to motivate behavior change must be developed and evaluated. Further research should seek unique features that distinguish between hospitals exhibiting relatively low versus high levels of staff compliance with policies.

9. In future studies, compliance should be measured by standardized covert observations. The number and composition of such observations was found to be an important confounding variable in this research.

BSI was formulated through a fresh look at unresolved cross-infection

problems. UP replied to an emotional response triggered by the fatal nature of AIDS, not by quantified occupational-risk assessment of blood-borne diseases (hepatitis B, with its quantitatively higher risk of morbidity and mortality for health care workers, should have motivated the development of such precautions much earlier). This dichotomy, together with a paucity of hospital-initiated applied research found in the biomedical literature, prompts one final recommendation. Hospitals have traditionally focused on problem identification as their basis for quality assurance. Some hospitals are now expressing interest in industrial methods of Total Quality Management (TQM) and Continuous Quality Improvement (CQI).[110] Infection control, like quality assurance, should be viewed as a journey of evolution, not simply enforced compliance with one set of rules. Administrators are long overdue in expecting qualified infection control or hospital epidemiology staff to provide important program planning and evaluation information.[111] [112] In fact, TQM and CQI bear many similarities to Williamson's method for finding "achievable benefit not achieved" opportunities to improve quality of service.[113] Hospital epidemiology and infection control programs should be expected and supported to provide the tools and mechanisms to take fresh looks at all aspects of hospital service. Their heritage of being reactive to adverse events will not continue to suffice in a future that requires a proactive focus on quality improvement.

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Appendix 1: Conceptual Models:

Comparison of Isolation Strategies
Infection Control Goals, Objectives and Assumptions

Table 21:
Comparison of Isolation Strategies

STRATEGY:	PURPOSE:	PROMPTED BY:	APPLIES TO:	DESCRIPTION:
TRADITIONAL STRATEGIES:				
Category-Specific Isolation CDC, 1983	Prevent the spread of microorganisms among patients, personnel and visitors.	Patient's Diagnosis	Certain body fluids and substances (disease-specific)	Selective application of supplementary precautions grouped into categories
Disease-Specific Isolation CDC, 1983	Prevent the spread of microorganisms among patients, personnel and visitors.	Patient's Diagnosis	Certain body fluids and substances (disease-specific)	Selective application of supplementary precautions selected item-by-item
NEW STRATEGIES:				
Body Substance Isolation Lynch, Jackson et al. 1987	Reduce cross-infection risk to patients, and protect staff from microorganisms harbored by patients	Type of Patient Contact	All body fluids and substances	Replaces Category- or Disease-Specific System with one set of hygienic measures for all
Universal Precautions CDC, 1987	Reduce risk to staff from bloodborne pathogens	Type of Patient Contact	All body fluids and substances	A basic level of hygienic measures used in conjunction with traditional system
Universal Precautions CDC, 1988 Revision	Reduce risk to staff from bloodborne pathogens	Type of Patient Contact and Body Fluid	Body fluids associated with hepatitis B transmission	A basic level of hygienic measures used in conjunction with traditional system

Table 22:
Infection Control Goals, Objectives and Assumptions

Long-term Goals:
1. Minimized occupational risk of nosocomial infection for staff
2. Minimized iatrogenic risk of nosocomial infection for patients
3. Minimized risk of widespread antimicrobial resistance for community

Assumptions:
1. Staff and patients can be infected through exposure incidents, but these incidents are preventable through "isolation" and/or other precaution protocols. UP assumes that isolation of identified cases is necessary and effective; BSI assumes that all cases cannot be identified reliably and that special "isolation" protocols to prevent direct or indirect contact transmission are inappropriate.
2. Hospital-acquired infections are sufficiently serious to warrant preventive action.
3. Transmission of exogenous infection to patients can be prevented.
4. Following expert guidelines will, in fact, reduce infection risk.
5. Prevention is more cost-effective than treatment alone.
6. Cross-infection contributes more to the prevalence of drug resistance than de novo development of resistant organisms.
7. Hospitals are major sources of novel drug resistance in the community.

Intermediate-term Objectives
1. Institutions will develop and update infection control policies and procedures from pertinent published guidelines.
2. Staff will follow infection control policies and procedures in providing patient care.
3. Hospitals will monitor infection rates and staff performance.

Assumptions:
1. Institutional programs review appropriate sources of information.
2. Policies developed from guidelines and refined through in-house monitoring are perceived as practical and beneficial by ward staff.
3. UP assumes that "isolation" is an effective behaviour-prompt to improve handwashing and gloving; BSI assumes that a multitude of isolation types is unnecessarily confusing.

Short-term Objectives
1. Pertinent expert guidelines will be available to hospitals.

Assumptions:
1. Guidelines will be effective in shaping institutional policy.
2. Expert interpretation is required.

Appendix 2: Hospital Survey Questionnaire Forms

English Version
French Version

TO: INFECTION CONTROL PRACTITIONER

FROM: David Birnbaum, MPH

RE: **Evaluation of Universal Precautions/Body Substance Isolation**

INTRODUCTION:

I am a Ph.D. student registered in an interdisciplinary program at University of British Columbia, supported by a Fellowship from the National Health Research and Development Program of Health and Welfare Canada. My thesis studies use and effectiveness of Universal Precautions and Body Substance Isolation. This study is endorsed by the Canadian Hospital Association. Your assistance in consenting to participate by completing this confidential questionnaire will be greatly appreciated. It should take no more than 15 minutes, and you are under no obligation to participate in subsequent phases.

This first phase investigates current Canadian hospital practices; a second phase will involve on-site study of implementation in selected hospitals; the final phase will compare effectiveness in reducing infection exposure risks to patients or staff. This questionnaire provides the means to indicate if you would like to receive preliminary results or details of subsequent phases. Published results will not identify individual facilities nor infection control practitioners by name or location. Please return your completed questionnaire in the mailing envelope provided or by FAX (604-875-4013). Please include your mailing address if you wish to receive final results of this survey or wish to participate further.

FACILITY DESCRIPTION:

Please fill in the blank or circle the appropriate number(s) to describe your facility:

1. MAJOR FUNCTION:
   (1) Acute-Care Primary Community Hospital
   (2) Acute-Care Regional Referral Hospital
   (3) University Teaching Hospital
   (4) Residential Care Facility
   (5) Other (specify) _____

2. NUMBER OF BEDS: _____

3. NUMBER OF INPATIENTS/YEAR: _____

4. NUMBER OF OUTPATIENTS/YEAR: _____

5. NUMBER OF INFECTION CONTROL PRACTITIONERS: FULL-TIME ___ PART-TIME ___

6. LOCATION:
   (1) City Centre
   (2) City Suburb
   (3) Town/Village
   (4) Unincorporated Area

7. DO YOU PROVIDE:
   (1) Hemodialysis
   (2) Drug Abuse Clinics
   (3) STD/AIDS Clinics
   (4) Internships
   (5) Residency Training

8. WHEN WERE YOU LAST ACCREDITED?
   Date _____
   Agency _____
   Status _____

UNIVERSAL PRECAUTIONS/BODY SUBSTANCE ISOLATION

Has your facility made a formal decision to adopt or reject UNIVERSAL PRECAUTIONS or BODY SUBSTANCE ISOLATION? Which one? What factors were influential in the decision?

