Implementing a Risk-Based Pharmacy Quality Audit Framework – Pilot Report

August 2017

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Owner	Medicines Control

Contents

1. Background

1.1. Medicines Control

Medicines Control undertakes a range of operational functions regulating the distribution chain of medicines and controlled drugs. Audits are conducted of individuals and organisations holding a regulatory instrument (licence) to assess compliance with regulatory requirements, aligning with the public safety intent of the legislative framework.

Pharmacy quality audits are planned audits assessing compliance of the holder of a Licence to Operate Pharmacy with regulatory requirements and quality aspects of the Pharmacy Services Agreement.

1.2. Risk-Based Audit Framework

Medicines Control is implementing a number of improvements to the pharmacy quality audit programme, transitioning to a risk-based framework. To date, these improvements have included significantly revised audit criteria and implementation of the Provider Regulation and Monitoring System (PRMS) to support the audit process, which has enabled electronic communications and user friendly audit report formats. In addition, auditees are able to view and respond to audit corrective actions securely though the Medicines Control Online System[1] (MCOLS).

Inspection audits are being introduced as the next step in the transition to a risk-based framework for the pharmacy quality audit programme.

1.3. Rationale

The current framework for pharmacy quality audits is considered to identify non-compliances and safety risks well, but there are areas where improvements could be achieved.

A key intent of the risk-based framework is to continue to drive changes in behaviour to ensure compliance by licensees, enhancing the patient safety intent of the legislative framework.

Implementation of the risk-based framework is also intended to reduce the compliance burden for pharmacies during audit processes, for example there is less onsite contact time between the auditor and pharmacist in an inspection audit.

In addition, Medicines Control is observing an increasing number of premises where the same or similar non-compliances are identified during sequential audits, indicating that corrective actions reported by pharmacies in response to an audit are not always fully implemented and/or sustained.

For these reasons inspection audits are considered to provide a good robust indicator of the standard of day-to-day pharmacy practice being conducted at a premises, and a key component of a risk-based pharmacy quality audit framework.

[1] Medicines Control Online System, available at https://medicinescontrol.health.govt.nz/mcols/

1.4. Strategic Alignment

1.4.1 New Zealand Health Strategy 2016[2]

Implementation of inspection audits as part of a risk-based pharmacy quality audit framework aligns with the principles of the strategic themes 'Value and High Performance' and 'Smart System', for example:

Promoting a culture of quality and safety improvement across health services so that those services minimise patient harm and achieve the best possible health outcomes.

Seeking improvements and innovations, monitoring and evaluating what we are doing, and sharing and standardising better ways of doing things when this is appropriate.

1.4.2 Pharmacy Action Plan 2016 to 2020[3]

Focus area 4 'Dispensing and supply services' of the Pharmacy Action Plan includes an action for the regulator to review the pharmacy audit process to ensure it complies with the Community Pharmacy Services Agreement Audit Strategy 2015-2025.

1.4.3 Pharmacy Audit Strategy 2015-2025[4]

Implementation of inspection audits as part of a risk-based pharmacy quality audit framework aligns with action points 2.3 and 5.4 of the Pharmacy Audit Strategy:

Strategy	Desired Outcomes	Measure of Success
2.3 Random and risk based audits used to verify that standards are maintained.	**2.3.a** Random, risk based pharmacy quality audits conducted by Medicines Control to verify that standards of pharmacy practice are maintained.	**2.3.1** Continually improving levels of compliance identified in audits. **2.3.2** Implementation of random, risk based pharmacy quality audits.
5.4 Audit selection processes (random and selected) will be consistent nationally.	**5.4.a** Adequate coverage for audit purposes is achieved within existing resource.	**5.4.1** Equitable opportunities exist for all Pharmacies to be selected for audit.

[2] New Zealand Health Strategy 2016, accessed at www.health.govt.nz/publication/new-zealand-health-strategy-2016
[3] Pharmacy Action Plan 2016 to 2020, accessed at www.health.govt.nz/publication/pharmacy-action-plan-2016-2020
[4] Pharmacy Audit Strategy 2015-2025, accessed at www.centraltas.co.nz/assets/Publications/Pharmacy-Documents/Pharmacy-Audit/CPS002AuditStrategy150911.pdf

1.5. Implementation

The phases and timeframes to implement risk-based audits in the pharmacy quality audit framework are outlined in the following table:

	Description	Timeframe
Phase 0 (Baseline)	A discrete phase to test the viability and value of inspection audits as part of a risk-based approach.	August – September 2016 (completed)
Phase 1 (Pilot)	Piloting inspection audits within the Auckland, Counties Manukau and Waitemata DHB regions to refine the approach for full implementation.	May – June 2017 (completed)
Phase 2 (Implementation)	Implementation of inspection audits as an integral component of a risk-based pharmacy quality audit framework.	2017/2018 audit year

2. Pharmacy Quality Audit Framework

2.1. Current and Risk-Based Frameworks

The following table outlines the key differences between the current framework and the risk-based framework for pharmacy quality audits.

	Current Framework	Risk-Based Framework
Description	200 pharmacy quality audits conducted across the DHBs per audit year.	50 pharmacy quality audits and 450[5] inspection audits conducted across the DHBs per audit year.
Number of pharmacies audited per audit year[6]	Up to 200	Up to 500
% licensed pharmacies audited per audit year	19.0%	47.6% (estimated)
Interval between audits at a pharmacy	4.1 years (average)	2.0 years (estimated)

2.2. Pharmacy Quality Audits and Inspection Audits

The following table outlines the key differences between a pharmacy quality audit and an inspection audit within the risk-based pharmacy quality audit framework.

	Pharmacy Quality Audit	Inspection Audit[7]
Description	Scheduled according to risk assessment by premises, including prioritisation for: • New premises (including pharmacy relocations) • Change of ownership (new operators) • Audits required subsequent to an inspection audit	Scheduled according to risk assessment by premises. May also be conducted to verify the implementation of corrective actions after a pharmacy quality audit.
Notification	At least 15 working days	No notification (unannounced)
Audit scope	All audit criteria applicable to the pharmacy services provided from the premises (up to 67 criteria)	The 10 current risk-based criteria[8]
On site duration	6-8 hours (average)	1-2 hours (average)[9]

[5] Based on the Phase 0 (Baseline) audits demonstrating that 3 inspection audits could be conducted with the same Medicines Control auditor resource required to conduct a pharmacy quality audit.
[6] Where appropriate, multiple audits may be conducted at a premises during an audit year.
[7] Note. Inspection audits are also conducted outside of the pharmacy quality audit framework, as occurs currently, in response to specific issues. The audit criteria assessed during these audits is determined on a case by case basis and approved by the Manager, Medicines Control.
[8] Additional audit criteria may be included at the discretion of the auditor where significant non-compliances are identified during the site audit, and with the approval of the Manager, Medicines Control where the inspection audit is being conducted to verify the implementation of corrective actions.
[9] Based on the Phase 0 (Baseline) audits.

2.3. Attainment Risk Ratings

Medicines Control auditors assign an attainment risk rating to each criterion assessed during an audit, based on the audit evidence and findings.

2.3.1 Attainment

The following attainment levels are incremental and based on a continuous quality improvement model[10].

	Attainment Level	Description
LP	Leading Practice	The auditee can clearly demonstrate achievement beyond the expected full attainment and evidence is available of actions taken based on findings from an internal review as part of a robust quality management system.
FA	Fully Attained	The auditee can clearly demonstrate implementation (such as practice evidence, training, records, visual evidence) of the process, systems or structures in order to meet the criterion.
PA	Partially Attained	The auditee is able to demonstrate evidence of appropriate process (such as policy/ procedure/ guideline), system or structure implementation without the required supporting documentation; or a documented process (such as policy/procedure/ guideline), system or structure is evident but the auditee is unable to demonstrate implementation where this is required.
UA	Unattained	The auditee is unable to demonstrate appropriate processes, systems or structures to meet the criterion.
NA	Not Applicable	The criterion is not applicable to the licensed activities and does not therefore apply.

[10] Adapted from NZS 8134.0:2010 Health and Disability Services (general) Standards (https://www.standards.govt.nz/)

2.3.2 Risk

When a partially attained (PA) or unattained (UA) attainment is assigned, a risk is then determined by the auditor, with reference to the Risk Management Matrix[11]. The auditor considers both safety and regulatory consequences, and the likelihood of occurrence, to determine the risk[12].

		LIKELIHOOD				
		frequent	**likely**	**occasional**	**seldom**	**rare**
SAFETY CONSEQUENCE	Consumers or service providers are at **extreme risk of harm or actual harm is occurring**	**Critical**	**Critical**	**High**	**Moderate**	**Moderate**
	Consumers or service providers are at **significant risk of harm**	**Critical**	**High**	**Moderate**	**Moderate**	**Moderate**
	Consumers or service providers are at **moderate risk of harm**	**High**	**Moderate**	**Moderate**	**Low**	**Low**
	Consumers or service providers are at **minimal risk of harm**	**Moderate**	**Low**	**Low**	**Low**	**Negligible**
	Consumers or service providers are at **insignificant risk of harm**	**Low**	**Low**	**Negligible**	**Negligible**	**Negligible**
REGULATORY CONSEQUENCE	**Serious and/or significant** deviation from regulatory requirements	**Critical**	**Critical**	**High**	**Moderate**	**Moderate**
	Moderate deviation from regulatory requirements	**High**	**Moderate**	**Moderate**	**Low**	**Low**
	Minimal deviation from regulatory requirements	**Moderate**	**Low**	**Low**	**Negligible**	**Negligible**

[11] Adapted from NZS 8134.0:2010 Health and Disability Services (general) Standards (https://www.standards.govt.nz/)
[12] Note. Where the safety and regulatory risks assigned differ, the greater risk is assigned.

