Audit of the Drug Treatment Centre (DTC) Pharmacies, 2012-2013

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Abbreviations

DTC = Drug Treatment Centre.

HIQA = Health Information and Quality Authority.

HSE = Health Service Executive.

NICE = National Institute of Health and Clinical Excellence.

PSI = Pharmaceutical Society of Ireland.

RCOG = Royal College of Obstetricians and Gynaecologists.

RCP = Royal College of Psychiatrists.

Stage 1: Select topic

Background – Rationale for Audit

The terms of reference of a report commissioned by the Health Service Executive (HSE) for review of the methadone treatment protocol included clinical governance and audit (Farrell & Barry, 2010). Implementing clinical audits is an internationally recognised way of getting evidence into practice (HIQA, 2012). Criterion four of the HSE Quality and Risk Management Standard mentions the Healthcare Audit, which includes both clinical and non clinical audit (Daly, 2008).

It is the duty of all healthcare professionals to ensure that they deliver the best care to their patients (HSE, 2007). The Drug Treatment Centre (DTC) pharmacies, due to the nature of the specialised services that they provide, are situated at different sites. Variations in practices were expected and accepted due to different staff operating at different sites.

The classification given by Donabedian (1980) of structure, process and outcome was used to focus on the areas of practice from which topics were selected (Daly, 2008; NICE, 2002; RCOG, 2003; Weeks *et al*., 2010). The objectives of this audit were to standardise and improve aspects of the pharmacy work area (dispensary), record keeping and operations (shown in Table 1).

Donabedian (1980) system of classification	Agreed topics for the pharmacy audit
Structure	Work area
Process	Records
	Operations
Outcome	None

Table 1: Agreed topics for the pharmacy audit

Stage 2: Review literature

The literature review identified the following as important for implementing an audit programme:

1. The selected topic should be of interest and importance to the staff involved (Daly, 2008; NICE, 2002) and also prioritise practices where baseline adherence is known or suspected to be poor (Kongnyuy & Uthman, 2009).

2. Criteria should be derived from published guidelines or evidence based best practices and acceptable to all staff involved (Weeks *et al*., 2010; NICE, 2002).

3. An appropriate level of performance should be agreed (RCOG, 2003).
4. A sample size which is enough to be representative should be determined for data collection (Copeland, 2005).
5. Data collection should be concurrent for immediate feedback on performance (NICE, 2002).
6. The data analysis should identify the degree to which actual practice (results of audit) meet the standards set (RCP, 2001a).
7. For feedback (reporting) to be effective it should be carried out both actively and passively (Ivers *et al.*, 2012; RCP, 2001a).
8. An action plan, developed upon reporting, should address the local barriers to change and identify those responsible for service improvement (Copeland, 2005).
9. A re-audit is needed to ascertain whether improvements in care have been implemented as a result of clinical audit (Snooks *et al*., 2005).
10. Systems, structures and specific mechanisms should be made available to monitor service improvements once the audit cycle has been completed (Copeland, 2005).

Stage 3: Set standards

Source of standards

The criteria for this audit were derived from the HSE Addiction Services policies, laws governing the Pharmacy profession and guidelines provided by the Pharmaceutical Society of Ireland (PSI). Sources used for developing criteria and audit questions are shown in Appendix I.

Standards set

The target for this audit was 80 % for structure and process element for an individual site (pharmacy) and is shown in Table 2. Structure element included criteria 1, 2 and 3 and the Process element had criteria 4 to 10.

Donabedian (1980) system of classification	Agreed topics for the Pharmacy audit	Criteria no.	Level of performance (target)
Structure	**Work area**	**1,2,3**	**80%**
Process	**Records**	**4,5,6**	**80%**
	Operations	**7,8,9,10**	

Table 2: Criteria and level of performance for audit tool.

The criteria agreed for the audit were:

1. The dispensary must have appropriate and adequate equipment to carry out daily operations of the pharmacy (PSI, 2008).

2. Equipment in dispensary must be hygienically maintained to prevent contamination in accordance with PSI (2012b) guidance for equipments.

