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**An Examination of the Impact of Ontario's Patient Restraint Minimization Act, 2001 on the Use of
Physical and Chemical Restraints Among Elderly Clients in Complex Continuing Care Facilities**

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**An Examination of the Impact of Ontario's Patient
Restraint Minimization Act, 2001 on the Use of Physical
and Chemical Restraints Among Elderly Clients in
Complex Continuing Care Facilities**

By

Sylvia Ralphs-Thibodeau

**Thesis submitted to the Faculty of Graduate and Postdoctoral Studies in
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University of Ottawa

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Abstract

In 2001, the Ontario provincial government passed an act to minimize the use of physical and chemical restraints in hospitals. This study utilized data from the Ontario Chronic Care Patient System (OCCPS) from April 1998 to March 2004. Data were analyzed using a simple interrupted time series design with visual and ITSACORR analysis to evaluate whether the act has resulted in a change in prevalence rates of physical restraints among elderly patients in Ontario's complex continuing care beds, both province wide and by facility type (i.e., rural, urban, small, large, private or public).

Provincial legislation to minimize the use of physical restraints was not effective. ITSACORR analysis coupled with visual analysis can be a useful combination of instruments to assess brief interrupted time series although neither method alone is without limitations.

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1. Introduction

On June 29th, 2001, Ontario passed an act to minimize the use of physical and chemical restraints in public and private hospitals. This thesis utilizes time series design to examine the impact of this policy on patient outcomes using data from the Ontario Chronic Care Patient System (OCCPS). The following introductory chapter describes the objectives and rationale of the thesis.

Objectives

The primary objective of this thesis is to evaluate whether Ontario's Patient Restraint Minimization Act, 2001 (Government of Ontario, 2001) has resulted in a change in the prevalence of physical and chemical restraint use among elderly patients in Ontario's complex continuing care¹ beds. Additionally, the thesis will evaluate whether prevalence of restraint use varies by facility type (i.e., rural or urban, small or large, private or public).

If the act has been successful, then the use of physical and chemical restraints will have declined. The anticipated pattern of decline in the use of restraints is guided by Rogers' (2003) Diffusion of Innovations Theory.

¹ The Ontario Health Services Restructuring Commission introduced, in 1997, the term *complex continuing care* to describe hospital-based chronic care (Teare et al., 2003). Patients occupying designated complex continuing care beds may receive long-term complex medical care, geriatric assessment and rehabilitation, psychogeriatric care, palliative care or respite care. Facilities that accommodate complex continuing care patients include hospitals, freestanding complex continuing care and rehabilitation facilities, and acute care hospitals with some designated beds (Teare et al., 2003).

Study Rationale

With institutionalized elderly patients, the use of physical and chemical restraints can lead to serious physical and psychological consequences including death. Ontario enacted legislation with the single purpose to minimize physical and chemical restraints in 2001. There have been no published studies that purposefully examine the impact of the Ontario policy in minimizing physical and chemical restraints.

A brief history of the use of physical and chemical restraints follows to contextualize their use on elderly institutionalized patients.

Physical and Chemical Restraints—A Brief History

Historians generally credit Dr. Philippe Pinel (1745 – 1826) of France as the first physician to introduce more humane methods of treatment for psychiatric patients including the removal of physical restraints (Levine, 1996). It took nearly a century for this humanitarian movement to result in legislation and regulations aimed at reducing the use of physical restraints for psychiatric patients (Evans & Strumpf, 1989) such as those promoted by the successful 19th century reformer, Dorothea Dix, in the United States (Kane, Williams, Williams, & Kane, 1993).

The introduction of physical restraints into nursing homes was based on a philosophical belief that restraints enhanced patient safety and reduced the need for constant supervision, thereby reducing human resource requirements (Kane et al., 1993). Kane and colleagues (1993) identified three influences on the changing attitudes towards the use of physical restraints in the institutionalized elderly...“a general questioning of medical precepts, the rise of geriatrics and a press for patient autonomy” (Kane et al., 1993, p 546).

Chemical restraints became integrated into the care of the institutionalized elderly with the introduction of psychoactive drugs in the 1960s (Kane et al., 1993). Kane and colleagues explain that in the 1960's, elderly patients from psychiatric institutions were discharged into nursing homes in the belief that chemical restraint of behaviour problems would avoid the necessity for care within psychiatric institutions. However, consequent adverse effects from psychoactive drugs such as excess sedation and falls raised extensive public concern (Kane et al., 1993). Thus, the movement to reduce restraints was expanded to include both physical and chemical restraints.

Extensive Restraint Use and Threats to Patient Safety

The use of physical and chemical restraints is ubiquitous among institutionalized elderly patients throughout most of the developed world. The effective minimization of both physical and chemical restraints is an important step towards improving patient safety among the institutionalized elderly. Early work in this field is sparse. Evans and Strumpf (1989) noted that there were only ten articles published between 1973 and 1988 on physical restraints and elderly non-psychiatric patients (Evans & Strumpf, 1989).

Castle and Mor (1998), reported that prevalence of physical restraints in US nursing homes ranged from 4% to 67.5% based on 16 studies published between 1989 and 1996. The consequent risk for potentially serious or even fatal consequences associated with physical restraints is noteworthy. Evans, Wood and Lambert (2003), reviewed 12 observational studies between 1987 and 1992 to assess patient injuries related to the use of physical restraints. They noted that physically restrained patients in residential settings were at greater risk of falls (pooled results from two studies OR 1.72, 95% CI 1.26-2.35), injuries from serious falls (OR 3.6, 95% CI 1.79-7.27) and fractures from falls (OR 4.89, 95% CI 1.79-13.36). In acute care settings, Evans and colleagues

(2003) reported an increased risk of death (pooled results from three studies OR 11.24, 95% CI 6.07-20.83), hospital-acquired infections (pooled results from two studies OR 3.46, 95% CI 1.93-6.22) and falls (pooled results from two studies OR 6.79, 95% CI 3.44-13.39). In 1992, Miles and Irvine (1992) used data from the Food and Drug Administration's Device Experience Network from 1982 to 1990 to determine the extent of deaths caused by physical restraints. They found that deaths (n=122) occurred most frequently among patients older than 70 years (78%), who were in nursing homes (85%) restrained by chairs (58%) or in beds (42%).

Six studies between 1991 and 2002 consistently showed that nurses and other caregivers in hospitals and nursing homes tended to have positive attitudes towards the use of physical restraints and believed that by using restraints, they were enhancing patient safety (Scherer et al., 1991; Hardin et al., 1994, Werner et al. 1994; Hennessy et al., 1997; Hantikainen and Kappeli, 2000; Myers et al., 2001). Braum and Lipson (1993) described positive outcomes of restraint use in situations when patients may be able to move more effectively while restrained. An example is that of a paralyzed patient who uses a half rail to turn around in bed. Restraints may also alert patients about unsafe situations. For example, a patient with both legs amputated may wear a belt restraint to remind him that he is unable to walk (Braum and Lipson, 1993).

Bedrails continue to be used for the institutionalized elderly, even though there appears to be no empirical evidence to support the belief that they increase patient safety (Capezuti et al., 2002). Studies of caregivers in long-term care facilities offer many reasons for using bedrails. These include for example, to prevent falls, to reduce interference with medical equipment or to control violent behaviour. Administrators encourage the use of restraints in an attempt to limit liability in the event that patients fall and injure themselves (Hardin et al., 1994; Janelli et al., 1994; Retsas and Crabbe, 1998).

Complex continuing care patients may occasionally need restraints when all possible alternatives have been attempted without success, particularly when patients interfere with medical equipment or exhibit violent or disruptive behaviour. The use of restraints in these instances should only be a short-term solution and the periodic release of restraints, close observation, and frequent re-assessment of the patient are essential (Capezuti et al., 2002).

Estimating the prevalence of chemical restraints is not straightforward since it is difficult to distinguish between psychotropic drugs being used as chemical restraints and psychotropic drugs being used as therapeutic agents. In a review of 19 studies (observational, pre and post) of nursing homes published between 1983 and 1990 (Harrington, Tompkins, Curtis & Grant, 1992), prevalence of psychotropic drug use were found to range from 33% to 90%. Many of the studies included in the review noted minimal records of diagnostic justification for psychotropic drug administration. Psychotropic drug use was associated with an increased risk of hip fractures (OR 2.0, $p < .001$) in a case control study of 1021 patients with hip fractures and 5606 controls (Ray, Griffin, Schaffner, Baugh, & Melton, 1987). There is also evidence that psychotropic drug use among elderly nursing home residents may increase psychosis or behavioural disturbances (OR 3.19, 95% CI 2.08-4.90; OR 3.16, 95% CI 1.72-5.80) (Draper et al., 2001).

Provincial Legislation to Minimize Restraint Use

In November of 2000, Frances Lankin, New Democratic Party health critic, put forward a private member's bill (Bill 135). The bill was intended to amend the Public Hospital Act so as to restrict the use of physical and chemical restraints in hospitals (Ontario Hospital Association, 2001). Lankin was reported to have begun lobbying for

change after witnessing the care received by her elderly institutionalized mother (Brennan, 2001).

Bill 135 was never passed but did create sufficient interest in the topic for the Ontario Hospital Association to form a task force to study the issue of restraints in depth. One day following the last formal meeting of the task force, Frances Lankin introduced a second bill on restraints that passed nine days after its introduction. Thus, in June 2001, the Province of Ontario became the first Canadian province to enact such legislation by passing Bill 85, An Act to Minimize the Use of Restraints on Patients in Hospitals and on Patients of Facilities. This is also known as the Patient Restraints Minimization Act 2001 (Government of Ontario, 2001). The Act applies to every hospital or facility that is licensed under the Public Hospitals Act or the Private Hospitals Act but not in circumstances where the Mental Health Act dictates the use of restraints. The Act defines *to restrain* as “the minimal use of such force, mechanical means or chemicals as is reasonable having regard to the person’s physical and mental condition” (Government of Ontario, 2001, p 1). The impact of Ontario’s strategy to regulate the use of restraints in the care of the elderly is at present unknown.

Interrupted Time Series Design to Measure Policy Impact

Time series data with an intervention that occurs at a specific time point can be used successfully to measure the impact of a variety of interventions including public policy (Shadish, Cook, & Campbell, 2002). The impact of such policies related to seat belts, highway speeds, and helmets for motorcyclists has been successfully measured using interrupted time series design (Wagenaar, Webster & Maybee, 1987; Ballart & Riba, 1995; Chen, Wilson, Meckle, & Cooper, 2000). Clinical trials would be impractical and inappropriate for measuring the impact of legislation on physical and chemical

restraints. Simple interrupted time series analysis requires sequential observations on a single variable in a population of interest prior to and following the introduction of an intervention (e.g. policy initiative).

Time series analysis is possible because in 1996, the Ontario Ministry of Health and Long-Term care mandated the collection of data on hospitalized chronic care patients using the Resident Assessment Instrument Minimum Data Set (interRAI/ MDS) version 2.0 thus creating the Ontario Chronic Care Patient System (OCCPS) (Teare, Hirdes, Ziraldo, Proctor, & Nenadovic, 2000). This database will be used to examine changes in patterns of restraint use. With the exception of status reports that have been periodically released by the Canadian Institute for Health Information (CIHI) (Teare et al., 2000, Teare et al., 2003, CIHI 2004), no relevant published research has used data from the OCCPS to report on the use of physical and chemical restraints among elderly hospitalized chronic care patients in Ontario. CIHI's status reports are health care performance reports for governments, regulatory bodies, health service providers and Canadian citizens, intended to demonstrate public accountability, promote evidence-based policy and improve the quality of health care (Teare et al., 2000, p.1).

Thesis Overview

The following four chapters include a review of relevant literature, a description of the methods, the results of analysis, and a discussion of the findings. Chapter two presents results of the literature search to establish that the prevalence of physical and chemical restraint use is both an international concern as well as a local issue within Ontario. A particular focus will be studies that have tested the impact of legislation, regulations or standards on the use of restraints. The characteristics of facilities that are

known to impact on the use of restraints are examined. The appropriateness of Rogers' (2003) Diffusion of Innovations Theory for the study of public policy is then discussed.

The third chapter presents the research questions that drive the analyses. An argument is built to justify the type of analysis chosen. This chapter also describes the database, variables and analysis procedures.

Chapter four presents the results in detail including relevant tables and figures. The final chapter discusses the findings. Conclusions are drawn after consideration of study limitations.

2. Literature Review

This chapter presents results of the literature review. The review covers three content areas: 1) the prevalence of physical and chemical restraint use among institutionalized older adults, including studies that report prevalence of restraint use before and after the introduction of legislation, regulations or standards; 2) the characteristics of facilities that influence the prevalence of physical and chemical restraint use; and, 3) Rogers' (2003) Diffusion of Innovations Theory as a framework to understand policy diffusion.

Approaches

A search was done for the three content areas using the following electronic databases: AARP Ageline (1978 – 2005); CINAHL; HealthSTAR (1999 – 2005); PsycINFO (1872 – 2005) and MEDLINE (1996 – 2005). The searches were limited to age 65 and older, from 1975 to the present, and to publications in either English or French.

Search terms for electronic databases for the first two content areas included, singly and in combination: *restrain, immobilize; physical, mechanical or chemical; long-term care, nursing home, institution, facility or hospital; prevalence or rate; policy, legislation or regulation; characteristics, attributes or identifiers; individual, resident, and patient*. Studies of interest were also found by scrutinizing reference lists and hand-searching specific journals from 1980 to the present (i.e., Health Education; Health Education Research; The Gerontologist; Age and Aging, The American Journal of the Geriatrics Society; and the Canadian Journal on Aging).

Search terms for electronic databases for the third content area included, singly and in combination: *diffusion, translation, transmission, dissemination, and innovation, policy, intervention, and framework, model, or structure*.

The Google Internet search engine was used to locate Ontario Provincial Acts as well as provincial guidelines and standards from Ontario on the use of restraints.

The Prevalence of Physical and Chemical Restraints

This section presents the known prevalence of restraint use internationally and within Canada². Evidence is offered as to the impact of U.S. federal legislation on the use of restraints. Prevalence studies are presented in six tables.

The literature search identified only four published papers from Canada on the topic of either physical or chemical restraints. One observational study looked at the characteristics of rural nursing homes in Saskatchewan (Morgan, Semchuk, Stewart, D'Arcy, 2002), a second discussion paper lamented the lack of national standards or data on restraints in Canada (Mackey & Rossy, 2002), a third study reported on an intervention to reduce physical restraints in a hospital in Manitoba (Powell, Mitchell-Pederson, Fingerote & Edmund, 1989), and finally an observational study compared the prevalence of physical restraints among long-term care residents in Switzerland and Quebec (Gobert & D'hoore, 2005).

Table 2.1 presents international comparisons of prevalence of physical restraints using Resident Assessment Instrument Minimum Data Set data. Up until 2002, Ontario had the highest prevalence for limb and trunk restraint use and the second highest prevalence for chair restraint use and limb, trunk, and chair restraint use combined, exceeded only by Spain. After 2002, Ontario prevalence dropped but there is no updated international prevalence available for comparison.

² Until recently, Ontario was the only province within Canada to collect data using the Resident Assessment Instrument Minimum Data. Therefore, U.S. studies that include prevalence from Canada, only report results from Ontario.

Table 2.1—International Comparisons of Physical Restraints Using Resident Assessment Instrument Minimum Data Set

Reference	Country	Sample size	Data Source	Prevalence (%) of Physical Restraints Used Daily (Less than daily)			
				Limb	Trunk	Chair Prevents Rising	Limb, Trunk and Chair Combined
Ljunggren, Phillips, & Sgadari, 1997	Denmark	3425	UMAAP*	0.0 (0.1)	0.7 (0.1)	1.6 (0.2)	2.2 (0.4)
	France	235	UMAAP	0.0 (0.9)	5.5 (2.1)	14.8 (4.2)	17.1(5.8)
	Iceland	770	UMAAP	0.3 (0.2)	3.1 (0.3)	6.5 (0.4)	8.5(0.6)
	Italy	1040	UMAAP	0.7 (0)	3.6 (1.4)	13.5 (1.3)	16.6(2.1)
	Japan	1240	UMAAP	1.3 (0.5)	0.4 (0.2)	3.2 (1.0)	4.5(1.5)
	Spain	525	UMAAP	2.1 (0.2)	3.7 (0.5)	37.9 (0.3)	39.6(0.7)
	Sweden	721	UMAAP	0.7 (0)	11.6 (3.1)	3.6 (0.3)	15.2(3.3)
	U.S.	339,251	UMAAP	0.9 (0.2)	12 (1.3)	5.8 (1.6)	16.5(2.4)
Hirdes, Mitchell, Ljunggren, & Schroll, 1999	Canada (Ontario)	893	RAI** Data from Toronto (Ontario) chronic care facilities	4.5	20.8	18.7	Not Reported
	Iceland	1233	UMAAP	0.3	3.1	6.5	
	Sweden	731	UMAAP	0.7	11.6	3.6	
	Denmark	3,425	UMAAP	0	0.7	1.6	
	A	339,251	UMAAP	0.9	12	5.8	
Teare et al., 2000	Ontario, Canada (1998/99)	20,296	OCCPS***	3	17	17	30
Teare et al., 2003	Ontario, Canada (2000/01)	MDS Ontario-wide	OCCPS	Not Reported			29
CIHI, 2004	Ontario, Canada (1996/2002)	MDS Ontario-wide	CCCPS****	1996 - 2.0 2002 - 1.1	1996 - 17.3 2002 - 9.7	1996 - 16.3 2002 - 10.6	Not Reported

*University of Michigan Assessment Archives Project

**Resident Assessment Instrument Minimum Data Set

*** Ontario Chronic Care Patient System

****Canadian Chronic Care Patient System

It is important to note that none of the studies in this table included bed rails as devices used for restraint. Historically, bed rails frequently have been omitted from studies of physical restraints, since there is debate as to whether they are in fact 'true' restraints (Evans & Strumpf, 1989). However, recently, bed rails have been recognized as physical restraints (Ontario Hospital Association, 2001; Marcy-Edwards, 2005).

Table 2.2 shows that patients in nursing homes and chronic care facilities internationally are receiving psychotropic drugs that may be used as chemical restraints. Time frames and cross-study drug groupings inhibit accurate comparisons between Ontario and other international sites. However, Ontario's prevalence of antipsychotic drugs in complex continuing care was consistently lower than those reported in Italy, Iceland and Sweden. Moreover, in 1996 Ontario's prevalence rate for antipsychotic drugs was the second lowest rate reported at any time. Between 1996 and 2002, the prevalence of all reported psychotropic drugs in Ontario increased with the largest increase reported in the use of antidepressant drugs.

Table 2.2—International Comparisons, Prevalence of Chemical Restraints

Reference	Country	Sample size	Data Source	Prevalence (%) of Chemical Restraints			
				Antipsychotic and/or Antianxiety/Hypnotic	Antianxiety/Hypnotic	Antipsychotic	
Hughes et al., 2000	Denmark 1992-1993	3,451	UMAAP*	44.4	34.1	16.9	
	Iceland 1994	1,254		70.3	61.8	24.5	
	Italy 1993	1,089		48.3	34.3	22.1	
	Japan 1992-1994	1,255		28.7	24.8	7.5	
	Sweden 1995-1996	1,068		50.5	35.5	26.5	
	U.S. 1993-1995	422,220		25.5	14.4	14.4	
				Hypnotic	Antianxiety	Antipsychotic	Antidepressant
Teare et al., 2000	Ontario, Canada 1998-1999	All MDS** Assessments in Ontario	OCCPS***	1988 – 8.0 1989 – 8.5	1988 – 32.0 1989 – 33.0	1988 – 16.5 1989 – 16.0	Not Reported
Teare et al., 2003	Ontario, Canada 2000-2001	All MDS Assessments in Ontario	OCCPS	Not Reported		2000 – 18.0 2001 – 18.3	Not Reported
CIHI, 2004	Ontario, Canada 1996 - 2002	All MDS Assessments in Ontario	OCCPS	1996 - 8.9 2002 - 9.3	1996 - 19.1 2002 – 22.0	1996 - 13.1 2002 – 18.0	1996 - 17.8 2002 - 27.3

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**Resident Assessment Instrument Minimum Data Set

** Ontario Chronic Care Patient System

Table 2.3 presents international prevalence studies of physical restraints excluding the U.S. These seven primary studies are grouped together because they use a variety of instruments to collect data other than Resident Assessment Instrument Minimum Data Set. International studies, while sparse, tell us two important things. First, the use of restraints is a continuing practice both in long-term and acute care facilities.

Table 2.3—International Reports of Prevalence of Physical Restraints

Reference	Country	Sample	Data Source	Restraint Prevalence
O'Keefe, Jack, & Lye, 1996	Great Britain	Patients n=668	Acute Care Geriatric Units-- observation by Geriatricians	Bed Rails--8.4% (night shift)
Whitehead, Finucane, Henschke, Nicklason, & Nair, 1997	Australia	Patients n=408	Teaching Hospitals Observation and Chart Audit	Restraints combined--8.5 - 18.5% (including bed rails)
Retsas & Crabbe, 1998;	Australia	272 Directors of Nursing (10,065 residents)	Postal Survey to Nursing Home Directors of Nursing	Restraints Combined--15.3% Vests--25.3% Restraining Belt 18.9% Bed rails--17.2% Lap Trays*--14.4% Geri-chairs**--10.5%
Retsas, 1998	Australia	Directors of Nursing n=285 (n=16,397 Residents)	Postal Survey to Nursing Home Directors of Nursing	Restraints Combined --25.5% Bed rails--39% Belts--29% Lap Trays*--12.9% Vests--5.1% Geri-chairs**-- 2.9% Other--2.2 %
Karlsson, Bucht, Eriksson, & Sandman, 2001	Sweden	Patients n=565	10 Nursing Homes 12 Group Living Units; Observation and Staff Questionnaires	Restraints Combined --21% Chair Belts--62% Geri-tables--35% Group Units for Demented: Restraints Combined --9%
Hamers, Gulpers, & Strik, 2004	Netherlands	Residents (n=265)	2 Nursing Homes and 1 Nursing Home Unit; Questionnaire Completed by Nurses	Restraints Combined --49% Bed rails--98% Belts--27% Geri-chairs**--36%
Kirkevold & Engedal, 2004	Norway	222 Nursing Homes, (n=1501 Residents)	Structured interviews conducted by trained research nurses with primary care giver and nurse in charge of ward	Regular Units: Restraints Combined --36.7% Special Care Units: Restraints Combined --45% Expanded definition of restraint used to include environmental restraints and physical force applied by staff members.

*Lap Trays are small fixed platforms that rest slightly above a person's knees when in the sitting positions and are usually used for serving food. They are considered a restraint when a person is unable to remove the device without assistance.

**Geri Chairs are wheeled recliners designed specifically for use with elderly patients. They often have fixed lap trays and a foot rest.

Second, there is variation in the operational definitions of physical restraints. For example, Karlsson and colleagues (2001) included locked rooms as physical restraints; while Kirkevold and Engedal (2004) included the physical holding of hands, legs or head during care and treatment procedures, electronic devices (unspecified) and mixing drugs into food or beverages, all within their definitions of physical restraints and electronic surveillance.

Bed rails are reported as restraints in four of the studies (O'Keefe, Jack, & Lye, 1996; Retsas & Crabbe, 1998; Retsas, 1998; Hamers, Gulpers, & Strik, 2004). This may reflect a growing awareness that bed rails may act as restraints. Moreover, it is interesting to note that bed rails appear to be the most prevalent physical restraint when they are reported.

Special care units (Kirkevold, Laake, & Engedal, 2004) and group units³ for demented residents (Karlsson, Bucht, Eriksson, & Sandman, 2001) have different prevalence for restraints when compared to their associated regular units or nursing homes. In Norway, special care units for demented residents appear to use more physical restraints (Kirkevold et al., 2004), while in Sweden (Karlsson et al., 2001), group living units have lower prevalence than the regular nursing home units. These contradictory findings suggest that segregating residents with dementia may serve to either increase or decrease the overall prevalence of physical restraints. It would be interesting to understand the factors within the group living units that minimized physical restraint use.

Table 2.4 presents recent international prevalence studies of chemical restraints using administrative data, surveys, and staff interviews as data sources. The studies in

³ The authors describe a group unit as a small unit for the care of 6 to 8 persons with dementia. These units are intended to offer patients a 'natural life situation' but with supervision (Karlsson et al, 2001, p.1723).

this table confirm that there is evidence of psychotropic drug administration to elderly institutionalized patients in nursing homes and long-term care facilities in the four countries represented. These studies investigated the four categories of drugs included in the previously noted studies using the Resident Assessment Instrument Minimum Data Set (reported singly or in combination) as well as other drugs grouped as neuroleptics, benzodiazepines, antihistamines and cognitive enhancers. Cross-study comparisons are limited because the grouping of drugs is not consistent across all studies.

Table 2.4—International Prevalence of Chemical Restraints

Reference	Country	Sample	Data Source	Restraint/Psychotropic Drug Prevalence (%)
Draper, Brodaty, Low, Saab, Lie, Richards, & Paton, 2001	Australia (Sydney)	647 residents from 11 Nursing Homes	Resident medication charts	Hypnotics—23.1%(30.5%)* Antipsychotics—21.3%(24.4%) Antidepressants—19.8%(20.1%) Anxiolytics—8.5%(10.2%) Lithium—0.6%(0.6%)
Gobert & D'hoore, 2005	Switzerland and Quebec, Canada	8183 Quebec, 7592 Swiss long term residents	PLAISIR**	Quebec: Hypnotics/ Anxiolytics —43.2% Antipsychotic—32.9% Antidepressants—17.5% Switzerland: Hypnotics/Anxiolytics—54.9% Antipsychotics—35.9% Antidepressant—27.7%
Margallo-Lana, Swann, O'Brien, Fairbairn, Reichelt, Potkins & Mint, 2001	England (Newcastle-upon-Tyne)	231 residents from 3 social care facilities and 6 nursing homes	Drug and demographic information sheets and interviews with residents and care givers	Neuroleptics—41% Benzodiazepines—17% Antidepressants—19% Cognitive enhancers—2% Other Psychotropics—3%
Ruths, Straand, & Nygaard, 2001	Norway (Bergen)	1552 residents in 23 Nursing Homes	Drug dispensary cards and survey data completed by nurses and physicians	Neuroleptics—28% Anxiolytics—16% Antidepressants—37% Antihistamines—35%

*Prevalence of regular prescribed use vs. 'as needed' bracketed value

**PLANification Informatisée des Soins Infirmières Requis (administrative resource management database)

A comparison of the prevalence, based on data from the Ontario Chronic Care Patient System in 2002 (Table 2.2) with those reported in the international studies in 2001, is provided in Table 2.4 (Draper et al., 2001; Margallo-Lana et al., 2001; Ruths et al., 2001). These findings suggest that Ontario complex continuing care residents may receive fewer antipsychotic and hypnotic drugs than nursing home patients in Australia, Great Britain and Norway. However, the relatively low prevalence of antipsychotic and hypnotic drugs in Ontario was reported during a period when Ontario had higher prevalence of physical restraints when compared to seven out of eight international sites as shown in Table 2.1.

Public Policy and Patient Restraints

Public policy in various forms has been implemented in a number of countries as a strategy to minimize the use of physical and chemical restraints. However, only studies from the U.S. support the effectiveness of this strategy. In Canada, the province of Ontario introduced the Patient Restraint Minimization Act in 2001 (Ontario Hospital Association, 2001). Only two other Canadian provinces have regulatory schemes: British Columbia and Quebec (McDonald, 2003). British Columbia has regulations under the Community Care and Assisted Living Act that apply to adult residential care facilities in that province (Clements, G. W., Special Health Law Consultant, Legislation & Professional Regulation, Ministry of Health, British Columbia, personal communication, July 20, 2006). Quebec regulates the use of restraints through the Professional Code (Quebec Professional Code, 2006). Other countries have introduced guidelines such as the Australian Nursing Homes Standards Monitoring Guidelines (Whitehead, Finucane, Henschke, Nicklason, & Nair, 1997) and the Swedish National Board of Health and Wellness Instructions (Karlsson, Bucht, Eriksson, & Sandman, 2001). In 1987, the

federal U.S. Omnibus Budget Reconciliation Act (OBRA 87), which included the Nursing Home Reform Amendments (NHRA), was passed (Shorr Fought, & Ray, 1994; Lantz, Giambanco, & Buchalter, 1996) to regulate the quality of care delivered in nursing homes and minimize the use of physical and chemical restraints. Regulations related to the act became effective in the fall of 1990.

U.S. studies have measured the impact of legislation on the use of physical and chemical restraints among nursing home residents. Tables 2.5 and 2.6 identify key studies undertaken with this purpose. Three of the listed studies in Table 2.5 are cohort studies primarily intended to identify the resident and/or facility level characteristics associated with the use of physical restraints (Castle et al., 1997; Castle, 1998; Sirin et al., 2002). The studies use data from 1990, 1993 (Castle et al., 1997; Castle, 1998) and 1996 (Sirin et al., 2002) thus allowing comparisons of prevalence of physical restraints prior to and after the introduction of the Nursing Home Reform Amendments and regulations in the U.S.