2.3.3 Rating Indicators

Rating indicators are a key component of the risk based audit framework, and are used by Medicines Control to indicate the risk associated with a specific premises or the risk associated with a specific audit criterion.

$$\text{Premises Rating Indicator} = \frac{\text{Sum of attainment risk values for all criteria assessed during the site audit}}{\text{Number of criteria audited during the site audit}}$$

$$\text{Criterion Rating Indicator} = \frac{\text{Sum of attainment risk values for the audit criterion during a specified time period}}{\text{Number of times audit criterion audited during a specified time period}}$$

The following table outlines the attainment risk values:

Attainment Risk		Attainment Risk Value
Leading Practice		15
Fully Attained		10
PA Negligible		9
UA Negligible		8
PA Low		7
UA Low		6
PA Moderate		5
UA Moderate		4
PA High		3
UA High		2
PA Critical		1
UA Critical		0

Whilst these rating indicators are an important tool for Medicines Control, it is important to note that they are *indicators*, and have limitations. For example a pharmacy with a high premises rating indicator may still have critical/high risk non-compliances, and a pharmacy with a lower premises rating indicator may have a leading practice attainment. A premises rating indicator is therefore *one indicator* of the standard of pharmacy practice at a pharmacy.

Criterion rating indicators are primarily used by Medicines Control to identify where regulatory resource should be prioritised when conducting audits, and to monitor changes in compliance over time.

As the risk based framework evolves over time, the rating indicators will also evolve to take account of additional relevant factors (for example regulatory licensing information, including incidents occurring at premises).

3. Pilot Overview

3.1. Pharmacy Selection

For the purposes of the pilot 90 pharmacies were randomly selected across the Auckland, Counties Manukau and Waitemata District Health Board regions. This random selection was achieved through use of analytical software, and included pharmacies across the risk spectrum.

3.2. Audit Criteria Selection

During the pilot each pharmacy was assessed against a defined set of 10 criteria, selected from the pharmacy quality audit tool. The 10 criteria are generally applicable to all pharmacies, irrespective of any specialised services that may be provided from the premises.

The criteria were selected with reference to their criterion rating indicator for the 2015/16 and 2016/17 audit years (approximately 18 months of 'baseline' data), and consideration of the number of critical and high risk non-compliances identified during this time period.

Criterion	Description
1.02.01	All staff are suitably qualified for the pharmacy services provided from the premises.
2.02.01	There is ready access at the premises to all the required pharmacy equipment.
3.03.02	Appropriate corrective actions are implemented, documented and reviewed contributing to continuous quality improvement.
4.01.02	Controlled drugs requiring storage in a safe, are securely held in an approved controlled drugs safe.
4.01.04	Fridge temperatures are consistently maintained between 2-8°C.
5.01.02	Prescription medicines are supplied in accordance with regulatory and professional requirements.
5.02.01	An approved form of controlled drugs register is appropriately and accurately maintained, and retained on the premises for four years.
5.05.04	Compounding records for individually compounded products are appropriately maintained and stored on the premises for at least three years.
5.07.04	Medicines requiring supply by an accredited pharmacist are recorded, sold and labelled in accordance with regulatory and professional requirements.
5.10.03	Compliance packaging is labelled sufficiently in accordance with regulatory and professional requirements.

In accordance with the audit framework, during an inspection audit additional criteria may be included at the discretion of the auditor where significant non-compliances are identified.

3.3. Anticipated Pilot Results

Medicines Control anticipated observing compliance above the baseline data, given that all pharmacies within the pilot DHB regions had been notified, and the 10 audit criteria had been clearly defined.

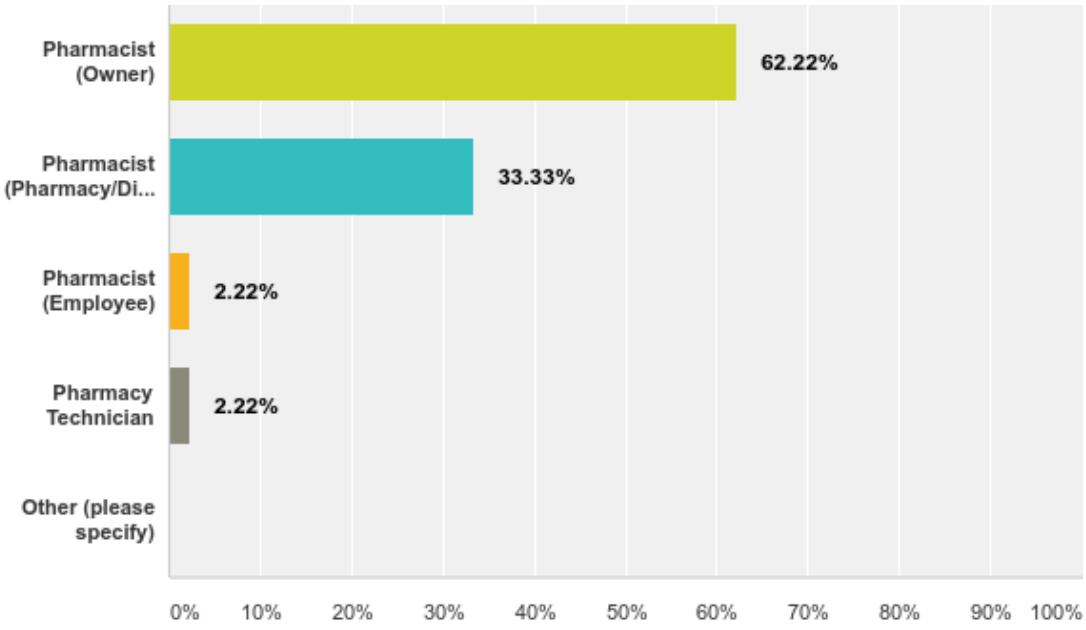
4. Pharmacy Feedback

Medicines Control requested feedback on the site audit from pharmacies who received an inspection audit during the pilot period, using an electronic survey. The information circulated with the survey clearly stated that all information provided would be suitably anonymised.

The pharmacy name was required to ensure that responses received were from pharmacies who had participated in the pilot, and to enable anonymous referencing of results to audit findings. The survey was open for a period of one week and reminder email notifications were sent.

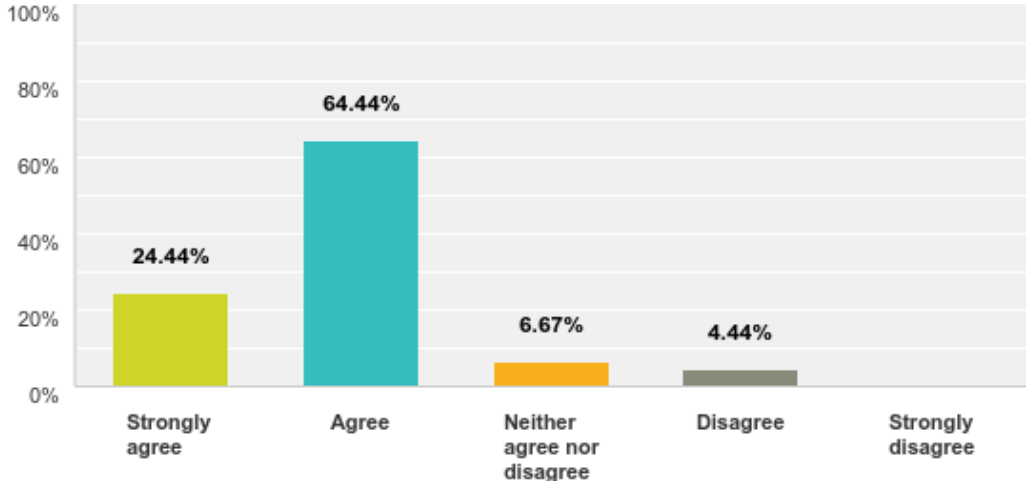
4.1. Responses

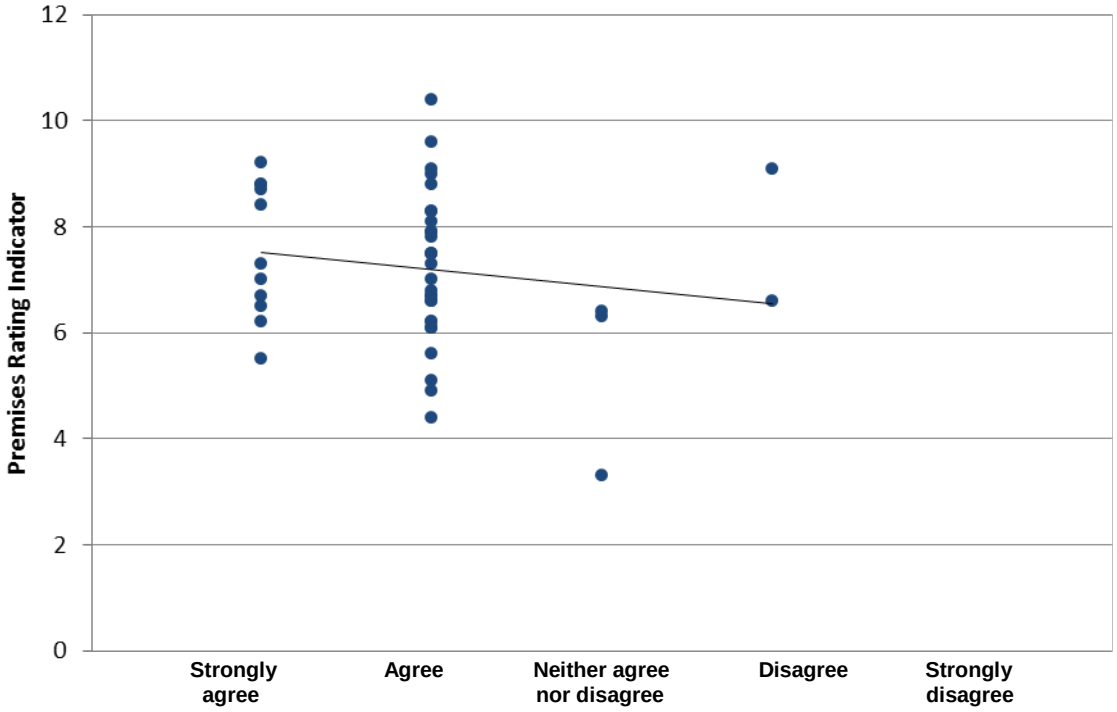
45 complete responses were received to the survey, representing 50% of the pharmacies audited. The majority of responses were received from pharmacist owners (62%), followed by pharmacists who were pharmacy or dispensary managers (33%).



