

The Implementation of an audit programme across Drug Treatment Centre (DTC) pharmacies

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Achal Kumar Gupta

Royal College of Surgeons in Ireland, achalkumargupta@rcsi.ie

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The Implementation of an Audit Programme across Drug Treatment Centre (DTC) Pharmacies

Achal Kumar Gupta

A dissertation submitted in part fulfilment of the
degree of MSc in Healthcare Management,
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Abstract

Implementing clinical audits is an internationally recognised way of getting evidence into practice. There is an increased emphasis towards conducting audits within the Health Service Executive. Drug Treatment Centre pharmacies, due to the nature of the specialised services that they provide, are situated at different sites, and variations in practices were expected and accepted. The aim of the project was to develop and implement an audit programme across eight pharmacies within an eight month period. The objectives were to design/develop and test the audit tool by collecting data across all pharmacies in collaboration with the staff. The HSE Change Model was used for implementing the project. The stages of initiation, planning, implementation and mainstreaming were followed. Both qualitative and quantitative tools were used to inform the change process. Resistance to change was managed by participation and involvement of the staff. The audit tool was successfully developed and tested by collecting data. A comparison of results of the first audit with the re-audit revealed positive progression towards standardisation. In conclusion, this project demonstrated the potential for improved practice standards through the development and implementation of a healthcare audit tool and process. Using a structured approach to the change process proved to be the success factor for sustained change delivery.

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Abbreviations

DTC = Drug Treatment Centre.

HIQA = Health Information and Quality Authority.

HSE = Health Service Executive.

ICGP = Irish College of General Practitioners.

NCQA = National Committee for Quality Assurance.

NHS = National Health Service.

NICE = National Institute of Health and Clinical Excellence.

PPG = Policy, Procedure and Guidelines.

PSI = Pharmaceutical Society of Ireland.

RCOG = Royal College of Obstetricians and Gynaecologists.

RCP = Royal College of Psychiatrists.

Chapter 1: Introduction

1.1 Introduction

To drive improvements in the quality and safety of healthcare it is important that all decisions are based on the best available evidence and up to date information. Implementing clinical audits is an internationally recognised way of getting evidence into practice (HIQA, 2012). The author's intention was to implement an audit programme across the Drug Treatment Centre (DTC) pharmacies in collaboration with the staff. DTCs are part of the Health Service Executive (HSE) and are referred to as Methadone or Addiction Clinics.

1.2 Nature of the change

All dispensing sites should have the same standards and the services provided at each pharmacy should meet with best practice guidelines. The nature of the change was to foster a commitment and appetite for measurement of practice and standards. This was to be achieved by developing and implementing a healthcare audit tool and process to measure standards of practice in the DTCs. This project involved the development and implementation of a Healthcare audit programme across eight pharmacies (in seven DTCs) with staff as key stakeholders.

The participation and involvement gave staff the opportunity to become familiar with the process. It also fostered engagement towards a commitment to conduct audits and use them as a way of generating changes (NICE, 2007). Overall, it was a learning experience that may pave the way for future multi-disciplinary audits.

There is an increased emphasis towards conducting audits within the Health Service Executive (HSE) at individual staff and organisational level (HIQA, 2012; HSE, 2007; 2010). The project commenced with the development of an

audit tool. The process of developing an audit tool itself facilitated in recognition of evidence based practices and ensured a move towards them (RCP, 2001a), thus leading to improvements and standardisation.

The implementation of this project also assisted in a move towards a culture of measurement. To ensure the success of the programme, involvement and engagement of all the key stakeholders was prioritised from the beginning of the project which helped in forestalling the resistance to change (Kotter & Schlesinger, 2008) to a large extent.

1.3 Rationale for implementing an audit programme

Audit is described as a powerful tool for quality improvements in healthcare (Gerrish & Mawson, 2005; McSherry & Pearce, 2011; Palmer, 2002). The terms of reference of a report commissioned by the HSE for review of the methadone treatment protocol included clinical governance and audit (Farrell & Barry, 2010). Criterion four of the Health Service Executive (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). Implementing clinical audits is an internationally recognised way of getting evidence into practice (HIQA, 2012). The implementation of this programme could facilitate the creation of islands of learning within the DTCs. These may develop into a critical mass of learning, over time, contributing to organisational development which incorporates Grundy's (1994) viewpoint on organisational learning.

The Pharmaceutical Society of Ireland (PSI) in the past has provided a practice guidance manual which is a self-audit tool geared towards community pharmacies (PSI, 2008). The operation of the pharmacies in the DTCs is different to that of their community counterparts. The implementation of the programme involved developing an audit tool specifically for the DTC

pharmacies. This necessitated examining the laws, the guidance given by the PSI and policies of the Addiction Services which facilitated discussion among staff about the aspects of care. The process further highlighted problems which may otherwise have remained unrecognised (RCP, 2001a).

Over the past few years some staff members working in the DTCs have received training in audits. Due to the present financial crisis funding for training and education is less likely to be available in the forthcoming years. This change project was a learning experience for team members, especially for staff new to the audit process. Audit, being a cyclical process (Boult & Maddern, 2007), proved to be a good improvement tool and acted as an opportunity for reflection. It not only enabled staff to evaluate their practice but further aided in developing practices and checklists appropriate to the needs of the DTCs. The results of this audit programme can be used as a benchmark for future initiatives. Carrying out audits is a requirement of competence assurance for the GPs (Collins, 2011) and could become a part of the pharmacist's continuous professional development in future.

1.3.1 Drug Treatment Centre Pharmacies

The HSE approves Methadone and Buprenorphine (e.g. Suboxone and Subutex) as drugs to be used in the DTCs for opiate addiction. Pharmacists are responsible for supervising the consumption of the drugs and play a crucial role in the success of treatment for the opiate (e.g. Heroin) addiction. Patients have to attend pharmacies a minimum of once a week for supervised consumption as per recommendations of HSE (2008a) and PSI (2005; 2011).

The 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 audit process helped in maintaining and achieving quality through review, monitoring and evaluation against agreed standards (Weeks *et al.*, 2010).

Clinical audit is an integral component of clinical governance (Palmer, 2002). There have been audits previously carried out in the DTCs but the scope of them was localised. The author intended to capitalise on the existing support for clinical audit within the organisational clinical governance framework as evidenced in Appendix I. Development and implementation of an audit programme involving all the disciplines would have been ideal. But due to limited resources and time constraints it was only feasible to implement the programme at pharmacy department level.

1.4 Aims and objectives

The vision of the change project was to establish a culture of continuous measurement and improvement. To achieve the vision the combined efforts of the pharmacy staff and the support of management were required. The aim of this project was to develop and implement an audit programme across eight DTC pharmacies within an eight month period.

The Specific, Measurable, Achievable, Relevant and Timely (SMART) objectives for successful implementation and evaluation of the change project were set as:

1. To design/develop an audit tool for the DTC pharmacies in collaboration with the pharmacy staff within the first four months of project commencement.
2. To test the audit tool by collecting data across the DTC Pharmacies in collaboration with pharmacy staff within a month of developing the tool.
3. To foster engagement in the development of an audit tool and commitment to a programme of audit amongst pharmacy staff throughout the project.
4. To utilize the results of the audit to support the standardisation of practice through a re-audit.

Implementation of the audit programme depended on the author's ability to lead while ensuring involvement and commitment of the pharmacy staff. The

activities identified, upon literature review, for successful development and implementation of the audit programme were as follows:

1. Agree on topic areas, scope, objectives and carry out a literature review.
2. Ascertain criteria and appropriate level of performance.
3. Develop an audit tool for data collection and a data analysis system.
4. Pilot the audit tool, collect data and conduct analysis, and provide department with a report.
5. Identify barriers, implement changes and develop a system for sustaining any needed improvements.
6. Re-audit at least one pharmacy.

1.5 Summary

Audit is described as a powerful tool for quality improvements in healthcare (Gerrish & Mawson, 2005; McSherry & Pearce, 2011; Palmer, 2002). The aim of this project was to develop and implement an audit programme across eight DTC pharmacies within an eight month period. Successful implementation of the project depended on the author's ability to lead and involve all stakeholders in the process.

In the following chapters the literature review and change process is outlined. Further change evaluation and outcomes are presented. The final chapter will discuss the impact of the project, recommendations for future improvements and overall conclusion.

Chapter 2: Literature Review

2.1 Introduction

The author's project involved implementing an audit programme across eight DTC pharmacies. The objectives were to design/develop and test the audit tool in collaboration with the staff and to utilise the results to support improvement and standardisation. This chapter presents a search strategy and review of the literature on Healthcare audit, particularly clinical audit. It will conclude by discussing the implications of the reviewed literature in relation to the author's choice of change project.

2.2 Search strategy and sources of information

The search strategy involved examining literature on audit in its broader context. It was narrowed down to include guidelines on developing and implementing audit programmes. The literature was obtained from text books, HSE intranet and HSELand and web-based databases including Google Scholar, Cochrane library and RCSI e-Journal Portal. Over 28 articles and two textbooks were reviewed.

The literature search went back to 2001, despite a comprehensive recent review on audits by Travaglia & Debono (2009), as the author found guidelines provided by RCP (2001a) for implementing an audit programme valuable. The bulk of the guidance for developing and implementing audits was derived from work carried out in the NHS and related organisations. For developing and implementing an audit programme guidance was derived from two textbooks and five guidance articles.

A separate search was conducted to find previously used audit tools. The search for audit tools applicable to the Irish jurisdiction that could be used for this project proved fruitless. This led to a further search for standards and

audit tool designs. For deriving the standards, guidelines provided by the Addiction Services, laws governing the Pharmacy profession and guidance provided by the PSI were reviewed. Reference material identified for developing audit criteria and questions for the audit tool is shown in Appendix II. The examples of audit tools provided by Royal College of Psychiatrists (2001b) and PSI (2008) self-audit were found relevant and used to support the design phase of the audit tool development.

2.3 Themes

Three themes emerged from the literature search and were selected as the focus of the review for the project. These themes are as follows:

1. Effectiveness of clinical audit and limiting factors.
2. Audit process.
3. Involvement of management, staff and regulatory bodies in audit.

2.3.1 Effectiveness of clinical audit and limiting factors

According to NICE (2002) in the NHS, clinical audits have mixed results, for every success story there are just as many failures. For quality improvement (QI) activities, audit and feedback appear to result in modest effects (Grimshaw *et al.*, 2006). Further, as per Cochrane review, audit and feedback show only small but potentially important improvements (Ivers *et al.*, 2012). The study suggests that the effectiveness depends on baseline performance and how the feedback is provided. In addition, the effect of audit and feedback may be influenced by the type of behaviour it is targeting.

The effect of baseline performance on the audit effectiveness is also confirmed in another study examining the use of criterion-based clinical audits. In this study, Kongnyuy & Uthman (2009) concluded that 'criterion-based clinical audit can improve obstetric practice and health outcomes especially if baseline adherence is poor' (p.8). They further suggest that

priority should be given to those practices where baseline adherence is known or suspected to be poor.

The counter argument to the above is provided by Travaglia & Debono (2009), in their review of literature they state that the limited success of audits is due to the conditions under which they are implemented, not because they are ineffective. According to them, the barriers which limit the success are lack of resources and planning, trust, priorities and the lack of expertise available in designing an audit project. Irrespective of the current limit of data available to support the effectiveness of audit programmes, they are still supported and implemented across the healthcare sector.

In their review Travaglia & Debono (2009) further identify the variables which determine the effectiveness and value of the clinical audit process as an improvement method. These variables include:

- clarity and measurability of the criteria and standards chosen;
- quality of the data available;
- engagement of clinicians;
- skills and training of participants;
- time involved to undertake an audit;
- use of information technology;
- feedback provided;
- if and how the findings are translated into quality improvement strategies; and
- evaluation of improvement strategies (closing the loop).

From the above the author concludes that the effectiveness of an audit programme depends on the conditions in which it is implemented and on the baseline performance. Further, the stages in the clinical audit cycle (NICE, 2002) making improvements (stage four) and sustaining improvements (stage five) are in themselves a change management project and could be a factor for its limited success. Improvements in care, implemented following a clinical audit, need ongoing monitoring and evaluation and no specific method has been recommended in any of the reviews. There is a further need for studies

to determine the most effective methods to sustain improvements in the healthcare sector. Other factors identified by the author upon literature review which need consideration while implementing audit programmes are:

- organisational culture (Palmer, 2002);
- protected time (NICE, 2002);
- leadership (NICE, 2002); and
- opportunities within the organisation to participate (Bowie *et al.*, 2012).