What advantages and problems do you foresee in implementing these strategies?

Do you have any data regarding implementation or operating costs as compared to category- or disease-specific isolation programs?

Regardless of policy, do you feel that at least half of ward staffs still recap used needles?

What type of disposal containers are in use, and how are needles transported from the point of use to the point of disposal (ie: recapped, placed on tray, stabbed into foam block, hand-carried, etc.)?

What additional information would you want, if any, in order to confidently recommend for or against Universal Precautions?

...to recommend for or against Body Substance Isolation?

CURRENT POLICIES:

FOR EACH POLICY PLEASE FILL IN EITHER ONE "YES" OR "NO" BOX IN EACH COLUMN TO INDICATE IF YOU HAVE ALREADY:

POLICY GUIDELINE & SOURCE:	RECEIVED PUBLICATION YES	NO	REVIEWED PUBLICATION YES	NO	ADOPTED GUIDELINE YES-DATE (mm/yy)	NO
Universal Precautions ends need for warning labels on specimens. CANADA DISEASES WEEKLY REPORT 1987;13S3	☐	☐	☐	☐	☐ _____	☐
Handwashing is unnecessary after removing gloves worn for anticipated contact with blood, secretions, mucous membranes or lesions unless hands are visibly soiled. ANN INTERN MED 1987;107:243	☐	☐	☐	☐	☐ _____	☐
Private room is recommended for Staph. pneumonia. 1983 CDC "GUIDELINE FOR ISOLATION PRECAUTIONS IN HOSPITALS"	☐	☐	☐	☐	☐ _____	☐
Private room not recommended for Staph. pneumonia. 1985 HEALTH & WELFARE CANADA "ISOLATION AND PRECAUTION TECHNIQUES" INFECTION CONTROL GUIDELINES	☐	☐	☐	☐	☐ _____	☐
Securely bag all trash & linen to prevent leakage; no additional labels, double bags or special handling are needed for infectious cases. ASEPSIS 1986;8(4):2	☐	☐	☐	☐	☐ _____	☐
Health care workers should be trained in infection-control procedures designed to prevent transmission of blood-borne pathogens and be advised to use these procedures for all patients. N ENGL J MED 1986;315:1562	☐	☐	☐	☐	☐ _____	☐
Universal Precautions don't apply to feces, urine, nasal secretions, sputum, sweat, tears, vomitus, saliva or breast milk unless they contain visible blood. MMWR 1988;37(24):377	☐	☐	☐	☐	☐ _____	☐

Would you like to receive preliminary results of this study? YES___ NO___

Would you like to participate further in this study? YES___ NO___

AU: Directeur du programme de contrôle des infections

DE: David Birnbaum, MPH

RE: **Évaluation des Précautions élémentaires/Isolation des substances organiques**

INTRODUCTION:

Je suis un étudiant au doctorat, inscrit à un programme interdisciplinaire à l'Université de Colombie-britannique. Je suis également boursier du Programme national de recherche et de développement en matière de santé. Mon sujet de thèse est l'utilisation et l'efficacité des Précautions élémentaires et de l'Isolation des substances organiques. Cette recherche est approuvée par l'Association des hôpitaux du Canada. Votre participation sera fort appreciée; il s'agit de compléter ce questionnaire confidentiel. Cela ne prendra que 15 minutes et vous n'êtes pas obligé de participer aux étapes subséquentes.

Cette première étape est une étude des pratiques actuelles dans les hôpitaux canadiens; une seconde étape consistera à l'implantation dans des hôpitaux sélectionnés; la dernière étape comparera l'efficacité à réduire les risques d'infection pour les patients et le personnel. Ce questionnaire vous permettra d'indiquer si vous désirez recevoir les résultats préliminaires ou le détail des étapes subséquentes. Les résultats n'identifieront pas les individus et les institutions ayant participé, ni par leur nom, ni par leur emplacement. Veuillez s'il-vous-plaît retourner ce questionnaire rempli dans l'enveloppe ci-incluse ou par FAX (604-875-4013). N'oubliez pas d'ajouter votre adresse si vous désirez recevoir les résultats finals de cette enquête ou si vous voulez participer aux étapes subséquentes.

DESCRIPTION DE L'ÉTABLISSEMENT:

Prière de répondre dans l'espace laissé en blanc ou encore d'encercler le ou les numéros décrivant votre établissement:

1. PRINCIPALE FONCTION:
   (1) hôpital communautaire de soins aigus
   (2) hôpital régional de références
   (3) hôpital d'enseignement universitaire
   (4) établissement résidentiel
   (5) Autre (spécifiez)_____

2. NOMBRE DE LITS: _____

3. NOMBRE DE PATIENTS PAR ANNÉE:_____

4. NOMBRE DE CONSULTATIONS EN CLINIQUES EXTERNES PAR ANNÉE:_____

5. NOMBRE DE PRATICIENS AU CONTROLE DES INFECTIONS:
   à plein temps:____ à temps partiel:____

6. EMPLACEMENT:
   (1) Centre-ville
   (2) Banlieue
   (3) Ville/village
   (4) Région non-incorporée

7. OFFREZ-VOUS:
   (1) Hémodialyse
   (2) Clinique de desintoxication
   (3) Clinique de MTS et SIDA
   (4) internat
   (5) postes de résidence

8. A QUAND REMONTE VOTRE DERNIERE ACCRÉDITATION?
   Date _____
   Agence _____
   Statut _____

PRÉCAUTIONS ÉLÉMENTAIRES/ISOLATION DES SUBSTANCES ORGANIQUES

Est-ce que votre établissement a formellement décidé d'adopter ou de rejeter les Précautions élémentaires ou l'Isolation des substances organiques? Laquelle des deux stratégies a été adoptée ou rejetée? Quels facteurs ont influencé cette décision?

Quels avantages et quelles difficultés prévoyez-vous dans l'implantation de ces stratégies?

Avez-vous des informations concernant les coûts d'implantation ou d'opération de ces stratégies comparativement aux programmes d'Isolation spécifique par catégories ou maladies?

Indépendamment des politiques, croyez-vous qu'au moins 50% du personnel affecté aux salles remballe les aiguilles utilisées?

Quel type de contenant est utilisé pour disposer des aiguilles et comment ces aiguilles sont-elles transportées de l'endroit d'utilisation à l'endroit où on en dispose (remballées, placées sur des plateaux, piquées dans des blocs de caoutchouc mousse, portées dans les mains, etc.)?

Quelles informations supplémentaires voudriez-vous recevoir, au besoin, pour pouvoir recommander ou déconseiller l'usage des Précautions élémentaires?

...pour recommander ou déconseiller l'usage de l'Isolation des substances organiques?