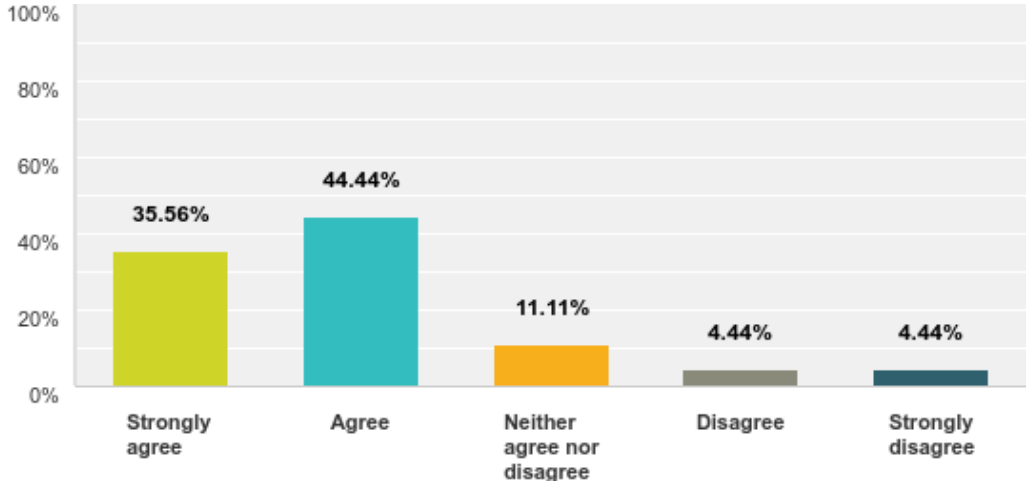
A number of statements were provided, against which the survey respondent was asked to select from a scale of strongly agree to strongly disagree. The statements and their responses are provided in the following sections. For each statement the responses have also been plotted against the premises rating indicator, to provide context.

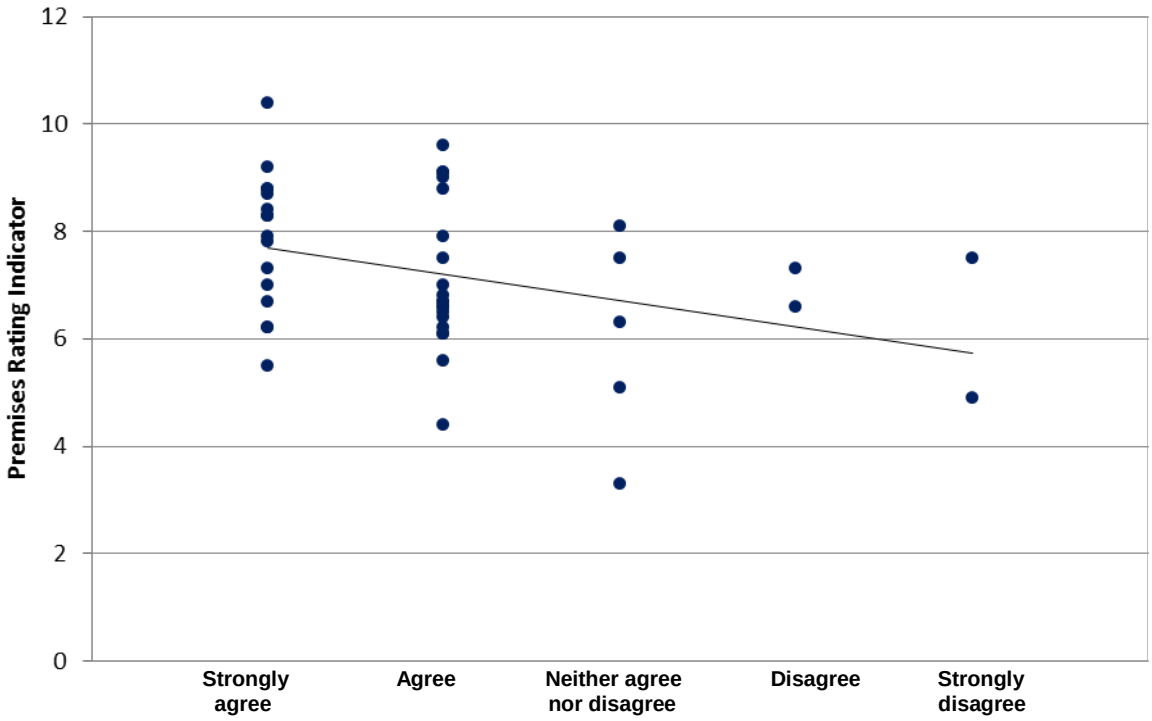
4.1.1 The scope of the audit was relevant and appropriate



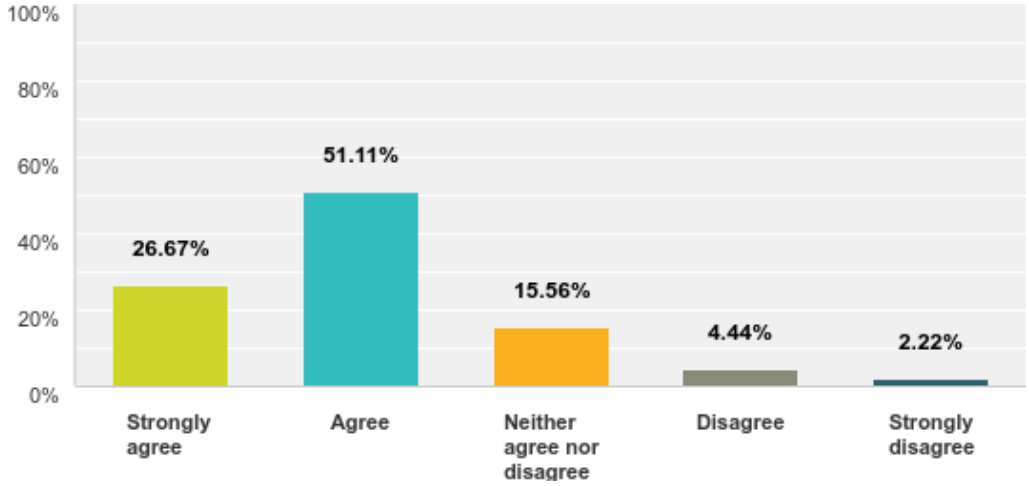


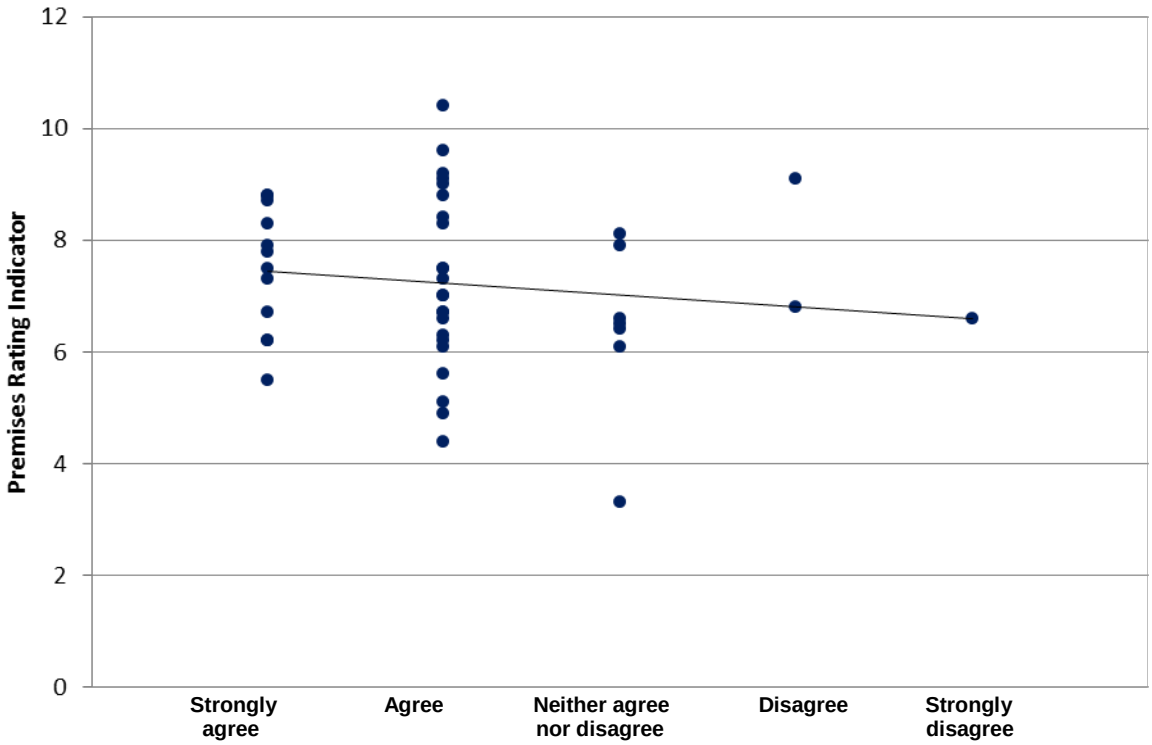
4.1.2 The site audit was conducted in a professional manner