3. The storage facilities in the pharmacy must comply with appropriate requirements as recommended in the Addiction Services policies and by PSI (2012a).

4. Pharmacy record maintenance and retention should comply with Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007 and the Misuse of Drugs Regulations 1988-2007.

5. Electronic (Q-Script) records should match to that of patient's details on the Methadone and Suboxone lists.

6. Pharmacists should comply with the record keeping requirements as recommended in the Addiction Services policies.

7. Pharmacists should comply with the prescription requirements as set out in Addiction Services policy, Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007 and the Misuse of Drugs Regulations 1988-2007.

8. Labelling of medicinal products must comply with Addiction Services policies and Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007.

9. Pharmacists must adhere to good dispensing practices in line with Addiction Services policies and PSI guidance.

10. Pharmacists must comply with Control Drug supervision requirements in line with PSI guidance for Pharmacists on the Safe Supply of Methadone.

Stages 4 and 5: Design audit/collect data

To design the audit tool for the data collection, examples of clinical audit projects provided by Royal College of Psychiatrists (2001b) were used as a template. Designing was done with the view to reaching conclusions about the general pattern of actual compliance, and to determine the degree to which actual practice is meeting the set standards (RCP, 2001a). The audit tool (Appendix II) comprised of 10 criteria and 64 questions.

Data collection was done over a period of two weeks by visiting each site. The data was collected by checking records and by direct observation. While collecting the data, it was observed that the discussions on the topic area

during the development of the audit tool stage had led to changes in behaviour (RCP, 2001a) and improvements in practice. No cases were excluded for the data collection as all samples were of similar kind. Adjustments made during data collection are shown in Appendix III.

Stage 6 and 7: Analyse data/ Feed back findings

The collected data was analysed, by calculating percentages, in order to establish overall achievement of each of the standards set. All the pharmacies scored above the agreed level of performance (80% for structure and process level separately). The results of the audit were emailed to all the pharmacy staff. The comparison of results of the data collected at different pharmacies (structure and process level combined) using the audit tool is shown in Figure 1 (detailed in Appendix IV).

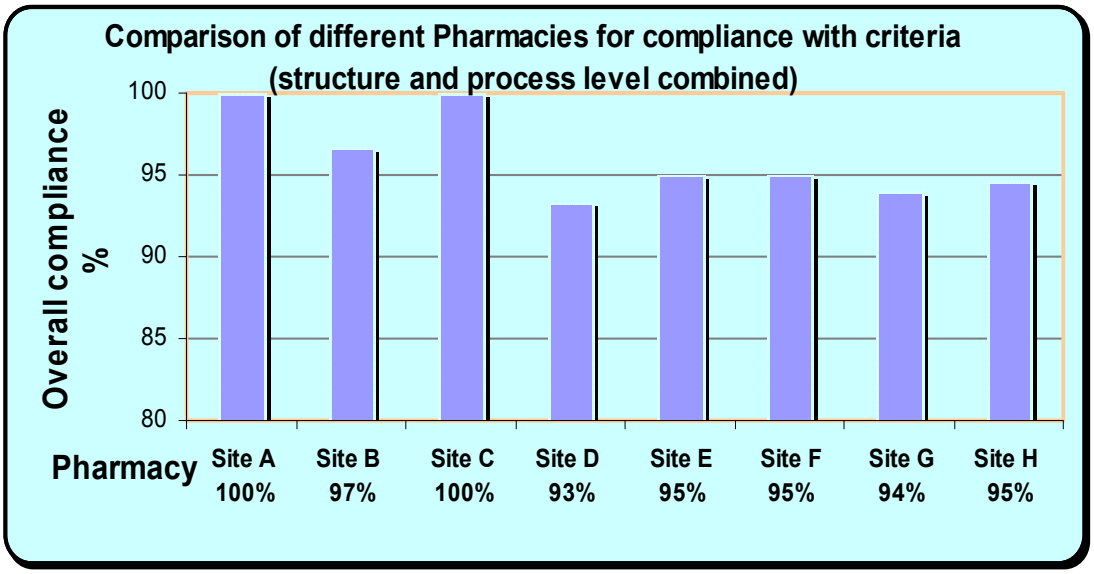


Figure 1: Graphical representation of overall compliance for each site.

