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Report on Client Safety Improvements

by Health Canada's Non-Insured Health Benefits Program
February 2007

Canada

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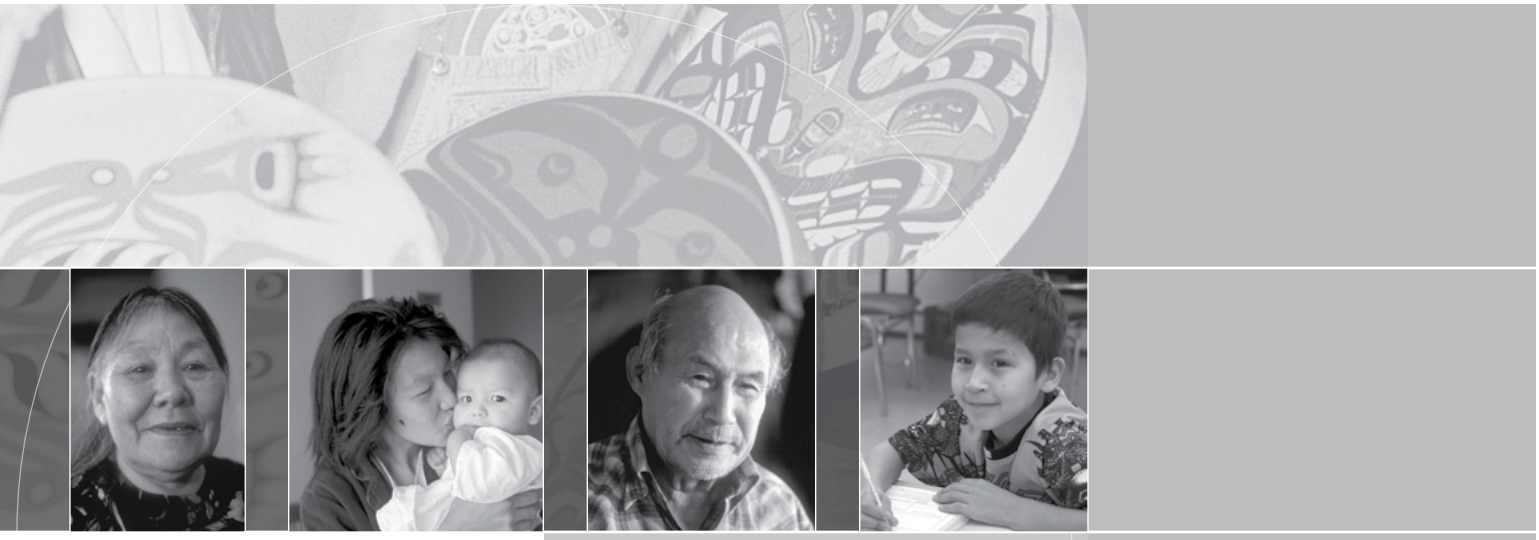

Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Table of Contents

Preamble

Health Canada's Non-Insured Health Benefits (NIHB) program provides a limited range of medically necessary goods and services to eligible First Nations and Inuit clients. The Program is part of Health Canada's First Nations and Inuit Health Branch (FNIHB). The overarching goal of this Branch is to address the gap in health status that exists between First Nations and Inuit and other Canadians.

NIHB does not dispense pharmaceutical benefits directly to clients. The Program, like other public and private drug plans, relies on physicians to issue prescriptions and pharmacists to dispense drug benefits based on professional judgement. NIHB, with the assistance of a third party claims processing contractor, reimburses pharmacists for the cost of the drug as well as a fee for professional dispensing services. Eligible drug benefits are 100% covered for clients.

Auditor General of Canada's interest in the Non-Insured Health Benefits program

Since 1993, the NIHB program has come under scrutiny from the Auditor General of Canada and the Standing Committee on Public Accounts. This document is an effort to provide an overview of recent actions and improvements the Program has undertaken with respect to prescription drug misuse.

Enhancing NIHB's approach to Client Safety

Since 2003 NIHB has improved its approach to client safety. This issue is a matter of great concern to the Program and Health Canada's First Nations and Inuit Health Branch and relates directly to the Branch's overall mission.

Between 2000 and 2004, NIHB initiated a program to solicit consent from every client as the foundation from which client safety measures could flow. This approach proved problematic and received little support from stakeholder organizations or clients at an individual level. As a result, a new approach was developed. Since February 2004, the Program uses its administrative authorities to promote optimal drug use. This approach recognizes that the vast majority of NIHB clients use prescription drugs in an appropriate way and focusses attention only on cases of concern.