POLITIQUES COURANTES:

Pour chaque politique, prière de placer un X dans la case "OUI" ou "NON" dans chacune des colonnes pour indiquer si vous avez déjà:

POLITIQUE ET SOURCE:	REÇU LA PUBLICATION OUI	REÇU LA PUBLICATION NON	REVU LA PUBLICATION OUI	REVU LA PUBLICATION NON	ADOPTÉ LA POLITIQUE OUI-DATE (m/a)	ADOPTÉ LA POLITIQUE NON
Les Précautions élémentaires ne requièrent plus d'avertissement sur les étiquettes des échantillons. CANADA DISEASES WEEKLY REPORT 1987;13S3	☐	☐	☐	☐	☐ _____	☐
Laver les mains n'est pas nécessaire après avoir enlevé des gants portés pour empêcher le contact avec le sang, les sécrétions, les membranes muqueuses ou les lésions, à moins que les mains ne soient visiblement souillées. ANN INTERN MED 1987;107:243	☐	☐	☐	☐	☐ _____	☐
Chambre privée recommandée pour pneumonie à staph. 1983 CDC "GUIDELINE FOR ISOLATION PRECAUTIONS IN HOSPITALS"	☐	☐	☐	☐	☐ _____	☐
Chambre privée n'est pas nécessaire pour pneumonie à staph. 1985 HEALTH & WELFARE CANADA "ISOLATION AND PRECAUTION TECHNIQUES" INFECTION CONTROL GUIDELINES	☐	☐	☐	☐	☐ _____	☐
Bien emballer tout déchet ou linge pour prévenir les fuites; les cas d'infection ne nécessitent pas d'autre étiquetage, ni sacs doubles, ni maniement spécial. ASEPSIS 1986;8(4):2	☐	☐	☐	☐	☐ _____	☐
Les travailleurs de la santé doivent être renseignés sur les procédures de contrôle des infections afin de prévenir la transmission des agents pathogènes par le sang; on doit aussi les aviser d'utiliser ces procédures pour tous les patients. N ENGL J MED 1986;315:1562	☐	☐	☐	☐	☐ _____	☐
Les Précautions élémentaires ne s'appliquent pas aux excréments, urine, sécrétions nasales, larmes, expectorations, transpiration, salive, ou lait de femme à moins que ceux-ci ne contiennent du sang de façon visible. MMWR 1988;37(24):377	☐	☐	☐	☐	☐ _____	☐

Voulez-vous recevoir les résultats préliminaires de cette étude? OUI___NON___
Voulez-vous participer aux étapes subséquentes de cette étude? OUI___NON___

Appendix 3: Nurses' Questionnaire Forms

English Version
French Version
Expected Responses, References and Question Pairings

TO: NURSING STAFF MEMBERS

FROM: David Birnbaum, MPH

RE: **INFECTION CONTROL PRACTICES SURVEY**

INTRODUCTION:

My work toward a Ph.D. at University of British Columbia, supported by a Fellowship from the National Health Research and Development Program of Health and Welfare Canada, involves researching the effectiveness of several different approaches to infection control measures. Your facility has elected to participate in this national survey; your help in answering this confidential questionnaire will be greatly appreciated.

Published results will not identify individual facilities nor staff members by name. You have been selected at random to receive a questionnaire. Please respond to every statement but do NOT write your name on the form. You are free to decline without repercussions if you do not wish to participate; to decline, please simply return the blank form.

PLEASE CIRCLE A NUMBER TO INDICATE WHETHER YOU (STRONGLY) AGREE, DON'T KNOW, OR (STRONGLY) DISAGREE WITH EACH OF THE FOLLOWING STATEMENTS:

STATEMENT	STRONGLY AGREE	AGREE	DON'T KNOW	DIS-AGREE	STRONGLY DISAGREE	COMMENTS (OPTIONAL)
1. Risk of AIDS and hepatitis B are equal: most needlestick exposures lead to infection with either disease.	1	2	3	4	5	
2. In order to implement necessary "isolation" precautions, patients should be screened for AIDS and hepatitis B upon admission.	1	2	3	4	5	
3. This hospital's policies require a special warning label on laboratory specimens from patients with AIDS or viral hepatitis.	1	2	3	4	5	
4. The primary purpose of "Body Substance Isolation" is to protect healthcare workers from AIDS and hepatitis B in the workplace.	1	2	3	4	5	
5. Hepatitis B virus in blood that has dried on environmental surfaces may still be infectious.	1	2	3	4	5	
6. All healthcare workers who receive three properly administered doses of hepatitis B vaccine will gain life-long immunity.	1	2	3	4	5	
7. I have received a complete series (3 doses) of hepatitis B vaccine.	1	2	3	4	5	
8. Body Substance Isolation is a system for infection precautions that eliminates the need for isolation categories (Strict, Enteric, etc.) except for one category for airborne communicable infections.	1	2	3	4	5	

STATEMENT	STRONGLY AGREE	AGREE	DON'T KNOW	DIS-AGREE	STRONGLY DISAGREE	COMMENTS (OPTIONAL)
9. Needlestick injury is the single most significant source of occupational infection with hepatitis B or HIV among healthcare workers.	1	2	3	4	5	
10. Used needles should be recapped immediately after use with patients to prevent needlestick injury.	1	2	3	4	5	
11. This hospital's policies prohibit recapping of used disposable needles.	1	2	3	4	5	
12. The risk of needlestick injury in manipulating the connections within IV lines (eg: mini-bag, heparin lock use, etc.) is higher than the risk of injury in giving injections with hypodermic syringes.	1	2	3	4	5	
13. A significant proportion of needlestick injuries result from missing or penetrating a cap while recapping used syringe needles.	1	2	3	4	5	
14. I have received instruction during the past year on this hospital's policies for safe handling of sharps.	1	2	3	4	5	
15. When suctioning, a single sterile glove is worn on the dominant hand to protect the patient from infection.	1	2	3	4	5	
16. Handwashing is NOT necessary after removing gloves unless the hands are visibly soiled.	1	2	3	4	5	
17. This hospital's policies require gloving for any activity likely to cause contact with blood, secretions, excretions, mucous membranes, or open lesions.	1	2	3	4	5	
18. The primary purpose of gloving under "Universal Precautions" is to protect patients from bacterial and viral cross-infections.	1	2	3	4	5	
19. Gloves do NOT provide any real protection since they leak and there isn't evidence showing that their use prevents transmission of infection.	1	2	3	4	5	
20. Gloves may be worn from patient to patient if gloved hands are washed between patients.	1	2	3	4	5	
21. I have received instruction during the past year on this hospital's policies for proper use and disposal of gloves.	1	2	3	4	5	

STATEMENT	STRONGLY AGREE	AGREE	DON'T KNOW	DIS-AGREE	STRONGLY DISAGREE	COMMENTS (OPTIONAL)
22. Universal Precautions and Body Substance Isolation require that vinyl or latex gloves be worn for every patient-care activity.	1	2	3	4	5	
23. Most studies have shown that nurses wash their hands adequately between patient care activities.	1	2	3	4	5	
24. Staff members who are NOT immune to chickenpox may safely care for patients with chickenpox or herpes zoster.	1	2	3	4	5	
25. I have received in-service instruction from this hospital explaining the application of "Universal Precautions".	1	2	3	4	5	
26. Universal Precautions or Body Substance Isolation eliminates a need for "biohazard" warning labels on specimens from infected patients.	1	2	3	4	5	
27. Everything discarded in any "isolated" patient's room should be incinerated or sterilized as "infectious waste".	1	2	3	4	5	
28. Universal Precautions prohibits disposal of any patient wastes in a community's sanitary landfill.	1	2	3	4	5	
29. This hospital's infection control measures are practical, effective, and well-documented.	1	2	3	4	5	
30. The primary purpose of Universal Precautions is to protect patients and staff from all types of nosocomial infections.	1	2	3	4	5	
31. I have had one or more needlestick injuries at this hospital during the past 30 days.	1	2	3	4	5	
32. This questionnaire was difficult to understand.	1	2	3	4	5	

Please return, whether completed or not, in the envelope provided.