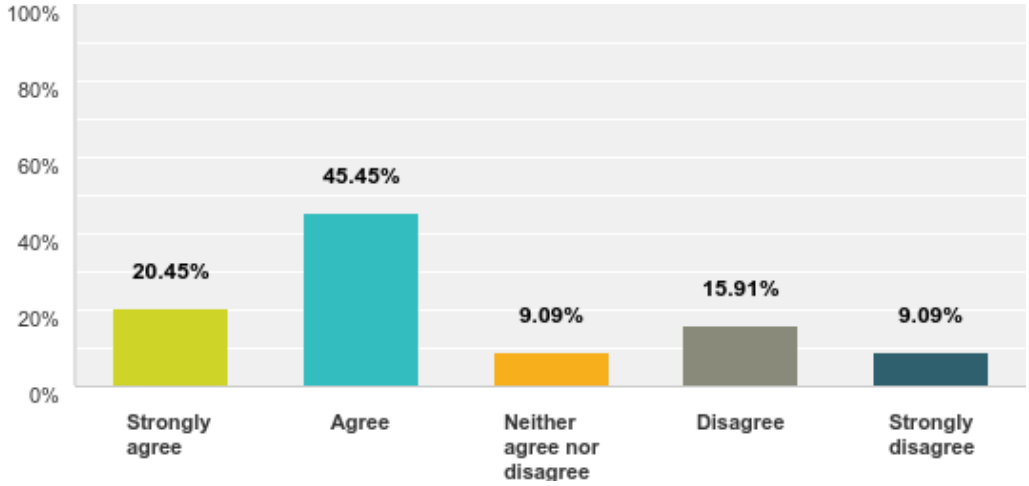


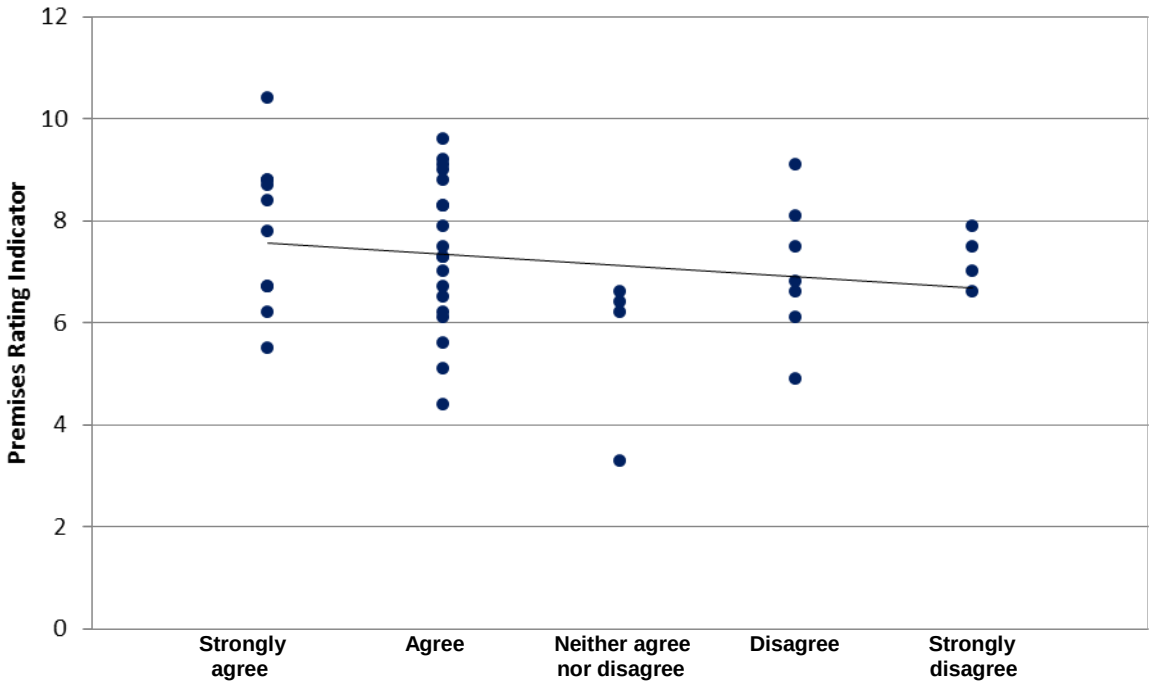
4.1.3 The site audit was of an appropriate duration



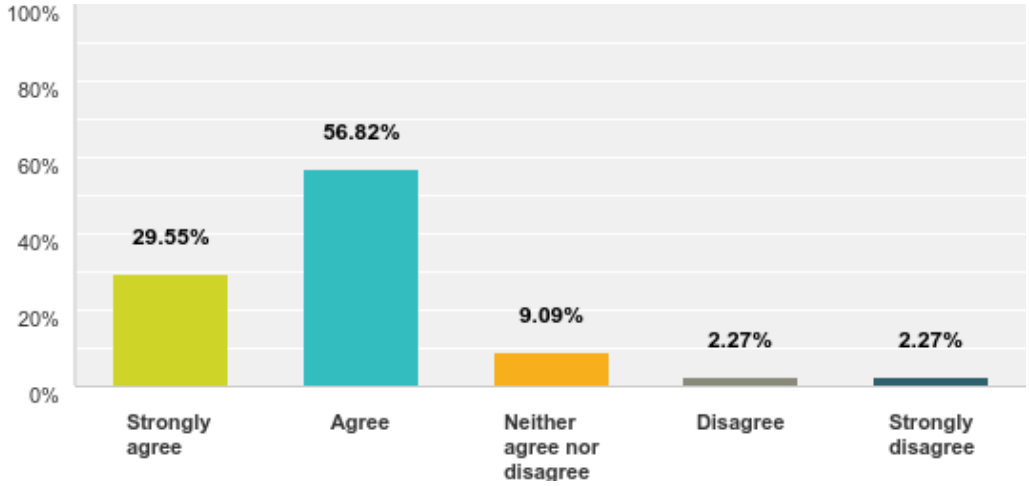


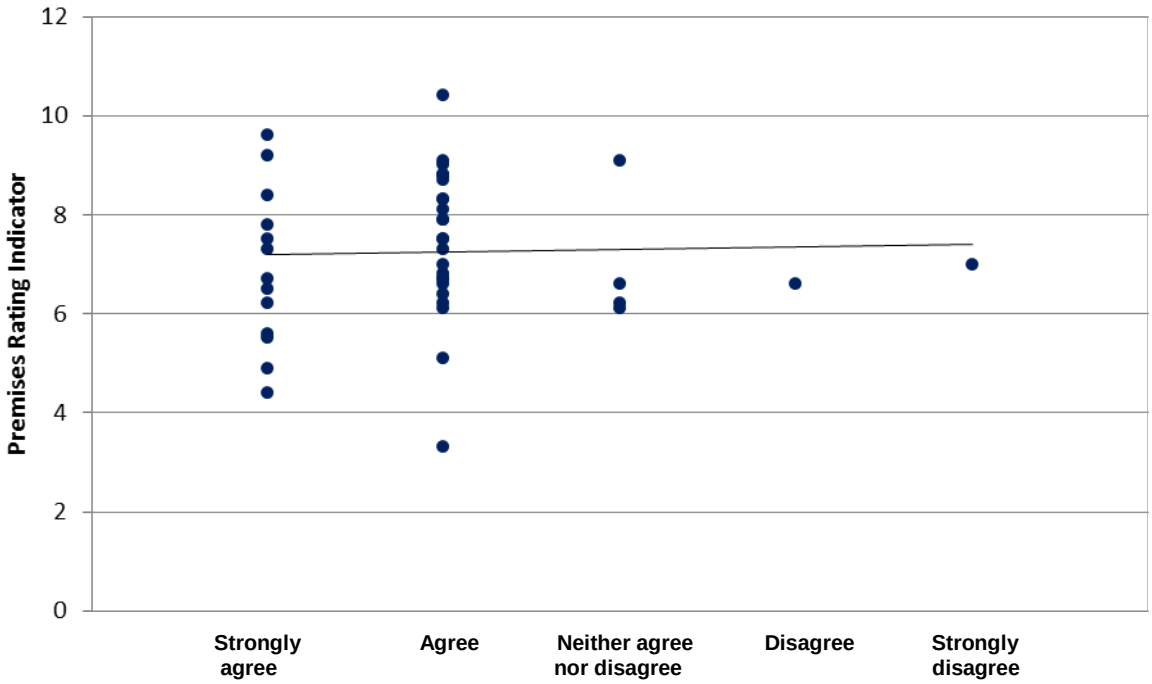
4.1.4 Disruption to activities was minimal during the site audit





4.1.5 The site audit resulted in improved practices at the pharmacy





5. Pilot Audit Findings

5.1. Attainment Risk Summary

The following table summarises the attainment risks[13] for the 90 premises[14] audited during the pilot, for the 10 audit criteria.

CRITERION	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
1.02.01	0	25	0	53	9	2	0
2.02.01	0	10	2	38	32	6	0
3.03.02	1	8	0	51	26	3	0
4.01.02	0	50	0	4	17	14	4
4.01.04	4	38	0	11	12	10	11
5.01.02	0	44	0	25	9	7	4
5.02.01	2	29	3	28	12	7	8
5.05.04	3	43	0	27	14	2	0
5.07.04	1	19	0	19	19	24	5
5.10.03	0	15	2	60	7	1	0
Total	11	282	7	315	154	78	33
%	1.3	32.0	0.8	35.8	17.5	8.9	3.8

[13] Note. Unattained and partially attained findings have been grouped by risk (e.g. 'unattained high' and 'partially attained high' attainment values have been grouped by 'high').
[14] Note. A total of 89 premises had audit findings as 1 pharmacy was identified to have ceased operating without notification to Medicines Control. The total number of attainment risk values is less than 890 (89 x 10) as a number of criteria were not assessed where for example the premises did not provide all services (e.g. compliance packaging).

5.2. Rating Indicators

5.2.1 Criterion Rating Indicators

The following table summarises the criterion rating indicators for the 10 criteria, and compares these to baseline rating indicators (calculated from approximately 18 months of audit data).

CRITERION	CRITERION RATING INDICATOR		CHANGE - +
	PILOT	BASELINE	
1.02.01	7.5	7.6	-0.1
2.02.01	6.4	7.4	-1.0
3.03.02	6.6	7.0	-0.5
4.01.02	7.4	7.8	-0.4
4.01.04	7.2	7.1	+0.1
5.01.02	7.7	7.3	+0.4
5.02.01	7.1	8.4	-1.3
5.05.04	8.3	8.3	±0.0
5.07.04	5.9	7.1	-1.2
5.10.03	7.4	7.5	-0.1

This demonstrates, compared to the baseline:

