

Evaluation of the HSE Naloxone Demonstration Project



Feidhmeannacht na Seirbhíse Sláinte
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HSE Naloxone Demonstration Project

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On behalf of the HSE
Commissioned by:
HSE National Social Inclusion Office

HSE Foreword for the Naloxone Demonstration Project

Naloxone is a semi-synthetic competitive opioid antagonist medication recommended by the World Health Organisation (WHO) for the treatment of Opioid overdose. In 2014 the WHO released guidelines recommending that 'People likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose'. Ireland has one of the highest rates of drug overdose in Europe and in 2013 in 42% of deaths where heroin was implicated the individual was not alone when the drug was taken. This represents a situation where, in line with WHO recommendations, a specific intervention with Naloxone could have saved a life.

The Naloxone Demonstration Project is therefore both a response to the WHO recommendations and also a response to Action 40 of the National Drugs Strategy (2009-2016) aimed at tackling the harm caused by the misuse of drugs. This was also a key action of the 2015 HSE Primary Care, Social Inclusion operational plan.

The project aimed to provide training in four locations around the country in relation to the recognition of and response to an overdose occurring due to opioid drugs. Training was provided to service users, service providers, family members and front line workers. In addition there was an active Train the Trainer component to the programme. During the project, close to 600 people received training and 31 people participated in the 'Train the Trainers' component of the project. Six General Practitioners were involved in the medical assessments and prescribing of 95 prescriptions of naloxone. Most importantly the evaluation notes that five administrations of naloxone occurred resulting in the prevention of five potentially fatal overdoses.

An important element of the demonstration project is this external evaluation that documents and reports on the implementation of the complete programme. As both a process and outcome evaluation this document represents a comprehensive overview of the naloxone demonstration project utilising qualitative and quantitative research methods. The final report presented here clearly demonstrates the significant benefits delivered to service users, service providers and family members alike. Credit must go to the reviewers for producing such a high quality piece of work that will have ongoing implications for the HSE Addiction services for years to come.

I am pleased to accept this evaluation and welcome the very positive findings. Particular thanks must go to Dr Denis O'Driscoll, Chief Pharmacist HSE Addiction services, who led and managed the whole project in an extremely professional and effective manner. Without his dedication and enthusiasm the project would not have been the success that is evident in this evaluation. The HSE Primary Care/ Social Inclusion division will continue to support the roll-out of the recommendations and the project in the knowledge that this initiative will result in further saving of lives.

Dr Eamon Keenan

National Clinical Lead HSE Addiction Services

Table of Contents

Executive Summary		page 5
Chapter One	Introduction	page 11
Chapter Two	Literature Review & Context	page 16
Chapter Three	Demonstration Project Implementation	page 27
Chapter Four	Outcomes & Early Impact	page 40
Chapter Five	Conclusion and Recommendations	page 51
Appendix 1	Quality Assurance Group Membership	page 60
Appendix 2	Photographic exhibition	page 61

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We thank Denis O' Driscoll, Chief Pharmacist, for his diligence and attention during the course of the field work. Our intention is that this research will deepen understanding of Naloxone as part of a suite of harm minimisation tools for those at risk of overdose, for front line workers in relevant service providing organisations and family members who wish to be prepared to care for their loved ones in the event of an overdose situation.

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Executive Summary

Naloxone is a medicine recommended by the World Health Organisation for treatment in opioid overdose cases. It acts by reversing, within minutes, the effects of opioid overdose. Its efficacy has been proven internationally.

The Naloxone Demonstration Project was established by the Health Service Executive (HSE) in 2015 to test the feasibility of making Naloxone available for use by opioid users in order to prevent death from overdose. The Demonstration Project falls under Action 40 of the *National Drugs Strategy (2009-2016)* which aims to tackle the harm caused by misuse of drugs. The Naloxone Demonstration Project fits within all four tiers of service provision in the National Drug Rehabilitation Implementation Committee's (NDRIC) framework and, in lay administration it has potential to be particularly useful in tiers one and two.

Ireland has one of the highest drug overdose rates in Europe. Opioids alone accounted for 7% of all 'poisoning deaths' in 2012¹ and opioid related deaths (ORDs) made up of single drug and poly-drug frequency was 220 (263 in 2011). Forty-two percent of people who died deaths where heroin (injecting or smoking) was implicated were not alone at the time they took the drug². This suggests that there may have been an opportunity to prevent these deaths through the administration of Naloxone.

The product used in the Naloxone Demonstration Project was Prenoxad™ (1mg/ml injection). It was made available in consultation with the Health Products Regulatory Authority (HPRA) and the Department of Health (DoH) as an unlicensed medicine as it has additional labelling to allow for lay administration in the Summary of Product Characteristics (SmPC). It is injectable, administered via the parenteral route and formulated in a specific overdose pack. Each pre-filled syringe contains five doses of Naloxone. The intention was that after a single individual use this use would be reported in accordance with agreed practice. The pack would be then be then discarded appropriately and the patient referred to their agreed point of contact for replenishment.

The Chief Pharmacist, Addiction Services, HSE, was authorised to lead and manage the Demonstration Project. All supplies of Naloxone were channelled through the Project Lead who was responsible for all procurement and replenishment of supply. The Naloxone Quality Advisory Group (QAG) was established to oversee the implementation of the project. Four locations were selected for the Demonstration Project - Dublin, Waterford/South East, Limerick and Cork. The Train the Trainer programme was delivered and representatives from each location attended. The rollout progressed steadily in Dublin and Limerick and moved more slowly in Cork and Waterford.

¹ HRB, 2014, 'Drug-related deaths and deaths among drug users in Ireland', Dec 2014

² http://www.hrb.ie/uploads/tx_hrbpublications/NDRDI_web_update_2004-2013.pdf

Factors that supported the speed of rollout in a given location included prior awareness of and engagement with the Project, presence of local champions, belief in the potential of Naloxone and the Project to make a difference, proximity to the Project leadership, willingness and capacity of local GPs to engage and support from the National Family Support Network.

A central element of the Demonstration Project was the formal briefing of drug users and training of those close to them (e.g. service providers, front line workers and family members) in the use of Naloxone and in recognising and effectively managing overdose events. A Train the Trainers component was also included for frontline staff in services. A full suite of training resources was developed.

Thirty-one individuals took part in the Train the Trainers component of the training. As of August 2015, 492 people took part in multi-disciplinary, multi-agency training sessions with more groups trained subsequently resulting in close to 600 people in total receiving the training.

A total of 95 prescriptions of Naloxone were issued during the Demonstration Project. The majority (67%) of these were issued in Dublin and the remainder (33%) were issued in Limerick. Six GPs in total were involved in the medical assessment and prescribing of these prescriptions³. During the time of the Demonstration there were no prescriptions issued from the other two Demonstration locations, Waterford and Cork. Prescriptions in Waterford commenced subsequently.

During the course of the Demonstration Project there were five administrations of Naloxone and potentially fatal overdoses were prevented for the five males involved. Four of the Naloxone administrations were administered by front line workers and one was administered peer to peer. All had participated in the Naloxone training delivered during the Demonstration Project.

In each of the incidents the Naloxone was administered to a person other than to whom it had been prescribed. This suggests that the availability of and easy access to Naloxone was crucial to the successful reversal of overdose. In two instances more than one dose of Naloxone was administered from the five dose syringe. This was judged necessary during the wait for the ambulance to arrive and deemed to work well.

In all instances an ambulance was called and at least one person or staff member remained with the patient until emergency services arrived as recommended during the training. In two instances the patient was admitted to hospital and discharged after a short period of observation.

³ Five in Dublin and one in Limerick

The front line workers managed the situations effectively and followed through on the precise steps that they had learnt and practiced during their training. Three of these were interviewed soon after the incident and all indicated a sense of pride and relief, empowerment and enhanced confidence to manage these types of situation.

The activation and engagement of a full range of stakeholders in the Demonstration Project was supported by the open and inclusive approach and communication from the outset. There was a partnership way of working between community and voluntary sector and the HSE and raising awareness of Naloxone within NDRIC and social care and community networks. Family members and the National Family Support Network were included and actively involved. There was openness to learning and constructive criticism which supported continuous improvement.

Feedback from stakeholders also points to areas that require attention. These include adopting a more measured and strategic approach to consultation post Demonstration. The drawing in of the full suite of stakeholders, especially those who doubt the Project, is an important success determinant. Some organisations and/or stakeholder groups are more cautious with respect to delivery of new programmes and need time to assess potential impact on their current service delivery. The presence and involvement of service user networks and organisations within the communication about Naloxone could be strengthened. More time could be invested in consultation pre implementation through formal and structured engagement with specific groups, e.g. service users, family members, GPs, trainers, etc. This would benefit from the support of a centre point of communication to manage ongoing consultation, briefings and PR during implementation.

The recommendations are summarised below and are set out in priority order of necessary action. Chapter Five contains the detailed rationale for each recommendation.

Recommendation One - Communication & Consideration

- 1.1 The results of this report should be discussed, early in 2016, within the QAG and the National Social Inclusion Unit within the HSE, to inform the action plan for the future.

Recommendation Two - Governance

- 2.1 The QAG should be strengthened by broadening its membership to include wider clinical expertise and clinical governance and more regional representation.
- 2.2 The terms of reference of the QAG should be revisited and revised accordingly.
- 2.3 The QAG should discuss possible options as to the best way forward for Naloxone and agree the strategy to achieve this, accompanied by an action research plan overseen by the QAG.

Recommendation Three - Planning and Preparation for Future Roll Out

- 3.1 The roll out of Naloxone should continue, in a measured, phased and strategic way, with attention on the Waterford/South East and Cork in the first instance. There should be dedicated resources and personnel assigned to Naloxone roll out in each region.
- 3.2 The phased roll out should be driven by the Chief Pharmacist and commence with an initial briefing/consultation with HSE personnel and relevant stakeholders in each location, e.g. professional bodies, GPs, pharmacists, clinical nurses and social care workers.
- 3.3 One other region should be drawn in, based on the NDRDI⁴ data, over the next twelve months.
- 3.4 There should be specific administrative support dedicated to the Naloxone roll out.

⁴ National Drug-Related Death Index, Health Research Board

Recommendation Four - Refining the Training

- 4.1 The Naloxone Training should be continued, incorporating the learning from this evaluation.
- 4.2 The training should be accredited by an appropriate body⁵.
- 4.3 A training schedule should be prepared and disseminated prior to delivery of any further training.
- 4.4 The scheduling of the Train the Trainer component should be such that participants have an opportunity to *practise* and apply their learning as soon as possible (ideally within three months) after receiving the training.
- 4.5 Accredited CPR training, delivered by a qualified and accredited tutor(s), should be built into the training programme⁶.
- 4.6 Opportunities for refresher training, peer support and reflective practice should be built into the suite of future training.
- 4.7 Collaborative work with the National Family Support Network should continue so as to include family members in all future training and development events.
- 4.8 There should be ongoing evaluation of all future training.
- 4.9 Pre and post training evaluation forms should be modified to include participant profile data

⁵ This is already in train in consultation with the Pharmaceutical Society of Ireland.

⁶ This is being introduced.

Recommendation Five – Briefing of Service Users

- 5.1 Training/briefing of service users in the use of Naloxone should continue and be informed by the learning from this evaluation of the Demonstration.
- 5.2 Training/briefing of service users should be monitored carefully. Front line staff members who deliver the training/briefing should be supported to ensure quality and consistency.
- 5.3 All front line workers should be trained and supported to work with their hard to reach clients.
- 5.4 Specific attention should be paid to monitoring those service users who have been briefed and prescribed Naloxone. This should include tracking their health, well-being and drug related behaviour over time, e.g. through replenishment records, repeat overdose incidents, etc.⁷

Recommendation Six – Research, Tracking and Monitoring

- 6.1 There should be continued research in Ireland in relation to Naloxone. A central theme will be the monitoring of the effect of Naloxone in reducing the number of fatal overdoses.
- 6.2 The research should be multi-disciplinary and overseen by the QAG with a particular emphasis on clinical governance. Partnering with an academic establishment or research organisation will drive and support future research.
- 6.3 There should be quarterly meta-analysis of the risk assessment forms (F2) and post incident forms (F5) to note any patterns in medical risk, drug related behaviour, frequency and features of overdose. It is important that there be continued vigilance in full completion of these records by all those responsible, i.e. pharmacists, GPs and front line workers.
- 6.4 The work that commenced during the Demonstration in cultivating the connections/relationships with peers in other countries implementing Naloxone, e.g. Wales and Scotland, should continue.

⁷ Currently all those participating in the Naloxone programme have given their consent to the sharing of their data for monitoring purposes.

Chapter One Introduction

1.1 Introduction

This report provides an account of the external evaluation of the Naloxone Demonstration Project that was rolled out in Ireland by the Health Service Executive (HSE) during 2015.

The HSE is committed to actions that serve to reduce the number of drug-related deaths and near-fatal drug poisonings. A key action set out in the Primary Care Division Operational Plan 2015 was to *“Implement a Naloxone Demonstration Project to assess and evaluate its suitability and impact (in line with National Drug Strategy Action 40).”*

1.2. Aims & Objectives of the Naloxone Demonstration Project

The purpose of the Naloxone Demonstration Project was to test the feasibility of making Naloxone available for use by opioid users in order to prevent death from overdose.

Naloxone is a medicine (an ‘opioid antidote’) commonly used by healthcare professionals and ambulance services to reverse the effects of an opioid overdose⁸ and bring the person back to consciousness. Prenoxad™ (1mg/ml injection) was made available under Summary of Product Characteristics (SmPC) agreed with the Department of Health. It is injectable, administered via the parenteral route and formulated in a specific overdose pack. It has additional labelling to allow for lay administration. Each pre-filled syringe contains five doses of Naloxone. The intention was that after a single individual use this would be reported in tune with agreed practice. The pack would be then be discarded appropriately and the patient sent back to their agreed point of contact for replenishment.