Stage 8: Change practice

Staff members were requested to email suggestions for making improvements in the areas where 100% compliance was not achieved. Informal discussions were held with the pharmacists at different sites in order to develop practical ideas for implementing required changes identified to achieve100% results.

In the bi-monthly pharmacy meeting the results were further discussed. For each site, a key person was identified to take responsibility for implementing the changes required as a result of the audit (Copeland, 2005).

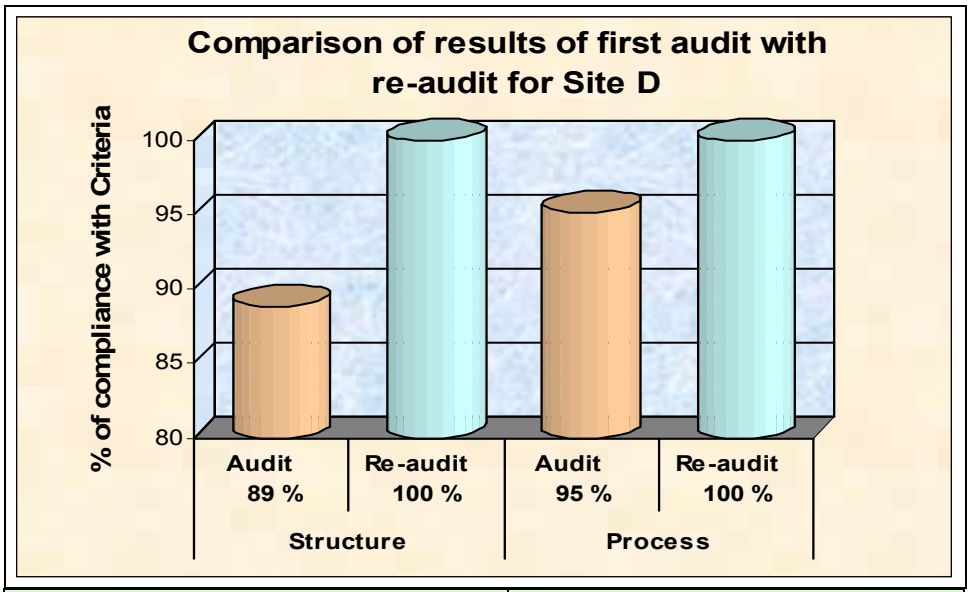
Stages 9 and 10: Review standards/re-audit

The audit tool (Appendix II) prepared for the audit earlier, which comprised of 10 criteria and 64 questions, was used for the re-audit. The target for the re-audit was set as 100% for structure and process element for an individual site (pharmacy) and is shown in Table 3.

Donabedian (1980) system of classification	Agreed topics for the Pharmacy audit	Criteria no.	Level of performance (target)
Structure	Work area	1,2,3	100%
Process	Records	4,5,6	100%
	Operations	7,8,9,10	

Table 3: Criteria and level of performance for re-audit.

A re-audit was carried out by randomly selecting one pharmacy as planned. The results demonstrated improvements which led to practice standardisation in the chosen topic areas. Comparison of the results of the first audit with the re-audit (structure and process level separately) is shown in Figure 2.



Structure		Process	
First audit	Re-audit	First audit	Re-audit
89	100	95	100

Figure 2: Comparison of results of first audit and re-audit for site D.

Comments on the Audit process

Resources

The implementation of the audit programme involved commitment and usage of staff time. This was calculated to be approximately 54 man hours from start to finish. Besides the usage of staff time, there was the cost of text books and travel expenses which amounted to approximately 100 Euros. It was ensured at all times that there were no disruptions to the services due to the process. Effective use of bi-monthly pharmacy meetings was made throughout the project.