Six years after regulations were introduced into the U.S. federal restraint minimization legislation, as shown in Table 2.5, the prevalence of physical restraints decreased by 19%. In a report by the U.S. Council on Scientific Affairs (Guttman, Altman & Karlan, 1999) on the use of restraints for patients in nursing homes, the authors commented that the potential extent of restraint minimization was greater than was first thought when the Omnibus Budget Reconciliation Act was introduced in 1987 and suggested that reducing prevalence to less than 5% may be an achievable target.

Table 2.5—Prevalence of Physical Restraints in the U.S. Pre- and Post-Omnibus Budget Reconciliation Act (OBRA)

Reference	Data Source	Sample	Pre-OBRA Prevalence	Post-OBRA Prevalence
Janelli, Kanski & Neary, 1994	Questionnaire mailed to Directors of Nursing in Nursing Homes in New York State with >100 beds	159 (49%) Respondents from Nursing Homes	Respondents reported a decrease in the use of physical restraints of from 1% to 97% with a mean value of 42%. (No pre-and post-data reported)	
Castle, Fogal, & Mor, 1997	Health Care Financing Administration (HCFA) evaluation, and Medicare / Medicaid Automated Certification Survey from 268 facilities (MDS* variables)	1990— n=2,170 1993— n=2,088 Nursing Home residents	1990 - 36% (use of physical restraints vs. no restraints--excluding bed rails)	1993 - 26%
Castle, 1998	On-line Survey and Certification of Automated Records (OSCAR)	15,000 Nursing Homes on average for years 1989 to 1996	1989 - 44% physically restrained	1991 - 21% physically restrained
Sirin, Castle, & Smyer, 2002	Data used by Castle et al. 1997 plus nursing home component of Medical Expenditure Panel Survey (MDS* variables)	1990— n=2,170 1993— n=2,088 1996—n >5000 Nursing Home residents	1990—36% (use of physical restraints vs. no restraints--excluding bed rails)	1993—26% 1996—17%

*Resident Assessment Instrument Minimum Data Set

The studies listed in Table 2.6 suggest that the U.S. legislation has been successful in reducing the use of antipsychotic drugs although the results for other psychotropic drugs is mixed.

Table 2.6—Prevalence of Chemical Restraints in the U.S. Pre- and Post-Omnibus Budget Reconciliation Act

Reference	Data Source	Sample	Pre-OBRA Prevalence (%)	Post-OBRA Prevalence (%)
Shorr, Fought, & Ray, 1994)	Nursing Home Files and Computerized pharmacy files	9432 Nursing Home Residents (Medicaid Enrolees)	Antipsychotic: 1989 — 23.9	Antipsychotic: 1991— 17.5 ($p<0.001$) with no associated increase in other psychotropic drugs
Garrard, Chen & Dowd, 1995	Minnesota annual Quality Assessment and Review Form	33,000 residents in 372 Minnesota skilled nursing facilities	Antipsychotic: 1987/88—23 Antianxiety: 1987/88—11 Antidepressant: 1987/88—14	Antipsychotic 1990/91—15 Antianxiety: 1990/91—12 Antidepressant: 1990/91—16%
Lantz, Giambanco, & Buchalter, 1996	Computerized pharmacy records March 1984 to July 1994	514 Nursing Home Residents	Antidepressant: March 1984 14.2% Anxiolytics/Sedative /Hypnotics: March 1984 —12.1 Antipsychotic: March 1984 — 12.4	Antidepressant: July 1994 26.1 Anxiolytics/Sedative /Hypnotics: July 1994 — 6.4 Antipsychotic: July 1994 — 8.6
Siegler et al., 1997	Recorded drug use and observation of physical restraints at four observations T1, T2, T3 and T4	643 Residents in three Nursing Homes, one control (C) and two with interventions(I ₁ , I ₂)	Neuroleptic: (T1) C-18.6 I ₁ -13.5 I ₂ -18.2 Benzodiazepine: (T1) C-32.8 I ₁ -37.2 I ₂ -22.3	Neuroleptic: (T4) C-11.3 ($p=0.014$) I ₁ -15.5 ns* I ₂ -19.0 ns Benzodiazepine (T4) C-26.6 ($p<.001$) I ₁ -27.0 ($p<.001$) I ₂ -18.2 ($p<.001$)

* ns = not significant

Design Issues

Prevalence reported in this thesis is drawn from a variety of study designs including cohort, cross-sectional, point prevalence, pre- and post-observational, and descriptive

studies using data from questionnaires. The quality of the reported results and the potential for meaningful comparisons among these studies are limited by features of their design including (1) study population and time frame, (2) definitions of devices and drugs, (3) data measurement, and (4) analysis.

Study Population and Time Frame

Differing patient characteristics, sampling frames, and time frames make cross-study comparisons less meaningful. The primary studies in Tables 2.1 and 2.2 draw data from assessments of patients in different kinds of facilities since they compare patients in nursing homes with those in complex continuing care facilities. Ljunggren and colleagues (1997) took steps to minimize the cross-national differences in patient mix by excluding pure rehabilitation wards and long-term care facilities with less-dependent residents. They also controlled for cognitive function and physical disability. Hughes and colleagues (2000) (Table 2.2) noted that low Japanese prevalence of chemical restraints may have been related to the fact that Japanese data came from facilities that were considered to be of the highest standard in Japan.⁴ The Japanese residents tended to be younger, and had less diagnosed depression and anxiety⁵.

Studies in Tables 2.1 and 2.2 may have included patients with a mix of ages. For example, in Canada, data from complex continuing care facilities included patients less than 61 years of age (approximately 10% of the patient population) (Teare et al., 2000). It is not clear whether nursing homes in the U.S. and in other international locations included such a wide age span.

⁴ The authors do not explain what constitutes a high standard.

⁵ No definition or ICD coding of depression or anxiety was offered by the authors.

Samples from nursing homes in Europe and Japan were relatively small compared to samples from U.S. nursing homes. Furthermore, some studies, such as those from Europe and Japan, provided data from selected regions that may not be representative of entire countries. A further example of regional results is found in Table 2.4 where a study reported point prevalence among elderly patients in a single catchment area in Newcastle-upon-Tyne in the north east of England (Margallo-Lana et al., 2001).

There are further design limitations imposed by the different or unspecified time periods during which data were collected. For example, the studies in Tables 2.1 and 2.2 reported that in the U.S., data were collected over a three-year period between 1993 and 1995 while Iceland provided data from 1994. As shown in Table 2.4, Gobert and D'hoore (2005) used administrative data collected throughout both Quebec and Switzerland using the same system (PLAnification Informatisée des Soins Infirmières Requis). However, they do not state the time frame within which the data were collected.

Cultural factors may influence the kinds of elderly patients who are institutionalized and the tolerance for certain kinds of restraints, further limiting cross-study comparisons. Knowledge of cultural factors might strengthen the interpretation of international comparisons of prevalence of restraint use. For instance, Ljunggren and colleagues (1997) speculated that the relatively high prevalence of chair restraints in Spain may be due to a cultural tolerance for this type of restraint.

Definitions of Devices and Drugs

All studies that used the Resident Assessment Instrument Minimum Data Set data used standardized definitions of physical restraints and psychotropic drugs although the aggregation of some data categories inhibits comparisons. An example of this is found in Table 2.2 where groups of drugs were reported together in some studies and separately in others.

Physical restraints are often defined by the researchers based on devices that are commonly in use. The study by Kirkevold and Engedal (2004) listed 26 possible physical restraints and included physical force or pressure, electronic surveillance, and locked rooms as physical restraints. By comparison, the Resident Assessment Instrument Minimum Data Set includes five categories of physical restraints: full bed rails, half bed rails, trunk, chair, and limb restraints (Teare et al, 2000). Standardized definitions are used for these categories of restraints. It is possible that the restraining belts reported by Retsas and colleagues (Retsas & Crabbe, 1998; Retsas, 1998) are in fact trunk restraints and lap trays that are equivalent to chair restraints although Geri-chairs are considered separately. Most researchers continue to exclude bed rails in prevalence studies of physical restraints, even in more recent studies such as that of Karlsson and colleagues in 2001 (Table 2.3) and Sirin and colleagues in 2002 (Table 2.5). An exception to this is the recent study by Edwards and colleagues (2006).

Data Measurement

The way in which data are collected affects the quality and comparability of the reviewed studies. All contributing countries used the Resident Assessment Instrument Minimum Data Set in the primary studies listed in Tables 2.1 and 2.2. However, countries outside the U.S. were using the instrument for the first time, potentially introducing measurement inaccuracies as health care professionals learned how to assess and code patient data.

Studies that used standard instruments that were valid and reliable provided the best opportunity for comparing results. Studies consistently used the Resident Assessment Instrument Minimum Data Set to collect data, which, although limited by other features of the study design, allowed comparison of similar patient characteristics as shown in Tables 2.1 and 2.2. The reliability and validity of the Resident Assessment

Instrument Minimum Data Set assessment tool has been established through a number of international studies (Fries et al., 2000; Hartmaier et al., 1995; Hawes et al., 1995; Morris et al., 1994). Resident Assessment Instrument Minimum Data Set data was also used for the last three studies listed in Tables 2.5 (Garrard et al., 1995; Lantz et al., 1996; Siegler et al., 1997).

Studies reported in Tables 2.3 through 2.6 used a variety of instruments to collect data. For example, studies listed in Table 2.3 used direct observation, staff surveys, mailed surveys, and structured interviews. However, only the two Australian postal surveys (Retsas & Crabbe, 1998; Retsas, 1998) addressed reliability and validity by reporting that the questionnaires were pilot tested and inter-rater reliability estimates ranged from 0.31 to 0.61. In Table 2.4, Gobert and colleagues (2005) used a common administrative database, which was approved by the Ministry of Health and Social Services in Quebec and the Medical-Social Centres in four Swiss cantons⁶, but no information is given about the reliability or validity of the data system.

The cross-sectional studies reported in Table 2.3 include studies from Great Britain (O'Keefe, Jack, Lye, 1996), Sweden (Karlsson et al., 2001), and Norway (Kirkevold et al., 2004). Each of these studies measured restraint use prevalence using direct observations, structured interviews, rating scales, and questionnaires. Trained health professionals are reported to have collected data only in the studies from Great Britain and Norway. There is the potential for inconsistent data collection when health professionals are not familiar with standardized procedures of data collection (Freidman, Furberg & DeMets, 1998). There are also potential problems when data from interviews

⁶ The twenty-six cantons of Switzerland are the states of the federal state of Switzerland. Historically each canton was a sovereign state, with its own borders, army, and currency; the current federal structure was established in 1848. http://en.wikipedia.org/wiki/Swiss_canton

with nursing staff are compared with data from chart audits as chart audits have been reported to overestimate the prevalence of restraint use (Edwards et al., 2006).

Two Australian studies (Retsas & Crabbe, 1998; Retsas, 1998) included in Table 2.3 reported results of a survey distributed to the directors of nursing homes. Response rates for the surveys were 64% and 65%, respectively. It is possible that nursing homes with a high prevalence of physical restraints were disinclined to respond to the survey, thereby introducing an under-reporting of actual restraint use. Prevalence was requested in the surveys but there is no explanation of how or when prevalence was measured. For example, direct observation during a daytime shift on a weekday might have produced different results than a 24-hour record of restraint use from a chart audit.

Janelli and colleagues (1994), used questionnaires designed by the researchers and mailed to 323 nursing homes several years after the introduction of the legislation (the survey date was not reported)⁷. The response rate was 49.2%. This study may have suffered from a volunteer bias, as the response rate was low. Respondents were asked to estimate the change in post-legislation prevalence in their facilities. How these estimates were obtained was left to the discretion of the respondent. Consequently, the changes in prevalence that are reported are suspect.

Sirin and colleagues used secondary cross-sectional study data from Castle and colleagues (1997) for the years 1990 and 1993, representing the pre-legislation period, and complete national data from 1996 representing the post-legislation period. The authors reported that there were limitations imposed by the different sources for pre-legislation and post-legislation data as the former were for ten states while the latter were national in scope.

⁷ The authors did not note whether the questionnaires were piloted or tested for reliability.

Analysis

The studies reviewed in this thesis used a variety of methods to compare prevalence. However, time series analysis was rarely used or was used inappropriately when time series data was available. Lantz and colleagues (1996) used administrative data on antidepressant, anxiolytic and antipsychotic drugs prescribed between 1984 and 1994 period in one nursing home. The authors compared data reported in 1984 to data for 1994 using a chi square statistic. However, the authors also presented bar graphs of time series data showing the implementation of Omnibus Budget Reconciliation Act and commenting on the results as presented visually. The authors did not perform any statistical tests of the time series data, which was appropriate since the series was very brief ($n=12$) and the data were not reported at regular intervals (Robey, Schultz, Crawford, & Sinner, 1999). However, the study demonstrated that visual analysis of time series data may be useful in the evaluation of restraint minimization legislation.

One example of the inappropriate use of time series analysis is the 1994 study by Shorr and colleagues. Their longitudinal study used data covering a 30-month period between 1989 and 1991 including the point at which the U.S. Omnibus Budget Reconciliation Act came into effect. The authors reported the results of visual analysis of time series plots of all 30 months of data. They then used ordinary least squares to calculate unbiased estimates of slopes, computed mean slopes and associated standard errors and then performed paired *t*-tests to detect statistically significant differences between the pre- and post-intervention periods. The authors' method of analysis assumes that the residuals of the standard errors are independent, normally distributed, random, and of constant variance, which is unlikely since positive autocorrelation typically occurs when time series data is collected monthly (Biglan, Ary & Wagenaar, 2000). The authors do not report whether they tested the time series data for autocorrelation.

Facility Characteristics and Physical and Chemical Restraints

This section presents the results of studies looking at facility characteristics associated with an increased risk of physical restraint use. Five descriptive cohort studies that were published between 1993 and 2002 are presented in Table 2.7. The studies were based on administrative data collected from U.S. nursing homes between 1987 and 1996. The studies reported on data collected from nursing homes in Pennsylvania (Zinn et al., 1993), North Carolina (Graber & Sloane, 1995), and ten U.S. states combined⁸ (Castle et al., 1997; & Sirin et al., 2002; Phillips et al., 1996). The results of these studies are mixed and no facility characteristics were found to consistently influence the use of physical restraints.

Zinn and colleagues (1993) found that in 1987, facilities with higher numbers of beds were associated with greater than expected prevalence of physical restraints ($p \leq 0.01$). While not statistically significant, Philips and colleagues (1996) reported that a slightly higher proportion of patients were restrained in facilities smaller than 120 beds than facilities with 121 or more beds (39.9% vs. 36.4%). Furthermore, Sirin and colleagues (2002) found that in 1996 larger facilities reported lower prevalence of restraint use than smaller facilities ($p < 0.001$).

Castle and colleagues (1997) reported from 1990 data, a higher risk of restraint use in facilities that had an occupancy rate falling into the top two thirds of the study population (OR 1.6, 95% CI 1.2-2.1); but in 1993 facilities in the top third reported an association with lower restraint use (OR 0.49, 95% CI 0.2-0.9). Using data from 1990, Phillips and colleagues (1996) noted that a higher but not statistically significant proportion of patients (40.2% vs. 37.2%) were restrained in facilities with an occupancy rate lower than the median of 96% occupancy.

⁸ California, Connecticut, Iowa, Maryland, Minnesota, Ohio, Oregon, Tennessee, Texas, and Virginia

Castle and colleagues (1997) found that patients in 1990 were more likely to be restrained if they were in for-profit facilities (OR 1.64, 95% CI 1.2-2.2). In 1993, facilities in an area with a Herfindahl index⁹ in the top third of all scores (i.e. an area of greater market competition) were more likely to be restrained (OR 1.4, 95% CI 1.01-1.9) while an index in the middle third had a reduced risk of being restrained (OR 0.61, 95% CI 0.5-0.8) (Castle et al., 1997). Patients in Alzheimer's special care units that same year were less likely to be restrained (OR 0.60, 95% CI 0.4-0.9) (Castle et al., 1997). Phillips and colleagues (1996) found no statistically significant difference in the proportion of patients restrained in for-profit facilities vs. non-profit facilities in 1990.

The proportion of registered nurses, licensed practical nurses or nurses' aides to residents was associated with either an increased or a decreased risk of being physically restrained. In 1990, Castle and colleagues (1997) reported that a high or medium number of nurses' aides to residents decreased the likelihood of restraint use (OR 0.73, 95% CI 0.5-0.97; OR 0.77, 95% CI 0.5-0.96). However, this had changed in 1993 to an increased risk (OR 1.44, 95% CI 1.1-2.1; OR 1.22, 95% CI 1.02-1.7). In 1991, Grabber and colleagues (1995) found that a high number of either licensed practical nurses or nurses' aides to patients was associated with a lower risk of restraint use ($p < 0.05$).

⁹ A measure of market competition derived from the squared market share of all nursing home beds in the area being assessed e.g. within a county (Zinn et al., 1993)

Table 2. 7—Facility Level Risk Factors for Physical Restraints

Reference	Cohort	Location		Facility Type					Patient Funding Source		Market Competition		High Numbers of Staff to Residents		
		Large vs. Small	Urban vs. Non Urban	Hospital Owned	For Profit	Non Profit	Chain ¹⁰	Within Special Care Units	Private	Public	Higher vs. Lower % Occu-pancy	Higher vs. Lower HFDL ¹¹	RN ¹²	LPN ¹³	Nurses' Aids ¹⁴
Zinn et al., 1993	1987	+	NA	NA	0	NA	NA	NA	0	0	0	0	0	NA	NA
Graber and Sloane, 1995	1991	0	0	NA	NA	0	0	NA	NA	0	0	NA	0	-	-
Phillips et al., 1996	1990	0	+	0	0	0	NA	NA	NA	0	0	NA	0	NA	NA
Castle et al., 1997	1990	0	NA	0	+	NA	0	0	NA	0	+	0	0	0	-
Castle et al., 1997	1993	0	NA	0	0	NA	0	-	NA	0	-	+	-	0	+
Sirin et al., 2002	1996	-	NA	0	0	NA	0	NA	NA	0	0	NA	0	0	0

0 = no association

+ = significant association with increased restraints

- = significant association with decreased restraints

NA = not included in the study

¹⁰ A group of associated facilities with the same owners or management.

¹¹ Herfindahl Index

¹² Registered Nurse

¹³ Licensed Practical Nurse

¹⁴ Nurses' Aide

Castle and colleagues (1997) reported that in 1993, a high number of registered nurses to residents decreased the risk of restraints (OR 0.43, 95% CI 0.2-0.9). Two factors are at play here: the numbers of nursing staff members and the qualifications of these nurses. Further study is required to better understand how each of these factors independently influences restraint use.

Phillips and colleagues (1996) found that some non-urban facilities had a statistically significant greater proportion of restrained patients than urban facilities (45.4% vs. 36.9%, $p < .05$). Urban facilities were within a metropolitan statistical area while non-urban facilities were counties adjoining a metropolitan statistical area. The authors noted that the non-urban counties were not truly rural as they bordered on a metropolitan statistical area.

Castle (2001) looked at the organizational and market characteristics of nursing homes that were early adopters of restraint minimization strategies. He used nationally representative (U.S.) data from 13,162 nursing facilities. Among the characteristics that he identified as associated with early adopters were larger bed size (OR 1.37, 95% CI 1.22-1.56) and percentage of private-pay residents (OR 1.57, 95% CI 1.59 -2.36).

The results of these studies are very mixed. There is some evidence to suggest that the location of a facility (urban vs. rural), the size, profit status, market competitiveness and lower staff patient ratios for certain categories of staff may be associated with an increased use of restraints. The Resident Assessment Instrument Minimum Data Set used for this thesis allowed further examination of three of these facility characteristics including size, location and profit status.

Rogers' Diffusion of Innovations Theory

in Time Series Policy Studies

Rogers' (2003) Diffusion of Innovations Theory was selected as the theoretical basis for this study because it is a robust theory with an extensive research foundation and has previously been used successfully to study the impact of public policy (Wagenaar, Webster, and Maybee, 1987; Chen et al., 2000; Balart and Riba, 1995). Rogers' Diffusion of Innovations Theory is, as of 2002, based on over 6200 empirical diffusion studies (Rogers, 2002). Rogers defined diffusion as "the process in which an innovation is communicated through certain channels over time among the members of a social system" (Rogers, 2003, p. 474), and describes an innovation as "an idea, practice, or object that is perceived as new by an individual or by another unit of adoption" (p. 475). Rogers' theory is considered a major influence that has contributed "significantly to the understanding of research utilization in health care decision making" (Dobbins, Ciliska, Rhonda, Barnsley, & DiCenso, 2004, p. 1).

The Hierarchy of Adopters

Rogers (2003) identified a hierarchy of adopters of an innovation beginning with *innovators*, and followed in succession by *early adopters*, *early majority*, *late majority* and *laggards*. Rogers described innovators as "venturesome" (Rogers, 2005, p.282). They are individuals who control fiscal resources and can afford to risk failure. They easily understand complicated information and can apply complex technological knowledge. They have the courage to explore and try new ideas. This group often has networks that expand beyond their peers and readily link with other innovators.

Early adopters might be termed 'champions' of an innovation within their local communities. Both peers and innovators respect them, and their opinions are sought out.

They tend to be strong members of their local community but do not cultivate extensive contacts beyond that community with the same enthusiasm as innovators.

The early majority are, as the name implies, one of the largest groups. They are avid communicators within their community but are not usually sought out for their opinions. This group provides an important link between those who adopt early and those who are reluctant to adopt a new innovation. The early majority will take their time to adopt the innovation and think carefully before acting.

The late majority is a group that is reluctant to adopt the innovation until most of their peers have already done so. Members of this group may need to be prompted by incentives particularly as they are likely to have access to fewer resources to introduce the innovation.

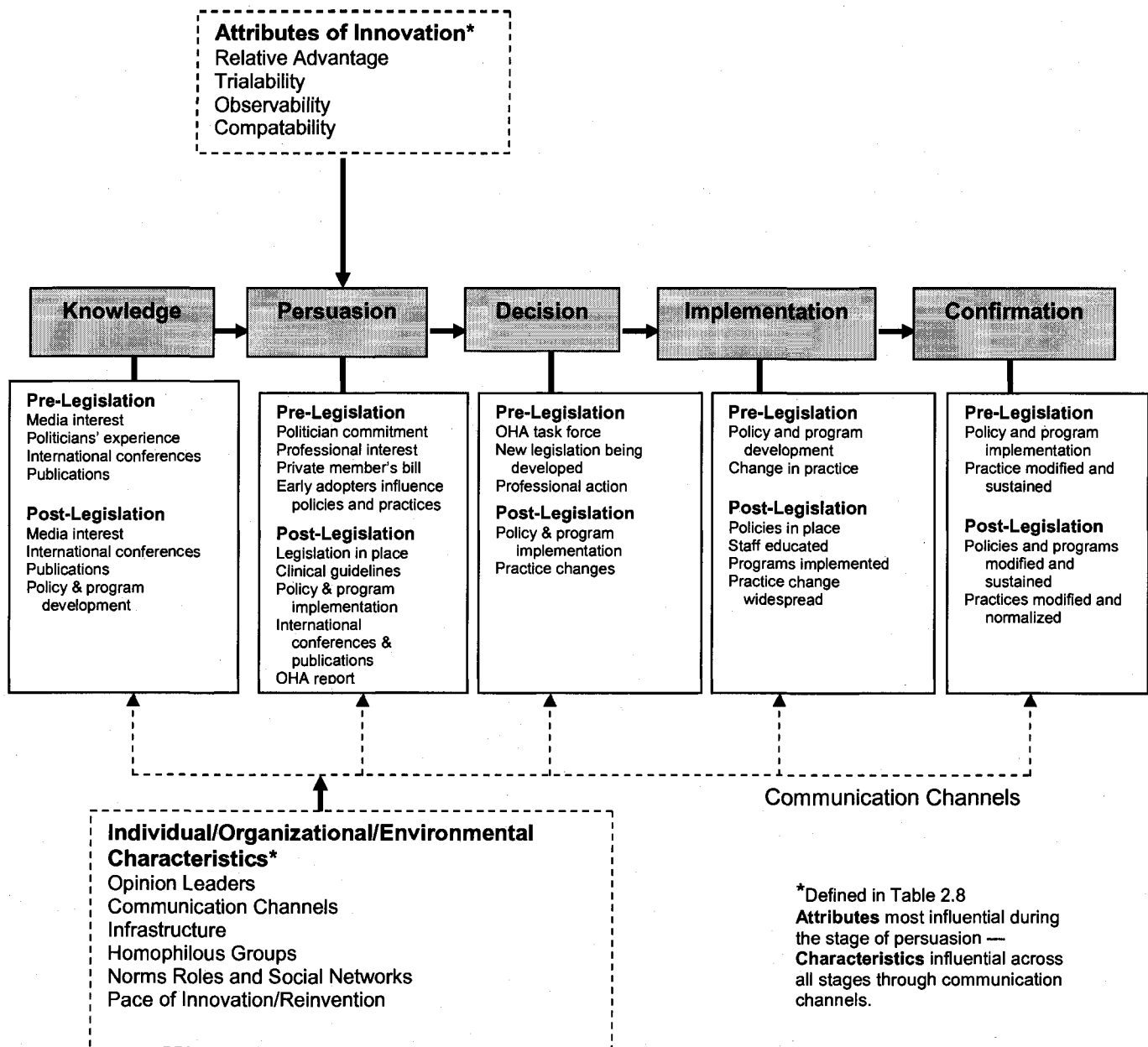
Laggards might be more appropriately named traditionalists. They view that the way things were done in the past was best. They are the last to adopt a new innovation. Generally they do not communicate vigorously within their communities.

The Five Stages of the Innovation-Diffusion Process

Rogers (2003) described five stages of innovation diffusion (knowledge, persuasion, decision, implementation and confirmation) as shown in figure 2.1. These stages reflect the process of introducing and adopting a new innovation. In this study, the practice of minimizing physical restraints is the innovation. Figure 2.1, shows the linear progression of diffusion of an innovation from the introduction of knowledge about the innovation until the change in practice is confirmed.

The first stage, or knowledge stage, of innovation diffusion occurs when a new idea or innovation is initially recognized. This process can be a passive introduction through such routes as advertising or reading material to which individuals might normally be exposed in the course of their regular lives.

Figure 2.1—Five Stages of the Innovation-Diffusion Process



In the second stage of innovation, known as the persuasion stage, the individual or unit of change has been exposed to information about the new idea or innovation and assimilates that information to form an attitude. The attitude formed at this stage is based on feelings related to the advantages or disadvantages of the idea or innovation. It is during this stage that the attributes of the innovation can influence the rate at which the innovation

is diffused. A positive attitude towards a new idea or innovation does not necessarily result in action particularly in the case of a preventative innovation (Rogers, 2002).

The third stage, or decision stage, is the stage at which a decision is made to adopt or reject the innovation. This stage may be influenced by the culture into which the innovation is introduced. A culture that is more group orientated vs. individualistic may adopt an innovation more rapidly (Rogers, 2003). Incentives may influence adoption at this stage and may be useful for preventive innovations since these kinds of innovations tend to diffuse slowly (Rogers, 2002). The fourth stage, or implementation, occurs when the innovation is put into practice. The final stage in the diffusion process, called confirmation, describes whether the adopted change will continue to be implemented or practised in the long term.

Dobbins and colleagues (2004) suggested that Rogers' Diffusion of Innovations Theory, while appearing linear, is not always linear since communities or groups may move forwards and backwards through the stages before reaching confirmation. Two distinct diffusion processes occurred relative to the legislation with the five stages occurring both before and after the introduction of the legislation.

Pre-Legislation Diffusion of Minimization of Physical Restraints

As shown in figure 2.1, the media focus on the use of physical and chemical restraints in Ontario and the politicians' personal experiences (e.g., Frances Lankin's mother was restrained while in hospital) contributed to the knowledge stage of Rogers' (2003) Diffusion of Innovations Theory. Additionally, health care workers were exposed to new knowledge about restraint minimization through international conferences and publications.

During the pre-legislation stage of persuasion, a Private Member's Bill was being written by Frances Lankin and discussed by colleagues. The introduction of this bill

demonstrated a commitment to the issue on the part of some politicians even though the bill was defeated.

Typically there are early adopters actively influencing attitudes in organizations at this stage. Ontario facilities that could be termed “lead” facilities due to early appreciation of the advantages of minimizing physical restraints, might have considered introducing or revisiting policies and practices related to the use of restraints during this stage.

Interest among health care professionals resulted in the Ontario Hospital Association setting up a task force on restraint minimization. This can be viewed as the decision stage for representatives of hospital members of the association since they made the decision to move forward with this issue by studying it further. This movement by the Ontario Hospital Association may have also helped to retain the momentum of diffusion since a new minimization bill was being drafted simultaneously.