The quality and safety improvement focus is shifting towards alternative systems-based QI methods, but research to suggest that these will be any more impactful is also lacking (Bowie *et al.*, 2012). While promoting rapid-cycle audit, Farrell & Hill (2012) state that duration of time between initiating the audit process, data collection and the analysis of results can be substantial. This often leads to a failure in 'closing of the loop', with little feedback for the hard work involved. In the author's view, there is a further need for research linking success of audit programmes with the time taken to complete them.

2.3.2 Audit process

A healthcare audit is an audit of current practice against standards in any aspect of healthcare and includes both clinical and non clinical audit (Daly, 2008). Clinical audit guidelines provided by NICE are widely used and approved for implementing audits. The stages described by NICE (2002) for implementing a clinical audit are preparing for audit, selecting criteria, measuring level of performance, making improvements and sustaining improvements. This section examines steps considered important by the author in the various stages of clinical audit.

2.3.2.1 Selecting topics for audit

The participation of staff in selecting topics is not always necessary, but may have a role in reducing resistance to change (NICE, 2002). The classification given by Donabedian (1980) of structure, process and outcome is widely used to focus on the areas of practice from which a topic may be selected for implementing an audit programme (Daly, 2008; NICE, 2002; RCOG, 2003; Weeks *et al.*, 2010).

Often, audits are an assessment of structure and process only, with little thought to the outcome, which is essential if services to patients are to be improved (Copeland, 2005). The Royal College of Obstetricians and Gynaecologists (2003) describes outcome measure as: 'the physical or behavioural response to an intervention' (p.2). It is further emphasised that the use of outcomes alone in assessing quality of care has limitations because not all patients who experience substandard care will have a poor outcome. It is recommended that in clinical specialities where the outcome is difficult to discern, it may be more useful to use process or even structure as a surrogate to outcome measure (Copeland, 2005). The identified characteristics for agreed audit topics should be:

- of concern (variations acknowledged by staff);
- of importance and interest to the team involved; and
- measurable i.e. standards/criteria are available to measure against (Daly, 2008; NICE, 2002; RCP, 2001a).

2.3.2.2 Criteria selection

Implementing an audit identifies gaps between what is done and what should be done (Seddon & Buchanan, 2006). In a nutshell it is a measure against standards. Standards can be used to develop explicit or implicit criteria which are systematically developed statements (NICE, 2002). Implicit criteria are used more in cases of adverse events.

A survey (involving 466 participants) regarding the methods used to select audit review criteria identified problems such as difficulties in coordination of

staff to undertake the task, lack of evidence, poor access to literature and high quality data, lack of time and motivation (Hearnshaw *et al.*, 2003).

Suggestions to overcome these problems included training of staff in searching published work and critical appraisal, and the inclusion of a detailed and transparent account in the audit protocol of how review criteria were selected.

For criteria to be valid and lead to improvements in care, they should be related to important aspects of care and be measurable (NICE, 2002). Weeks *et al.* (2010) and NICE (2002) recommend that the agreed criteria should be:

- derived from good quality guidelines;
- capable of being measured;
- able to define clearly what is being measured ;
- acceptable to all participating staff; and
- realistic for the capacity of the facilities.

2.3.2.3 Level of performance

In many audit programmes no explicit targets are set and the aim is to improve upon current performance. There is insufficient evidence to determine whether it is necessary to set target levels of performance (NICE, 2002). However, reference to levels achieved in audits undertaken by other professionals is considered useful (RCOG, 2003). Benchmarking techniques have been used to set target levels and have helped participants to avoid setting low or unrealistically high levels of performance. It is recommended that the level of performance should be acceptable to all the stakeholders involved in the audit.

2.3.2.4 Data collection and reporting

In their comprehensive review of literature on audits, Travaglia & Debono (2009) discuss retrospective and concurrent methods of data collection but do

not recommend one over the other. According to NICE (2002), the concurrent method of data collection gives a team more immediate feedback on its current performance and can act as a positive reinforcement tool to improve or maintain practice. The author's inclination towards concurrent data collection is strengthened by the viewpoint of Copeland (2005) that it allows for accurate real time accrual of data which reflects current rather than historical practice. The quality of the data gathered for the audit is dependent on factors such as sample selection and size, data sources, data abstraction tools, training of data reviewers and how it is analysed (Travaglia & Debono, 2009). It is suggested that the sample size of the data to be collected should be small enough to allow for data acquisition but large enough to be representative (Copeland, 2005).

Reporting should be non punitive, timely and meaningful in order for recipients to act on it appropriately (Hysong *et al.*, 2006). In a meta-analysis based on 'Feedback Intervention Theory' Hysong (2009) concluded that audit process and feedback effectiveness is enhanced when feedback is delivered frequently and with specific suggestions for improvement. It is recommended that while reporting, areas of weak practice or potential risk should be highlighted so that standards or local policies/ guidelines can be developed (McSherry & Pearce, 20011). A combination of passive feedback (written information) and active feedback (discussion of findings) seems to be preferable when communicating the findings of a project (RCP, 2001a). The results of the Cochrane review by Ivers *et al.* (2012), in the author's view, sums up the different viewpoints and should be sufficient for providing feedback. According to the findings of their review, the feedback may be most effective when:

- the person responsible is a colleague;
- it is provided more than once;
- it is given both verbally and in writing; and
- it includes clear targets and an action plan.

2.3.2.5 Completing the audit cycle (action planning and re-audit)

In order to implement changes there is a need for coordination, monitoring (Renshaw & Ireland, 2003), and identifying responsible people (Copeland, 2005). The action plan developed on reporting may involve refinement of the audit tool particularly if the results are inconclusive (Copeland, 2005). It is further suggested that 90% of audits with an action plan should be re-audited.

It is suggested by Kongnyuy & Uthman (2009) that an attempt should be made, wherever possible, to complete the audit cycle by conducting a re-audit. Snooks *et al.* (2005) states that a re-audit is necessary to understand the effects of the changes made. In the author's view, completing an audit cycle by conducting a re-audit is necessary and should demonstrate improvements. It is recommended by Copeland (2005) that if improvements are sustained a monitoring process can replace the audit. Auditing should be reactivated if performance deteriorates. It is also suggested that the results may be disseminated locally and nationally where possible.

2.3.3 Involvement of management, staff and regulatory bodies in audit

There is an increased emphasis towards conducting audits within the HSE at individual staff and organisational level (HIQA, 2012; HSE, 2007; 2010). The Healthcare Audit Criteria and Guidance document places responsibility on senior local managers to ensure that the structures and processes for healthcare audits are in place (Daly, 2008). Further, the line managers are responsible for ensuring that staff members are aware of the structures and processes, and with facilitation of protected time and support. Implementing an audit programme can make use of the resources available within the HSE. It would also help to ensure that staff members are following best practices and delivering high standards of care.

A multi-disciplinary audit programme with patients/service users as one of the stakeholders is recommended within organisations (Copeland, 2005; HSE,

2007). This requires commitment and training of all the disciplines involved. Training is also recommended for the patients/service user group. In a survey of service user involvement in clinical audits Moore (2008) suggests that the organisational culture of user involvement needed to be improved, and the health professionals educated and informed about the value of consumer involvement. The HSE has experienced major changes and budgetary constraints in recent years (HSE, 2012a; 2012b). With the current budgetary restrictions in place training for staff and patients/ service users is not available within the HSE.

Audit is considered a valuable tool by the Irish College of General Practitioners (ICGP). Under the new professional competence system, it is now obligatory for practicing General Practitioners to conduct at least one audit per year (Collins, 2011). It is further recommended that practitioners spend a minimum of one hour per month on audit activity. In recent years, the standards and practice unit of the PSI has provided a self-audit tool for pharmacists and pharmacy owners (PSI, 2008). This is an extensive document and covers most of the legislation governing the pharmacy profession and guides towards the standards. There seems to be recognition by the regulatory bodies (ICGP & PSI) in Ireland that an audit can be used as a key component of education and continuing professional development. Audit, being a cyclical process (Boult & Maddern, 2007), can be a good improvement tool and serve as an opportunity for reflection.

2.4 Implications for the change project

The objectives of implementing this programme were to design/develop and test the audit tool in collaboration with the staff and further utilise the results to support improvement and standardisation. The DTC pharmacies are located at different sites due to the nature of the specialised services provided by them. The need for resources, particularly protected time and considerable planning, to ensure the success of the programme was felt (Travaglia &

Debono, 2009). 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).

The potential of an audit to lead to better quality of care can be hindered by staff resistance, insufficient understanding of the concept and lack of administrative support (Muffler *et al.*, 2007). The approach for this change project was a bottom-up approach. For this, it was considered necessary that management must be visible and demonstrate by their actions that accountability is a priority, and they are committed to improving accountability

arrangements (HSE, 2010). The factors for the successful implementation of this project were identified as:

- support and commitment from senior management;
- interest and commitment of all members of the team/ buy-in from the staff;
- communication;
- project design (agreeing on standards, audit tool for data collection);
- validity and independence of data collected; and
- reporting (no blame and confidentiality maintained at all levels).

2.5 Summary

Implementing an audit identifies gaps between what is done and what should be done (Seddon & Buchanan, 2006). Irrespective of the current limit of data available to support the effectiveness of audit programmes, they are still supported and implemented across the healthcare sector. For criterion-based audit, priority should be given to those practices where baseline adherence is known or suspected to be poor. There is insufficient evidence to determine whether it is necessary to set target levels of performance. Feedback appears to be important in the success of audits and a combination of passive and active feedback is required for it to be effective. A re-audit is necessary to understand the effects of the changes made.

There seems to be recognition by the regulatory bodies (ICGP & PSI) in Ireland that an audit can be used as a key component of education and continuing professional development. Audit, being a cyclical process (Boult & Maddern, 2007), can be a good improvement tool and serve as an opportunity for reflection. Leadership, team work, culture and support of both staff and managers are considered important for successful implementation of audits. The next chapter presents the steps taken to implement an audit programme across eight DTC pharmacies using the HSE change model.

Chapter 3: Change Process

3.1 Introduction

Change is a continuous and adaptive process in which all the elements are interrelated and can influence each other (HSE, 2008b). The project involved developing and implementing an audit tool and process with the purpose of fostering commitment and appetite for measurement of practice and standards within the DTCs. At the outset, the chapter provides a critical review of current change theory and models, with clear justification for the choice of the change model used. The remainder of the chapter critically presents the steps undertaken in implementing the change using the HSE model.

3.2 Approaches and aspects of change- a critique

Change is an ever-present feature of organisational life, both at an operational and strategic level (Burnes, 2004b). There has been assertions made that up to 70 % of change initiatives fail (Higgs and Rowland, 2000, 2005; Miller, 2001). While questioning the inherent failure rates in terms of the ambiguities of change, the context-dependent nature of change, competing perceptions and measurability it is concluded by Hughes (2011) that there is no valid and reliable empirical evidence to support a narrative that up to 70 % of change initiatives fail.

3.2.1 Change approaches and models

The two main approaches to change management appear to be planned and emergent (Bamford & Forrester, 2003). Planned approaches are based principally on the work of Kurt Lewin. This approach holds the viewpoint that old behaviour has to be discarded before any new ones can be adopted successfully. It has been criticised for not taking into account factors like

organisational conflict and politics, and is relevant only to small-scale changes in stable conditions. In response to criticism of the planned approach to organisational change, the emergent approach has gained ground (Burnes *et al.*, 2003; Todnem By, 2005).

Emergent change emphasises 'bottom-up' action rather than 'top-down' control in commencing and implementing organisational change (Bamford & Forrester, 2003). The role of management in this approach is more of facilitation rather than to control. Lewin's planned approach to change is based on four mutually reinforcing elements, namely Field Theory, Group Dynamics, Action Research and the 3-Step model, which are used in combination to bring about effective change (Burnes, 2004a). If these elements are viewed separately then criticism seems to hold, but when viewed alongside each other the planned approach becomes much more robust. Young (2009) presented a meta-model for change, while sharing Lewin's view on the need to adopt a holistic approach when implementing changes. According to McAuliffe & Van Vaerenbergh (2006) planned and unplanned change cannot be easily separated and interplay between these shapes the future of any organisation.

The other approach to change is organisational development, which is a collaborative top-down, bottom-up process that recognises the importance of building the commitment and leadership of top-level decision makers and involving all stakeholders in the change process (Worren *et al.* 1999; Farias & Johnson, 2000). The HSE change model is classified as 'planned' but there seems to be an inclination towards organisational development approach. In this model, the details of the change are determined in the 'Planning stage' which seems to be its unique feature.