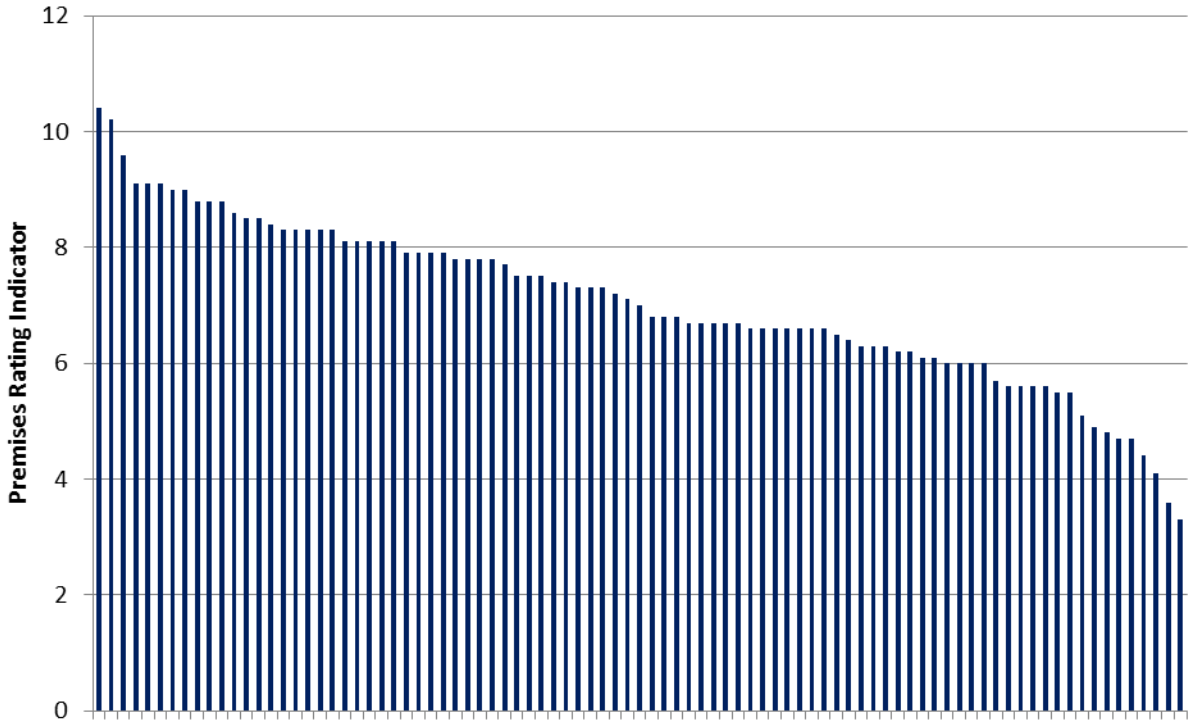
- 2 criteria have an improved rating indicator;
- 1 criterion has the same rating indicator;
- 4 criteria have a low to moderate reduction in their rating indicator; and
- 3 criteria have a significant reduction in their rating indicator.

This supports the observed trend of an increasing number of premises where the same or similar non-compliances are identified during sequential audits, indicating that corrective actions reported by pharmacies in response to an audit are not always fully implemented and/or sustained.

As inspection audits are unannounced, and thus no preparation can occur, these results add to the evidence that inspection audits provide a more accurate snapshot of pharmacy practice occurring at a premises.

5.2.2 Premises Rating Indicators

The following bar graph displays the distribution of the premises rating indicators for the pilot audit findings (each bar represents a pharmacy), with the bars arranged in descending order of premises rating indicator.



Whilst it is encouraging to see that there are a number of premises with high rating indicators, the bar graph is reflecting a general lower standard of pharmacy practice than expected.

The rate at which the premises rating indicators fall towards the right hand side of the bar graph is of particular concern. A number of regulatory actions (refer section 6) are being taken in response to audit findings, particularly in response to pharmacies with low premises rating indicators and where public safety concerns have been identified.

5.3. Summary of Audit Findings by Criterion

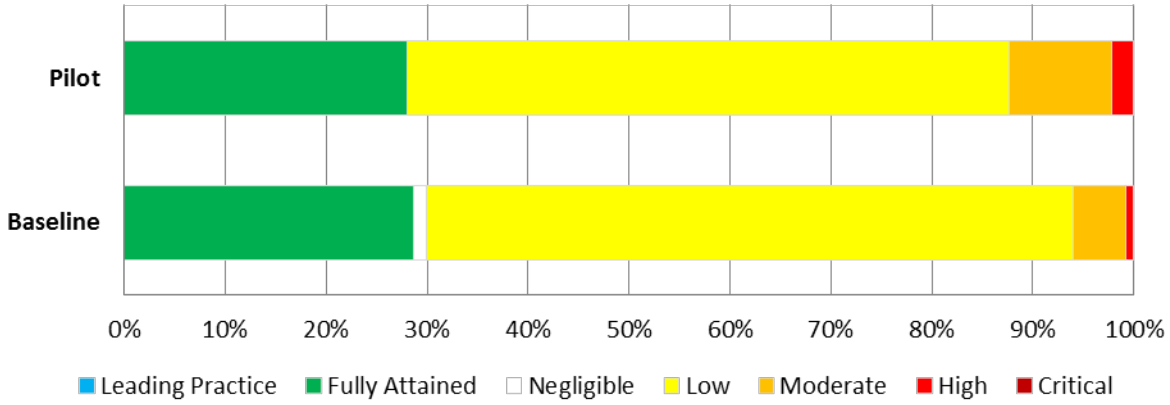
5.3.1 Criterion 1.02.01 (PCY003)

All staff are suitably qualified for the pharmacy services provided from the premises.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
0	25	0	53	9	2	0
0%	28%	0%	60%	10%	2%	0%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.5	7.6	-0.1

Comparison with baseline:



Generally non-compliance assigned low or moderate risk for this criterion related to the inability of the auditee to demonstrate evidence of:

- qualifications held, or active participation in an approved training scheme, for non-pharmacist dispensary staff; and/or
- completed training in accredited services for pharmacists providing these services from the premises.

During the pilot a high risk non-compliance (with immediate corrective action) was assigned at a premises where an unqualified staff member was working in the dispensary.

It is expected that a licensee verifies qualifications and accreditations at the point of employment (including when engaging a locum staff member), during employment (for example when training in accredited services is completed), and can demonstrate this as an integral part of their quality management system.

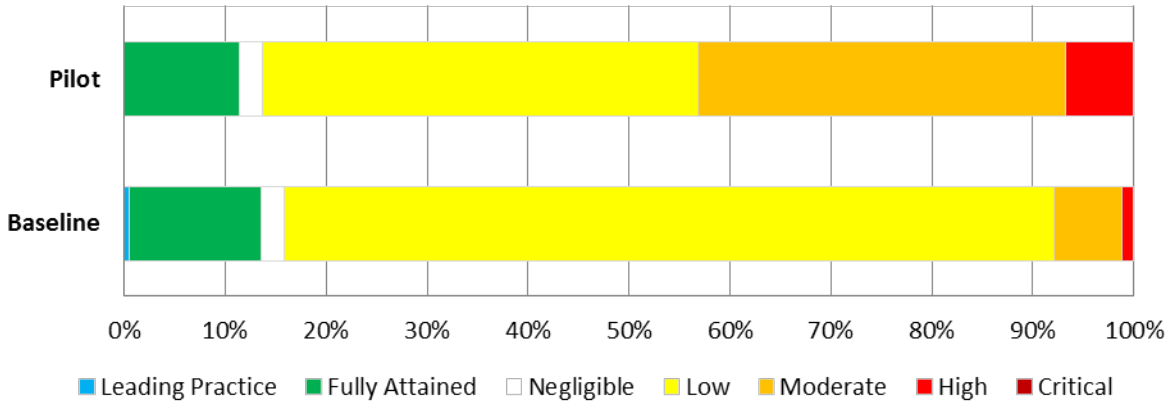
5.3.2 Criterion 2.02.01 (PCY008)

There is ready access at the premises to all the required pharmacy equipment.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
0	10	2	38	32	6	0
0%	11%	2%	43%	36%	7%	0%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
6.4	7.4	-1.0

Comparison with baseline:



A significant increase in the proportion of non-compliance assigned moderate risk and above for this criterion was observed during the pilot, when compared to the baseline data. This related to auditees not being able to demonstrate the required equipment was readily accessible and maintained at the premises.

Of particular concern was the number of premises in which weighing equipment did not have a current certificate of accuracy. Auditors noted that the date of last certification of accuracy was in some cases between four and six years ago (often aligning with the date of the previous pharmacy quality audit), with the equipment regularly being used as part of the compounding process.

In respect of reference resources, auditors identified that at many premises the resources were either absent or out of date. Where electronic reference resources were referred to by auditees, many could not be readily accessed (for example the staff did not know the passwords for websites).

In a number of cases pharmacy equipment was identified to be shared between premises, and whilst these were recorded as being available at the previous phamacy quality audit, they were not therefore available at the inspection audit.

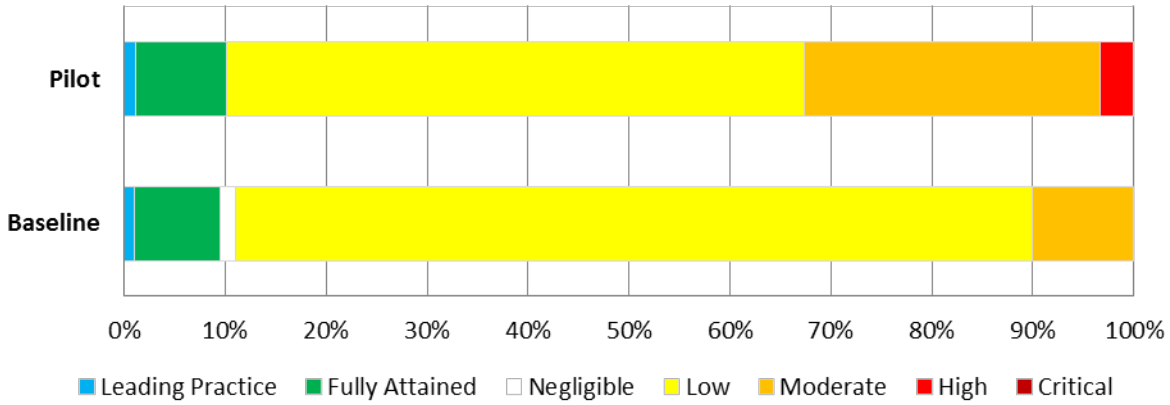
5.3.3 Criterion 3.03.02 (PCY015)

Appropriate corrective actions are implemented, documented and reviewed contributing to continuous quality improvement.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
1	8	0	51	26	3	0
1%	9%	0%	57%	29%	3%	0%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
6.5	7.0	-0.5

Comparison with baseline:



Although the proportions of leading practice and fully attained findings are relatively static, the compliance with this criterion remains very low, and a significant proportion of the non-compliances identified during the pilot were at higher levels of risk.

A general theme identified during the pilot was an absence of, or poor quality, documentation of near misses and dispensing errors. This makes it challenging for licensees to conduct a meaningful review without the required documentation to work from.

Leading practice was achieved by one auditee who could demonstrate that a robust quality management system had been implemented in a comprehensive way in order to prevent patient harm.

