

A Framework for Implementing National Respiratory Guidelines in Wales

By

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A Thesis

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Declarations

I hereby declare that this thesis represents my own work which has been done after registration of PhD at Swansea University and has not been previously included in thesis or dissertation submitted to this or any other institution for a degree, diploma, or other qualification.

I have read the University's current research ethics guidelines and accept responsibility for the conduct of the procedures in accordance with the University's policies. I have attempted to identify all the risks related to this research that may arise in conducting this research, obtained the relevant ethical and/or safety approval (where applicable), and acknowledged my obligations and the rights of the participants.

Signed



Rhys Jefferies

1st October 2022

Aim

Implementation of evidence-based practices in healthcare takes a long time (1). However, this is necessary to realise the value of interventions or innovations, use of new products, services, procedures, and drugs (2).

The aim of this work is to develop a suitable conceptual framework to guide the implementation of two novel national guidelines across NHS Wales. One guideline was developed in urgent response to the international COVID-19 pandemic, whilst other guidelines were developed for managing common chronic lung diseases (asthma and COPD) over time. The assumption is that achieving good implementation in these two very different scenarios will lead to a more successful intervention, with greater healthcare professional satisfaction, and more patient benefit (3).

The fundamental goal of guideline implementation is to achieve widespread acceptance and utilisation of the guidelines by healthcare professionals. This study aims to answer the following research question:

- How may a formal implementation framework increase the acceptance, adoption, and adherence of national clinical guidelines by NHS staff across Wales?

Motivation for the Study

Chapter 12 of Implementation Science 3.0 (4) states: "There has been relatively limited incorporation of empirical findings from implementation science into routine implementation practice" and later emphasising "implementation science runs the risk of limited obvious or immediate applicability in real-world implementation practice" (pg.12). This is partly because implementation science and implementation practice, whilst closely entwined; each carry a different set of needs and priorities (5). I believe that a good understanding and application of the principles of implementation science is fundamental to delivering national programmes to standardise care, which is aligned with the requirements of Welsh Government policy (6–9). This study involves an exploration and real-world observation in the delivery of national clinical guidelines. However, in this context, this thesis is unusual as there is no defined protocol of a medical intervention.

Whilst working as a clinical physiologist in Aneurin Bevan University Health Board (UHB) I wrote a letter to the Minister for Health and Social Services (now First Minister), Mark Drakeford in July 2014 (Appendix A) calling for the standardisation of diagnostic spirometry across primary and secondary care in Wales, following the publication of the first Respiratory Delivery Plan (10). This was my first step to opening doors to practicing the principles of implementation science. I formally joined the National Respiratory Health Implementation Group (RHIG) in 2016 and helped create a unique integrated and centrally coordinated process for delivering large scale, multi-professional and public facing interventions to support national guidelines. We encouraged the application of evidence-based practices through widespread communication, aligning primary and secondary care, and capturing local opinion-leaders and clinical leads to generate wide-reaching influence over learned healthcare professionals and patients. This integrated approach through coordinated implementation efforts had not been done at this scale in respiratory care in Wales before.

To hear positive feedback from healthcare professionals and patients about the respiratory innovations – people whom I have never met before that live across the country demonstrates the reach and scale of this achievement. To hear from a nurse from Leeds during a respiratory conference complimenting the work in Wales emphasised the benefit of centralising structures to provide more accessible training to people. Whilst observing my son's tennis lesson, a doctor from the local tertiary cancer centre complemented the COVID-19 hospital guideline and how

it had been their primary source of information at a time of need. A neighbour, only few doors down from me complimented a COPD app he had been recommended by his nurse. These are only a few examples that bring to life the real impact that a successful implementation campaign has had on people (which I refer to as the target population throughout this thesis). It is common for recipients of innovations to never experience them (11–13). Therefore, I take great satisfaction and gratitude in witnessing the benefits this work has brought to a diverse target profile.

Contribution

This study is a combination of observational assessments using mixed methods methodology to assess the real-world application of a theoretical implementation framework based on the literature to increase practical adoption of national guidelines across NHS Wales. My contribution to work generating data for this thesis includes:

- 1. Co-ordinated the Respiratory Health Implementation Group (RHIG) 2015-2022 (14) in my salaried role (secondment) to Public Health Wales.
- 2. Co-authored the National Respiratory Delivery Plan for Wales, published by Welsh Government (10).
- 3. Chaired national steering groups to develop the implementation strategy and implementation interventions.
- 4. Managed the development of bespoke implementation interventions, including the development of national guidelines for COPD (15) and asthma (16), and COVID-19 (17,18), primary author of the spirometry competency training programme (19), supported the development of the Royal College of Physicians (RCP) National Asthma and COPD Audit (NACAP) quality improvement programme for primary care (20), and project managed the development of four patient self-management apps (21,22).
- 5. Designed, applied, and adapted the implementation framework.
- 6. Undertook critical observation and evaluation of implementation and intervention outcomes within the scope of the programme.
- 7. Author or co-author of relevant scientific research publications directly relating to this work.

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- 1. EBM Live Conference Utilising Implementation Science Software (ISS) to successfully reach fully implementation of an intervention at scale and pace (July 2022)
- 2. NHS Confederation and British Lung Foundation Lessons following the design and implementation of an NHS Wales COVID-19 Recovery App for patients (June 2021)
- 3. Health Service Journal (HSJ) Principles for the implementation of a national COVID-19 hospital guideline (September 2020)
- 4. Delivering value-based healthcare Welsh Government National Clinical Leads Forum (January 2020)
- 5. Update of the National Respiratory Delivery Plan a British Lung Foundation event (November 2019)
- 6. Standardising Asthma Care in Wales event hosted by Betsi Cadwaladr UHB, sponsored by GSK (February 2019)

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Abstract

Introduction

Implementation outcomes are necessary to experience clinical impact of interventions in the real world. Clear synergy exists between evidence-based clinical recommendations in clinical guidelines and the evidence-based process of implementing them, however less than a quarter of clinical guidelines are implemented using a framework.

Methods

Critical review and analysis of the published literature provided the basis for developing framework constructs to facilitate the process of implementing national clinical guidelines in Wales. This is an observational assessment using mixed methods to assess the acceptability and adoption of novel national clinical guidelines in Wales. The framework is adapted in preparation for formal validation.

Results

A conceptual framework for implementing clinical guidelines at scale was developed from the literature and findings from thematic analysis of potential guideline adopters in Wales. This was deemed relevant to wider strategies and was therefore applied to the implementation of novel asthma/COPD and COVID-19 guidelines. Applying the framework demonstrated widespread acceptance and adoption of the guidelines across all Health Boards in NHS Wales, however evidence of widespread adherence of the guidelines with fidelity remains unproven as this requires longitudinal observation of process and clinical outcome benefits relating to each guideline recommendations.

Conclusions

The differentiation of contexts between the two case studies presented here highlights the difference in pace and urgency of implementation to optimise penetration of a guideline

implementation strategy across a target population in Wales. It addresses much of the ambiguity of definitions and joins common principles to create a framework that can be recommended for further testing with other clinical specialities and contexts outside of Wales. Whilst the COVID-19 pandemic introduced a major barrier to guideline adoption for asthma and COPD, it also presented a unique scenario that stimulated large-scale use of a novel COVID guideline. Whilst it was too soon to explore the correlation between implementation strategies, guideline adherence, and clinical outcomes – achieving acceptance and adoption of the guidelines lays the foundations for further exploration of social benefits on a national scale.

Abbreviations

Abbreviation	Full Term
A&E	Accident and Emergency
ABU	Aneurin Bevan University [Health Board]
AGP	Aerosol Generating Procedure
AHP	Allied Healthcare Professional
AIF	Active Implementation Framework
AIM	Acceptability of Intervention Measure
AIRE	Asthma Insights and Reality in Europe
AM	Assembly Member
AMD	Associate Medical Director
ARDS	Acute Respiratory Distress Syndrome
ARTP	Association of Respiratory Technology & Physiology
AWMSG	All-Wales Medicines Strategy Group
BBC	British Broadcasting Corporation
BCU	Betsi Cadwaladr University [Health Board]
BLF	British Lung Foundation
BMJ	British Medical Journal
BTS	British Thoracic Society
CAV	Cardiff and Vale [University Health Board]
CE	Conformite Europeenne
CFIR	Consolidated Framework for Implementation Research (CFIR)
CI	Confidence Interval
CICI	The Context and Implementation of Complex Interventions framework
CIHR	Canadian Institutes of Health Research
CISG	Conceptual Implementation and Sustainability Guide
СМО	Chief Medical Officer
COM-B	Capability, Opportunity, Motivation - Behaviour
COO	Chief Operating Officers
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease 2019 (SARS-CoV-2)
CPAP	Continuous Positive Airway Pressure
CPD	Continuous Professional Development
CTM	Cwm Taf Morgannwg [University Health Board]
D&I	Dissemination & Implementation science
DGH	District General Hospital
ED	Emergency Department
ERIC	Expert Recommendation Strategy Change
FD	Finance Director

GARD	Global Alliance against Chronic Respiratory Disease
GFD	Guideline Facilitator Dashboard
GINA	Global Initiative for Asthma
GMS	General Medical Services
GP	General Practice/Practitioner
НСР	Healthcare Professional
HD	Hywel Dda [University Health Board]
IAM	Intervention Appropriateness Measure
ICNARC	Intensive Care National Audit & Research Centre
ICST	Institute of Clinical Science & Technology
ICU	Intensive Care Unit
IPC	Infection Prevention and Control
IRLM	Implementation Research Logic Model
ISLAGIATT	It Seemed A Good Idea At The Time
K2A	Knowledge to Action
KaT	Knowledge-activated Tools
KEL	Keir Edward Lewis
KPI	Key Performance Indicator
KT	Knowledge Translation
LiHcO	Lean in Healthcare Questionnaire
LMC	Local Medical Council
LMS	Learning Management System
LTSI	Learning Transfer System Inventory
MARS	Mobil App Rating Scale
MAU	Medical Assessment Unit
MCQ	Multiple Choice Question
MERS	Middle East Respiratory Syndrome
NACAP	National Asthma and COPD Audit Programme
NCCDPHP	National Center for Chronic Disease Prevention
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPT	Normalization Process Theory
NWIS	NHS Wales Informatics Service
OFCOM	Office of Communication
ORCA	Organizational Readiness for Implementing Change Measures
ORIC	Organisational Readiness for Implementing Change
PARiHS	Promoting Action on Research in Health Sciences Framework
PHW	Public Health Wales
POLASTMA	Polish National Programme of Early Diagnosis and Therapy of Asthma
PPE	Personal Protection Equipment
PRECEDE- PROCEED	Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation Policy and Enabling Constructs in Educational and Environmental Development

PRISM	Practical, Robust, Implementation and Sustainability Model
ProAR	Program for Control of Asthma
PT	Powys Teaching [Health Board]
QI	Quality Improvement
QIF	Quality Implementation Framework
QOF	Quality Outcomes Framework
QR	Quick Response
QUERI	Quality Enhancement Research Initiative Model
RCP	Royal College of Physicians
RCT	Randomised Control Study
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
REP	Replicating Effective Programs
RHIG	Respiratory Health Implementation Group
SARS	Severe Acute Respiratory Syndrome
SB	Swansea Bay [University Health Board]
T&C	Terms and Conditions
T1	Translation phase 1
TCU-ORC	Texas Christian University Organizational Readiness for Change
TDF	Theoretical Domains Framework
ToIOM	Taxonomy of Implementation Outcomes Model
UHB	University Health Board
UHB	University Hospital Wales
URL	Uniform Resource Locator
WCP	Welsh Clinical Portal
WHO	World Health Organization
WTS	Welsh Thoracic Society

"It takes an average of 17 years for research evidence to reach clinical practice".

Balas & Boren., 2000 (1)

"Patients receive 54.9% of recommended evidence-based care for prevention and chronic illness care".

McGlynn et al., 2009 (23)

"Two-thirds of organisations' efforts to implement change fail".

Damschroder et al., 2009 (24)

Chapter 1:

Introduction

Chapter Objectives

- 1. Explain the rationale for this study and its potential contribution to implementation science.
- 2. Describe the programme structure and demographics of NHS Wales.
- 3. Introduce implementation science and its relevance to guideline implementation.

Rationale for this Study

Healthcare itself has a "daunting range of diverse stakeholders" (25) (pg. VII). This leads to multiple evolving demands, interests, and requirements that are unpredictable because they make up more than the sum of their equal parts. Healthcare is complex because it has a high degree of interrelatedness and many components. It therefore costs a lot, it is distributed unevenly, it is (most often) too large and unwieldy to coordinate or to make change quickly, and it defies simplistic solutions (25). Moreover, implementation of national programmes is complex (26,27). It requires a change in behaviour of potentially thousands of people that have different interests, roles, responsibilities, and often with competing demands within organisations that have different cultural routines, standards, missions, and expectations (27).

To implement successfully means a target organisation is routinely using an intervention as it was designed according to the original research protocol (28). However, this is rarely achieved to its maximum effect in the real world because the real world is often very different to the conditions from the original research: randomised control trial or a pilot study (29). Outside of the research protocol, organisations, and the people within them behave differently, because they may not have the capacity to perform to the desired level of precision and quality, their environment may be incompatible with the proposed practice, there is insufficient time to deliver the intervention optimally, users lack the skills or knowledge, or there is simply a lack of desire or willingness to use an intervention in the same way as it was originally designed (30).

It is crucial at this point in this thesis to consider the context for this study, especially the predominant focus to implementation science, where in fact a much broader reflection has been considered. A paper by Greenhalgh and Papoutsi in 2018 emphasise the challenges faced by the health system where conventional research design needs to address the mismatch between the patient in the guideline and the patient in the bed. This essentially reiterates the *know-do gap* that fosters the division between evidence-informed practice and clinical benefit (27). The authors expanded on this perspective in 2019, with a focus on *spread and scale* up of innovations and improvements – widening the complexity-informed lens to a broader logic. Application of three lenses helps inform the design and implementation of spread and scale-up programmes from small-scale to large national system-wide transformation. Whilst they are each presented discretely, notably there is considerable cross-over between these (31).

However, considering each in context to its core function provides a valuable landscape to the drivers and barriers to implementation:

- 1. Implementation science the mechanistic lens a systematic, sequential, and structured top-down approach to introducing and spreading focused interventions or improvement techniques.
- 2. Complexity science the ecological lens assessment of emergent, interdependent, and adaptive properties and how best to deal with things, people, and processes that drive uncertainty, unpredictability and emergent causality that is inherent in a system that is made up of dynamically changing interrelationships and tensions.
- 3. Social science the social lens considers what people believe and feel, and why they act the way they do, through perceptions and reactions to the actions of others, and how they may accept or refuse to align with programme objectives and goals (31).

Instinctively, there is a common thread that links people to structures and processes, whilst considering the expectedly unpredictable nature of implementation, spread and scale in healthcare. This is an important perspective to consider when assessing feasibility and defining objectives for large-scale national programmes, to manage expectations for system-wide change, and to anticipate the challenges that the programme will inevitably face. A major driver for this work is to introduce a concept based on implementation science principles to guide the process of implementing interventions within a complex and wide social system. The intention is that many recipients can indeed experience the benefits of interventions when it is needed the most.

However, implementation is notoriously slow and often leads to failure (32). This is partly because implementation is often unstructured, unfocused, unplanned, and disconnected; a subject to the – "It Seemed A Good Idea At The Time" (ISLAGIATT principle) – where interventions are developed without exploring the theory necessary to understand the context or influences on activity for the target population (33). Whereas empirical research is routine learning for healthcare professionals, implementation practice is not (34). This is a major cultural conundrum in healthcare and an important driver for this work. Focusing on the mechanistic (structured and systematic) lens, implementation science brings theory, evidence, and structure to the implementation process of evidence-based practices (35); although rarely does it enunciate to the layperson, clinician, or manager, explicitly – how to do it. Nor does it

adequately define the attitudes and barriers, the pressures, and risks, that [non-academic] implementers must expect throughout the process to achieving implementation success (29). Furthermore, there remains a divide between the academic science and practice of implementation, and the common-sense practicalities of *getting on and doing it* (4). These barriers are not mutually exclusive, but there is the risk that those tasked with implementing exercise none of these effectively, and so become ineffectual in their endeavours. Simply put – implementation success leads to clinical intervention success; implementation failure leads to clinical intervention failure. Although this argument is only true when the ecological lens and social lens are also considered.

Contribution to the Field of Study

Perhaps the first most important outcome for implementing clinical guidelines is that the people, who will potentially use them, indeed accept them. The goal is to increase high-quality care and reduce the use of inappropriate interventions (36). Provided the environment allows and people can access them, once user acceptance is achieved, adoption and adherence to the guidelines is possible (37), which forms the primary aim of this study.