Additional points

- For reporting results of the audit, both active and passive feedback (Ivers *et al.*, 2012; RCP, 2001a) were used.

- The success of the project was attributed to the fact that the staff and line manger were consulted and involved from the beginning of the project.

Hints from contributors

- Though the audit tool was piloted earlier with the view to detect and correct any problems (Daly, 2008; NICE, 2002), during the data collection the need for instructions to be more descriptive was felt. It would be advisable to use a previously tested audit tool for data collection if possible.

- It would be beneficial that the data be collected with the help of two staff members and the size of the audit tool for data collection kept small.

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Weeks, A., Lightly, K. & Ononge, S. (2010). *Let's do audit - A practical guide to improving the quality of medical care through criterion-based audit*. London: RCOG Press.

Appendices

Appendix I – Reference material used for developing criteria and audit questions.

Health Service Executive (2008). *Clinical guidelines for addiction pha*rmacists. Dublin: HSE Dublin North City -Addiction Services.

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Appendix II – Audit tool for Data Collection

Audit of the Pharmacy Department
Site (Pharmacy): _____ (please use alphabets e.g. A, B, C, etc.)

1. **Equipment:** The dispensary must have appropriate and adequate equipment to carry out daily operations of the pharmacy (PSI, 2008).

	Please check	y/n	na
1	Are graduated cylinders of volumes (5/10ml, 50 /100ml, 250ml, and 500 ml) available?		
2	Are there two working methadone pumps present?		
3	Is apparatus (triangle) available for counting tablets?		
4	Are measuring cups available to aid patient take away (methadone) compliance?		
5	Is Yellow bin with purple lid (for disposing tablets) present and is not full?		
6	Is designated bin present for disposing waste material?		
7	Is a sink with hot and cold running water working within the dispensary area?		
8	Is marked confidential bin available for disposal of paper waste containing confidential information?		

2. Hygiene: Equipment in dispensary must be hygienically maintained to prevent contamination in accordance with PSI (2012) guidance for equipments.

	Please check	y/n	na
1	Are methadone bottles and tablet vials in closed drawers, if not are the lids applied to them?		
2	Is apparatus (triangle) for counting tablets clean?		
3	Is counting (triangle) equipment cleaned after use (especially after using uncoated tablets)?		

3. Storage: The storage facilities in the pharmacy must comply with appropriate requirements as recommended in the Addiction Services policies and by PSI.

	Please check	y/n	na
1	Are all Rx/lists which are no longer in use stored either in the pharmacy or in a safe place, not accessible to any unauthorised personnel?		
2	Are medicines the only product stored in the pharmaceutical refrigerator?		
3	Are medicines stored away from any apparatus which will significantly alter local temperature (e.g. radiators)?		
4	Is pharmaceutical refrigerator temperature gauge displaying between 2-8 ℃?		

4. Pharmacy record maintenance and retention should comply with Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007 and the Misuse of Drugs Regulations 1988-2007.

	Please check last 3 pages of Methadone Register from current date.	y/n	na
1	Is the Methadone register signed by the pharmacist in indelible ink?		

Appendix II – Continued

2	Are transactions recorded on a daily basis with a running stock balance kept in the Methadone register?		
3	Is the Methadone register free from any obliterations, cancellations and alterations (any corrections are made by dated marginal note /footnote)?		
Please check last 2 pages of Suboxone Register from current date.			
4	Is the Suboxone register signed by the pharmacist in indelible ink?		
5	Are all transactions recorded on a daily basis with a running stock balance kept in the Suboxone register?		
6	Is the Suboxone register free from any obliterations, cancellations and alterations (any corrections are made by dated marginal note/footnote)?		
Please check folder for daily audit report (pick 2 days in current month and check date and time on the report to verify)**.**			
7	Is daily audit printout done on the day to which it relates or within 24 hours of that date?		
8	Is daily audit printout signed, dated and filed by the pharmacist on duty?		