A central element of the Demonstration Project was the formal briefing of drug users and training of those close to them (e.g. service providers, front line workers and family members) in the use of Naloxone and in recognising and effectively managing overdose events.

The Demonstration Project aimed to involve 600 people receiving take-home Naloxone within the current legislative framework. The primary target population was drug users at risk of opioid overdose in the community and ex-prisoners on release.

⁸ Definition of Opioid Overdose: difficulty breathing, turning blue, lost consciousness, unable to be roused, collapsing occurring in conjunction with opioid use (opioids such as heroin, methadone, morphine, oxycodone, tramadol, fentanyl or codeine).

1.3 Budget

The Demonstration Project was funded through the HSE National Social Inclusion Office. The final budget agreed was €62,500 to cover administration, design and delivery of training across the four demonstration sites, distribution of the Naloxone kits, recording and tracking of prescription, research and external evaluation

1.4 Management & Governance

The Project was led by Denis O'Driscoll, Chief Pharmacist, Addiction Services, HSE. As Project Lead he was authorised to manage the Demonstration Project with responsibility for developing the project plan, implementing and monitoring the project schedule, financial oversight and performance monitoring. All supplies of Naloxone were channelled through the Project Lead who was responsible for all procurement and replenishment of supply.

The Naloxone Quality Advisory Group (QAG) was established to oversee the implementation of the project (see Appendix for membership).

The objectives of the QAG were to:

- Oversee planning and roll-out of a Naloxone Demonstration.
- Advise on the evaluation of the pilot.
- Make recommendations for next steps following the evaluation.
- Publish findings in a peer reviewed journal.
- Plan and oversee required proposal/action (e.g. legislative changes) to support legal provision of Naloxone to opioid users and their family members.

1.5 Scope of the Evaluation

This external evaluation was commissioned by the HSE to accompany the Demonstration Project, to document and report on the implementation.

There were two elements to the evaluation: a process evaluation and an outcome evaluation.

The aim of the *process evaluation* was to determine the nature and quality of the programme implemented by investigating:

1. The implementation of the main elements of the programme.
2. The nature and quality of the training sessions.
3. Participants' views of the programme as a whole.

The aim of the *outcome evaluation* was to investigate:

1. Learning and other outcomes from the training sessions.
2. Practical application of Naloxone in overdose situations.
3. Practical application of other harm-reduction actions in overdose events.
4. The effect of Naloxone in reducing the number of fatal overdoses.

1.6 Evaluation Methodology

The evaluation formally commenced in **June 2015**. The field work was action research oriented, given the nature of the Demonstration Project, and was conducted between **June and October 2015**.

The methodology included a blend of qualitative and quantitative research techniques in order to meet the terms of reference. The principle component of the methodology was a classic stakeholder analysis designed to invite inclusive and voluntary input into the evaluation process across the full range of stakeholders. This was purposefully intended to fit with the unfolding implementation across four different locations and in anticipation of potential variance across these sites.

The following is a summary of the main elements in the methodology:

Desk Research:

- A review of recent, relevant literature with a particular focus on noting the use of take-home Naloxone in other jurisdictions, e.g. Scotland and Wales.
- Review of all training records and resource materials developed and used during the Demonstration, e.g. training manuals, videos, resource packs, scheduling and administration documentation.
- An open e-invitation was issued by the Chief Pharmacist to all stakeholders to contribute to the evaluation process by contacting the evaluation team directly and in confidence during the course of the Demonstration Project. This was structured around the following e-questionnaires some of which were returned on line and others discussed during research visits and/or telephone interviews conducted by the evaluators:
 - E-questionnaire for completion by front line workers (6)
 - E-questionnaire for completion by managers of services (3)
 - E-questionnaire for completion by trainers (6)
- Analysis of all secondary data relevant to the Project, e.g.

- SPSS analysis of pre and post training questionnaires (n=492), containing Opioid Overdose Knowledge Scale (OOKS) and Opioid Overdose Attitude Scale (OOAS)⁹ to gauge progression post training.
- Prescriptions issued and replenished and related data (excel spread sheets from two of the pilot sites - Dublin and Limerick).
- Incident Follow Up Reports (Form 5).

Field Research:

- Consultations and ongoing communication with the HSE Chief Pharmacist/Project Manager of the Demonstration Project. The purpose of these consultations was to:
 - Track the Demonstration Project as it unfolded.
 - Access data on roll out of training including nature of the learning, quality, attendance, challenges arising, etc.
 - Access data on prescriptions issued and replenished, risk analyses conducted, service user assessment, etc.
 - Gain access to key stakeholders including trainers, HSE personnel, medical professionals, front line workers, family members, etc.
 - Note strengths and weaknesses of the process.
- Consultations with the Quality Advisory Group (QAG). The purpose of these consultations was to:
 - Gain their input into the evaluation from the outset (both individually and as a group).
 - Present an interim report in September 2015 for consideration and discussion (meeting to discuss this on 6th October 2015).
 - Become alert to challenges as the Demonstration Project unfolded.
 - Record drug related deaths.
- Observation of training delivery at Merchants Quay Ireland (MQI) on 4th August 2015.
- Research visits to a sample of four service providers¹⁰ for consultation with management and staff trained in the use of Naloxone.

⁹ This scale was developed and validated by Anna Williams, John Strang and John Marsden from the Addictions Department, Institute of Psychiatry and Psychology and Neuroscience, Kings College, London. The psychometric properties were tested and published in: Williams, AV, Strang, J & Marsden, J (2013). Development of Opioid Overdose Knowledge (OOKS) and Attitude (OOAS) Scales for take home naloxone training evaluation. *Drug Alcohol Dependence*. 132(1-2): 383-6.⁹

¹⁰ Merchants Quay Ireland, Ana Liffey Drug Project (Midwest), Cedar House, Mc Garry House, Novas Initiatives, Limerick.

- Consultations with medical professionals (6) and relevant HSE senior personnel (7) working in social inclusion and substance misuse nationally and within the four demonstration sites.
- Consultations with family members who attended Naloxone training sessions (4).
- Case stories of Naloxone administration during the life time of the Demonstration Project (5 case stories).

1.7 Structure of this Report

Following this introduction, Chapter Two presents a review of the literature and sets the Demonstration Project in context. Chapter Three describes the implementation of the Project and Chapter Four looks at early outcomes and impact. Chapter Five draws conclusions and offers pointers to inform decision making in relation to further roll out of Naloxone and related supports.

Chapter Two Literature Review & Context

This chapter sets out the salient points from a review of recent, relevant literature and policy documentation. It places the Demonstration Project in context as one intervention in the suite of Ireland's responses to the increase in drug related deaths.

2.1 Drug-Related Overdoses

Ireland has one of the highest drug overdose rates in Europe. Data from the National Drugs Related Death Index (NDRDI)¹¹ showed that in 2012 all 'poisoning deaths' related to drugs came to 350 (down from 384 in 2011). Opioids alone accounted for 7%, analgesics which had an opioid compound was 5%, poly-substances including opioids (e.g. methadone, analgesics, heroin) was 40%. In total, opioid related deaths (ORDs) made up of single drug and poly-drug frequency was 220 (263 in 2011). The median age for all poisonings was 40 (it was lower for men at 38 and higher for women at 49). This concurs with the international experience where most deaths occur in experienced drug users in their late 20s and early 30s rather than in inexperienced drug users. The Irish age profile is a little higher and seems to reflect an ageing population on methadone treatment¹². Recent Irish data indicates that over two fifths (42%) of people who died of deaths where heroin (injecting or smoking) was implicated were not alone at the time they took the drug. This suggests that there may have been an opportunity to prevent these deaths through the administration of Naloxone.¹³

2.2 National Drugs Strategy

The overall objective of the National Drugs Strategy (2009-2016) is to tackle the harm caused by misuse of drugs. The actions set out to achieve this centre on reduction in supply, prevention, treatment, rehabilitation and research. Action 40 relates specifically to the Naloxone Demonstration Project in that it refers to responding to drug related deaths through three specific actions. The first action is the development of a National Overdose Prevention Strategy, which is in progress. The second is a coordinated response to the rise in deaths indirectly related to substance abuse. The third action is a review of the regulatory framework in relation to prescribed drugs.

¹¹ HRB, 2014, 'Drug-related deaths and deaths among drug users in Ireland', Dec 2014

¹² HSE Central Treatment List

¹³ http://www.hrb.ie/uploads/tx_hrbpublications/NDRDI_web_update_2004-2013.pdf

2.3 NDRIC

The National Drugs Rehabilitation Implementation Committee (NDRIC) was set up to oversee and monitor implementation of recommendations from the Report of the Working Group on Drug Rehabilitation (2007); to develop agreed protocols and Service Level Agreements (SLAs); to develop quality standards, building on existing standards; to oversee case management and care planning processes, and to identify core competencies and training needs and ensure these needs are met.

NDRIC developed a framework for drug rehabilitation interventions (2010). The framework arose out of recommendations made by the Working Group on Drugs Rehabilitation¹⁴.

The NDRIC framework aims to assist service providers to plan and implement a range of approaches to provide an Integrated Care Pathway for former and current drug users. The framework recognises that drug users have many and varied needs, which may require a range of supports and interventions by different service providers.

The research shows that well coordinated service provision eases client navigation through the system and strengthens the possibility of effective care and treatment. Good coordination increases efficiency in gathering and managing client data and minimises any need for clients to provide the same information repeatedly to multiple organisations. This generates an encouraging sense of positive movement and progression for clients as they encounter different services in the course of their treatment and care.

NDRIC describes a Rehabilitation Pathway in the context of four tiers of service provision. The first tier includes interventions with a primary focus on psycho-social care and support, e.g., family support, training and employment support, education, access to accommodation and suitable housing support, etc. The second tier centres on treatment related interventions, e.g. pharmacies, primary care, community-based services, specialist addiction services, etc. The third tier comprises specialist treatment related interventions in prison, community and/or hospital settings. The fourth tier is specialist dedicated inpatient or residential units and wards. The Naloxone Demonstration Project fits within all four tiers of service provision and Naloxone (as a lay administration) has potential to be particularly useful in tiers one and two.

2.4 Naloxone

Naloxone is a medicine recommended by the World Health Organisation for treatment in opioid overdose cases. It acts by reversing the effects of opioid overdose within minutes. Its efficacy has been well proven internationally.

Naloxone has been in use in Ireland in intravenous form in medical settings, for many years, by emergency services personnel and healthcare professionals. Intramuscular and nasal take home versions of the product have been introduced in other countries.

¹⁴ Report of the Working Group on Drugs Rehabilitation, May 2007, HSE

A national Naloxone Advisory Group (established to oversee the design, delivery and evaluation of an educational intervention for overdose prevention and Naloxone distribution by general practice trainees¹⁵) determined that the intervention of choice is the intranasal formulation (IN). This formulation has yet to be authorised and licensed on the European market, recently an IN has been licensed for use in the USA (www.adaptpharma.com/press-releases/).

The version of Naloxone used in the demonstration project was an injectable prefilled syringe (Prenoxad™) containing five doses (0.4ml). This product has additional labelling for lay administration in cases of emergency. It is a prescription only product.

Overall, the research suggests that Naloxone is suitable for precautionary carrying on their person by those who use opioids (e.g. heroin), are participating in opioid substitution therapy (e.g. methadone), leave prison with a history of opioid use and/or have previously used opioid drugs and a history of overdose.

2.5 Application of Naloxone – International Findings

The average annual number of drug-related deaths over the nine year period 2004-2011 was 346¹⁶. Opioid overdose accounted for over sixty percent of fatal overdoses in Ireland.

Naloxone is an opioid antagonist that can temporarily reverse the effects of opioid overdose. This can provide a window of opportunity to prolong a life while waiting for emergency services to arrive and medically treat a person who has overdosed. Naloxone can be administered intramuscularly, intravenously or by nasal spray. The Demonstration Project used the intramuscular version of the product.

Research by Wheeler¹⁷ concluded that providing Naloxone kits to laypersons has the potential to reduce death as a result of overdose, is safe to administer and cost effective.

Naloxone has been available to counteract drug overdose in the USA for over two decades and in some EU countries (e.g. Italy) since the 1980s. It was introduced in Wales in 2009 and in 2011, Scotland was the first country to adopt take home Naloxone (THN) as a funded public health policy. Evaluations of both the Scottish¹⁸ and Welsh¹⁹ pilot projects were conducted.

¹⁵ 'Development and process evaluation of an educational intervention for overdose prevention and naloxone distribution by general medical practice trainees', Jan Kilmas, Mairead Egan, Helen Tobin, Neil Colman and Gerard Bury. BMC Medical Education (2015) 15:206

¹⁶ NDRS 2012, HRB 2014

¹⁷ Wheeler, E., et al, 2014, 'opioid Overdose Prevention Programs Providing Naloxone to Laypersons – United States 2014', Centers for Disease Control and Prevention.

¹⁸ Watt, Glenys, et al, Research Findings No. 51/2014. Service Evaluation of Scotland's National Take Home Naloxone Programme.

¹⁹ Bennett, T., Holloway, K., 2011, 'Evaluation of the Take Home Naloxone Demonstration Project', Ymchwil Gymdeithasol Social Research No.13

The combined learning from these evaluations is summarised below.