NIHB's Four Pillars to Client Safety

The NIHB Program is beginning to see positive impacts as a result of a number of key interventions. The four pillars to NIHB's approach to client safety, include:

1. **Warning messages** to pharmacists regarding drug interactions and repeat prescriptions
2. **Rejection messages** to pharmacists regarding client drug therapy history
3. Client and Program level **trend analysis** of prescription drug use
4. The creation of an independent expert **advisory committee** to provide input, evaluations and recommendations for improvements to the program

Pillar 1

Warning messages to pharmacists

Communication between the NIHB program and the front-line pharmacists is essential in protecting client safety. As the Auditor General has noted, NIHB has implemented a number of significant changes to enhance the important relationship between the program and pharmacists. NIHB has been part of an industry-wide system since the early 1990's that allows the Program to send messages electronically in real-time to pharmacists at the point of sale to warn them about potential client safety issues including drug interactions and repeat prescriptions (for the full list of warning codes see appendix 1).

These warning messages are important tools that supplement pharmacists' professional judgement at the point of sale.

The NIHB Program actively monitors the number of pharmacy claims that are flagged with warning messages or rejected by this system. In 2005, the NIHB Program received 10.7 million pharmacy claims. During the same period, 495,000 warning or rejection messages were sent by the NIHB Program to pharmacies across the country. NIHB also actively monitors pharmacists' use of codes to override the Program's rejected claims. When pharmacies are found to be overriding warnings frequently, concerns will be raised by the program. If the pattern continues, the pharmacy may be audited to ensure that the Program's financial integrity and client safety are not being compromised.

Action: 495,000 warning messages to pharmacists per year

Result: Pharmacists armed with important information to enhance client safety

NIHB actively monitors pharmacists' overrides of these messages

325,000 of these prescriptions (66%) not filled during the 2005 calendar year

NIHB's new warning message for narcotics, benzodiazepines and methadone

In April of 2006, the NIHB program took an additional step to improve Program accountability and client safety. A special warning message was established to address issues identified by the Auditor General, as well as the clinical evidence around the health risks associated with the misuse of specific drugs of concern. These drugs include *narcotic*-based drug products (opioids such as morphine, codeine, and oxycodone which are used to relieve pain), *benzodiazepines* (so-called "minor" tranquillizers, sleep aids and anti-anxiety medications) and *methadone* (a long-lasting synthetic opioid used to treat pain and/or opioid addiction).

In designing the new warning message, it was important to recognize that all of these drugs have clinically valid applications. For example, narcotic treatments are crucial pain management tools for patients suffering from terminal cancer and have very valid and much needed applications, particularly when the patient reaches a palliative care stage. Therefore, the new warning message was designed to focus attention on cases where there are concerns around potential misuse, and where continued utilization is difficult to justify.

The new warning message, called the NE code, addresses situations where clients access:

- 3 or more benzodiazepines;
- 3 or more narcotic-based drugs;
- 3 or more narcotics in combination with 3 or more benzodiazepines;
- a prescription for methadone in association with narcotic-based drugs.

The new warning provides a message to pharmacists indicating that potential misuse of prescription drugs should be explored. It is one more tool to supplement their professional judgement and to protect client safety. Other federal, provincial and territorial drug benefit plans have taken an interest in NIHB's new warning message and may follow NIHB's lead in developing similar warning messages in the future.

From April to August 2006, NIHB issued 8,355 NE warning codes to pharmacists. Projected over the calendar year, this would equate to just over 20,000 codes in a 12 month period. When compared to the number of claims NIHB processed in a year (10.7 million in 2005), the percentage of clients using prescription drugs in this range is very small (less than one tenth of one percent). However, preliminary indications suggest positive impacts for this group of clients.

Action: New point of sale warning code to alert Pharmacists of potential misuse of narcotics/benzodiazepines and methadone

Result: Reductions in the number of clients claiming multiple narcotics, benzodiazepines or methadone in association with another narcotic based drug

Pillar 2

Rejection messages regarding drug therapy patterns

Special approvals required for patterns of concern

The NIHB program also provides rejection messages to pharmacists when a client's claims history indicates potential misuse or overuse of acetaminophen-based opioid products (Tylenol 3, Oxycet/Percocet), as well as benzodiazepine type drugs. These rejection messages are different from the warning or rejection messages described above. It is not possible to override these messages. As a result, a pharmacist must contact NIHB's Drug Exception Centre, a national toll-free call centre, to obtain the Program's approval before the program will authorize payments for the medication in question. Once contacted by the pharmacist, the Drug Exception Centre will, in turn, follow up with the client and the prescribing physician to authorize the further use of the drug in question under the Program.