5. Electronic (Q-Script) **records should** match to that of patients on the Methadone and Suboxone lists.

		y/n	
Please select 6 patients randomly <u>to check all three</u> (if Suboxone is dispensed at site; please use 1 patient from Suboxone list and 5 patients from Methadone list).			
1	Does patient's Doctor records in Q-Script match with that on Methadone/Suboxone list?		
2	Does patient's name in Q-Script match with that on methadone /Suboxone list?		
3	Does patient's date of Birth in Q-Script match with that on methadone /Suboxone list?		

6. Pharmacists should comply with the record keeping requirements as recommended in the Addiction Services policies.

		y/n	
Please check			
1	Is received Methadone stock recorded in the beginning of controlled drug register?		
2	Is log book for GMS and methadone Rx supplied to Doctors present?		
3	Is record of drugs received by Pharmacy (from Central Pharmacy) kept in a folder/book?		
4	Are records of disposed medications present?		
5	Are records kept of medications supplied to nursing staff?		
6	Are records of breathalyser calibration present?		
7	Are records of checking pump calibration present?		
8	Are records of archived pharmacy paperwork available?		
9	Are records of regular fridge cleaning present?		
10	Are records of daily monitoring of fridge temperature present?		
11	Is patient absenteeism recorded on daily basis?		
12	Is activity levels from Q-Script (profit enquiry) recorded at end of each session?		
13	Is alcohol meter reading recorded in the miscellaneous comment section of Q-Script (please select 5 patients who are breathalysed daily and check)?		

Appendix II – Continued

7. Pharmacists should comply with the prescription requirements as set out in Addiction Services policy, Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007 and the Misuse of Drugs Regulations 1988-2007.

		y/n	na
	Please check		
1	Is handwritten prescription for Suboxone present to support the current Suboxone list?		
	Please select two changes on current Methadone list and check		
2	Are changes to Methadone lists supported by dose adjustment sheets?		
	Please check current Methadone lists		
3	Are all Methadone lists in use signed by Doctors?		
4	Are Methadone lists signed by a pharmacist on a daily basis?		
5	Is Volume of methadone dispensed recorded in the appropriate space on the lists on a daily basis?		
	Please check current Suboxone lists		
6	Are Suboxone lists signed by a pharmacist on a daily basis?		
7	Is Quantity of Suboxone dispensed recorded in the appropriate space on the lists on a daily basis?		

8. Labelling of medicinal product must comply with Addiction Services policies and Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007.

		y/n	na
	Please check by selecting two labels		
1	Does medication name on the label match to what is dispensed?		
2	*Does the label for the methadone take-away bottle clearly state these warnings?* • May cause drowsiness. • If affected do not drive. • Avoid alcohol. • It is dangerous to exceed stated dose. • This medication should be taken only by the person for whom it is prescribed.		
	Does the label for medications clearly indicate the following:		
3	Patient name?		
4	Name and address of supplying pharmacy?		
5	Date of dispensing?		
6	Name of the preparation, its form and its strength, where applicable?		
7	Directions for use, including dosage, frequency of use and method of administration?		
8	The words 'keep out of reach of children'?		