Health care workers in some facilities reached the implementation stage prior to the legislation as early adopters influenced the early majority by forming committees, drafting new policies and developing minimization programs that began to change practice. Facilities that were successful in drafting policies and implementing minimization programs may have reached the stage of confirmation prior to the legislation.

Cue-to-Action

Rogers (2003) defines a *cue-to-action* as “an event occurring at a time that crystallizes a favourable attitude into overt behavioural change” (p. 176). A cue-to-action is particularly useful for preventative innovations such as the minimization of restraints that is intended to decrease the potentially negative effects of restraint use.

Ontario’s restraint minimization legislation was an intervention that was viewed as a cue-to-action that would launch a second wave of diffusion of the innovation to minimize restraints. Simultaneously, another cue-to-action was identified as the Canadian Council

on Health Services Accreditation's new national patient restraint standards (W. Nicklin, personal communication, January 10, 2006). Other cues-to-action that subsequently reinforced the implementation of restraint minimization included the practice standards published by the College of Nurses of Ontario (CNO, 2005). These provincial practice standards most likely arrived when the early majority were beginning to implement new practices.

Post-Legislation Diffusion of Minimization of Physical Restraints

The media coverage continued into the period immediately after the passage of the new minimization legislation, building knowledge across the province. This knowledge was added to the foundation of information that continued to build through international conferences and publications on restraint minimization. As patient care started to include strategies to minimize restraints, healthcare providers began to learn more about the innovation and this in turn influenced their attitudes towards it. Attitudes were also expected to be influenced by clinical guidelines becoming more readily available in Ontario through the work of the Registered Nurses Association of Ontario¹⁵.

Soon after the legislation, the Ontario Hospital Association published the results of the patient restraint task force (2001). The decision stage was anticipated through the development of facility policies, the education of staff and the implementation of programs as described within the legislation. These activities would inevitably lead to confirmation as practice was customized to fit facility cultures and staff became comfortable with fewer physical restraints.

¹⁵ The Registered Nurses Association published clinical guidelines on Dementia, Depression and Delirium in 2002 that included recommendations on the minimization of physical restraints.

During the confirmation stage, there is danger that the innovation may be rejected. For example, if nursing staff cease using bed rails as restraints and then notice that patients appear to be falling more frequently they may begin to use bed rails as restraints once again. In reality though, the frequency of falls following the removal of bed rails as restraints may have been offset by the reduced severity of injuries (Capezuti et al., 2002) — a fact that may not have been recognized by nursing staff.

Ideally, regulations associated with the legislation would have arrived within the implementation stage to act as an incentive towards confirmation. Enforcement strategies during the implementation stage would have helped move the diffusion process towards confirmation. For example, in the U.S. federal legislation regulations requiring auditors to do unscheduled inspections helped to enforce facility compliance.

The diffusion pattern anticipated, based on Rogers' Diffusion of Innovations Theory, promised a pattern of change in the post-legislation period that would likely prove statistically significant. There are a number of principles that are known to influence the speed and channel that the process of diffusion takes. These principles include certain attributes of the innovation as well as the way that an innovation travels among individuals, organizations or environments (Rogers, 2003). These attributes and channels may facilitate or hinder the diffusion of an innovation and are included in Figure 2.1 and defined in Table 2.8.

Table 2.8—Principles of Innovations that Facilitate or Hinder Diffusion

Attributes of an Innovations	Definition
Relative Advantage	Whether an innovation is seen as better than existing practices or products.
Trialability	Whether individuals or communities can envision easily trying the innovation particularly with the resources available.
Observability	Whether the innovation can be seen being tried or practised.
Compatability	How an innovation is viewed and whether it is consistent with values, beliefs and current practice.
Individual/Organizational/Environmental Characteristics	Definition
Opinion Leaders	Individuals who tend to be influential in the early stages of adoption and are more likely to notice or introduce a new innovation.
Communications Channels	The many channels (people and media) through which information about an innovation may travel
Infrastructure	The existence of established routes of communication throughout an organization.
Homophilous Groups	Communities of similar, like-minded individuals
Norms Roles and Social Networks	The rules and norms of a social system and the informal communication channels through which an innovation moves

Empirical evidence (Rogers, 2003) has identified a predictable distribution curve that describes the adoption of a new innovation. The pattern of adopting an innovation usually follows a normal bell curve based on frequencies of each adopter category. However, a plot of the cumulative frequency of adopters produces an S-shaped curve that rises slowly at

first then accelerates as a larger proportion of individuals adopt the innovation. It then increases at a slower rate as laggards adopt the innovation.

Rogers' Diffusion of Innovations Theory in this thesis applies to the overall community of health-care providers who care for patients in complex continuing care beds in Ontario as well as the communities within each individual facility or type of facility. The theory substantiates the notion that there could be a different pattern of diffusion among the different types of facilities such as urban, rural, small, large, private and public.

In order to understand how Rogers' Diffusion of Innovations Theory might apply to time series studies that measure the impact of public policy, primary studies that used a time series design to measure the effectiveness of public policy on health related outcomes were examined. Three time series studies that were published between 1985 and 2000 were chosen and are listed in Table 2.9. Principles of the theory were found in each of these studies. These studies provide further support for the selection of Rogers' Diffusion of Innovations Theory to underpin this thesis.

Table 2.9—Evidence of Principles of Rogers' Diffusion of Innovations Theory in

Time Series Studies

Reference	Design	Public Policy	Data Source	Attributes or Characteristics Influencing Policy Diffusion/Adoption
Wagenaar, Webster and Maybee 1987	Time series design	Mandatory restraints of young children travelling in motor vehicles in Michigan, U.S.	Police and hospital data on injuries to children from car accidents from 1978 to 1983	Communication Channels accompanied by extensive public information and education; Relative Advantage of Innovation minimal fines of \$10 and infrequent citations offer limited incentive to parents Diffusion pattern S curve with acceleration following the introduction of the policy
Chen, Wilson, Meckle, and Cooper, 2000	Time series design	Introduction of Photo Radar to prevent speeding in British Columbia, Canada	Speed data from photo radar devices from Sept. 1995 to Nov. 1996	Communication Channels preceded by extensive public education; Norms, rules and social networks extensive media coverage of opposition by politicians and the public Relative Advantage of Innovation drivers were issued with warning letters in the first five months after which traffic violation tickets were issued
Ballart and Riba, 1995	Time series design	Mandatory helmets for small motorbike drivers in Barcelona, Spain	Police records on motorcycle accidents, December 1990 to October 1993	Relative Advantage of Innovation penalties were issued when helmets were not used Communication Channels preceded by publicity campaign Observability police were rigorous in the application of the law Diffusion pattern S curve of accident reduction with acceleration following introduction of the law

Samples of primary studies that did not use time series design but that measured the impact of public policy on health related outcomes were examined. Five studies published between 2002 and 2006 were chosen as examples and are included in Table 2.10.

Table 2.10—Research on Policy Diffusion and Adoption Influences

Reference	Study Design	Data* Source	Policy	Attributes and Characteristics Influencing Policy Adoption/Diffusion
Pankratz, Halfors and Cho, 2002	Pre- and Post-Surveys	Surveys from a convenience sample of 104 school district coordinators	U.S. Federal Drug Prevention Policy	Compatability/Relative Advantage of Innovation --financial incentives, complexity, and observability enhanced policy acceptance
Halfors and Godette, 2002	Pre- and Post-Surveys	Same data source as Pankratz et al. 2002	U.S. Federal Drug Prevention Policy	Infrastructure -- policy inhibited by decentralized decisions and lack of program guidance
Spurlock, 2005	Pooled time series cross-sectional	55 Health Departments based on data from LHDTCS, SFFES, KASS, KDPH	Tobacco Cessation Programs	Communication Channels --Number of tobacco cessation programs; Infrastructure --funds available for counter advertising, and Homophilous Groups -- higher mean age in population
Deverell, Randolph, Albers, Hamilton, and Siegel, 2006	Time series	U.S. Census from 1990 to 2000 and enactment of state-wide smoke-free laws	Local Smoke Free Ordinances	Diffusion Pattern --slow concave S curve from 1993 to 2004 with notable acceleration in 2001 Homophilous Groups -- initially groups with higher education, above the poverty, non rural, and non-ethnic were afforded greater protection

*Legends for Data Sources

LHDTCS--Local Health Department Tobacco Cessation Survey

SFFES--Smoke-Free Food Establishment Survey

KASS--Kentucky Agricultural Statistics Service

KDPH--Kentucky Department for Public Health

These studies were also reviewed for the principles of diffusion from Rogers Diffusion of Innovations Theory (2003). Four of the principles as well as evidence of the typical diffusion curve were noted as shown in Table 2.10.

Summary

An accurate picture of the prevalence of physical and chemical restraint use is inhibited by inconsistent methods used to collect data and varying definitions of restraints. The Resident Assessment Instrument Minimum Data Set has been used to assemble information about physical restraints and psychotropic drugs in some international studies and in studies from Ontario, Canada. These studies suggest that Ontario may have a higher prevalence of physical restraint use than most other sites using this data set.

The collection of data using the Resident Assessment Instrument Minimum Data Set was mandated in the U.S. for all nursing homes as part of the federal legislation on restraint minimization. This has allowed researchers to study the impact of this legislation. However, studies tend to use pre- and post-study designs even when time series data may have been available.

Evidence of facility characteristics that influence the use of restraints is inadequate to confidently describe facility environments that help promote or inhibit restraint minimization although facility size and proprietary status may be important. Time series design has rarely been used to study the impact of public policy.

Rogers' Diffusion of Innovations Theory is robust and has been previously used as a basis for studies measuring the impact of public policy. There is evidence to suggest that Rogers' Diffusion of Innovations Theory can be helpful in guiding time series analysis and in understanding the influence of public policy interventions on communities.

3. Methods

This chapter identifies the research questions, the design and the source of data; presents eligibility criteria; defines dependent and independent variables; and, describes time series analysis procedures.

Research Questions

Research question 1

Following the introduction of patient restraint minimization legislation, was there a significant change in the prevalence of physical and chemical restraints used on elderly patients in Ontario's designated complex continuing care beds?

Research question 2

Following the introduction of patient restraint minimization legislation, did changes in the prevalence of physical and chemical restraints vary according to the type of facility (i.e., urban or rural, large or small, private or public)?

The analysis of chemical restraints was omitted from this thesis for considerations that are discussed in greater detail in Chapter 5.

Research Design

Interrupted Time Series

A simple interrupted time series design with brief series data (fewer than 50 pre- and post-intervention observations) was used. In a simple interrupted time series design, data are collected at repeated points in time (ideally at equidistant observations), an intervention is introduced, and then data are collected at repeated points in time after the

intervention. The purpose of an interrupted time series design is to detect whether there is an effect following an intervention and determine whether that effect was greater than expected based on the trajectory of the pre-intervention trend (Ramsay et al., 2003). The introduction of the Ontario Patient Restraint Minimization Act (2001) is operationalized as the intervention for this interrupted time series design.

Interrupted Time Series for Autocorrelation (ITSACORR)

Crosbie (1993) developed a method of time series analysis called Interrupted Time Series Analysis for Autocorrelation, which is called ITSACORR. He created a software program to perform ITSACORR analysis that is distributed without charge and is intended to facilitate the work of both clinicians and clinical researchers.

From 1970 to the present, there has been consensus among most time series analysts that both visual analysis and data analysis of brief time series data can be problematic (Huitema & McKean, 1998; Onurn, 1997; Shadish et al., 2002). However, a combination of both, used judiciously, may help to decipher the meaning of brief time series results (Robie et al., 1999). ITSACORR has been widely used to analyze results that have been published in peer reviewed journals and doctoral dissertations as recently as 2005 (Broomfield & Expie, 2005; Callow & Waters, 2005; Maughan, Christiansen, Jenson, Olympia, & Clark, 2005; Zawoyski & Attwood, 2005). Both ITSACORR and visual analysis will be used to analyze data for this thesis.

Methods of Interrupted Time Series Analysis

In choosing the most appropriate method of analysis for the data in this thesis, a number of options were considered. Table 3.1 summarizes methods that have been used by researchers to analyze interrupted time series data. Limitations of other methods that

influenced the decision to use ITSACORR for this thesis are related to the sample size requirements, the presence of autocorrelated data, violation of assumptions, and high error rates.

Interrupted time series design traces its origins to the study of laboratory animals in experimental conditions where data from repeated observation were collected until a stabilized pattern occurred and no further trends appeared (Crosbie, 1993). Effects were considered significant when visual observation of data showed large, abrupt changes following an intervention. Today, literature that deals with interrupted times series design for brief series is found predominantly in the social sciences and often in literature related to single-case brief series interrupted time series design.¹⁶

Visual inspection of graphical analysis has long been a method of analysis to identify obvious effects. However, in the 1970s and 1980s the reliability of visual analysis was subject to criticism since judgment among experts was shown to be inconsistent. Crosbie (1993) compiled studies in which experts had analyzed graphical data and found that inter rater reliability ranged from .39 to .61 (Crosbie 1993). Nevertheless, there is still support for the use of visual analysis and several principles have been suggested to strengthen the interpretation of graphical displays of time series data Franklin, Allison, Gorman, 1997). Franklin and colleagues (1997) suggested that *central location*, *variability*, and *trend* could be explored visually to determine significance. They suggest that pre- and post-intervention phases be clearly delineated.

¹⁶ This was found by searching conventional medical databases such as Medline and HealthStar with few results and then finding a rich pool of literature within PsychInfo.

Gottman (1981) described a non-parametric method proposed by O. R. White¹⁷ in the mid 1970's using a binomial approach and C-test. In this approach, the trend line is computed using the pre-intervention data and then projected through the second phase. A binomial test is used to detect whether there is a statistically significant change in the trend line over the second phase. The rationale for the split is that if the trend line continues through the second phase then the proportion of scores that fall above the trend line in the second phase is equal to the proportion of scores above the trend line in the first phase. The assumptions of this method are that the data are not influenced by the previous outcomes or in other words that the data are independent. Gottman pointed out ... "autocorrelation (the problem that the binomial test is supposed to overcome) means that a score can be predicted from its predecessors, so when the binomial test is used with autocorrelated data its assumptions are violated " (p. 368). However, time series data are most often autocorrelated, that is, they are not independent. Autocorrelation is assessed using an autocorrelation coefficient which is "...a modified form of the Pearson product-moment correlation coefficient in which one variable in a series of data values ordered in time and the other variable in the same time series is lagged or advanced by k time periods (or 'time-lags') (p.162) (Gorman & Allison, 1997). The second potentially erroneous assumption with the binomial method is that the trend in the pre-intervention phase would have continued throughout the post-intervention phase in the absence of the intervention.

In the early 1970s, researchers proposed that the analysis of change could be statistically analyzed using analysis of variance (ANOVA), followed by a simple t -test. Using this method, researchers would assume all pre-intervention observations constituted

¹⁷ White, O.R. (1974). *The "split middle"—a "quickie" method of trend estimation. Experiential Education Unit, Child Development and Mental Retardation Center, University of Washington.*

a single group of data while observations after the intervention comprised a post-intervention group. The fact that time series data are not independent violates one of the key assumptions of ANOVA. While ANOVA is robust enough to withstand some minor violation of assumptions, this is not the case with the independence of observations (Biglan et al., 2000; Crosbie, 1993). The bias in time series analysis using ANOVA is most often downward resulting in an inflated t statistic. As a consequence, the effect of an intervention may appear to be statistically significant when it is not, resulting in a Type 1 error or rejecting the null hypothesis when in fact it may be true.

Cook and Campbell (1979), in their seminal text on interrupted time series analysis, introduced Box and Jenkins' autoregressive integrated moving average or ARIMA modeling for time series analysis as the solution for eliminating unbiased estimates of error in a series. Onurn (1997) noted that, twenty-one years after its introduction, in 1976, ARIMA modeling is still the analysis of choice for interrupted time series analysis. Unfortunately, approximately 100 observations (observations) are necessary to accurately "model trends, seasonality, and the structure of the correlated error " (Shadish, Cook, & Campbell, 2002, p. 198).

Interrupted time series experiment (ITSE) was introduced by Gottman in the early 1980s (Gottman, 1981). This method evaluates both the pre-intervention and post-intervention data but also considers the autocorrelation terms (Biglan, Ary, & Wagenaar, 2000). Interrupted time series experiment uses the General Linear Model (GLM) and then the final result is an omnibus F-test and t -tests on the slope and intercept (Crosbie, 1993; Gottman, 1981). Unfortunately, accurate interrupted time series experiment model development still requires at least 50 to 100 observations for pre- and post- intervention phases.

Crosbie further built on the interrupted time series experiment method to provide better Type 1 error control and increased statistical power through interrupted time series

experiment for autocorrelation, which he called ITSACORR (Crosbie, 1993). He identified a bias in the lag-1 autocorrelation of the interrupted time series experiment method with small sample sizes. This bias was controlled and then the ITSACORR statistical model was built based on the interrupted time series experiment model. Crosbie created tables based on ITSACORR analyses with incrementally changing sample sizes and lag-1 autocorrelation. He was able to show that as the sample size decreased and the lag-1 increased positively, then the underestimation of the omnibus F statistic increased. According to Crosbie (1995) the autocorrelation coefficient can be accurately calculated with a number of formulae if there is no pre-intervention slope. When slope exists, the autocorrelation coefficient is inflated. Crosbie dealt with this problem by estimating the autocorrelation coefficient and using a general linear model to estimate the intercept, slope and autocorrelation coefficient simultaneously.

According to Franklin and colleagues (1996) Crosbie was able to achieve: high (>0.80) statistical power with sample sizes of 30 observations or more; and, less biased *t*-tests of regression coefficients for moderate (5-10 standard deviations) effects. He also commented that Crosbie warned that when the series was <20 observations and combined with a high lag-1 autocorrelation ($r > 0.6$), the test statistic would be inflated. Crosbie (1995) states "one limitation of ITSACORR is that, with moderate change in intercept and high levels of positive autocorrelation, a spurious change in slope is reported" (p. 387).

From 1970 to the present, there has been consensus among most time series analysts that both visual analysis and data analysis of brief time series data are problematic (Huitema & McKean, 1998; Onurn, 1997; Shadish et al., 2002). Both visual and data analysis are required for brief series data (Robie et al., 1999). A combination of both, used judiciously, may help to decipher the meaning of brief time series results. ITSACORR and visual analysis were chosen for this thesis so as to minimize the likelihood

of inflated Type 1 error, to ensure that methodological assumptions were not breached, and to accommodate the small sample size of the data being analyzed.

Table 3.1—Comparison of Proposed Methods of Interrupted Time Series Analysis

Analysis	Description	Sample Size	Limitations
Visual	Observation of graphs seeking large abrupt changes	No special requirement	- Change must be large and abrupt -Graphs may be misinterpreted -Visual analysis should be integrated with statistical analysis
Analysis of Variance (ANOVA) and <i>t</i> -test	Analysis of Variance followed by simple <i>t</i> -test	Minimum of 5 post-intervention observations	-Inflated Type 1 error due to autocorrelation - assumes pre-intervention trend is constant - assumes sample trend line same as population trend line
Autoregressive Integrated Moving Average (ARIMA) Modelling	Statistical modeling characterized by three structural parameters: stationarity, autoregression, and moving average	Minimum 50 to 100 observations	- Models are unstable with <50 points
Binomial	An exact test of the statistical significance of deviations from a theoretically expected distribution of observations into two categories.	No requirement noted	-Result in inflated error rate and Type 1 error
C Statistic	Contrasts the slope of the pre-intervention data with post-intervention data	No requirement noted	-Error rates extremely high when applied to autocorrelated data and Type 1 error is likely
TMS*	Precursor to Interrupted Time Series Experiment (ITSE) Uses General Linear Model (GLM) and <i>t</i> -test	Minimum 50 to 100 observations per phase required	-Assumes a constant level in the pre-intervention phase -Technically demanding
Interrupted Time Series Experiment (ITSE)	Controls autocorrelation and uses a <i>t</i> -test to assess change Less biased than the C-test	Minimum 10 pre-and post-observations provided that change is < 5 standard deviations	- Type 1 error inflated - Underestimates positive autocorrelation

*No expansion of this acronym was offered by authors

Data Source

This thesis uses secondary data from the Ontario Chronic Care Patient System (OCCPS) managed by the Canadian Institute for Health Information (CIHI). These data have been collected on a quarterly basis since 1996 based on assessments of patients occupying provincially designated chronic care beds. The data are collected using Resident Assessment Instrument Minimum Data Set Version 2.0 assessments. The Resident Assessment Instrument Minimum Data Set is “a comprehensive assessment tool containing over 400 elements documenting the clinical and functional characteristics of residents, such as cognition, communication, vision, mood and behaviour, psychosocial well-being, physical functioning, continence, disease diagnoses, nutritional status, skin condition, medications, and special treatments and procedures” (CIHI, 2004, p 4). The reliability and validity of the Minimum Data Set assessment tool has been established through a number of international studies (Fries et al., 2000; Hartmaier et al., 1995; Hawes et al., 1995; Morris et al., 1994). In a move to create a pan-Canadian comparable database for patients receiving complex continuing care, the Ontario Chronic Care Patient System converted to the Continuing Care Reporting System (CCRS) over the time period March 31, 2003 to July 1, 2003 (CIHI, 2004—user guide accompanying data cut).

The term *complex continuing care* came into existence in the mid 1990's to describe more accurately the level of care received by chronic care patients (Hirdes et al., 1999). The care required by this group falls into the general categories of complex medical care, geriatric assessment and rehabilitation, psychogeriatric care, palliative care and respite care (Teare et al., 2003). Patients who occupy designated complex continuing care beds are found in three types of facilities: free standing complex continuing care facilities, acute care hospitals with a wing or ward dedicated to complex continuing care, and small hospitals with a few complex continuing care beds in a larger unit (CIHI, 2004).

The data were provided through the Canadian Institute for Health Information's Graduate Student Data Access Program. Data for this thesis were made available from the Continuing Care Database¹⁸ in April 2005. The Canadian Institute for Health Information allowed only truncated postal codes limited to the first three digits. The Ottawa Hospital Ethics Research Board approved the research protocol (#2005307-01H) for the thesis study on May 5th, 2005.

Aggregation of Data

Although the data were provided as individual assessments dated by month, it was necessary to aggregate the data to quarterly assessment periods. This was because each assessment record commenced as of the date of admission and assessments were then completed every three months. Therefore, the full complement of complex continuing care patients was captured over three months. The unit of analysis for this study was quarterly assessments.

Eligibility

Some assessments were not considered eligible for analysis. Patients who were aged <65 years were not included in the analysis since the intent of the analysis was to examine the impact of the legislation among elderly patients. Comatose patients were removed since these types of patients are not at risk of being restrained. The continuing care reporting system defines restraint use as "the use of any device (e.g., physical or mechanical, material or equipment, attached or adjacent to the resident's body) that the resident cannot easily remove and that restricts freedom of movement or normal access to

¹⁸ The Continuing Care Database managed by the Canadian Institute for Health Information contains data from the Ontario Chronic Care Patient System. The Ontario Chronic Care Patient System is a database that contains the Resident Assessment Instrument Minimum Data Set from Ontario.

his or her body (CIHI 2004, p 57). Comatose patients were identified primarily through variable B1 in which the patient was identified as either comatose or not comatose. Due to errors in coding of variable B1 found in the Canadian Institute for Health Information's data, other variables had to be used to identify all comatose patients including: B2A *assessing short-term memory*, B2B *assessing long-term memory*, and B4 *cognitive skills*, C4 *making self understood*, and G1HA *measuring self-performance related to eating*.¹⁹

Variables

Outcome Variables

The primary outcome variables of this study are the prevalence of physical restraints. For each type of restraint, the prevalence was determined for each quarter using the number of assessments of patients who were restrained, divided by the total number of assessments of patients who were at risk of being restrained in that quarter.

The Resident Assessment Instrument Minimum Data Set elements that were used to calculate the prevalence of physical restraints are listed in Table 3.2. For the purpose of this thesis, a physical restraint is any device that is captured by the five Resident Assessment Instrument Minimum Data Set variables: 1) *limb restraints*, 2) *trunk restraints*, 3) *chair prevents rising*, 4) *full bed rails*, and 5) *other bed rails*. Most types of physical restraints are captured by these five categories. Each coded device captures several types of restraints. For example, the category *trunk restraint* may include a number of devices or belts applied to a patient's chest or waist to limit mobility and *chair prevents rising* may

¹⁹ This error in coding was discovered when applying the decision tree to classify patients by cognitive status using the Cognitive Performance Scale (Morris et al., 1994).

include any kind of obstruction that could not be removed by the patient and prevented the patient from getting up out of the chair.

Table 3.2—Outcome Variable—Definitions of Physical and Chemical Restraints

Resident Assessment Instrument Minimum Data Set Assessment Variables for Physical and Chemical Restraints	Definition of Variables According to Resident Assessment Instrument Minimum Data Set Assessments
P4A_FULL_BED_RAILS	Indicates whether the following device or restraint was utilized for the resident in the last 7 days: Full bed rails on all open sides of bed. 0 - Not used 1 - Used less than daily 2 - Used daily
P4B_OTHER_TYPES_OF_RAILS	Indicates whether the following device or restraint was utilized for the resident in the last 7 days: Other types of side rails used, e.g. half rail, one side. 0 - Not used 1 - Used less than daily 2 - Used daily
P4C_TRUNK_RESTRAINT	Indicates whether the following device or restraint was utilized for the resident in the last 7 days: Trunk restraint. 0 - Not used 1 - Used less than daily 2 - Used daily
P4D_LIMB_RESTRAINT	Indicates whether the following device or restraint was utilized for the resident in the last 7 days: Limb restraint. 0 - Not used 1 - Used less than daily 2 - Used daily
P4E_CHAIR_PREVENTS_RISING	Indicates whether the following device or restraint was utilized for the resident in the last 7 days: Chair prevents rising 0 - Not used 1 - Used less than daily 2 - Used daily

Other Variables

Other Resident Assessment Instrument Minimum Data Set variables as listed in Table 3.3 were used to: provide demographic information, allow the aggregation of data by quarterly assessments, assess eligibility, and differentiate between types of facilities.

Table 3.3—Other Resident Assessment Instrument Minimum Data Set Variables

Assessment Variables	Definition of Variables
POSTAL_CODE	Mailing address postal code of the facility providing care to the resident. The postal code must have an A9A9A9 format to be accepted by CCRS. The postal codes were truncated to three digits to protect confidentiality.
DESIGNATED_MOH_BEDS	The number of Ministry designated continuing care beds at the facility providing care to the resident. Valid Codes ranged from 1-9999, any missing numbers were indicated as "."
AGE_AT_ASSESSMENT	Age of residents at assessment. $\text{Age} = [(\text{Assessment date} - \text{Birth Date}) / 365.25]$
AA2_SEX_CODE	Resident's sex. Valid codes include: M - male F - female O - other
A3_ASSESSMENT_DATE	This element captures the assessment reference date for a specific ASSESSMENT_ID. This date indicates the last day of the assessment observation period. The SAS® software format is DATE9. (DDMMYYYY), e.g. 01APR2004. This field must contain a valid calendar date. This field is part-suppressed as per the Canadian Institute for Health Information's Privacy and Confidentiality guidelines. Only the month and the year provided.
AA8_ASSESSMENT_TYPE	Indicates the reason for assessment. Valid codes include: 1 - Admission full assessment (required by day 14) 2 - Full annual assessment 3 - Significant change in status full assessment 4 - Significant correction of prior full assessment 5 - Quarterly assessment 10 - Significant correction of prior quarterly assessment
B1_COMATOSE	Indicates whether the resident is comatose. 0 - No 1 - Yes
B2A_SHORT_TERM_MEMORY_OK	Indicates whether the resident's short term memory is OK/appears to recall after 5 minutes. 0 - Memory OK 1 - Memory problem 8 - Comatose
B2B_LONG_TERM_MEMORY_OK	Indicates whether the resident's long term memory is OK/appears to recall long past. 0 - Memory OK 1 - Memory problem 8 - Comatose

B4_COGNITIVE_SKILLS	Indicates how the resident made decisions regarding tasks of daily life. 0 - INDEPENDENT: decisions consistent/reasonable 1 - MODIFIED INDEPENDENCE: some difficulty in new situations only 2 - MODERATELY IMPAIRED: decisions poor; cues/supervision required 3 - SEVERELY IMPAIRED: never/rarely makes decisions 8 - COMATOSE
C4_MAKING_SELF_UNDERSTOOD	Indicates how the resident is able to express information content/make self understood, however able and by whatever means. 0 - UNDERSTOOD 1 - USUALLY UNDERSTOOD, difficulty finding words or finishing thoughts 2 - SOMETIMES UNDERSTOOD, ability is limited to making concrete requests 3 - RARELY/NEVER UNDERSTOOD 8 - COMATOSE
G1HA_EATING_SELF	Indicates the resident's ADL Self-Performance, not including set-up, over the past 7 days for the following activity: Eating. 0 - INDEPENDENT. 1 - SUPERVISION. 2 - LIMITED ASSISTANCE. 3 - EXTENSIVE ASSISTANCE. 4 - TOTAL DEPENDENCE. 8 - ACTIVITY DID NOT OCCUR during entire 7 days
OWNERSHIP_CODE	Ownership of the facility providing care to the resident. If more than one code is applicable to the facility, the one that finances the greatest proportion of continuing care beds should be selected. 1 - Proprietary 2 - Religious 3 - Lay (not-for-profit, non-profit voluntary organization, societies) 4 - Municipal 5 - Provincial/Territorial 6 - Federal

Preliminary Database Preparation

The Canadian Institute for Health Information delivered the data-cut from the Ontario Chronic Care Patient System Database as a SAS® software flat file that included 192,873 assessments collected between April 1998 and March 2004. In order to create a data subset on which to perform analyses, the following actions were performed using SAS® 9.1 statistical software:

- Assessments were discarded where the variable *Age_at_Assessment* was <65.
- Assessments were discarded where the value of variable *B1_COMATOSE* was '1' indicating that the patient was comatose.
- Assessments were discarded where patients were identified as comatose for all of five variables including *B2A_SHORT_TERM_MEMORY_OK*, *B2B_LONG_TERM_MEMORY_OK*, *B4_COGNITIVE_SKILLS*, *G1HB_EATING_SUPPORT*, and *G1HA_EATING_SELF* even if they were not originally coded as comatose in the variable *B1_COMATOSE*.
- The variable for gender includes a third option "other" as well as male and female. The "other" gender represents <1% of the population at each assessment and was not reported in the results as a separate gender category although included in all analyses.
- Data were checked for missing cell values and possible outliers by running frequencies of all variables. The following issues were noted:
 - a. In the variable *AGE_AT_ASSESSMENT*—one person is aged 170 years. This obvious outlier was coded as missing but the assessment was retained for analysis.
 - b. The variable *AA2_SEX_CODE* shows 6 observations with no code for gender. This represents 0.004% of the database and was coded as missing.
 - c. The variable *DESIGNATED_MOH_BEDS* shows 76 observations with no designated beds within the facility in which the patient resides. Discussion with the Canadian Institute for Health Information's representatives revealed that this meant that a facility was inactive at the time of the report. An inactive facility is one that accommodated designated beds for complex

continuing care patients at the time of the assessment but has since changed and no longer has any designated beds. Assessments with no designated beds were included in the dataset although these assessments were not represented in the analysis of large and small facilities.