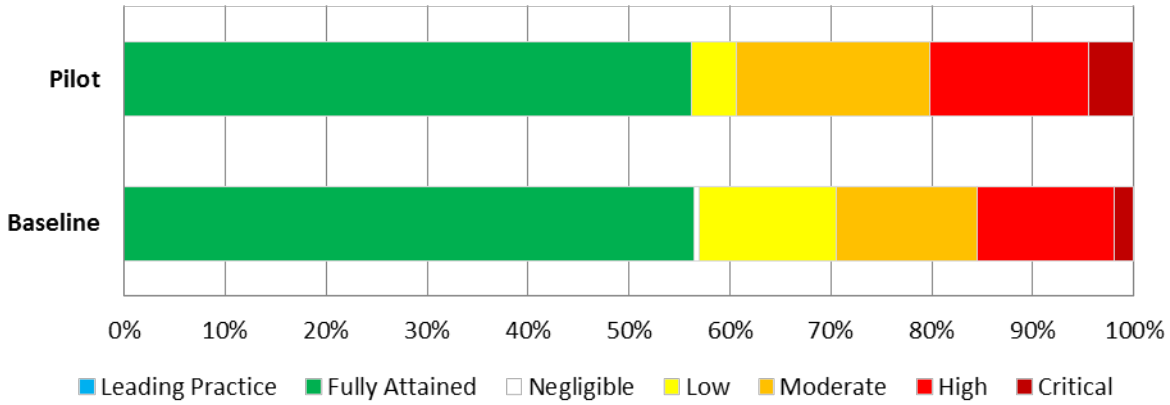
5.3.4 Criterion 4.01.02 (PCY017)

Controlled drugs requiring storage in a safe, are securely held in an approved controlled drugs safe.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
0	50	0	4	17	14	4
0%	56%	0%	4%	19%	16%	4%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.4	7.8	-0.4

Comparison with baseline:



Compliance with this criterion has remained relatively static, however of concern was the increased proportions of moderate, high, and critical risk non-compliances identified. This indicates that inspection audits are identifying non-compliances of a higher level of risk for this criterion than pharmacy quality audits, suggesting that practice assessed at pharmacy quality audits is generally not reflective of day to day practice.

Two themes were identified at premises where high and critical risk non-compliances have been assigned:

- inadequate fixing of controlled drugs safes to the premises, and in particular where the safe was not attached to the premises in any way; and
- controlled drugs requiring safe custody not being stored in a safe. Examples identified during the pilot included methadone (stock and dispensed) on dispensing benches for prolonged periods, controlled drug stock (including bottles of codeine, dihydrocodeine oxycodone and methylphenidate) stored on dispensary shelving and in office areas. At one premises large quantities of controlled drugs were stored on dispensary benches, still in the paper bags as received from a wholesaler over the preceeding months, from which dispensings had been made.

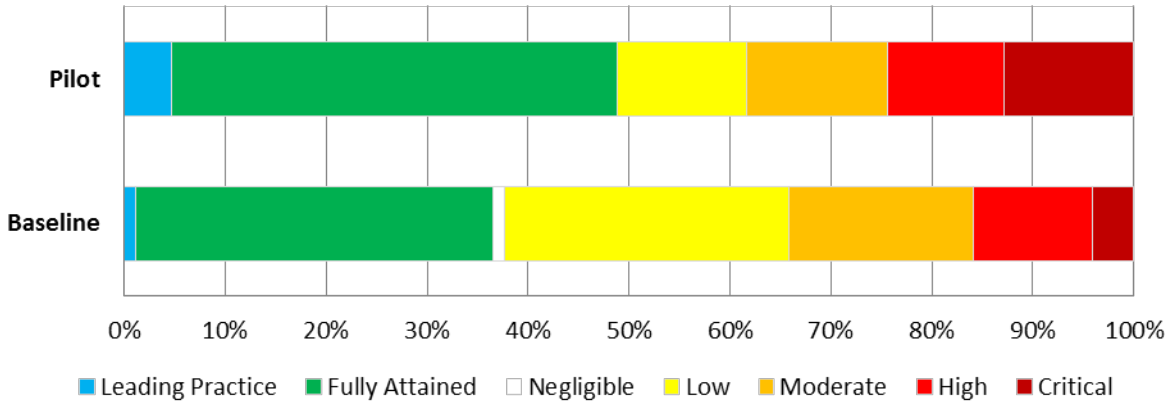
5.3.5 Criterion 4.01.04 (PCY019)

Fridge temperatures are consistently maintained between 2-8°C.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
4	38	0	11	12	10	11
5%	44%	0%	13%	14%	12%	13%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.2	7.1	0.1

Comparison with baseline:



It was encouraging to see improvement in compliance for this criterion in relation to the baseline data. Of particular note was the increase in leading practice which reflected quality management systems that had been implemented at premises, for example identifying that some medicines have expiry dates based on cumulative exposure and for this reason the pharmacy was maintaining a fridge incident log to collect this information and inform viability assessments of the stock if required.

However, increased compliance for this criterion was offset by the increase in critical risk non-compliance, resulting in only a small quantitative change in the criterion rating indicator. A total of eleven critical risks were assigned.

Auditors noted general trends relating to a lack of temperature records, documentation demonstrating that temperatures were out of range (often significantly) and for extended periods of time (with no corrective actions taken). In addition, some auditees were simply unaware of how to check fridge temperatures, and at one premises falsified records were identified.

It is of particular concern that approximately 25 percent of the pharmacies audited were assigned high or critical risks, indicating practice in a manner which constituted serious and significant risks to patients.

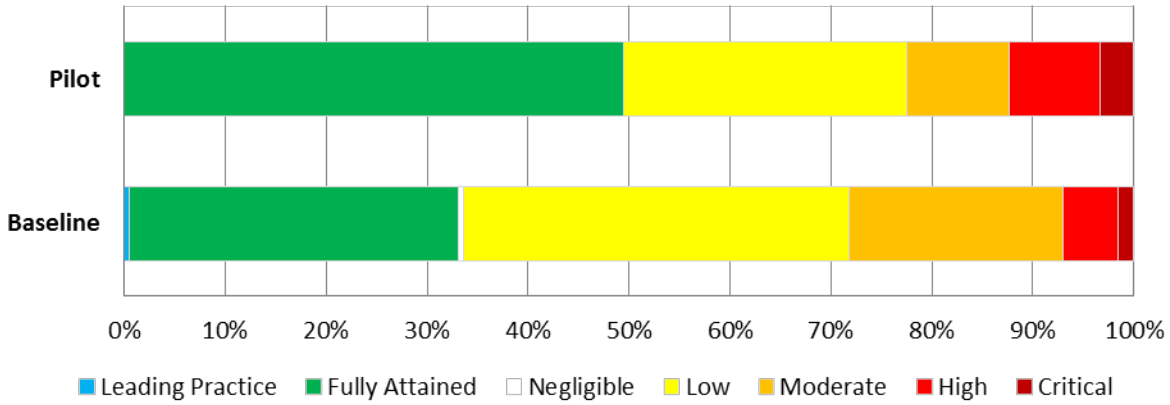
5.3.6 Criterion 5.01.02 (PCY023)

Prescription medicines are supplied in accordance with regulatory and professional requirements.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
0	44	0	25	9	8	3
0%	49%	0%	28%	10%	9%	3%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.7	7.3	0.4

Comparison with baseline:



An overall improvement in the standard of practice was demonstrated for this criterion, as indicated by a positive change in the rating indicator.

Although a significant improvement in full compliance was seen, the proportion of critical and high risk was above that in the baseline data.

For critical or high risk non-compliances, the evidence often demonstrated that emergency supplies were made in quantities which considerably exceeded the allowable quantity. At one premises sales of paracetamol tablets were identified to have been made in significant quantities per transaction (for example 1000, 3000 and 5000 tablets) without a prescription.

There was also a general trend of non-compliance when selling repacked medicines such as Gee's linctus, particularly where the auditee could not demonstrate knowledge of where to check the classification of a medicine[15].

[15] Medicines classification database, available at www.medsafe.govt.nz

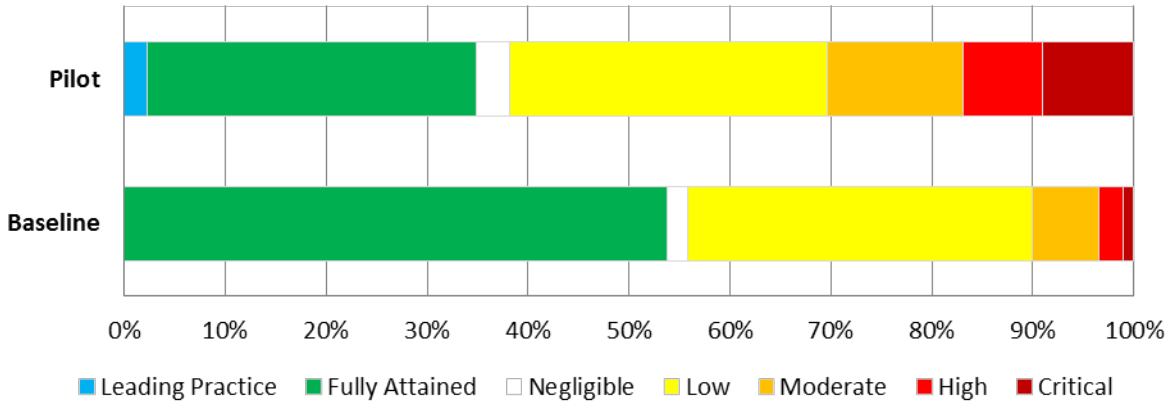
5.3.7 Criterion 5.02.01 (PCY027)

An approved form of controlled drugs register is appropriately and accurately maintained and stored on the premises for at least four years.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
2	29	3	28	12	7	8
2%	33%	3%	31%	13%	8%	9%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.1	8.4	-1.3

Comparison with baseline:



Although it is encouraging to see leading practice attained by a number of auditees during the pilot, there was a significant reduction in the number of pharmacies demonstrating compliance with this criterion. This was associated with a notable increase in moderate, high and critical risk non-compliances.

Within the non-compliances there were two general trends with regards to discrepancies:

- Significant discrepancies that indicated systemic issues. At a number of premises there were in excess of 20 discrepancies between the stock on hand and the corresponding running balance in the register.
- Minor discrepancies that indicated inconsistent compliance with the pharmacy's procedures. Primarily this related to calculation errors in the register and discrepancies that were readily explained by the auditee as resulting from a small number of missed entries.