9. Pharmacists must adhere to good dispensing practices in line with Addiction Services policies and PSI guidance.

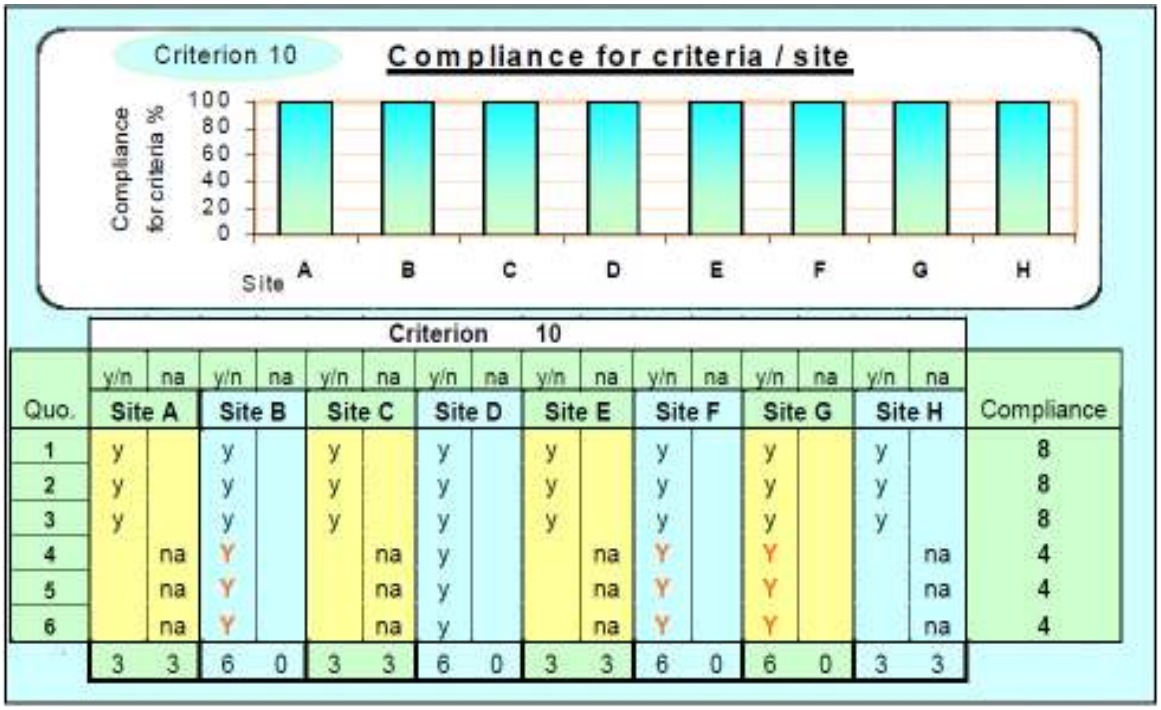
		y/n	na
	Please observe during dispensing.		

Appendix II – Continued

1	Are tablets given to patients at hatch (as part of supervision) presented in a disposable cup?		
2	Are medications not in blister packs given in child resistant containers (decision not to use a CRC is supported by appropriate recording of the intervention)?		
3	Are take away doses difficult to measure dispensed in separate bottles (decision to use one bottle is supported by appropriate recording of the intervention)?		
4	Are all loose tablets counted using the appropriate apparatus?		
	10. Pharmacists must comply with Control Drug supervision requirements in line with PSI guidance for Pharmacists on the Safe Supply of Methadone.		
		y/n	
	Please observe during dispensing.		
1	Does the ingestion of supervised Methadone occur under direct supervision of the pharmacist?		
2	Does pharmacist ascertain before handing out dose that patient is fit to consume Methadone?		
3	Did pharmacist ascertain that patient has consumed their Methadone dose either by talking to the patient or by offering a drink of water?		
4	Does the consumption of supervised Suboxone occur under direct supervision of the pharmacist?		
5	Does pharmacist ascertain before handing out dose that patient is fit to take Suboxone?		
6	Did pharmacist ascertain that patient has consumed their Suboxone dose either by talking to the patient or by offering a drink of water?		

Appendix III – Adjustments made during data collection.

For Criterion 10, during the data collection, assumptions were made in response to questions four to six for three sites (site B, F and G). This was done due to the fact that the patients for the supervised consumption of Suboxone were not present at the time of data collection and is marked by red colour 'Y'. For site D the responses recorded reflect the observations made.