- Data were aggregated into quarterly assessment periods by combining data over three-month periods.

Once all ineligible assessments were removed the new dataset included 144,758 assessments. New variables were created for the analysis of the data and are described along with the rationale for each variable in Table 3.4. There are five types of physical restraints.

Table 3.4—New Variables Created to Facilitate Analyses

Variable	Description
Assessment Dates	Recoded three-month intervals between April 1998 and March 2003 and numbered the quarters sequentially from 1 to 24.
Chair Restraint	Recoded data such that any use of this restraint either daily or less than daily is coded as '1' and no restraint use coded as '0'.
Full Bed rails	Recoded data such that any use of these restraints either daily or less than daily is coded as '1' and no restraint use coded as '0'.
Other Rails	Recoded data such that any use of these restraints either daily or less than daily is coded as '1' and no restraint use coded as '0'.
Trunk Restraints	Recoded data such that any use of these restraints either daily or less than daily is coded as '1' and no restraint use coded as '0'.
Limb Restraints	Recoded data such that any use of these restraints either daily or less than daily is coded as '1' and no restraint use coded as '0'.

Cognitive Performance Scores (1)	Used decision tree (Morris et al, 1994) to create SAS® software code to logically designate Cognitive Performance Scores between 1 and 6. This involved considering the values of B1_COMATOSE, B2A_SHORT_TERM_MEMORY_OK, B2B_LONG_TERM_MEMORY_OK, B4_COGNITIVE_SKILLS, C4_MAKING_SELF_UNDERSTOOD, G1HA_EATING_SELF
Cognitive Performance Scores (2)	Recoded CPS values of '0' and '1' as '0' and then recoded CPS values of 2 through 6 as '1'. i.e., '0' equals intact and '1' equals impaired.
Designated Beds	Recoded the values of this variable to collect the number of MOH beds into groups of 50 numbered from 1 to 9 (i.e. code 1= 1 to ≤50 designated beds, code 2=50 to ≤100 etc.)
Small and Large Facilities	Recoded the values of this variable to collect the number of MOH beds into two groups: code 1 ≤100 beds (small), and code 0 >100 beds (larger)
Postal Codes	Recoded the values to 1=rural location and 0=urban location based on postal codes. Based on information received from Canada Post, any postal code with a '0' in the second position identifies a rural address.
Ownership Codes	Recoded the values to 0=non-proprietary (public ownership) and 1=proprietary (private ownership).

Analyses

Univariate Analysis

The population for each quarter was described using frequencies for population size, and gender, and descriptors for age. Frequencies were also used to identify the population sizes in the various facility types.

Calculation of Prevalence

Dummy variables of "0=not used" and "1=used" were coded for each physical restraint variable at each quarterly assessment. This coding removed intensity of use by

combining results of assessments for daily use of restraints with those of less than daily use. The rationale for this choice was to allow the calculation of prevalence of physical restraints overall. Recent status reports from the Canadian Institute for Health Information based on analyses of data from the Ontario Chronic Care Patient System included prevalence of daily physical restraints (Teare et al., 2000; CIHI 2004). The prevalence of restraints that were used less than daily were not included or assessed separately and no explanation was given for this coding strategy. Since the Ontario legislation was intended to minimize the use of all physical restraints, then the occasional (or less than daily) use of restraints would be a practice that the legislation would affect.

Once it was established that there were no visually or statistically significant²⁰ changes in restraint use following the legislation, the data were re-analyzed on province-wide assessments without the imposed dummy variables to include prevalence of both daily and less than daily restraint use. These data were further stratified by intensity, age, gender and cognitive status. Age was divided into two categories: 65 to 79 years, and 79+ years. These groupings were chosen since each contained approximately half the entire population. The stratification and calculation of prevalence was done in six groupings for each physical restraint province wide (i.e., daily by age, daily by gender, daily by cognitive status and then less than daily by age, less than daily by gender and less than daily by cognitive status). The stratification groupings were chosen in part to ensure reasonable numbers of assessments in each category²¹.

SAS® software's frequency procedure was used to calculate the prevalence of physical restraints overall and by sub groups based on facility type. Sub group analyses of

²⁰ Limb restraints were found to have changed significantly based on ITSACORR analyses in two instances but these were not considered clinically important and are discussed further in the discussion chapter.

²¹ Stratification of all variables combined resulted in some categories having <3 assessments.

the prevalence of physical restraints were carried out to distinguish results from small facilities (<100 beds) or large facilities (≤ 100 beds), rural facilities or urban facilities, and private facilities or public facilities. Prevalence data by quarterly period were used to form a new dataset of time series data for further analysis. SAS® was used to create code to assign each patient's Cognitive Performance Scale (Morris et al., 1994) and the code for this is included in Appendix M. All other analyses were performed using the ITSACORR software program.

Visual Analysis

Several strategies enhance the visual analysis. Province wide and facility type prevalence data were plotted for all physical restraint types combined. On graphs, a space containing a broken line distinguishes the pre-and post-intervention phases. These combined plots allowed the pre-and post-prevalence of physical restraints to be visually analyzed. Separate charts were then created plotting the prevalence of each physical restraint in a pre-legislation phase chart and then in the post-legislation phase chart. A regression line was inserted for each pre- and post-intervention phase (Microsoft Excel—Add Trend Line Function) and the two plots were positioned so that the pre-and post-regression lines could be compared province wide and by facility type for each restraint.

Statistical Analysis of Time Series Data

ITSACORR analysis (Crosbie, 1993) was used to analyze each physical restraint province wide and by facility type. Crosbie (1993) created software for ITSACORR analysis and offers it freely via the Internet. The ITSACORR program is DOS-based. The user is prompted to input the number of pre- and post-intervention values, then input the data, make any corrections and then perform the analysis. A sample of the output from the

program is included in Appendix K. ITSACORR cannot accommodate additional variables to allow control for confounding.

ITSACORR provides the results of an omnibus F-test for overall change and *t*-tests for slope and intercept. If the omnibus F-test was not statistically significant then the results of the *t*-test were not reported since Crosbie (1993) acknowledges that the *t*-test results are only relevant in the presence of a statistically significant omnibus F-test. The Lag-1 autocorrelation coefficient can impact the statistical power of the results (Crosbie, 1993).

Testing the Impact of Cognitive Impairment

In order to assess potential confounding of prevalence of physical restraints by cognitive impairment, prevalence data were stratified to examine prevalence among patients who were cognitively impaired vs. those who were cognitively intact.

Cognitive impairment was measured using the cognitive performance scale (Morris et al., 1994). Assessments with a cognitive performance score from 2 through 6 were identified as cognitively impaired while assessments with scores of 1 were identified as cognitively intact. In order to test confounding, the prevalence of physical restraints province wide was stratified and plotted for both pre- and post-intervention phases. The prevalence of restraint use for cognitively intact vs. cognitively impaired patient assessments was then visually analyzed.

4. Results

This chapter begins by presenting details of sample size and patient demographics. Next, both the visual and statistical analyses of the prevalence of all physical restraints are described. These results are presented province wide for all complex continuing care beds in Ontario, and then by facility type including rural or urban, small or large, and private or public.

Patient Demographics

The database contained 144,758 resident assessments from across Ontario including data from all 24 quarterly time periods from April 1998 to March 2004. The average number of assessments in each time period was 6031. The mean age of the residents over all 24 time periods was 80.3 years ($SD \pm 7.65$) with very little fluctuation across observations. Females made up 57.6% of the population over all time periods while males made up 42.4%. Table 4.1 displays the number of assessments for each time period, the mean age and standard deviation, and the proportion of males and females.

Table 4.1—Patient Demographics 1998 to 2004 (n= 144758)

Quarterly Assessments	n	Mean Age	SD	Female	%	Male	%
1998	6183	80.3	± 7.8	3634	58.8	2549	41.2
	6175	80.4	± 7.7	3593	58.2	2582	41.8
	6311	80.3	± 7.8	3665	58.1	2646	41.9
1999	6265	80.1	± 7.8	3639	58.1	2626	41.9
	6127	80.3	± 7.7	3613	59.0	2514	41.0
	6037	80.1	± 7.7	3500	58.0	2537	42.0
	6043	80.2	± 7.7	3489	57.7	2554	42.3
2000	6088	80.1	± 7.6	3488	57.3	2600	42.7
	6074	80.1	± 7.6	3508	57.8	2566	42.3
	6019	80.1	± 7.7	3481	57.8	2538	42.2
	5905	80.2	± 7.7	3398	57.5	2507	42.5
2001	6097	80.0	± 7.6	3495	57.3	2602	42.7
	6081	80.1	± 7.6	3490	57.4	2591	42.6
	5987	80.2	± 7.6	3419	57.1	2568	42.9
	6191	80.2	± 7.6	3592	58.0	2599	42.0
2002	6040	80.2	± 7.6	3423	56.7	2617	43.3
	5863	80.3	± 7.7	3341	57.0	2522	43.0
	6010	80.4	± 7.6	3449	57.4	2561	42.6
	5990	80.3	± 7.6	3436	57.4	2554	42.6
2003	5876	80.4	± 7.6	3329	56.7	2547	43.4
	5696	80.4	± 7.6	3259	57.2	2437	42.8
	5803	80.5	± 7.6	3310	57.0	2492	42.9
	5960	80.6	± 7.6	3444	57.8	2515	42.2
2004	5937	80.5	± 7.6	3402	57.3	2532	42.7

Analysis of Prevalence of Physical Restraints

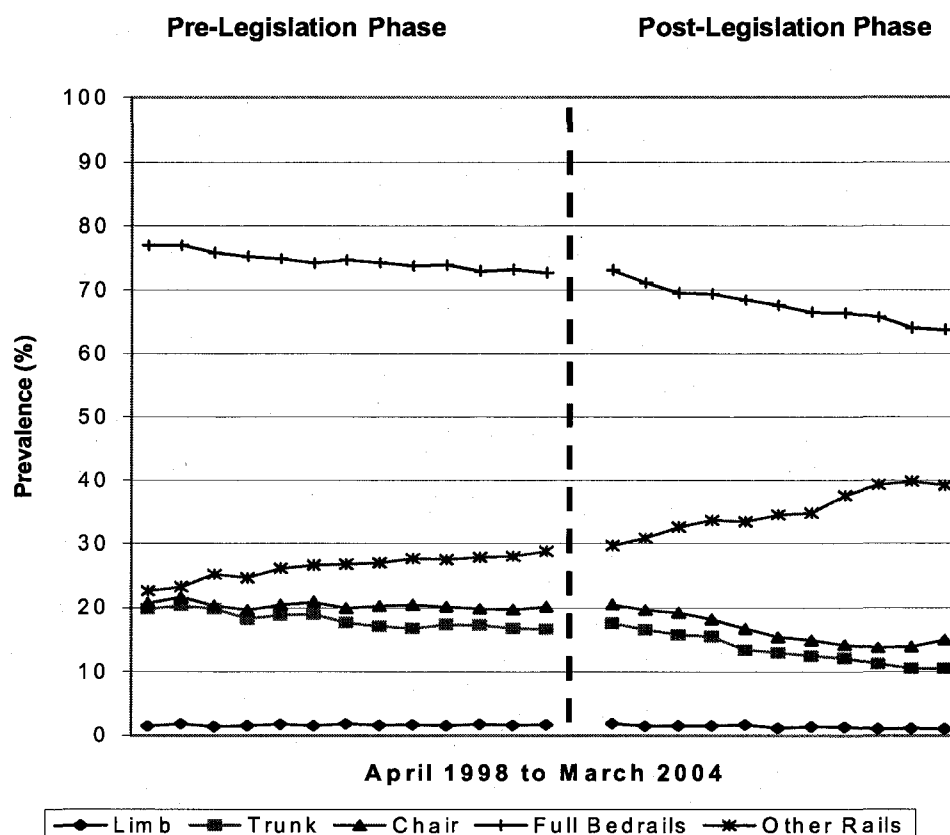
This section presents the findings of visual and statistical analyses of the prevalence of physical restraints using assessments from complex continuing care beds from April 1998 until March 2004. Plots of physical restraints province wide and by facility type are included in this section.

Physical Restraints Province Wide

Visual analysis of physical restraints province wide.

The smallest absolute change was that of limb restraints. Based on Figure 4.1, in both the pre-intervention and post-legislation phases, the most frequently used restraints were full bed rails, followed in descending order by other rails, chair restraints, trunk restraints, and limb restraints.

Figure 4. 1—Prevalence of Physical Restraints Province wide



The prevalence of trunk restraints exhibited a downward slope in the pre-legislation phase that was amplified slightly in the post-legislation phase (see Appendix B).

Changes in the prevalence of chair restraints and full bed rails exhibited a similar pattern to trunk restraints with bed rails having the most consistent downward trend and largest absolute decline in prevalence (see Appendix C and D).

The prevalence of other rails was the reverse of full bed rails with an upward prevalence slope in the pre-legislation phase that was amplified post-legislation.

The prevalence of limb restraints exhibited a very slight upward slope²² in the pre-legislation phase and a downward slope in the post-legislation phase (see Appendix A).

²² The pre- and post-legislation slopes are determined by the direction of the regression line on each graph.

Statistical analysis of physical restraints province wide.

Table 4.2 presents the results of ITSACORR analysis for all physical restraints province wide. Calculating the omnibus F-test for overall change and *t*-tests for slope and intercept as appropriate, only limb restraints exhibited an overall statistically significant change ($p = 0.03$) due to a statistically significant change in slope ($p = 0.01$).

Table 4.2—ITSACORR Analysis of Physical Restraints Province wide

	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	$p = 0.03$	$p = 0.65$	$p = 0.35$	$p = 0.46$	$p = 0.32$
Intercept <i>t</i>	$p = 0.42$				
Slope <i>t</i>	$p = 0.01$				

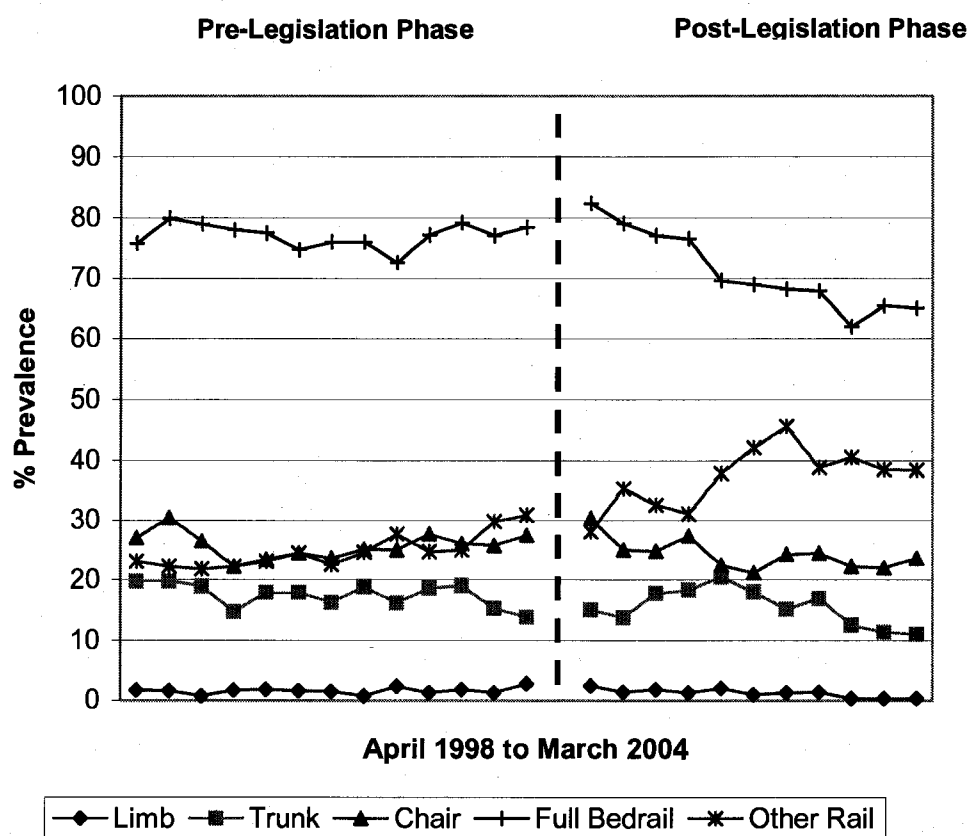
Physical Restraints in Rural and Urban Facilities

The following section presents the findings of visual and statistical analysis of prevalence of physical restraints from rural and urban facilities between April 1998 and March 2004 based on postal codes. The average number of assessments per quarter was 382 (6.3%) for rural facilities and 5,649 (93.7%) for urban facilities.

Visual Analysis of Physical Restraints in Rural and Urban Facilities

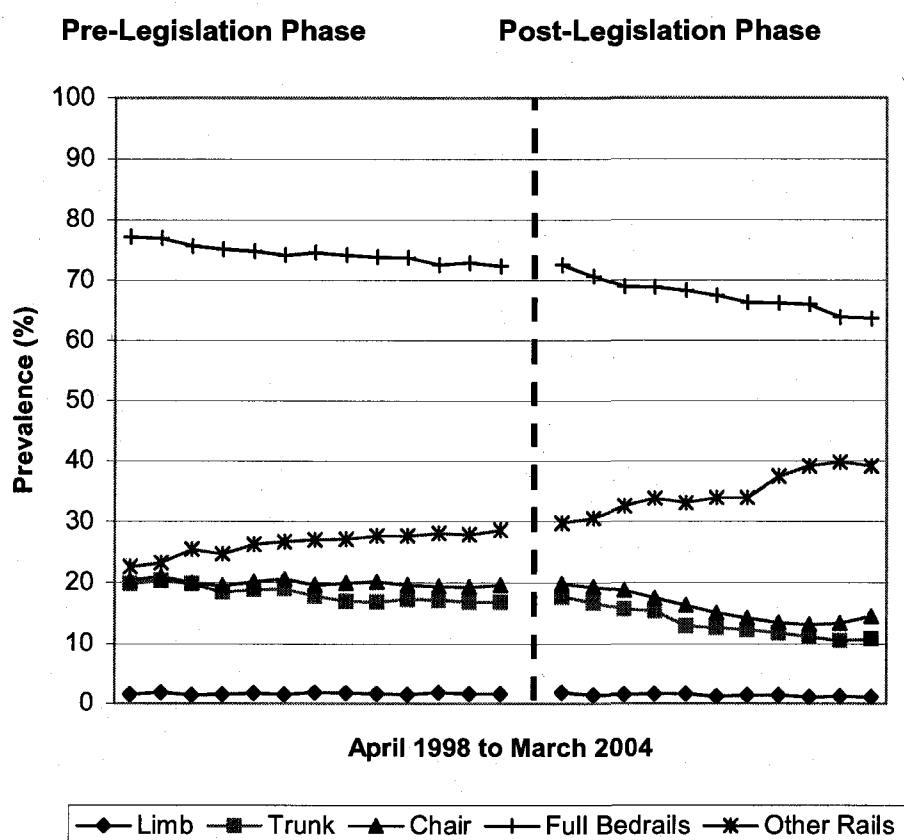
Based on Figures 4.2 and 4.3, the most frequently used restraints in both kinds of facilities, during the pre-legislation and post-legislation phases, were full bed rails, followed in descending order by other rails, chair, trunk, and limb restraints.

Figure 4.2—Prevalence of Physical Restraints in Rural Facilities



Trunk restraints exhibited a downward slope in both the pre- and post-legislation period although in rural facilities the prevalence fluctuated widely in both phases (see Appendix B). In urban facilities, the post-legislation slope of both chair and trunk restraints followed a similar downward slope. However, chair restraint prevalence was more constant in the pre-legislation phase and then tracked a downward slope post-legislation. In rural facilities prevalence fluctuated in both phases (see Appendix C).

Figure 4.3—Prevalence of Physical Restraints in Urban Facilities



In rural facilities, prevalence of full bed rails varied considerably in the pre-legislation phase and had a steep downward slope in the post-legislation phase. In urban facilities, there was a downward slope in the pre-legislation phase that increased slightly in the post-legislation phase (see Appendix D).

Other rails exhibited an upward slope in both the pre- and post-legislation phases in both types of facilities (see Appendix E). In urban facilities the post-legislation phase slope was amplified.

In both types of facilities, limb restraints exhibited a slight upward slope in the pre-legislation phase and a slight downward slope in the post-legislation period (see Appendix A).

Statistical Analysis of Physical Restraints in Rural and Urban Facilities

Table 4.3 presents the findings of ITSACORR analysis for all physical restraints in rural and urban facilities. Calculating the omnibus F-test for overall change and where appropriate, *t*-tests for slope and intercept, the overall change for limb restraints in rural facilities approaches significance ($p = 0.051$) and in urban facilities is statistically significant ($p=0.04$) accompanied by a statistically significant change in slope ($p = 0.01$).

Table 4.3—ITSACORR Analysis of Physical Restraints in Rural and Urban Facilities

Rural Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	$p = 0.051$	$p = 0.32$	$p = 0.54$	$p = 0.72$	$p = 0.86$
Urban Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	$p = 0.04$	$p = 0.75$	$p = 0.30$	$p = 0.46$	$p = 0.33$
Intercept <i>t</i>	$p = 0.53$				
Slope <i>t</i>	$p = 0.01$				

Physical Restraints in Small and Large Facilities

The following section presents findings of visual and statistical analysis of prevalence of physical restraints from small facilities (<100 beds) and large facilities (≥ 100 beds) between April 1998 and March 2004. The average number of assessments per quarter from small facilities over the 24 time periods was 3283 (53.6%) and from large facilities was 2745 (46.4%).

Visual Analysis of Physical Restraints in Small and Large Facilities

Based on Figures 4.4 and 4.5, in both types of facilities, full bed rails were the most prevalent restraints followed in descending order by other rails, chair, trunk and limb

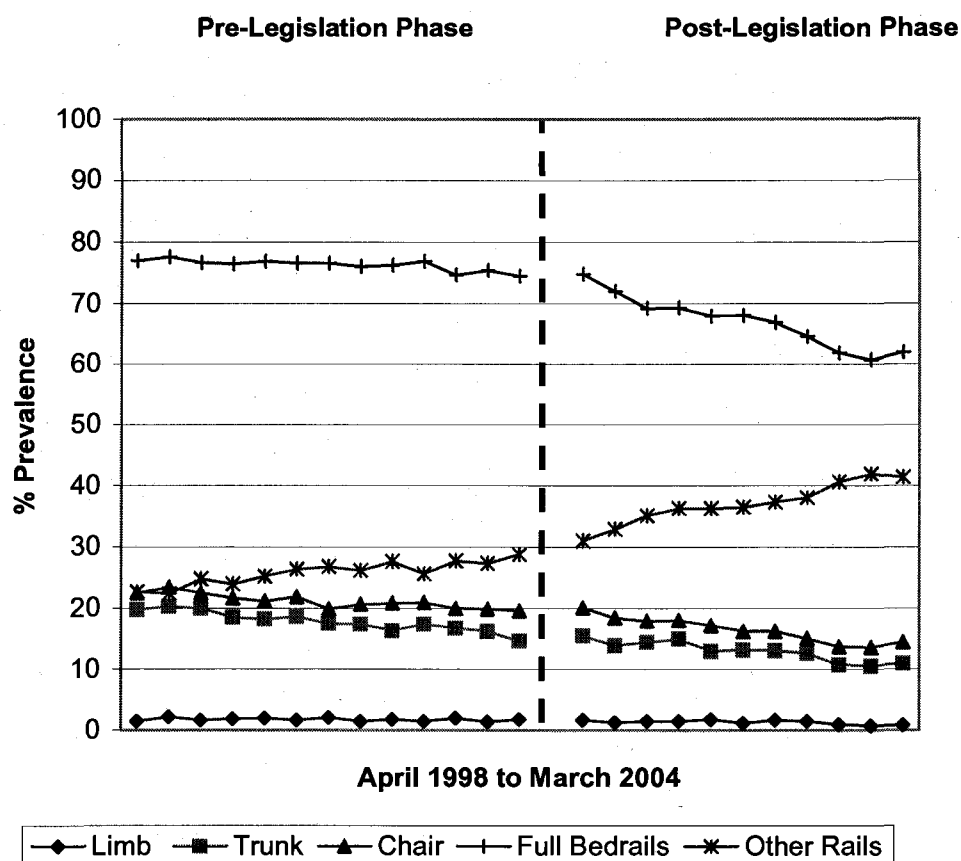
restraints, except in large facilities during the first half of the pre-legislation phase when trunk restraint prevalence marginally exceeded chair restraint prevalence.

In small facilities the prevalence of limb restraints exhibited a very slight downward slope in the pre-legislation phase, which was amplified in the post-legislation phase although prevalence in both phases fluctuated somewhat (see Appendix A). Pre-legislation prevalence of limb restraints in large facilities exhibited an upward slope followed by a downward slope in the post-legislation phase. Prevalence fluctuated throughout both phases in large facilities but to a lesser extent than in small facilities (see Appendix A).

In both small and large facilities, the prevalence of trunk restraints exhibited a downward slope in the pre-legislation phase that continued throughout the post-legislation phase and was amplified in large facilities (see Appendix B).

In small facilities the prevalence of chair restraints exhibited a downward slope in the pre-legislation phase that continued into the post-legislation phase. Large facilities exhibited an upward slope in the pre-legislation phase and then a downward slope in the post-legislation phase, however, the prevalence rose steadily in the last three time periods suggesting a reversal in trend (see Appendix C).

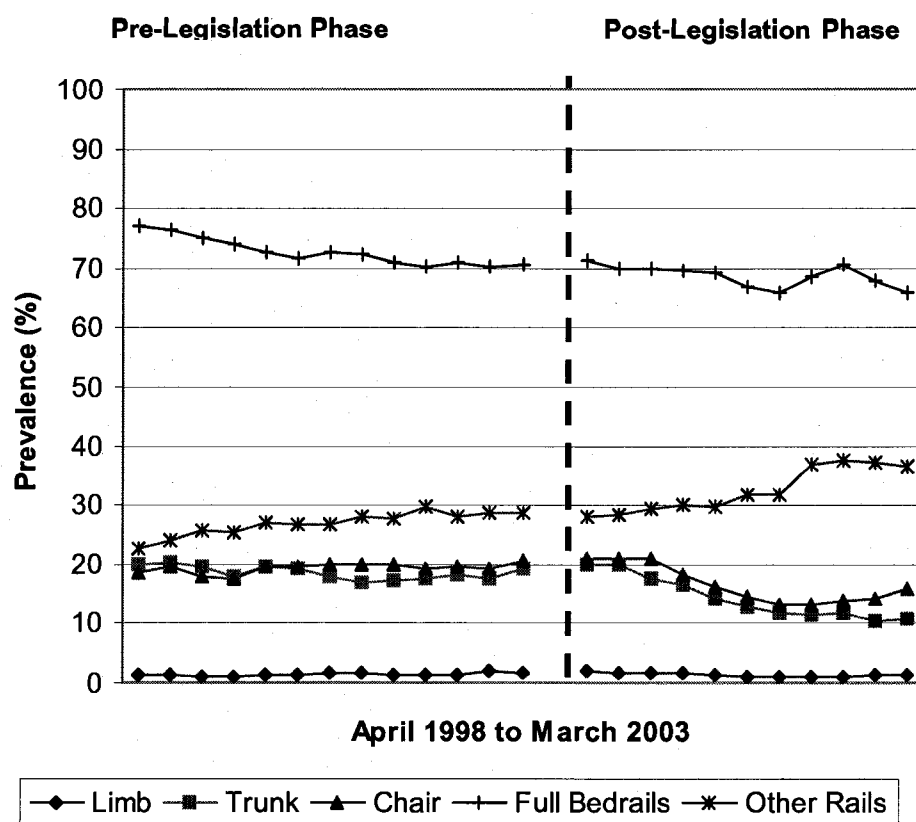
Figure 4.4—Prevalence of Physical Restraints in Small Facilities



In both types of facilities, the prevalence of full bed rails exhibited a downward slope in the pre-and post-legislation phases. In small facilities the downward slope amplified in the post-legislation phase while in large facilities the slope flattened out (see Appendix D).