Whilst the key outcome of the programme is to demonstrate improvement in clinical care there are several key objectives/stages that must first be met. An implementation strategy that introduces the guidelines into practice must first be accepted by the target audience. Clinical practice guidelines should improve both the quality and process of care, as well as patient outcomes. Clinicians and managers must choose from numerous, often differing, and occasionally contradictory, guidelines, often compounded by concerns about their quality and development. Adoption of guidelines of questionable validity can lead to the use of ineffective interventions, inefficient use of scarce resources, and potentially, harm to patients (38). Low adherence to clinical guidelines can also be attributed to practitioners' lack of awareness regarding their existence (36). For the purpose of this study acceptance, adoption, and adherence are defined as:

- Acceptance is considered the opposite to the term rejection. It signifies the positive decision toward using an innovative solution (39). Acceptance for the introduction of novel clinical guidelines relates to the intention of target users to using them.

- Adoption is the official endorsement of the guideline from policy makers in settings where the guideline is intended to be implemented, where an organisation endorses a guideline through its relevant governance structures. Once the organisation provides its "seal of approval," the guideline is ready for dissemination and implementation (38).
- Adherence is the uptake of evidence-based practices recommended within the clinical guidelines by organisations and end-users. Typically, this is limited by patient, clinician, and system barriers to following the guideline and the recommendations within it (36), and determined by user compliance with guideline recommendations (40).

The first part of this study explores the application of implementation frameworks for national guidelines. This work draws on the literature to identify the relevant features of implementation frameworks to develop a conceptual framework that can be tested and applied to national respiratory guidelines in Wales. It addresses much of the ambiguity of definitions and joins common principles to create a framework that can also be recommended for further testing with other clinical specialities, or possibly programmes outside of healthcare. Of note:

- The conceptual framework has been developed drawing on several existing frameworks
 and models from the literature and is applied across NHS Wales through
 implementation of national clinical guidelines. Further validation is required so that the
 framework can be empirically tested in other settings, which will be discussed in detail
 in the final chapter.
- 2. The COVID-19 pandemic has had major impact on this research; for over two years there was a significant impact in the delivery of other high-quality respiratory care. COVID-19 affects the respiratory system, which leaves people with a respiratory condition more vulnerable to the effects of the virus than for healthy people (41). Isolation, to avoid contact and spread, was an effective way to prevent infection; however, this also limited contact with healthcare providers, monitoring and diagnosis assessments, beneficial social activity, exercise, and other interventions recommended in evidence-based clinical guidelines. Inevitably, care standards for asthma and COPD were compromised worldwide during this time, which proved a major conundrum for the author. However, the pandemic also presented a novel opportunity to implement national COVID-19 hospital guidelines. The unique position of a pandemic opened doors and reduced barriers to introducing innovative ways of working. It was also a

time where the evidence-base changed quickly, heightened scrutiny regarding the robustness of a huge influx of new evidence, and a sense of desire within the healthcare community to trusted and appropriately peer reviewed and relevant evidence (42). The implementation framework could therefore be applied in both an existing pathway (COPD and asthma) and a new situation (COVID-19) simultaneously.

The primary objective of this study is to demonstrate evidence of acceptance, adherence, and adoption of the guidelines. However, there are multiple cofounding factors influencing population health on a national basis that were compounded during the period where this research was conducted. These have been captured for each chapter as a description of discrete strengths and weaknesses. Further details are provided in Chapter 6 (Case study 1 – COPD and asthma guidelines) and Chapter 7 (Case study 2 – COVID-19 guidelines); both contexts illustrating different drivers and barriers to guideline use.

Demographics of Wales

Wales has a population of approximately 3.1 million people (43). Around 24% of people in Wales live in relative income poverty, higher than the UK average (20%) (44), and through post-industrial legacy it has relatively high prevalence of unhealthy behaviours, such as obesity and smoking (45). Wales is highly mountainous country, mostly flanked by a rugged coastline to its north, south and west perimeter, with nearly its entire east side joined to England. Its geographical orientation, its lack of motorway joining the north and south of the country, diverse healthcare needs from an aging population, and cross-border arrangements with NHS England makes standardisation of healthcare notoriously difficult. There is no large District General Hospitals (DGH) in mid-Wales at all (Powys Teaching Health Board).

Overall responsibility for NHS Wales was devolved in 1999. NHS Wales comprises seven Health Boards responsible for delivering health services within a geographical area (Figure 1.1). Each area is divided into 64 regional clusters (46). Health Boards provide emergency services and a range of primary, secondary, and in some areas, specialist tertiary care services. NHS Wales also funds General Practice (GP) services, dental services, pharmacies, and sexual health services (47). In addition to the Health Boards, three trusts also provide clinical services – the Welsh Ambulance Service, Velindre University NHS Trust offering cancer services, and Public Health Wales (PHW). NHS Wales directly employs around 88,000 staff making it the biggest employer in Wales (48,49). As of June 2021, there are 7,217 medical and dental staff, including 2,782 consultants (48) and in March 2020, 1,962 GPs (50). Furthermore, there are 35,930 nursing, midwifery, and health visiting staff (48).

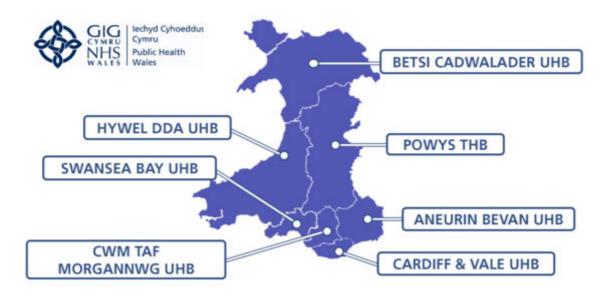


Figure 1. 1: The seven Health Boards across Wales. Taken from https://phw.nhs.wales/services-and-teams/screening/diabetic-eye-screening-wales/service-user-questions/health-boards-map/

National Programme

Fundamental to any aspect of implementation work is the programme within which it is governed and delivered. The Welsh Government Delivery Plans provide a frame of reference for action for Health Boards, Trusts, and partner organisations. They seek to develop clinical leadership throughout the health service and set a common direction for service improvement. These plans set out nationally agreed actions and define performance measures and outcomes that have since been brought under the auspices of a national clinical framework (51).

National programmes cross borders between Health Boards and Trusts. There is often central funding and an expectation that Health Boards adhere to the principles and actions laid out within it, through their local delivery. In 2016, in line with the 7 other national delivery plans, £1 million was allocated annually by Welsh Government to help implement the Respiratory Delivery Plan. The Respiratory Delivery Plan is overseen and delivered by the Respiratory Health Implementation Group (RHIG), which comprises senior clinicians and executives/managers representing Health Boards and Trusts in Wales.

Respiratory diseases cause one in seven deaths and one in seven adults are being treated for a respiratory condition in Wales (52). In 2014, the Minister for Health and Social Services, Mark Drakeford AM, commissioned the Respiratory Health Delivery Plan with the key aims of: 1) preventing poor respiratory health 2) detecting respiratory disease early 3) delivering fast and effective care 4) improving information and 5) promoting research. Each of the seven Health Boards in Wales put forward local plans addressing these themes, and representatives met to discuss the most important key issues. There was overwhelming agreement that improving the standards of COPD and asthma diagnosis was the most pressing need, with priorities including national prescribing guidelines for COPD and asthma (this is discussed in detail in Chapter 6) and improving access to smoking cessation and pulmonary rehabilitation. RHIG's vision was to implement large-scale innovations as a centralised structure to facilitate local tailoring; aligning with wider government policy (6,7) to reduce unwarranted local variation in care. To achieve this, the respiratory delivery plan in 2016 (10) sought to implement change using the following high-level strategy:

1. Standardise recommendations through All Wales guidelines.

- 2. Develop and utilise digital innovations to increase reach and penetration across primary and secondary care.
- 3. Centrally measure impact through the implementation group (RHIG).

Central funding is managed by a 'host' organisation. This was formerly Cardiff and Vale University Health Board and later in 2019, Public Health Wales (PHW). Therefore, the RHIG is a voluntary representation and not a legal entity so does not have the power to mandate or enforce. However, the group has some autonomy deciding how the investment is spent but is held accountable to Welsh Government policy and performance review. This offers a unique opportunity to be bold, creative and to implement innovations at scale – not always feasible in typical Health Board finance structures.

RHIG will be referred to as the 'Programme' throughout this thesis.

Guideline Implementation Strategies in Wales

The expectation from Welsh Government is that Health Boards, local authorities, and Trusts use NICE guidance (53) through:

- Developing systems and processes for disseminating, implementing and risk assessing against NICE guidelines and quality standards.
- Identifying gaps and action required to improve the quality of services.
- Providing reassurance to Welsh Government that NICE Guidelines have been considered.
- Ensuring new medicines recommended are available within a given deadline and report on this.
- Signing up as stakeholders and comment on developing guidelines (para. 9)

Applying the evidence base and recommendations from NICE (and in many cases other UKwide guidelines), these have been tailored into national guidelines specifically for Wales for a range of clinical areas. In the early 90s variation in clinical biochemistry practice in Wales led to the development of tailored national guidelines. Implementation relied on adherence following circulation of the guidelines to all clinical biochemistry departments in Wales. A decade later three surveys were dispatched to assess adherence to the recommendations indicating laboratories are 'generally' following guideline criteria and are adapting practices to align with the recommendations (54). Whilst the authors conclude the guidelines have been widely accepted leading to more efficient and effective use of laboratory services, little is reflected on the observation that continued adaption of practices a decade later. This perhaps reflects the time it takes to embed novel guidelines, particularly where a modest singledimensional implementation strategy is applied. In 2021, all Wales Guidance was published to support care decisions for the last days of life (55). The guidelines have received endorsement from each of the seven Health Boards and Velindre NHS Trust (cancer services). It follows the typical structure for clinical guidelines with a flow chart and a range of tools such as validated questionnaires to support decision making. However, there is no clear access to training or evidence of an implementation plan or strategy. The Welsh Pain Society are in early phases (open for consultation) for developing an All-Wales Guideline for safe and effective use of opioids for chronic non-cancer pain in adults (56). The call references using evidence-based and consensus methodology to developing the guidelines, but also adapting and dissemination strategies, although no further details are currently disclosed.

Definitions and Key Principles

Implementation science is a relatively new discipline and there remains ambiguity in definitions and poor lineation between concepts and terms used within the literature (29). This chapter attempts to define key terms and to standardise these to develop a conceptual framework for implementation practice for national clinical guidelines in NHS Wales.

What is meant by 'Implementation' in healthcare?

The process of implementation is fundamental to the delivery of socially acceptable benefits (37). The Model of Hypothesised Pathway of Change demonstrates a prerequisite for clinical outcomes – to generate positive implementation outcomes through leadership engagement, mobilising available resources, establishing clear goals, and making the programme of work a priority (57). Programme outcomes, including clinical and social benefits, can only be realised once implementation has been successful (Figure 1.2).

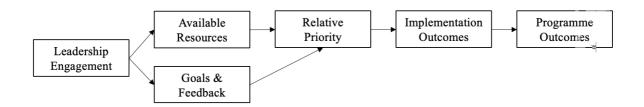


Figure 1. 2: Model of Hypothesised Pathway of Change (57) demonstrating the prerequisite necessity for the generation of implementation outcomes, prior to experiencing programme (including intervention) outcomes.

'Implementation' (noun) is "the process of putting a decision/plan/thing into effect; execution" (58). Implementation science – is the scientific study of methods to promote the systematic uptake and application of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care (59). Other terms for implementation include knowledge translation, knowledge application, knowledge exchange, knowledge transfer, knowledge integration, and research utilisation (60,61). Implementation research looks at how to help people do things in the best possible way (62).

Other definitions from notable experts include: "The applied research that aims to develop the critical evidence base that informs the effective, sustained and embedded adoption of interventions by health systems and communities" (63)(pg.3). An emphasis on the research of what informs an organisation and its people how to do something according to the original protocol. Or, simply put: "The application and integration of research evidence into practice and policy" (64)(pg.26). The introduction to the book written by a prominent leader in the field of implementation science, Fixsen, et al. (37) articulates the fundamental purpose of implementation practice. This excerpt offers an eloquent and comprehensive description of the topic by emphasising its value, complexity, and potential for impact:

"To implement is to use. It is a truism that people cannot benefit from innovations they do not experience. That is, if innovations are not used as intended, they cannot produce intended results. This fact is the basis for implementation practice and science. The purpose of implementation is to assure the full and effective use of innovations in practice, that is, their use with fidelity and socially significant outcomes. Whatever facilitates or impedes the full and effective use of innovations in practice is the subject matter for implementation practice, policy, and science" (pg.1).

In Durlak's paper 'Studying Program Implementation is Not Easy, but it is Essential (65)', he emphasises; it is "not evidence-based programs [sic] that are effective, but it is well-implemented evidence-based programs that are effective" (pg.1124) and adds that – implementation, is what is experienced on the ground.

To emphasise the common focus on interventions, the United Nations asserted that they "know what works" in taking care of the health of women and children (66)(pg.3). In another instance, the World Health Organization (WHO) Commission on the Social Determinants of Health has

laid out effective interventions to improve the health of populations and to establish health equity (67). Experts know what good is and what it is people should be doing. The difficulty is creating an environment, awareness, a culture, the motivation, and desire for everyone to do it.

While interventions, which are theoretically effective, are relatively well known, their level of coverage is weak (68). The conditions for their effective implementation are poorly understood (69). In fact, studies have demonstrated only 50% effectiveness of interventions because of the multitude of barriers to their implementation (70). To emphasise this impact, a study evaluating the evidence base in cirrhosis and hepatitis highlights the ever-changing demands on professionals. For research articles published between 1945 and 1999, only 60% of the evidence was still valid by the year 2000. Furthermore 19% were obsolete and 21% were considered incorrect and harmful (71). This emphasises the complexity ensuring practitioners deliver services consistent with the evidence base. This is often presented in the form of clinical guidelines; however, guidelines are not consistently adhered to, resulting in 30-45% of patients in some cases receiving care inconsistent with the evidence, and as much as a quarter of care being potentially harmful (23,72). It is not enough to know if a health intervention is effective; it is also necessary to understand "why the intervention works, how, for whom and in which contexts" (69)(pg.1). Implementation science essentially bridges the gap between theory and effective practice (73). At the core of implementation science is the question: "How do we get what works to the people who need it, with greater speed, fidelity, efficiency, quality, and relevant coverage?"(74)(para. 9).

Clinical Guidelines

Clinical guidelines capture the evidence-base through a display of actions and recommendations to guide healthcare professionals to deliver safe and effective care (75). Where guidelines capture the evidence-base, implementation science is concerned with the structured process of widespread compliance with evidence-based practices (2). Clear synergy exists between evidence-based clinical recommendations in guidelines and the evidence-based process of implementing them. However, clinical practice is not always consistent with their recommendations (76–78). Lack of clinician knowledge, understanding, and awareness of guidelines are considered some of the main barriers to guideline adherence (76,79). Clinicians cannot adhere to guidance they do not know about. Yet, as little as 21% of guidelines are

implemented using a framework (80). Fundamentally, without successful implementation, the people the guidelines are intending to help (i.e., patients) cannot experience the expected impact of evidence-based clinical interventions.

Summary

Clinical outcomes can only be realised once implementation of an intervention is successful. This study uses implementation science to guide a structure for implementing novel clinical guidelines, which has not been delivered using a framework in Wales before.

The scope of this undertaking is to achieve widespread acceptance and adoption of the guidelines across the seven Health Boards in NHS Wales. This is proposed within a programme of work tightly aligned with government policy. The intention is that a structured approach to implementing national respiratory guidelines will demonstrate implementation impact. This will subsequently facilitate assessment of patient benefit on a scale that has not been achieved in respiratory medicine in Wales before. To achieve this, an implementation framework influenced by implementation science will be applied.

Chapter 2: Developing the Framework

Chapter Objectives

- 1. To draw on the relevant literature to develop a process for the design of the implementation framework.
- 2. Based on the synthesis of the literature, present detailed steps to developing an implementation framework for testing in preparation for formal validation.

Process for Developing the Framework

The methodology for developing and testing the framework is broken down into four key steps:

- i) Critical analysis of the literature.
- *ii)* Using this to design the initial framework.
- iii) Applying and testing the framework in the real-world.
- *iv)* Adapting the framework based on the lessons learnt, in preparation for formal validation.