The planned change model of Young (2009) and Kotter's (2007) emergent change model both emphasise the steps to be followed to successfully implement a change. In the author's view, there is a need for flexibility while implementing the change which a step model cannot provide. The author concurs with the view of Coram & Burnes (2001) that approaches to change

are applicable to different situations and focus on different aspects of the organisations. Further, in some situations it may be necessary to combine, either concurrently or sequentially, different approaches to change.

3.2.2 Designing change

Difficulty in fostering and implementing change becomes greater with older and larger organisations (Zeffane, 1996). Most organisations have routines for functioning and managers often make the false assumption that what worked in the past will also work in the future. According to Bamford & Forrester (2003) : 'Initiative fatigue is one of the prime causes of failure, and to waste some of the organisation's energy and goodwill on a poorly thought out programme may jeopardise the success of later initiatives – organisational memory' (p.562). Further, scepticism as a result of the failure of previous initiatives can act as a resisting force (Gill, 2002).

Approaches which are 'result-driven' have greater potential for improvement because they focus on achieving specific, measurable goals (Appelbaum & Wohl, 2000). Frequently, organisations start to change things without first establishing a baseline which makes it impossible to monitor progress or to quantify the magnitude of change required or achieved (Young, 2009). It is important that initiatives are launched with clearly established criteria for success and means of achieving them in consultation with stakeholders. While designing change the level of 'personal change adaptability' of the people should also be taken into account (Miller, 2001).

A successful change process requires time. Skipping steps can only cause an illusion of speed and produce an unsatisfactory result (Kotter, 2007). This strongly points to the fact that change advances through stages which are built upon each other. Moving too quickly and involving people, especially those who do not have the information needed to design the change correctly, may affect the results of future change initiatives. In situations where change is a must, time to plan and adjust is likely to be minimal with no room to

negotiate. Progressing on the thoughts of Kotter & Schlesinger (2008), it is right to say that while approaching change situations strategic choices need to be made regarding speed of the effort, planning and involvement of others.

3.3 Rationale for selecting HSE change model

Most of the major studies of change focus on the private sector and tend to derive their approaches to change from it. It is argued that there is no 'one best way' to manage organisational change and public sector organisations need to adopt an approach to change which matches their needs and situation (Coram & Burnes, 2001). The Healthcare sector is different from other organisations so considering using the HSE change model seemed logical for implementing this planned change, though the evidence of its efficacy is limited.

Managing change according to 'textbook theory' is difficult (Buchanan *et al.*, 1999) and there is a need for manoeuvrability while implementing it. The HSE model draws its approach from other models of change. The steps are grouped under four stages: initiation; planning; implementation; and mainstreaming. This project involved developing and implementing an audit programme which has its own steps for proceeding. In the author's view, it was easier to implement this project under the stages identified within the HSE change model.

The HSE is a large-sized organisation providing a multitude of services. The approach adopted in the HSE change model for implementing planned change incorporates both the structural and cultural aspects of healthcare organisation. Further, emphasis on the 'Initiation stage' within the model is very detailed, which in the author's view was good for the success of this project. Also, consideration for the use of this model was that the change was being undertaken in an Irish health organisation, and the model is based upon change within the Irish healthcare system.

It is important at each and every step to communicate and consult with the staff members involved (Appelbaum & Wohl, 2000). This should be supplemented with effective leadership and is identified as a necessity to any change project success (McAuliffe & Vaerenbergh, 2006). The model recognises the need to appreciate and respond to staff fears and concerns, with particular emphasis on the importance of engaging people in the process of change. The author was able to incorporate 'short-term wins' (Kotter, 2007) for defining and engineering visible performance improvements within the HSE change model. Overall, the model resonated with the author's requirements for implementing this change.

3.4 The change processes

3.4.1 Initiation

This is the first stage of the change process. The purpose of this stage is to create readiness and a considered case for change, to establish a sense of shared responsibility, and to scope out a solid foundation for successful change (HSE, 2008b). This section elucidates the steps taken for initiating this project.

All DTC pharmacies provide similar services and their operations are governed by the same PPGs and laws. Despite this, on numerous occasions variations in practices were observed and brought up in the conversations among staff members. The author, with the help of a few staff members, carried out Five whys analysis (Appendix III) to understand the problems (McAuliffe & Van Vaerenbergh, 2006). The conclusion was reached that implementing an audit programme could be used to achieve standardisation. Furthermore, it would help to bring about the necessary changes to improve the services.

The key stakeholders for this change project were identified as pharmacy staff members and the line manager (Appendix IV). It was accepted that support of senior management was also required for the programme. A key requirement for change is leadership (Kotter, 2007). The author held meetings with the pharmacists who had previously undergone audit training and the chair of the Audit Committee to explore the feasibility of the project. The proposal was presented to senior management and no objections were made, as conducting audits is part of the current Clinical Governance framework within the DTCs (Appendix I).

One of the problems in relation to change is that it is exciting for those who do it and threatening for those to whom it is done (Gill, 2002). For this the author, in the role of change agent, visited each DTC and discussed the feasibility of developing and implementing the audit programme. The discussions included explaining the reasons for the need for change (Appelbaum & Wohl, 2000; Heracleous, 2002; Kotter & Schlesinger, 2008). No resistance was encountered and enthusiasm towards the initiative was observed among staff. The process also helped in identifying change champions, and encouraged participation and buy-in of staff members. The staff who had previously attended audit training agreed to assist in the process. A request to purchase textbooks on audit was approved by senior management despite current financial constraints. This further, demonstrated endorsement by management towards the project and helped to strengthen enthusiasm of the change champions.

To improve the chances of successfully implementing a change, conducting an organisational analysis that identifies the current situation and problems is necessary (Kotter & Schlesinger, 2008). A SWOT analysis (Appendix V) was carried out by the author with the help of change champions to assist in assessing capacity for change (McAuliffe & Van Vaerenbergh, 2006). While identifying the strengths and weaknesses in the analysis it was highlighted that communication would be an issue. As pharmacies are located at different sites, communication had to be primarily by emails and telephone. The issues requiring agreement and consideration of all pharmacy staff needed to

be discussed in the pharmacy meetings, held every second month. For this it was deemed necessary to be prepared in advance of the meetings.

Furthermore, a Force-field analysis (Appendix VI) was carried out. The resistors, like 'lack of knowledge' and 'training', were identified as issues which needed to be worked upon to implement the change successfully. Implementing this project was identified as a first-order change as it warranted improving the present situation. It was identified in SWOT and Force-field analysis that deep rooted values, communication barriers and capability gaps could be sources of resistance, which were in alignment with the Pardo del Val & Fuentes (2003) conclusion of empirical research involving Spanish companies undergoing small changes.

Implementing an audit programme challenged the taken-for-granted beliefs of staff (Zeffane, 1996). The team had concerns that if some pharmacies decided not to co-operate, it would be difficult to implement the programme. Some who participate initially may not want to implement the improvements (changes) identified, seeing that others never participated in the first place. For this, it was identified that from the very start staff needed to be informed and consulted (Appelbaum & Wohl, 2000; Heracleous, 2002; HSE, 2008b) in all stages of development of the audit programme, particularly in agreeing on criteria and level of performance for the audit tool.

The objectives and activities for the change project are already discussed in chapter one. For developing the audit programme it was necessary to agree on the topic areas and to outline the initial objectives and outcomes. According to NICE (2002), participation of staff in the selection of audit topics is not necessary, but it enables concerns around reporting to be addressed and may also help in reducing resistance in later stages. For selecting the topic areas brainstorming was carried out with the help of some pharmacy staff using Donabedian (1980) classification of structure, process and outcome. This helped in initialising the development of the audit tool. In agreement with the staff the scope was elucidated as 'within the remit of the pharmacy department and for all the DTC pharmacies'. The objectives for the

audit were agreed as 'to standardise and improve' aspects of the chosen topic areas.

Before the bi-monthly meeting, the scope, objectives and agreed topics were communicated to all pharmacy staff along with senior management via email. Sending emails to senior management was considered important as it demonstrated that management was interested and supported the project (Heracleous, 2002; Kotter, 2007). Agreed topics for audit under structure and process element, along with scope and objectives, are shown in Appendix VII.

At the end of this stage a project impact statement was prepared (Appendix VIII). It was anticipated that this change project would help to achieve standardisation and improvement within the department and also highlight the standards which should be adhered too. Furthermore, this would give staff a chance to learn from the process and may pave the way for future multidisciplinary audits involving patients.

3.4.2 Planning

This stage was identified as important for the success of all the future stages. It involved building commitment and devising the plan for developing and implementing the audit programme. To further assess the likelihood of success of the change the DICE score was calculated.

3.4.2.1 Building commitment

The scope and objectives of the audit were discussed at the pharmacy meeting with the view of building and gaining visible commitment. To inform and equip staff with resources needed for decision making (Zefanne, 1996) a presentation was given by a pharmacist trained previously in audits. This further helped to enforce the vision. The timeline for developing and implementing the audit programme (Appendix IX), which acknowledged

'short-term wins' (Kotter, 2007), was distributed to make staff aware of the steps that needed to be followed. To ensure participation from all pharmacies it was emphasised that pharmacy anonymity would be maintained while reporting the results. It was also agreed that the data be collected concurrently and that a sample of the audit tool be emailed a month before the data collection was planned.

To assess the likelihood of the success of the change, the framework given by Sirkin *et al.* (2005), which concentrates on Duration, Integrity, Commitment and Effort (DICE), was explored in collaboration with the staff. The DICE score for this initiative was calculated to be eight (Appendix X), indicating that the project was in 'Win Zone' and was likely to be successful. The framework helped to recognise that some staff members may lack enthusiasm.

3.4.2.2 Developing the implementation plan

Searches for initiatives undertaken by other professionals for the audit tool were inconclusive. For developing the audit tool it was required to have (a) criteria, (b) level of performance, and (c) audit questions. The Addiction Services policies, laws governing the Pharmacy profession and guidelines provided by the PSI were reviewed to devise criteria. It was felt that the level of performance should be set, though evidence to support its necessity is insufficient (NICE, 2002).

The DICE framework (Sirkin *et al.*, 2005) had revealed earlier that staff may lack enthusiasm towards the programme. Taking this into account and with a view to ensuring commitment and reducing resistance, it was decided that the input of all staff, in agreeing criteria and level of performance, was necessary. This was also considered important for staff to understand the process.

As the eight pharmacies were located over seven sites it was not possible to involve all staff directly. For this, it was planned that criteria for the audit tool would be devised in consultation with the pharmacy staff (NICE, 2002; Weeks

et al., 2010) in three stages and is discussed in greater detail in the 'implementation stage'. To reduce the workload at later stages, it was further planned to develop questions for the audit tool in parallel to that of criteria. This was considered necessary for generating some extra time should any step require more time than specified in the timeline for implementing the programme (Appendix IX).

For reporting results of the audit, it was agreed to use both active and passive feedback (Ivers *et al.*, 2012; RCP, 2001a). Reporting and data analysis plans for the first audit are shown in Appendix XI. It was agreed to keep the design of data analysis system for the re-audit simple and only compare the results of the two audits at Donabedian's (1980) structure and process level.

Plans for the data collection involved collecting quantitative data only, with no comment section, as there was no accessible structure for analysing and interpreting the qualitative data. The sample size to be collected was to be decided, keeping in mind time, cost and size of the audit tool (Daly, 2008). Systematic sampling was to be used for selecting patients from the prescription list. Where systematic sampling was not possible it was planned that data would be collected randomly.

3.4.3 Implementation

This stage involved materialising the plans which were developed earlier. Though it was hard to determine the cut-off point, the author is of the view that it ended with the analysis of data collected. This stage involved developing and testing the audit tool by collecting the data and further re-enforcing the vision. Adjustments were made to the original plan of implementing the audit programme with the view to address resistance, but the overall change process was kept on track.

3.4.3.1 Developing the audit tool and data analysis system

Initially, 14 criteria were derived from the literature review for the audit tool. The criteria were prioritised into 'must do' or 'should do' on the strength of research evidence and impact on outcome (NICE, 2002). In the second stage, the author visited each site and consulted with the pharmacists who were not involved initially in the development of the criteria. It was done to ensure a group approach to decision making and action taking was in place for implementing the change (Applebaum & Wohl, 2000). It further helped to communicate the vision for change (Kotter, 2007). The third stage was final in the agreement process and primarily involved communication by emails. At the end of this stage, 10 criteria were agreed by all staff members.

The implementation of the plan for agreeing on criteria for the audit tool did not go well. Most of the pharmacies agreed with the developed criteria, but staff at some sites objected. Individuals or groups can react very differently to change - from passively resisting it, to aggressively trying to undermine it, to sincerely embracing it (Kotter & Schlesinger, 2008). Therefore, correct assessment is often not intuitively obvious and requires careful thought. It was evident that within different sites subcultures existed and developing and implementing the audit programme required a move towards Charles Handy's (1999) 'Task culture' from the existing 'Power culture'.