Action: Development of rejection messages to address client claims history

Result: A more rigourous approval process for patterns of concern

Maximum Allowable quantities for Acetaminophen-based narcotics as well as benzodiazepines

In January 2005, NIHB expanded the number of products subject to a maximum allowable dose to include all acetaminophen-based narcotic combination products (i.e. Tylenol 3), which resulted in a threefold increase in the number clients rejected due to exceeding maximum allowable doses (from 73 in 2005 to 214 in 2006 during a comparable 12 month period).

Action: Closer monitoring of acetaminophen based narcotic drugs and special approvals required

Result: 3 fold increase in the number of rejected claims

Clients are often unaware of the long-term consequences of acetaminophen-based products. Serious negative health effects can result from prolonged use, including liver damage if recommended dosages are exceeded. As a result, the Program as of January 1, 2007, applies a maximum allowable dose rule to all acetaminophen-based products.

Pillar 3

Client and Program level trend analysis

Client level Analysis and Follow-up with Health Care Providers

The Program has developed a methodology that allows NIHB staff to anonymously identify clients at highest potential risk for misuse of benzodiazepines and/or narcotic-based products. This approach has been reviewed and endorsed by NIHB's Drug Use Evaluation Advisory Committee (see Pillar 4 – page 7).

Anonymous client profiles identified through this process are reviewed by NIHB pharmacy consultants, all of whom are licensed health care professionals. When concerns are flagged, and where the NIHB Program has the consent of the client to do so, the NIHB Program will follow up directly with health care professionals. Since November 2004 when this activity was re-commenced, the Program has made more than 1,000 interventions with both physicians and pharmacists involved in the prescribing and dispensing to clients who may be at risk. These interventions have been well received by health care professionals and have led to changes in utilization patterns.

Action: Ongoing monthly reviews of client profiles by NIHB pharmacy consultants

Result: Over 1,000 interventions with pharmacists and medical doctors since 2004

The Prescription Monitoring Program

Based on the success of the work described above, NIHB established a Prescription Monitoring Program (PMP) on January 1, 2007, which will focus initially on benzodiazepine and narcotic based drugs. This program complements existing activities and promotes the optimal use of medications by allowing the Program to enhance its interventions when drug use patterns of concern are observed. Client drug use patterns with respect to the number of physicians visited and the number of NE warning codes generated on an on-going basis will also be a criterion by which the Program may place clients into the PMP. This program requires that clients have future claims verified and authorized by a pharmacist at NIHB's Drug Exception Centre. If clients or their health care providers cannot provide evidence to support the continuation of drug therapy, the Program reserves the right not to pay for the drugs requested.

Action: Establishment of a prescription monitoring program for clients with drug use patterns of concern

Anticipated Result:
Improved monitoring and tighter approval process for clients with established patterns of drug misuse

Program level analysis, identification of issues and adjusting program requirements

NIHB also actively analyses broad patterns of utilization, prescribing, and dispensing, on an on-going basis. This work is conducted at NIHB Headquarters by a team of professional pharmacists and policy experts. Once issues are identified, program interventions to prevent recurrence of inappropriate prescription drug use are developed. For example, drugs subject to overuse/misuse have been recommended for removal from open-benefit status to limited-use benefit status, or in certain circumstances, have been removed from the approved drug benefit list entirely. In addition, the program releases periodic bulletins to health providers to ensure that they have access to the information they need to serve NIHB clients well (see appendix 5). NIHB professionals also are in active discussions and dialogue with their federal, provincial and territorial counterparts who operate similar drug benefit plans and contribute to best practice knowledge across jurisdictions.

Action: Ongoing program level analysis and improvements

Result: Ongoing review of drug utilization

Analysis and early identification of trends

Improved communication with health care providers

Pillar 4

NIHB's Drug Use Evaluation Advisory Committee

In order to further ensure accountability and transparency, the Program created the NIHB Drug Use Evaluation Advisory Committee late in 2003. The purpose of this committee is to provide independent expert advice to promote the improvement in health outcomes of First Nations and Inuit clients through effective use of pharmaceuticals. The Advisory Committee is comprised of various health care professionals, including four First Nations physicians. It meets four times per year and reviews drug-use trends for NIHB clients and makes recommendations for program interventions and follow-up on specific issues.