- A clear management and reporting structure is an important success determinant for the roll out of Naloxone as a public health measure in any location. For example, in Scotland a national co-ordinator was appointed in a dedicated capacity to oversee local management of the project.
- Better results were achieved when participants participated in all the components of the training, e.g. recognising and managing an overdose episode, role play/practice in administration of Naloxone, CPR, simulation etc. This concurs with the findings of recent research conducted in Ireland by Kilmas *et al* and reported in the BioMed Central²⁰. This research found that simulation was the most effective training delivery method.
- Incremental and phased roll-out of the programme enhanced adjustment, acceptance and higher uptake.
- Including prisons as a setting for Naloxone training and administration works well. The research shows that as many as half of drug overdoses occur with ex-prisoners²¹. However, because prisoners on release could possibly obtain their Naloxone twice, i.e. when leaving prison and when in the community, this must be carefully monitored as it has potential to distort the data.
- The most effective way to deliver Naloxone training to service users is through one-to-one briefings and through outreach rather than in groups.
- The research alerts us to the importance of time and process in generating awareness and understanding of the value and potential of Naloxone. The training performs an important function in this regard. As more people participate in the training and more kits are distributed people's understanding and appreciation of Naloxone and its use is growing. Leading by example takes time and yet works well with a critical mass of people paving the way for others.
- Trainers in community sites in Wales reported better learning outcomes and benefits than those in prison sites.
- The main benefits cited, arising from the Naloxone training, were improved knowledge and understanding of opioid overdose, improved ability to recognise the signs of an opioid overdose and clearer understanding of the correct actions to take in an overdose situation. Other outcomes included improved skills to successfully conduct CPR and place a person in the recovery position correctly and to administer Naloxone.

²⁰ 'Development and process evaluation of an educational intervention for overdose prevention and naloxone distribution by general medical practice trainees', Jan Kilmas, Mairead Egan, Helen Tobin, Neil Colman and Gerard Bury. BMC Medical Education (2015) 15:206

²¹ Zander, et al, 2005, 'National Investigation into Drug Related Deaths in Scotland', www.scotland.gov.uk/Publications/2005/08/03161745/17507

- Participants expressed greater confidence and willingness to administer Naloxone. Participants who were drug users were more likely, after attending the Naloxone training, to have increased contact with the relevant support agencies and to want to receive testing for Hepatitis C and HIV. There were also reported incidents of drug users re-evaluating their heroin use and the harms relating to it.
- The main reasons for re-ordering Naloxone kits were kits being lost or mislaid, use of the kit on self or another (more usually the latter), and kits passing their expiry date. In a small percentage of cases, kits were confiscated by the authorities.
- The results from the pilot project in Scotland show that around 5% of the Naloxone kits distributed were used to assist in an overdose incident. The figure for Wales was somewhat higher at 7%. Subsequent national monitoring data for Scotland suggests at least 6% and more likely 9% usage.
- Data from Wales indicates that of 22 reported cases of overdose where Naloxone was administered, 21 survived and one did not (96% survival rate). Of note are the additional seven people who experienced an overdose episode but declined assistance.
- The survival rate showed no measurable difference in outcomes when compared with the control group. The common factor in both groups was that there was someone there able to help and support. It is likely that this *capable human presence* increases the likelihood of survival and this warrants further monitoring and research over time to confirm. The number of overdose events that were not witnessed and went on to be fatal or recoverable was unknown. Case studies of deaths where Naloxone was not administered showed that the majority were alone at the time of overdose.
- Those who had received training in the use of Naloxone were more likely to use other harm reduction actions such as CPR, placing the person into the recovery position correctly, calling for an ambulance and calling the police. Having a capable individual present who can take effective action is critical to survival.
- In Scotland, re-supply due to loss of the product was quite common (44% of community re-supply).
- Sufficient supply and availability of Naloxone is a key success determinant. Bird et al (2014)²² recommend that nations gauge the sufficiency of provision against a target of twenty times their (most recent past) mean annual number of opioid related deaths, with minimum provision being at least nine times this number. Applied in an Irish context this means annual supply of between 2,030 and 4,500 would be required.

²² Bird, S.M., Parmar, M., Strang, J., 'Take-home naloxone to prevent fatalities from opiate-overdose: Protocol for Scotland's public health policy evaluation, and a new measure to assess impact', *Drugs, Education, Prevention and Policy*, 2015, 22 (1), p.66-76

However, based on the experience of Glasgow²³, where there is a comparable addiction population and experience of the Irish demonstration project to date, the Chief Pharmacist estimates that annual supply is more likely to be around 600 per annum.

- It is generally recognised that General Practitioners are important stakeholders in the successful delivery of Naloxone. Some medical professionals express reservations about the use of Naloxone by laypersons. While this is understandable, the research to date indicates that the risks of Naloxone misuse have been reported as very low²⁴.
- The engagement of GPs and their acceptance and championing of Naloxone is an important determinant in the successful reach of any programme. A study in Scotland by Matheson et al (2014)²⁵ highlights a number of challenges to positive participation by GPs in any such programme. These challenges included:
 - Substance misuse is not generally considered part of the expected everyday body of work for GPs.
 - Challenge for GPs to find time to attend training in general.
 - Concerns about drug user behaviour and attitudes. Some expressed concern that the availability of Naloxone might influence negative changes in behaviour, e.g. those who were previously fearful of using heroin might start using if Naloxone is available or existing heroin users might increase their dosage as a result of the availability of Naloxone (there is no evidence to date of this negative effect).
 - Perception of drug users where drug use is viewed as more of a criminal matter than a health matter.
 - GPs see their primary role as one of prescribing, and not of briefing or training (e.g. in the use of Naloxone) with most feeling this work is more suited to nurses, key workers, addiction counsellors, etc.
 - The research indicates that providing a strong clinical evidence-base for the use of Naloxone will encourage GP participation. Payment is also a factor. Most believe that the preferred person to deliver Naloxone briefings to patients is the front line worker with most contact with the patient. This is rarely a GP.

Research²⁶ in the US found that organisations providing syringe exchanges and harm reduction programmes for injecting drug users were early adopters of opioid overdose prevention

²³ The number of kits supplied in Glasgow was no more than 599 in any given year.

²⁴ Ashworth, A. J. & Kidd, A. 2001, 'Take Home Naloxone for Opioid Addicts. Apparent Advantages may be balanced by Hidden Harms.' *British Medical Journal*, 323, 935.

²⁵ Matheson, C., et al, 2014, 'Reducing drug-related deaths: a pre-implementation assessment of knowledge, barriers and enablers for naloxone distribution through general practice', *BMC Family Practice* 2014, 15 (12).

²⁶ Doe-Simkins, M., et al, 2009, 'Saved by the nose: bystander administered intranasal naloxone hydrochloride for opioid overdose', *American Journal of Public Health*, 99, p.788-91; Enteen, L., et al 2010, 'Overdose prevention and naloxone prescription for opiate users in San Francisco', *Journal of Urban Health*, 8, p.931-41

programmes, including the use of Naloxone. This suggests that there is a cultural predisposition and preparedness to embrace such measures.

A scan of evaluations of the use of Naloxone indicates high survival rates where it is administered. There is little comparative data available about outcomes that occur without the use of Naloxone. A study in Chicago indicated that heroin related overdose deaths in Cook County fell by 20% in the year after the introduction of Naloxone and 10% in the subsequent two years²⁷. Research by Bird et al²⁸ found that 19 out of 20 cases of accidental overdose will be resolved irrespective of whether or not Naloxone is administered.

Source	Deaths prevented : lives lost when Naloxone used	Deaths prevented : lives lost when Naloxone not used
USA Los Angeles (Wagner et al 2010)	26:4 (87%) ²⁹	Na
USA San Francisco (Seal 2005)	15:0 (100%)	Na
USA New York (Galea 2006)	10: 0 (100%)	Na
USA Baltimore (Tobin 2009)	19: 0 (100%)	Na
Wales (Bennett 2011)	21:1 (96%)	38:1
Scotland Glasgow (Shaw 2008)	10:1 (95%)	Na
Scotland Lananhshire (McCauley 2010)	2:1 (67%)	Na
U.K. South east/south west, midland/.north (Stray 2008)	12:0 (100%)	6:1
Ireland demonstration project	5:0 within a five month period ³⁰ (100%)	Na

²⁷ Maxwell, et al, 2006, 'Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths', The Haworth Press.

²⁸ <http://informahealthcare.com/dep> ISSN: 0968-7637 (print), 1465-3370 (electronic)
Drugs Educ Prev Pol, 2014 Early Online: 1-11

Take-home naloxone to prevent fatalities from opiate-overdose: Protocol for Scotland's public health policy evaluation, and a new measure to assess impact. Sheila M. Bird, Mahesh K. B. Parmar, and Professor John Strang.

²⁹ A total of 35 overdose events were recorded but the outcomes in respect of 5 were unknown.

³⁰ There were three more reported administrations of Naloxone in the period after this evaluation was completed, i.e. November - December 2015.

2.6 Impact of Naloxone

A survey by Wheeler et al (2014) of 140 managers of organisations in the US known to provide Naloxone kits to lay persons found that from 1996 to June 2014 surveyed organisations had provided Naloxone kits to 152,283 laypersons and had received reports of 26,463 overdose reversals (17%)³¹.

The European Monitoring Centre for Drugs and Drug Addiction (2015)³² completed a meta-analysis of available studies on take-home Naloxone. The results found that educational and training interventions complemented by take-home Naloxone affected a decrease in overdose related deaths and improved knowledge and attitudes about the correct use of Naloxone and the management of witnessed overdoses amongst opioid-dependent patients and their peers.

2.7 Cost effectiveness

Research, in the United States, by Coffin and Sullivan (2013)³³ into the cost effectiveness of lay distribution of Naloxone found that it was cost-effective in every scenario examined. It was found to be cost-saving when it resulted in fewer overdoses and/or medical emergency activations. Coffin et al estimated that 6% of national deaths due to overdose would be prevented by distributing Naloxone and that one death would be prevented for every 227 kits distributed.

2.8 Training & Briefing in the Use of Naloxone

There are a range of methods to disseminate training and briefing in the use of Naloxone.

The methods include:

- a cascade method whereby a core group of healthcare professionals (or other professionals) are trained to train other healthcare professionals, who in turn train front line workers to brief drug users;
- direct provision of training to drug users and their families;
- direct provision of training to mixed groups of professionals who in turn train drug users, and
- direct provision of training mixed groups of professionals and drug users.

The most effective single method for disseminating training in the use of Naloxone has not yet been identified³⁴. The challenges noted in relation to achieving effectiveness with the cascade methods relate to the large size of caseloads and people, while well intentioned, are too busy to train/brief others.

³¹ Wheeler, E., et al, 2014, 'Opioid Overdose Prevention Programs Providing Naloxone to Laypersons – United States', *Morbidity and Mortality Weekly Report*

³² EMCDDA, 2015, 'Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone', Luxembourg.

³³ Coffin, P., Sullivan, S., 2013, 'Cost-effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal', *Annals of Internal Medicine*, 158, p.1-9.

³⁴ Mayet et al, 2011, 'Impact of training for healthcare professionals on how to manage an opioid overdose with naloxone: Effective dissemination is challenging', *International Journal of Drug Policy*, 22, p.9-15

The results of this research for the Irish Demonstration Project also point to challenges in terms of scheduling training/briefing sessions, maximising attendance, achieving consistency of input across locations and groups, post course evaluation and support.

The nature, quality and extent of training is also important including the delivery methods (e.g. face to face tutoring, simulation/practice/role plays and/or DVD) use of resource materials and whether the learning is group based or one to one. A study of family members and carers, many of whom witness overdoses³⁵, showed that group-based training resulted in better outcomes on the Overdose Knowledge scale and the Overdose Attitudes scale than those who received information only by way of a booklet with DVD enclosed. The group based learning environment offered information using oral presentation (tutor) and DVDs combined with practice in the correct actions to take in an overdose event. This includes practice in administering Naloxone.

The Scottish evaluation found that one-to-one training in a community setting was more effective than group training but that group training could be effective in a prison setting³⁶.

Other non-injectable forms of delivering Naloxone have been developed. For example, in April 2014 the FDA approved a new hand-held auto-injector specifically designed for family members and caregivers. Furthermore, there are two clinical trials currently underway in Denmark and Norway examining the use of injectable Naloxone with the use of a mucosal atomizer device (MAD). This is attached to the injection and sprayed into the nostrils.

2.9 Legislative Context

Under existing legislation, Naloxone is licensed in Ireland in injectable form for provision to a patient through a prescription from a medical doctor.

There was significant preparation and ground work completed in advance of the Demonstration. The following is a summary of the steps that paved the way for the Naloxone Demonstration Project in Ireland:

- During a meeting between the HSE and Department of Health in May 2013 it was agreed that the Demonstration Project would operate within the confines of existing legislation. A number of possible locations were considered.

³⁵ Strang et al, 2008, 'Family carers and the prevention of heroin overdose deaths. Unmet training need and overlooked intervention opportunity of resuscitation training and supply of naloxone', *Drugs: education, prevention and policy* 15 (2), p.211-218

³⁶ Watt, G. et al, 2014, 'Service Evaluation of Scotland's National Take-Home Naloxone Programme', Scottish Government Social Research.

- There was detailed discussion between the Chief Pharmacist, the HSE and the Department of Health about the product and which version of Naloxone was appropriate and legal for use in Ireland. The Chief Pharmacist expressed a preference for an intranasal naloxone (INN) formulated product. However, as there was no authorised INN product available at the time of the Demonstration the next best product of choice was the prefilled fives dose product which was authorised in a member state (Prenoxad™). This had been used in other national naloxone programmes. This product was only licensed to be used via the intramuscular route. The programme is awaiting clinical trial results, mentioned above, on the use of the mucosal atomizer device (MAD) with the Naloxone syringe.
- It was agreed that prison settings would be included and a Doctor would issue a prescription which would be dispensed within the prison and sealed and handed over to the individual on release.
- The community settings for the project would operate through the clinics where the clinic Doctor would issue a prescription and have it supplied on site by the Doctor.
- The Gardai were asked to participate in the Demonstration Project and were invited to attend training.
- The Naloxone formulation, as a pre-filled syringe (Prenoxad™), was made available to the Irish market on the basis that within the current SmPC (Summary of Product Characteristics) it contains additional labelling for the administration of the product by caregivers, front line workers, family members, drug users, addiction clinic staff, etc. These discussions took place in collaboration with the Department of Health, HSE and HPRA. Dialogue is on-going, between HPRA and the manufacturer, about the formulation's authorisation and licensing status in Ireland.
- It was agreed that safety concerns about accidental contact with Naloxone syringes and safe working with sharps would be addressed through the training.
- The Chief Pharmacist maintains a register of all those prescribed with Naloxone and is implementing a system to remove out of date Naloxone syringes from circulation. Each person will be contacted six months in advance of the noted expiry date to alert them of the need to apply for a replacement.
- Consideration of the types of locations and health professionals that could be permitted to store, supply and administer stocks of Naloxone in order to comply with existing strict rules for the chain of supply and record keeping of prescriptions.
- In order to address safety concerns regarding regression into respiratory depression the training strictly emphasises the importance of calling for an ambulance.
- The training addresses safety concerns about the competence and coherence of drug-users to administer Naloxone to a person experiencing an overdose.