The author was able to use elements of 'expert power' which were gained through the literature review for securing agreement on the criteria. The diminution of criteria over the stages (Appendix XII) demonstrated resistance to the change itself. In the author's view, it would have been easier to get agreement in a dedicated meeting. By visiting the sites individually the author was not able to use change champions expertise for obtaining agreement. Some criteria which were considered important by the team had to be dropped for this programme due to lack of agreement. The author, at this stage, was in agreement with Waddell & Sohal (1998) viewpoint that 'resistance plays a crucial role in drawing attention to aspects of change that

may be inappropriate, not well thought through, or perhaps plain wrong.’(p. 545).

Level of performance for the audit was agreed as 80% for the structure and process element for each pharmacy, though there is insufficient evidence to determine its necessity (NICE, 2002). The finalised criteria along with level of performance were emailed to pharmacy staff and senior management (Appendix XII). The involvement of staff in agreeing criteria and level of performance helped them to understand the process. It also highlighted the best practices and guidelines available on the topic areas while maintaining enthusiasm towards the change.

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 comprised of 10 criteria and 64 questions and was considered manageable.

During the stages in the agreement of criteria, concerns were expressed by some staff members regarding the data to be collected. To address this issue, it was decided to email the developed audit tool to all the staff members. This new adjustment was made to the implementation plan in order to slow down the development (HSE, 2008b) of the audit tool phase and increase communication. There seems to be consensus among scholars (Appelbaum & Wohl, 2000; Elving, 2005; Gill, 2002) that communication has an effect not only on readiness, but also on addressing uncertainty to change, thus minimising resistance. This addition to the plan helped in obtaining consensus on the data to be collected and addressed concerns around reporting. The process further helped in identifying the confusing items and affirmed the procedure for recording responses. To track the amendments and to avoid unnecessary emails, staff members were requested to email their suggestions directly to the author. The consultation work was done via email and by use of

telephone mostly. The communication method used led to unexpected resistance during the data collection and is discussed later in the chapter.

Upon consultation, minor modifications were made in the language and the structure of some questions in the audit tool to avoid ambiguity or confusion at the data collection stage. The finalised version of the audit tool was emailed to all the stakeholders a month before the collection of data was planned. This demonstrated the first 'short-term win' (Kotter, 2007) for the project.

The data analysis system was developed based upon the reporting and data analysis plans made during the planning stage by the team. Piloting and evaluating the audit tool and data analysis system in advance was logical and necessary as they were designed and developed originally for the project (RCOG, 2003; RCP, 2001a). Audit tool for data collection and analysis system employed for this programme are shown in Appendix XIII and XIV respectively.

3.4.3.2 Data collection

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. Ideally, this should have been done by two staff members. Lack of resources and planning are identified as barriers which can limit the success of audit programmes (Travaglia & Debono, 2009). The team, while designing the project, had taken into account 'time and availability of staff' (identified as a resistor, Appendix VI) but had overlooked the effect of staff annual leave (holidays). The data was collected by the author alone to keep the project on track as some staff members were on holidays.

No cases were excluded for the data collection as all samples were of similar kind. Efforts were made to maintain the accuracy of data collected. Adjustments made during data collection are shown in Appendix XV. For each site, data identifier was used for reporting purposes. To avoid any confusion

later, a copy of data compiled was offered to each site at the time of data collection.

While collecting the data there was unexpected resistance at one site. The leader's behaviour is described as 'bad' if it is associated with bullying and coercion (Higgs, 2009). For the successful completion of the task, the author adopted a facilitative and enabling approach (Higgs and Rowlands, 2005) and visited the site later to complete the data collection in agreement with the staff. Also, dissension was noted towards instructions on the audit tool at another site. The author was able to use 'communication' (Kotter & Schlesinger, 2008) for overcoming the resistance and collected data successfully. The resistance towards instructions was attributed to the fact that, for obtaining consensus on the data to be collected, telephone and emails were used primarily. This meant that all staff members were not able to participate in every discussion. On further analysis of the matter, it was revealed that the instructions were not prescriptive enough. Furthermore, the author had to visit some sites twice due to the volume of data that needed to be collected. The audit tool comprised of 64 audit questions and was initially considered manageable. But during data collection it became apparent that the audit tool was cumbersome.

Data analysis involved identifying cases where compliance was not achieved and to establish the areas that needed improvements. The recorded responses for each site were entered into the data analysis system. Each case not meeting the target was given consideration whether or not the result was due to acceptable circumstances (RCP, 2001a); no such cases were identified. The reasons for variations in results between different pharmacies were not investigated.

3.4.4 Mainstreaming

This stage has two components, to embed the change, and to evaluate and learn. The success of any project is dependent on its leadership being able to

embed the change and has been described in the HSE (2008b) change model as “making it ‘the way we do our business.’ ” (p. 61). This section discusses the first component, and the evaluation component will be discussed in chapter four.

The results of the first audit (Appendix XVI) were emailed to all the pharmacy staff. This was considered necessary to address any concerns around the reporting (NICE, 2002). Staff members were further requested to email suggestions for making improvements in the areas where 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 as a result of the audit. The report was later sent to senior management, including the line manager, exhibiting the second ‘short-term win’ (Kotter, 2007) for the project. No site was individually identified while reporting.

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). The proposal to re-audit within the next two months was supported by the line manager. 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 is shown in Appendix XVII.

The author and the team, from the beginning of the project, were of the opinion that it would be hard to re-audit all the pharmacies. For this reason, plans to re-audit one pharmacy and compare its results with the previous audit were made. The team had failed to explore all avenues available to re-audit all the pharmacies.

While further exploring ways to maintain sustainability and re-enforcing change (Kotter, 2007) consideration was given to conduct the re-audit as a self-audit. The modified audit tool was sent to all the pharmacies and a

request was made to conduct a self assessment. This initiative was further re-enforced by the line manager. It helped to enhance the role of staff in the process and also ensured that the steering of the change did not take the form of micro-management (Young, 2009).

The author has received self-audit forms from four pharmacies and intends to analyse the data in the coming months. Participation of staff in the self-audit demonstrates commitment towards the initiative. Also, it is the intention of the author and some other pharmacists to look at the developed criteria not used for this programme and start a new audit cycle. The records have been made of the audit methodology and change initiative so that the experiences gained can be used for future programmes. There is interest expressed by one pharmacist to conduct another audit involving patients.

The initiative was driven by the author with the support of the change champions. The implementation of this project provided the staff with the experience of implementing an audit programme. In the author's view, a new audit could be developed and implemented, provided staff members are assigned protected time (Daly, 2008; NICE, 2002).

3.5 Summary

The development and implementation of this audit programme using the HSE change model has been achieved. Conducting organisational analysis at initiation and planning stages helped in informing the change process. Staff involvement during the change process, through their approval and resistance, was a key factor in shaping the implementation of this programme. A re-audit was carried out by randomly selecting one pharmacy. The results of the re-audit demonstrate improvements which have led to practice standardisation in the chosen topic areas for the audit. The next chapter will outline and discuss the evaluation process.

Chapter 4: Evaluation

4.1 Introduction

Evaluation has been defined as a process of reviewing an experience, determining its worth or value and deciding what needs to be changed or further developed (HSE, 2008b). While implementing this project a cycle of audit was successfully completed. This chapter evaluates the objectives set out in chapter one of this change project. It also assesses the project in relation to the overall expected outcomes mentioned in the project impact statement.

4.2 Evaluation models and tools

Evaluation is critical to understanding the level of success of an intervention (NCQA, 2007). There are several models for evaluation and the choice should be influenced by factors such as time, resources, expertise and availability of staff. The evaluation model by Kirkpatrick has been categorised as result or goal-based on the typology (McNamara *et al.*, 2010). It is geared towards evaluating training and development programmes. One of the other models used for evaluation is Jacob's ten stage model. The approach of this model is based on stakeholder empowerment, constructivist concepts of knowledge and social transformation. In the author's view, none of the above mentioned models are suitable for evaluating the objectives of this project.

This project involved developing and implementing an audit programme and the impact cannot be fully evaluated unless another audit cycle is initiated. However, it seems logical to put value on the quantity and quality of the effort (NCQA, 2007). For this, while evaluating the objectives, the author intends to address the following:

- What aspects should be enhanced or discontinued for future programmes?

- Is the project implementation having the desired results, and was it worth the investment of time and resources?
- Was the project implemented as planned?

While discussing self-evaluation McNamara *et al.* (2010) states: ‘... quality of student learning has to be seen in relation to the quality of teacher’s learning.’ (p.7). For this reason, to learn further from the initiative it seems worthwhile to compare the outcomes of the project to those expected in the project impact statement.

4.3 Objective evaluation and discussion

4.3.1 Design/develop the audit tool for the DTC pharmacies

The audit tool development involved selecting and agreeing on criteria and questions for the audit programme. It is demonstrated throughout this dissertation report that the participation and involvement of all the stakeholders was given priority. The three stages in the development of the audit tool are shown in Table 1 (detailed in Appendix XII). The participation of all staff in agreeing on criteria helped them to understand the audit process while highlighting the best practices and guidelines available.

Agreeing on criteria and audit questions	Stage One	Stage Two	Stage Three
	Selected from literature review	Agreed initially	Finally agreed
Criteria	14	11	10
Audit questions	133	80	64

Table 1: Stages in development of the audit tool.

To ensure clarity and measurability of the criteria and standards (Travaglia & Debono, 2009) the audit tool was developed over three stages (Table 1). In

stage one, 14 criteria and 133 questions were selected from the literature review. In the second stage, the author visited each site and consulted with the pharmacists who were not involved initially in the development of the criteria. In the third stage, the communication was by emails and telephone. The finalised audit tool with 10 criteria and 64 audit questions is shown in Appendix XIII.

The development of the audit tool over the stages ensured that the agreed criteria were realistic for the capacity of the facilities and acceptable to all the participants (NICE, 2002; Weeks *et al.*, 2010). Resistance has been described as a source of energy and innovation as it encourages the search for alternative methods and outcomes (Waddell & Sohal 1998). Following resistance, an adjustment was made to the implementation plan to get consensus on the data to be collected.

In the results of the evaluation survey (Figure 2), in response to statement five, the staff members unanimously 'strongly agree' that consultation and involvement throughout the development of the audit tool was exercised. They also 100%, 'strongly agree' that the audit process was communicated effectively to them (statement seven). The author concludes that the objective of designing/developing the audit tool in collaboration with staff members, as set out in chapter one, was achieved.

4.3.2 Testing the audit tool

The second objective involved testing the audit tool by collecting data across the eight pharmacies in collaboration with the staff. Data collection was conducted over a two week period by the author. 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. The comparison of results of the data collected at different pharmacies using the audit tool is shown in Figure 1.

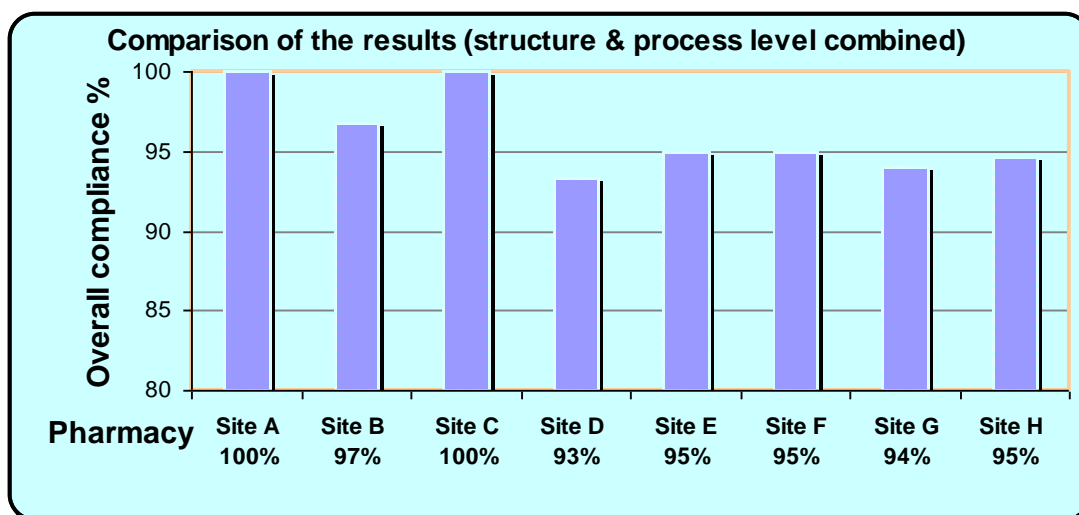


Figure 1: Graphical representation of overall compliance for each site.