In particular, the Committee has dedicated itself to reviewing a wide range of drugs (23 studies complete/ongoing) with a view to improving client safety (see appendix 2). The Committee periodically sends the results of its analysis to health professionals across the country through its Drug Use Evaluation Bulletin. In addition, on the advice of this committee, the Program has sent letters raising concerns to top prescribers of benzodiazepines. Other contributions include the development of the new NE code for narcotics, benzodiazepines and methadone. It is anticipated that the Committee will continue to provide valuable advice to the Program and further program enhancements will occur as a result.

Action: Creation of a professional advisory body to identify and evaluate emerging drug use issues and to communicate to health care professionals

Result: 23 studies of specific drugs, enhanced awareness of NIHB client patient safety concerns and needs

Evaluating Outcomes

The Program is committed to measuring and demonstrating the impact of interventions described in this document. The advice of the Drug Use Evaluation Advisory Committee has been valuable in helping NIHB develop a sound measurement methodology that can produce useful data over the long term. To date, the Program has developed a number of indicators which appear to demonstrate the positive influence of NIHB's interventions. Two of these indicators are detailed below:

Changes in benefit status

In October 2005, the NIHB Program changed the benefit status of a prescription pain patch called Duragesic. This product is a long-acting narcotic product that was being

requested in increasing numbers for a number of years. As a result of evaluations that concluded this particular drug was subject to overuse, the Program changed its benefit status from Open Benefit to Limited Use. As mentioned previously, changing the status of a drug from open benefit to Limited Use requires an evaluation and special authorization from NIHB's Drug Exception Centre. Claims data show that, since these restrictions were put in place, the Program has effectively reversed the utilization trend for this particular narcotic-based drug (see Appendix 3).

Action: Changes to access to the narcotic-based drug Duragesic

Result: Reversal of the usage trends for this drug in 2006

Almost 1000 fewer claims for Duragesic since change in benefit status

Impacts of Program interventions on benzodiazepine use

The range of interventions highlighted in this document are aimed at reducing problematic drug use. One of the main areas of concern has been benzodiazepine use. This class of drug is meant to be a short-term remedy for individuals coping with anxiety or sleep problems. There is little clinical evidence to support long-term use of this class of drug. Physical addiction can often result from long-term use and can produce adverse health and social effects, particularly in seniors. The NIHB program has undertaken specific evaluations of trends in benzodiazepine use to measure the effectiveness of recent interventions. The number of clients accessing benzodiazepines, the number of claims approved and the number of clients exceeding the maximum recommended daily dose of 40 mg per day all have declined in 2006 (see appendix 2).

Finally, the Program has also taken a measure of the number and percent of clients who access more than two different drugs of concern. Significant reductions in the number of clients in this category have been achieved in 2006 (see appendix 2).

Action: Tightening of a range of policies and program activities around benzodiazepines

Result: Reductions in the number of clients accessing benzodiazepines

Reductions in the number of claim lines for benzodiazepines

Reductions in the number of clients claiming 2 or more prescription drugs in the benzodiazepine category

Complementary community-level approaches

The First Nations and Inuit Health Branch is also actively working at the community level to promote healthy lifestyles and to prevent the misuse and abuse of prescription drugs. The Branch has initiated demonstration projects aimed at raising awareness of harms associated with prescription drug abuse and delivering evidence based prevention strategies that will address prescription drug abuse. Linkages are being established among First Nations and Inuit communities, academic institutions, health care organizations, and other local organizations. Intermediate results will provide a better understanding of how to design, integrate and implement effective intervention strategies that are culturally specific and knowledge based. The long term objective of the demonstration projects is to develop culturally appropriate, evidence-based prevention and promotion strategies that prevent the misuse and abuse of prescription drugs, leading to improved health outcomes for First Nations and Inuit people.

Action: Demonstration projects in First Nations and Inuit communities to promote healthier use of prescription medications

Result: Improved understanding of the impacts of use of prescription drugs among First Nations and Inuit people

Improved health outcomes

Conclusion

Since 2003, the Non-Insured Health Benefits program has taken an active, evidenced-based and measured approach to further develop client safety activities. This approach stresses the appropriate use of medications with a view to achieving the best possible health outcomes for First Nations and Inuit clients. Significant program measures are now in place, and the Program is committed to monitoring and measuring these enhancements. Initial indications demonstrate reductions in the potential misuse of prescription drugs. However, these trends will need to be evaluated over time and program measures will be created and implemented to complement and build on the work undertaken since 2003.