A: Membres du Personnel/Infirmières

DE: David Birnbaum, MPH

SUJET: **Enquête sur les Stratégies pour Contrôle d'Infection**

INTRODUCTION:

Mes travaux envers un Ph.D. à l'université de la Colombie Brittanique, appuyés par un bourse du Programme National de Recherche et de Dèveloppement en Matière de Santé, Santé et Bien-être Social Canada, impliquent une recherche sur l'efficacité d'un certain nombre de stratégies différents utilisées pour le contrôle d'infection. Votre section de service a choisi de participer à ce questionnaire national; nous apprécions beaucoup votre collaboration en répondant à ce questionnaire confidentiel.

La publication des résultats se gardera d'identifier, soi les sections de service particulières òu les membres du personnel. Votre nom a été selectionné à la pige pour recevoir ce questionnaire. Veuillez s.v.p. répondre à chacune des questions, mais prier de ne pas écrire votre nom sur le formulaire. Le choix de répondre à ce questionnaire est facultatif et sans répercussion, quel que soi ce choix. Si vous optez de ne pas y répondre, veuillez renvoyer le formulaire comme tel.

VEUILLEZ ENCERCLER LE NUMÉRO INDIQUANT VOTRE CHOIX DE PRÉFÉRENCE: (1) ABSOLUMENT D'ACCORD, (2) D'ACCORD, (3) NE SAIS PAS, (4) PAS D'ACCORD OU (5) DEFINITIVEMENT PAS D'ACCORD POUR CHACUN DES ENONCÉS SUIVANTS.

ENONCÉS	ABSOLUMENT D'ACCORD		NE SAIS PAS		DÉFINITIVEMENT PAS D'ACCORD	COMMENTAIRES
1. Les risques d'enquérir le CIDA òu l'hépitate B sont équitables: la plupart des ouvertures d'aiguilles sont précurseurs de l'infection de soi l'une ou l'autre des maladies.	1	2	3	4	5	
2. Afin d'implanter les précautions d'isolation nécéssaires, les patients devraient subir un examen scrutaire pour déterminer l'existence de CIDA et d'hépatite B avant admission.	1	2	3	4	5	
3. Les politiques de cet hopital exigent une étiquette d'avertissement identifiant les spécimèns de laboratoire provenant de patients avec le CIDA ou l'hépatite viral.	1	2	3	4	5	
4. Le but primordial d'Isolation de Substance Organiques est de protéger ceux et celles au service de la santée, de l'infection du CIDA et d'hépatite B dans le milieu du travail.	1	2	3	4	5	
5. Le virus d'hépatite B peut être encore infectueux même s'il se trouve dans le sang asséché sur une surface environnementale.	1	2	3	4	5	

ENONCÉS	ABSOLUMENT D'ACCORD		NE SAIS PAS		DÉFINITIVEMENT PAS D'ACCORD	COMMENTAIRES
6. Toute personne au service de la santé qui reçoit 3 doses de vaccin Hépatite B proprement administrées est immunisée pour la vie.	1	2	3	4	5	
7. J'ai reçu l'immunization complète du vaccin Hépatite B (3 doses).	1	2	3	4	5	
8. L'Isolation de Substances Organiques est un système pour les précautions envers l'infection, qui élimine la nécéssité de catégories d'isolation (eg. STRICT, ENTERIC, etc.) sauf une catégorie d'infection transmissible aéroportée.	1	2	3	4	5	
9. Dans ce métier, le foyer d'infection avec l'hépatite B ou le HIV qui est le plus significatif entre ceux ou celles au service de la santé est la blêssure d'aiguille.	1	2	3	4	5	
10. Les aiguilles usager doivent être recapsulées immédiatement suivant leurs usage sur le patient afin de prévenir toute blêssure d'aiguille.	1	2	3	4	5	
11. Les politiques de cet hôpital interdisent le recapsulement des aiguilles-à-jeter usagées.	1	2	3	4	5	
12. Le risque de blessure d'aiguilles, subit durant la manipulation des connections de ligne IV contrairement au même risque provenant de piqures, est beaucoup plus élevé.	1	2	3	4	5	
13. Une proportion considérable de blessure d'aiguilles sont le résultat de la pénétration de la capsule ou de manquer la capsule avec l'aiguille durant le recapsulage.	1	2	3	4	5	
14. Durant cette année passée j'ai reçu de l'instruction des politiques de cet hôpital envers le maniement des objets à pointe aigüe.	1	2	3	4	5	
15. Pour protéger le patient contre l'infection, il est nécéssaire de porter qu'un gant stérile sur la main principale durant l'aspiration.	1	2	3	4	5	
16. Après avoir enlevé les gants, ce n'est pas nécéssaire de se laver les mains à moin que les mains soient visiblement souillées.	1	2	3	4	5	

ENONCÉS	ABSOLUMENT D'ACCORD		NE SAIS PAS		DÉFINITIVEMENT PAS D'ACCORD	COMMENTAIRES
17. Les politiques de cet hôpital requient que, pour toutes activitées ou le contacte avec le sang, les sécrétions, les excrétions, les membranes muqueuses, ou les blêssures ouvertes est possible, les gants doivent être portés.	1	2	3	4	5	
18. Le but primordial des "Précautions Élémentaires" qui éxige qu'on portent les gants, est de protéger les patients contre les infections-croisées viral et bactériens.	1	2	3	4	5	
19. Les gants, puisque ils coulent, n'offrent pas de vrai protection et il n'a pas d'évidence que l'usage des gants prévient la transmission des infections.	1	2	3	4	5	
20. On peut porter les gants de patient à patient si on se laves entre chaque patient.	1	2	3	4	5	
21. Durant cette année passée j'ai reçu de l'instruction des politiques de cet hôpital envers l'usage et la disposition de gants.	1	2	3	4	5	
22. "L'Isolation de Substances Organiques" et les "Précautions Élémentaires" requient que je porte de gants de vinyle ou de latex pour chaque activitée avec mes patients.	1	2	3	4	5	
23. Les infirmières se lavent les mains suffisament bien entre chaque patient, ce qui est indiqué par la plupart des études.	1	2	3	4	5	
24. Tout personnel de l'hôpital qui ne sont pas immunisé contre la varicelle peuvent quand même soigner, sans risque, ceux qui ont la varicelle ou les herpes zoster.	1	2	3	4	5	
25. J'ai déja reçu de cet hôpital des instructions expliquant l'application des "Précautions Élémentaires".	1	2	3	4	5	
26. Les "Precautions Élémentaires" ou "l'Isolation des Substances Organiques" éliminent le besoin d'etiquette d'avertissement "bio-hazard", pour les spécimèns des patients infectés.	1	2	3	4	5	
27. Tout objets abandonnés dans la chambre "isolée" d'un patient, devraient êtres incinérés ou stérilizés comme "déchêts infectueux".	1	2	3	4	5	

ENONCÉS	ABSOLUMENT D'ACCORD		NE SAIS PAS		DÉFINITIVEMENT PAS D'ACCORD	COMMENTAIRES
28. Les "Précautions Élémentaires" empêchent que toutes ordures ou déchêts des patients soient enlevés au terrain dépotoir sanitaire de la communauté.	1	2	3	4	5	
29. Les mesures utilisés pour le controle d'infections de cet hopital sont éfficace, pratique et bien documentées.	1	2	3	4	5	
30. Le but primordial de les "Précautions Élémentaires" est de protéger les patients et le personel de l'hopital contre tout les types d'infections nosocomiales.	1	2	3	4	5	
31. Durant les derniers trente jours à cet hôpital, j'ai subis une blessure d'aiguille.	1	2	3	4	5	
32. J'ai eu de la difficultée à comprendre ce questionnaire.	1	2	3	4	5	

Veuillez renvoyer ce formulaire dans l'enveloppe fourni, rempli ou non.