During the data collection the author had to visit some sites twice due to the volume of data that needed to be collected. 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. For future initiatives, it would be more beneficial that the data be collected with the help of two staff members and the size of the audit tool for data collection kept smaller.

The data collected using the audit tool, on analysis, was able to capture the compliance with the standards. Each pharmacy was able to identify the areas needed for improvement and see where they stood in comparison to the others. Though the data was collected by the author alone, this demonstrates successful accomplishment of the second objective. Adjustments made during the data collection and the results of first audit are shown in Appendix XV and XVI respectively.

4.3.3 Evaluation of engagement and commitment of staff

To evaluate the engagement of pharmacy staff in the development of the audit tool and commitment towards the audit programme a survey (Appendix

XVIII) was conducted. Out of 16 staff members eight responded. The response rate of 50 % to the survey asserts the fact that cultural and behavioural changes are needed to underpin the change successfully. The respondents agreed to all the statements in the survey and no disagreement was noted.

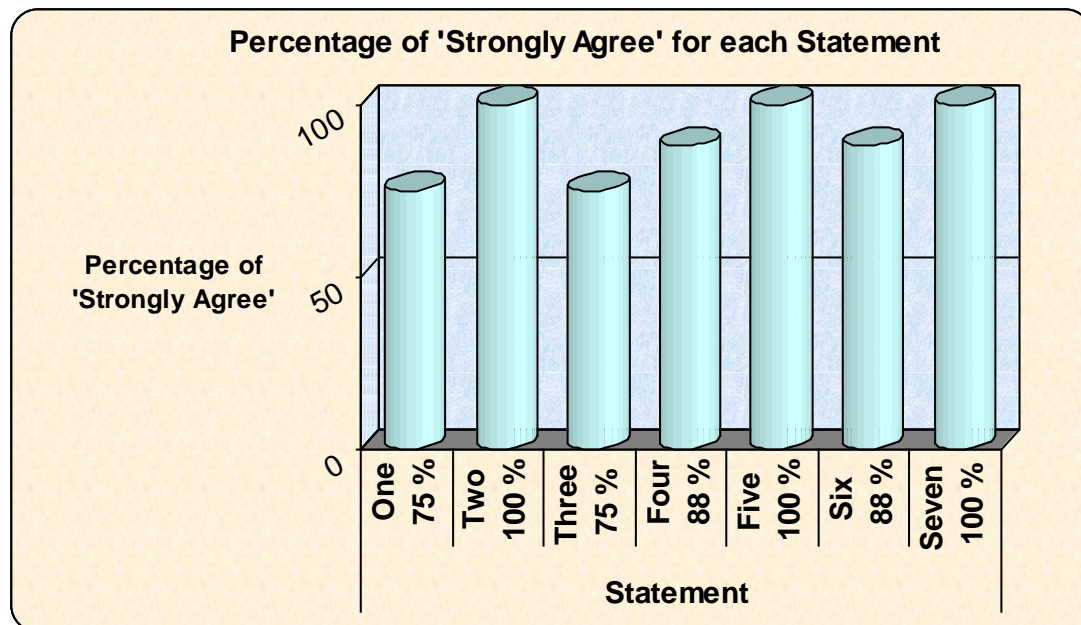


Figure 2: Results of the evaluation survey.

The graphical representation of the results of the survey is shown in Figure 2. All staff members who responded agree unanimously that the programme was implemented in a professional manner (statement two). In total, 75 % of respondents were in strong agreement that the implementation of the audit programme was necessary and relevant for the DTC pharmacies (statement one). Also, the same percentage of staff agreed that the implementation of the programme made them confident to conduct and participate in future audit programmes (statement three). Therefore, in the author's view, implementation of the audit programme was worth the investment of time and resources.

Furthermore, 88 % of respondents said the implementation of the audit programme contributed towards awareness and knowledge of evidence

based best practices (statement six). Also, the same percentage agreed that the audit programme was able to provide fair recommendations for implementing changes (statement four).

The comments by respondents to the evaluation survey are noted below:

- 'I found the audit process a great tool to improve and standardise work practices.'
- 'Personally, I felt the audit was hugely beneficial both in terms of scope and relevance. It would be more beneficial to the service, if all staff were strongly encouraged to undertake at least one audit in their individual base clinic.'

4.3.4 Comparison of results of first audit with re-audit

The fourth objective was to utilize the results of the audit to support the standardisation of practice through a re-audit. From the beginning of the project priority was given to those areas where baseline adherence was suspected to be poor (Ivers *et al.*, 2012; Kongnyuy & Uthman, 2009). The data collection itself had led to changes in behaviour, as had the staff discussions on the topic areas (RCP, 2001a) during the criteria agreement stages. Data analysis of the first audit, which was carried out at all eight pharmacies, showed that there was a move towards standardisation.

The confidentiality of each site was maintained while reporting results. This ensured that implementing the audit programme was seen as a 'no blame' approach for fixing errors (NICE, 2002). Upon reporting of the results, there was an open constructive discussion held in the bi-monthly pharmacy meeting. Practical ideas for making improvements were developed, e.g. loose bottles could be stored in plastic boxes if facilities are not available for proper storage. For each site a responsible person was identified for implementing changes (Copeland, 2005).

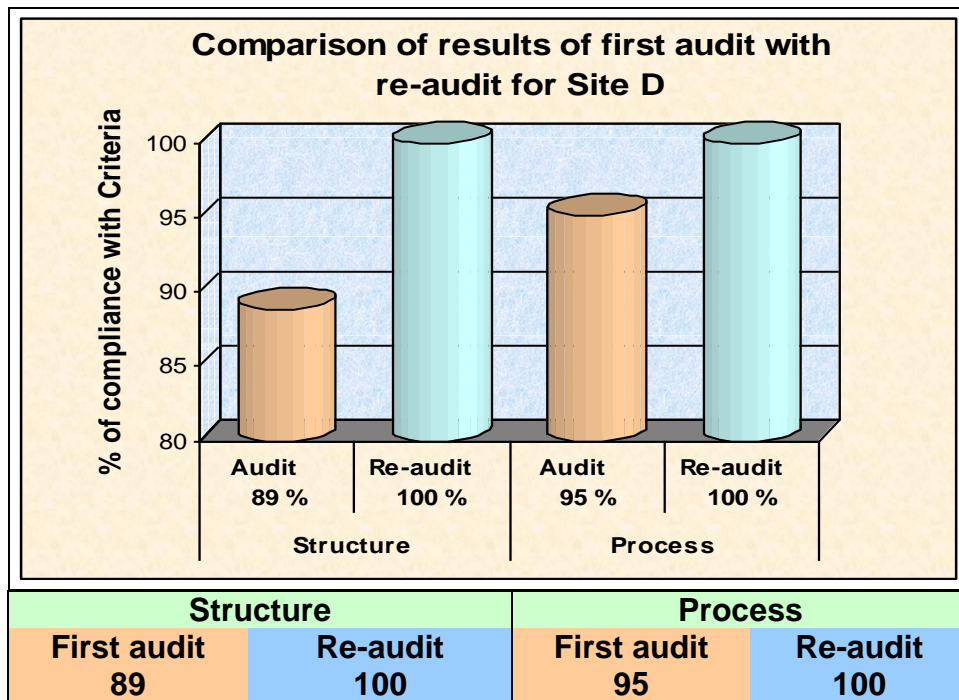


Figure 3: Comparison of results of first audit with re-audit for site D.

The comparison of the results of the first audit with re-audit for one site (at structure and process level) is shown in Figure 3 (detailed in Appendix XVII). The result of the second audit, which was carried out by selecting one pharmacy randomly, further proved that the project was successful. Thus, the fourth objective was achieved, and the implementation of the audit programme had the desired results of practice standardisation and improvement. It demonstrates that the project was implemented as planned.

4.4 Project impact statement

With the implementation of the project a cycle of audit has been completed. In the author's view, it is important to assess the project in relation to the overall expected outcomes mentioned in the project impact statement (Appendix VIII). Realistically, not all the outcomes have been achieved but progress has been made and the summary is as follows:

Behavioural Outcomes - Staff members are familiar with the audit process and the author was impressed by their willingness to get involved. The

implementation of the audit programme aided in better understanding of evidence based guidelines and assisted in standardising practices across all pharmacies.

Structural Outcomes - Training requirements and needs are still determined by management i.e. top-down approach. Responsible staff members have been indentified in each DTC pharmacy for implementing changes. Interest has been expressed but no staff member has taken responsibility for conducting audits.

Personal Outcomes - The author was able to take lead in development and implementation of the audit programme while ensuring participation and involvement of the pharmacy staff. Despite resistance and modifications to the original implementation plan the project was completed on time with the help of change champions.

Cultural Outcomes – Development of the audit tool with staff involvement fostered commitment towards the audit, which supported standardisation and improvement within the department. Practical and cost effective solutions for making improvements were developed. It would be premature to state that there is a continued commitment towards audit.

4.5 Financial impact and benefits

The implementation of the audit programme involved commitment and usage of staff time. This was calculated to be approximately 54 man hours (Appendix XIX). 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 meetings was made throughout the project.

There is awareness of the audit process particularly of the criterion-based audit within the department. Implementing clinical audits is an internationally recognised way of getting evidence into practice (HIQA, 2012). While implementing the project, an audit was successfully carried out using Donabedian (1980) classification of structure and process. At structure level, work area that included equipment, hygiene and storage conditions within the pharmacy were audited. The standardisation and improvement in these areas should have a direct impact on patient health and wellbeing.

At the process level, records and pharmacy operations were audited. It involved auditing dispensing practices and supervision requirements for the controlled drugs, which are known to have the potential for abuse and dependency (PSI, 2011). DTC pharmacies play a crucial role in opiate addiction treatment and auditing these areas should have a wider impact on patient health and community. Though hard to assign a value in terms of monetary gains to the Addiction Services, the benefits of developing and implementing this audit programme outweigh any costs incurred.

4.6 Summary

The participation and involvement of staff was given priority during the development and implementation of the programme. Also, the audit process was thoroughly communicated to all the stakeholders. An audit tool with 10 criteria and 64 audit questions was successfully developed. The data collected using the audit tool was able to capture the compliance with the standards. The response rate of 50 % to the survey asserts the fact that work needs to be done for bringing cultural change. Implementation of the programme increased staff confidence to conduct and participate in future audits. Results of the audit were used to inform practice improvements which led to standardisation. This was confirmed by carrying out a re-audit. Overall, the author is satisfied with the implementation of the audit programme and the feedback compounds this view.

Chapter 5: Discussion and Conclusion

5.1 Introduction

In this final chapter of the dissertation, the strengths and limitations of implementing the project and organisational impact of the change are outlined. The chapter also presents the recommendations for future improvements in the area of audit implementation for the organisation. In concluding this dissertation the author will summarise the change process and reflect on personal learning as a change leader.

5.2 Strengths and Limitations of the project

The approach for this project was 'result- driven' as the change project aimed to develop and implement an audit programme (Appelbaum & Wohl, 2000). For implementing this project the guidelines for audit provided by NICE (2002) and Weeks *et al.* (2010) were followed. The prescription used for effectively managing change was encouraging participation from as many employees as possible, addressing their concerns, and ensuring that the author and change champions acted as role models (Heracleous, 2002). The author, in the role of change agent, was able to demonstrate high adaptability levels during the development of the audit tool and data collection.

The relevancy of the implemented audit programme for the department and communication was given priority at all times. It was effectively communicated that the change is for everyone (Miller, 2001). Support of the line manager and some of the pharmacy staff with previous audit training added anchorage and benefit to the whole project.

The implementation of the project was facilitated by the use of analysis tools in the 'Initiation' stage of the change process. The project was adapted following resistance during the 'Implementation' stage. For communicating the

results of the audit, both active and passive feedback was used (Ivers *et al.*, 2012; RCP, 2001a). Further, it was ensured that practical solutions were developed for implementing improvements required as a result of the audit process.

The pharmacies were located at different sites due to the nature of the specialised service provided by them. The change needed to be implemented across eight pharmacies which made time a limiting factor for the project. While developing the audit tool, to ensure involvement, the author had to visit each site individually.

Further, the data was collected by the author alone and this meant the recorded data was an interpretation of what the author perceived and saw on a particular day. Though the audit tool was piloted (NICE, 2002; Daly, 2008) at two sites earlier, the need for it to be more prescriptive was felt while collecting the data. The validity of the data collected would have been strengthened more if it had been collected with the assistance of another staff member. The variations in results between the pharmacies were not investigated.