- Consideration of cost. A budgetary impact assessment of the cost of Naloxone for the Demonstration Project was conducted³⁷.

2.10 Summary of Chapter Two

Opioid use is a significant factor in drug-related deaths in Ireland. Naloxone is a medicine that acts by reversing the effects of opioid overdose within minutes. Its efficacy has been proven internationally. International experience indicates a high level of success in terms of survival rates when Naloxone is administered in an overdose situation. Another factor that can affect a positive outcome is the presence of a capable person able to take appropriate action in an overdose situation, e.g. remain calm, qualified in first aid and trained in CPR.

Good quality comprehensive training is an important component of any Naloxone programme. Other important and related success determinants include GP, pharmacist and service provider (e.g. outreach service, homeless services, needle exchanges) commitment and participation and sufficient reach of the product to those in need within a population.

Under current legislation in Ireland, Naloxone is licensed as an injectable formulation for provision to a patient through a prescription from a medical doctor. The next chapter explores the implementation of the Naloxone Demonstration Project in Ireland during 2015.

³⁷ Midway through this process the manufacturer repackaged the product and increased the price (npr.org/sections/health-stats/2015/09/10/439219409/naloxone-price-soars-key-weapon) (NB associated with the USA did not affect us but when Martindale repackaged to an overdose kit Prenoxad™ increased from 5 to 25 euro)

Chapter Three

The Naloxone Demonstration Project Implementation

The Naloxone Demonstration Project commenced in February 2015 after two years of preparatory work. This chapter details the implementation of the Naloxone Demonstration Project during 2015. The ground work that preceded and paved the way for the Project is described. This is followed by an overview of the programme roll out across the four selected locations. The challenges encountered during the implementation are noted.

This chapter is based on the analysis of secondary data and the analysis of stakeholder consultations and site visits completed as part of the evaluation methodology.

3.1 Milestones in the Demonstration Project

The following is a summary of the developmental stages and milestones for the Naloxone Demonstration Project.

The high level milestones for the project were as follows:

- Meetings, preparation and promotion of the HSE intention to drive a Naloxone Demonstration Project in Ireland (October 2014 – January 2015).
- Consultation with key stakeholders within the Department of Health, Health Products Regulatory Authority (HPRA), National Family Support Network (NFSN), voluntary support network, Irish Prison Service (IPS), Ana Liffey Drug Project (ALDP), Merchants Quay Ireland (MQI), National Drug Rehabilitation Implementation Committee (NDRIC), SafetyNet, Primary Care, Pre-Hospital Emergency Care Committee (PHECC) and the HSE Addiction Services.
- Design and preparation of training schedule and resource materials. Requested involvement of service users groups, SURF (Service Users Regional Forum) and UISCE (Union for Improved Services, Communication and Education³⁸)
- Completed design of half day training programme for testing during the Demonstration Project.
- Agreement of external evaluation tendering and procurement process with the National Social Inclusion Office. Issuing of invitation to tender for the evaluation process (early 2015).
- Appointment of Eustace Patterson Ltd as the external evaluation team to accompany the Demonstration Project (May 2015).
- Meetings of the Quality Advisory Group to oversee proposed train the trainer modules (January – February 2015).
- Clarification with the manufacturer regarding multiple dose product and possible use of a disappearing needle (February 2015).

³⁸ Drug Users Forum based in Dublin North Inner City

- Decision on the proposed locations for the Demonstration based on data from National Drug-Related Death Index Committee (NDRDIC), the Health Research Board (HRB), National Ambulance Service and Dublin Fire Brigade Ambulance Data.
- Consideration given to the capacity of organisations to fulfil the criteria of rolling out training, availability of prescribers and also access to the more difficult and chaotic client (February 2015).
- Importation of the product Prenoxad™ via the Exemption Medicinal Product (EMP) route as discussed with Department of Health and HPRA (February 2015).
- First train the trainer programme delivered in the South East (Waterford 24th/25th February 2015).
- Development of online site with www.drugs.ie to facilitate the training including online videos and literature.
- Train the trainer programme delivered in Dublin (March 2015).
- Formal launch of the Demonstration Project by the Minister for Health (21st May 2015).
- Roll out of training on site at proposed Demonstration locations³⁹, e.g. Dublin, Cork, Limerick and Waterford (March – September 2015).
- Evaluation initiation meeting with HSE Social Inclusion Office (11th June 2015).
- Evaluation field work commences in June 2015 and runs through until the end of October 2015, including review and analysis of all secondary data, issuing of e-questionnaires to stakeholders and site visits to five locations.
- Dissemination of the evaluation tools for prescribing, dispensing and administration of Naloxone (May 2015).
- Lead HSE Trainer successfully achieved recognised qualification as a fully accredited CPR Tutor/Community Responder to enhance the training in response to feedback.
- Participation of the Naloxone Demonstration Project in International Overdose Awareness Day August 31st 2015 (www.ioad.com).
- Interim Evaluation Report of the Demonstration Project presented to the Quality Advisory Group (October 2015).
- Targeted training continues with delivery to specific groups, e.g. registrars (September – December 2015).
- Discussions about possible inclusion of FDA approved nasal formulation of Naloxone deferred until the product is authorised (October 2015).
- Demonstration Project formally completed (December 2015).

³⁹ open access for all services regardless of Prenoxad™ availability to them on site

3.2 Demonstration Project Locations

Four locations were selected for the Demonstration Project - Dublin, Waterford/South East, Limerick and Cork. The Train the Trainer programme was delivered and representatives from each location attended.

The rollout progressed steadily in Dublin and Limerick and moved more slowly in Cork and Waterford. The factors that supported the speed of rollout in a location included:

- Prior awareness of and engagement with the Project.
- Local champions of the Project (including GPs, HSE management and service providers) already in situ and energised to follow through and support practicalities of implementation.
- Belief in Naloxone and the potential of the Project to make a difference, e.g. prevent deaths, support family members, fit successfully within harm minimisation work.
- Proximity to the Project leadership, including involvement/representation in the QAG.
- Practicalities including clear communication of the process and referral pathways, strong and clear links to GPs, clear prescribing systems, etc.
- Acceptance, willingness and availability of GPs locally to engage with the project, promote and prescribe Naloxone.
- Support from the National Family Support Network (NFSN) and its membership on the ground locally.

3.3 Accessing Naloxone –Pathways

There was a number of ways in which a service user could access Naloxone during the Demonstration Project. These pathways are summarised in the figure overleaf.

The common crucial elements across the pathways are the briefing of the service user about Naloxone and the role of the GP in medical assessment and prescribing of Naloxone. The briefing about Naloxone may occur one to one or in a group and with or without the support of a video learning accompaniment. The briefing must be conducted by a trained person (usually a front line worker in a service providing organisation) in tune with the specifics outlined in the Naloxone and Overdose Training Resource Pack.

The first access route is where a service user is working with a key worker/outreach worker in a service (e.g. a homeless support organisation). The key worker (who has been trained in the use of Naloxone and briefing of others) conducts a risk assessment and briefs the service user about Naloxone. The service user is then referred to the GP (attached to the service) who conducts an assessment and prescribes the product to the service user reiterating the main points from the Naloxone training. These briefings/meetings may occur on the same day or across a number of sittings.

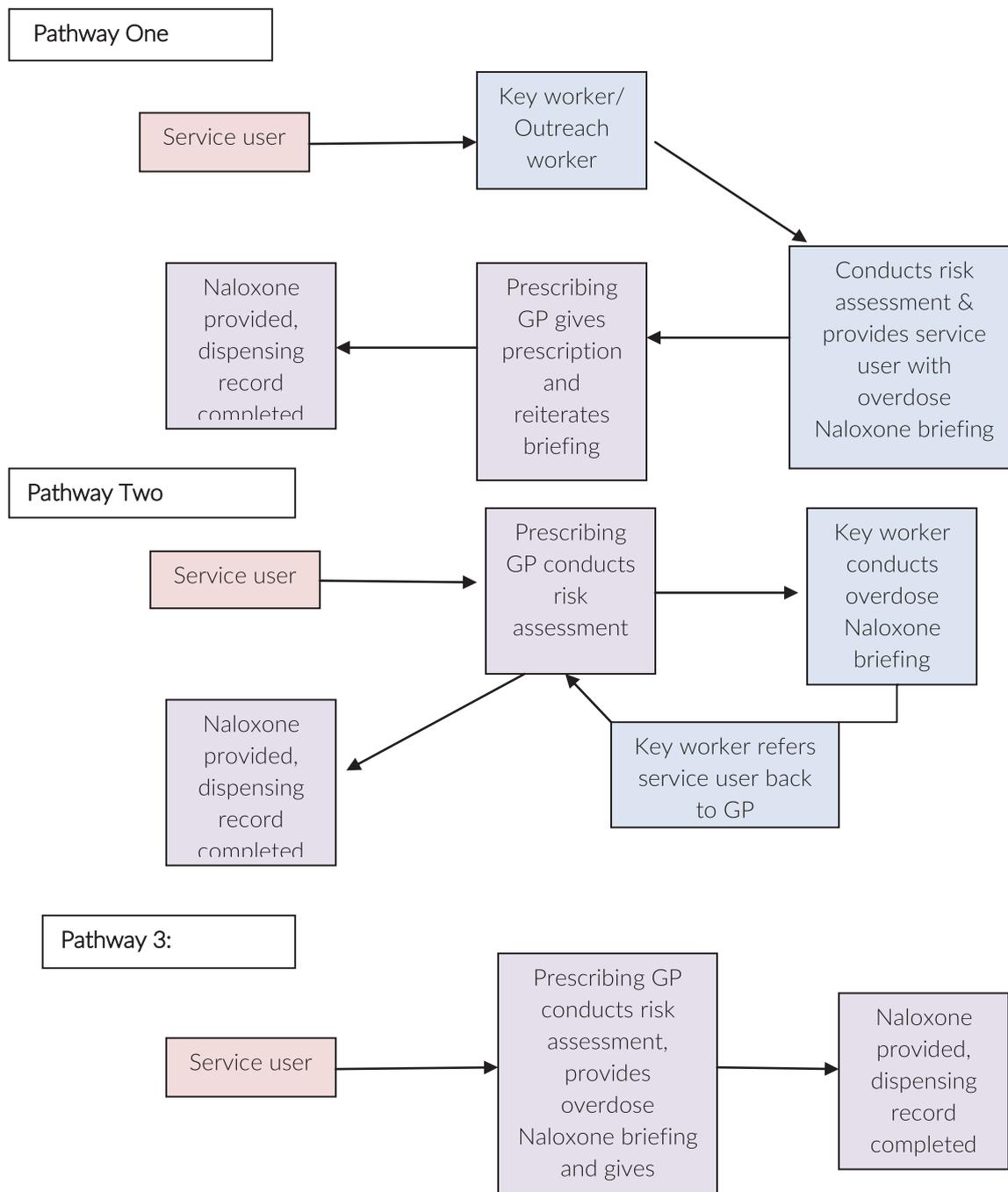
Evaluation of the HSE Naloxone Demonstration Project

The second access route is where the service user directly accesses a GP in a service providing organisation or healthcare setting. The GP conducts a risk assessment and refers the service user to a key worker for a detailed briefing about the use of Naloxone. The key worker then refers the service user back to the GP to receive a prescription.

The third access route is where a service user directly accesses their GP (e.g. in the community), who has attended the Naloxone training, and who conducts a risk assessment, briefs the service user and provides them with a prescription for Naloxone.

In all instances, the prescribing GP must complete a prescription and supply record which is returned to and retained by the Chief Pharmacist.

Naloxone Access Pathways



3.4 Naloxone Training Model

The design of the Naloxone training was led by the Chief Pharmacist (Denis O' Driscoll) and the National Liaison Pharmacy Worker (Tim Bingham) with initial and ongoing consultation with a wide range of stakeholders including the QAG. In the spirit of inclusion, a multi-disciplinary, multi-agency approach was adopted from the outset.

The overall aim of the training is to cover overdose prevention and the role Naloxone plays and its application in overdose situations.

The Demonstration Project employed a cascade methodology to disseminate the training across the four demonstration locations⁴⁰. This methodology commenced with selecting and training a group of individuals (31) to participate in the Train the Trainer programme. The next step was to *cascade* all further training/briefing through these Trainers on location in the system across all four Demonstration sites. The intention was that this group of Trainers were qualified, prepared and on hand to deliver the training locally and/or in response to needs arising.

The second layer of the cascade model focused on delivering the training to a multi-disciplinary, multi-agency audience. The advantage of this approach ensured a broad base of services and professions participated in the training (e.g. pharmacists, GPs, nurses, frontline workers from a range of service providers, etc.). This included family members (relatives of those at risk of overdose) who comprised an estimated 16% of those trained. As of the end of August 2015, 492 people had received this training with more groups trained subsequently.

The inclusive approach to training delivery in the early stages of the Demonstration limited opportunity to tailor the training to specific cohorts, e.g. GPs, senior nurses, prison officers, registrars, etc. This was addressed later in the timeline through the delivery of training to very specific professional groupings, e.g. registrars and pharmacists.