This follows a similar methodology used in the development of other implementation frameworks or models (26,81–84). The Theoretical Domains Framework used six steps: identifying theories and constructs; simplifying into theoretical domains; evaluating the domains; conducting a cross-disciplinary evaluation and synthesis of the domains and constructs; validating the domain list; and piloting a series of interview questions to elicit views about the framework (81). The Context and Implementation of Complex Interventions (CICI) framework by Pfadenhauer (26) used a three-step process to develop an initial framework. This involved firstly identifying relevant model frameworks through literature searches. The initial framework was then applied to three different theoretical scenarios, and where assessments revealed inconsistencies in the interpretation of terms, the model was adapted accordingly. The revised framework then underwent extensive application by the researchers in different settings and external peer-review by three experts. Both these examples demonstrate a step-process broadly comprising analysis of the literature, testing of the model, and adaptation following external validation through Delphi methodology.

The implementation framework in this research will undergo the first two steps resulting in a modified framework that has been tested in the real world in two case studies (Chapters 6 and 7). This research applies an exploratory mixed methods sequential study design through exploring a concept before validating it (85). This approach is considered effective for greater versatility in discovering new ideas, where interviews generate primary and direct data that identifies common themes and issues in depth before validation by quantitative assessments (85).

Subsequent study will involve validating the framework through peer review, or further testing in different settings (Figure 2.1). This final stage of validation is outside the scope of this study because it was not feasible to complete this phase within the time available. Furthermore, developing and implementing clinical guidelines requires a considerable period of consultation and approval, in usual cases.

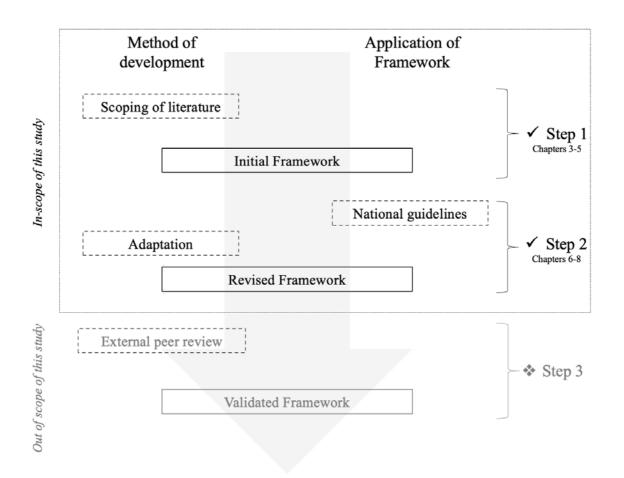


Figure 2. 1: Development and Application of the Implementation Framework based on Pfadenhauer's validation process of their CICI framework (26). Step 1 and step 2 are within scope of this study.

Step 0: Scoping of Literature

A literature search applying the terms 'implementation science' offered a broad spectrum of articles. Those offering a broad perspective of implementation science were read and used to provide the basis for the introduction to the field. Key textbooks and papers were included. This section provides a wide perspective of implementation science to offer a high-level structure to developing the framework.

Step 1: Initial Framework

Step 1a: High-Level framework

A high-level framework was developed based on the five categories of implementation frameworks outlined by Nilsen (86) and modified using the criteria used for appraising applicability of the CICI framework (26):

- (i) Is the framework conceptually simple, clear, and coherent?
- (ii) Can it be applied in different settings, demonstrating versatility and generalisability?
- (iii) Is the framework compatible with the other theories, frameworks, or models?

The framework was then assessed against the checklists developed by Moulin to determine high-level structural completeness (87). The checklist accentuates the broad principles of implementation to understand the baseline, common actions, barriers, and enablers, when planning.

Step 1b: Review and synthesis of the literature

The criteria for the analysis of relevant frameworks and models are structured using Nilsen's taxonomy of implementation theories, models, and frameworks (86) discussed in Chapter 3 (*Implementation Theories, Frameworks, and Models*). Nilsen developed a simple taxonomy of implementation theories that is specifically relevant to the respiratory programme central to this research, because of its practical nature of introducing implementation interventions into

the real world. Furthermore, Tabak *et al.* identified 61 dissemination and implementation models to help researchers better identify and select models to inform their work (88). Both Nilsen and Tabak are leading experts in implementation science in healthcare and offer a comprehensive landscape for implementation with a broad high-level structure to initiate the search process (74).

The literature review was initiated through selecting studies from the work of Nilsen and Tabak and applying backward and forward snowballing and citation tracking (89) to identify studies presenting implementation process models that are specifically relevant to implementing at scale (part 1). This methodology was chosen because ambiguity in terms made searching for implementation process models (according to the taxonomy presented by Nilsen) unwieldy, as each search criteria listed mostly irrelevant and unrelated studies to this research, perhaps a reflection of the infancy of this field of study. The limitations to this approach are discussed in Chapter 4. However, two separate standard systematic searches for implementation process models were undertaken in PubMed and Medline with forward tracking searches in Google Scholar using similar methodology to Pfadenhauer (26); the latter search was based on a landmark paper by Aarons et al. (90). This paper has relevance to this study because it recognises that implementation models should be shaped by the service contexts. Furthermore, they advanced a conceptual model of factors they believed had the strongest influence on evidence-based practices within publicly funded organisations. Selection of papers was centred on studies implementing at scale, and where they emerged, studies relating specifically to implementing guidelines were assessed.

Further synthesis and critical analysis of 20 implementation process models was undertaken to determine the functional elements of the framework (*part 2*). The process for developing the initial framework is presented in the schematic Figure 2.2.

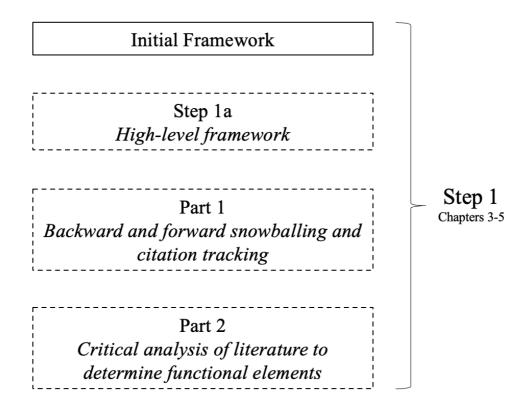


Figure 2. 2: Step 1 actions illustrating Step 1a: developing a high-level framework, and the subsequent parts within step 1: Part 1, backwards and forward snowballing, and citation tracking, followed by Part 2: critical analysis of the literature to determine the functional elements of the proposed framework.

Step 1b: Framework domains and components

The implementation process domain of the framework was further constructed using the following criteria based on features of the 20 frameworks critiqued:

- *i.* Format and structure of the framework
- ii. Logic and interactions between domains and constructs
- *iii.* Content and instruction

Constructs, domains, relevant steps, and features identified within the literature are listed and ordered into a sequence where it is relevant to the process of implementation (81). These are simplified in format, logic, and instruction to form the core features of the framework.

Step 1c: Developing an Implementation Strategy for NHS Wales

A slightly different approach is taken with determining an appropriate implementation strategy, because the way implementation strategies are presented in the literature is markedly different to implementation process models and frameworks, therefore it is assigned a separate chapter (Chapter 5). The distinction between implementation process models and implementation strategies is described in Chapter 5. Both are considered in this study to be the core features of the implementation framework; this is explored in more detail in the next chapter.

The implementation strategy domain of the framework is developed specifically for the target population in Wales through ethnographic observation; that is deemed highly appropriate when assessing complex issues (91). Feasibility of an implementation strategy for Wales was assessed via the Learning Transfer System Inventory (LTSI) (92). Semi-structured interviews were conducted with healthcare practitioners in primary and secondary care who manage respiratory patients to determine the key levers and barriers to adoption of implementation strategies with a focus on education and application of guidelines. Following a request through individual Health Board Respiratory Teams and the GP network via the Associate Medical Directors for each Health Board to participate in interviews, several healthcare professionals were selected against set criteria below (Table 2.1).

	Criteria
Inclusion	1. A practicing healthcare professional within primary or secondary care.
	2. An employee within a GP practice or Health Board in NHS Wales.
	3. Uses respiratory guidelines (any) to support management of respiratory patients.
	 Uses spirometry (preforms and/or interprets) to support the diagnosis of COPD and asthma.
Exclusion	1. Healthcare professionals that do not directly manage respiratory patients.
	2. Healthcare professionals that do not see patients face-to-face.
	3. Research healthcare professionals with no clinical input.

Table 2. 1: Inclusion and exclusion criteria for interviewees.

The questions are listed in Appendix B. Consent (see Appendix C) was obtained, the interviews were audio recorded using a handheld Dictaphone, and these were transcribed verbatim. A thematic analysis of the interview data was conducted following a combination of the guide published by Braun & Clarke's framework (93) and the six-step Template Analysis developed by Brooks *et al.* (94) (Table 2. 2). The Braun & Clarke framework is a simple six-step process detailing the key elements for robust analysis as well a helpful 15-point checklist for conducting good thematic analysis. The Template Analysis is a similar model, which adds further clarity for phase four. Therefore, a combination of the two frameworks was applied.

Following further analysis and process of deducing to common themes, the analysis derived several themes from the original list, with associated codes following second round analysis. Within the clusters selected, themes were generated as enablers or barriers associated for that cluster. Against each theme further detailed codes were generated. Assigned to these codes are the important data identified during thematic analysis. Relevance and importance were mainly determined by the frequency with which themes were highlighted by the interviewees.

Braun & Clarke Methodology	Template Analysis	Phases applied		
Phases				
1. Familiarising yourself with	1. Become familiar with the	1. Familiarise yourself with your		
your data	accounts to be analysed	data		
2. Generating initial codes	2. Carry out preliminary coding	2. Generate initial coding		
	of the data			
3. Searching for themes	3. Organise the emerging	3. Organise emerging themes		
	themes into meaningful clusters	into meaningful clusters		
4. Reviewing themes	4. Define an initial coding	4. Define an initial coding		
	template	template		
5. Defining and naming themes	5. Defining and naming themes	5. Define and name themes		
6. Producing the report	6. Finalise the template and	6. Produce the report		
	apply it to the full data set	-		

Table 2. 2: The phases from Braun & Clarke and Brooks et al., and the phases applied in this study.

Results from the interview data are presented against the two clusters – the enablers to learn; and the enablers to apply learning, which are aligned with the LTSI (95). The Learning Transfer System Inventory (LTSI) is an instrument that identifies factors affecting the process of transferring knowledge between different contexts. The LTSI was selected to structure the interview questions. It constructs knowledge transfer into three major groups – personal, training, and work environment factors. The constructs are segmented into two periods learning and application of learning. The LTSI was the first empirically tested instrument for understanding the various processes that occur around knowledge transfer (96). It helps practitioners understand the various processes that occur around knowledge transfer and shows how they interact with each other, how they are independent and how their influence on knowledge transfer can be modelled. This underpins guideline development as a tool to transfer knowledge through a range of ways. For example, knowledge on a single guideline poster and associated education that is accessible to guideline adopters helps overcome some of the primary barriers to guideline adoption (79,92). Themes are matured through detailed analysis and presented below through interview captions. To demonstrate the collective inclusion and contribution to the data, all interview participants are labelled interviewee 1-7.

Step 2: Revised Framework

Step 2a: Application of framework

The initial framework is applied in the implementation of national guidelines for NHS Wales in two different contexts.

National management and prescribing guidelines for COPD/asthma published in June 2019 and February 2020, respectively (15,16), presented in Chapter 6 (Case Study 1)

National management guideline for COVID-19 published in March 2020, presented in Chapter 7 (Case Study 2) (97).

For both guidelines, all users across Wales were exposed to the guideline simultaneously. A parallel cluster and stepped wedge methodology was considered (98). However, unlike other pragmatically controlled studies such as the 2-year stepped interventional programme replicating the Michigan central venous-blood prevention measures across multiple Intensive

Care Units in NHS England (99), this was not feasible given the national directive and pan-Wales communication and publication on a centralised web tool.

Step 2b: Adapting the framework

The framework was adapted based on real-world observations of the implementation of the guidelines in two distinctively different contexts: the standardisation of chronic disease management for asthma and COPD across primary and secondary care (presented in Chapter 6); and the management of acute COVID-19 in hospitals (presented in Chapter 7). Adaptation to the framework is described against each case study and summarised in Chapter 8.

Step 3: Validated Framework

The validation of the framework falls outside the timeline and scope of this thesis. However, how this may be undertaken in future research is detailed in Chapter 8.

Summary

The framework is devised using a three-step process, a similar methodology applied by others (26,81–84). Scoping of the literature assesses the relevance of implementation science for guideline implementation and guides the development of a high-level framework. Critical analysis of the literature provides the basis for developing the framework constructs necessary to facilitate the process of implementing clinical guidelines in practice.

The next chapter takes a wide exploration of the implementation science literature as the preliminary step (step 0 – scoping the literature) to developing the constructs to a framework that can be applied to the implementation of national clinical guidelines in Wales.

Chapter 3: Scoping of the Literature

Chapter Objectives

- 1. Introduce the concept of implementation science and practice, what it means, and its relevance to this study.
- 2. Explore how implementation differs from diffusion and dissemination.
- 3. Describe different implementation theories, models, frameworks, and strategies.
- 4. Propose a high-level conceptual implementation framework for introducing national respiratory guidelines based on the broad understanding of implementation science.

Implementing Evidence-Based Practices

Evidence-base practices relate to empirical research delivered through basic science research and human clinical research illustrated in the first two boxes interlinked with translation phase 1 (T1) in Figure 3.1. Following the sequence of basic research, treatment development, efficacy, and effectiveness, dissemination, and implementation features towards the final step; 'translation to practice' (100).

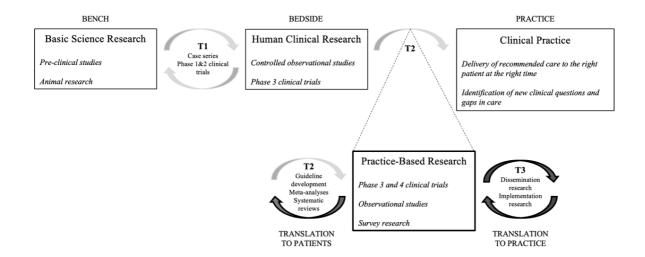


Figure 3. 1: The process for developing usable innovations from evidence into practice. Adapted from the current National Institutes of Health Roadmap for Medical Research (100) (pg.405).

Translation is the "process of moving something from one place to another" (58)(para 2). To achieve this, it needs a vehicle and a process to get from its original source, for instance a randomised controlled trial (RCT) to its destination, for this example – routine practice to benefit patients (60). However, to achieve the benefits, it must be practiced in the way it was studied in its original controlled environment (101). Where this does not happen, there is a loss of fidelity, potentially leading to reduced quality and/or efficacy of the intervention, and failure to yield the same outcomes in the real world (102).

Implementation practice forms part of the Diffusion-Dissemination-Implementation continuum (103). Diffusion is the passive, untargeted, and unplanned spread of new practices. Diffusion is the process by which an intervention or innovation, is communicated throughout the target population (60) through certain channels over time between the members of a social system (104). However, frustratingly, diffusion of innovations can take a long time (105). So much so, that by the time the innovation is experienced by the target population, it may be irrelevant or even out of date (1), which will raise concerns about its clinical effectiveness and safety (106). Dissemination is the active spread of innovations involving planned and structured strategies to reach a target population. Whereas implementation is the process of adoption and institutionalisation of new practices within the target organisation following a series of targeted and planned activity (86).

Diffusion of Innovations

The more people that know about an innovation and the more it is accepted, the more the innovation will be used and the likelihood it will spread to others. The context, relevance, and interest in the subject matter will determine whether the innovation is received at all. The endpoint of diffusion is that members of the social system adopt the new idea, intervention, behaviour, product, innovation etc. (103). The currency for adoption, therefore, is the observation of change – that is, a person within the social system doing something differently to before. It is the measure of adoption and change that Rogers' work concludes; lending important principles for change management techniques applied across sectors (107). Adoption of an innovation does not happen concurrently across the target population. In fact, it is the spread of the adoptability of the people within the target population that has the greatest impact on system change (107). Some people are more likely than others to adopt a given innovation at a particular time. This may be influenced by several implementation principles such as

readiness, motivation, and capacity (108). However, Rogers defined distinct characteristics in people who adopt innovations early, compared to those who do so later, or perhaps not at all (Figure 3. 2).