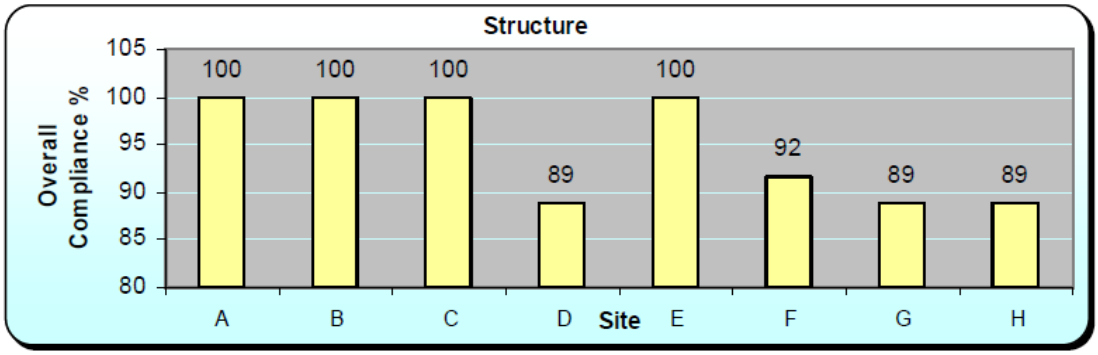


	Criterion 10															
	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	
Quo.	Site A		Site B		Site C		Site D		Site E		Site F		Site G		Site H		Compliance
1	y		y		y		y		y		y		y		y		8
2	y		y		y		y		y		y		y		y		8
3	y		y		y		y		y		y		y		y		8
4		na	Y			na	y			na	Y		Y			na	4
5		na	Y			na	y			na	Y		Y			na	4
6		na	Y			na	y			na	Y		Y			na	4
	3	3	6	0	3	3	6	0	3	3	6	0	6	0	3	3	

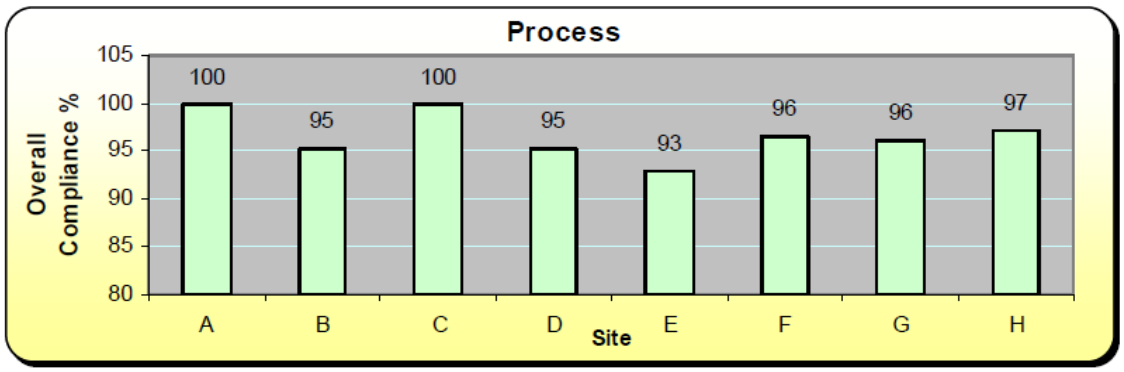
Appendix IV – Results of the audit

Structure and Process analysis for each site:

Donabedian system (SPO model) of classification was used to classify criteria into structure and process. The target for this audit was 80 % for structure and process for each pharmacy (site). The results for the Structure element which included criteria 1, 2 and 3 and for the Process element which included criteria 4 to 10 are shown below.



Site	A	B	C	D	E	F	G	H
Criterion 1	100	100	100	100	100	100	100	100
Criterion 2	100	100	100	67	100	100	67	67
Criterion 3	100	100	100	100	100	75	100	100
Structure	**100**	**100**	**100**	**89**	**100**	**92**	**89**	**89**



Site	A	B	C	D	E	F	G	H
Criterion 4	100	**88**	100	100	100	100	88	100
Criterion 5	100	100	100	67	100	100	100	100
Criterion 6	100	**92**	100	100	88	100	100	80
Criterion 7	100	100	100	100	75	100	86	100
Criterion 8	100	**88**	100	100	88	75	100	100
Criterion 9	100	100	100	100	100	100	100	100
Criterion 10	100	100	100	100	100	100	100	100
Process	**100**	**95**	**100**	**95**	**93**	**96**	**96**	**97**