The training is specific and yet versatile for adaption for bespoke groupings. The National Family Support Network made progress in this regard by tailoring (expanding) the training to meet the needs of family members. This bespoke training includes time spent on concerns about family members who are addicted to illicit drugs, coping with a family member who is vulnerable to overdose and the stress that this can cause within families. This broadens out the training experience for family members in a positive way all the while recognising that a family member cannot be prescribed Naloxone to hold on behalf of their relative who is using drugs and vulnerable to overdose.

⁴⁰ Mayet et al International Drugs Policy 2011, Impact for training health professionals

The learning from the evaluation tells us that a more specific and targeted approach to the delivery of the training from the outset would have facilitated tailored training for certain cohorts. It would also have supported more precise sequencing and timing of the training to coincide with the available supply of Naloxone, confirmed access to a prescribing GP, general housekeeping (e.g. lap tops and video equipment to show the Naloxone training video) and organisational readiness, e.g. preparedness of organisations to incorporate Naloxone into their suite of service provision.

3.5 Content of Training

The Demonstration Project provided an opportunity to develop a robust Naloxone and Overdose training programme with a full suite of accompanying resource materials. The content was informed by comprehensive prior research driven by the Project lead and consideration of the learning and good practice emerging from similar projects elsewhere.

During the time frame of the Demonstration Project, a full set of training materials was designed, tested and refined. This means that the first round of training sessions were test runs and all participated in the spirit of this learning. The timing, the process, the content and delivery methods were all under scrutiny and feedback was sought from all stakeholders. All aspects were refined over the life time of the Project in tune with this feedback.

A central objective of the training was to develop and strengthen the awareness of frontline workers in all aspects of overdose. This covered overdose risk factors, observable signs of overdose, what Naloxone is and how to administer it and what to do in an overdose situation. Full participation in the training was a prerequisite for frontline workers seeking to access the Naloxone and Overdose Frontline Workers Pack for use on location in their service. This pack includes a training manual and related resource materials for use by frontline workers with service users in conjunction with four videos available on www.drugs.ie/naloxone.

The manual covers overdose risks, what Naloxone can and cannot do, where to keep Naloxone, how to identify an opioid overdose, calling an ambulance, procedures for obtaining resupplies of Naloxone, what to do in the event of needle-stick injury and steps to take in responding to an overdose.

The manual contains five forms:

- F1: Checklist of learning which must be completed by each frontline worker in respect of each service user they have trained.
- F2: Opioid risk assessment form where an assessment of the service user is carried out by a frontline worker and is reviewed by a GP.
- F3: Naloxone Demonstration Project Data Recording: Use & Supply form to be completed by GPs.
- F4: Naloxone Demonstration Project Supply Consent to Share Information for Evaluation Purposes form to be completed by the frontline worker and GP.
- F5: Incident Report Follow-up Form to be completed by a frontline worker and GP when an overdose is reported

3.6 Data Management and Collection Systems and Completion of Forms

A project of the size, purpose and impetus of the Demonstration Project requires significant resources. The range of administrative supports necessary to manage and track a project of this nature includes training design and production of resource materials, logistics, event management, scheduling/time tabling of training events, monitoring and evaluating pre and post training and responding to issues as they arise. Given the nature of the Demonstration it was also necessary to have sturdy administration systems and procedures around procurement, ordering and monitoring stock, prescribing, recording prescriptions, monitoring replenishment of supplies and tracking usage.

During the Demonstration significant inroads were made in setting up systems to manage and track the work. These include excel spread sheets for recording and tracking prescriptions, the use of Opioid Overdose Knowledge Scale (OOKS) and Opioid Overdose Attitude Scale (OOAS) to evaluate training and the suite of forms for recording critical incidents (F1 to 5 mentioned above). Compliance with completing and returning these forms is crucial from a clinical governance stance. It is also valuable data for research purposes and longitudinal analysis of the effect of Naloxone in reducing in reducing the number of fatal overdoses.

The results of the evaluation show that there was significant underestimation of the work load and precision required to accomplish the full extent of the administration necessary for the project. This warrants consideration into the next phase.

3.7 Demonstration Project Implementation

The analysis of the stakeholder consultations conducted during the evaluation draws attention to aspects of the Demonstration Project that worked well. The results also highlight the lessons learnt and the challenges to prepare for into the next phase of the Project.

The results are presented in the following four sections. The intention is to inform future decision making in relation to Naloxone and possibilities beyond the Demonstration Project.

3.7.1. Stakeholder Involvement

The Demonstration Project was a test run with a purpose. It was, from the outset, heralded as an opportunity to learn about Naloxone and how to train the relevant stakeholders so that they are aware of its potential, its merits and limitations and how best to use it in appropriate, safe and life affirming ways.

Stakeholder involvement was deemed an important success determinant from the outset. The stakeholders include front line workers, family members, HSE management, medical and pharmaceutical professionals, paramedics, psychologists, Gardai, ambulance and social care workers and all the relevant professional bodies associated with the aforementioned.

The results of the evaluation draw attention to what worked well in relation to activating and encouraging good involvement by the full range of stakeholders.

Aspects of stakeholder involvement that worked well:

- Open and inclusive approach and communication from the outset.
- Partnership working between community and voluntary sector and HSE.
- Communication, network and raising awareness of Naloxone within NDRIC and social care and community networks.
- Inclusion of family members and the National Family Support Network.
- Openness to learning and constructive criticism in the spirit of learning and continuous improvement.

Aspects of stakeholder involvement that require attention:

- Slow down the consultation process and adopt a more measured and strategic approach to consultation post Demonstration.
- Continue to draw in the full suite of stakeholders, especially those who doubt the Project. This worked well at the commencement of the demonstration and is worth continuing as open conversation and thought sharing will bring forward the quality of the product and the process.
- Strengthen the presence and involvement of service user networks and organisations within the communication about Naloxone.
- Acknowledge that some organisations and/or stakeholder groups are more cautious with respect to delivery of new programmes and need time to assess potential impact on their current service delivery. 0010. This means that they need time for internal review and preparation prior to commencement.
- Invest more time in consultation pre implementation through formal and structured consultation with specific groups, e.g. service users, family members, GPs, etc.
- Activate a centre point of communication to manage ongoing consultation, briefings and PR during implementation.
- Strengthen communication with and support for the small cohort of trainers so that they are clear in their role as champions of the Project and confident in their capacity to deliver training locally. This could be achieved through regular check (telephone or meeting) in with trainers.
- Broaden the membership of the QAG to include more regional representation and widen clinical presence to include advocates and opponents of Naloxone.

3.7.2. Governance

The Demonstration Project, as any project, required good governance at a number of levels.

The results of the evaluation draw attention to what worked well in relation to governance with a particular emphasis on clinical, ethical and financial governance.

Aspects of governance that worked well:

- One single point of contact and leadership for the Demonstration – this conveyed a drive and positive energy that characterised and carried the Project from the outset.
- The composition, presence and work of the Quality Advisory Group which comprised of a mix of community and voluntary organisations, service providers, the Health Service Executive (HSE), National Family Support Network (NFSN) and health professionals.
- Access to expert clinical advice and goodwill in terms of advice and guidance, e.g. pharmacists, medical practitioners and addiction specialists.
- Drawing on the experience and wisdom of programme leaders and clinicians in the UK and Scotland for advice and guidance prior to and during implementation.

Aspects of governance that require attention:

- Clarify and strengthen the terms of reference for the QAG and broaden its membership to formally include decision making/influencing clinical representation and HSE regional management and clinical representation (e.g. from the four locations and beyond). This has happened informally to date, through consultation with clinical experts in each of the regions and the Addiction Services within the HSE.
- Share the responsibility for management and promotion beyond one individual (the Chief Pharmacist) and into the regions.
- Set out stronger and clearer communication and reporting channels and lines of responsibility for governance of addiction services within the HSE and across the four locations.
- Achieve evenness in the awareness and commitment across the HSE locations and work through any doubt and resistance by HSE management, healthcare staff and health professionals.
- Seek appropriate, workable and practical ways to embed Naloxone within addiction clinical governance⁴¹.
- Resource the administration of the Project to ensure continuity and effectiveness of record keeping, communication, publicity materials, web site maintenance, etc.

⁴¹ A review by the HSE of addiction clinical governance is currently underway.

3.7.3. Project Management

A Demonstration of this size and nature required dedicated project management and administrative resources.

The results of the stakeholder consultations show that there was a clear vision and strong leadership within the Project. This imbued the roll out with a clear sense of purpose and a positive drive to press on and complete. There were clear signs that the administrative aspect of the Project was under resourced. This was compensated for through collaborative working, shared support and goodwill across the organisations that championed the Project. This is unlikely to be sustainable into the future.

Aspects of the project management that worked well:

- Political will and support from the Minister and strategic alignment with the policy commitments, e.g. National Drugs Strategy.
- Clear vision and strong leadership on the part of the Project Lead and anchoring the Demonstration within the National Drugs Strategy.
- Support from senior management within the social inclusion units in the HSE and the Department of Health.
- Drive, energy and enthusiasm from key stakeholders and champions within services and health sector.
- Activation of existing networks and in particular the NGO sector.
- Preparation and ground work driven by the Chief Pharmacist, the QAG members and others within the network of front line organisations that have been calling for Naloxone for some time.
- Good will and inter agency support and cooperation which was crucial to this time limited project. For example, one of the service providers assigned a member of their staff to help with record keeping and another supplied administrative/secretarial support.
- Speedy decision making and ready access to information and expertise.
- Leadership, support and responsiveness of the members of the QAG.
- Good work ethic and commitment to testing the training materials through an iterative methodology through a small core team of trainers.
- Broad reach, wide dissemination of training and high attendance of representatives from the sector of those serving the needs of people vulnerable to overdose and their loved ones.
- Direct access to the pharmaceutical company supplying the product.
- Rigorous procurement and distribution of supply through a courier network.

Aspects of project management requiring attention:

- Whilst firmly acknowledging that the Demonstration Project worked to an agreed tight time line the learning indicates that the time and resource constraints had an adverse impact on certain aspects of the work. There were some signs that the Project was rushed and under resourced administratively. A more measured approach would allow time for preparation, communication and consultation as mentioned in a previous section.
- Provide adequate resourcing in terms of administration staff and management time. The results indicate that three days per week is necessary to manage the roll-out of a project of this size. Full time administrative support is a necessity.
- Acknowledge the distinctiveness of the four locations as each progressed in accordance with its own features and factors. There were examples of people attending training early on and then a lapse of time before they had any opportunity to apply their learning. This calls for more careful timing and sequencing of training events. It also calls for more preparation of GPs, including their briefing, training and resourcing, to conduct medical assessments and prescribe Naloxone.
- Allow time for reflection post training event so as to refine materials and prepare for the next event. There were times when more time was needed to update and refine materials for quality assurance purposes.
- Consider developing and sharing a training calendar (on the website) so that people have sight of the time table of Naloxone Training Programme and may choose to attend for refresher courses.
- Achieve consistency in quality of training across a diversity of organisations by monitoring and supporting the roll out of training/briefing in service provider locations. The active Trainers (31) are calling for support and encouragement, continuous professional development (CPD) and quality assurance.
- Disseminate training packs and resource materials uniformly and consistently across the four locations. This was achieved to an extent by making all materials available on line.
- Continue to respond to the expressed (and some unexpressed) concerns of some stakeholders (particularly medical professionals) around the use of Naloxone in its current form (e.g. size of dosage, delivery mechanism (injectable) and believed risks of reuse?)
- Access to Naloxone - ensuring that stocks are disbursed in a timely manner.
- Consider outsourcing of training for future accreditation and maintenance of qualifications.
- Continue discussion/consultation with community pharmacists, PCRS and GPs so that the full suite of services and supports are in place in each location.

3.7.4. Legislation

The legislative context is of utmost importance to the Naloxone Demonstration Project. For some stakeholders it was a dominant theme and talking point. Naloxone is prescription only medication and must be prescribed by a GP and stock may only be held by a qualified medic. This means that it cannot legally be held in services for emergency use. This is considered a serious limitation by service providers and family members.

Aspects that worked well in terms of the legislative context:

- The Naloxone Demonstration Project alerted all stakeholders to the legislative context and raised awareness and understanding of what a prescription only medication is.
- It provided a space for concerns (e.g. amongst some HSE management and health professionals) about the legislation to be expressed.
- The training was meticulous about the legislative requirements and all those who participated were well informed and cognisant of their responsibility. This proved challenging at times especially in instances where trainees found it difficult to understand and accept the binds of the legislation and the limitations it presents to the full access to Naloxone and preparedness for an overdose emergency.
- As an Exemption Medicinal Product (EMP), the Chief Pharmacist honoured the legislative requirements by ordering the product and maintaining supply records.
- The Demonstration drew attention to and augmented understanding by stakeholders of the status of Naloxone on importation as an EMP as already authorised in the UK.
- The Project supported the inclusion of Naloxone in public health consultation for deregulation of emergency medication (outcome of consultation process is pending).

Aspects of the current legislative arrangements that require attention:

- Acceptance of and working within the current legislation means that all service providers must be aware of the reality and follow through on requirements even if they doubt their validity. This requires ongoing training and briefing of front line workers to equip them with the competence and confidence to brief the end user about Naloxone, as a prescription product. There has been some uneven interpretation of the legislation and some grey areas exist. This has caused concern amongst stakeholders and calls for ongoing robust communication, openness and thought leadership if the current legislation prevails⁴².