In both facilities, the prevalence of other rails exhibited an upward slope in the pre-legislation phase that amplified slightly in the post-legislation phase (see Appendix E).

Figure 4.5—Prevalence of Physical Restraints in Large Facilities



Statistical Analysis of Physical Restraints in Small and Large Facilities

Table 4.4 shows the results of ITSACORR analysis for all physical restraints in small and large facilities. Calculating the omnibus F-test for overall change for physical restraints within small facilities there are no statistically significant results to report.

Table 4.4—ITSACORR Analysis of Physical Restraints in Small and Large Facilities

Small Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	p = 0.22	p = 0.57	p = 0.48	p = 0.60	p = 0.22
Large Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	p = 0.34	p = 0.30	p = 0.27	p = 0.86	p = 0.29

Physical Restraints in Private and Public Facilities

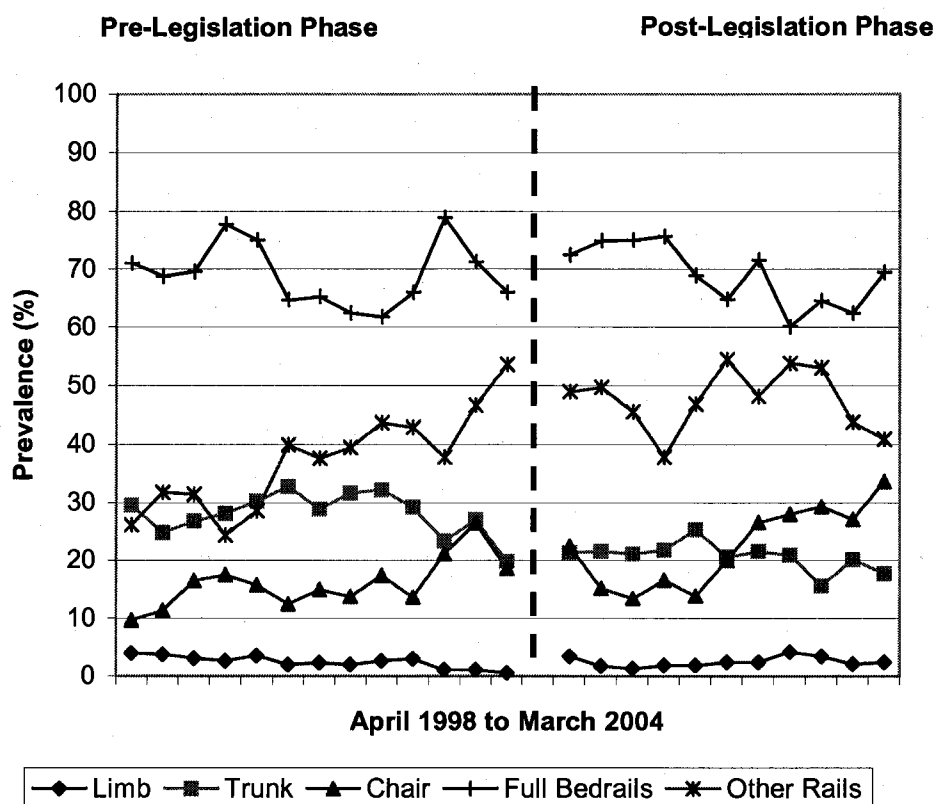
The following section presents findings of visual and statistical analysis of prevalence of physical restraints from private and public facilities between April 1998 and March 2004. Using Resident Assessment Instrument Minimum Data Set coding for ownership, it was possible to identify the number of assessments from facilities that were privately owned (proprietary) and the number of assessments from facilities that were publicly owned (non-proprietary). The average number of assessments per quarter from private facilities in Ontario over the 24 time periods was 162 (2.7%) and from publicly owned facilities was 5869 (97.3%).

Visual Analysis of Physical Restraints in Private and Public Facilities

As shown in Figures 4.6 and 4.7, full bed rails were the most prevalent restraints in public facilities followed by other rails, trunk, chair, and limb restraints throughout both phases. Private facilities exhibited a similar pattern, however, trunk restraints exceeded other rails at three observations in the pre-legislation phase while chair restraints exceeded trunk restraints throughout the last four time periods in the post-legislation phase. Since the prevalence of physical restraints in private facilities fluctuated widely, this hindered accurate visual analysis.

In private facilities, prevalence of limb restraints exhibited a downward slope in the pre-legislation phase and an upward slope in the post-legislation phase. The upward direction of the change in intercept seemed large immediately following the legislation although the prevalence then dropped markedly in two subsequent time periods and the overall direction of the slope based on the regression line was upward. In public facilities, the prevalence exhibited an upward slope in the pre-legislation phase and a downward slope in the post-legislation phase (see Appendix A).

Figure 4.6 –Prevalence of Physical Restraints in Private Facilities



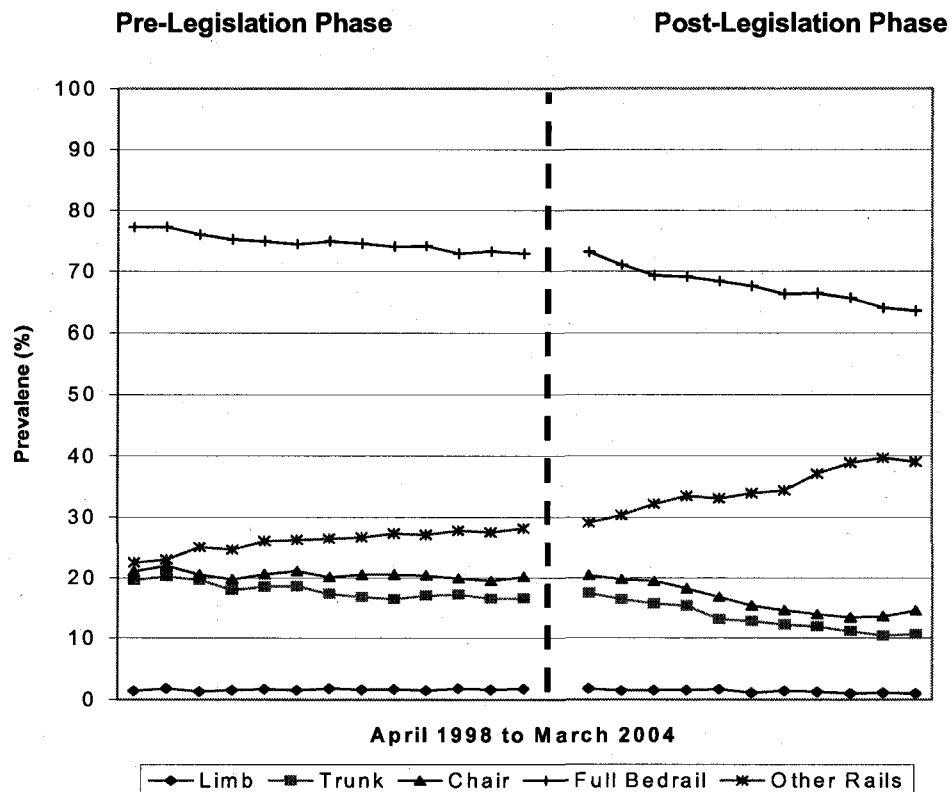
In both private and public facilities, the prevalence of trunk restraints exhibited a downward slope in the pre-legislation phase. The slope continued into the post-legislation phase in private facilities while in public facilities it was amplified slightly (see Appendix B). In public facilities, the slope of chair and trunk restraints followed a similar pattern with similar prevalence.

In private facilities, the prevalence of chair restraint exhibited an upward slope in the pre-legislation phase that initially declined and rose in the post-legislation phase. In public facilities, the pre-legislation phase exhibited a very slight downward slope that was

amplified in the post-legislation phase although prevalence rose in the last two time periods (see Appendix C).

In both private and public facilities, the prevalence of full bed rails exhibited a downward slope in the pre-legislation phase that was amplified in the post-legislation phase (see Appendix D). In both types of facilities, the prevalence of other rails exhibited an upward slope in the pre-legislation phase. This was most evident in private facilities. In public facilities the post-legislation phase slope was amplified and in private facilities it changed direction to a slight downward slope based on the direction of the regression line although the prevalence fluctuated widely (see Appendix E).

Figure 4.7—Prevalence of Physical Restraints in Public Facilities



Statistical Analysis of Physical Restraints in Private and Public Facilities

Table 4.5 shows results of the ITSACORR analysis for all physical restraints in private and public facilities. Calculating the omnibus F-test for overall change for physical restraints within private and public facilities there are no statistically significant results to report.

Table 4.5—ITSACORR Analysis of Physical Restraints in Private and Public Facilities

Private Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	p = 0.14	p = 1.0	p = 0.24	p = 0.42	p = 0.25
Public Facilities	Limb	Trunk	Chair	Full Bed rails	Other Rail
Omnibus F	p = 0.06	p = 0.66	p = 0.41	p = 0.45	p = 0.22

Stratification by Intensity, Gender, Age and Cognitive Status

As discussed in Chapter 3 (p. 55-56), additional ITSACORR analyses were carried out on six stratified groups: daily by age, daily by gender, daily by cognitive status and then, less than daily by age, less than daily by gender and less than daily by cognitive status). The results are shown in Appendix H. Only two results were statistically significant. One was for limb restraints used less than daily among cognitively impaired patients; the second was for chair restraints used less than daily among cognitively intact patients.

Stratification by Cognitive Status

This section summarizes the results of stratifying, by cognitive status, the prevalence of physical restraints. Stratification was done on province wide data to assess whether or not cognitive status was a potential confounder. Cognitive impairment may be considered a potential confounder because it is an independent risk factor for the outcome, and is associated with the exposure. Since cognitive impairment is associated with an increased

use of physical restraints (Castle & Mor, 1998), the prevalence of restraint use in the cognitively impaired patient group would likely be greater than the prevalence of the cognitively intact group. The stratified prevalence over time was plotted on graphs that are presented in Appendix F. Regression lines were added to these graphs to assist with visual analysis.

If confounding was not present, any impact of the legislation would affect the prevalence of physical restraints in the cognitively impaired group in the same way as in the cognitively intact group. Both bed rails and other rails exhibit similar patterns of prevalence over time in the post-legislation phase suggesting that cognitive impairment is not a confounder for these restraints.

One surprising finding revealed by stratifying the prevalence was that both before and after the introduction of the legislation, full bed rails were more prevalent in the cognitively impaired group, while other rails were more prevalent in the cognitively intact group. In summary, there is evidence to support the potential for confounding by cognitive impairment in the use of limb, trunk, and chair restraints.

Summary

Table 4.6 shows a summary of all results of visual and statistical analysis of the prevalence over time of physical restraints. The arrows in each cell of Table 4.6 indicate the direction of the prevalence over time in the pre- and post-intervention phases.

Table 4.6—Summary of Physical Restraints

Physical Restraint (Mean Population)	Province-Wide n=6032		Rural n=382		Urban n=5649		Small n=3283		Large n=2745		Private n=162		Public n=5869	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Limb	→	↓*	↑	↓	↑	↓*	↓	+↓	↑	↓	↓	↑	↑	↓
Trunk	↓	+↓	↓	↓	↓	↓	↓	↓	↓	+↓	↓	↓	↓	+↓
Chair	↓	+↓	→	↓	↓	+↓	↓	↓	↑	↓	↑	+↑	↓	+↓
Full Bed rail	↓	+↓	↓	+↓	↓	↓	↓	+↓	↓	-↓	↓	+↓	↓	+↓
Other Rail	↑	+↑	↑	↑	↑	+↑	↑	+↑	↑	+↑	↑	→	↑	+↑

↑ = increased use
 ↓ = decreased use
 → = prevalence constant

* Statistically significant change
 - Slope diminishes
 + Slope amplifies

Based on visual analysis, none of the changes in intercept between the pre-legislation phase and the post-legislation phase of any physical restraints province wide or in any type of facility showed large abrupt changes. There are only two instances where ITSACORR analysis confirms a statistically significant change in prevalence following the introduction of the legislation. These occurred in limb restraints province wide and in urban facilities. Limb restraint use was rising prior to the legislation and then dropped during the post-legislation phase. There are six other instances where the pre-legislation phase exhibited an upward slope that changed to a downward slope following the legislation, but in all these other cases this was not accompanied by statistically significant results for overall change.

This was the pattern for limb restraints within rural, large, private and public facilities; and, chair restraints in large facilities.

Based on visual analysis alone, there are two instances where the prevalence was rising prior to the legislation and then, following the legislation, the upward slope stabilized, that is, other rails in private facilities and full bed rails in large facilities.

The legislation appears to have had no effect on physical restraints in six instances: trunk restraints in rural, urban, small and private facilities; chair restraints in small facilities; and, other rails in rural facilities.

Based on visual analysis, chair restraints, other rails, and full bed rails are the physical restraints that appeared to have changed most following the legislation. Chair restraints changed in all facilities to a more pronounced decline following the legislation except within small facilities while full bed rails changed to a more pronounced decline in all facilities except urban facilities. Other rails changed to a more pronounced increase province wide and in urban, small, large, and public facilities.

Other rails in all facilities and chair restraints in private facilities were the only physical restraints to increase in both the pre-legislation and the post-legislation phases. For other rails this climb was visibly increased following the legislation province wide and in urban, small, large, and public facilities.

Based on stratification, cognitive impairment appears to have been a confounder for all physical restraints excluding all types of bed rails.

5. Discussion

The objectives of this thesis were, primarily, to evaluate whether Ontario's Patient Restraint Minimization Act, 2001 (Government of Ontario, 2001) resulted in a change in prevalence of physical and chemical restraint use among elderly patients in Ontario's complex continuing care beds and, secondarily, to evaluate whether prevalence of restraints varied by facility type (i.e., rural or urban, small or large, and private or public). This chapter discusses how these objectives were met and what was learned from the analysis. Comments are made regarding the integrity of the study design and its impact on internal and external validity. The findings are then reviewed in light of Roger's Diffusion of Innovations Theory. Methodological issues related to interrupted time series design and in particular to ITSACORR analysis are presented. The chapter ends with recommendations and an overall conclusion.

Removal of Psychotropic Drugs from Analysis

A chemical restraint is defined by the OHA as "...a psychopharmacologic drug, not required to treat medical symptoms" (OHA, 2001, p15). This definition requires a subtle judgement that is beyond the scope of MDS assessments. Researchers do not agree on how to capture data about the use of chemical restraints and have used various methods (Harrington, Tomkins, Curtis, & Grant, 1992).

The variables for psychotropic drugs received from the Canadian Institute for Health Information were not included in the analysis as was originally intended. After careful thought, it was recognized that the potential for bias in the presentation and discussion of any results related to psychotropic drugs and their use as chemical restraints was considered too great. There was a high degree of uncertainty in determining whether a psychotropic drug was prescribed as a chemical restraint or for valid therapeutic use such

as the treatment of depression or chronic existing psychiatric disorders. This might have been mitigated somewhat if the data provided from the Canadian Institute for Health Information for this study had included additional variables such as the patient diagnosis. For example, in the Provincial Status Report by the Canadian Institute for Health Information (Tear et al., 1999), patients with schizophrenia or hallucinations were excluded from an analysis of psychotropic drugs. However, it was also noted in the report that patients with Tourette's Syndrome, Huntington Chorea, paranoid states and psychosis could not be excluded from the data since they are not included in the Resident Assessment Instrument Minimum Data Set diagnosis pick-up list. A rigorous study of the use of psychotropic drugs as chemical restraints clearly will require a more sensitive instrument and is an area where further study is essential.

Impact of the Legislation

Overall Impact of the Legislation

There was no notable evidence of large abrupt changes in either slope or intercept to suggest that the Ontario Patient Restraint Minimization Act (2001) has changed the practice of using physical restraints. The two instances where statistically significant changes occurred were, in both cases, the least prevalent restraint (limb restraint province wide and in urban facilities) and could only be visually appraised using a narrow numerical range for plotting prevalence.

The Special Case of Bedrails

Prior to and following the introduction of the legislation, the prevalence of *other rails* increased not only province wide but also in every other identified type of facility excluding private facilities. The increasing prevalence of *other rails* raises suspicion that they are

being coded as restraints when in fact they may be what has been termed *enabling devices* (OHA, 2001, p.16) that allow patients to autonomously move about in bed or even in and out of bed. For example, at one large free standing complex continuing care facility in Ontario, post legislation, nurses were coding all half rails as restraints (Rozon, Vickie, Personal communication August 12, 2005).

The increasing prevalence of other rails is accompanied by a decrease in the prevalence of full bed rails. This suggests that other rails may be replacing full bed rails. It is possible that the diminishing prevalence of *full bed rails* reflects a reduction in the number of beds with two, full bed rails. Most hospital beds now have four half rails instead of two full bed rails (Rozon, Vickie, Personal communication August 12, 2005). The diminishing prevalence of full bed rails may not represent a change in the practice of using bed rails but rather a change in bed design. The use of bed rails, while acknowledged as potentially a true restraint (OHA, 2001), will remain controversial until the Resident Assessment Instrument Minimum Data Set is modified to reflect a change in bed design and other rails are coded as restraints only when they are used to prohibit patients from exiting their beds. Algorithms that can assist staff in distinguishing when bed rails are truly being used as restraints are available in the literature (Edwards et al., 2006).

Stratification of bed rail prevalence by cognitive status revealed that full bed rails are more prevalent among the cognitively impaired population while other rails are more prevalent among the cognitively intact. This suggests that these two groups may be using different kinds of beds. If cognitively impaired patients are more often accommodated in beds with full bed rails this casts further doubt on whether cognitively intact patients are truly restrained by other rails as suggested by the climbing prevalence of other rails.

The view that bed rails enhance the safety of patients may be held not only by hospital staff but also by patients themselves (Ralphs-Thibodeau et al., 2006). However, there appears to be no empirical evidence supporting the view that bed rails enhance

safety (Capezuti et al., 2002). Knowledge of how a bed rail is used as a restraint and the approach facilities are using to code bed rails as restraints in the Resident Assessment Instrument Minimum Data Set must precede a full understanding of bed rails as restraints. This is an area where further research is needed.

In the latter half of the post-legislation period, there is a worrisome increase in prevalence of *chair* restraints in the last two time periods in small facilities and the last three time periods in large facilities. This suggests that restraint practices or coding practices have changed recently. It would be valuable to explore this further.

Study Validity

This section discusses features of the study design and their impact on internal and external validity.

Internal Study Validity

There are eight classic threats to validity in time series analysis studies (Biglan et al., 2003; Shadish, Cook and Campbell, 2002) including history, testing, instrumentation, instability, regression, selection, statistical conclusion, *and control of Implementation of the independent variable.*

History: History refers to events that occur around the time of an intervention that may have an impact on the dependent variable. For example, in a time series study looking at the introduction of legislation requiring the use of helmets for motorcycles and mopeds, police threats of strong sanctions coinciding with the introduction of the helmet legislation likely influenced adherence to the legislation (Ballart and Riba, 1995). Although no such sanctions were coincident with the Ontario restraint minimization legislation, there was substantive media coverage of the issue of restraint use among the institutionalized elderly

in the period before the legislation was introduced. Similarly, the health-care system underwent a re-organization in the early nineties in which hospitals were closed and patients transferred to other facilities. These two events could have influenced the use of restraints by increasing public awareness and therefore expectations of care and alerting health-care workers to restraint use as problematic, causing a change in practice.

Ramsay and colleagues (2004) reported that in time series analysis concurrent changes over time might impact the outcome of an intervention. In order to appreciate how this occurred in this study, the interpretation of the results are discussed within the context of Rogers' Diffusion of Innovations Theory, later in this chapter.

Testing: When assessments are repeated with subjects over time, the assessment itself may influence the results. This is clearly seen when public opinion polls are conducted repeatedly in small communities creating new discussions among members of the community and potentially highlighting issues that were previously unnoticed thus changing opinions (Biglan et al., 2000). There is the possibility that repeatedly collecting data for the Resident Assessment Instrument Minimum Data Set may alert health-care workers to such issues as restraint use and spark interest in exploring clinical practice questions and then applying new evidence-based techniques—this might be particularly so in an environment where media coverage or the introduction of minimization legislation has created further interest in the topic.

Instrumentation: The methods that are used to record administrative data can affect the quality and consistency of this data. Patient data for the Resident Assessment Instrument Minimum Data Set are usually collected by nurses in the clinical area. The quality of the data may be dependent upon the training that nurse coders receive, their individual commitment to collecting quality data in spite of other priority responsibilities, and the organizational culture as it pertains to the perceived value of Resident Assessment Instrument Minimum Data Set.

Problems associated with the interpretation and collection of data are addressed on an ongoing basis by the Canadian Institute for Health Information through a data quality enhancement program (<http://www.cihi.ca>) and any changes or improvements to the data are made publicly available. The Canadian Institute for Health Information also offers ongoing educational opportunities such as web conferences and workshops (www.cihi.ca) that are geared to those responsible for coding Resident Assessment Instrument Minimum Data Set data. It is possible that nurses might be influenced to 'adjust' data collection related to restraints in light of negative public opinion about restraints. However, this seems unlikely because this would be a departure from professional behaviour.

Since the Resident Assessment Instrument Minimum Data Set is lengthy and complicated, the first two years of data collected were not included in this study, allowing for a period of orientation for Resident Assessment Instrument Minimum Data Set coders. It is presumed that the quality of the data collected after that point was better. Nevertheless, inaccurate interpretation of Resident Assessment Instrument Minimum Data Set coding or inexperience with the instrument may have introduced a minor threat to validity.

Patient assessments identified as significant corrections or changes in status were absent in the data provided by The Canadian Institute for Health Information. This is recognized as possibly allowing instrumentation bias and constitutes a minor threat to internal validity. Corrected assessments accounted for approximately 1% of all assessments (Teare, 2002). Corrections or changes might have affected any of >300 Resident Assessment Instrument Minimum Data Set elements, nevertheless, it is possible that inaccurate data was introduced by not including the corrected assessments. However, if the Canadian Institute for Health Information had included the corrected or changed assessments, this would have added duplicate assessments into the data set.

Instability: The data that are being collected may be subject to variability for a number of reasons including the instability of the data itself. Trends and cycles can be seasonal or

subject to fluctuations in staffing (eg., during flu season or times of vacation) or some other force. In the smaller facilities in this study, there was extensive variability, which might be related to patient turnover, or staff turnover. The potential for bias in interpreting results from these small samples must be considered.

Regression: Over time, there is a tendency for data points to migrate towards the mean value, particularly in the case of outliers or extreme values (Shadish et al., 2002). In time series studies, the impact of the tendency towards regression to the mean can be limited by ensuring that the pre-intervention phase has reached a stable pattern. Some regression to the mean effect would need to be considered in interpreting the results of this study since the pre-legislation period for physical restraints was not stabilized but was following a trend to either increase or decrease in most instances.

Selection: The threat of selection bias for time series studies is based on the potential for different communities to respond differently to an intervention based on characteristics of the community rather than the intervention itself. The threat of selection bias can be due to a change in the population receiving the intervention. In this study, rural and private facilities may be subject to selection bias if there is a relatively large turnover within the already small population of patients. Thus, each subsequent assessment might be measuring a slightly different population. Additionally, the population of elderly patients being assessed is changing over time as they are getting older, potentially more frail, less mobile, and more cognitively impaired.

Statistical conclusion: Time series studies share a common threat with all studies in that statistical analysis is subject to the threats of low statistical power and violated test assumptions. The limitations imposed by brief time series have been reflected in some published studies where assumptions have been overlooked in the interest of going beyond visual analysis (Ramsay et al, 2004). Over the last two decades, a number of brief series designs have been promoted and then shown to be producing inflated results as was

discussed more fully in Chapter 2. Most commonly, the statistical analyses would overlook the impact of autocorrelation and the lack of independence of the data points. While there is no perfect method of analysis for brief time series data, the method that is most commonly promoted at the moment is ITSACORR although very recent publications are suggesting that even ITSACORR may be problematic (Huitema, 2004). It is suspected that even ITSACORR analyses may be underpowered although this cannot be determined definitively through information that is available about the program.

Control of Implementation of the independent variable (Biglan et al., 2000): This threat to validity occurs when it is difficult to discern whether any measured impact is due to the intervention or whether it is due to other influences. A lack of control of the independent variable is a common problem when the intervention is the introduction of a new policy or legislation (Biglan et al., 2000). It is difficult to differentiate between the effect of the policy or legislation and the effect of media publicity related to the policy. The publicity that preceded the introduction of the Ontario Patient Restraint Minimization Act (2001) may have influenced both pre- and post legislation changes in restraint use.

External Study Validity

The study population for this thesis included all eligible elderly complex continuing care patients in Ontario based on provincially mandated patient assessments. Thus, external validity for the entire province is assured by the strength of the data. The data originates from the Ontario Chronic Care Patient System that is managed by the Canadian Institute for Health Information. It contains the complete population of patient assessments using Resident Assessment Instrument Minimum Data Set Version 2.0 from across Ontario. However, the results of this study cannot be generalized to the approximately 10% of complex continuing care Ontario patients who are <65 years old.

Interpretation of Results in Light of Theoretical Framework

This section discusses the pre- and post-legislation prevalence patterns of physical restraints within the context of Rogers' Diffusion of Innovations Theory. The theory also helps to explain what may have impeded the impact of the legislation.

Understanding Pre-Legislation Prevalence Patterns

Since Canada and the U.S. share a border and most of the literature on restraints originates from within the U.S. and is readily available in Canada, it is likely that the U.S. restraint minimization strategies may have influenced nursing care in Ontario facilities prior to the introduction of the provincial patient restraint minimization legislation. A portion of nursing managers and educators in Ontario may have acted as innovators and early adopters. Innovators usually include up to 2.5% of the population of potential adopters of an innovation and are characterized by extensive communication networks, greater financial resources, superior understanding of complex technical knowledge and an inclination to take risks (Rogers, 2003, p.282). Additionally, early adopters who include 13.5% of potential adopters are more likely to include individuals whose opinions are sought and respected within their communities.

Innovators in Ontario may have included nurse researchers and academics that attended international conferences and regularly communicated with U.S. nursing colleagues. Early adopters may have included Ontario nurse educators and managers whose work brought them in contact with the innovator group and who themselves acted as opinion leaders for students and facility nursing staff. The diffusion of ideas related to restraint minimization through these two groups may account for some of the decline that was seen in trunk and chair restraints in Ontario prior to the introduction of legislation.

Understanding Post-Legislation Prevalence Patterns

Rogers (2002) noted that preventative innovations tend to diffuse slowly due in part to the lack of immediate rewards for adoption. He identified the attribute of perceived relative advantage of the innovation as being the strongest influence for adoption and that any strategies that increase the relative advantage of the innovation would speed up the rate of adoption. Rogers (2003) also described the impact of a "cue-to-action" as particularly useful in triggering positive attitudes towards preventative innovations.

Three possible cues-to-action for restraint minimization occurred in Ontario in the summer of 2001: the College of Nurses of Ontario published related standards of practice, the Canadian Council on Health Services Accreditation published related national standards, and the Ontario Government passed the Patient Restraint Minimization Act. While all three were intended to reduce the use of physical restraints in hospitals, the legislation was the cue that was created in response to public demand and was seen as the major policy initiative to change nursing practice.

Theoretically, the legislation would motivate a change in practice. The lack of statistically significant impact on restraint use following the legislation may have been related to the vague language within the Act and the lack of regulations associated with the legislation subsequent to the Act. Without regulations, many issues such as content of facility policies, reporting procedures, and staff training were not fully addressed. Castle (1998) used administrative data to plot prevalence of restraint use after the introduction of Omnibus Budget Reconciliation Act in 1987 in the U.S. and noted that most of the decline occurred in 1991 following the implementation of regulations associated with the act. Therefore, the addition and enforcement of regulations associated with Ontario's restraint minimization legislation might promote a statistically significant decrease in prevalence of physical restraints by increasing the perceived relative advantage of the legislation. For example, if facility funding from the Ministry of Health and Long-Term Care were tied to

accurate reporting of restraint use and facilities were subject to unscheduled inspections under regulations associated with the legislation, then there would be a clear advantage in complying with the legislation and facilities would be highly motivated to minimize restraint use.