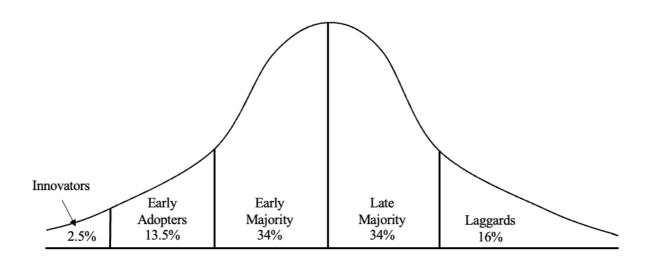


Figure 3. 2: Adopter categorisations based on innovativeness. Taken from Rogers (104) (Figure 7-2 p. 247).

Innovators are the first to accept and trial something new (109). Early adopters embrace new things and are open to change. Early adopters accept an innovation before the average – but they do not lead change. Late adopters take time to adopt. They often wait for others to confirm the benefits of the change. Laggards are sceptics of change, the most difficult to convince, and last if not ever to adopt the innovation at all.

Rogers also detailed a paradigm of variables determining the rate of adoption of innovations, including – perceived attributes of innovations (relative advantage, compatibility, complexity, trialability, observability); the type of innovation-diffusion (optional, collective, authority); communication channels (e.g., mass media, interpersonal), the nature of the social system (e.g., norms, degree of interconnectedness, etc.); and the extent of the change agent's promotional efforts (104). However, Dearing and Cox argue that several contextual aspects of diffusion go unstudied. Competing or complementary innovations offer choice to the target population of adopters, which changes the projection of adoption – as a result of progression and adaptation (105). Failures are most common, and deceleration can indicate a decision to abandon it for another one (110), whilst non-adopters influence others to reject an innovation even once socially confirmed (111) (Figure 3. 3).

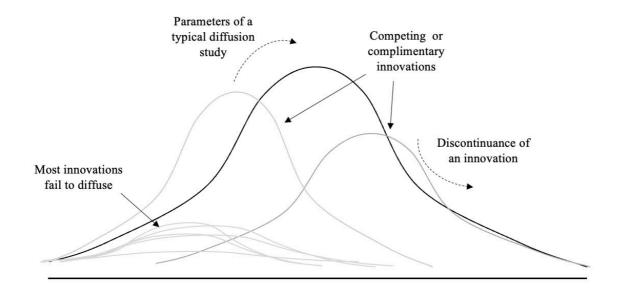


Figure 3. 3: Other contextual factors that influence the adoption of innovations (105)(pg. 184).

Active Dissemination

In contrast to diffusion, where innovation spreads passively through communication channels, dissemination is proactive, with intentional efforts to get the intervention into the hands of the people who can use it (112). Dissemination is the process of sharing research findings and evidence-based practices with stakeholders within the social system (113). Dissemination science applies concepts from diffusion and marketing to increase the likelihood of knowing about a particular innovation, intervention, research, or practice. Dissemination differs from diffusion as it is targeted – typically involving purposeful distribution of information and intervention materials to the target population (114).

Figure 3. 4, adapted from the work of Shannon and Weaver several decades ago (115) illustrates a basic model that will be used as a structure for reference in the development of the implementation framework because it has such relevance to overcoming key barriers to clinical guideline adoption, which is assessed in Chapter 5. The simplified model by Shannon and Weaver suggests a *message* is delivered by a *source* through a *channel* to the *audience*.

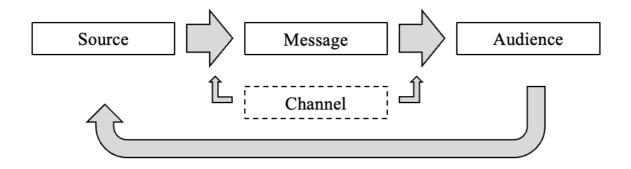


Figure 3. 4: Model for dissemination research (115)

Dearing and Singhal argue that dissemination science differs to diffusion as it "only concerns efficacious (internally valid) and effective (externally valid) innovations", rather than any innovation (103)(pg.4). Further, the authors add that dissemination investigations are a priori interventions to affect the adoption within the target service; that is "intermediaries between change agencies and end-users" and a focus on organisations as units of adoption, not individuals. Dissemination science therefore "pairs strategies to achieve innovation adoption with strategies to achieve effective use" (103)(pg.310); thus, emphasising the proactive and planned nature of dissemination activity. The 21st century has seen an explosion in dissemination opportunities through better and wider connections between people and the ability to transfer large volumes of information, automated content, and data (116). Digital dissemination can happen in more effective ways to the traditional mechanisms. Social media is widely used by researchers and innovators to get their research out to a wider audience (117,118). Social media can reach a wide audience and generate greater penetration within the target population more quickly through scheduled automated communication campaigns using personalised and engaging content. The close relationship between the efforts and processes between dissemination and implementation means this area of study is commonly referred to as Dissemination & Implementation (D&I) science (119); however, for the purpose of simplification, implementation science will be used throughout this thesis.

Many studies of implementation examine the period before dissemination to understand the feasibility, practicality, and acceptability prior to scale up (120). Less has been studied post-dissemination, partly because of the time it takes for diffusion to occur (105). The consumption of knowledge, capacity to retain it, the views of opinion leaders and peers, and individual perceptions around the innovation, influence the rate and magnitude of adoption. Gradual exposure encourages better understanding and reduces uncertainty around it as the innovation effectively becomes less 'new' or risky. Rejection can occur at any stage. However, rejection of the innovation is not entirely due to a negative perception. Potential adopters may forget about it following first exposure, or do not have the opportunity to use it in the real world; thus, emphasising the value of repeated multi-faceted efforts to stimulate adoption through system-wide implementation.

Implementation Practice

Implementation studies explore what happens prior to, during, and after adoption occurs (103). The key question for most studies of implementation is the effect of translating field-based tests into real-world scenarios (121) culminating in sustained use and normalisation of programme components and activities (122). Just over 20 years ago, Grol and Grimshaw stressed that *evidence-based practice* must be complemented by *evidence-based implementation* (123). The past two decades have been marked by significant progress with better understanding of implementation barriers and facilitators and the evolution of implementation strategies. Implementation science is increasingly gaining credence as a revolution in healthcare, partly because it is being recognised as the thing that-makes-the-thing happen, but also offers answers to why it (very often) does not happen. The result is a proliferation of applied studies, particularly in healthcare (124–127), but also in education (128–131).

For context, a simple search on PubMed for the term 'implementation science', illustrates a dramatic exponential rise in the numbers of publications over time with nearly 9000 publications in 2021, compared to only 10% of that number in a single year, ten years ago. Since 2014 the Journal of Implementation Science has gradually increased its impact. Implementation science remains a relatively new field of study bridging influence and expertise from many specialisms such as psychology (32), sociology (132), policy (133) and quality improvement (134). Whilst the intention is to integrate and apply the research evidence (efficacy) into the real world (effectiveness), the study of implementation science, its theoretical modelling and wide range of published application frameworks is perhaps increasing its complexity. This will inevitably widen the gap between dissemination and implementation science experts and the people who need to apply it to generate the necessary behaviour change in clinical practice (Figure 3. 5). Therefore, the scientific application and specialist knowledge of implementation experts is likely to stimulate a proliferation in specific implementation roles within healthcare organisations.

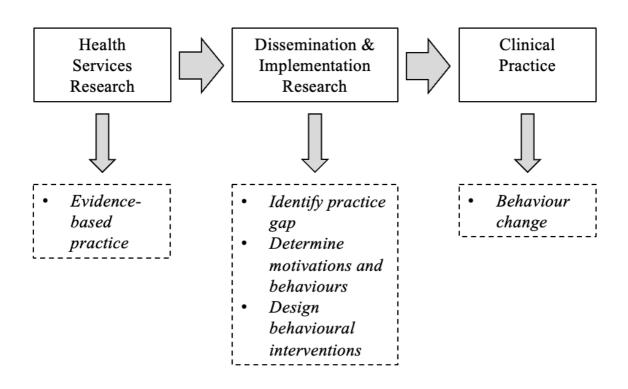


Figure 3. 5: Relationship between evidence-base, dissemination and implementation science and clinical practice (135).

Implementation Frameworks, Theories, and Models

Reassuringly, systematic reviews of implementation frameworks have identified commonalities, such as the necessity for a clear rationale and high-quality evidence-base, organisational and stakeholder alignment, adopter and organisational capacity and readiness, facilitation, and contextual-drivers (82,88). This lends towards simple and replicable principle-based approaches. Although, differences exist between implementation frameworks, implementation theories and implementation models as they are interpreted or applied in different contexts. Furthermore, the terminology is often used interchangeably (86). Nilsen's synopsis of implementation frameworks, theories, and models deduced further categories based on their applicability in research and practice, frequently used by researchers, healthcare leaders, and policy makers (Figure 3. 6). In the face of increasing number of these and the ensuing complexity and ambiguity in the scope of implementation science, Nilsen outlines a complete taxonomy for the field of implementation science. Nilsen identifies three principal aims for the theoretical approaches used (86):

- 1. To describe and/or guide the process of translating research into practice requires a *process model*.
- 2. To understand and/or explain what influences implementation outcomes requires determinant frameworks, classic theories, and implementation theories.
- 3. To evaluate implementation requires an evaluation framework.

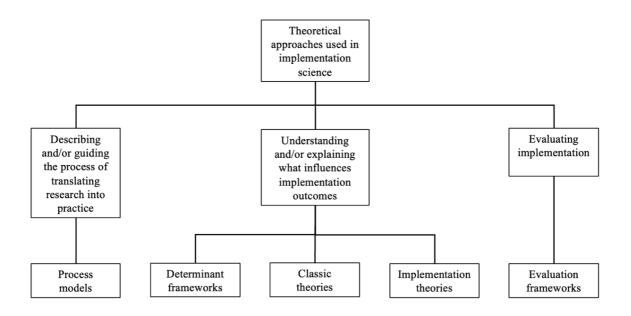


Figure 3. 6: Taxonomy of implementation theories, models, and frameworks (86).

The taxonomy describes five theoretical approaches used across implementation science (expanded with descriptions in Table 3. 1). An implementation framework describes factors believed to influence an outcome, but it does not explain how or why that outcome will occur. Frameworks offer an overarching structure including hierarchical categories and their relationships to one another. An implementation theory on the other hand is far more explanatory. Whilst it describes testable phenomena, it also attempts to explain the factors, which influence an outcome, whereas an implementation model describes a deliberate simplification of the practical processes to translating evidence into practice. Theories and frameworks generalise findings and synthesise conclusions into simplified explanations of implementation phenomena for application by implementers and researchers (136).

Taxonomy sub-group	Description
Process Models	Used to describe or guide the process of implementing
	research/interventions into practice.
Determinant Frameworks	Determinant frameworks help identify the barriers and facilitators of
	implementation
Classic Theories	Explore the characteristics of the innovation with respect to potential
	adopters and the environment within which it is being implemented
Implementation Theories	Guide the action and planning of implementation but do not describe the
_	explicit steps for undertaking the implementation process
Evaluation Frameworks	Provide a structure for evaluating the action, process, and outcome of
	implementation

Table 3. 1: Taxonomy sub-groups for implementation models, frameworks and theories proposed by Nilsen (86).

Functionally, process models involve the application of implementation theory into practice using stages, phases, and steps. An implementation process model can be used to implement interventions as part of a structured, planned, implementation strategy. However, some experts indicate there is a scarcity in research detailing the steps and processes for undertaking implementation (137). This is perhaps because the process of implementation cannot be generalised beyond a specific intervention or innovation, context, or environment.

Determinant frameworks help identify the barriers and facilitators of implementation (137). Common frameworks include the Consolidated Framework for Implementation Research (CFIR), which is composed of five major domains including; intervention characteristics, inner settings (of implementation organisation), outer setting (including external context and environment), characteristics of the individuals involved in the implementation (often referred as actors, facilitators, implementation team, etc.) and the implementation process, which includes the strategies and tactics used to influence intervention adoption (138). Other examples of determinant frameworks include the Theoretical Domains Framework (TDF) (81), the Normalization Process Theory (NPT) (132), the Promoting Action on Research in Health Sciences Framework (PARiHS) (139), and the Practical, Robust, Implementation and Sustainability Model (PRISM) (140). Close synergy exists between implementation process models and determinant frameworks with marked cross over between the two.

Classic theories explore the characteristics of the innovation with respect to potential adopters and the environment within which it is being implemented. These are sometimes called descriptive or normative theories where innovation adoption is considered passive with a naturalistic process of change (141). The change process is therefore observed in the behaviours of the adopters and across the system within which the innovation is being adopted. Implementation theories generalise findings into a simple presentation that can be applied across a range of settings. Theories guide the action and planning of implementation but do not describe the explicit steps for undertaking the implementation process (136). Theories help identify determinates and drivers of implementation, they guide implementation research through framing research questions and hypotheses, whilst testing the appropriate relationships, and facilitate the contextualisation of the findings (142). Common implementation theories include the Organizational Readiness for Change (143), Implementation Climate (144), and again, the NPT (145), which emphasises cross over between categories.

Evaluation frameworks provide a structure for assessing the actions, processes, and outcomes of implementation (13). Whilst Nilsen identified evaluation frameworks as a category of its own, he also emphasised the commonalities between other frameworks and models and where other models have been applied for the purposes of evaluation, such as the TDF (81,146), the NPT (147,148), and COM-B (149,150). Furthermore, application of the PARIHS framework (139) and the Consolidated Framework for Implementation Research (CFIR) (151) have also resulted in the development of instruments to measure implementation outcome, some of which may be listed in the helpful guide, the implementation outcomes repository (152). This highlights the inherent value of implementation outcome measures as part of the implementation process to determine success, failure, and impact. Therefore, these will function as key features for the implementation framework that emerges from this study.

Implementation Strategies

Implementation strategies are not considered in the taxonomy presented by Nilsen (86). However, it has been included here as a significant function of the implementation process. Implementation strategies are "the actions taken to enhance adoption, implementation, and sustainability of evidence-based interventions" (153)(para.2). Implementation strategies provide the how-to – the specific methods, mechanisms, and tools to promote the adoption of sustaining evidence-based practices. Implementation strategies are essential to support the implementation of interventions (154–156). The components of an implementation strategy are designed specifically to overcome barriers for the adoption, to increase the pace and effectiveness of implementation (157).

Fundamentally, implementation requires some-thing to implement (158). This could be innovations, products, practices, procedures, and drugs. However, the term 'interventions' is a broad term and for this study it is avoided, as it can also denote multiple dimensions of the programme, such as the clinical evidence-base, the clinical procedure, the clinical practice, or action, for instance. The term 'innovations', whilst commonly used in the literature, is similarly problematic as it suggests something is new or unique (141). Eventually, the intention is that the new behaviour will indeed become routine, and therefore the innovation is no longer new at all – institutionalised – perhaps the ultimate desire of implementation efforts (159). Whilst clinical interventions and implementation interventions are fundamental features of any

implementation programme, the terms are often entwined (160), but are proposed here as separate entities to emphasise their discrete purpose and value (see Table 3. 2 for definitions).

For clarity of terms, clinical interventions are the programmes, practices, principles, procedures, products, pills, or policies (74) that delivery systems enact to improve health behaviours, health outcomes, or health-related environments (155). Implementation interventions are considered here as the usable products within an implementation strategy. Implementation interventions facilitate the adoption of evidence-based (clinical) practices.

Implementation strategies describe the actions relating to the application of evidence-based practices (3). Carefully selected implementation strategies are necessary to support successful implementation of clinical guidelines (161), particularly when they are introduced into complex environments (i.e., healthcare systems). It must overcome a range of potential barriers to encourage adoption of evidence-based practices (79). Inadequate consideration and/or execution of an effective implementation plan will impede the target audiences' adherence with them (162). A good implementation strategy increases the probability of evidence-based practices to exist. Therefore, it is considered here to be a core function of the implementation framework. As a result of this wide analysis of the broad literature around implementation science, the functions: (i) implementation process and (ii) implementation strategy, are considered most essential for implementation practice of clinical guidelines.

Term	Definition	Other terms used in the literature
Framework	"Graphical or narrative representation of the key factors, concepts, or variables to explain phenomenon of implementation" (163)(pg.3).	Model, theory, process, structure, guide
Implementation strategy	the 'how to' element for the target population to deliver evidence-based practices – the specific methods, mechanisms, and tools to promote the adoption of sustaining evidence-based practices. Implementation strategies are essential to support the implementation of interventions (156)	Interventions, innovations, plan, enablers, drivers, barriers, knowledge transfer, process
Implementation interventions	The usable products within an <i>implementation Strategy</i> . Implementation interventions facilitate the adoption of evidence-based practices (154)	Intervention, innovations, products, things
Intervention	The programmes, practices, principles, procedures, products, pills, or policies – the seven P's that have demonstrated to improve health behaviours, health-related environments, or health outcomes (155)	Innovation, clinical intervention, service, drugs, evidence-base practices

Table 3. 2: Summary of key definitions applied to this study, and which form the basis for the framework.