⁴² The Minister for Health issued regulation on October 23rd 2015. This provided for the supply and administration of specified prescription-only medicinal products without a prescription (including naloxone) to a person by a pharmacist or by an individual appointed by a listed organisation for the purpose of saving life or reducing severe distress in emergency situations. This is in instances where the pharmacist or individual has completed an approved course of training in the administration of such products and the management of any adverse reaction. Medicinal Products (Prescription & Control of Supply) amendment No 2 2015 SI No 449 www.statutebooks.ie

- Constant open dialogue is necessary about the legislative situation that surrounds Naloxone. This is best achieved through formal and informal communication channels, to ensure that all are fully briefed and informed, are aware of the regulations and the implications of accessing stocks. This includes a central point of contact, details of forms required, payment arrangements, distribution outlets, stocks, etc.
- Building a body of evidence to question and challenge the current legislation, as appropriate, through a measured, ethical and evidence based methodology. Areas for consideration include:
 - Re-regulation of the product as a non-prescription emergency medication to enable wider distribution and holding of stock by non-prescribing outlets (e.g. pharmacies, service providers, family members).
 - Ensuring appropriate systems to allow service users, staff in service providers and families to access the product safely, in tune with regulation and without undue hindrance.
 - Decision on distribution outlets: e.g. engaging and training pharmacies as a possible distribution outlet that could also brief family members and service users in the safe and appropriate use of the product.

3.8 Summary of Chapter Three

The Naloxone Demonstration Project commenced in February 2015 in four locations (Dublin, Waterford/South East, Limerick and Cork). There was over two years of preparatory work in advance of commencement. This included setting up the Quality Advisory Group (QAG), development of comprehensive training including resource materials, the Train the Trainer component and training programme for front line workers and family members.

The rollout progressed steadily in Dublin and Limerick during 2015 and commenced in Waterford towards the end of 2015. There was active participation by Cork based service providers in the Train the Trainer Programme and front line training during the Demonstration time line. However, Cork did not become operational in terms of prescribing of Naloxone during the course of the evaluation.

The factors that supported the roll-out included prior awareness of and engagement with the Project; the presence of local champions; belief in the efficacy of Naloxone; clear communication of the process and referral pathways; acceptance, willingness and availability of GPs locally to engage and prescribe Naloxone from the outset and support from the National Family Support Network and its membership on the ground locally. The Project also supported the inclusion of Naloxone in public health consultations about deregulation of emergency medication. The next chapter examines the outcomes and early impact of the Demonstration Project.

Chapter Four Project Outcomes & Early Impact

This chapter sets out the project outcomes and the early impact of the Naloxone Demonstration Project.

The Demonstration Project unfolded actively in Dublin and Limerick (with Waterford coming on stream later in 2015). This centred on a small number of championing organisations, mainly those serving the needs of vulnerable adults (including people experiencing homelessness and addiction) through psycho-social care and support.

4.1 Naloxone Prescriptions

A total of 95 prescriptions of Naloxone were issued during the Demonstration Project. The majority (67%) of these were issued in Dublin and the remainder (33%) were issued in Limerick.

Six GPs in total were involved in the medical assessment and prescribing of these prescriptions. The majority (5) of the GPs are Dublin based and one is based in Limerick. During the time of the Demonstration there were no prescriptions issued from the other two Demonstration locations, Waterford and Cork. Towards the end of the Demonstration the GP based in Waterford HSE Addiction Team (St Otterans), commenced prescribing and supplying Prenoxad™. Also in this time line the Drug Treatment Programme in the Irish Prison Service activated the provision of product in Mountjoy Prison, Dublin.

The Chief Pharmacist holds the records of all prescriptions and patient details safely and confidentially in password protected Excel files

4.1.1 Dublin

Of the total 95 prescriptions, 64 prescriptions were issued in Dublin from five service providers/locations of Naloxone supply from 03/06/2015 to 04/11/2015:

- 41 (64%) at Merchants Quay Ireland
- 10 (16%) at Granby Centre
- 6 (9%) at Haven House (Crosscare)
- 4 (6%) at St John's Lane
- 3 (5%) at Cedar House

The average is almost 13 products supplied per month

- 45 (70%) were prescriptions to male patients.
 - Average age was 35
- 19 (30%) were to female patients.
 - Average age was 31
- All patients were receiving Naloxone for the first time.
- All patients gave their consent.
- Risk assessments were conducted by front line workers (7) in the five main service providers that the patients had contact with, i.e. Merchants Quay Ireland, Crosscare, Cedar House, Granby, and St John's Lane.

4.1.2 Limerick

There were 31 prescriptions⁴³ issued in Limerick from two service provider/locations of Naloxone supply from 11/04/15 to 29/10/2015.

- Mc Garry House/Novas Initiatives (14)
- Ana Liffey Drug Project (17)
- 20 (65%) were prescriptions to male patients
 - Average age was 37
- 11 (35%) were to female patients
 - Average age was 31
- The majority (81%) of patients were receiving Naloxone for the first time and the remaining 19% were on their second supply.
- All patients gave their consent.
- Risk assessments were conducted by front line workers in the two main service providers that the patients had contact with, i.e. Mc Garry House/Novas Initiatives and Ana Liffey Drug Project.

⁴³ This includes resupplies of six making it a total of 25 unique patients. Three of the resupplies were to female patients and three to male patients.

4.2. Naloxone Training

An open invitation was extended to all services to attend the Naloxone and Overdose Training. Stakeholders became aware of the training through the Project Lead, the National Family Support Network (NFSN) and the network of front line workers operating throughout addiction and homeless services. This ensured that a diverse range of organisations and individuals with different skills, knowledge and experience attended the training. This ensured inclusion and a broad base of supporters and raised awareness of Naloxone and managing a drug overdose incident.

The Chief Pharmacist is the centre point for storage of all returned records of training sessions. They are held safely and confidentially in paper and/or Excel files.

Train the Trainer

Thirty-one people from relevant service providing organisations participated in the two-day Train the Trainer Programme. The result is a cohort of professional people within services primed and ready to cascade the Naloxone training to their peers as a safeguard to prevent opioid related deaths with the population of services users and beyond. Many trainers are incorporating the learning from the Naloxone training into their repertoire of harm minimisation tools. This strengthening of awareness about overdose and understanding of the precision steps to take in the event of an overdose is a significant positive outcome of the Demonstration Project.

4.2.1 *Briefing of Service Users*

Of the thirty-one trainers, approximately one third proceeded to apply their learning to *cascade* the Naloxone training to their peers, service users and family members.

It is estimated that some services will have up to one hundred service users that they may target for the Naloxone training on site. This is being achieved through a range of methods. These methods include outreach to service users in their homes in some instances, spontaneously catching service users at opportune moments when they are attending a service and/or through prearranged Naloxone briefings on site. The choice of method is dependent on the mindset, readiness and capacity of service users to absorb the briefing content and attend for a medical assessment. A sizeable cohort of service users is deemed, by service providers, to be too chaotic in their drug use and poor health to attend the briefing. The reality is that front line workers make judgement calls as to who to and how to deliver the Naloxone briefing during the course of their work. Factors that enable this to proceed include the ready availability of a GP on site and confidence that the Naloxone is ready to be prescribed as necessary. There are also practical considerations such as availability of a room to conduct the briefing and necessary resource materials, e.g. lap top, monitor or TV to show video.

4.2.2 Front Line Training

In line with stated objectives, by the end of evaluation period October 2015, close to 600⁴⁴ people had participated in the Naloxone training that was delivered during the time frame of the Demonstration Project.

Those who participated in the training were mainly front line personnel working in services across the Demonstration sites (Dublin, Limerick, Cork and Waterford). This includes over fifty service providing organisations (including front line workers in a range of homeless and social care settings, HSE and Irish Prison Service personnel, GPs, pharmacists and outreach workers). These frontline workers are briefed in the role and use of Naloxone as an opioid antidote/reverser. In addition, 79 family members have been trained by the Family Support Network (FSN) with the support of local frontline workers.

The vast majority were invited to complete a pre and post training evaluation sheet offering their response to a set of six questions. These questions were anchored on the Opioid Overdose Knowledge Scale (OOKS) and Opioid Overdose Attitude Scale (OOAS). They captured the degree of confidence post training in (a) using the kit and (b) providing information on overdose and Naloxone administration.

These questions centred on the following:

- Participant profile
- Factors that increase the risk of a heroin overdose
- Indicators of an opioid overdose
- Actions to take when managing a heroin overdose

As part of the evaluation methodology as at July 2015 the pre and post evaluations of 492 participants were entered into an SPSS⁴⁵ database. The results show significant positive shifts in knowledge and awareness of how to recognise and manage an overdose situation and administer Naloxone correctly

⁴⁴ The completed evaluation sheets for 492 were included in the SPSS analysis for this evaluation. This was completed in August 2015. Further numbers were trained in the period August to October 2015. Thus the actual number of people trained is closer to 600.

⁴⁵ Statistical Package for the Social Sciences (SPSS)

The summary results of the SPSS analysis are as follows:

- The majority of participants (77%) were Dublin based. A further 10% were Cork based, 10% were in Waterford and 3% were Limerick based.
- The participants came from the full range of services that support the needs of those affected by problematic drug use, e.g. HSE, pharmacists, the Prison Service, homeless, hostel and addiction service providers, health care, nursing personnel and students of addiction studies.
- The majority (75%) had previously completed CPR/BLS training. It is unknown how recent that this training was completed for each. Those that had not completed this training were advised to do so.
- There was good understanding *pre training* of the factors that increase the risk of a heroin overdose (ranging from 72% to 95% across the eight factors measured – see table one). This had shifted upwards by a small number of percentage points post training for five factors. It remained the same for two and decreased slightly for two factors, i.e. taking larger than usual doses of heroin and using heroin after not having done so for awhile (see table one).
- The majority understand the importance of calling an ambulance in the event of an overdose. After receiving the training this rose to 99% compared to 95% before the training.
- The majority understand the importance of staying with a person who is experiencing an overdose and waiting until the ambulance arrives to tend to the person. After receiving training this rose to 98% compared to 95% before the training.
- Awareness about the effects of Naloxone improved as a result of the training (see table three). Understanding about responding to an overdose situation through use of the recovery position and mouth to mouth resuscitation if necessary also improved.
- The majority understand that it is not appropriate to give stimulants or inject with salt solution or give milk to a person experiencing an overdose.
- The feedback indicated that over half (54%) felt very confident to use Naloxone after the training. A further 38% felt somewhat confident, 7% were a little confident and 1% were not confident at all.
- Over half (57%) indicated that they felt very confident, as a result of the training, to provide information on overdose and Naloxone administration. A further 35% were somewhat confident, 7% were a little confident and 1% were not confident at all.

Table One: Factors that Increase the Risk of a Heroin Overdose (n=492⁴⁶)

	Pre Training	Post Training
1. Taking larger than usual doses of heroin	95%	93%
2. Switching from smoking to injecting heroin	89%	90%
3. Using heroin with other substances	89%	92%
4. Using heroin again after a Detox treatment	93%	93%
5. Increase in heroin purity	90%	91%
6. Using heroin again after not having done so for a while	94%	93%
7. Using heroin again after release from prison	83%	92%
8. Using heroin alone when no one else is present	72%	87%

Table Two: Indicators of an Opioid Overdose (n=492)
(Respondents beliefs pre training⁴⁷)

	Respondents who believed that this was a indicator of an overdose
Having blood shot eyes	17%
Very small pupils	69%
Agitated behaviour	19%
Slow/shallow breathing	86%
Lips, hands or feet turning blue	85%
Loss of consciousness	92%
Unresponsive	94%
Fitting	37%
Deep Snoring	49%
Rapid Heart beat	29%

⁴⁶ This is the number of completed evaluation sheets included in the SPSS analysis for this evaluation. This was completed in August 2015. Further numbers were trained in the period August to October 2015. Thus the actual number of people trained is closer to 600.

⁴⁷ Respondents beliefs post training were not collected. It is recommended that future evaluation sheets be updated to capture this data.

Table Three: Truths About Effectively Managing An Overdose Situation

	Pre Training 'True'	Post Training 'True'
If the first dose of naloxone has no effect a second dose can be given	52%	94%
The effect of naloxone is shorter than the effect of heroin and methadone	47%	87%
There is no need to call an ambulance if I know how to manage an overdose	3%	1%
After recovering from an opioid overdose the person must not take any heroin, but it is ok to drink alcohol or take sleeping pills	5%	16%
A person may overdose again even after having received naloxone	75 ⁴⁸ %	92%

Table Four: Things to do to Manage an Overdose Situation (n=492)

	Pre Training	Post Training
1. Call an ambulance	95%	99%
2. Stay with the person until ambulance arrives	95%	98%
3. Mouth to Mouth resuscitation	48%	71%
4. Place correctly in the recovery position	88%	92%
5. Give naloxone	83%	94%
6. Check for breathing	91%	93%

4.2.3 Family Members

The results of the SPSS analysis for those who attended the training sessions organised by the NFSN and dedicated to family members (76) differ slightly from the results for the full population. A slightly higher percentage, i.e. 66% of family members felt very confident to use Naloxone after the training. A further 30% felt somewhat confident and 3% was a little confident. Sixty-three percent of family members indicated that they felt very confident, as a result of the training, to provide information on overdose and Naloxone administration. A further 26% were somewhat confident, 9% were a little confident and 1% were not confident at all.

⁴⁸ 22% indicated that they did not know and after training this had shifted positively to no do not knows, i.e. 98% knew that it is possible to overdose again even after having received Naloxone.

We cannot be certain of the precise reasons for this variation and the higher confidence levels amongst family members when compared with others who attended the training, e.g. health professionals, service providers.

Contributory factors may be the longer time spent training and the tailoring of the training for family members. This includes the extra time and process devoted to experiential learning and discussion of the emotional aspects of coping with and managing an overdose situation. Sessions also allowed for continuous discussion and asking of questions and family members had the chance to practice the recovery position and watch a demonstration of CPR. They also had lots of time to practise injecting on oranges.

This confirms the commitment of family members and their wish to be prepared and in control in the event of an overdose situation involving their loved one. The consultations with family members conducted as part of the evaluation verify this sense of solace and confidence that family members feel. This is irrespective of whether or not they ever actually use Naloxone.