5.3 Organisational impact of the change and implications for management

There is an increased emphasis towards conducting audits within the HSE at individual staff and organisational level (HIQA, 2012; HSE 2007; 2010). The successful implementation of this project has helped in the creation of islands of learning within each DTC and has laid the foundations for future audits. It has also highlighted best practices within the department. There is awareness and new expectations towards opportunities to participate in audit programmes (Bowie *et al.*, 2012) within the pharmacy department and other stakeholder groups. The project was felt to be a useful team-building exercise and audits are seen as a positive process rather than a fault finding activity by the department.

The new skills acquired by staff are sustainable resources and can offer a valuable opportunity for strengthening clinical governance within the DTCs. It would be an added advantage if training could be provided to the staff members. Future audit programme results could require financial commitment from management for implementing any changes required. The staff may also need to be allocated protected time (Daly, 2008; NICE, 2002) for conducting audits.

5.4 Recommendations for future improvements

The change project is implemented but not all outcomes have been achieved. The author feels that foundations have been put in place to facilitate future audit programmes. The recommendations for future improvements are as follows:

- A copy of the publication of the author's project distributed to all disciplines. This would provide staff with a working example of the time, resources and steps required to implement an audit programme.
- To induce healthy competition and ensure adherence to the best practices, the name and location of the pharmacy should be identified while reporting and the results made available to all stakeholders.
- Staff members willing to engage in audit programmes need to be encouraged and allocated time specifically for conducting audits. Conducting audits would improve staff understanding of guidelines and best practices, and further help in achieving standardisation across all the DTCs.
- Interested staff should be provided with training and funds should be made available for the audit projects.
- A patient satisfaction survey to improve pharmaceutical care should be explored. This may give feedback on areas where audit is needed and help in enhancing relations between patients and pharmacists.

- A multi-disciplinary audit with patients as stakeholders would be beneficial for the service. For this to succeed, training needs to be arranged for the interested patients and the expectations of patient contact with different members of the team needs to be clarified.
- To implement changes, there is a need to identify responsible staff and leaders within the DTCs. Management has to start exploring ways to develop internal resources rather than relying on external sources.

All the above mentioned recommendations for future improvements can be accomplished if management and staff collaborate. The author's project has set the wheels in motion and provided a benchmark for future audit programmes.

5.5 Conclusion

In conclusion, a vital change project has been developed and implemented despite initial resistance and limited resources. The author has produced a poster to summarise this project (Appendix XX). A new perspective on implementing audits as a way of generating changes (NICE, 2007) and implementing evidence based guidelines has been established. This is acknowledged by staff in the evaluation survey. The success of the project was due to staff involvement and support of management. The author's facilitative and enabling leadership approach was effective in steering the process in the right direction and to a successful conclusion.

The stages in the development of the audit tool provided the author with an opportunity to engage with all staff and take on board their ideas for the audit programme. The staff discussion on the criteria itself led to improvements in the aspects of practice which were taken casually at times. Carrying out an audit further identified the problems which may otherwise have remained unrecognised. The standardisation across DTC pharmacies was enforced by data collection and staff discussions on the results of the audit. This project

has demonstrated the importance of partnership in developing practical ideas for implementing changes.

Bringing change to any organisation only comes about if someone initiates it. Getting all stakeholders on board ensures that a common vision and plan is developed and implemented. The successful implementation of this project has made the author confident in taking on new initiatives and completing them on time, in a professional manner. The author feels that the project was achievable because of the skills and knowledge acquired throughout this course. Overall, the experience shows the author is capable of leading a change process from start to finish while working as part of a team.

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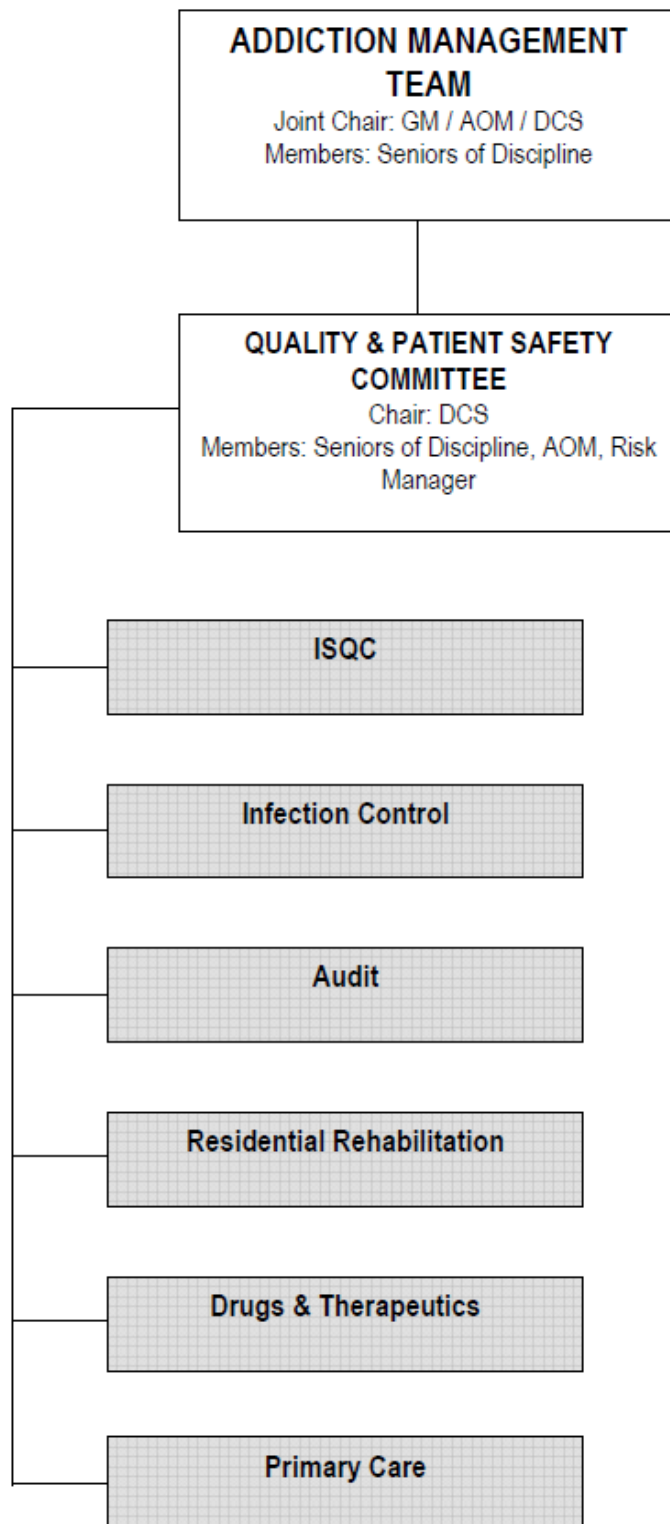
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Appendices

Appendix I – Addiction Service Clinical Governance Framework.



Appendix II – Reference material identified for developing criteria and audit questions.

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

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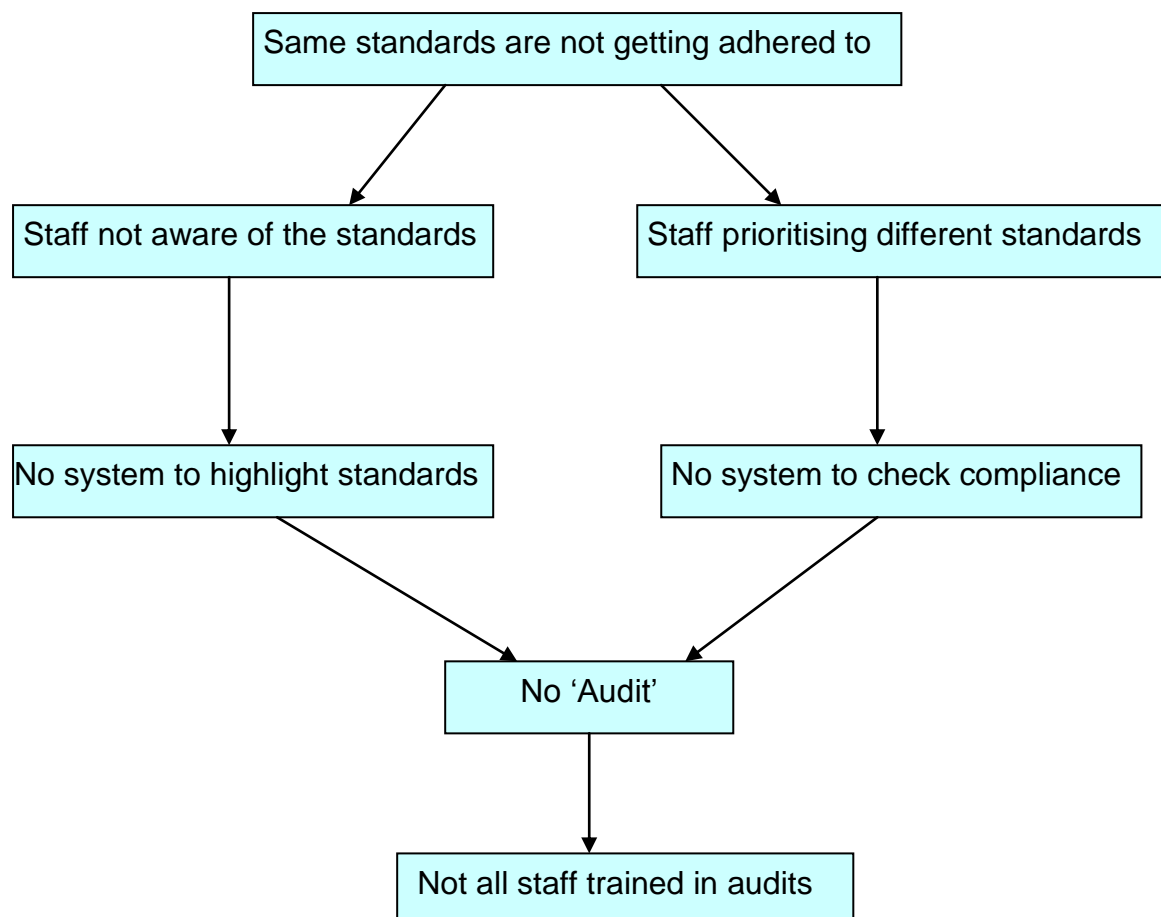
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Appendix III – Five whys.

Defining the problem:

Variations in practices were observed at some sites

Why it is happening?



Appendix IV – Stakeholder Analysis.

<p>High Importance</p>	<p><i>Satisfy</i></p> <ul style="list-style-type: none"> ▪ Line manager (Chief pharmacist) 	<p><i>Manage</i></p> <ul style="list-style-type: none"> ▪ Pharmacy staff (with and without audit training)
<p>Low Importance</p>	<p><i>Monitor</i></p> <ul style="list-style-type: none"> ▪ Doctors ▪ Counsellors ▪ Nurses ▪ Outreach ▪ General assistants ▪ Secretaries ▪ Patients 	<p><i>Inform</i></p> <ul style="list-style-type: none"> ▪ Senior management (Area Manager & Deputy Area Manager) ▪ Chair of Audit Committee.
	<p>Low influence</p>	<p>High influence</p>

Appendix V – SWOT Analysis.

To assist in assessing capacity for changes a SWOT analysis was done. A SWOT analysis as per Ansoff (1965) is an analysis of an organisation's strengths, weaknesses, opportunities and threats in order to decide on actions to be taken

Strengths	Weakness
<ul style="list-style-type: none">⊕ Support of Chief Pharmacist⊕ IT skills within Pharmacy department.⊕ Pharmacists with previous training in Audits.⊕ Existing Clinical Governance framework in Addiction Services.⊕ Financial support from management.	<ul style="list-style-type: none">⊕ Audit programme has to be implemented at different locations.⊕ Communication has to be primarily by emails and telephone as pharmacies are situated at different sites.⊕ Audit tool for data collection needs to be developed in collaboration with the staff.⊕ Data analysis system to be developed.⊕ Improvements identified as a result of the audit need to be made across eight pharmacies.⊕ Financial constraints in the HSE.
Opportunities	Threats
<ul style="list-style-type: none">⊕ To act on National Standards for Safer Better Healthcare (HIQA, 2012).⊕ To improve safety.⊕ To create culture of quality enhancement.⊕ All dispensing sites will be standardised.⊕ To develop new policies.	<ul style="list-style-type: none">⊕ Change in management.⊕ Time needed by the staff to carry out activities and implement changes.⊕ Increase in workload of staff.⊕ Staff morale due to further cuts.⊕ Organisational culture.⊕ Sub-culture at different dispensing sites.⊕ Autonomy of dispensing sites.