QUESTION:	EXPECTED REPLY	REFERENCE	PAIR
1 Risk of AIDS and hepatitis B are equal: most needlestick exposures lead to infection with either disease.	DISAGREE	1	5
2 In order to implement necessary "isolation" precautions, patients should be screened for AIDS and hepatitis B upon admission.	DISAGREE	2	26
3 This hospital's policies require a special warning label on laboratory specimens from patients with AIDS or viral hepatitis.	(site specific)	-	0
4 The primary purpose of "Body Substance Isolation" is to protect healthcare workers from AIDS and hepatitis B in the workplace.	DISAGREE	3	30
5 Hepatitis B virus in blood that has dried on environmental surfaces may still be infectious.	AGREE	4	1
6 All healthcare workers who receive 3 properly administered doses of hepatitis B vaccine will gain life-long immunity.	DISAGREE	5,6	24
7 I have received a complete series (3 doses) of hepatitis B vaccine.	(site specific)	-	0
8 Body Substance Isolation is a system for infection precautions that eliminates the need for isolation categories (Strict, Enteric, etc.) except for one category for airborne communicable infections.	AGREE	3	18
9 Needlestick injury is the single most significant source of occupational infection with hepatitis B or HIV among healthcare workers.	AGREE	7,8	12
10 Used needles should be recapped immediately after use with patients to prevent needlestick injury.	DISAGREE	7,8,13,16,	13
11 This hospital's policies prohibit recapping of used disposable needles.	(site specific)	-	0
12 The risk of needlestick injury in manipulating the connections within IV lines (eg: mini-bag, heparin lock use, etc.) is higher than the risk of injury in giving injections with hypodermic syringes.	AGREE	9	9
13 A significant proportion of needlestick injuries result from missing or penetrating a cap while recapping used syringe needles.	AGREE	9	10
14 I have received instruction during the past year on this hospital's policies for safe handling of sharps.	(site specific)	-	0
15 When suctioning, a single sterile glove is worn on the dominant hand to protect the patient from infection.	DISAGREE	10	19
16 Handwashing is NOT necessary after removing gloves unless the hands are visibly soiled.	DISAGREE	11	23
17 This hospital's policies require gloving for any activity likely to cause contact with blood, secretions, excretions, mucous membranes, or open lesions.	(site specific)	-	0
18 The primary purpose of gloving under "Universal Precautions" is to protect patients from bacterial and viral cross-infections.	DISAGREE	12	8
19 Gloves do NOT provide any real protection since they leak and there isn't evidence showing that their use prevents transmission of infection.	DISAGREE	12,13	15
20 Gloves may be worn from patient to patient if washed between patients.	DISAGREE	3,11,12,13	22
21 I have received instruction during the past year on this hospital's policies for proper use and disposal of gloves.	(site specific)	-	0
22 Universal Precautions and Body Substance Isolation require that vinyl or latex gloves be worn for every patient-care activity.	DISAGREE	12,13	20
23 Most studies have shown that nurses wash their hands adequately between patient care activities.	DISAGREE	14,15	16
24 Staff members who are NOT immune to chickenpox may safely care for patients with chickenpox or herpes zoster.	DISAGREE	16	6
25 I have received in-service instruction from this hospital explaining the application of "Universal Precautions".	(site specific)	-	0
26 Universal Precautions or Body Substance Isolation eliminates the need for "biohazard" warning labels on specimens from infected patients.	AGREE	12	2
27 Everything discarded in any "isolated" patient's room should be incinerated or sterilized as "infectious waste".	DISAGREE	17	28
28 Universal Precautions prohibits disposal of any patient wastes in a community's sanitary landfill.	DISAGREE	17	27
29 This hospital's infection control measures are practical, effective, and well-documented.	AGREE	-	0
30 The primary purpose of Universal Precautions is to protect patients and staff from all types of nosocomial infections.	DISAGREE	1,13,12	4
31 I have had one or more needlestick injuries at this hospital during the past 30 days.	-	-	0
32 This computer program was difficult to use.	-	-	0

References for Nurses' Questionnaire

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7. Elmslie K, Mulligan L, O'Shaughnessy MV. Occupational Exposure to the Human Immunodeficiency Virus Among Health-Care Workers in Canada. CDWR 1988;14(43):197-200.

8. Marcus R, CDC Cooperative Needlestick Surveillance Group. Surveillance of Health Care Workers Exposed to Blood from Patients Infected with the Human Immunodeficiency Virus. N ENGL J MED 1988;319:1118-23.

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Appendix 4:
Efficacy of MIDI for Epidemiologic Typing of *Staphylococcus epidermidis*

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ABSTRACT

Lack of an adequate typing system has hampered our understanding of the epidemiology of infections caused by coagulase-negative staphylococci (CNS). CNS have become recognized as important nosocomial pathogens, and the principal cause of infections associated with invasive devices. Sensitive, specific and convenient methods are needed to evaluate whether implementation of guidelines for infection control reduce the risk of nosocomial infections from CNS and other pathogens. Existing typing methods are either not convenient for use in most hospital laboratories or lack adequate specificity to distinguish between strains. The Microbial Identification System (MIDI, Microbial ID Inc., Newark, Delaware), a semi-automated system for fatty acid methyl ester (FAME) analysis, shows considerable promise for clinical and epidemiologic applications. Its predictive accuracy and reliability were tested using epidemiologically-related and replicated CNS isolates as well as CNS from epidemiologically unrelated clinical infections. These isolates were obtained from five established hospital culture collections in diverse geographic locations. Two-hundred isolates were fully characterized in five days by one person using MIDI, and results were consistent with those produced by more expensive and time-consuming conventional typing methods. MIDI, an attractive alternative to molecular microbiology methods, may offer important advantages to hospital epidemiologists and infection control programs.

INTRODUCTION

Universal Precautions (UP) is an expensive strategy for preventing occupational infection of healthcare workers with bloodborne pathogens. The nation-wide cost of UP per human immunodeficiency virus infection prevented is estimated at between one-million and ten-million dollars.[1] [2] It has been suggested that UP or another strategy, Body Substance Isolation (BSI), might also reduce patients' risk of nosocomial infections, thus improving the cost-effectiveness of these strategies. However, the few studies of compliance or effectiveness under UP or BSI that are available present contradictory findings. Therefore, although UP and BSI advocate gloving for patient-care activities, its value as an infection control measure is not precisely known. Methods to trace the sources of specific infections are needed to further our understanding.