Appendix 1

Table 1: NIHB Point-of-Sale Warning and Rejection Messages

Message	Code*	Description
Drug to drug interaction potential	***ME (hard)***	***Indicates that drug may interact with another current drug, based on an accurate days supply submission.***
Duplicate Therapy	MX (soft)	Indicates that the client has received a drug from the same therapy class.
Duplicate Therapy Multi-Pharmacy	MZ (soft)	Indicates that the client has received a drug from the same therapy class; however, the original prescription was filled at another pharmacy.
Duplicate Drug	***MW (hard)***	***Indicates that the client has received the same drug (same chemical entity) and has used less than 2/3 of the medication based on the days supply.***
Duplicate Drug Multi-Pharmacy	***MY (hard)***	***Indicates that the client has received the same drug (same chemical entity) and has used less than 2/3 of the medication based on the days supply; however the original prescription was filled at another pharmacy.***
Potential Misuse of Prescription Drugs	NE (soft)	Indicates • 3 or more benzodiazepines • 3 or more opioids • 3 or more benzodiazepines and 3 or more opioids • methadone in combination with other opioid drugs

* NB: the codes noted above are not acronyms; the letter codes are not initials for other terms

The codes and messages described in Table 1 in bold font denote "hard" edit rejection codes. Claims submitted through the NIHB Point of Sale system which prompt any of these three messages will not be accepted for payment. In order to submit the claim for payment, pharmacists who receive these rejection codes must provide an override code back to the NIHB Program to explain the action that they took, based on their professional judgement, in deciding to dispense the claim. In cases where pharmacists choose to override a rejected claim, the prescriptions are paid by NIHB.

Table 2: Pharmacy Codes for Overriding* NIHB Rejection Messages

Code	Interpretation
UA	Consulted Prescriber and Filled Rx as Written
UB	Consulted Prescriber and Changed Dose
UC	Consulted Prescriber and Changed Instructions For Use
UD	Consulted Prescriber and Changed Drug
UE	Consulted Prescriber and Changed Quantity
UF	Patient Gave Adequate Explanation, Rx Filled as Written
UG	Cautioned Patient, Rx Filled as Written
UI	Consulted Other Source. Rx Filled as Written
UJ	Consulted Other Sources. Altered Rx and Filled
UN	Assessed Patient. Therapy is Appropriate.
MR	Replacement, Item Lost or Broken.

* In order to override NIHB warning codes, pharmacists must report on their actions to NIHB by sending an override message that details the specific action taken as a result of the warning message.

Appendix 2

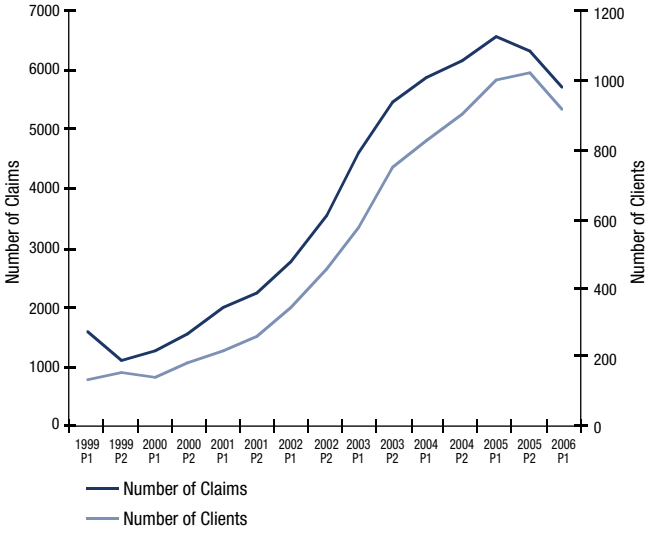
Drug Use Evaluation Advisory Committee Reviews and Ongoing Analysis

DUE Reviews Conducted to Date	Ongoing and Planned Analysis
• Diabetes medications	• Statins
• Benzodiazepines	• Updated and standardized reporting on diabetic and antibiotic medication use
• Antidepressants	• Diabetic test strips
• Opioids	• Asthma
• Methylphenidate for ADHD	• Community and physician profiling
• Biologics for Rheumatoid Arthritis	• Methadone
• Contraceptive Use	• Evaluations of various NIHB Program interventions
• Antibiotics	
• Plavix	
• Cox-II and Proton Pump Inhibitors	
• Folic acid and prenatal vitamins	
• Smoking cessation aids	
• Clients with more than 50 prescriptions in 90 days	
• Emergency dispensing trends in the Program	
• Acetaminophen use	
• Drug use trends in seniors	