Overall the results show that the training has had a significant positive impact on awareness and knowledge of overdose and ability to manage overdose situations including the administration of Naloxone.

The results also signal that some further refinement of the training and after training support is required to ensure that all those who participate feel *fully confident* in their own competence in managing overdose situations and in the use of Naloxone. This includes adjusting the training (content and time) to ensure full coverage and competence in relation to CPR and practicing the administration of Naloxone. This has been addressed and one of the lead trainers has completed instruction and is now a qualified and accredited CPR instructor. The results also point to a need for ongoing support and refresher training into the future.

4.2.4 *Feedback from Trainees*

Qualitative comments about the training written onto evaluation sheets included the following:

Very thorough training, succinct and accessible

Training was a bit rushed in the end. Do not feel confident showing someone else.

I think day long training on CPR (something similar to the 1HitKit training) would be beneficial.

Need more training in the area as there are obviously grey areas, e.g. blood spatters.

Training was clear and well delivered.

Really helpful – thank you

Very good and informative

The training was very thorough.

Visual aids are very good and work well with service users

Very relevant for all staff and service users

Very good, information given very clearly

Arising from trainee feedback aspects of the training that require attention (many of which have been addressed already) include:

- A call for CPR training to be delivered by a qualified CPR trainer and full coverage and practice of CPR during the training.
- Some concerns about the use of an injectable version of the product being normalised.
- A call to consider safe non-injectable options.
- Some concerns about distribution of and access to Naloxone, e.g. in the regions where there was no known GP ready and available to prescribe.
- Building space into the training for questions and answers and more discussion about managing overdose situations and the effect of Naloxone in reducing the number of fatal overdoses.

4.3 Use of Naloxone Kits in Overdose Situations

During the course of the Demonstration Project there were five administrations of Naloxone and potentially fatal overdoses were prevented for the five males involved. The combined case stories are presented below.

Combined Case Stories of Naloxone Administration during the Demonstration:

- Five males were administered Naloxone as a measure to reverse accidental overdose. The age range was 31 to 50 and.(This fits with NDRDI data)
- Four of the Naloxone administrations were administered by front line workers and one was administered peer to peer. All had participated in the Naloxone training delivered during the Demonstration Project.
- Three were administered by females and two by males.
- Four of the administrations were on the premises of service providers or within the immediate surrounding area, e.g. court yard area outside the building.
- In each of the incidents the Naloxone was administered to a person other than to whom it had been prescribed. This suggests that the availability of and easy access to Naloxone was crucial to the successful reversal of overdose.
- In two instances more than one dose of Naloxone was administered from the five dose syringe. This was judged necessary during the wait for the ambulance to arrive and deemed to work well.
- In all instances at least one person or staff member remained with the patient until emergency services arrived.
- In all instances an ambulance was called and arrived at the scene.
- In two instances the patient was admitted to hospital and discharged after a short period of observation.
- The front line workers managed the situations effectively and followed through on the precise steps that they had learnt about and practised during their training.
- In four of the five cases the service providing organisations completed the appropriate post incident paper work (F.5.⁴⁹), debriefings and review. Some of these reports contained more detail than others. All indicated that they learnt from the experience and felt that the training was invaluable in preparing them to respond appropriately.
- Stocks of Naloxone were replenished in all incidents with some delay for supplies to Limerick.
- Those consulted (3) as part of this evaluation all reported a sense of enhanced empowerment and surety after the Naloxone administration. Their confidence in the procedure for managing an overdose event had increased as had their sense of their own confidence in being useful in such a situation.

⁴⁹ The Form 5 (F.5) is an Incident Follow Up Report which must be completed post administration of Naloxone. It contains details of the incident, profile of the person who overdosed, actions taken, e.g. calling ambulance, CPR, waiting with the person and whether the person attended hospital, etc.

- These interviews were held soon after each event (i.e. within a week) and each possessed a strong sense of pride and relief that they had contributed to saving a life. The harrowing reality of witnessing an overdose was palpable as was the positive sense of being able to take appropriate action to prevent a fatal overdose.

According to one front line worker:

'It was my first time administering Naloxone. I was happy to see the Naloxone work and to observe the service user's vital signs returning to normal. Two other services users witnessed it being administered to their friend. They saw first-hand what Naloxone can do. Since the administration four more service users have signed up for the Naloxone briefing and to receive their prescription'.

Another front line worker, verified the above saying 'clients understand Naloxone now, they know how to use it and it is important that they have access to it'.

- In one incident staff found trying to open the Naloxone pack (whilst also wearing gloves) a bit difficult. They suggested *'an easy to grab tab might work better for easy opening, as opposed to a twist and break seal'.*

4.4 Summary of Chapter Four

During the Demonstration Project five deaths were prevented in the period up to October 31st 2015. These deaths were prevented through the appropriate administration of Naloxone after determining that the individuals in question were showing signs of opioid overdose.

Six GPs were involved in issuing and supply of 95 prescriptions for Naloxone (Prenoxad™) between the Dublin and Limerick locations. This implies that 95 service users, at high risk of overdose, completed the Naloxone briefing as part of a harm minimisation programme. They now have access to Naloxone on their person for administration in the event of an overdose.

Thirty-one participants completed the Train the Trainer modules. Close to 600 others, mainly frontline workers from a wide range of organisations, and family members, were trained in recognising and effectively managing an overdose situation and responding to these situations with the use of Naloxone.

The results show positive shifts in awareness and attitudes and knowledge of how to recognise and manage an overdose situation and administer Naloxone correctly. The majority of participants have gained in confidence to manage such an event. The learning indicates that further refinement of the training and after training support is required to ensure that all those who participate feel fully confident in their own competence in managing overdose situations and in the use of Naloxone.

The next chapter draws conclusions from the research and makes recommendations for the roll-out of Naloxone.

Chapter Five

Conclusions and Recommendations

This chapter draws together the overall results of the evaluation of the Demonstration Project. It sets out recommendations to guide decision making into the future. The reach of the Demonstration is highlighted, alongside principle learning. This is the nature of a demonstration project as its primary purpose was to place a spotlight on the strengths, breakthroughs and the learning in order to inform decision making and future planning.

5.1 Overall Conclusions

The Naloxone Demonstration Project, a harm reduction measure, was supported by the National Social Inclusion Office (Primary Care) of the HSE and fits within the suite of actions under the National Drugs Strategy.

The Demonstration successfully contributed to the reversal of potentially fatal overdoses in five (5) separate situations⁵⁰ through the administration of Naloxone in accordance with the set procedure for managing overdose situations. These potential deaths were prevented by front line workers and/or peers activating the effective overdose management procedures learnt during their Naloxone training during 2015. Table 5.1 shows comparison data across a number of regions/countries.

Source	Death Prevented : lives lost when Naloxone used	Deaths Prevented : lives lost when Naloxone not used
USA Los Angeles (Wagner et al 2010)	26:4 (87%) ⁵¹	Na
USA San Francisco (Seal 2005)	15:0 (100%)	Na
USA New York (Galea 2006)	10: 0 (100%)	Na
USA Baltimore (Tobin 2009)	19: 0 (100%)	Na
Wales (Bennett 2011)	21:1 (96%)	38:1
Scotland Glasgow (Shaw 2008)	10:1 (95%)	Na
Scotland Lananhshire (McCauley 2010)	2:1 (67%)	Na
U.K. South east/south west, midland/.north (Stray 2008)	12:0 (100%)	6:1
Ireland demonstration project	5:0 within a five month period ⁵² (100%)	Na

⁵⁰ A further three deaths were prevented in Ireland with the use of Naloxone in the period following this evaluation and post the Demonstration period, i.e. November 2015 – January 2016.

⁵¹ A total of 35 overdose events were recorded but the outcomes in respect of 5 were unknown.

⁵² There were three more reported administrations of Naloxone in the period after this evaluation was completed, i.e. November – December 2015.

The evaluation of the Naloxone Demonstration Project formally commenced in **June 2015**. The field work was action research oriented, given the nature of the Demonstration Project, and was conducted between **June and October 2015**.

The overall conclusion is that the Demonstration Project raised awareness of overdose and generated knowledge and competence to manage an overdose situation safely and effectively with the use of Naloxone. Five, potentially fatal, overdoses were reversed.

The project was a good return of investment (€62,500) in that it provided overdose management training to over 600 people across the full suite of services providers and support organisations that work with illicit drug users. It expanded conversations and activated learning about overdose and the potential of Naloxone in overdose situations. It was an inclusive project and activated much goodwill and networking across the social inclusion sector.

There was strong commitment to the Naloxone Demonstration amongst service users, service providers and family members. It progressed swiftly in Dublin with Naloxone prescribed the day after the Minister's announcement. Limerick followed in August 2015 and Waterford, in November 2015.

The main drivers were the NGOs supported by the Project Lead and a circle of supportive champions including medical and allied professionals with a history and understanding of working within a social inclusion ethos.

The Demonstration stimulated conversation and raised questions about how we work with drug users, how we support their families and the suite of services and supports provided. It has opened discussion and progressed discussion about governance, ethics, procurement, supply and safe storage.

Naloxone is, at its simplest, a pharmaceutical product with the capacity to reverse the effects of an opioid overdose. The results of this evaluation indicate that Naloxone, as a concept, is also a catalyst for positive change in behaviour in drug use and harm minimisation. It fits within the suite of supports, services and treatment for drug users, i.e. harm minimisation, Opioid Substitution Treatment (OST), needle exchange, detoxification and treatment of addiction. It is a valuable addition to the toolkit of harm minimisation and forms part of an overall strategy to affect a change in opioid related drug deaths.

The benefits of Naloxone is more widely known and accepted by many in its current formulation as a pre-filled injectable device.

It is envisaged that as there is now an FDA approved Itranasal formulation, that the project will seek to include such a device into the new legislation once there is a product licensed to the European market.

Naloxone has been most welcomed by family members and front line workers who work with those at risk of overdose.

5.2. Impact

The Demonstration Project has had significant outcomes and early impact in a number of ways. These include:

- Awareness raising about the correct procedures in an overdose situation amongst an estimated 700 front line staff, family members and service users. The project has expanded the conversation about overdose, being at risk and the drills and actions that we can use to manage these situations effectively.
- The numbers and range of services that participated in the training, which resulted in knowledge, understanding and networking outcomes that extends beyond Naloxone.
- Providing families with peace of mind. It provides a sense of control, preparedness and reassurance to family members who have loved ones at risk of overdose.
- Empowering service users to help themselves and peers. The Naloxone product and the accompanying briefing is a way of opening up conversations with drug users who are at risk of overdose. It is a tangible activator or conversation starter that supports front line workers in their harm reduction work.
- Six GPs have prescribed Naloxone consistently over the course of the Demonstration, five in Dublin and one in Limerick. A seventh GP commenced prescribing in Waterford towards the latter end of the Demonstration time period.
- Ninety-five people have been prescribed Naloxone with more coming on stream as prescription mechanisms bed down in each location.
- Naloxone has been administered on five separate occasions during the second half of 2015 and five fatal overdoses were reversed (three in Dublin and two in Limerick). These administrations have engendered a positive feeling of empowerment and possibility amongst all involved.

5.3. Learning

The Demonstration Project was open and iterative and generated a lot of learning during implementation.

Commitment

There was commitment to the Demonstration Project across the range of organisations that have been calling for this intervention for some time. The Project was welcomed and there was appreciation of the movement and action to assess the use of Naloxone in Ireland.

Some stakeholders showed signs of doubt and hesitancy and efforts were made to draw these into the discussion and decision making. It is important that this continues and that there is dedicated time, inclusive communication and careful consultation to ensure that *all* stakeholders contribute and shape the optimal model for future roll out of Naloxone in Ireland. This fits with the learning from other countries.

It is important to draw all stakeholders (medical, pharmaceutical, social care, psychological, etc.) together and share evidence to influence positive change, as ethically and clinically appropriate, e.g. change in formulation of the Naloxone from injectable to nasal and any progressive changes in the legislation.

Collaboration

There was good collaboration and working between members of the Quality Advisory Group, the Project Lead and those service providers working directly with people at high risk of overdose. There were many examples of organisations working together and sharing their resources in the interest of the Naloxone Demonstration Project and for the greater good. There is scope to strengthen this collaboration even further through governance structures such as the QAG and networking with appropriate professional bodies.

Governance and Management

The Project was under resourced in terms of the personnel necessary to manage and administer a project of this size and influence, e.g. ongoing communication with stakeholders, precision data collection and record keeping, training scheduling and structuring, refinement of materials, preparation and dissemination of resources and everyday logistics.

Further development needs include:

- Developing and managing systems to monitor the training as it rolls out, e.g. tracking and supporting participants and delivery in outreach locations.
- Developing and managing systems for effective distribution of Naloxone, extending its reach and looking at ways to reach those most at risk of opioid overdose.
- Developing and managing systems to monitor prescriptions and related administration uniformly across the sites.
- Developing and managing communication systems to respond to questions and concerns of managers, front line workers, service users and family members. A central reliable and professional communication point is important given the changing landscape of drug addiction and the questions and concerns that arise.

The QAG provided a useful sounding board and support to the Project Lead. There is scope to validate and strengthen this capacity through stronger terms of reference and a broader membership. Any intentions to raise awareness and value of Naloxone will be strengthened by including medical expertise and HSE representation across the four locations and beyond.

Practicalities

The learning from the Demonstration alerts us to many practicalities that warrant attention as we continue to include Naloxone in the suite of supports that fit within the harm minimisation model of operation. This learning relates to timing or sequencing of Naloxone training, access to a GP and access to a supply of Naloxone for immediate prescription. There were times during the Demonstration when training was completed too far in advance of the availability of Naloxone.

To maximise momentum the training of front line workers must be accompanied by availability of Naloxone on site in their services and availability of a GP to conduct the medical assessment and prescribe. The availability or easy access to a GP is an important component of service provision, irrespective of the ways in which Naloxone is available or distributed into the future. Family members are calling for reassurance in this regard.