High-level Framework

As a result of the broad scoping of the literature it has been possible to generate a high-level framework (Figure 3. 7). The high-level framework is a simple reference point for planners and implementers because it provides a possible structure and focus to the key areas for planning. Further critical analysis of the literature will use the evidence-base to design a conceptual implementation process model and an implementation strategy function to the framework. This will constitute the framework that will be tested to implement national clinical guidelines in different settings in Wales.

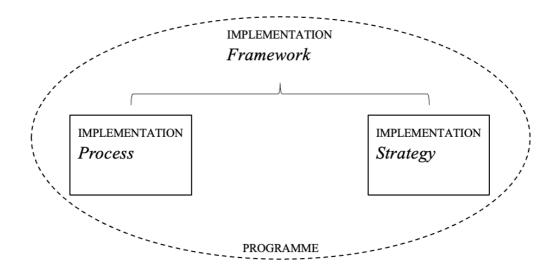


Figure 3. 7: The high-level framework based on the landscape of implementation science illustrating the active components that are determined to be essential for the practice of implementation of national guidelines at scale.

The constructs function within a *Programme* is depicted by an oval dashed line that encapsulates the framework components and the domains within them. This symbolises the constraints of the framework functions with respect to the scope, vision, remit, and jurisdiction of the programme. Conceptually, the high-level framework consists of two key implementation functions – the implementation process (the *how*) (83,164–167) and an implementation strategy (the *what*) (79,133,154,168–172). This is further developed with consideration of the programme at a national level (10,14,19).

- 1) The Implementation Process guides the course to translating research into practice.
- 2) The *Implementation Strategy* details the techniques to overcome potential barriers to implementation and to facilitate the implementation process.

Whilst in practice, the framework's high-level components (implementation process and implementation strategy) are not discrete, they are purposefully designated separate functions, as their planning, development, and practical application are remarkably different. It is not presented in this way within the literature and assessment of the literature within this thesis indicates the two functions are frequently combined or interchangeable, which has the potential for ambiguity that may impact the effectiveness of implementation activity (160). This is considered by the author to be a crucial benefit to this framework as it makes the practical application of implementation clearly defined against two core components. To emphasise this point, the components can be assigned against the checklist proposed by Moullin *et al.* when planning for implementation (87) (Table 3. 3).

Recommendation	Implementation Process	Implementation Strategy
Select a suitable framework(s).	X	X
Establish and maintain community stakeholder engagement and partnerships.		X
Define issue and develop research or evaluation questions and hypotheses.		Х
Develop an implementation mechanistic process model or logic model.	х	
Select research and evaluation methods.		X
Determine implementation factors/determinants.		X
Select and tailor, or develop, implementation strategy(s).		X
Specify implementation outcomes and evaluate implementation.	X	
Use a framework(s) at micro level to conduct and tailor implementation.		Х
Write the proposal and report.	X	

Table 3. 3: The high-level framework as a checklist against the ten recommendations for using implementation frameworks in research and practice proposed by Moulin *et al.* (87).

Strengths

This chapter has taken a broad perspective of diffusion, dissemination, and implementation science to identify the core functions of an implementation framework to support the practice of clinical guideline acceptance, adoption, and adherence in Wales. The chapter identifies some landmark papers of relevance. This shapes the high-level conceptual framework that provides a structure for a deeper dive into the key aspects of each function of the framework that will be explored in the following chapters.

An exploration of common terms used within the literature and simple descriptions of terminology was undertaken to alleviate ambiguity. This was considered by the author of this thesis to be a critical objective when scoping the literature.

Limitations

The predominant focus on the article by Nilsen from 2015 (86) that shapes the high-level framework structure presented in this chapter, may potentially render the framework structure obsolete should further evidence emerge that changes or refutes the argument poised by Nilsen. Whilst efforts have been undertaken to broaden the argument to incorporate further studies, the challenge was to remain specific to the objectives and scope of this study. A wide exploration of factors influencing clinical behaviour beyond knowledge transfer and implementation of evidence-based practices was not undertaken.

Despite increasing work on theoretical-based implementation science principles in healthcare (172-175) there are also critics (176,177) who argue, "theory is not necessarily better than common sense" (86)(pg.9). Indeed, this has been encountered by the author here, through personal and professional reflections, which has perhaps led to the desire to create a simple format that is relevant and that can be applied as routine practice. An analysis of key implementation models, theories, and frameworks shows a pattern of common themes that can be organised with the flexibility to allow personalised approaches to implementation within different settings and contexts. The taxonomy proposed by Nilsen guides this analysis but is considered for this study incomplete, as it also requires additional functions – implementation strategies and implementation interventions (86). It is intended that the development of the framework within this study offers a more comprehensive guide that hopes to alleviate

confusion in	i terms,	and most	importantly,	the prism	through	which	efforts	must be	applied in
practice.									

Summary

Fundamental to this thesis is distinguishing *implementation effectiveness* from *intervention effectiveness*. This is critical for transporting evidence-based practices from controlled settings into real-world clinical practice (2). When such efforts fail to deliver, it is important to know if the failure occurred because the clinical intervention was ineffective in the new setting – clinical intervention failure – or if a good clinical intervention was deployed incorrectly leading to – implementation failure (13).

By studying the success and failure of adoption within various disciplines, this allows implementers to implement different interventions, into different organisations, within different contexts. Unfortunately, evidence-based (i.e., good) interventions may be disbanded, while poorly supported clinical interventions (i.e., not good) may run for years unknowingly, because of poor implementation (178). Balas & Boren concluded over 20 years ago – that it takes around 17 years to experience only a small proportion of the desired intervention impact (1). Whilst this is largely considered out-dated, the point of significance is made. Disproportionate efforts are dedicated to addressing the clinical intervention and the evidence-base that directly or indirectly relates to its discovery, rather than the intent to getting its implementation right (179). The Model of Hypothesized Pathway of Change (57) highlights, that positive implementation outcomes are needed before clinical outcomes can be realised. Whilst it can take decades before a clinical intervention is institutionalised as part of everyday practice (180), implementing this using the principles of implementation science can potentially reduce this period to two to four years (28).

The next chapter offers a comprehensive understanding of the most common implementation process models identified in the literature. Each will be compared in their design, their function, the level of instructional or descriptive content, and during which period(s) they implementation applies.

Chapter 4: Initial Framework

Implementation Process Model

Chapter Objectives:

- 1. Identify the key features of common implementation process models through theoretical analysis.
- 2. Explore the application of key relevant frameworks in the real-world.
- 3. Develop an implementation process model as a core function of the framework for implementing national clinical guidelines.

Implementation Process Models

The review of implementation process models was undertaken to identify key attributes, such as the format and structure, constructs, target (system or person), level (high or detailed) and classification (descriptive, instructional, or conceptual). These are deemed essential to select the most appropriate functions for designing a framework for guideline implementation (Table 4. 1). Furthermore, the period through which each model is best applied (pre-, peri-, post-) was determined according to the Generic Implementation Framework (163). Finally, a focus on the application of relevant process models where there is evidence in the literature beyond their theoretical description. The following section analyses the relevant implementation process models identified and presented in Table 4. 1 to identify common features and constructs relevant to guideline implementation that will subsequently be incorporated into the framework developed as part of this study.

Name	Format	Period			Constructs	Target		Level		Classification			Evidence of application in practice
		Pre	Peri	Post		System	Person	High	Detailed	Descripti ve	Instructio nal	Concept ual	•
Framework for Research Utilization (181)	Linear, 5 stages	х	х	х	Link with decision point.	X		X		X			N
The CIHR Model of Knowledge Translation (164,182)	Cyclic, 6 KT (knowledge transfer) opportunities	x			Knowledge transfer opportunities at each stage.		X	X		x			Y
The NCCDPHP Knowledge to Action (K2A) Framework (183)	Linear, 3 phases, 9-steps	x	X	x	Evidence, action, and decision points. Evaluation.	X		X		X			Y
The Stetler Model (184–186)	Linear, 5 phases	х	х		Sequential actions and transitions between phases.		X		х		х		Y
The ACE Star Model of Knowledge Transformation (187)	Cyclic, 5 phases	х	х		Five conceptual phases depicted by the points of a star.		X	X				X	N
The Knowledge-to-Action Model (83)	Cyclic, 7 steps	х	х	х	Knowledge creation separated from action cycle (application).	X		X			X		Y
The Iowa Model (165)	Linear, 7 action stages, 3 decision points		х		Actions based on yes/no answers to key decision points. Progress or adaptation.	X			x		X		Y
The Ottawa Model (188)	Linear, 3 phases, 6 constructs	х	X		Interlinked constructs progressing through the phases with feedback.	X			X	X			Y
The Coordinated Implementation Model (189)	Linear, multiple stages	Х	x		External factors integrating 'internal' environment			X				X	Y
Translating Evidence into Practice Model (166)	4 stages	х	х		Stepwise progress between the stages	X			х		Х		Y
The Quality Implementation Framework (82)	Cyclic, 4 phases		x		Each phase is supported by an implementation checklist.	X			Х		X		Y

Parkers Implementation Process Model (137)	Linear, three phases		X	Comprises three qualitative methods to gain stakeholder engagement.	X		X			X		N
Dobbin's Framework for Dissemination and Utilisation of Research (190)	Linear, 5 stages (Knowledge, persuasion, decision, implementatio n, and confirmation).	X	х	Multi-level factors that influence adoption of innovations (innovation-, organisational-, individual-, environmental-related).	X			x	x			N
Funk's Model for Improving the Dissemination of Nursing Research (191)	Linear, 4 categories and 28 items (characteristics of the adopter, the95rganizatio n, the innovation, and the communication).	X	X	Dissemination components listed, influenced by mechanisms to achieve.		X		x		x		N
Clinical Practice Guideline Implementation Model (192)	Linear, 6 categories (Identify CPG, stakeholders, environmental readiness, implementatio n strategies, evaluation, resources).		X	Interconnections between the categories progressing linearly.	X		X				x	Y
The John Hopkins Nursing EBP Model and Guidelines (193)	Cyclic, 6 stage (inquiry, practice question,		X	Interconnections between practice and learning environment to generate	X		X				X	Y

	evidence, translation, best practices, practice improvements)				improvements to inform the evidence base.							
Rosswurm and Larrabee's Model for EBP Change (194)	Linear, 6 step (assess, link, synthesise, design, implement and evaluate, integrate, and maintain).	X	x	x	Progressive steps with detailed checklist against each step to reach an end point.		X		X	x		N
Advancing Research Through Close Clinical Collaboration Model (195)	Linear, multiple interconnected steps		X		Progressive steps with discrete actions listed with a focus on generating qualitative and quantitative outcomes	X			Х	Х		N
The Clinical Scholar Model (196)	Linear, 6-step (Observe, determine, analyze, synthesize, apply & evaluate, disseminate)	х			Progressive steps to creating evidence-based practices ready for dissemination.		X		х	x		N
Quality Enhancement Research Initiative Model (QUERI) (197)	Linear, 4 interconnected components (Research, clinical QI, impact, translation)	х	х		Impact is determined by research and QI domains leading to translation of evidence-based practice	х		X			Х	Y

Table 4. 1: Summary and contrast between the most common implementation process models applied in healthcare

Implementation Periods

The proposed model accounts for all phases to accommodate the full cycle of implementation that is necessary for implementation practice. The following sub-headings provides a structure to critique each model against its period of focus: pre-implementation, [peri] implementation, and post-implementation (Table 4. 2). This is based off the approach taken by the development of the Generic Implementation Framework conceived from the observation that it was indeed plausible not all implementation frameworks include the full range of concepts and factors that influence the implementation process (163). Subsequently, the authors surmised that users face the challenge of selecting multiple frameworks. Through critical analysis of the literature, the authors developed a high-level conceptual framework spanning pre-implementation, the process of implementation, and post-implementation as an aide-mémoire to ensure all concepts are considered. In practice, the post-implementation period is seldom presented independently within the literature; although tools to assess sustainability exist (140,159,198,199). Therefore, for the purpose of critiquing the literature the term is dropped here. Instead, it is replaced by 'multiple-implementation period models', which span more than one period of the implementation process: either (i) pre- and peri-, (ii) peri- and post-, or (iii) pre-, peri- and post-. Furthermore, to deduce to its simplest form the suffix peri- is also dropped; therefore 'periimplementation' is simply 'implementation'.

Period	Description
Pre-implementation	The period of discovery and analysis of evidence-based practices, scoping
	and working up a proposal to implement.
Peri-implementation	The decision to implement followed by a period of planning, preparing, and
[implementation]	executing active and coordinated efforts of implementation.
Post-implementation	Normalisation of behaviours and processes within a given setting following
_	intervention adoption.

Table 4. 2: The three periods of implementation determined by synthesis of the literature, resulting in similar findings to the overarching concepts presented by the Generic Implementation Framework (163).

Most implementation process models traverse multiple phases of implementation, e.g., the Stetler model traverses five phases (184). Others, such as the Canadian Institutes of Health Research (CIHR) model of Knowledge Translation (164) function only in only a single phase. Whereas many classic and determinant models focus on the pre-implementation phase, so do several implementation process models. Knowledge translation is an outcome of interactions between researchers and users of the evidence-base (60). The Clinical Scholar Model has detailed instruction for knowledge translation, working on the premise that users of knowledge produce better patient outcomes (196). The model guides individuals in the early stages of learning, focusing on the key principles to observe, analyse, synthesise, apply, evaluate, and disseminate evidence, thereby promoting a critical learning culture for future researchers. From a practical basis, however, this model does not offer any practical guidance for dissemination or implementation practice. The Iowa model also focuses the early phase of implementation (165). It was developed by the University of Iowa Hospitals and Clinics in the 1990s to support nurses to apply research findings into practice to help improve patient care (200). The model begins by identifying where evidence-based practice is needed and within the model is considered either a problem-focused trigger or a knowledge-focused trigger. Problem triggers may emerge from local information such as risk management data, quality assurance and improvement data, whereas knowledge-focused triggers utilise organisational standards and guidelines, philosophies of care, and new information, from the literature. The literature is then assembled, critiqued, and evaluated for use in practice.

The Quality Enhancement Research Initiative (QUERI) Model (197) focuses on the latter phases of implementation with an intersection linking research and clinical practice and a quality-improvement focus, encouraging a re-design of organisational structures and policies and implementation of new information technology and performance metrics (201). The model is initiated through small-scale pilot projects to assess feasibility, progressively moving towards regional and national scale. Feasibility assessments by a core group of early adopters allow intervention re-design and adaptations to take place before scaling. Maintaining a focus on quality improvement and the mid to late phases of implementation, Meyers *et al.* (82) addressed three goals to better understand the complex and dynamic nature of implementation. From the synthesised 25-implementation frameworks, the researchers ranked the frequency with which each step was included within these frameworks. Their focus was predominantly the process of implementation to construct a four-phase, 14-step Quality Implementation Framework (QIF). However, some ambiguity within each of the steps leaves room for

interpretation, which increases the risk of applying each step without the precision from which its original source describes.

Peterson *et al.* (including, as co-author, Everett Rogers) applied a framework for research utilisation to seven case studies (181). The model spans across all phases of implementation and includes six sequential stages:

- (i) Research development.
- (ii) Dissemination.
- (iii) Intent to adopt.
- (iv) Implementation and adaptation.
- (v) Institutionalisation, and
- (vi) Diffusion.

Each stage is linked through agent resources via information channels. This presents a simple conceptual transition from one stage to the next. The researchers concluded that community participation is a critical factor in the utilisation of research, therefore unique contexts must be considered. Similarly, the Knowledge to Action Framework (KTA) adapted by the National Center for Chronic Disease Prevention (NCCDPHP) is commonly applied to health and social policy (183). This framework encompasses three core phases:

- (i) The research phase.
- (ii) The translation phase.
- (iii) The institutionalisation phase.

For each phase several events must take place. The research phase includes, discovery studies, efficacy studies, effectiveness, and implementation studies, with supporting structures that are applied in all phases to facilitate the process. Support structures could include implementation drivers such as assessing organisational capacity, readiness, alignment, and training, i.e., the things that need to exist to address the personal and organisational factors influencing behaviour (172).