Staphylococcus epidermidis, for example, is clearly the most common pathogen in intravascular (IV) device-associated sepsis, but the relative importance of different routes of infection is uncertain.[3] If entry-site skin flora migrating along cannulae cause most IV CNS infections, then infection control measures must focus on antiseptics, time limits for site use and minimizing trauma of the insertion site. If contamination of IV hubs by exogenous flora is more frequent, then a focus on asepsis, including use of gloves under either UP or BSI, may reduce the risk of common source or cross-infection. Evidence supporting the former view may be biased by use of microbiologic rather than clinical definition of infection in some studies. Further, it is not difficult to imagine that variation in hospital practices would lead to variation in the extent of hub contamination at different times or places. A convenient typing system would allow individual hospitals to monitor the origin of such infections, periodically adjusting the emphasis of their own

infection control program accordingly.

The basis for an epidemiologically useful typing system is to exploit documented species diversity, but this is often comparable to hitting a moving target with tools of uncertain precision, accuracy or reliability. Existing typing systems are not adequate for tracing the origin of nosocomial CNS infections.[4] Fatty acid methyl ester (FAME) analysis as a qualitative pattern-recognition method is well-established for species-level identification (eg: anaerobes). Eerola and Lehtonen recently demonstrated its reliability in distinguishing between species of different aerobic genera as well as between strains within species, but noted that different univariate correlation methods used for data analysis are not equivalent.[5] Subsequent work suggested the future ability to discriminate between epidemiologically related and unrelated strains.[6] MIDI (Microbial ID Inc., Newark, Delaware) automates quantitative analysis of over 200 fatty acid metabolic products and comparison with proprietary database libraries by multivariate statistical methods. New library entries can be created by individuals when isolates with an unrecognized pattern are encountered, and subsequent samples are automatically compared to this updated library.

MIDI establishes species-level identifications through principal component analysis of ratios of FAME peak areas. This multivariate, quantitative approach promises superior ability over simple pattern recognition to differentiate between organisms. In addition to providing genus-species identifications, MIDI software can also display the degree of relatedness of isolates on two-dimensional principal component plots and on cluster analysis dendrograms. However, MIDI has not been applied to epidemiologic typing of CNS. Since it may offer advantages to both clinical laboratories and hospital epidemiologists, its discriminatory power, predictive accuracy, intra- and inter-laboratory reliability

for subspecies typing of CNS need to be documented.

MATERIALS & METHODS:

DESCRIPTION OF ORGANISMS

One-hundred and eighty-three well-characterized coagulase-negative staphylococci (CNS) from clinical specimens were obtained from culture collections in five geographically distinct areas. Their identification and antimicrobial susceptibility profile were determined in the contributing laboratories using conventional methods approved by the National Committee for Clinical Laboratory Standards (NCCLS). Identifications were confirmed subsequently by one of us (MP) using the scheme of Kloos and Schleifer. Some of these collections have been described elsewhere.[7] [8]

Among the 183 are six groups containing epidemiologically related isolates: ten *S. haemolyticus* blood culture isolates from neonates in Ontario; three pairs of matching blood and intravascular cannula tip *S. epidermidis* isolates from British Columbia; five *S. epidermidis* isolates from an outbreak of surgical wound infections attributed to a surgeon's hand flora in Rhode Island and twelve consecutive *S. epidermidis* isolates from one immunosupressed patient in Iowa. Their epidemiologic relatedness was assessed on the basis of the following criteria, in descending order of importance (see Table 23):

1. Epidemiologic evidence of time-space clustering
2. Matching biotype/susceptibility profile
   a) No differences = no evidence that isolates are different
   b) 1 difference = isolates might be different
   c) ≥2 differences = isolates are different
3. Molecular methods, if done, show no differences
   a) Plasmid Profile
   b) Restriction endonuclease analysis (REA)
   c) Hybridization (probe or DNA [RFLP])

Other isolates obtained from each collection differ from each other by conventional microbiological typing and/or lack of epidemiologic suspicion of

common-source or cross-infection relatedness among them.

The remaining 155 isolates were judged to be epidemiologically unrelated by methods that meet or exceed current standards of infection surveillance practice. Forty-eight unrelated blood culture isolates collected over a 6 month period in one Ontario children's hospital exhibited unique combinations of biotype, susceptibility profile and plasmid profile, and no evidence of time-space clustering. Fifty-seven unrelated blood culture isolates from a university hospital in Iowa were unique in their combined biotype, susceptiblity profile, slime production, synergistic hemolysis, plasmid profile and restriction digest patterns. Forty-two unrelated blood culture isolates in a British Columbia university hospital were selected from a collection spanning 3 years; they were considered unrelated episodes on the basis of no time-space clustering. Three isolates from intravascular lines in a North Carolina university hospital were also judged to be unrelated, in spite of comparable biotype and susceptibilty profiles, on the basis of epidemiologic assessment.

The majority of these isolates, primarily *Staphylococcus epidermidis*, meet CDC criteria for clinical significance[9]. Twenty-six of the 183 were blood culture contaminants (included to study how closely they would be related to clinically-significant isolates). One isolate was replicated eighteen times (group #7) to test intra-laboratory reliability. The entire set of 200 randomly-numbered clones was analyzed blindly and independently in two facilities with established MIDI systems (under supervision of Microbial ID Inc. staff in their laboratory, and in a university hospital clinical laboratory) to test inter-laboratory reliability. Media inoculation was done in Class II laminar airflow hoods, and colony morphology was inspected on subcultures (to check for contaminants) immediately after receipt of isolates from contributing laboratories

and again just prior to MIDI analyses.

MIDI TECHNIQUE

Analysis was conducted in accordance with MIDI instructions.[10] Briefly, isolates were quadrant-streaked onto trypticase soy agar (TSA) plates (BBL) and harvested in log-phase growth after 24 (±2) hours' incubation at 28°C in air. Approximately one 4mm loop-full of bacteria was scraped for each sample. Each sample was then saponified, methylated, extracted and cleaned before removing its organic layer for injection into MIDI's gas chromatography system. Calibration standards and a negative control blank were run with each batch, and one positive control specimen (*Xanthomonas maltophilia*, ATCC 13637) was run each day. MIDI's aerobic bacteria library (Ver. 3.30) was used for interpretation. Samples with suboptimally low gas chromatography results (total peak area <80,000 or <85% of peak area used by the naming algorithm) were repeated after concentration by evaporation.

STATISTICAL ANALYSIS

MIDI computes an index for each isolate through principal component analysis of ratios of cellular fatty acid content. Cluster analysis of these indices was applied[11] with Euclidian distances calculated by the simple and Ward's[12] linkage methods. Empirically, the replicated (group #7) isolates' joining distances were examined to determine an optimal strain-level joining distance. The MIDI system software and SYSTAT (version 4.1, Systat Inc., Evanston IL) were used for statistical analysis. Discriminatory power was calculated as Simpson's Index, the probablity that two isolates selected at random would be placed into different typing categories.[13] Sensitivity, specificity, positive and negative predictive accuracy were evaluated by comparing MIDI's predictions with the known related or unrelated nature of

isolates.

RESULTS

All 200 isolates were typable and their analysis was completed in 5 days by one of us (DB). Nearly two-thirds of an inexperienced operator's first batch of extracts had low peak areas and required concentration, but subsequent batches rarely suffered this problem.