Following the introduction of the legislation, the diffusion curve as described by Rogers (2003) was expected to accelerate. It was hoped that this would occur within the post-legislation phase under study and so result in statistically significant changes in the use of restraints. This expectation was not met, perhaps due to the lack of enforcement measures in the legislation. It must also be noted that there may not have been sufficient time for the diffusion process to occur. Data from the Canadian Institutes for Health Information may not have covered the time period inclusive of the final confirmation stage.

Based on the beliefs of some elderly patients and their families, minimizing the use of physical restraints potentially decreases patient safety (Ralphs-Thibodeau et al., 2006). This belief, while unsubstantiated in the literature, would be perceived as a negative attribute of restraint minimization further slowing its diffusion. Adhering to the legislation may have been viewed as costly by administrators in facilities requiring new equipment such as minimal restraint equipment (e.g. half bed rails) that could be removed by patients if desired. The potential costs would have contributed to the perceived negative attributes of the innovation.

Rogers (2003) noted that innovations that do not follow the typical diffusion curve may have characteristics that inhibit their diffusion, for example, the innovation may be socially unacceptable or apply to a very limited sub-group within a population. It is well known that nursing care staff and facility managers often have a strong belief that physical restraints enhance patient safety and require fewer human resources to provide care (Hanikainen, & Kappeli, 2000; Myers, Nikoletti, & Hill, 2001). Management and staff in some facilities may have viewed Ontario's restraint minimization legislation as contrary to popularly held

beliefs, thereby limiting the rate of diffusion. Educational programs for nurses about alternatives to physical and chemical restraints may need to be intensified.²³

Rogers (2003) noted that the implementation stage can be lengthy when the adopter is an organization because it may take some time to fully implement the innovation throughout an organization (Rogers 2003). The preventive nature of restraint minimization and the fact that it was to be diffused through multiple facilities in Ontario may be another reason why the innovation diffused slowly.

ITSACORR Analysis

This section discusses the limitations associated with interrupted time series analysis for brief time series (<50 observations) including those associated with ITSACORR analysis. Further limitations of ITSACORR analysis are then discussed in light of statistically significant results.

Time Series Methodological Issues

Much of the work that has been done to build understanding of brief time series analysis is found in the field of psychology within research related to single subject²⁴ studies (Franklen et al., 1997). Epidemiological studies have tended to focus on longer time series of >50 observations and used time series regression techniques or autoregressive integrated moving average (ARIMA) models (Ramsay, 2004). These methods are not appropriate when the series is short or the assumptions of the regression technique are violated. In both short and longer time series data, autocorrelation of data limits potential

²³ The Ontario Restraint Minimization Act requires staff training but the content of training was intended to be addressed by a future, and as of yet not established, regulation.

²⁴ Studies with a sample of only one individual.

analyses, as the assumption of data independence cannot be met and all time series analysis must adjust for autocorrelation.

Limitations of ARIMA Modelling for Brief Time Series

For the last two and a half decades, Autoregressive Integrated Moving Average (ARIMA) statistical modelling as developed by Box and Jenkins in 1970²⁵ has been the analysis of choice for time series data with more than fifty observations (Shadish, Cook and Campbell, 2002). Shadish and colleagues recognize the problem with using what they term “ordinary” statistics i.e., using a *t*-test to compare before and after time series data. The main problem is autocorrelation, which refers to the situation where observations are related to their predecessors. Autocorrelation results in a lack of independence of observations which is an assumption of many “ordinary” statistical procedures. Alternate statistical methods that have been attempted with brief time series were discussed in greater detail in Chapter 3 (p 44-49).

The extent of autocorrelation in time series data must be estimated. Some authors have indicated that this requires over 100 observations to build an appropriate statistical model (Shadish, Cook and Campbell, 2002) while other researchers recommended using from 50 to 100 or more observations depending on the number required to get autocorrelation estimates that approach stability (Biglan et al., 2000). Either way, this study fell short of the prerequisite number of observations with only 24. This severely limited the likelihood of obtaining stable estimates of autocorrelation.

It was tempting to use the monthly observations for this study which would have resulted in over 70 observations and allowed autoregressive integrated moving average (ARIMA) statistical modelling. However, Ramsay and colleagues (2004) suggested that in

²⁵ Box, G.E. P. & Jenkins, G.M. (1970). *Time series analysis: Forecasting and contro.*(3rd Edition).

Englewood Cliffs, NJ: Prentice-Hall.

interrupted time series design, each time period must capture data from at least 80% of the total number of participants in the study and that observations should be equidistant. The original data from the Canadian Institute for Health Information's Ontario Chronic Care Patient System included assessments by month since the quarterly assessments were based on the date of patient admission. These monthly data were problematic since the assessments in each month represented only a portion of the full patient population. At the onset, the decision was made to group the assessments into quarterly periods that would capture the full study population. Technically, the observations are not equidistant, however, it is a pragmatic approach that allowed data analysis.

The Limitations of ITSACORR

The ideal methodology for brief time series analysis is still to be developed. The Interrupted Time Series Analysis for Autocorrelation (ITSACORR) as designed by Crosbie (1993) and based on the work of Gottman has been used with apparent success over the last decade by researchers and graduate students (Broomfield & Expie, 2005; Callow & Waters, 2005; Maughan et al., 2005; Zawoyski & Attwood, 2005). Recently, Crosbie's ITSACORR analysis was criticized in an article by Huitema (2004). Huitema suggested that the interrupted time series experiment (ITSE) on which ITSACORR is based, has four flaws. "First, the logical foundation for the interrupted time-series design is violated. Second, there are conditions under which the contrast size is likely to be largely arbitrary. Third, ambiguities in the specifications of the design matrix can lead to inconsistencies in the size of the contrast estimate. Fourth, the size of the contrast is partly a function of the autoregressive order if a trend is present in the first phase" (Huitema, 2004, p. 32). However, this author used data from Huitema's examples that were used to illustrate these flaws, and ran ITSACORR analysis. The results were consistent with visual analysis in contrast to the inconsistent results of ITSE as reported in Huitema's paper. Huitema

referenced two unpublished papers as justification of his further problems with ITSACORR, neither of which was accessible.

Crosbie warned that short time series ($n < 20$ observations) combined with high first-lag autocorrelation ($r > 0.6$) will result in inflated test statistics. This limitation should not affect the analysis contained in this thesis, as there are 24 observations. Another limitation is that ITSACORR may have inadequate statistical power. Crosbie (1995, p. 386) used a programmed change in intercept (equal to five standard deviations) combined with different sample sizes and lag-1 autocorrelation values to examine any systematic effects of changes on statistical power. He concluded that statistical power is adequate for all levels of lag-1 values when n is > 20 observations and there is a programmed change in intercept but no change in slope. What is not clear is what the power would be with a programmed change in slope with differing values of n and lag-1 autocorrelation. This raises the suspicion that for some sample sizes there may be inadequate statistical power for time series data with changes in slope.

Limitations of visual analysis

Visual analysis of time series data, while not without limitations, can be an effective method, particularly when the pre-intervention phase is stable and the post-intervention phase shows large abrupt changes (Franklin, Allison and Gorman, 1997). Visually, the researcher looks at three parameters in graphic presentations: the central location or level plotted as the mean, median or mode; the trend which is usually shown by applying a line of best linear fit or regression line; and, variability or the fluctuations about the mean (Franklin, Allison and Gorman, 1997). The separation of phases by dotted lines or a space and the insertion of a regression line are both intended to aid the researcher in interpreting graphically displayed results. Adjusting the numerical boundaries can also change the interpretation by shrinking the numerical boundaries of the graph to emphasize patterns and changes.

Shrinking the numerical boundaries was used in the graphical display of the time series data for the two instances where ITSACORR analysis resulted in statistically significant results. The graphs as displayed in Appendix A, showed that there had been a small change in direction of the prevalence before and after the legislation was introduced. While this seemed to explain the rationale for the statistically significant results, the variability was extremely small as was the overall prevalence. The statistical results may have been either accurate or spurious but the change was small and unimportant—particularly from a clinical perspective.

All time series data for all physical restraints were initially plotted with small numerical boundaries with the intention of facilitating the interpretation of graphical presentations as shown in Appendices A through E. Regression lines were added to reveal the direction of any change in slope. This visually suggested that the legislation had influenced the use of most physical restraints. This view conflicted with the conclusion reached when visually analyzing the prevalence of all restraints combined within smaller but constant numerical boundaries. A more accurate conclusion was reached when the impact of the visual analysis was considered within the context of very small numerical boundaries. The lesson learned was that visual analysis is far from a perfect science and must be used with discretion.

Statistically Significant Results with ITSACORR

A curious result in the analysis in this thesis was the statistically significant results obtained on the ITSACORR analysis of limb restraints province wide and in rural facilities. Although there was a slight change in direction of slope on visual analysis, numerically that change was small. It was considered possible that the low prevalence of limb restraints may have decreased the variance calculated for a proportion ($V = p(1-p)/n$), thus increasing the statistical power of the analysis (n = number of observations or time

periods in the series). One must assume that statistical significance was not found on *limb* restraints in other facilities since the change in slope in the post-intervention period was not sufficiently large. Crosbie's publications (1993; 1995) do not provide enough information to replicate the analysis performed by the ITSACORR program and so limit further understanding of issues with statistical power. However, the author of this thesis contacted Dr. Crosbie to question these results. He re-analyzed the prevalence data for *limb* restraints province wide and within urban facilities both visually and using ITSACORR. He concluded that the statistically significant results were consistent with visual analysis.

Following stratification of province wide data by frequency of use, age, gender and cognitive status, two additional statistically significant results were obtained. The first was for limb restraints used less than daily among cognitively impaired patients ($p = 0.038$), and the second was for chair restraints used less than daily among cognitively intact patients ($p = 0.035$). These results are either accurate or spurious. Sampling error can lead to spurious results and multiple testing increases this likelihood (Oleckno, 2002). However, if the results were accurate then in the case of the limb restraints, the legislation may have inhibited the occasional use of limb restraints among cognitively impaired patients. However, since limb restraint prevalence was $<2\%$ both before and after the legislation, then this result is of questionable clinical importance. For chair restraints, if the results were accurate, then the legislation may have inhibited the occasional use of chair restraints among cognitively intact patients. This suggests that the legislation may have prompted a change in the understanding or coding of chair restraints or the type of equipment being used among the cognitively intact. Traditional Geri-chairs may have been understood as enablers for this group or may have been replaced by chairs with quick-release mechanisms that could be operated by patients.

Recommendations

The following recommendations are suggested based on the outcome of this thesis:

1. Wait until the prerequisite 50-100 observations have been added to the Ontario Chronic Care Patient System and then perform more sophisticated Autoregressive Integrated Moving Average (ARIMA) statistical modelling.
2. Encourage further methods development to analyze brief times series including the potential to adjust for potentially confounding variables.
3. Modify the Resident Assessment Instrument Minimum Data Set to include a single element for all bed rails that are used as restraints.
4. Educate those responsible for coding the Resident Assessment Instrument Minimum Data Set on how and under what circumstances any form of bed rail would constitute a restraint to improve coding accuracy.
5. Mandate collection of data using the Resident Assessment Instrument Minimum Data Set on all elderly institutionalized patients in Ontario and eventually within all other provinces and territories allowing assessment of the extent of restraint use in this vulnerable population.²⁶
6. Analyze data on restraint use for patients in complex continuing care beds who are <65 years of age to assess the extent and patterns of physical restraint use. The Ontario minimization legislation applies to all hospitalized patients and was not limited to one age group. However, the 65 year and older group were chosen for this thesis since this group is known to be at risk of being restrained. The <65 year group in complex continuing care beds in Ontario has not been well studied.

²⁶ The Ontario Ministry of Health and Long-Term Care are in the process of introducing the Resident Assessment Instrument Minimum Data Set into long-term care facilities throughout Ontario.

7. Stratify the prevalence of physical restraints by cognitive impairment in future reports from the Ontario (or Canadian) Chronic Care Patient System to draw attention to the potential confounding by cognitive impairment.
8. Publish more Canadian prevalence studies on the use of physical restraints for all institutionalized elderly in Canada to make full use of available data and to note any provincial or territorial differences.
9. Add regulations to the Ontario Patient Restraint Minimization Act (2001) to include incentives to adherence such as unscheduled inspections and clear policy guidelines for facility policies and staff education.
10. Apply Rogers' Diffusion of Innovations Theory to policy-related time series analysis to help interpret patterns of diffusion and the positive and negative influences of cues to action.

Conclusion

Based on both visual and statistical analysis, Ontario's restraint minimization act has not had any measurable influence on the use of physical restraints among elderly patients in complex continuing care beds either province wide or in urban, rural, large, small, private or public facilities. ITSACORR analysis coupled with visual analysis can be a useful combination of methods to assess brief interrupted time series although neither method alone is without limitations.

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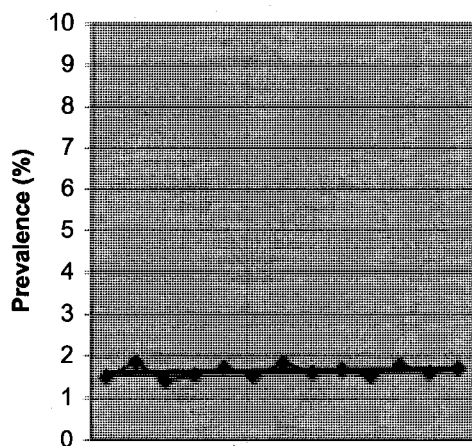
Appendix A

Limb Restraints Province wide and by Facility Type

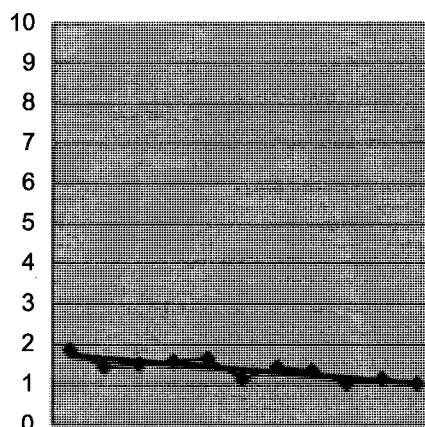
Pre- and Post-Legislation

The following plots show the pre- and post-legislation phases of the prevalence of all limb restraints province wide and by facility type with the addition of a regression line. These plots are intended to facilitate visual analysis so as to identify direction of any slopes, large abrupt changes in intercept, and differences between the pre- and post-legislation phases.

Limb Restraints Province-Wide

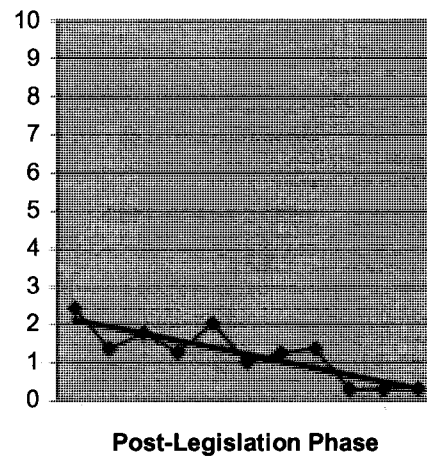
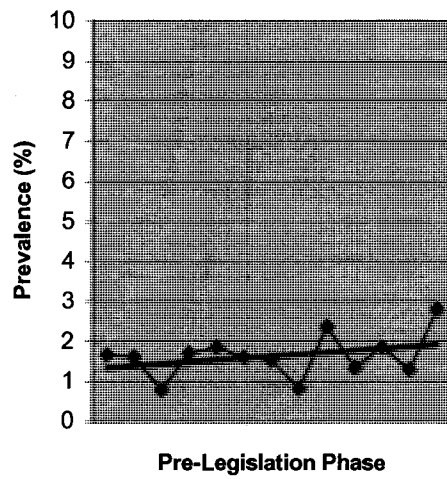


Pre-Legislation Phase

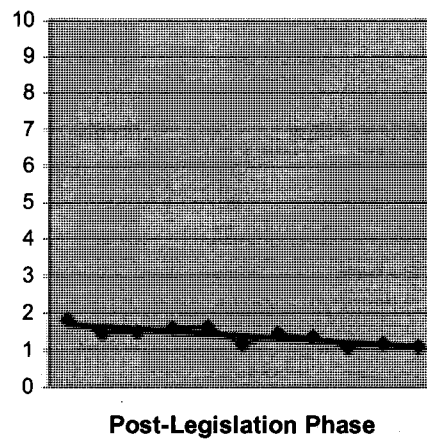
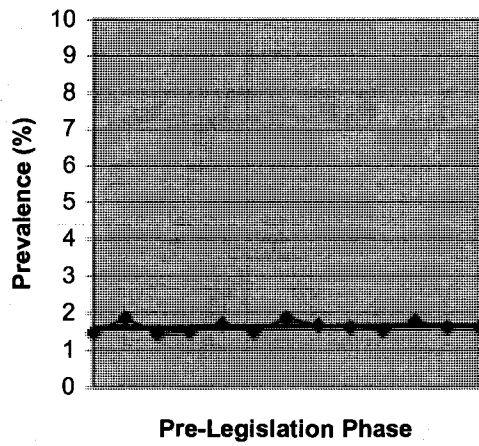


Post-Legislation Phase

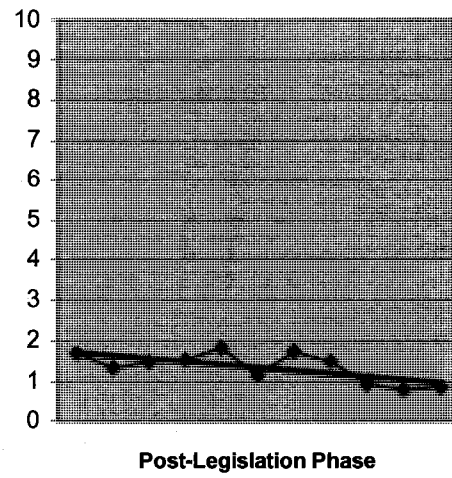
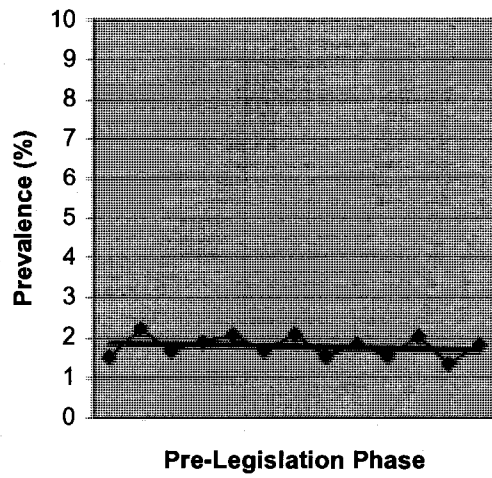
Limb Restraints in Rural Facilities



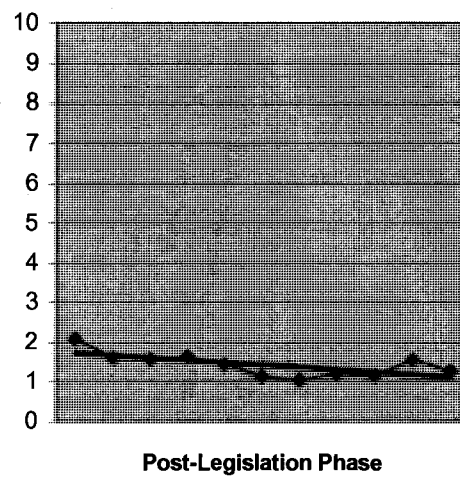
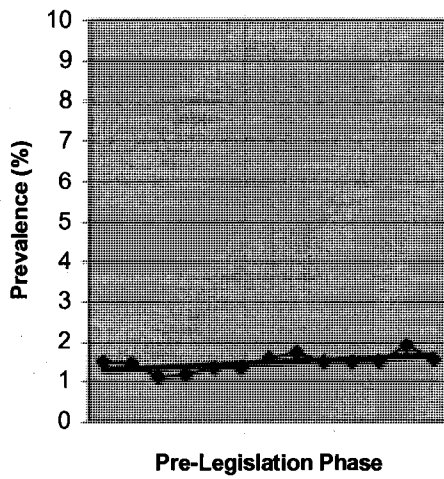
Limb Restraints in Urban Facilities



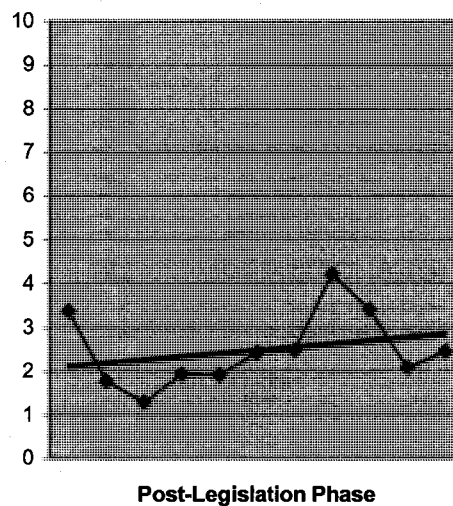
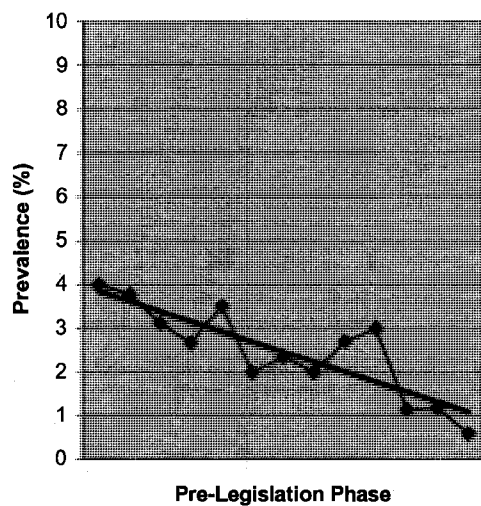
Limb Restraints in Small Facilities



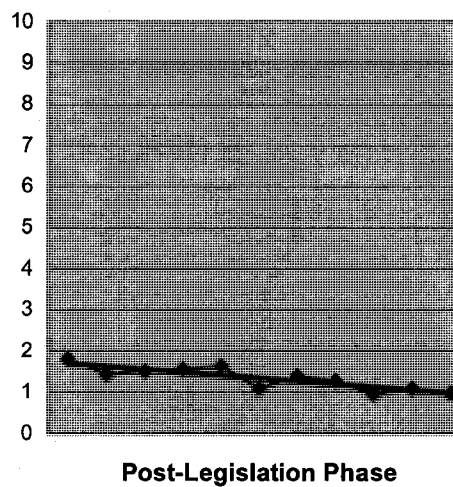
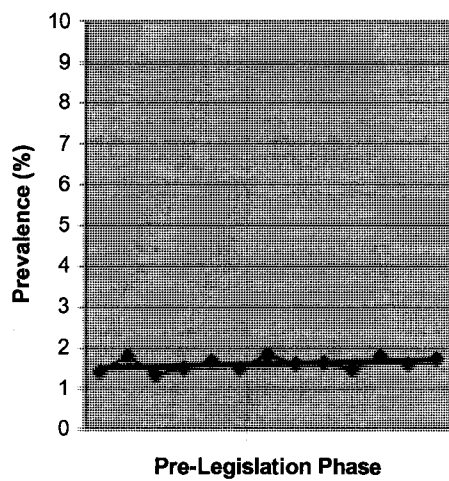
Limb Restraints in Large Facilities



Limb Restraints in Private Facilities



Limb Restraints in Public Facilities



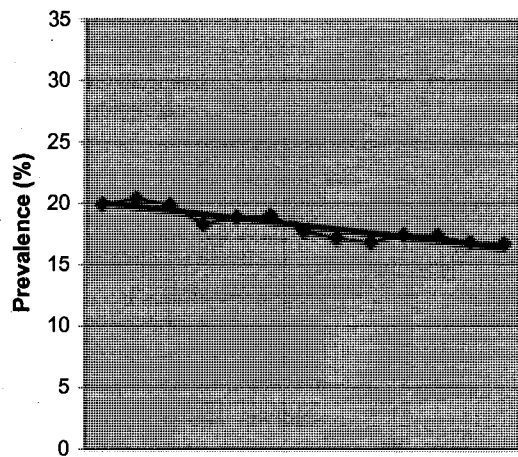
Appendix B

Trunk Restraints Province Wide and by Facility Type

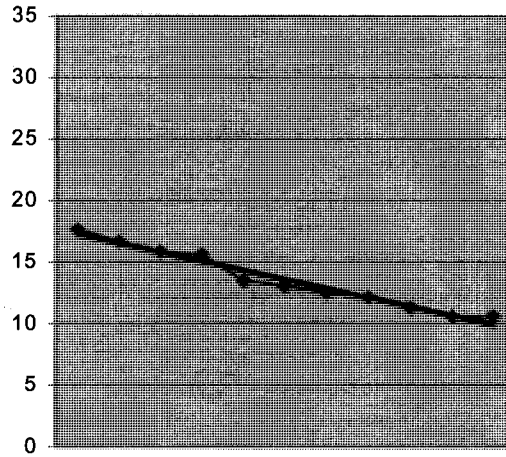
Pre- and Post-Legislation

The following plots show the pre- and post-legislation phases of the prevalence of all trunk restraints province wide and by facility type with the addition of a regression line. These plots are intended to facilitate visual analysis so as to identify direction of any slopes, large abrupt changes in intercept, and differences between the pre- and post- legislation phases.