Appendix VI – Force-field Analysis

For determining the actions needed to support the implementation of the programme drivers and resistors were identified. As recommended by Kurt Lewin (1951), resisting forces were reduced rather than increasing the driving forces for implementing the change.

Drivers →	← Resistors
<p>Chief Pharmacist →</p> <p>Pharmacy staff enthusiasm →</p> <p>Pharmacists trained in audit before →</p> <p>Professional development →</p> <p>Need for new pharmacy equipment →</p> <p>Move towards best practices →</p>	<p>← Status quo</p> <p>← Audit may highlight bad work practices</p> <p>← Increase in workload of pharmacy department</p> <p>← Concerns around staffing within the pharmacy department</p> <p>← Time and availability of staff</p> <p>← Budgetary restrictions</p> <p>← Lack of knowledge regarding audit</p> <p>← Lack of training in audit</p>

Appendix VII – Agreed topics, scope and objectives for the audit.

Topics for audit

Donabedian (1980) system of classification	Agreed topics for the pharmacy audit
Structure	Work area
Process	Records
	Operations
Outcome	None - As team were of the view that for measuring the 'outcome' input of other disciplines would be required, which was outside the scope of this audit.

Scope: This audit is for the Pharmacy department only and will be carried out at all dispensing sites. The criteria for this audit will be derived from the Health Service Executive (HSE) Addiction Services policies, laws governing the Pharmacy profession and guidelines provided by the Pharmaceutical Society of Ireland (PSI).

Objective: The objectives of this audit are to standardise and improve aspects of the pharmacy work area (dispensary), record keeping and operations.

Appendix VIII – Project Impact Statement

Describe here how things are now in relation to the issue	Describe here how things should (ideally) be when the issue has been addressed
<p><u>Behavioural</u>: describe current patterns of behaviour /attitudes of the key people involved with the issue</p> <ol style="list-style-type: none"> 1. Staff not familiar with the audit programme. 2. Management keen to implement audits but due to financial constraints no training provided. 3. Staff aware of evidence based guidelines but variations in practice exist. 	<p><u>Behavioural</u>: what sort of behaviours would (ideally) be evident when the issue has been addressed?</p> <ol style="list-style-type: none"> 1. Staff familiar and participating in the audit programme. 2. All pharmacy staff would demonstrate better understanding of evidence based guidelines and should be able to implement them across all the pharmacies.
<p><u>Structural</u>: describe the way roles and responsibilities are currently organised</p> <ol style="list-style-type: none"> 1. Training requirements and needs determined by management i.e. top- down approach. 2. No responsible person for implementing changes within the DTC pharmacies. 3. No staff member responsible for conducting audits. 	<p><u>Structural</u>: describe how roles/responsibilities would be organised once this issue has been addressed</p> <ol style="list-style-type: none"> 1. Training and needs would be provided by management on staff request i.e. bottom-up approach 2. Responsible person identified within each DTC pharmacy for implementing changes. 3. Staff members identified for conducting audits.
<p><u>Personal</u>: describe how you participate in and contribute to the current reality</p> <ol style="list-style-type: none"> 1. I try my best to adhere to evidence based guidelines 2. I try to use available resources and to develop a systematic approach to empower staff. 	<p><u>Personal</u>: describe how you will participate in and contribute to the new reality</p> <ol style="list-style-type: none"> 1. I will personally take lead in developing and implementing an audit programme while ensuring participation and involvement of staff.
<p><u>Cultural</u>: describe “how things are done around here” now, e.g. accepted ways of doing things, implicit understandings</p> <ol style="list-style-type: none"> 1. Variations in work practice are currently accepted. 2. Change initiatives have cost implications and should be declined. 3. ‘We are doing our best’. 	<p><u>Cultural</u>: what will be “the way things are done around here” when the issue has been addressed?</p> <ol style="list-style-type: none"> 1. Upon implementation of an audit programme staff should adhere to required standards. 2. Practical and cost effective solutions for implementing changes would be developed. 3. Continued commitment towards audit.

Appendix IX – Gantt chart

Healthcare Audit	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	March	April	May
Prepare for audit	Win support and commitment	Agreeing on scope and objectives							
Selecting Criteria		Literature review	Agreeing on criteria and standards						
Measuring performance				Develop audit tool	Piloting the tool				
			<u>Short-term Win</u> →	Circulate finalised audit tool	Data collection	<u>Short-term win</u> ↓			
					Data analysis	Reporting			
Making improvements							Identifying barriers and implementing changes		
Sustaining improvements								Developing structure and systems	
								Re-audit one pharmacy	
Write up study									Conclude
Submit Thesis									20 th May

Appendix X – DICE framework.

According to Sirkin *et al.* (2005) projects with DICE scores between 7 and 14 were usually successful. Those with scores over 14 and less than 17 are unpredictable and the projects with scores over 17 were usually unsuccessful.

The factors that determine the outcome of any transformation initiative.		Points	Dice Score = $D + 2(I) + 2(C1) + C2 + E$		Zone
D.	Duration	1	1	8	'Win Zone' (Projects with scores between 7 and 14 are usually successful)
I.	Integrity	1	2		
C.	The commitment to change by top management (C1)	1	2		
	Commitment of employees affected by the change (C2) display.	2	2		
E.	Effort	1	1		

Appendix XI – Reporting and data analysis plans for the first audit.

Reporting was to be done by:

- a. active feedback using Criterion analysis for each site; and
- b. passive feedback using Structure/Process and Question/response analysis.

Based on the reporting the data analysis for the first audit would involve:

1. Criterion analysis for each site: The purpose of this section would be to discuss the results with the pharmacists at each site.
2. Structure/Process analysis for each site: This would highlight the level of performance for each element and would be used for reporting results.
3. Question/response analysis: This would also be used for reporting results. The purpose would be to identify the criteria which require attention regardless of individual pharmacy results achieved in Structure and Process analysis.

Appendix XII – Agreed criteria and level of performance for audit tool

Agreed topics for the Pharmacy audit		<u>Stage One</u>	<u>Stage Two</u>	<u>Stage Three</u>	Level of performance (target)
		Criteria developed	Criteria agreed initially	Criteria agreed finally	
Structure	Work area	6	4	3	80%
Process	Records	3	3	3	80%
	Operations	5	4	4	
	Audit questions	133	80	64	

Criteria are classified using Donabedian system (SPO model) into structure and process. Structure element includes criteria 1, 2 and 3 and the Process element has criteria 4 to 10. The target for this audit is 80 % for structure and process element for an individual site (pharmacy).

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 (2012) 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.
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

Appendix XIII – Audit tool for Data Collection

Audit of the Pharmacy Department

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

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

		y/n	na
Please check			
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?		

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

		y/n	na
Please check			
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)?		

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

		y/n	na
Please check			
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 °C?		

- 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.

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

Appendix XIII – 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	na
Please select 6 patients randomly to check all three (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	na
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 XIII – 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 <u>label</u> match to what is dispensed?		
2	Does the label for the methadone take-away bottle clearly state these warnings? <ul style="list-style-type: none"> • 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 XIII – 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	na
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?		

Contributors:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

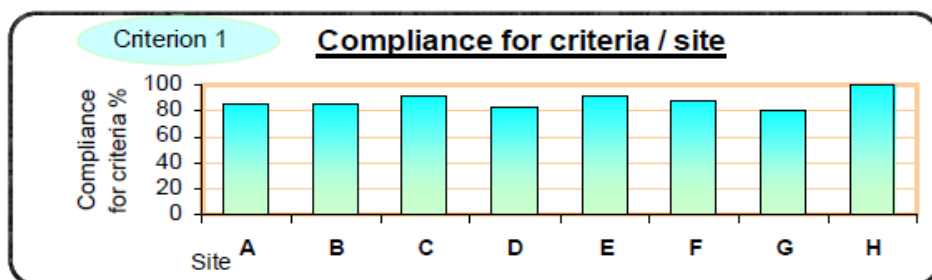
Criteria and audit questions agreed by:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Appendix XIV – Data Analysis system sample

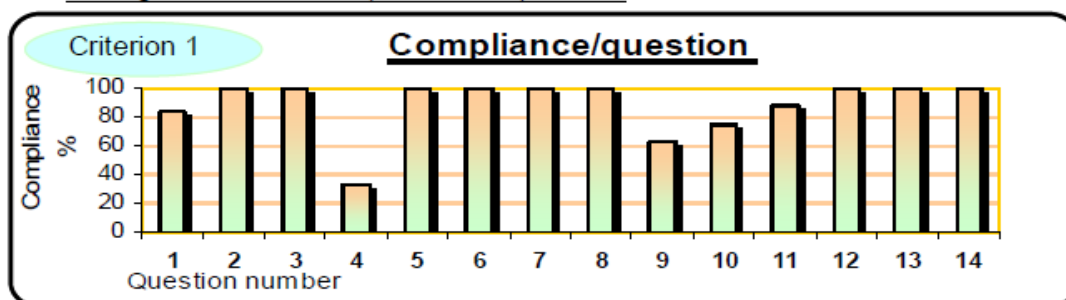
Data analysis tool was developed using Microsoft Excel 2003. Functions like 'COUNTIF' and 'IF' along with average were used. Further rounding off was done for percentages. Conditional formatting was used to highlight percentages of 'Yes' to identify any shortfalls in compliance

Quo.	Criterion 1																Compliance
	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	y/n	na	
	Site A		Site B		Site C		Site D		Site E		Site F		Site G		Site H		
1	y		y		y		n		y		y		na		na		5
2	y		y		y		y		y		na		y		na		6
3	y		y		y		y		y		y		y		y		8
4	n		n		y		n		y		na		n		na		2
5	y		y			na		na		na		na		na		na	2
6	y		y			na	y			na		na		na		na	3
7	y		y		y		y		y		y		y		y		8
8	y		y		y		y		y		y		y		y		8
9	n		n		n		y		y		y		y		y		5
10	y		y		y		y		y		n		n		y		6
11	y		y		y		y		n		y		y		y		7
12	y		y		y			na		na		na		na		na	3
13	y		y		y		y		y		y		y		y		8
14	y		y		y		y		y		y		y		y		8
	12	0	12	0	11	2	10	2	10	3	8	5	8	4	8	6	



Percentage of 'y' for Criterion 1 per site (for 14 Questions)	
Site	Percentage
A	86
B	86
C	92
D	83
E	91
F	89
G	80
H	100

Orange = need attention (less than 80)



Percentage of 'y' achieved per questions.

Question	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Percentage	83	100	100	33	100	100	100	100	63	75	88	100	100	100

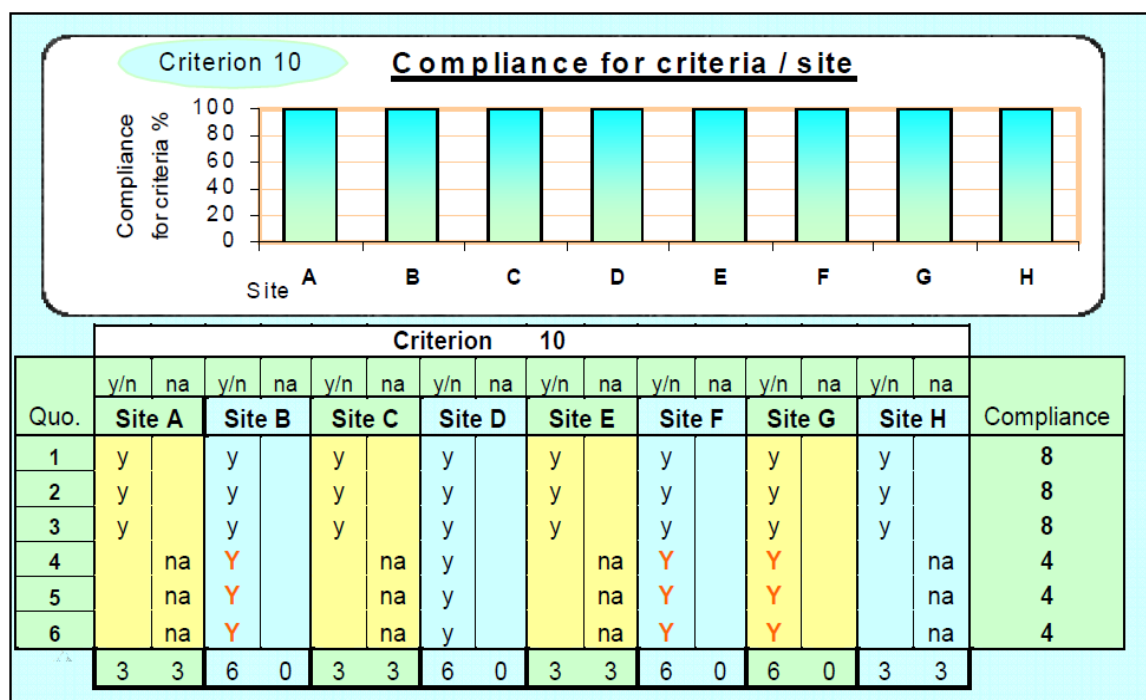
Orange = need attention (less then equal to 70)

Yellow = monitor (from 71 to 79)

Green = Acceptable (80 and above)

Appendix XV – Adjustments made during data collection.