It is also important that all the relevant resources materials, e.g. training packs, visual aids, DVDs, record forms and briefing documents are readily available and personnel fully understand their fit and use. Services must also have access to the necessary lap tops and/or monitors to play the training DVD. It is good practice to have Naloxone posters/brochures displayed in full visibility on site in service provider receptions and/or open areas.

This ensures continuity and conveys the messages of harm minimisation and safety openly within each service. This invites curiosity and raises awareness of Naloxone and its purpose amongst those who are as yet unaware.

Cascade Model

The evaluation shows that the cascade model has merits, particularly in terms of efficiency and inclusiveness of training delivery. It is useful to consider supplementary ways to achieve a systematic approach to the delivery of training across the range of stakeholders, variety of organisations and diversity of workers coming forward for training.

The trainers were open to feedback and the training materials were refined as the project unfolded. All materials are available online at www.drugs.ie along with open and clear information from the Chief Pharmacist about the Demonstration Project and its purpose.

Prisons

Prisoners are accepted as being a high risk group for accidental overdose particularly within the first two to four weeks post release. The Irish Prison Service participated in the roll-out of the training and some delays were experienced in the prescribing of Naloxone to prisoners pending release. These were resolved towards the end of the Demonstration.

Supply and Distribution of Naloxone

The majority of stakeholders believe that the current legislation is a barrier to the wider availability of and access to Naloxone. Currently its use requires a prescription. This means that it cannot be held safely in stock by families or service providers for use in the event of an emergency. The five administrations that occurred during the Demonstration indicate that the freedom to hold/store Naloxone carefully and safely in assigned locations is more in harmony with the reality as it currently stands.

To enhance distribution and access to Naloxone, an amendment to the Prescriptions Regulations was required and this was achieved in October 2015. This amendment may serve to enable exemption from prescription control of a medicinal product, e.g. in a specific establishment by a person who has completed certified training. Such training could be accredited and a register of those who successfully completed the training could be maintained. This could be a safe, practical and cost effective way to go into the future.

For people not on the Central Treatment List or known to the addiction services it was suggested that it may be possible to work with select pharmacies involved in the needle exchange programme. This could work on the basis of an assessment leading to the hand out of a Naloxone pack to an individual with selected doctors subsequently issuing the necessary prescription. Such a methodology would require a clinical policy to ensure that doctors were in agreement and that correct and robust protocols were in place to allow for issuing a prescription after the event.

5.4 Recommendations

The following are the recommendations based on the results of the evaluation of the Demonstration Project. These recommendations centre on communication, consultation, training design, robust research and planning for future roll out and distribution of Naloxone in Ireland.

The recommendations are set out in priority order of necessary action.

Recommendation One - Communication & Consideration

We recommend that the results of this evaluation are given careful consideration in advance of decision making for the future roll out of Naloxone. To expedite and structure this period of consideration we recommend that the results are discussed, early in 2016, within the QAG and the National Social Inclusion Unit within the HSE. The purpose is to inform the action plan for the future.

Recommendation Two - Governance

We recommend that the QAG be strengthened by broadening its membership to include wider clinical expertise and clinical governance and more regional representation. The terms of reference of the QAG should be revisited and revised accordingly.

The first task of this strengthened QAG will be to discuss possible options as to the best way forward for Naloxone and agree the strategy to achieve this. One option is continuance under the current legislation. Another is to develop a comprehensive case/strategy for reregulation. This will take time, preparation and a careful plan. Another option is to explore the availability, cost, distribution and training implications of an intranasal formulation of the product. All options should be accompanied by a firm action research plan (see also recommendation six) overseen by the QAG.

Recommendation Three - Planning and Preparation for Future Roll Out

We recommend continuance of the roll out of Naloxone in a measured, phased and strategic way with attention on the Waterford/South East and Cork in the first instance. We recommend dedicated resources and personnel assigned to Naloxone roll out in each region.

We recommend continued support to build on the ground work completed in Waterford and draw Cork further into the fold. The rationale is to achieve an even pace and reach across all four original Demonstration areas, open out discussion and maximise the learning from the evaluation. This will pave the way to progress to other areas with a clearer plan of action and sense of steps necessary, i.e. communication, training, distribution, administration, support, monitoring, academic research, etc.

We recommend that the phased roll out be driven by the Chief Pharmacist and commence with an initial briefing/consultation with the HSE and relevant stakeholders in each location. These stakeholders include professional bodies, GPs, pharmacists, clinical nurses and social care workers. The content of this briefing will be informed by the results of this evaluation. The purpose is to raise awareness of Naloxone and prepare for the next phase of roll out.

We recommend drawing in one other region, based on the NDRDI data, over the next twelve months. Following a favourable review of progress further roll out nationally might then proceed.

We recommend that there is specific administrative support dedicated to the Naloxone roll out. This is vital given the precision and vigilance that is required to comply with the collection, collation and management of the full range of forms (e.g. F1 – F5), patient/prescription data and training records. This calls for a dedicated role with responsibility for issuing forms, following up on forms/records, maintaining a secure data base and being the contact point for all data relevant to Naloxone distribution.

Recommendation Four - Refining the Training

We recommend continuance of the Naloxone Training incorporating the learning from this evaluation. This includes refinements to the scheduling/timing and administration of future training for front line workers and briefing of service users.

We recommend that the training be accredited by an appropriate body. This is already in train in consultation with the Pharmaceutical Society of Ireland.

We recommend that a training schedule be prepared and disseminated prior to delivery of any further training. This could communicate the nature of the training, aims, learning objectives and timetable across regions.

The Train the Trainer component achieves optimal effect when participants have an opportunity to practise as soon as possible after receiving the training when their newly acquired knowledge and skills are fresh (ideally within three months).

We recommend that this aspect of timing (i.e. early opportunity to apply the new skills in the work place) is given careful consideration in the scheduling of future training programmes. The current cohort of trainers is a ready and able resource to deliver future training subject to refresher training, clarity of purpose/role and ongoing central support.

We recommend that accredited CPR training, delivered by a qualified and accredited tutor(s), is built into the training programme. This is already being introduced.

We recommend that opportunities for refresher training, peer support and reflective practice be built into the suite of future training.

We recommend that the collaborative work with the NFSN continues so as to include family members in all future training and development events.

We recommend ongoing evaluation of all future training. The OOKS and OOAS pre and post tools have worked well and should continue to be used to gauge progress. It is important that all completed training evaluation forms are monitored and analysed regularly to note the quality of training and any adjustments necessary.

We recommend that the pre and post training evaluation forms are modified to include participant profile data, e.g. service type, qualification and length of experience, CPR training completed, when completed and accrediting body. This will build a robust data bank that will facilitate full analysis of training participation and competence by region, qualification, etc.

Recommendation Five – Briefing of Service Users

We recommend that the training/briefing of service users in the use of Naloxone continues mindful of the learning from the Demonstration. This includes noting and working to address the challenges in reaching and drawing in service users most at risk of accidental overdose and those currently beyond the reach of services (i.e. acutely marginalised as a result of their addictions and life events).

We recommend that the briefing of service users is monitored carefully and supported. Given the somewhat spontaneous and understandably opportunistic nature of the briefing of some service users it is important that front line staff members are supported to achieve quality and consistency in their delivery. This includes easy access to resource materials and support to deliver messages/information briefly and succinctly in a range of outreach settings. It is also important to align all briefings with access to the required medical assessment/GP and Naloxone prescription.

We recommend that all front line workers are trained and supported to work with their hard to reach clients. This includes space and opportunity to discuss, work through and find solutions to the challenges that they encounter in the course of their harm minimisation work, e.g. service user capacity, readiness, willingness, perceptions of Naloxone, etc.

We recommend that specific attention is placed on monitoring the service users briefed and prescribed Naloxone and tracking their health, well being and drug related behaviour over time, e.g. through replenishment records, repeat overdose incidents, etc. Currently all those participating in the Naloxone programme have given their consent to the sharing of their data for monitoring purposes. It is important that this aspect of practice continues. This links to the research recommended in recommendation six.

Recommendation Six – Research, Tracking and Monitoring

We recommend continued research in Ireland in relation to Naloxone. This will be usefully informed by the meticulous tracking of prescriptions, risk analysis, medical assessments, number of overdose incidents and Naloxone replenishments. A central theme will be the monitoring of the effect of Naloxone in reducing the number of fatal overdoses. We recommend that the research is multi-disciplinary and is overseen by the QAG with a particular emphasis on clinical governance. Partnering with an academic establishment or research organisation will drive and support future research.

We recommend quarterly meta-analysis of the F2 - risk assessment forms and F5 – post incident forms to note any patterns in medical risk, drug related behaviour, frequency and features of overdose. These F2s and F5s alongside the excel spread sheets of prescriptions and replenishments will form an important body of data that lends itself to useful research over time into the patterns of behaviour and health within that cohort of drug users.

To this end it is important that there is continued vigilance in full completion of these records by all those responsible, i.e. pharmacists, GPs and front line workers.

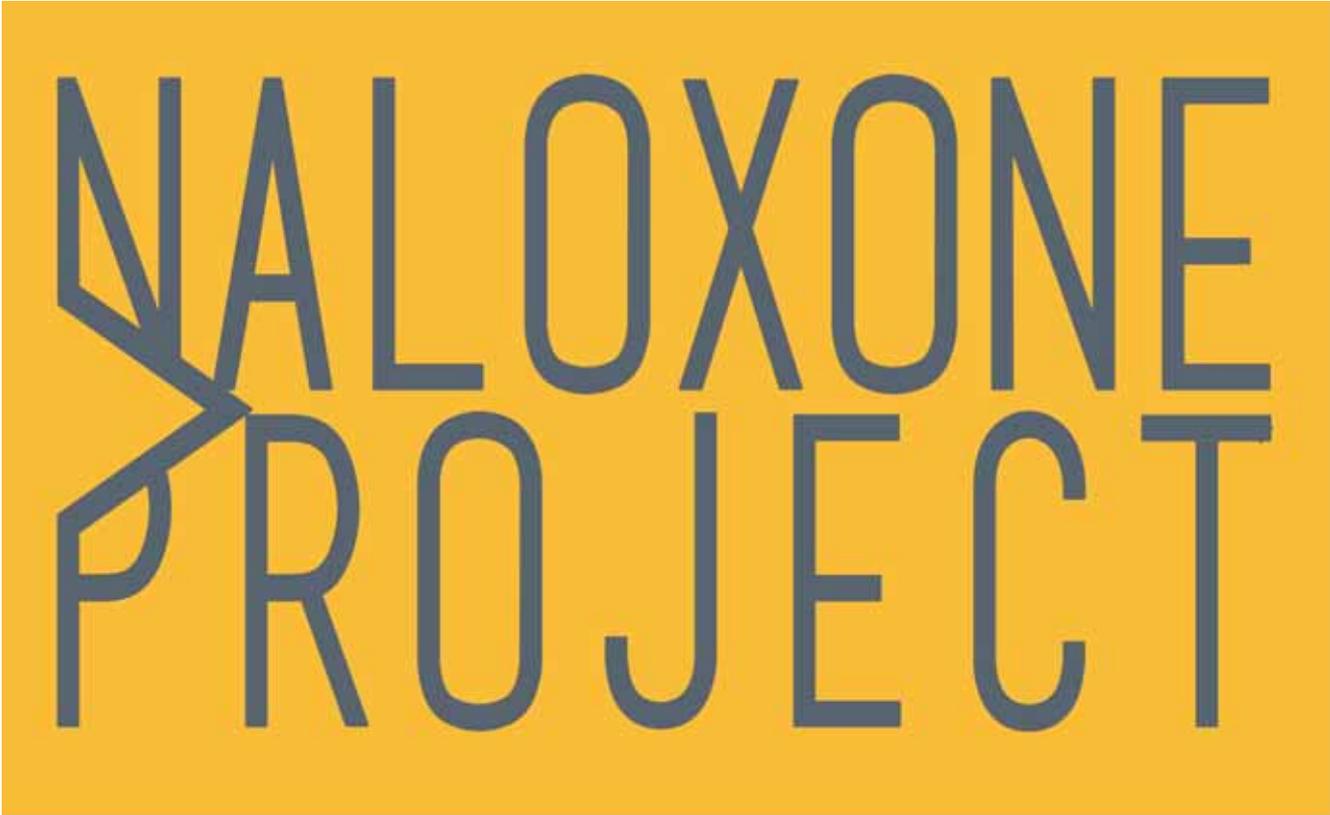
We recommend continuing the good work that commenced during the Demonstration in cultivating the connections/relationships with peers in other countries implementing Naloxone, e.g. Wales, Scotland. This is with a view to ensuring a robust and progressive Irish contribution to the body of international knowledge and understanding of what is working well and shared learning from practice elsewhere.

Appendix One:

Membership of the Quality Advisory Group – Naloxone Demonstration Project

- Denis O' Driscoll, Chief Pharmacist, Addiction Services, HSE
- Tim Bingham, National Liaison Pharmacy Worker (HSE)
- Joseph Doyle, HSE Social Inclusion
- Megan O' Leary, Development Coordinator, National Family Support Network (NFSN)
- Tony Duffin, Director, Ana Liffey Drug Project
- Dawn Russell, Ana Liffey Drug Project
- Mark Kennedy, Head of Day Services, Merchants Quay Ireland
- Emily Reaper, UISCE (Union for Improved Services, Communication and Education)

Appendix Two:
Photographic Exhibition for International Overdose Awareness Day 2016

The logo features the words "NALOXONE" and "PROJECT" in a bold, blue, sans-serif font. The text is set against a solid yellow rectangular background. The word "PROJECT" is positioned directly below "NALOXONE".

NALOXONE
PROJECT

The slogan "SAVES LIVES" is written in a black, sans-serif font. It is centered horizontally and flanked by two horizontal black lines that extend to the left and right edges of the page.

— SAVES LIVES —