Trunk Restraints Province Wide

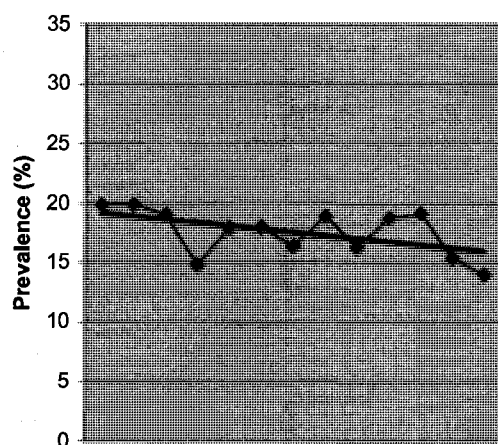


Pre-Legislation Phase

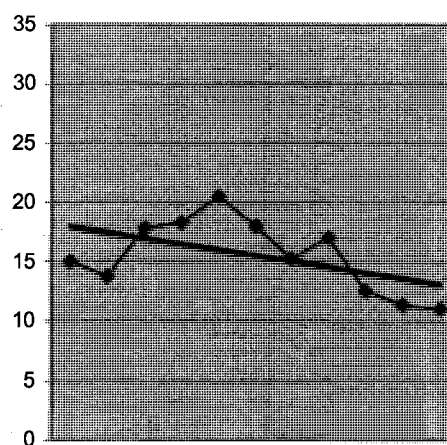


Post-Legislation Phase

Trunk Restraints in Rural Facilities

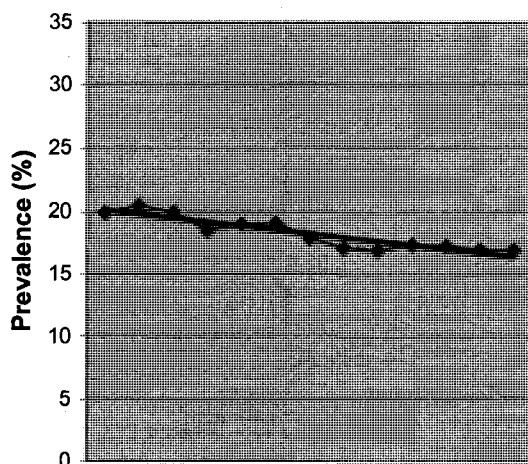


Pre-Legislation Phase

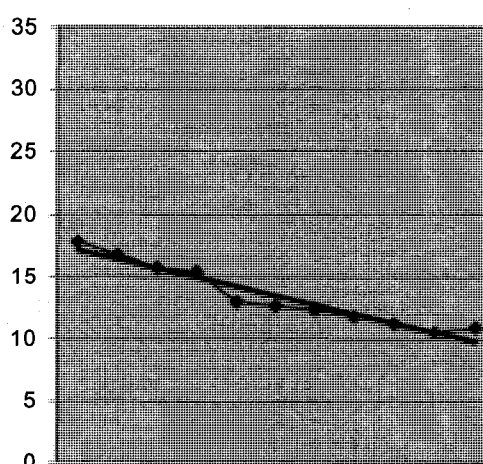


Post-Legislation Phase

Trunk Restraints in Urban Facilities

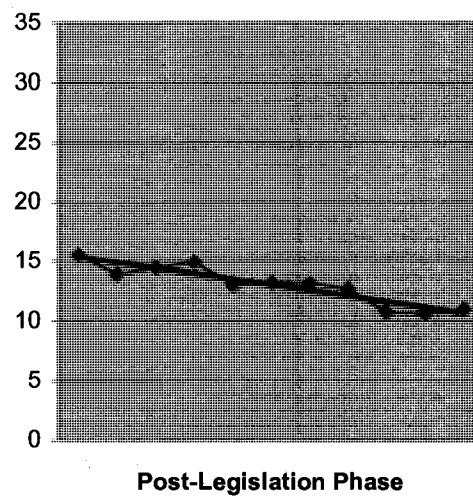
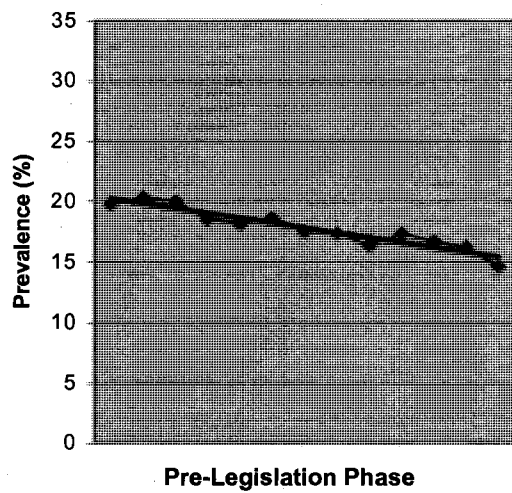


Pre-Legislation Phase

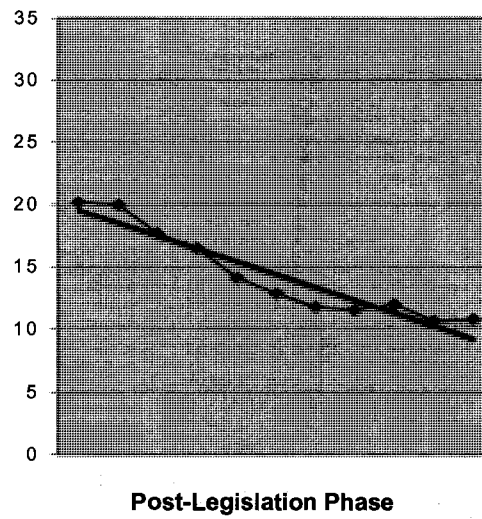
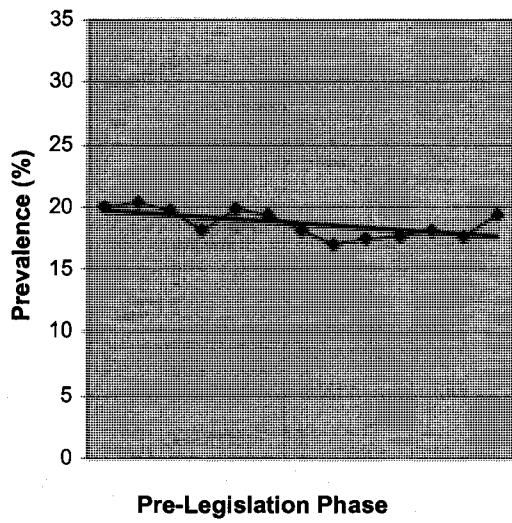


Post-Legislation Phase

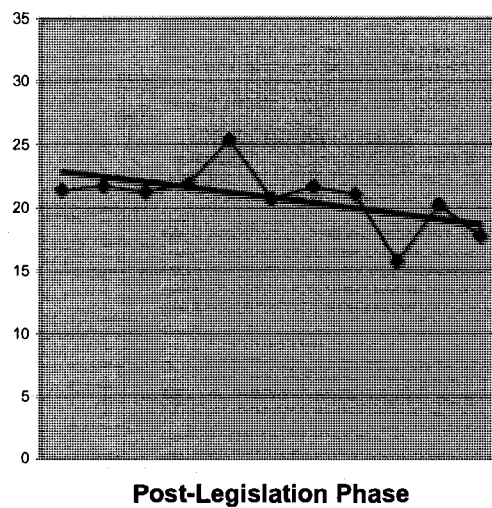
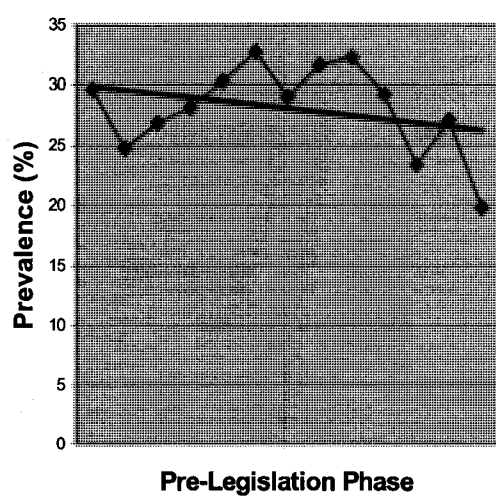
Trunk Restraints in Small Facilities



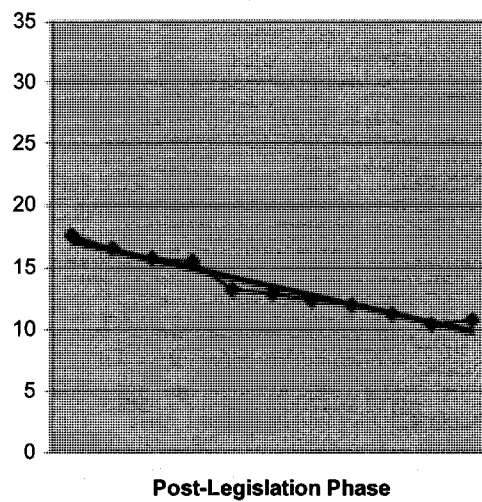
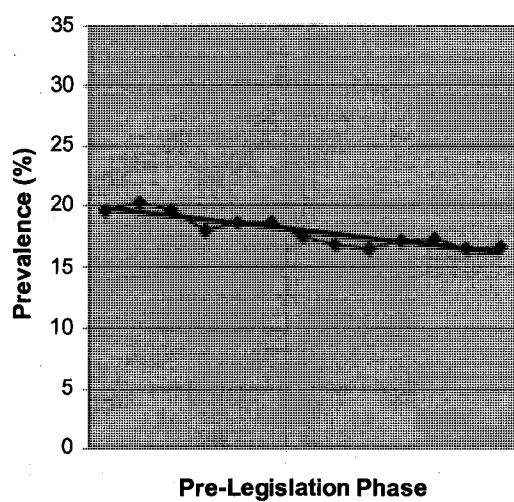
Trunk Restraints in Large Facilities



Trunk Restraints in Private Facilities



Trunk Restraints in Public Facilities



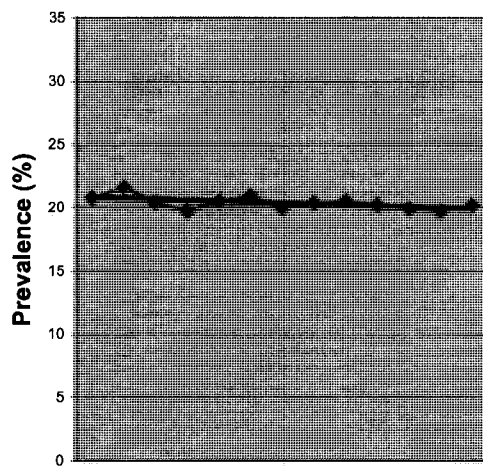
Appendix C

Chair Restraints Province Wide and by Facility Type

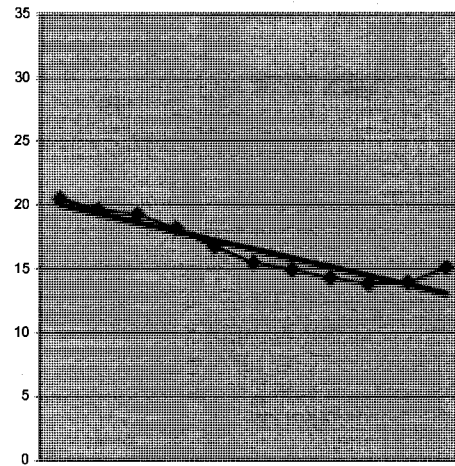
Pre- and Post-Legislation

The following plots show the pre- and post-legislation phases of the prevalence of all chair restraints in large facilities and by facility type with the addition of a regression line. These plots are intended to facilitate visual analysis so as to identify direction of any slopes, large abrupt changes in intercept, and differences between the pre- and post- legislation phases.

Chair Restraints Province Wide

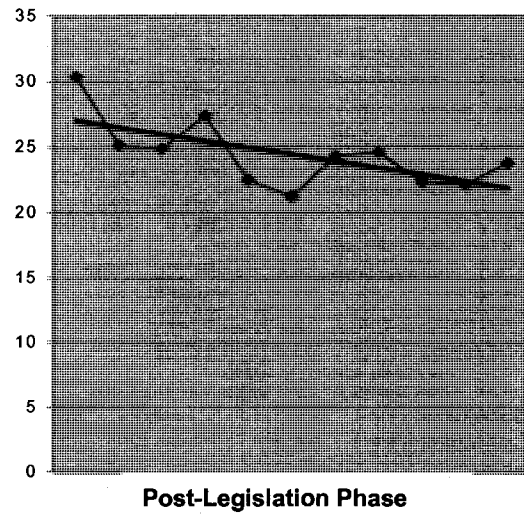
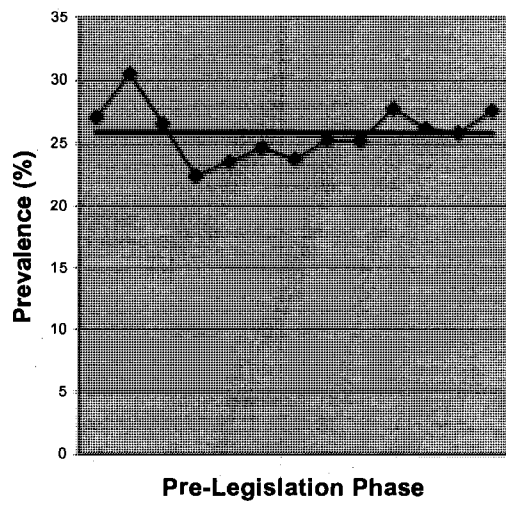


Pre-Legislation Phase

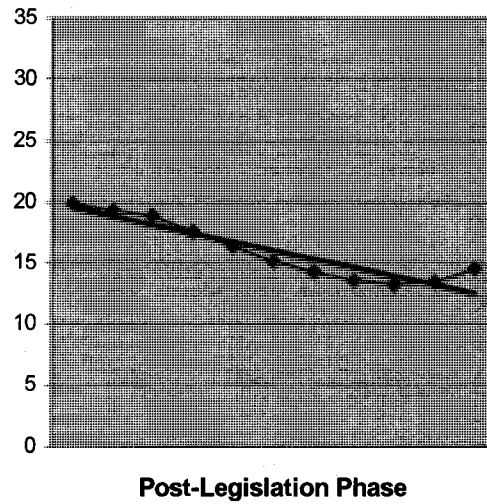
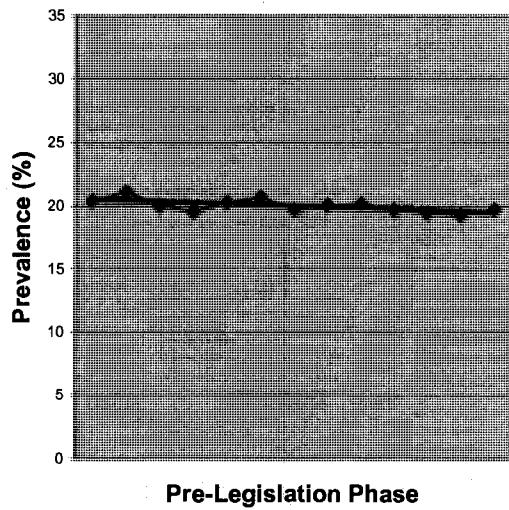


Post-Legislation Phase

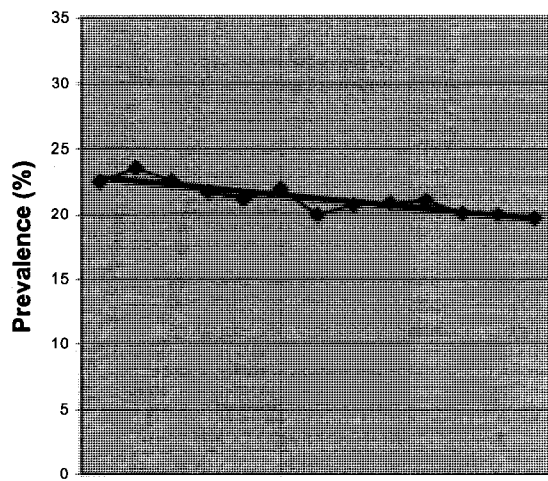
Chair Restraints in Rural Facilities



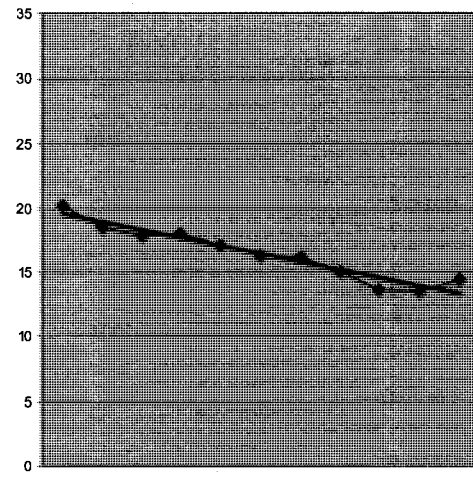
Chair Restraints in Urban Facilities



Chair Restraints in Small Facilities

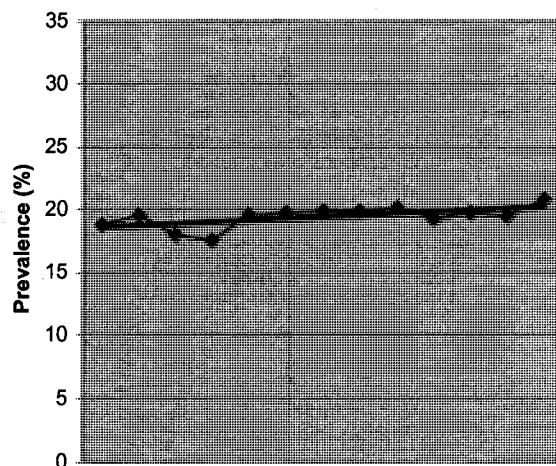


Pre-Legislation Phase

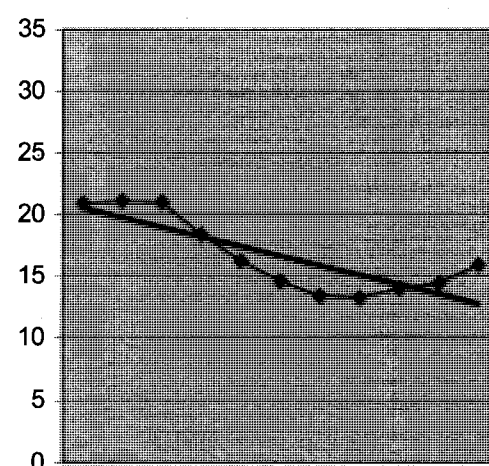


Post-Legislation Phase

Chair Restraints in Large Facilities

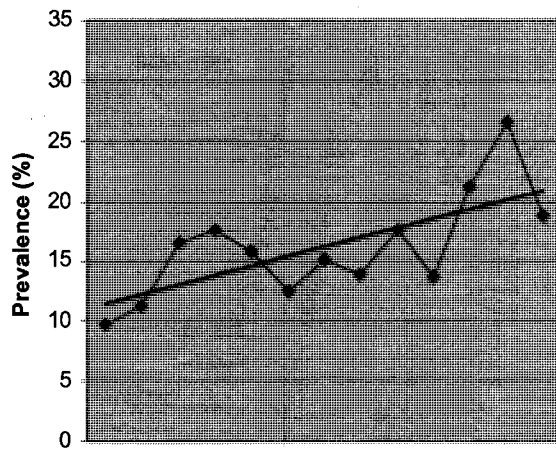


Pre-Legislation Phase

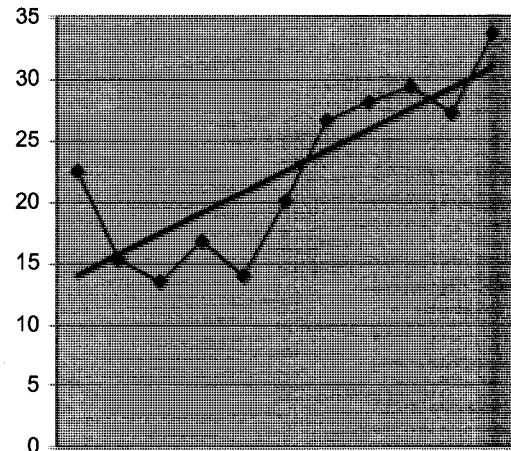


Post-Legislation Phase

Chair Restraints in Private Facilities

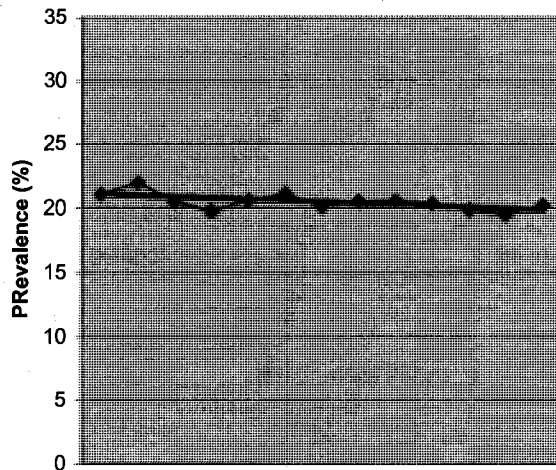


Pre-Legislation Phase

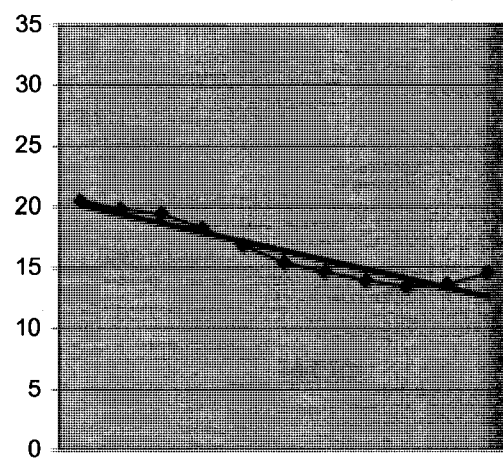


Post-Legislation Phase

Chair Restraints in Public Facilities



Pre-Legislation Phase



Post-Legislation Phase

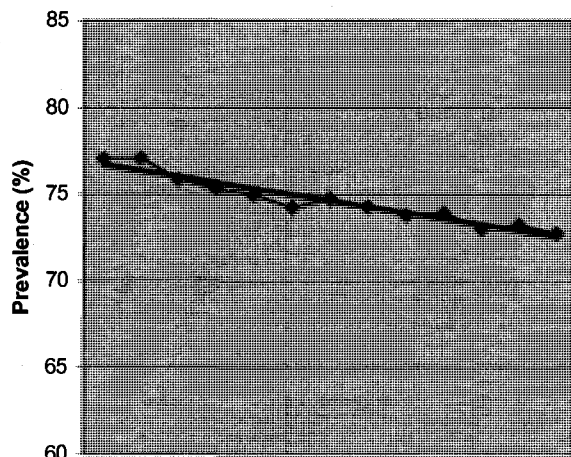
Appendix D

Full Bed Rails Province Wide and by Facility Type

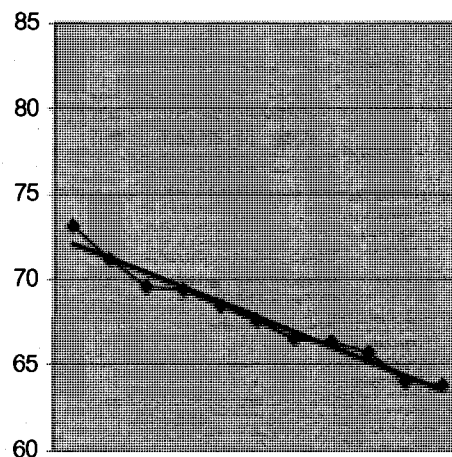
Pre- and Post-Legislation

The following plots show the pre- and post-legislation phases of the prevalence of all full bed rails province wide and by facility type with the addition of a regression line. These plots are intended to facilitate visual analysis so as to identify direction of any slopes, large abrupt changes in intercept, and differences between the pre- and post- legislation phases.

Full Bedrails Province Wide

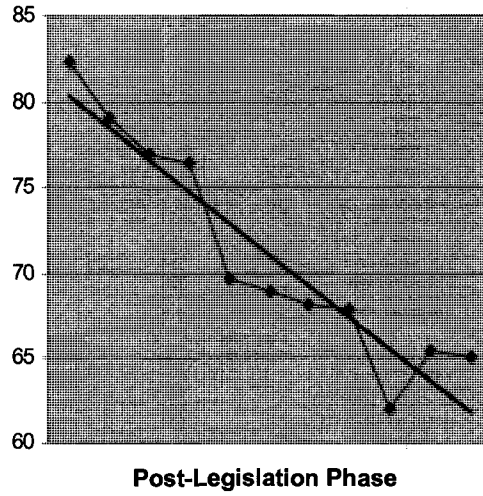
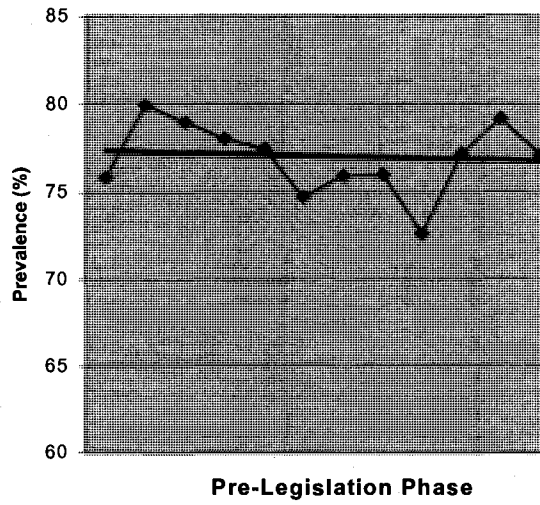


Pre-Legislation Phase

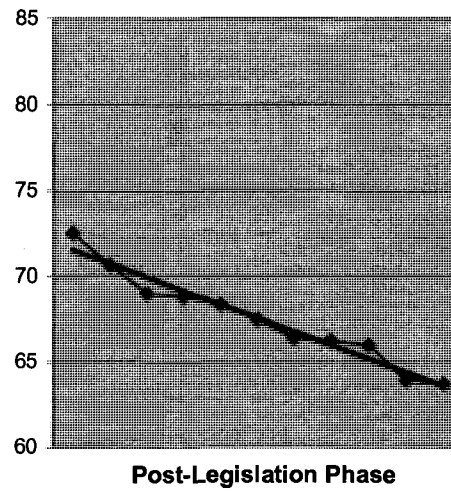
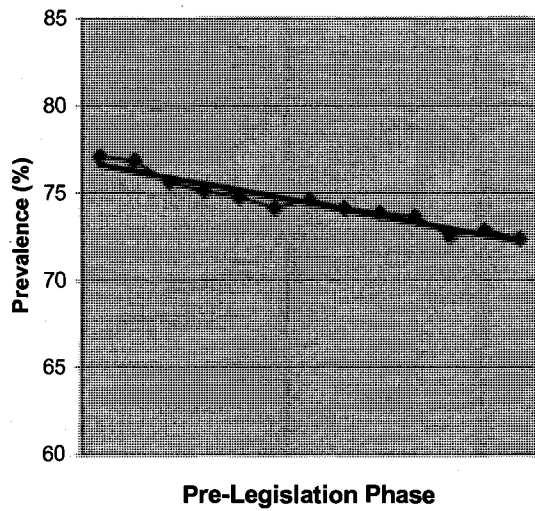


Post-Legislation Phase

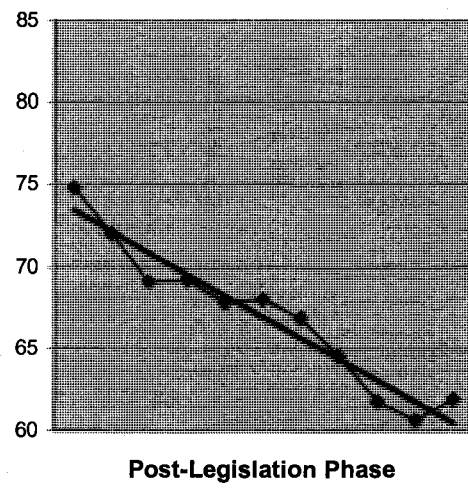
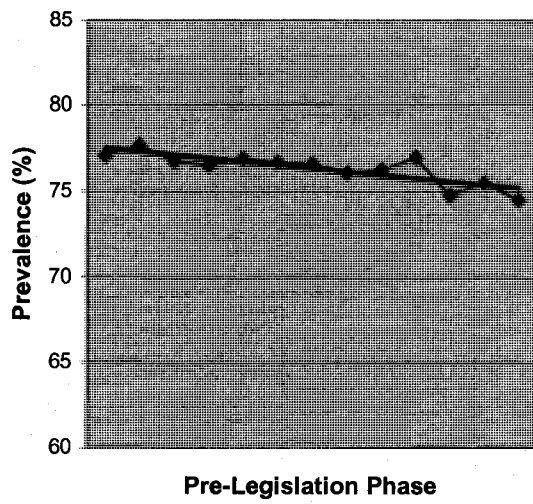
Full Bedrails in Rural Facilities



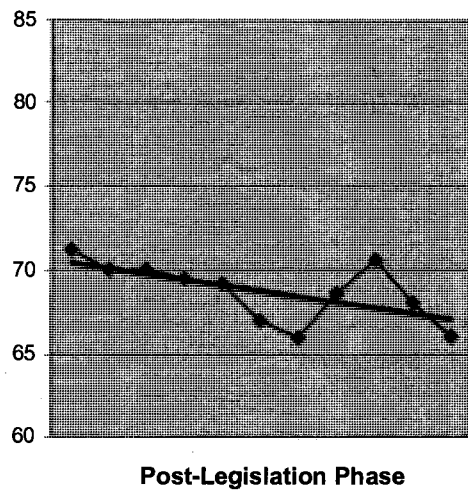
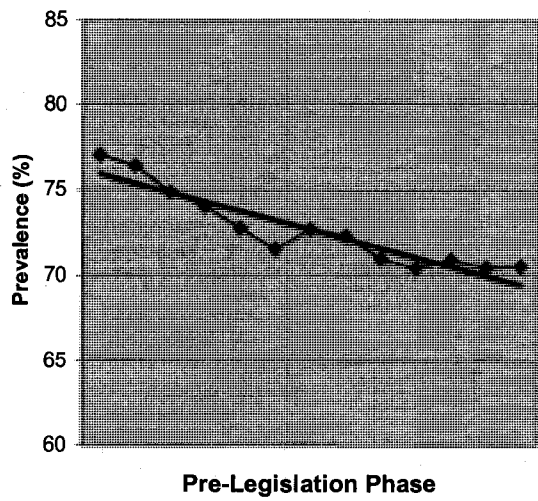
Full Bedrails in Urban Facilities



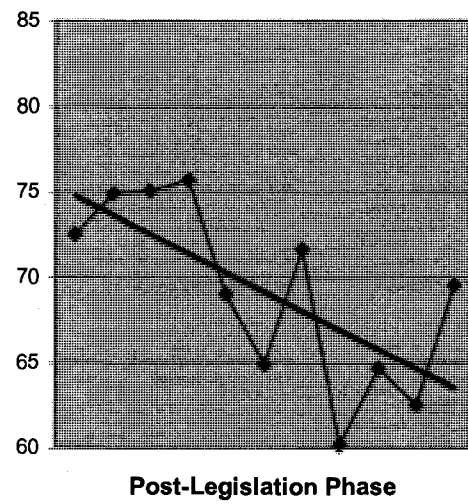
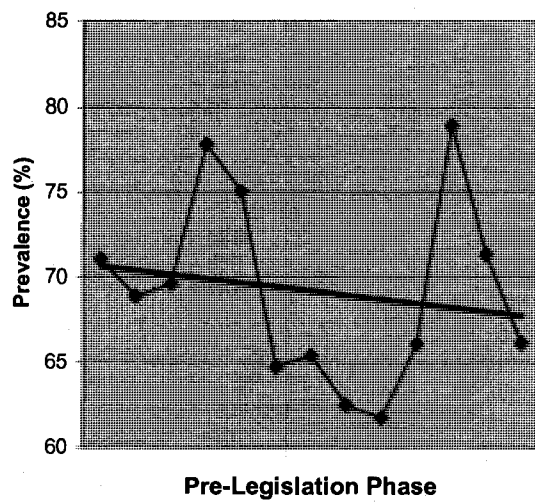
Full Bedrails in Small Facilities



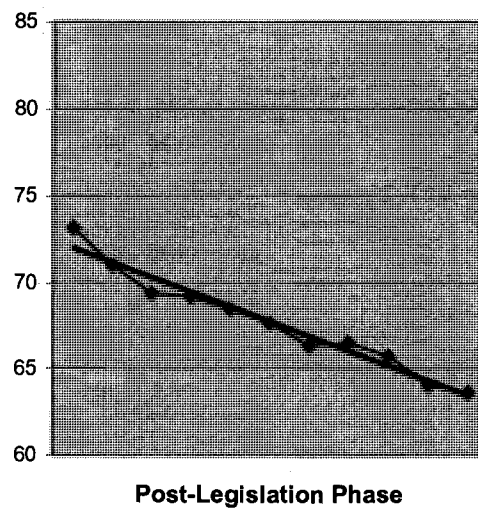
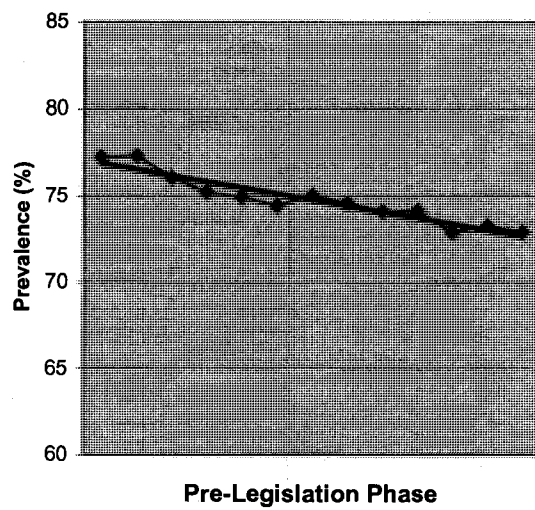
Full Bedrails in Large Facilities



Full Bedrail in Private Facilities



Full Bedrails in Public Facilities



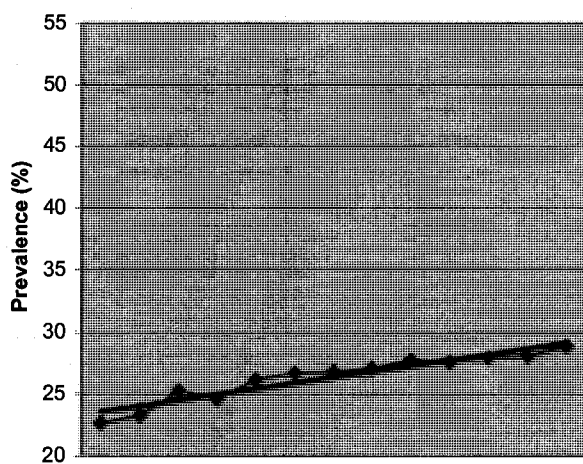
Appendix E

Other Rails Province Wide and by Facility Type

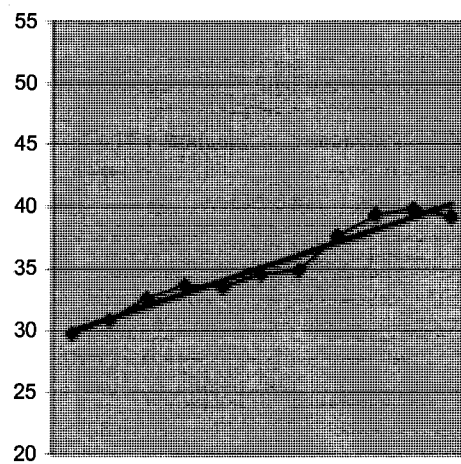
Pre- and Post-Legislation

The following plots show the pre- and post-legislation phases of the prevalence of all other rails province wide and by facility type with the addition of a regression line. These plots are intended to facilitate visual analysis so as to identify direction of any slopes, large abrupt changes in intercept, and differences between the pre- and post- legislation phases.