Format, Constructs, and Instruction

The CIHR model comprises a research cycle superimposed by six opportunities to facilitate knowledge translation (164). The aim is that each of the six opportunities encourages interactions, communications, and partnerships between researchers and research users. Whilst the model provides a simple stepwise process that integrates the discovery of evidence-based practices towards its application in clinical practice, it does not address the processes necessary to undertake it. It offers little instruction between the final key stages. An important strength of this model, however, is the emphasis on the close relationship between the evidence base (through researchers) and the target population (research knowledge users) throughout the entire cycle. In fact, it emphasises this relationship early by highlighting the target population within the very first process domain. Early inclusion of the target population focuses sufficient attention to develop user-readiness, facilitating their awareness and clarity of the research aims from the outset. In doing so, the system or organisation can align with the research findings at an earlier stage than traditional methods where results are only known following its publication.

The framework by Dobbins assumes that adoption of research evidence into real-world decision-making is influenced by a multitude of characteristics relating to the individual, organisation, environment, and the innovation (190). This offers a holistic perspective about the potential barriers and facilitators for implementation. The Dobbins framework offers a binary perspective of implementation. Whilst several functions exist against each of the five stages, fundamentally this culminates in the decision to a) adopt, or b) reject the innovation. Roger's Diffusion of Innovations Theory largely influenced the framework with significant focus on the characteristics of adopters, their environment, and the organisation within which they work. Using a similar approach, the Stetler Model focuses on the individual's decision to adopt or reject an innovation, a hallmark of an early phase implementation model (202). This was later refined by Stetler in 1994 (185), and further updated in 2001 (186). The earliest model was designed to facilitate application of research findings through influencing the behaviour of the practitioner, rather than changing the system or organisation. Stetler comments in her 1994 article, that the original model was indeed "a pragmatic attempt to make research real for students and thus, eventually, for practitioners" (pg. 15). The model assumes that the users' characteristics and external characteristics influence the use of knowledge. The original model did not have any research basis – instead it tested causal hypotheses. Since then, it has been

widely cited and the latest updates have informed both practice level and organisational level change through implementation of evidence-based practices. The 2001 model has five linear phases. Each phase is designed to facilitate critical thinking about an intervention based on research findings, an analysis of the use of evidence in context of its practical application, and actions to mitigate human error in the decision-making process (186). Implementers follow a sequential arrow system throughout each phase and across into the next.

The Stetler model offers criteria to determine the feasibility of the evidence-base to address a particular problem. This includes an evaluation of substantiating evidence, current practice, and the extent to which there is a need for change. The fit of an intervention to the practice of potential users and the setting and the feasibility of implementing the intervention are achieved through assessment of the three r's; risk (and benefit), availability of resources and readiness of the stakeholders to accept change. For each of the three outcomes of phase III, specific direction is given to each in phase IV for translation/application. This phase is the 'how-to' for implementation. Phase V includes routine and dynamic evaluation relating to the change process, goal-related progress, and results/outcomes. However, despite adapting the model over many years, the lack of attention to good design and busyness of the content, which is compressed into small boxes, makes it practically unappealing to use. Design quality aside however, the detail is indeed helpful and has been applied in many areas of healthcare of relevance to this study, for example, the application of diabetic foot ulcer prevention guidelines (203). In terms of its functionality, the rigor around the analysis of the evidence base is comprehensive and continues throughout the whole model. Fundamentally, the model mostly focuses on the early phase decision to adopt evidence-base practices, rather than supporting the process of implementation.

During the similar period to Stetler's earlier work, again focusing on the application of nursing research to improve practice, Funk, Champagne, Tornquist, and Wiese developed Funk's Model for Improving the Dissemination of Nursing Research (191). Its focus is to reach practicing nurses with research findings whilst providing support to those undertaking the research. The model proposes two core strands:

- (i) Dissemination components, and
- (ii) Mechanisms to achieve.

Each strand has three categories within which is offers a list of instructions. The model is simple and supports the individual researcher by focusing on the elements perceived to influence the implementation of research recommendations. The emphasis lies in the quality of the research, characteristics of communication, and facilitation, having similar characteristics to that posed by Kitson *et al.* several years later (2). The *mechanisms-to-achieve* strand offers a list of implementation interventions, such as newsletters, consultation, and conferences. The limitation to this level of prescription, however, is that the proposed implementation interventions become obsolete when they become outdated, or as new interventions are discovered and developed. Therefore, a more dynamic system to accommodate change is required, described here in the next chapter (Implementation Strategies).

The Coordinated Implementation Model by Lomas (189) supports the transfer of research knowledge into practice by emphasising the impact of multiple stakeholder groups. Administrative, adopter, and policy alignment create an environment that facilitates the adoption of research information to benefit patients. The model focuses on the target population, in the case of this study the practitioner, at the centre with an emphasis on potential barriers and influencers, which demonstrates attributes of a determinant framework. Whilst an observation of the QUERI Model (197) is that most decision points occur in the early phase with specific importance on the planning/stakeholder engagement as part of preimplementation. This means, agreement that the problem exists, the solution is found in the innovation proposed, and all key stakeholders agree the implementation should commence. For this reason, the model would benefit where the four stages have distinct binary decision points, such as, Phase 1 – decision point – to implement – Y/N; proceed, or not. Another observation is the frequency with which the synthesis of the frameworks identified the importance of 'monitoring implementation' - step 12 in phase 3. This featured in 96% of the frameworks used in their synthesis. However, for this study, these would be considered implementation strategies – rather than features of the implementation process.

Of particular interest in the Framework for Research Utilization is that diffusion resides in the final stage. What this tells us is that the word spreads better once an intervention has been implemented and institutionalised, and that success can be imitated. The model provides a structured sequence of events that leads to institutionalisation, an area that is a neglected area of implementation research (204). Similarly, for the Iowa model a decision point determines

whether there is sufficient evidence to guide practice. Where this is the case, the intervention is developed with process evaluation and outcome measures, piloted, and modified as needed. Where there was insufficient evidence, further research, consulting with experts and determining scientific principles is necessary. Both aspects of work culminate in a second decision point, which asks – is the change appropriate for adoption in practice? Subsequently, practice can change, and relevant outcomes monitored. The model provides a simple step-bystep process map for progressing the decision of applying the evidence-base into practice. It is simple and incorporates a start and end point. Conceptually it is single-dimensional and decision points are clear through the universal use of triangle boxes. The model predominantly focuses on the decision to apply evidence and lists the sources of evidence that would help determine the need for change. However, it does not guide the process of change through implementation methodology. This encourages an intervention heavy focus and fails to address the implementation aspect of change management at an early enough stage of adequate quantity and significance. This emphasises the common focus on frameworks to the pre-implementation phase and exploration of the evidence-base; whereas in this study the objective is to shift focus more broadly, to encompass the periods following the initial decision to implement the clinical intervention.

In contrast, the ACE (Academic Center for Evidence-Based Practice) Star Model (187) is a cyclic sequence of five steps transposing scientific work into practice. Stevens at the Academic Center developed it for Evidence-based Practice in the University of Texas Health Science Centre. It is the basis of many textbooks and one of the most used frameworks within evidencebased nursing (187). The steps illustrate the various forms of knowledge translation as the evidence-base is moved through a cycle of research discovery and integration. Each cycle informs new research depicted by five points on a star, in order: Discovery research, Evidence summary, Translation into guidelines, Practice integration, and Process and Outcome evaluation. A similar systems-level approach is presented by the 2004 Ottawa Model (188), which is an example of a planned change theory with some similarities to the KTA and CIHR models. The model incorporates three indistinct phases of assessment, monitoring, and evaluation with a series of interconnecting areas. The first phase involves assessing the barriers and supports for innovation adoption. These are categorised into three interconnected domains - evidence-based innovation, potential adopters, and practice environment - each listing a range of variables that will support or hinder intervention adoption. Once these are considered, implementation strategies are developed to manage barriers, to transfer the innovation to

adopters, and follow-up. Once adoption is achieved, patient, practitioner, and system outcomes are assessed for impact. Each has a feedback loop to monitor and assess barriers and supports, presumably to facilitate adaptation where it is necessary.

The KTA adapted by the National Center for Chronic Disease Prevention (NCCDPHP) (183) leads the implementation team from the research phase to the translation phase. This involves a process of deduction depicted by an inverted triangle indicating that knowledge is tailored and becomes more specific to the creation of its tools. Knowledge is then selected and undergoes a process of application (action cycle) (Figure 4. 1).

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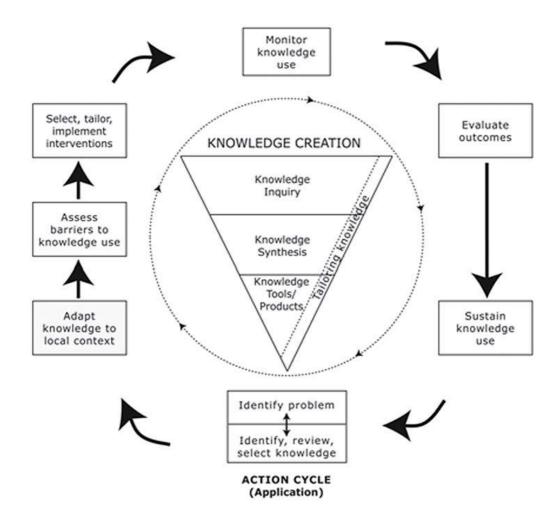


Figure 4. 1: The Knowledge-to-Action (KTA) Model by the National Center for Chronic Disease Prevention (NCCDPHP) (183).

The translation phase includes four distinct activities starting with the process for translating knowledge into products, then dissemination, then engagement, with a final decision point to adopt [or not] – following which, the expectation is to apply the intervention into practice. This framework can be adapted to a condition or intervention, and for simplicity, standard terminology and definitions are used. Within the translation phase scientific knowledge from studies are converted into 'products', which could take the form of guidelines, education, toolkits, protocols, and training. In this context 'products' are synonymous with implementation interventions or the discrete assets of an implementation strategy. The model features feedback loops where data, or field-based practices can be introduced back into the research phase to build a more robust evidence base. This can then adapt products, which subsequently stimulates a series of updates to maintain fidelity.

The main benefit of this framework is that conceptually, implementers can begin the process at any stage of the knowledge-to-action process, in a non-linear and recursive translation processes (205,206). For example, local ward data repeatedly informs a new or modified pathway in an audit cycle. Evaluation here is an on-going process throughout all stages. Whilst this may potentially lead to some application error, the authors stress that, through collaboration between researchers, practitioners, and other health professionals, all must be held accountable for the outcomes of the implementation (183).

The action cycle has seven phases that theoretically interject with the knowledge creation process. Adapting to local contexts, where barriers are assessed; it is tailored and implemented, monitored, and evaluated for sustained use. The cycle continues where discrepancies initiate further inquiry, synthesis and tailoring of the knowledge tools/products. Conceptually, this model provides a comprehensive map for the early-implementation phase of knowledge creation to apply into practice through a series of actions. The inverted triangle provides a visually appealing funnel-like deduction of knowledge as it is tailored into specific knowledge tools and products before commencing an action cycle.

Critique of the Application of Process Models in Practice

An underlying assumption of implementation is that knowledge availability leads to knowledgeable actions (11). However, the notion of a 'theory-practice' gap remains an issue in many fields. By adopting the phenomenon of knowledge mobilisation, theory-practice gaps can be identified when knowledge is mobilised in action (207). The findings from their case study of Information and Communication Technology (ICT) graduates who are required to engage with theory and use it in their practice indicates that professionals frame their situations by drawing mainly upon a practical rather than a theoretical knowledge base acquired through experience and socialisation. Wurz *et al.*, (208) acknowledge few beneficial interventions that translate from research into practice, resulting in an increasing knowledge-to-practice gap that is likely to have a negative impact on patients who miss out on these opportunities. The authors emphasise that cultivating effective partnerships and ensuring methodological rigour and scalability in real-world settings can be difficult, and researchers seldom publish examples of how they addressed these challenges and translated their evidence-based opportunities into practice. Addressing this issue, the authors present three cases of successful implementation:

- (i) guiding theories and frameworks
- (ii) strategies to facilitate and maintain partnerships, and
- (iii) scalability and sustainability plans as the common traits for success (203).

Some process models described above (Table 4.1) have been applied widely in practice to guide evidence-based practices. The Iowa EBP model for example, has received nearly 4000 requests for permission to use it. Models that offer supplemental tools and additional instruction and guidance, such as the John Hopkin's model, which facilitates the implementation process (193). Contrastingly, higher level conceptual models only provide this structure, therefore the evidence of their application in practice is limited or does not exist at all. It is likely whilst they guide the planning and orientation of efforts, additional frameworks are necessary to provide a step-by-step guide to implementation that can be measured objectively and reported as such. In a scoping review of 19 models and frameworks undertaken by Dusin *et al.*, (209), it is concluded that most models and frameworks offer a narrow description of the steps required to implement EBP. Whilst only a few provide diverse instruction, completeness, and usability that is represented in their routine application in practice.

Given that the objectives for the national respiratory programme in Wales was to apply digital interventions to promote evidence-based practices, it seems appropriate as a starting point, that the application of the most relevant implementation frameworks for digital interventions are considered to determine their impact. Engagement with digital support tools, as a core feature of the implementation strategy, provides an appropriate signal of user acceptance (39,210). For this study, it was an achievable measure that could be tracked and quantified to demonstrate penetration and reach.

Whilst the implementation process models identified in Table 4. 1 display relevant nomenclature and theoretical construct – these otherwise return limited evidence in their application in practice. This suggests many of these are indeed limited to a theoretical framework alone. However, there is a clear trend to select common frameworks that have delivered multiple successes across several contexts. Confounding this observation, the more these frameworks are applied, adapted, and deliver reported benefits, naturally the more they will be replicated thereafter. However, contrastingly, less cited (and therefore evidence of use) frameworks are more likely to remain theoretical and unproven despite representing theoretical relevance and genuine potential for application. Nevertheless, researchers are more likely to use applied frameworks that are considered relevant and appropriate that have been selected, tested, and reported in the literature. A recent study by Esmail et al., (211) explored the drivers to the use of technology in healthcare and identified knowledge translation theories, models, and frameworks to determine their suitability. The study undertook purposeful sampling of 22 international experts in health technology reassessment and knowledge translation. They identified the Consolidated Framework for Implementation Research (CIHR) and Knowledge-to-Action (KTA) frameworks as the most suitable frameworks, albeit not meeting the overall >70% agreement score, highlighting the wide heterogeneity in the perceptions of implementing frameworks. Nevertheless, this research confirms the strong benefits of applying multiple perspectives when testing implementation frameworks.

The CIHR has been applied exclusively in the literature as a determinant framework exploring barriers and enablers for implementation in a range of contexts within healthcare (212–221). Whilst the KTA framework, based on commonalities of over 30 planned-action theories, has been applied extensively in practice from planning, through to implementation and evaluation purposes in a range of different settings within and outside of healthcare. Furthermore, the American Thoracic Society published a joint report with the European Respiratory Society in

2012 describing integrated and coordinated efforts in COPD guideline development, dissemination, and implementation strategies (222) and recommend application of the KTA cycle (60).

Comparing the application of the KTA framework to no framework at all, Xu et al., (223) investigated the quality-of-care transition for joint arthroplasty patients. The quasi-experimental study assessed 160 patients who underwent joint arthroplasty at a tertiary hospital from September to November 2018 and January to March 2019 that were selected as participants using convenience sampling. The control group received routine medical care, while the observation group received medical care based on the KTA framework. The researchers concluded that the observational group received best quality of care through general self-care preparation and written plan dimensions, although little difference in doctor-patient communications or health monitoring outcomes was observed (218).

Around a similar time, in response to scaling surgical safety advances, the 2019 Global Ministerial Patient Safety Summit called for a focus on implementation strategies, especially in low- and middle-income settings. White et al., (224) hypothesised that through applying the KTA framework more than 50% of participants (in this case, Cameroon, identified as a lowincome setting) would be using the nationwide World Health Organization (WHO) Surgical Safety Checklist (penetration) in the correct manner (fidelity) 4-months post-intervention. Based on knowledge-to-action, there were 3 phases to the study implementation: problem identification (lack of routine checklist use in Cameroonian hospitals), multifaceted implementation strategy (3-day multidisciplinary training course, coaching, facilitated leadership engagement, and support networks), and outcome evaluation at 4 months. Three hundred and fifty-one operating room staff members from 25 hospitals received training. Checklist use (penetration) increased from 20% (95% confidence interval [CI], 16–25) to 56% (95% CI, 49-63); fidelity for adherence to 6 basic safety processes was high: verification of patient identification was 91% (95% CI, 87-95); risk assessment for difficult intubation was 79% (95% CI, 73–85): risk assessment for blood loss was 88% (95% CI, 83–93) use of pulse oximetry was 93% (95% CI, 90–97); antibiotic administration was 95% (95% CI, 91–98); surgical counting was 89% (95% CI, 84–93); and fidelity for non-technical skills measured by the WHO Behaviorally Anchored Rating Scale was 4.5 of 7 (95% CI, 3.5-5.4). The authors (219) concluded that a multifaceted implementation strategy introduced through the KTA framework generated nationwide scale-up adoption of WHO surgical safety checklist.