Appendix 3

Impact of changing the listing status of a narcotic-based pain killer (Duragesic) from open-benefit to Limited-use benefit in October 2005

Graph 1: Duragesic Utilization Trends

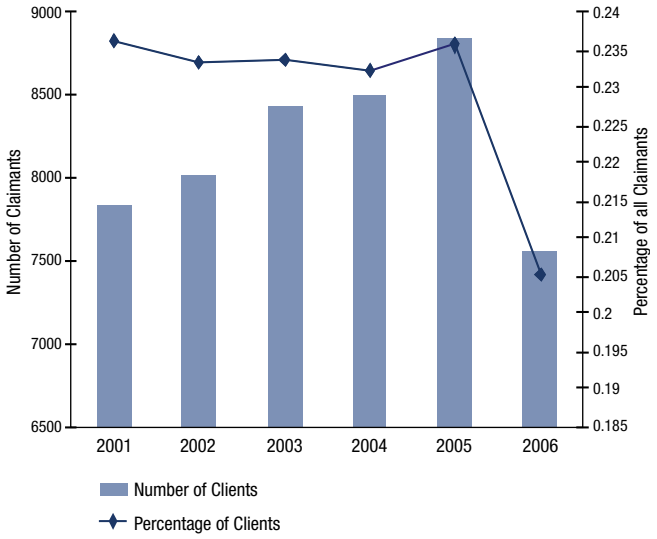


In 2005, NIHB changed the benefit status of Duragesic from open to limited use benefit. As a limited-use drug, Pharmacists must receive a prior approval from NIHB's Drug Exception Centre before the program will authorize payment for the drug. This extra level of approval often serves as a red flag for pharmacists and can lead the pharmacist to discuss the situation with the client and the physician regarding the safety of the course of treatment. In this case, the change in benefit status has led to a reduction in the number of claims as well as a reduction in the number of clients using this narcotic under the program.

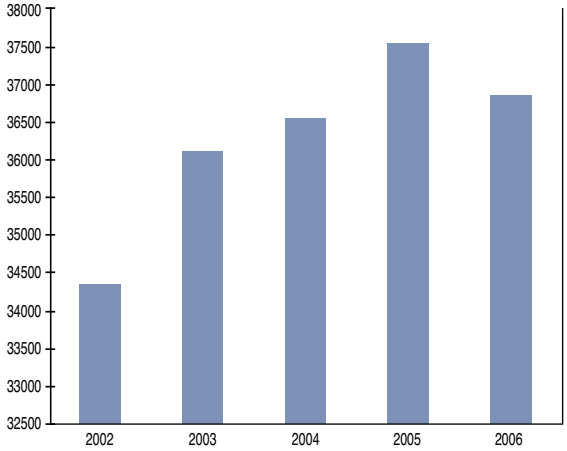
Appendix 4

Evaluating Outcomes of NIHB Interventions

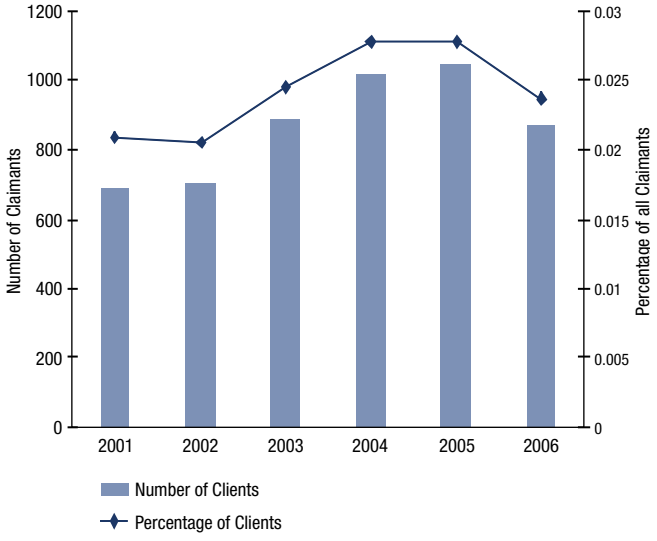
Graph 2: Number and % of Clients with 3 or more narcotics, benzodiazepines or methadone in association with narcotics



Graph 4: Number of Distinct Clients Claiming a Benzodiazepine



Graph 3: Number and % of Clients Exceeding 40 mg of Benzodiazepine Type Drugs Per Day



NB – figures reflect a sample of 126 days from the same period in successive calendar years.