A critical distance to distinguish between related and unrelated isolates was established emperically by examining the Euclidian distance at which known epidemiologically-related isolates joined. Group #7 was taken as the "gold standard" for clonal origin. These replicated isolates all joined at 5.4 units, but exhibited independent clustering at 4.5 units on a dendrogram generated by Ward's method. Thus, any isolates joining at less than 4.5-5.4 units could be considered clustered into the same typing category, whereas isolates joining at more than 5.4 units would be assigned into different categories. This is illustrated in Figure 12.

Single and Ward's linkage methods yielded similar groupings. At least 46 typing categories were readily apparent, with a Simpson's Index of ≥0.93 (Table 24). Approximately half of the categories contained a single isolate.

There are seven groups of related isolates in the test set. Group seven was created artificially by replicating one isolate eighteen times. MIDI found three clusters joined at 0.7-2.1 units, and linkage of these clusters at 4.5-5.4 units. The former range is consistent with previous experience for repeated analysis of the same isolate (personal communication, Myron Sasser), and the possibility of a mixed culture was noted.

Group one consisted of 10 blood culture isolates from one neonatal nursery, identified by the contributing laboratory as *S. haemolyticus* with identical

susceptibility profile, restriction endonuclease pattern and hybridization to three drug-resistance probes. This resistant strain was endemic in several adjacent hospitals, the affected infants had overlapping hospitalization dates during a 5 month period, but there was no conclusive evidence to establish or rule out common source or cross-infection. MIDI identified two isolates (obtained within three days of each other) as related to each other and to a third (joined at 1.9 Euclidian distance units) and fourth (at 5.4 units).

Group two consisted of matching blood culture and intravascular cannula isolates from a single patient. MIDI placed these two (and other epidemiologically-unrelated isolates) in a single category. This patient had three CNS isolated from an intravascular line; only one matched the blood isolate's susceptibility profile. MIDI correspondingly typed the isolates with matching profiles as related and the other two as unrelated. The correctly paired isolates joined at 2.6 Euclidian distance units, and subsequently were identified as *S. epidermidis* whereas the other two cannula isolates were confirmed as *S. intermedius* and *S. auricularis.* On the basis of susceptibility profile differences, the two related isolates could be distinguished from most of the epidemiologically-unrelated isolates in this MIDI typing category.

Group three similarly consisted of paired blood and cannula isolates from another patient. MIDI placed these two and other epidemiologically-unrelated isolates in a single category. The correctly paired isolates joined at 1.2 Euclidian distance units. On the basis of susceptibility profile differences, four subcategories correctly separated the two related isolates from three mutually unrelated isolates.

Group four also consists of paired blood and cannula isolates from one patient. These were correctly matched, again with unrelated isolates as well, at

a distance of 3.8 units, and susceptibility profile differences created subcategories correctly separating related from unrelated isolates.

Group five consisted of *S. epidermidis* from a surgeon's hands, two infected surgical wounds, and two blood cultures. Temporal clustering, plasmid analysis, EcoRI restriction endonuclease digests, antibiograms and biotyping document this as a common-source outbreak. MIDI typed the four patient-isolates as related (3 joined at 1.4 units and the 4'th at 2.8) but the surgeon-isolate was in a different category (joined at 10.6 units). Susceptibility profile differences created subcategories correctly distinguishing the outbreak patient isolates from unrelated isolates. This is illustrated in Figure 12: isolates joining to the right of the distance marked as ⁞ did not cluster into the typing category containing the outbreak patient isolates.

Group six, a series of twelve *S. epidermidis* isolates from one immunosupressed patient, was identified by MIDI as two clusters and two unrelated isolates. One cluster consisted of two isolates from blood cultures drawn on the same day (joined at 2.1 distance units). The second contained eight isolates obtained over several months (joined at 4.5 units). Since the susceptibility profiles differ, at least two distinct clusters are correctly identified by MIDI for group six.

DISCUSSION

A "gold standard" for comparison was established by available epidemiologic and microbiologic information with clinical isolates. It is reasonable to assume that such information is valid for ruling out relatedness. However, it cannot be considered conclusive proof of relatedness when it failed to find differences: testing with another substrate or enzyme, or a more powerful method might reveal differences. MIDI's grouping together of isolates shown by other methods

to be epidemiologically unrelated may be an error resulting from detecting taxonomically similar (but epidemiologically unrelated) strains. MIDI's separation of isolates grouped together by other methods may be an error or may indicate that MIDI is a more powerful typing method. Although MIDI's predictions closely paralleled the "gold standard" results, MIDI's failure to cluster all of Group 5's isolates into one category is of concern. The surgeon's hand isolate had been found identical to the patient isolates by whole plasmid gels, plasmid REA and pulsed field electrophoresis analysis of chromosomal DNA. These results are promising, but further work is required to document MIDI's accuracy

MIDI conveniently accomodates large numbers of isolates, can supply a typing result for every isolate, and its material costs for complete identification are low (about $1.30 per isolate). One-tube sample preparation (saponification [sodium hydroxide in methanol], methylation [hydrochloric acid in methanol], extraction [hexane in methyl tert-butyl ether], sample cleanup [sodium hydroxide]) and automated analysis accomodate identification of up to 45 samples per technologist-day per machine. One person can process as many as 30-50 isolates in about 4 hours, depending upon experience. Performance of gas chromatography requires an additional thirty minutes per sample. MIDI's waste can be recycled or biodegraded. Compared to other typing systems, a relatively small amount of plastic is discarded. Glass, water and sodium chloride are the major waste products.

Growth of CNS on TSA plates at 24 hours was often relatively light. Better growth might be achieved on blood agar at 37°C, but MIDI's library for this condition is not as well established as their aerobic 28°C TSA library. Improved reproducibility with blood agar at 37° has been reported for other aerobic bacteria.[14] This problem was easily overcome by using a heavier

inoculum. Streaking two rather than one TSA plate is another possible strategy when poor growth is anticipated, and offers the additional advantage of allowing an immediate repeat extraction in case a critical sample is ruined by an error in technique. Concentrating extracts for a second chromatography run, the standard procedure when MIDI's printout warns of unacceptably low peak areas, was also simple and effective: 84% of "flagged" results attained acceptable peak areas after concentration. Difference in joining distance between "flagged" results versus concentrate results (due to new peaks emerging above detection limits) changed the typing category assigned in 16% of these samples (Fig. 13).

FAME analysis by gas-liquid chromatography may be particularly cost-effective for epidemiological typing of clinical or environmental isolates as compared to current alternatives. Successful application to the subspecies level has been reported with staphylococci.[5, 15] However, discerning epidemiologic relationships is more difficult than simply establishing taxonomic relationships. MIDI was used recently in a small study of *Pseudomonas cepacia* in cystic fibrosis centers; a low but promising discriminatory ability was determined among 42 isolates from 5 centers (Simpson's index, the probability of two randomly-selected isolates being assigned to different typing categories, was 0.775).[16] The present study of CNS involves a larger number of isolates selected specifically to minimize the chance that they were related by unrecognized common source or cross-infection. In comparison to molecular typing methods now available to characterize isolates, MIDI promises to be a relatively powerful, rapid and inexpensive tool.