In a different setting, Fitzgerald *et al.*, (225) applied the KTA framework to determine the needs and barriers surrounding nutrition counselling in the US to develop nutritional resources for healthcare professionals and patients in primary care. Both groups identified the need for nutritional resources (such as patient handouts, community nutritional classes and cooking classes, grocery guides and cooking videos) would help promote health-eating behaviours. The study represents a structured application of the KTA framework from needs analysis to developing tailored interventions, although at the point of publication it was yet to be determined the outcome of these interventions.

Exploring strategies to overcome barriers to the utilisation of breastfeeding guidelines in a Spanish Hospital, Ramos-Morcillo *et al.*, (226) undertook a qualitative study through semi-structured interviews of managers and clinical professionals in maternity and paediatric departments to assess the implementation of the Registered Nurses' Association of Ontario breastfeeding CPG from 2012 through 2015. Deductive content analysis was performed following the stages in the KTA framework, which identified five key themes:

- 1. Problem as opportunity
- 2. Adequate context and adapted recommendations
- 3. Extent of implementation
- 4. Impact of results
- 5. Knowledge use normalisation.

Focusing on clinical guidelines, to determine clinician adherence and perceptions to stroke rehabilitation guidelines, Moore *et al.*, (227) assessed pre- and post-training intervention based on the KTA framework, with a focus on implementation facilitation, implementation leadership, and a bundle of knowledge translation interventions that targeted specific barriers. Adherence to the guidelines increased from 46% to more than 85% after 6-months, remaining consistent 48-months after implementation, and generating high clinician perception scores. The authors concluded that the success of implementation was a result of effective knowledge translation, facilitation, and use of the framework to develop the plan. Maintaining a focus on training, Jain *et al.*, (228) applied the KTA framework in a school of urban Jodhpur to assess the challenges and gaps associated with health promotion to tailor interventions based on the local need. Knowledge was assessed three and 6 months after implementation of a range of educational resources and tools. Knowledge transfer was demonstrated through an increase in

assessment scores from 42% to 96% with a 20% reduction in tobacco consumption. Whilst the authors acknowledged the value of the KTA framework they also reinforced the importance of tailoring interventions to the local needs and resources, which is supported by other studies (229).

When a new guideline is published, there is a need to understand how its recommendations can best be implemented in real-world practice. However, seldom are guidelines published with a roadmap to support organisations to promote adherence to their recommendations (76). Tilson et al., (230) applied the KTA framework to implement newly published physical therapy guidelines for patients with peripheral vestibular hypofunction across five clinical sites in the US with established rehabilitation services. To determine the impact of implementation the researchers conducted preliminary gap surveys and meetings to determine the target behaviours that would be critical to improving guideline adherence before assessing behaviour change 6months after guideline implementation. Target behaviours differed between sites with more experienced therapists compared to those less experienced, yet adherence was mixed, and success was most common with behaviours relating to documentation and offering patients low-technology resources to support home exercise. Despite mixed results, the authors (225) concluded the KTA framework provided an effective process model for multiple sites and contexts to implement a common guideline. Multimodal interventions focused to targeted behaviours, providing monthly feedback, and developing communities of practice was associated with long-term adherence. Further successful strategies included the use of local (rather than external) opinion leaders, securing therapist availability for community meetings, and the rate of provider turnover likely impacted the implementation impact of this project.

National clinical guidelines for stroke are considered the most important sources of robust evidence for stroke care; however, implementation within real practice is often slow to respond. Alatawi (231) developed a conceptual model based on the KTA to implement national stroke guidelines to understand implementation strategies for physiotherapist practice in stroke rehabilitation in Saudi Arabia. Drawing on panel meetings with expert physiotherapists 75 recommendations were released to a broader sample of specialist stroke physiotherapists as an online questionnaire with a follow up focus group to capture the challenges and enablers to implementations. Sixty-one recommendations were accepted for application in real practice, whereas only 14 recommendations were rejected. The authors conclude this research presents the first empirically derived framework that establishes the contribution of physiotherapy to

stroke rehabilitation reaffirming the importance of supportive organisational culture, the specific need of end users, patient factors, and transferability of the evidence.

The breadth of evidence demonstrating the successful application of the KTA framework, especially in context to clinical guideline implementation, reinforces the value of a structured approach to implementation. The usability of the KTA framework, wide application in different contexts and its subsequent social and academic endorsement makes it an attractive framework to use. However, knowledge of how to apply these interventions successfully and sustainably at scale is often lacking (224). From a practical perspective, the KTA has no clear starting point, and the two discrete functions – action cycles and knowledge creation – can be a little disorientating for readers. Whilst considered an implementation process model within the literature, it is also viewed as a theoretical framework for knowledge translation (232). Frequently, as seems to be the case for most implementation process models, it is instead applied as a determinant framework generating specific themes describing local or intervention-related barriers and enablers. However, it does not expand on the implementation step, only its position in the process of knowledge generation and application in practice. Therefore, for this study, adopting key principles captured by the highly relevant and widely applied KTA framework was undertaken. Furthermore, expanding the focus on the implementation process as a discrete element of the framework was considered necessary to try and develop a framework that had clarity and reproducibility.

Other frameworks have been applied in similar scenarios with proven success, further indicating that selection of a framework is largely the preference of the implementing team. Pronovost *et al.*, (166) present a method for knowledge translation in a collaborative, integrative, and systematic model for dissemination of knowledge using an example of its application to reduce infections associated with insertion of central lines. This was later matured into the Johns Hopkins Quality and Safety Research Group (193). The scope for this model is to support implementation of large-scale projects. They identify five key components to the model called the Translating Evidence into Practice Model:

- 1. A focus on the system rather than individualised patient care.
- 2. Engagement with the interdisciplinary team to embed a feature of ownership within the intervention.

- 3. Centralised technical support researchers develop measures based on the evidence for local hospital teams.
- 4. Encouraging local level adaptation of the intervention; and,
- 5. Fostering an integrative and collaborative culture.

The Michigan Keystone ICU project led by Pronovost demonstrated large and sustained reduction in rates of catheter-related bloodstream infections in over 100 ICUs across Michigan, US (233). Each hospital ICU implemented several patient-safety interventions, according to a cohort study design, where the effect of each intervention was monitored against specific safety measures. The median infection rate per 1000 catheter days decreased from 2.7 (interquartile range 0.6-4.8) in the baseline period to 0 (0-2.4) in the 18 months after the intervention. Over the 18-month observation period, more than half of the units reduced their infection rate to zero, and the overall mean rate was reduced by 66%. Whilst the researchers could not establish a causal relationship between the programme and clinical outcomes, they highlighted that no other improvement interventions occurred during this time. Later research using controlled designs suggested that the results were likely to be valid (234).

The researchers have since included two additional parameters to the implementation model: endure and extend (166). Endure reflects sustainability, a common feature of implementation science frameworks – in this case the hospital teams were asked to add this project into the hospital's quality improvement programme. Working with the hospital quality improvement teams would also help them to extend, or spread, the intervention to other areas of the hospital where central lines were also inserted, like the 'diffusion' step in the Framework for Research Utilization (181). They report it took around one year to develop and pilot a new programme before it was ready for wider implementation (scaling up). Key lessons from the application of this model include a focus on cultural changes and context, rigorous measurement, and centralisation of technical work (166). Furthermore, successful implementation resulted when clinicians were most engaged and perceived the measures and results to be valid, and where they saw the results and realised satisfaction in their work, thereby taking local ownership (166).

Some have questioned whether the achievements from Keystone could be replicated elsewhere under different circumstances and context (235). Matching Michigan (234) was a patient safety initiative that was implemented in 223 Intensive Care Units (ICU) across NHS England,

inspired by a success of the Michigan Keystone ICU project (99). The goal was to replicate the success of the Michigan project in reducing CLABSIs, ultimately improving patient outcomes and reducing healthcare costs. The initiative focused on collaboration, data collection, and the spread of best practices across NHS hospitals. However, unlike the study design applied in Keystone, Matching Michigan applied a stepped wedge study design involving clusters of ICUs joining in a staged sequence. This detected a strong secular trend towards decreasing rates of infections that was not observed in Keystone. Clusters of ICUs waiting to join the study reduced their infection rates and the same rate as those within the study. Many improvement programmes fail to exceed the natural progression observed in non-interventional settings despite accepting improvement is unlikely to occur without cause (234). Further, the 'decline effect' explains the challenges associated with replicating results which appear to be promising in other settings. The decline effect is in part over-interpretation of small studies due to publication bias but also to lacking account for randomness (236).

It is argued that whilst substantial efforts have been employed to improve implementation of healthcare interventions, there remain concerns about the application and replicability of implementation frameworks in the real-world (237). Reporting benefits within the literature does not perhaps reflect the true distinction between success and failure and replicability in the real world, due to selective bias, over-interpretation, decline effect, and secular trend, for example (234–236). Based on the review in this thesis, failed implementation is reported considerably less frequently that successful cases. If the 'know-do' gap remains relevant today, there probably remains essential learning captured into unsuccessful implementation endeavours that could potentially address gaps such as adherence and sustainability (198,199,237).

Whilst the KTA is considered the most relevant to this study based on its application to clinical guidelines, notably the source of this recommendation stems to Canada where the model originated (182,238). Whilst this is not exclusively the case, it suggests a localised spread in the utilisation of the KTA that has subsequently generated a proliferation in successful cases. Experts in implementation science advise to stop producing more models and frameworks and to apply what currently exists into practice (239). Others add that application of any framework is better than no framework at all (223). However, the decision was made within this research to remove ambiguity in implementation terms to develop a framework based on published work that could be applied initially to NHS Wales. The starting point was to distinguish the

implementation process from implementation strategy. This is considered an essential feature of implementation practice that the author has not seen reported in the literature.

An Implementation Process Model for Clinical Guidelines

The constructs (phase, order, description, enablers, outcomes, and decision-points) have been compiled through critical analysis of the literature. Expanding on the high-level structure to the framework in Figure 3. 7, the implementation process model (Figure 4. 2) includes a series of dependent phases, similarly to the Stetler Model (184–186), Ottawa Model (188), Framework for Research Utilization (181), and the constructs from the widely applied KTA framework (183). Phases progressing from left to right depict a linear process according to time, which, influenced by the work of Rogers (104), is considered here to be an essential factor for adoption of innovations across target populations.

Whilst most implementation models cross multiple periods, several focus only on the early period, which does not address the primary objective of this study. Nevertheless, key to the transition between periods is the decision to continue, i.e., checkpoints to ensure the right interventions are implemented and the right outcomes are achieved before progressing. To facilitate decision points, it is commonplace to determine implementation outcomes before transition to the next phase or period. Logically, the decision between period one and period two is a binary decision to adopt or reject the intervention, a notable function of the Dobbins (190), Stetler (184–186), and QUERI models (197), but whilst this instruction may be absent in many other frameworks, logically, it is likely to be a decision point in practice. The target organisation determines the transition into period three – the post-implementation phase, akin to institutionalisation denoting the sustainability of interventions. The model phases include a brief description of the phase similarly to most models. Each phase description and detailed instruction is provided in Table 4. 3.

IMPLEMENTATION

Periods

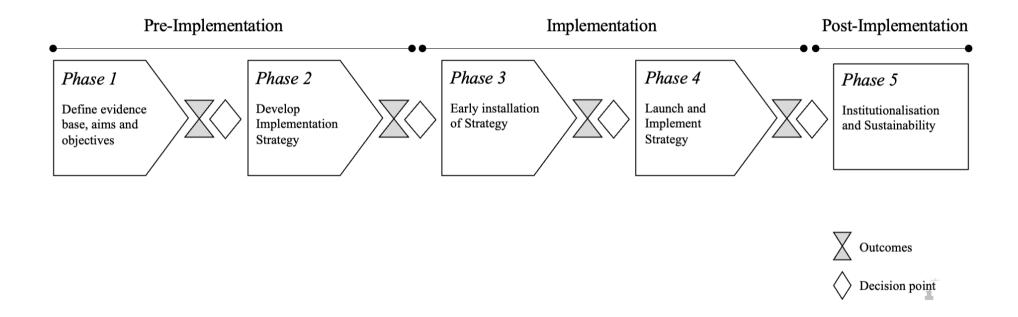


Figure 4. 2: Implementation process model as a function of the implementation framework.

Period	Phase	Phase description	Phase instruction	
Phase 1: Pre-implementation	1	Define evidence base, aims and objectives	A scoping and intervention design phase within a small high-level team. The outcome for this phase is to translate the project specification into an implementation strategy plan. This is determined by the Implementation Team and involves assess the appropriateness, feasibility, acceptability, and appropriateness of a given intervention within the target organisation. Outputs of this phase include creating the governance structure, organisational structure around the target, an assessment of organisational readiness and capacity to adopt the intervention.	
	2	Develop implementation strategy	An implementation plan and the discrete elements of the strategy are developed. These include identifying the enablers of implementation and to overcome barriers (implementation drivers) and the interventions implemented through design, launch and learning across the target population (detailed later in this chapter).	
Phase 2: Implementation	3	Early installation of strategy	Trialability, adaptation, and optimising the environment for implementation – this is a high-risk phase as the planning and development efforts of phase 2 are put to test in a self-selecting sample of early adopters. This phase is managed tightly by the Implementation Team, includes real-world observations, and inclusion of a Power Layer, and observation and analysis of early adopters within the Target Layer to determine the feasibility and acceptability of the intervention in the real world (target organisation). The installation phase involves soft launch of the implementation interventions and observations in the real world, with conservative dissemination and awareness to reach the early adopter group. This ensures that any adaptations to the implementation strategy can take place prior to formal implementation.	
	4	Launch and implement strategy	To embed and scale up activities for intervention adaptation at the required scale, determined by the target population. This is managed by the Implementation Team and involves active efforts by the Power Layer to scale up local adoption, in a similar way to a pyramid scheme, to generate exponential growth and spread within the target population. Fidelity is assessed to ensure the intervention is being utilised as prescribed, with frequent analysis of penetration and adoption across the target organisation. This is the active phase of implementation where the adaptations and improvement to the implementation strategy from phase 2 is expected to address early implementation outcomes (feasibility, acceptability, appropriateness). This phase expects to see the diffusion of adoption as	

			per Rogers Theory of Diffusion (104), where the mass population of late adopters is reached.
Phase 3: Post-implementation	5	Institutionalisation and sustainability	The point of implementation saturation, a plateau in engagement and adoption following active implementation (phase 3). Sustainability is the institutionalisation of the intervention within the target population – a result of implementation efforts and the implementation strategy. The outcome measures of intervention appropriateness, relevance, penetration, fidelity, and value determine the degree of implementation success. Value realisation and maintenance are key outcomes aligning with intervention outcomes to reach social significant impact.

Table 4. 3: Detailed instruction for each implementation step within the phases of implementation depicted by the implementation process model in Figure 4. 2.

Implementation outcomes precede decision points between phases. The most frequently applied implementation evaluation frameworks are the RE-AIM and PRECEDE-PROCEED frameworks. These originate in public health research and specify outcome factors that should be assessed as part of implementation studies. The RE-AIM framework consists of the 5 domains which makes up the pneumonic – Reach, Effectiveness, Adoption, Implementation, Maintenance (240). The PRECEDE-PROCEED again is a play on the pneumonic representing Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation Policy and Enabling Constructs in Educational and Environmental Development (241). The main drawback for both frameworks is their inherent association with the study of implementation research rather than the actual practice of implementation.

It is for that reason that the Taxonomy of Implementation Outcomes Model (ToIOM) by Proctor *et al.* (13) is favoured, which aligns more closely with the periods leading to institutionalisation (sustainability). Drawing on the literature the authors presented the following measures: acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, and sustainability. Definition of implementation outcome terms according to Proctor *et al.* and their proposed salience by implementation stage and suggested measurement are presented in Table 4. 4. Measures are assigned to each phase to facilitate transition to the next phase. This is influenced by the relationship between implementation outcomes and local context (26).