In addition it is concerning to note that a number of pharmacies were identified to have not maintained entries in their controlled drugs register, for certain controlled drugs, for significant periods of time.

The findings for this criterion may in part be attributable to the inspection audit process having no notification period, removing the ability for pharmacies to review and 'tidy up' their controlled drugs registers before a scheduled pharmacy quality audit. Pharmacies that performed well against this criterion generally maintained controlled drugs registers at the point of dispensing, and this practice is encouraged.

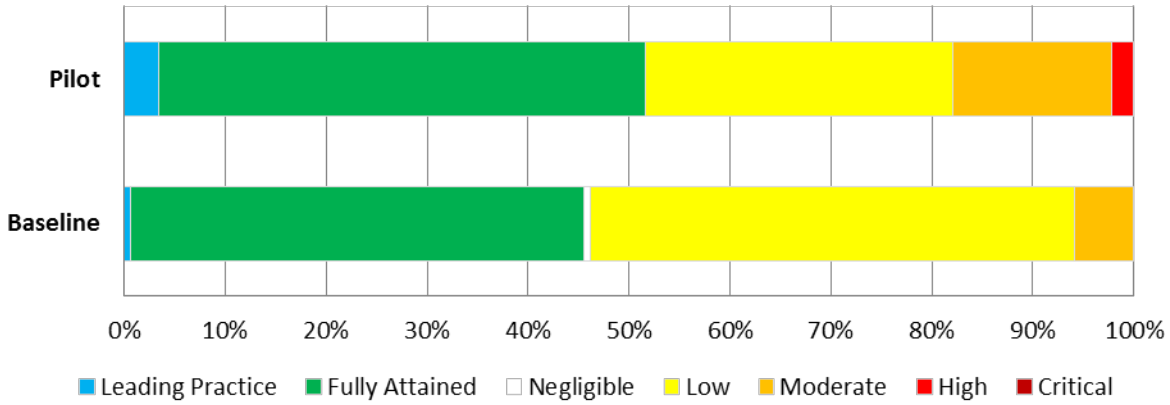
5.3.8 Criterion 5.05.04 (PCY042)

Compounding records for individually compounded products are appropriately maintained and stored on the premises for at least three years.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
3	43	0	27	14	2	0
3%	48%	0%	30%	16%	2%	0%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
8.3	8.3	±0.0

Comparison with baseline:



Compliance with the requirements of this criterion was higher during the pilot than compared to baseline data, and increases were seen in both leading practice and fully attained audit findings. However, there was no change in the criterion rating indicator due to increased levels of moderate and high risk non-compliances.

A higher level of full compliances was seen and this was contributed by pharmacies maintaining good quality compounding records, including a copy of the product label, and retaining these records in an easily retrievable manner.

There were three general trends in respect of non-compliances for products compounded at a premises:

- compounding records not maintained;
- compounding records maintained but incomplete; and
- the use of out of date starting materials, indicating insufficient quality checks during compounding processes.

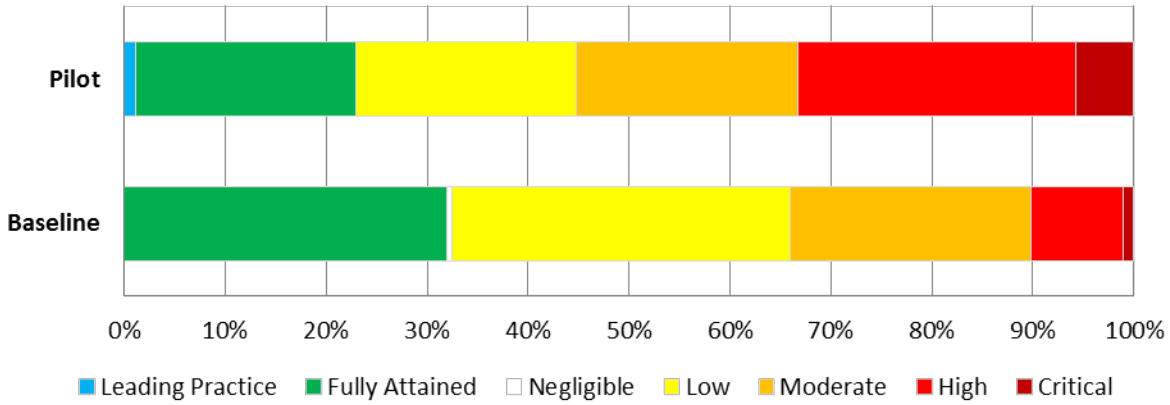
5.3.9 Criterion 5.07.04 (PCY055)

Medicines requiring supply by an accredited pharmacist are recorded, sold and labelled in accordance with regulatory and professional requirements.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
1	19	0	19	19	24	5
1%	22%	0%	22%	22%	28%	6%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
5.9	7.1	-1.2

Comparison with baseline:



The large proportion of significant non-compliant audit findings for this criterion relates to the sale and supply of sildenafil, and is an issue of particular concern.

Auditor feedback identified that most pharmacists were aware of the requirements for the supply of sildenafil. This suggests that the non-compliances do not appear to be directly related to the quality of the training programme. Rather, pharmacists were making conscious decisions to supply outside of the specified parameters.

Significant non-compliance often involved multiple factors. These included the supply of sildenafil:

- in quantities exceeding 12 tablets;
- to patients where the blood pressure or pulse recorded was outside of the allowable parameters;
- to patients with conditions which required referral;
- without assessment forms being completed or fully completed;
- outside of the 12 month period following a full assessment.

Leading practice was also observed. This related to a pharmacist who had conducted an internal review, identified significant deficiencies in records made by a previous pharmacist, and then proactively implemented a system to ensure that all patients were not resupplied sildenafil without a new full assessment being made.

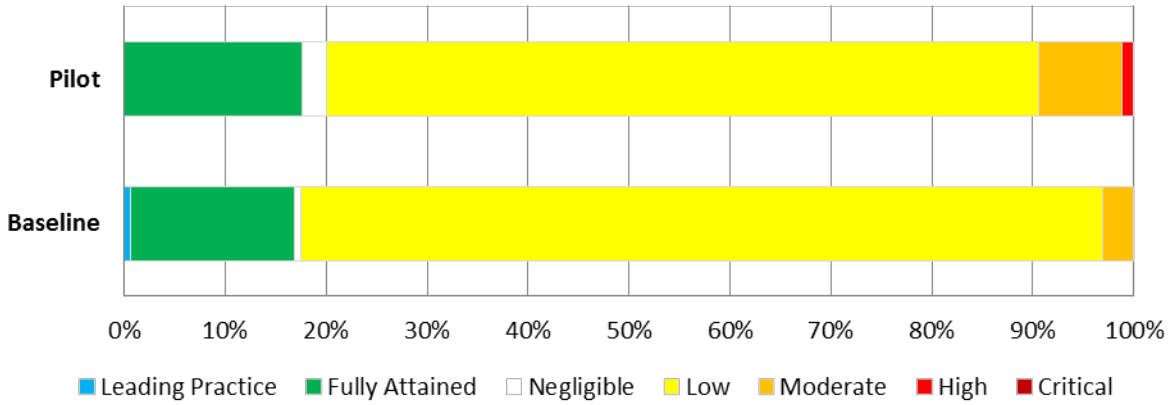
5.3.10 Criterion 5.10.03 (PCY063)

Compliance packaging is labelled sufficiently in accordance with regulatory and professional requirements.

LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
0	15	2	60	7	1	0
0%	18%	2%	71%	8%	1%	0%

CRITERION RATING INDICATOR		
PILOT	BASELINE	CHANGE
7.4	7.5	-0.1

Comparison with baseline:



The criterion risk indicator was relatively consistent between the pilot and the baseline for this criterion, with small increases in the proportion of moderate and high risk non-compliances.

For the non-compliances identified, the risk was generally low and related to:

- truncation of instructions on the labelling for compliance packing; and
- cautionary and advisory information not always being provided in full.

5.4. Additional Audit Criteria

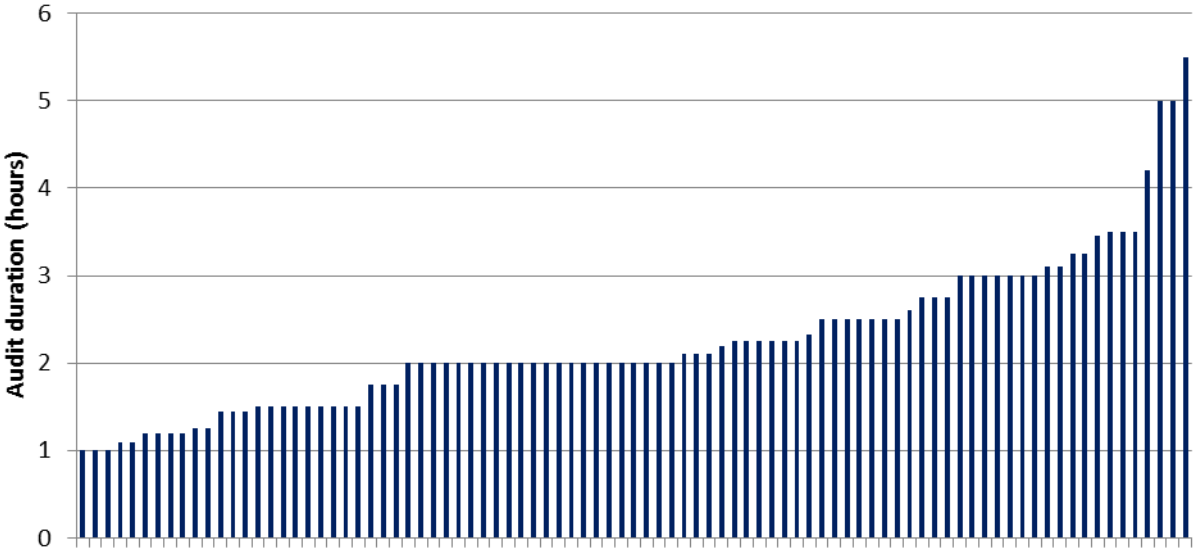
During the pilot, a total of 41 additional audit criteria (i.e. in addition to the defined set of 10 criteria) with moderate, high or critical risk non-compliances were assigned by auditors. The following table provides a summary[16].