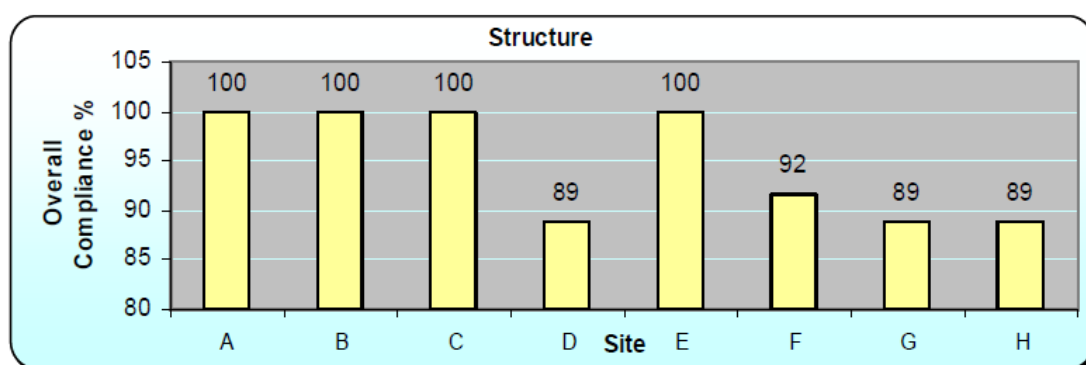
For Criterion 10, during the data collection, assumptions were made in response to questions four to six for three sites (site B, F and G). This was done due to the fact that the patients for the supervised consumption of Suboxone were not present at the time of data collection and is marked by red colour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



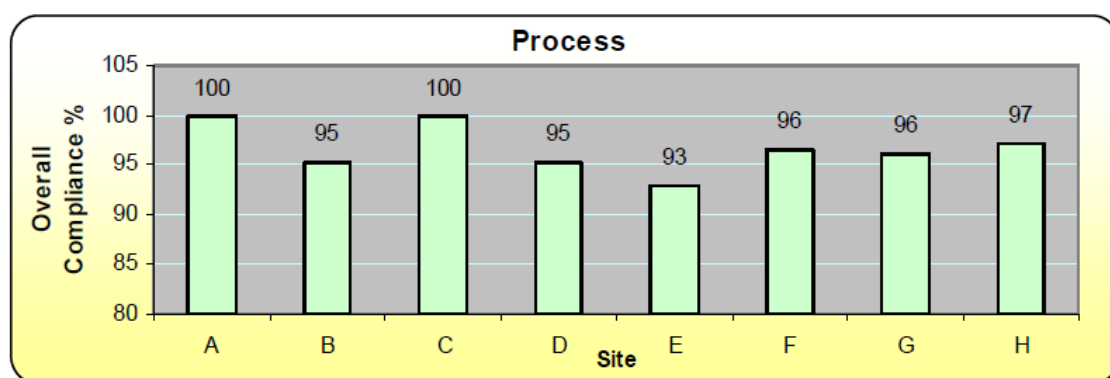
Appendix XVI – Results of the first audit

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 9 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

Appendix XVI – Continued

Question/response analysis :

It was mentioned in a previous email that the questions which have compliance rate:

- (i) of less than or equal to 70 %, will require policies or guidelines to be developed in consultation with pharmacy staff;
- (ii) between 71 to 79 %, will merit discussion regarding possible improvements; and
- (iii) 80% or above will be considered acceptable.

Out of 64 questions only 12 had a response rate of less than 100 %.

	Data items	Overall compliance
1	Are methadone bottles and tablet vials in closed drawers, if not are the lids applied to them?	63%
2	Does medication name on the label match to what is dispensed?	63%
3	Are medicines the only product stored in the pharmaceutical refrigerator?	80%
4	Is the Methadone register free from any obliterations, cancellations and alterations (any corrections are made by dated marginal note /footnote)?	88%
5	Is daily audit printout done on the day to which it relates or within 24 hours of that date?	88%
6	Does patient's date of Birth in Q-Script match with that on Methadone /Suboxone list?	88%
7	Is record of drugs received by Pharmacy (from Central Pharmacy) kept in a folder/book?	88%
8	Are records kept of medications supplied to nursing staff?	75%
9	Are records of checking pump calibration present?	75%
10	Is handwritten prescription for Suboxone present to support the current Suboxone list?	75%
11	Is Volume of methadone dispensed recorded in the appropriate space on the lists on a daily basis?	88%
12	<p><i>Does the label for the methadone take-away bottle clearly state these warnings?</i></p> <ul style="list-style-type: none"> • 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. 	88%

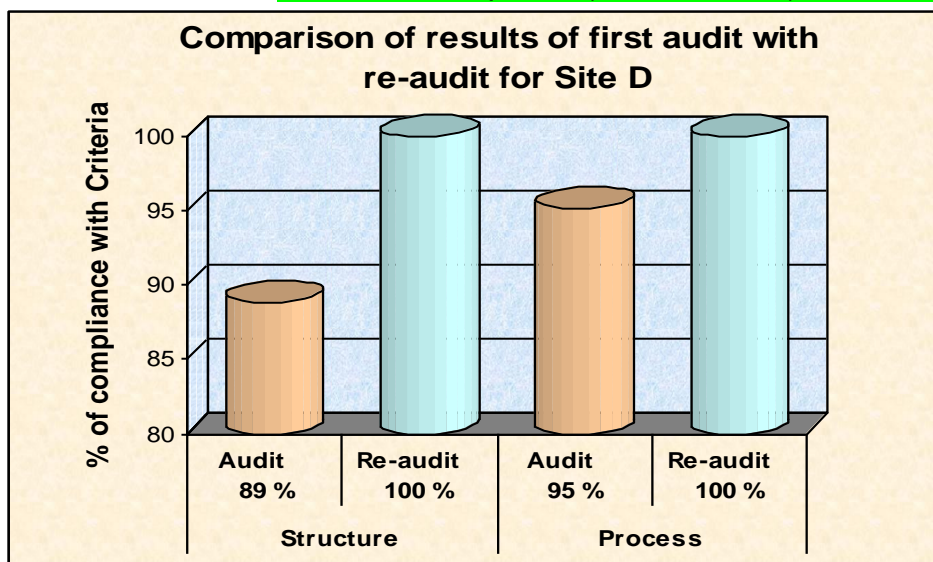
Appendix XVII – Comparing results of the first audit with re-audit for Site D.

Comparison of results for Site D

Orange = need attention (less then equal to 70)

Yellow = monitor (from 71 to 79)

Green = Acceptable (80 and above)



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

Site D	Audit	Re-audit
Criterion 1	100	100
Criterion 2	67	100
Criterion 3	100	100
Structure	89	100
Site D	Audit	Re-audit
Criterion 4	100	100
Criterion 5	67	100
Criterion 6	100	100
Criterion 7	100	100
Criterion 8	100	100
Criterion 9	100	100
Criterion 10	100	100
Process	95	100

Appendix XVIII – Evaluation survey.

(1)	(2)	(3)	(4)
Strongly disagree	Disagree	Agree	Strongly agree

Give each statement a grade from 1 to 4 to indicate your choice

1	The audit programme was necessary and relevant for the DTC Pharmacies:	
2	The audit programme was implemented in a professional manner:	
3	The implementation of the programme made staff more confident to conduct or participate in future audits:	
4	The audit programme results provided unfair recommendations for changes and improvements:	
5	The staff were consulted and involved throughout the development of the audit tool process:	
6	The development of the audit tool process did not contribute towards awareness and knowledge of evidence based guidelines:	
7	The audit process was communicated effectively to staff/ management:	

Additional Staff/ Management comments:

Appendix XIX – Approximate staff time utilised for implementing this audit programme


Activity undertaken	Approximate man hours
Agreeing on topic, scope and objectives	3
Literature review	15
Agreeing on criteria and audit questions	10
Develop and pilot the audit tool and data analysis system	8
Data collection	8
Data analysis	5
Reporting and discussing results for implementing changes	3
Re-audit and reporting	2
Total	54

Appendix XX – The poster for dissemination of the change project.

The Implementation of an Audit Programme across Drug Treatment Centre (DTC) Pharmacies

Student ID.10106995

MSc in Healthcare Management,
Institute of Leadership, Royal College of Surgeons in Ireland



RCSI
ROYAL COLLEGE OF SURGEONS IN IRELAND
COLAISTE BÍOGA NA MÁINLEÁ IN ÉIRINN
Institute of Leadership
www.rcsileadership.org

Introduction

It is the duty of all healthcare professionals to ensure that they deliver the best care to their patients.¹ There is an increased emphasis towards conducting audits within the HSE at individual staff and organisational level.^{1,2}

There have been audits before in the DTCs but the scope of them was localised. The DTC pharmacies, due to the nature of the specialised services they provide, are situated at different sites. Variations in practices were expected and accepted due to different staff operating at different sites.

Change Process

➤ The HSE Change Model (Fig.1) was used for developing and implementing the audit programme across the DTC pharmacies.

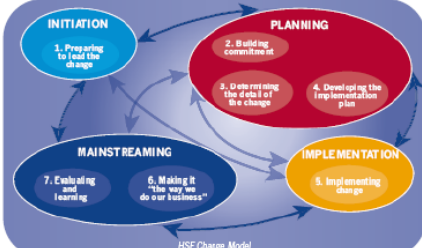


Figure 1: HSE Change Model.⁴

Evaluation

➤ The audit tool with 10 criteria and 64 questions was designed/developed using Donabedian SPO classification⁸.

➤ Data was collected at 8 sites (Fig.2).

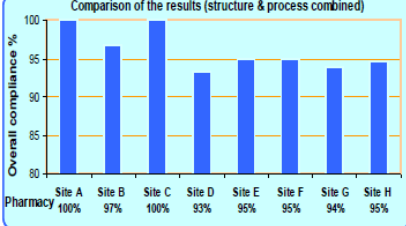


Figure 2: Graphical representation of overall compliance with criteria for each site.

➤ A survey was conducted to evaluate staff engagement and commitment.

➤ A re-audit was conducted at one site, and results compared (Fig.3).

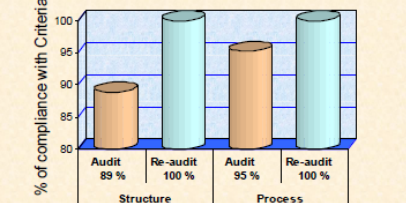


Figure 3: Comparison of results of first audit with re-audit for site D.

Aims & Objectives

Aim:

- To develop and implement a Healthcare audit³ programme across eight DTC pharmacies within an eight month period.

Objectives:

- To design/develop an audit tool in collaboration with the staff.
- To test the audit tool by collecting data across the DTC pharmacies.
- To foster engagement in the development of an audit tool and commitment to a programme of audit amongst pharmacy staff throughout the project.
- To utilize the results of the audit to support the standardisation of practice through a re-audit.

Initiation

- Identify need for change & stakeholders
- Buy-in from management & staff
- Identify change champions
- SWOT and Force-field analysis
- Agree scope & objectives for the audit programme

Planning

- Timeline for implementation established
- DICE score⁵ = 8 = 'Win Zone'
- Literature reviewed for criteria & audit questions
- Plans made for data collection, analysis & reporting

Implementation

- Criteria & audit questions agreed
- Following resistance ⇒ process slowed down⁴ & communication increased⁶
- Audit tool designed/developed & finalised (short-term win⁷)
- Data collected & analysed

Mainstreaming

- Results reported (short-term win⁷)
- Staff members identified for implementing changes
- Repeat audit done at one site
- Conduct re-audit as self-audit
- Commence new audit cycle

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Organisational Impact

➤ The successful implementation of this project has helped in the creation of islands of learning within DTCs and has laid the foundations for future audits.

➤ The project was felt to be a useful team-building exercise and audits are seen as a positive process rather than a fault finding activity.

Conclusion

A vital change project has been developed and implemented despite initial resistance and limited resources. A new perspective on implementing audits as a way of generating changes⁹ and implementing evidence based guidelines has been established. The success of the project was due to staff involvement and support of management.