Other Rails Province Wide

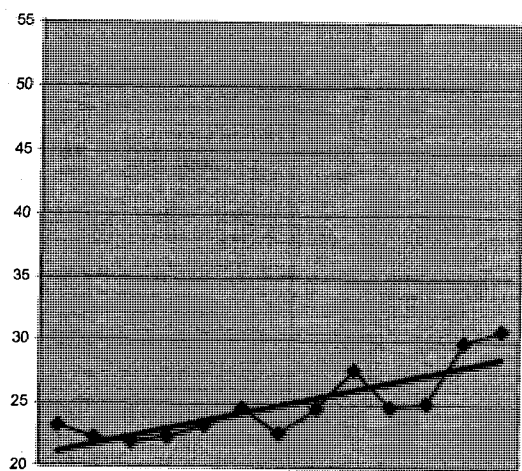


Pre-Legislation Phase

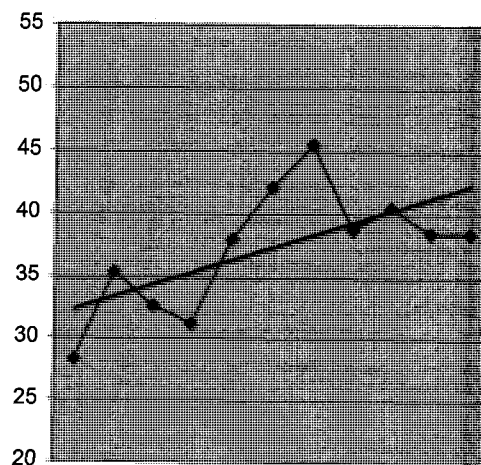


Post-Legislation Phase

Other Rails in Rural Facilities

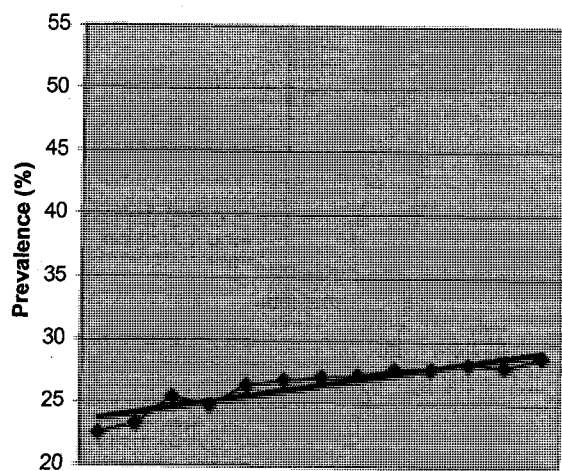


Pre-Legislation Phase

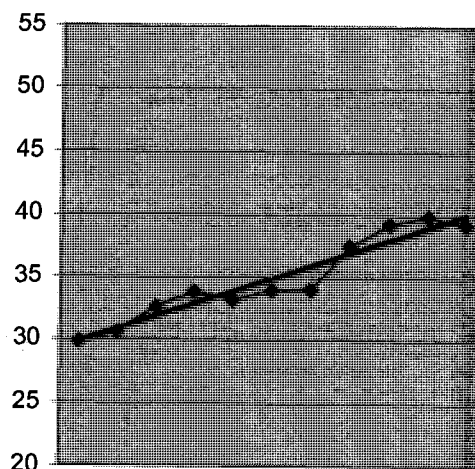


Post-Legislation Phase

Other Rails in Urban Facilities

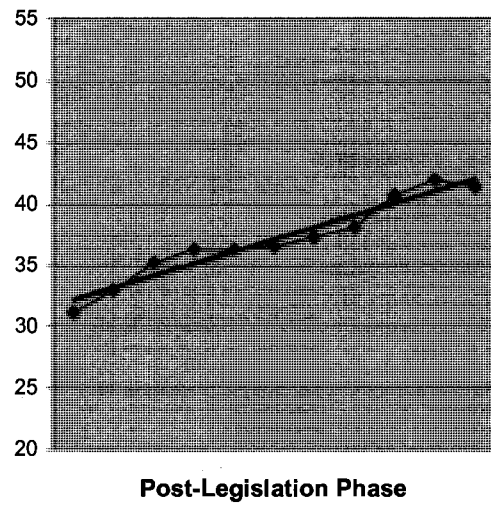
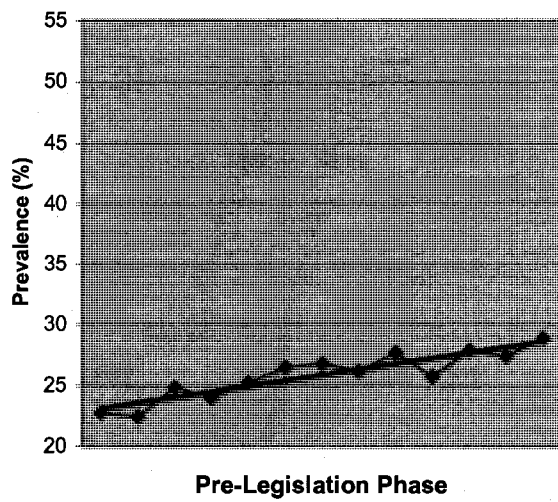


Pre-Legislation Phase

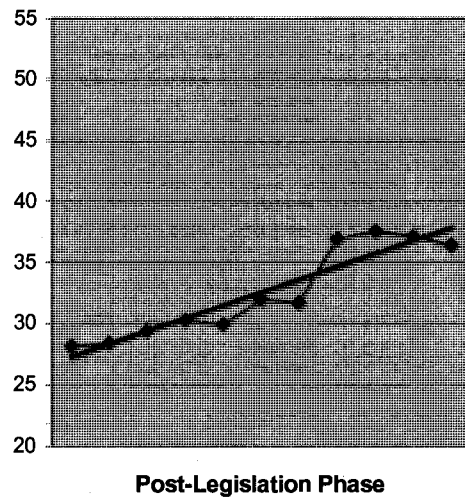
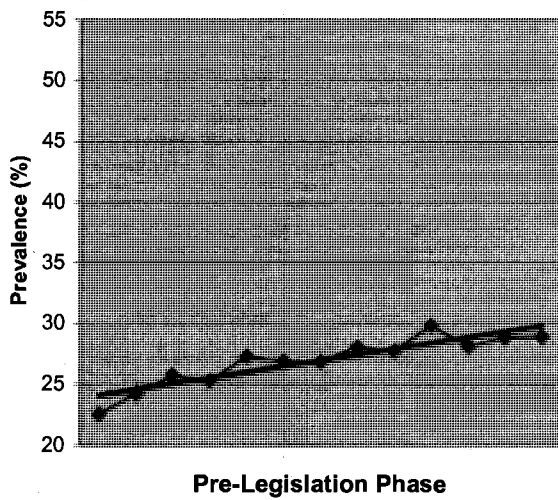


Post-Legislation Phase

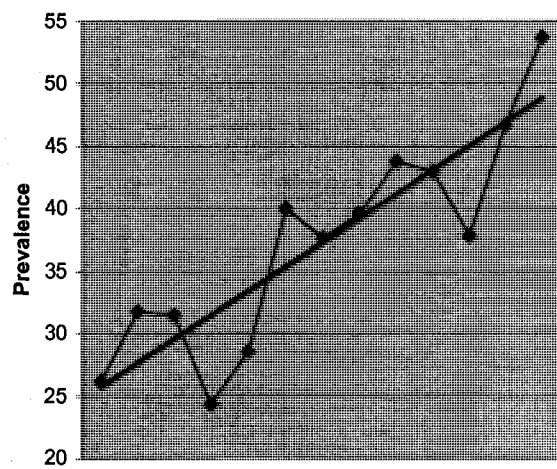
Other Rails in Small Facilities



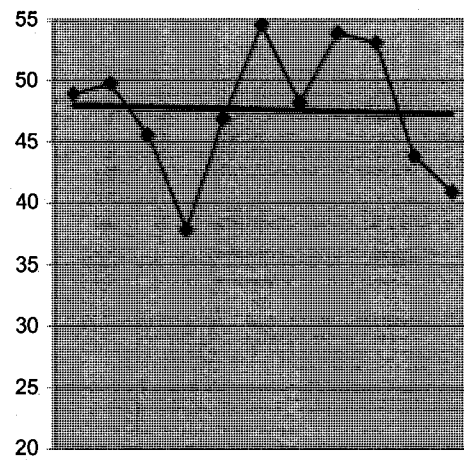
Other Rails in Large Facilities



Other Rails in Private Facilities

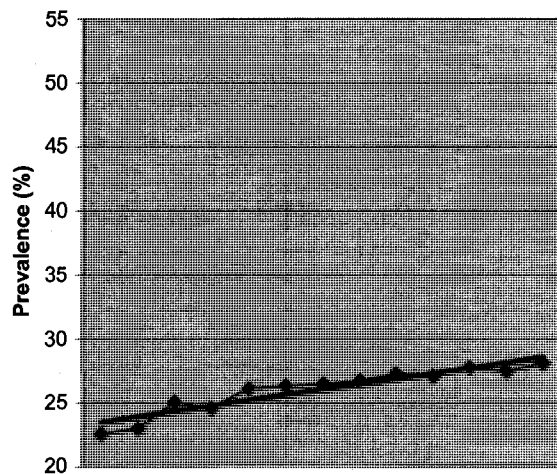


Pre-Legislation Phase

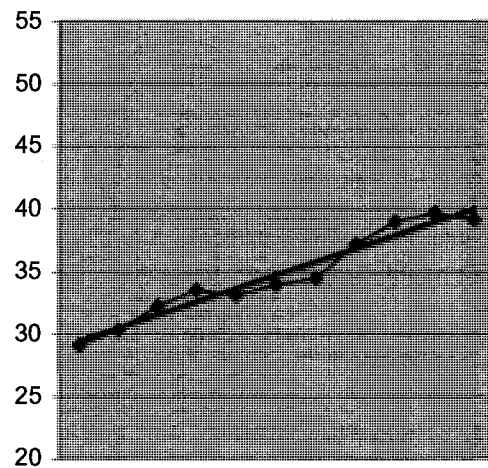


Post-Legislation Phase

Other Rails in Public Facilities



Pre-Legislation Phase



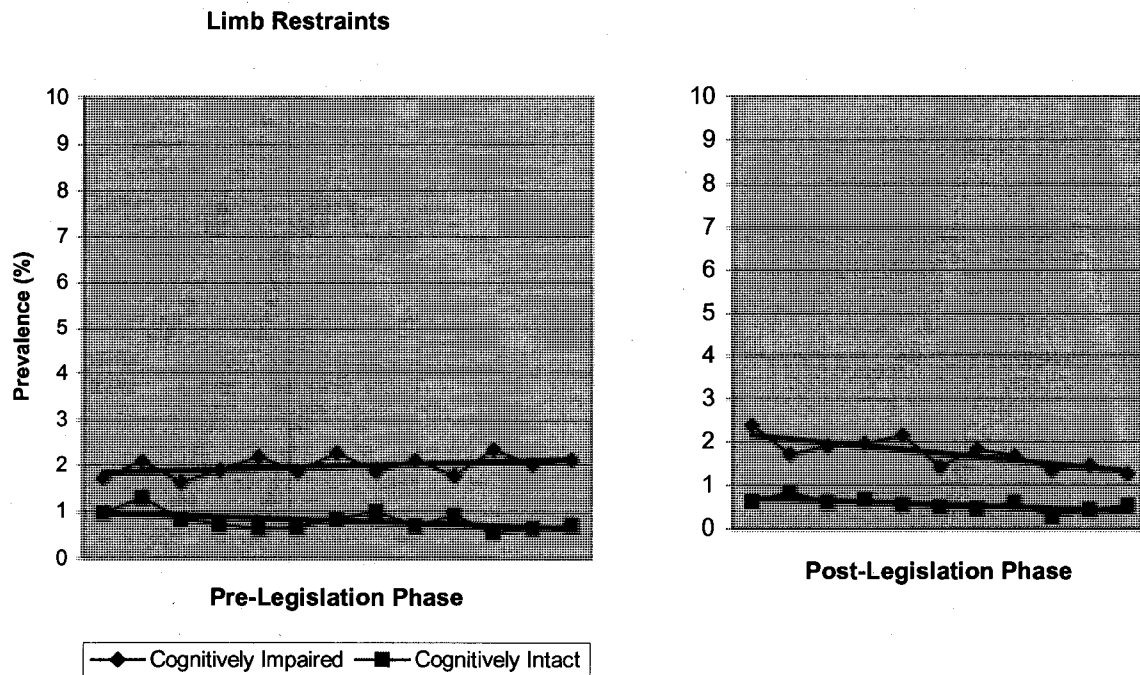
Post-Legislation Phase

Appendix F

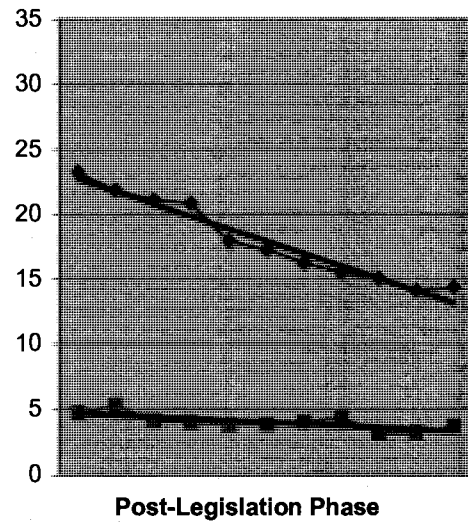
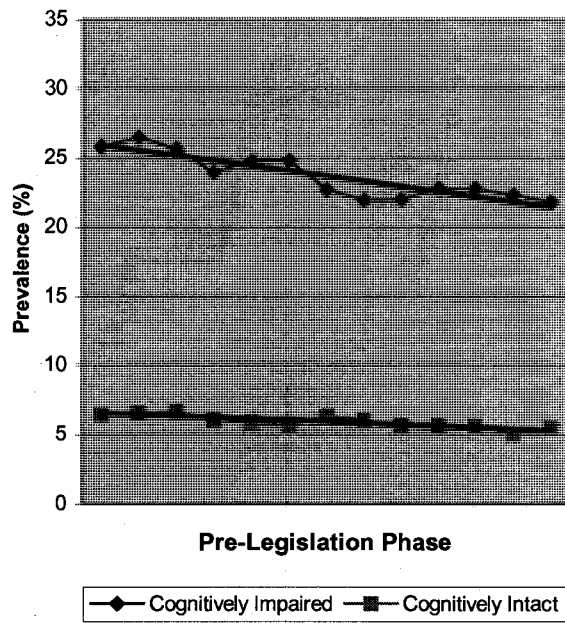
Prevalence Plots of Stratified Groups:

Cognitively Impaired vs. Cognitively Intact Patients

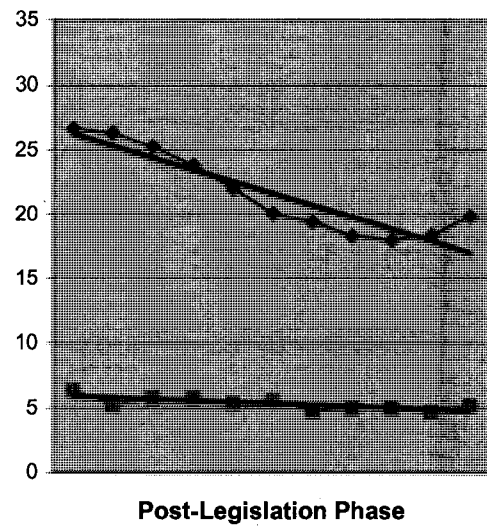
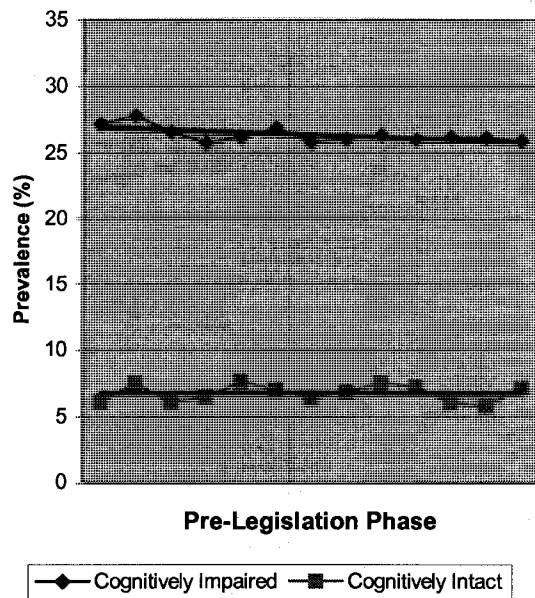
The following plots show the pre- and post-legislation phases of the prevalence of all physical restraints province wide with the addition of a regression line. These plots are intended to facilitate visual analysis to investigate the possible confounding influence of cognitive impairment.



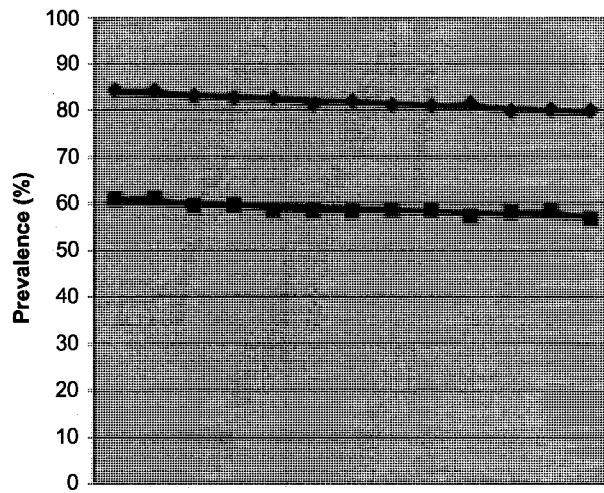
Trunk Restraints Province Wide



Chair Restraints Province Wide

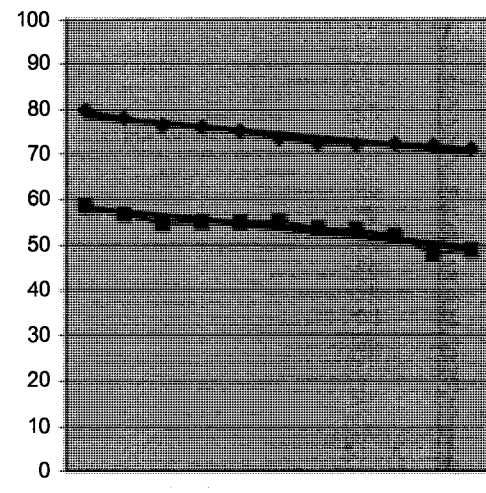


Full Bedrails Province Wide



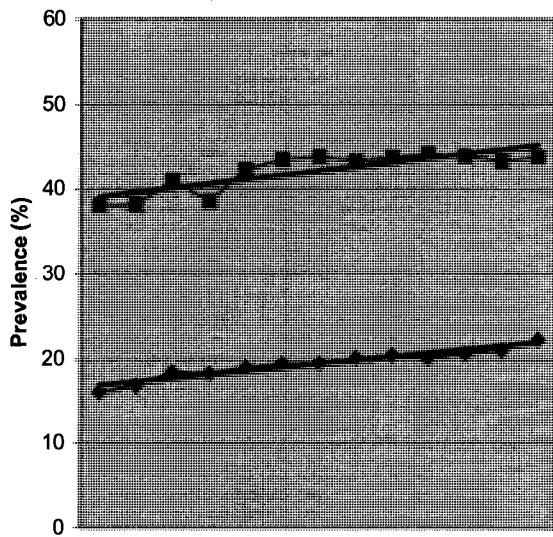
Pre-Legislation Phase

—◆— Cognitively Impaired —■— Cognitively Intact



Post-Legislation Phase

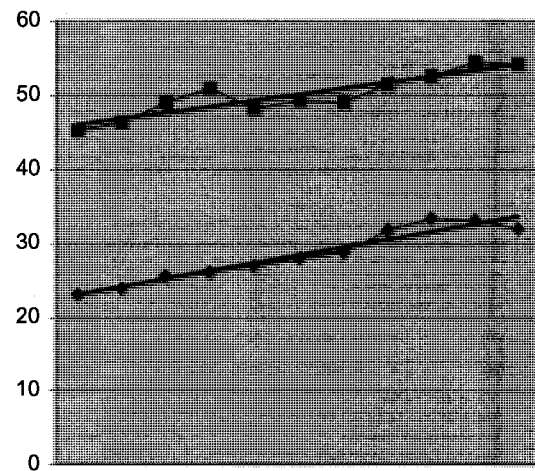
Other Rails Province Wide



Pre-Intervention Phase

—◆— Cognitively Impaired —■— Cognitively Intact

Other Rails Province Wide



Post-Intervention Phase

Appendix G

ITSACORR Software Sample Output

ITSACORR Version 1.0

limb Restraints All Assessments April 1998 to March 2004

13 Pre-intervention scores

1.47	1.83	1.38	1.52	1.70	1.49	1.82	1.59	1.65	1.50
1.76	1.57	1.68							

11 Post-intervention scores

1.84	1.42	1.49	1.55	1.63	1.12	1.40	1.33	1.00	1.11
1.01									

OVERALL Test of change in intercept & slope:

F(2, 19) = 4.047, p = 0.034

	SSIntercept	t(19)	SSSlope	t(19)
Phase 1	1.609	13.047	0.003	0.166
Phase 2	1.772	13.560	-0.069	-3.624
Change, t(19) =	0.828, p = 0.418		-2.834, p = 0.011	

Appendix H

ITSACORR Analysis of Physical Restraints by Intensity of Use

	FULL BED RAILS	
	Daily (p value)	Less than Daily (p value)
Impaired	0.220	0.364
Non-Impaired	0.296	0.853
Male	0.238	0.413
Female	0.542	0.768
Age 1	0.335	0.576
Age 2	0.513	0.314
	OTHER TYPES OF RAILS	
	Daily (p value)	Less than Daily (p value)
Impaired	0.088	0.456
Non-Impaired	0.411	0.624
Male	0.244	0.604
Female	0.426	0.254
Age 1	0.234	0.419
Age 2	0.443	0.300
	TRUNK RESTRAINTS	
	Daily (p value)	Less than Daily (p value)
Impaired	0.557	0.660
Non-Impaired	0.951	0.342
Male	0.519	0.772
Female	0.482	0.626
Age 1	0.340	0.733
Age 2	0.298	0.494

	LIMB RESTRAINTS	
	Daily (p value)	Less than Daily (p value)
Impaired	0.155	0.038
Non-Impaired	0.327	0.094
Male	0.359	0.470
Female	0.728	0.084
Age 1	0.466	0.192
Age 2	0.795	0.107
	CHAIR PREVENTS RISING	
	Daily (p value)	Less than Daily (p value)
Impaired	0.581	0.461
Non-Impaired	0.446	0.035
Male	0.604	0.141
Female	0.723	0.433
Age 1	0.864	0.271
Age 2	0.452	0.584

Appendix I

Sample SAS® Code to Classify Patients on the Cognitive Performance Scale

```
data THESIS.Ccc65_and_over_COPY;
    set THESIS.Ccc65_and_over;
    if B4_COGNITIVE_SKILLS =3
    and G1HA_EATING_SELF =4 then
        CPS = 6;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS =3
    And G1HA_EATING_SELF =0
    Then CPS = 5;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS = 3
    And G1HA_EATING_SELF = 1
    Then CPS = 5;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS = 3
    And G1HA_EATING_SELF = 2
    Then CPS = 5;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS = 3
    And G1HA_EATING_SELF = 3
    Then CPS = 5;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS = 0
    and C4_MAKING_SELF_UNDERSTOOD = 0
    and B2A_SHORT_TERM_MEMORY_OK = 0
    then CPS = 0;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
    If B4_COGNITIVE_SKILLS = 0
    and C4_MAKING_SELF_UNDERSTOOD =0
```

```
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 1;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 2
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 2
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 2
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 2
and B2A_SHORT_TERM_MEMORY_OK = 0
```

Then CPS = 3;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 2
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 3;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 0
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 2;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 2;
run;

data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 0
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 2;

run;

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
and C4_MAKING_SELF_UNDERSTOOD = 0
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 1
And B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 0
And B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 2
And B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 4;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 2
And B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 4;
run;
```

```
data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 3
And B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 4;
run;
```

```

data THESIS.Ccc65_and_over;
    set THESIS.Ccc65_and_over;
If B4_COGNITIVE_SKILLS = 2
And C4_MAKING_SELF_UNDERSTOOD = 3
And B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 4;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 0
and C4_MAKING_SELF_UNDERSTOOD = 1
and B2A_SHORT_TERM_MEMORY_OK = 0
Then CPS = 1;
run;

```

```

data THESIS.Ccc_05_07_19;
    set THESIS.Ccc_05_07_19;
If B4_COGNITIVE_SKILLS = 1
and C4_MAKING_SELF_UNDERSTOOD = 3
and B2A_SHORT_TERM_MEMORY_OK = 1
Then CPS = 3;
run;

```