CRITERION		MODERATE	HIGH	CRITICAL
2.01.01	The premises are suitable for the provision of pharmacy services and are maintained in a manner that minimises risk of harm to the service providers and consumers	2	1	1
2.01.02	There is sufficient security to ensure all pharmaceuticals remain secure	2	0	0
3.01.01	There are approved and maintained policies and procedures (SOPs) that are aligned with current good practice and service delivery, reflecting the processes in the pharmacy	1	0	0
3.02.02	Health Information is stored securely and confidentiality is maintained by all staff	1	0	0
4.01.01	Pharmaceuticals are stored appropriately and are suitable for dispensing	3	2	1
4.01.03	Pharmaceuticals requiring refrigerated storage, including any products requiring critical monitoring, are stored appropriately	1	1	0
4.01.05	Ambient room maximum temperatures are consistently maintained below 25°C	3	0	0
5.03.03	Dispensed opioid substitution treatment medicines are labelled in accordance with regulatory and professional requirements	0	1	0
5.04.01	Clozapine is dispensed appropriately and records are maintained in accordance with the clozapine dispensing protocol	0	0	1
5.05.05	Master batch documents are appropriate and suitable batch compounding records are retained on the premises for at least 3 years	1	0	0
5.05.07	Repackaging documents and labelling are appropriate and retained on the premises for at least three years	7	4	2
5.10.01	Compliance packaging services are provided in a safe and appropriate manner that produces accurately dispensed medicines of an acceptable and consistent quality	1	0	0
5.10.02	De-blistering of medicines meets all regulatory and professional requirements	1	2	0
5.11.01	Automated packaging services are provided in a safe and appropriate manner that produces accurately dispensed medicines of an acceptable and consistent quality	0	2	0
	Total	23	13	5
	%	56	32	12

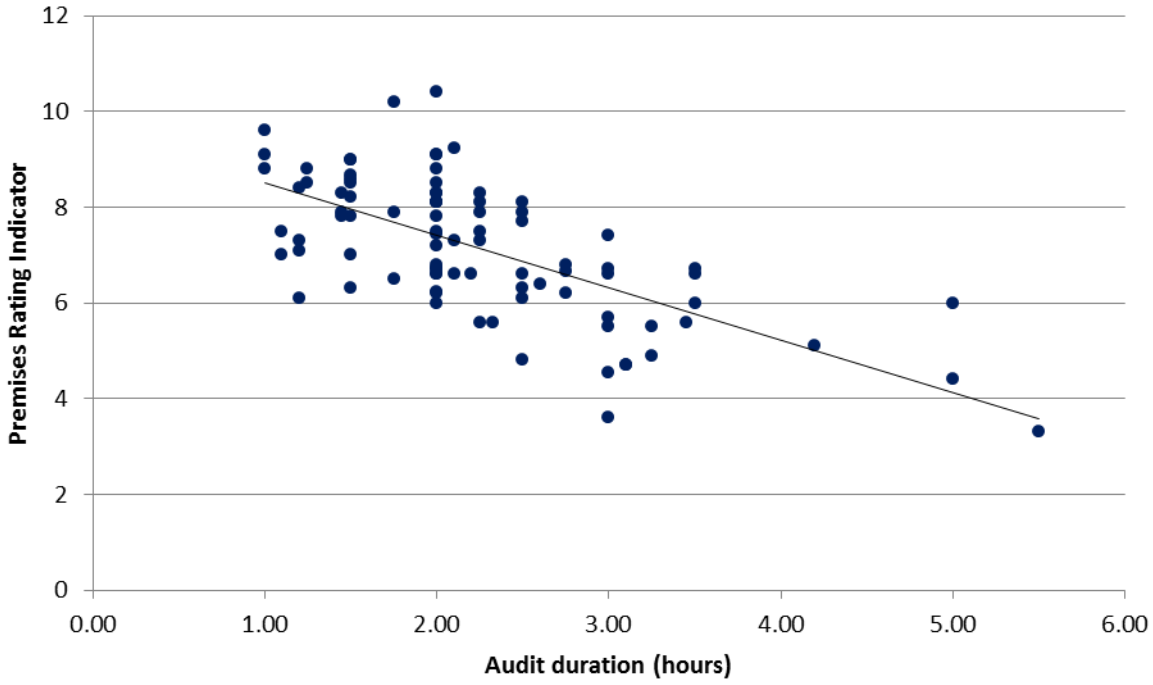
[16] Note. Unattained and partially attained findings have been grouped by risk (e.g. 'unattained high' and 'partially attained high' attainment values have been grouped by 'high').

5.5. Audit Duration

The following bar graph displays the audit duration for each premises audited (each bar represents a pharmacy). The bars are arranged in ascending order of audit duration.



When the audit duration is plotted against the premises rating indicator for each audit, a strong correlation is demonstrated between the level of compliance and the duration of the audit (i.e. the greater the level of compliance, the shorter the audit).



6. Regulatory Actions

The primary focus of regulatory action is to ensure public safety. In response to the pilot findings Medicines Control has taken, or is in the process of taking, a number of regulatory actions:

- The imposition of an additional operating condition on a Licence to Operate Pharmacy, to restrict the services provided from the premises;
- The imposition of a fine ($2,000) for serious and sustained non-compliance relating to refrigerated storage of medicines;
- Regulatory letters requesting explanations for significant non-compliance and/or further information to determine if further regulatory action is required;
- Follow-up audits (to assess the extent of compliance in the period since the initial inspection audit):
    - approximately 10 inspection audits
    - approximately 5 pharmacy quality audits
- Notifications to the Pharmacy Council pursuant to section 34 of the Health Practitioners Competence Assurance Act 2003
- Provision of relevant anonymised audit data relating to functions conducted by other organisations, for example the Pharmacy Council and Pharmaceutical Society.

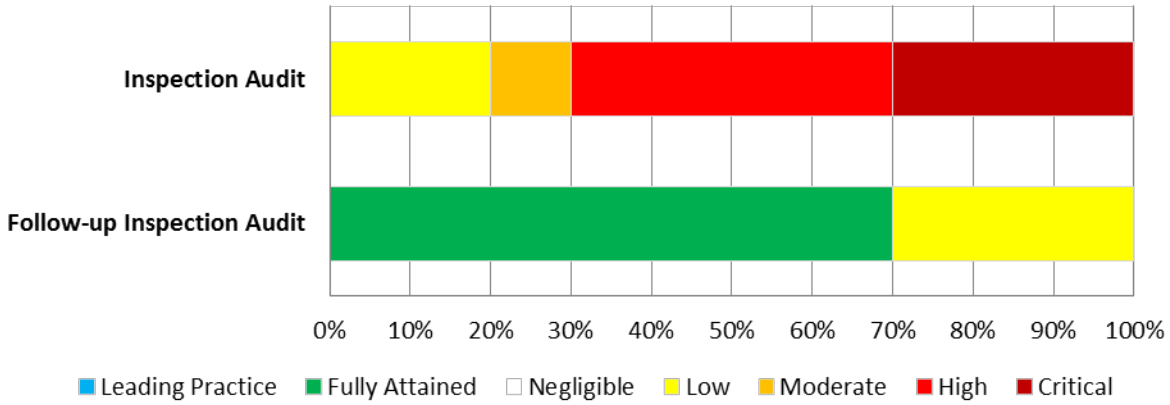
These actions are in addition to corrective actions required to be completed by auditees for the non-compliances identified during the inspection audit at their premises.

6.1. Follow-up Inspection Audits

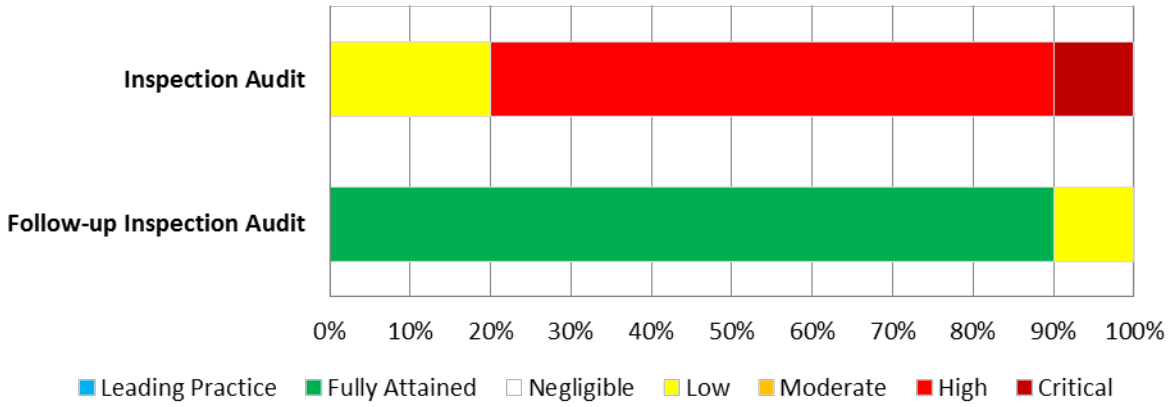
At the time of writing this report, the findings from two of the follow-up inspection audits were available. A high level comparison of the audit findings between the initial inspection audit and the follow-up inspection audit, for each premises, indicates that significant improvement is occurring.

Medicines Control will be continuing to monitor these premises to ensure that corrective actions are sustained over time.

Pharmacy A



Pharmacy B



7. Conclusion

The findings of this audit pilot clearly demonstrated that unannounced inspection audits are a robust indicator of the standard of day-to-day practice at a pharmacy, and as such form a valuable component of the risk-based pharmacy audit framework.

Although still in progress, the results of follow up inspection audits being conducted at premises where serious and significant non-compliance were identified are demonstrating improvement in practice, and therefore patient safety.

The pilot has demonstrated that Medicines Control is able to use the risk based framework to increase the efficiency and effectiveness of regulatory resources, and take a more proactive approach to identifying and managing risks.

Medicines Control is continuing to work closely with key stakeholders including the District Health Boards, Pharmacy Council, Pharmaceutical Society and pharmacy sector agents, and is hosting a forum in late September/early October to agree sector actions to drive quality improvement.

Medicines Control will be working with DHBs to implement the risk based audit framework nationwide during the 2017/2018 audit year.