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Table 23:
Characterization of Epidemiologically-Related Isolates by Lab of Origin

	GROUP NUMBER					
CRITERION	1	2	3	4	5	6
Epidemiology Shows Time-Space Clustering	±	+	+	+	+	±
Biotype/Susceptibility Profiles Match	+	+	+	+	+	±
Plasmid Profile	+	-	-	-	+	+
REA	+	-	-	-	+	-
DNA Probe/RFLP	probe	-	-	-	RFLP	-

Note: + = clearly documented by contributing laboratory,
± = incompletely documented,
- = not done.

Table 24:
Summary of MIDI's Typing Performance

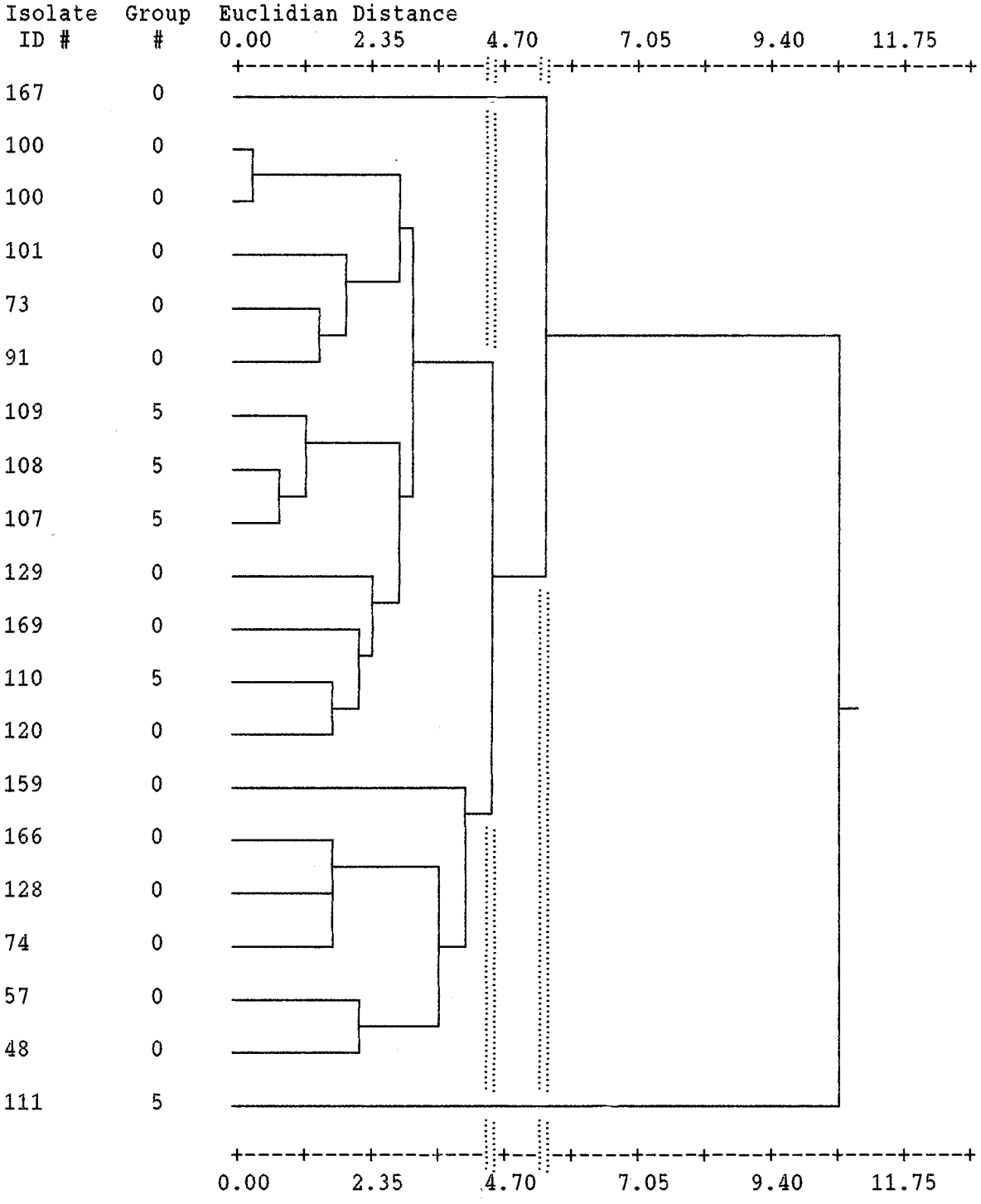
CLUSTER ANALYSIS METHOD	Ward's Method		Single Linkage
THRESHOLD LIMIT Euclidean Distance	4.5	5.4*	4.6
Number of Categories Created Number containing only 1 isolate	66 34 (52%)	46 21 (46%)	57 29 (51%)
Simpson's Index	≈0.96	≈0.93	≈0.96
Sensitivity	┼	┼	┼
Specificity	┼	┼	┼
Positive Predictive Accuracy	┼	┼	┼
Negative Predictive Accuracy	┼	┼	┼
Inter-Laboratory Agreement	╪	╪	╪

* Group #7's isolates all joined at 5.4 units, but exhibited independent clustering at 4.5 units. These isolates were all subcultured from isolate #1, which appeared mixed when subcultured for MIDI analysis. Further work will be required to determine whether these eighteen reference isolates were pure or mixed. It is unlikely that the threshold limit could be set any lower than 3.8, the joining distance for group #4.

┼ Qualitative results described in text; quantitative results not yet available.

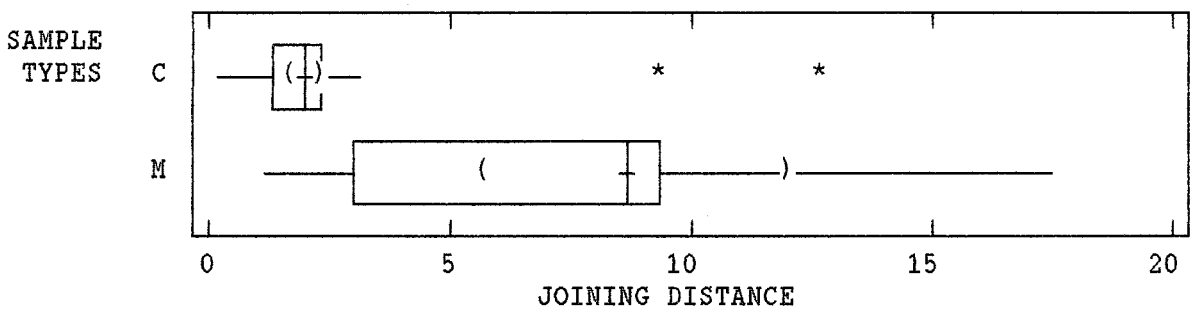
╪ Results not yet available.

Figure 12:
Section of MIDI Dendrogram Containing Group #5 Isolates



KEY: ⁞ indicates 4.5-5.4 unit joining distance limit
0 = epidemiologically-unrelated isolates
5 = epidemiologically-related isolates

Figure 13:
Joining Distances of Repeated Assays



Legend: C = concentrated vs. unconcentrated sample
M = morphotype "a" versus "b" for isolates exhibiting variants in colony size, texture or color

Note: Two morphotypes of isolate #1 join at distance 9.4

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