Using the KTA framework, Chamberland *et al.*, (242) designed and implemented evidence-informed educational interventions intended to support the development of students' clinical reasoning skills in a renewed medical curriculum. Using mixed-methods design, students' engagement with the programme was monitored as well as focus groups with students and stakeholders to determine implementation outcomes (Fidelity, Feasibility, Appropriateness, Acceptability, Adoption, and Penetration). Students spent a mean of 24 min on the activity (fidelity outcome) with a high completion rate (between 75% and 95%; feasibility outcome) of the entire activity each time it was done. Focus group data from students and stakeholders suggest that the activity was acceptable, appropriate, feasible, adopted, and well-integrated into the curriculum, although little is described to validate these findings against a standard measure. Nevertheless, the authors acknowledged the importance of applying

a structuring framework, working closely and deliberatively with key stakeholders, of building upon concurrent evaluations to adapt iteratively the educational intervention to the local context and, while taking students' needs into consideration.

The ToIOM depicts outcomes to the most optimal position in the implementation process (early, mid, or late implementation). These have been replicated and aligned by implementation period within the model (Figure 4. 3). However, they do not describe how these measures are assessed, instead implementers must choose suitable assessment tools and mechanisms to collect the information.

Implementation	Definition	Salience by	Measurement
Outcome Acceptability	"The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory"	Early for adoption Ongoing for penetration Late for sustainability	Survey Qualitative or semi-structured interviews Administrative data
Adoption	"The intention, initial decision, or action to try to employ an innovation or evidence-based practice"	Early to mid	Administrative data Observation Qualitative or semi-structured interviews Survey
Appropriateness	"The perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer, and or perceived fit of the innovation to address a particular issue or problem"	Early (prior to adoption)	Survey Qualitative or semi-structured interviews Focus Groups
Cost	"Cost impact of an implementation effort"	Early for adoption and feasibility Mid for penetration Late for sustainability	Administrative data
Feasibility	"The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting"	Early (during adoption)	Survey Administrative data
Fidelity	"The degree to which an intervention was implemented as it was prescribed in the original protocol, or as it was intended by the programme developers"	Early to mid	Observation Checklists Self-report Administrative data
Penetration	"The integration of a practice within a service setting and its subsystems"	Mid to late	Case audit Checklists
Sustainability	"The extent to which a newly implemented treatment is maintained or institutionalised within service setting's ongoing, stable operations"	Late	Case audit Checklist Case audit Qualitative or semi-structured interviews

Table 4. 4: Definition of implementation outcome terms according to Proctor and their proposed salience by implementation stage and available measurement (13).

IMPLEMENTATION

Outcomes

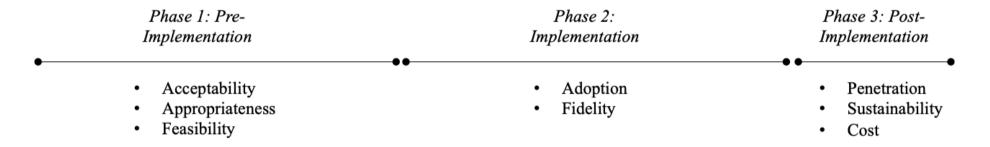


Figure 4. 3: Implementation outcomes by implementation period.

Strengths

Given that we see a saturation of published multi-purpose implementation frameworks (243), a scoping review applying citation tracking (244) and snowballing methodology (89) of commonly used implementation process models was applied. Whilst this does not conform to a systematic literature review process – for this purpose, it was considered appropriate and pragmatic (244–246). Citation tracking for frameworks sourced from commonly referenced articles highlights the frequency and application of common implementation process models in healthcare. This search methodology is considered by some to be more reliable than database searches (247). Rather than exploring the wide range of frameworks with irregularities in terminology, this study has instead considered commonly referenced frameworks and undertaken a more detailed exploration into their constructs. A detailed examination of relevant cases describing their use in a range of healthcare settings was also undertaken to determine their practical application, relevance to this study and context, and replicability.

This is possibly one of the first studies to explore implementation process models in detail to determine common features and constructs. The KTA framework has been applied to several clinical guideline implementation studies (223,225–227,229,230,248) and it is recommended by established respiratory societies that have a broad membership (222,238). Researchers that have applied the framework propose tailoring implementation and strategies to the local context. This study expands on the KTA framework, by trying to remove the ambiguity in its constructs (*implementation process* and *implementation strategy*) and offers a systematic linear flow focusing on the implementation process Independently of tailored interventions, which is considered a separate component of the framework and described in detail in the next chapter.

Limitations

While citation tracking and snowballing can be useful methods for exploring related research, it is important to be aware of their potential limitations:

1. Incomplete coverage: Citation tracking relies on the availability and accuracy of citations within the literature. Not all articles or publications may be adequately cited or indexed, leading to incomplete coverage of relevant studies (244). This can result in

- missing out on key articles that may be important to the research question. Key articles were identified and reviewed, with further exploration of notable books on the subject. Furthermore, additional searches for the latest work published by leading researchers were undertaken to mitigate the risk of missing key papers.
- 2. Bias and selective citation: Researchers may selectively cite articles that support their own arguments or confirm their preconceived notions (249). This can introduce bias and limit the scope of information obtained through citation tracking. It is important to critically evaluate the relevance and quality of the cited articles; and maintain internal assessments of potential bias (250,251).
- 3. Time-consuming and resource-intensive: Conducting citation tracking can in some cases be time-consuming, especially when following chains of citations across multiple articles in topics that has a broad and extensive evidence base (252). It requires manually reviewing each citation, locating the corresponding articles, and assessing their relevance. This process can be resource-intensive, particularly when dealing with many citations and must be balanced with regards the relevance and value of the search aims and outcome. However, given the relatively new field and ambiguity in terms it was felt this was a more effective use of time compared to a systematic literature review.
- 4. Lack of context: Citation tracking primarily focuses on identifying related articles based on their citation connections. However, it may not provide the full context or understanding of the content and findings of the cited articles. This limitation can make it challenging to assess the quality and relevance of the studies solely based on citation information (246).
- 5. Potentially limited to published literature: Citation tracking often focuses on published articles, which may overlook relevant research that is not yet published or available in traditional academic journals, or altmetrics with low quality datasets and limitations to the systems they were archived (253). This limitation can restrict the scope of information obtained through citation tracking but this is also a limitation when undertaking systematic reviews through online search engines. Information from blogs, websites, government and university webpages, reports and white papers, and other sources of other non-academic articles were also included in the scoping review within this study.

6. Difficulty in identifying negative or null findings: Citation tracking is more likely to identify articles that are frequently cited or have positive findings (253). Negative or null findings may not be as widely cited or easily identified through citation tracking alone. This bias can limit the comprehensive understanding of a research topic (254) and was a noted observation when exploring the applied use of implementation frameworks from the literature.

While citation tracking can be a valuable supplementary method for literature exploration, it is generally recommended to combine it with other research methods, such as systematic literature reviews. It is well published that several theoretical frameworks remain conceptual or perhaps applied in only one setting (255) therefore, a pragmatic approach to evaluating commonly reported frameworks was considered appropriate for this process. Focusing on the challenges and successes to the application of published frameworks provides a more tangible benefit when tailoring to the national context of respiratory care in Wales. Whilst this approach has limitations, indeed, experts suggest a plateau has been reached and instead the application and meeting challenges posed in applying published frameworks in the real world provides greatest benefit for implementation programmes such as this.

Summary

This review of the literature has covered Nilsen's taxonomy of five categories of frameworks that provides a broad perspective and comprehensive guide to the landscape of implementation science (86). Whilst the taxonomy covers the breadth of implementation science frameworks, models, and theories, it does not adequately consider the complexity of reporting processes within the literature or the influence of context (26). Implementation science is notably complex; largely due to the multitude of intrinsic and extrinsic factors that must be aligned to ensure innovations or new interventions are accepted and used (65). The ambiguity of terminology used and conceptual versus theoretical or empirical, makes evaluation of the literature particularly difficult. This was overcome by focusing on the broad work of Nilsen (86), Fixsen (3), and Durlak (65), as these authors offer a comprehensive landscape of the subject. However, terminology and implementation approaches overlap, which makes choosing an appropriate model, framework, or theory particularly challenging. Reassuringly, there are guides available (74). However, experts in implementation science advise to stop producing more models and frameworks and to apply what currently exists into practice (239). This study therefore applies the existing literature to propose a framework for implementing clinical guidelines at scale in Wales. The framework can be applied systematically with clearly defined outcome measures across the phases of implementation. In doing this, the most valuable and practical assets of all frameworks, models, processes, and relevant strategies have been assessed and considered pragmatically for their practical use.

The focus of this chapter was to review and evaluate common implementation *process models* because they guide the practical efforts of implementation, considered here an essential component of guideline implementation. Table 4. 1 highlights commonly reported implementation process models identified from the literature. These have been critiqued against key attributes such as the format and structure, constructs, implementation period, target, level, and classification, as these are deemed essential when selecting the most appropriate functions for designing an implementation process model for guideline implementation. The implementation process model developed in this study provides the architecture and structure to manage the process for introducing a clinical guideline strategy across NHS Wales, on a national level, which has been largely influenced by the KTA framework that is recommended and commonly applied to digital and guideline implementation projects worldwide (242). The implementation process model is tailored to

focus solely on the process of implementation, thus excluding any notion of implementation interventions at this point. The reason for this, is that implementation interventions are tailored and varied, whilst the implementation process is structured and systematic.

The process model developed in this study includes phases of implementation and early, mid, and late outcome measures of implementation. This is a more prescriptive tool to support the practice of implementation (163). How this is achieved is through implementing a carefully planned implementation strategy. The literature around the implementation strategy function of the framework deemed most relevant to clinical guideline implementation is assessed in the next chapter.

Chapter 5: Initial Framework

Implementation Strategy

Chapter Objectives:

- 1. Evaluate the evidence base to develop an implementation strategy structure for clinical guideline implementation.
- 2. Refine the strategy structure to consider the requirements of potential guideline adopters for respiratory guidelines in NHS Wales.
- 3. Expand the implementation framework to incorporate the features of the implementation process model and implementation strategy that can be applied in the implementation of national guidelines for NHS Wales.

Implementation Strategy Domains

Exploration of the literature provides evidence of specific tailored strategies that have varying impact in different contexts. It is recommended to undertake a multi-faceted approach to implementation (256–258) to increase the probability and delivering implementation outcomes and social benefit. The Cochrane Collaboration's Effective Practice and Organization of Care (EOPC) group has undertaken over 130 systematic reviews of the subject (171), especially focusing on common strategies such as educational meetings (259), audit and feedback (257), printed educational materials (260), and local opinion leaders (261), for example. Grimshaw et al., identify that median absolute effect sizes across implementation strategies are similar (262). Taking a broad perspective on implementation strategies, these are the tools and assets that form [implementation] interventions, which collectively, stimulate the desired response that aligns with the programme aim(s). Systematic reviews of implementation strategies have already been undertaken by others. Several taxonomies describe the range of different implementation strategies applied in healthcare. Notably, Mazza et al. (161) reviewed conference abstracts, and Fischer et al., performed a metanalysis of relevant articles relating to the barriers to guideline adherence (79). Other taxonomies are devised through surveys and interviews with experts (a Delphi exercise) (137).

Adherence to clinical guidelines is frequently used as a measure of quality of care (263). Guidelines decrease the gap between research and clinical practice (76), which is consistent with the vision of implementation science (29). Mazza defines an implementation strategy in the context of clinical guideline implementation as a purposeful procedure to achieve clinical practice compliance with the recommendations proposed by the guideline (161). Mazza identified several strategies to support guideline implementation that are closely aligned with the more generic-focussed work undertaken by Powell (264). However, Gagliradi and members of the Guidelines International Network Implementation Working Group note in the first line of their systematic review of trends in guideline implementation that there is no reliable way to choose strategies for implementing guidelines facing different barriers (265). This emphasises the need for flexible approaches according to the type of guideline, subject matter, target population, target organisation and context. The intention for this study, therefore, is to use the framework to apply a tailored strategy that is relevant to the context and structure in NHS Wales and for the specialism of interest described, that has adequate flexibility for local tailoring.

Other researchers have attempted to detail common strategies for guideline implementation. Fischer et al., reviewed 69 articles up to the end of 2015 (79). They applied qualitative synthesis to describe and categorise both the common barriers to guideline adoption and effective strategies tailored to overcome these barriers. For each of the three categories: (i) personal factors, (ii) guideline-related factors, and (iii) external factors; a list of barriers and interventions was described. Personal factors were further deduced to 'physician's knowledge' and 'physician's attitude'. Common organisational strategies include a change in quality assurance, quality improvement and/or performance measurement (32% of studies); a change in information and communication technology (30% studies), and creation of an implementation team (14% studies). Common professional strategies include – distributing guideline materials (24% studies); identifying barriers to guideline implementation (21% studies); educating groups (21% studies) and individual healthcare professionals (8% studies); feeding back guideline compliance data (13% studies); and providing reminders (8% studies). Further refinement is necessary to provide more granular detail in recommendations to overcome issues, particularly relating to patient-focused interventions, audit and feedback, quality improvement, electronic forms of implementation, and electronic reminders. Whereas a multifaceted strategy involving training, consultation and audit is considered an effective approach to implementation (171).

Earlier studies highlighted discrete implementation strategies across the phases of implementation. The Replicating Effective Programs (REP) framework (266), lists identifying need and barriers in phase one; developing a community working group in phase two; training, technical assistance, feedback, and refinement in phase three; and re-customising the delivery in the final phase of maintenance and evolution. Eccles emphasises the first step in developing guidelines is to clarify the target audience, which helps structure the guideline, ascertains the most important objectives, and informs the style of content (267). DiCenso *et al.*, developed a toolkit to support healthcare organisations struggling to find ways to implement guidelines after concluding that little time or attention was being applied to implementation strategies (83,192). They proposed that the probability of guideline adoption increases when key objectives are met, or when using principles like that listed by the Conceptual Implementation and Sustainability Guide (CISG) support tool (137) and the Clinical Practice Guidelines Implementation Model (192) presented side-by-side in Table 5. 1.

Sub-domains of the CISG: Implementation Support Tool	Key Objectives for the CPG Implementation Model
Develop an implementation and sustainability plan according to identified implementation objectives and readiness with a sustainability assessment.	A systematic process is used to identify a well-developed, evidence-based clinical practice guidelines (CPG).
Identify the purpose and scope of implementation and sustainability and determine the objectives and goals for implementation.	An assessment of environmental readiness for CPG implementation is conducted.
Identify stakeholders and clarify roles and communication mechanisms among the team.	Appropriate stakeholders are identified and engaged.
Assess the fit and effectiveness of the potential intervention.	Evidence-based implementation strategies that address the issues raised through the environmental readiness assessment are used.
Identify barriers and facilitators of implementation and sustainability and consider using an appropriate determinant framework	Consideration of resource implications to carry out these activities is adequately addressed.
Assess context and characteristics of the adopter environment including its capacity to sustain the intervention	A systematic process is used to identify a well-developed, evidence-based clinical practice guidelines (CPG).
Develop the monitoring and evaluation plan	An evaluation of the implementation is planned and conducted.

Table 5. 1: The sub-domains of the Conceptual Implementation and Sustainability Guide (CISG) Support Tool (137) in comparison to the re-ordered objectives determined by the Clinical Practice Guidelines Implementation Model (192).

Whether for disease management or standardising procedural practice, the choice of topics included within the guideline must be determined by the target audience and their need (267). The context to guideline adoption includes disease that has premature mortality, avoidable mortality, or impact on the quality of life of patients (79). Contextual drivers with greatest impact to guideline adoption include:

- *i.* a highly prevalent disease.
- ii. a commonly used clinical procedure.
- iii. high associated costs.
- iv. current variations in practice (267).

National audits for Wales suggest variation in practice for COPD and asthma and inappropriate prescribing practices that are costly and deemed wasteful (20). Both are highly prevalent and require common clinical procedures to diagnose and monitor severity. For COVID-19, this was not the case. Little was known about the disease in early 2020, but it became synonymous with premature mortality, acquiring substantial attention from the public, government, and media.

National Approaches in other Countries

Multifaceted implementation strategies have variable success. The National Respiratory Audit Programme (NRAP), previously the National Asthma and COPD Audit Programme (NACAP), has provided continuous audit data collection and reporting of asthma and COPD care across primary and secondary care (20). Whilst the audit has served as the most valid assessment of COPD and asthma care in England and Wales on a national level, translating this directly into large scale improvement has yet to be achieved, despite evidence suggesting positive correlations with patient care (268). The audit team has attempted to align audit data with other data collection requirements to encourage participation and aligning this with associated incentives (for example Getting it Right First Time (GiRFT)) and quality improvement initiatives, whilst avoiding duplication of efforts) (269). The NACAP improvement strategy includes:

- Data to support improvement
- Quality improvement methodological support to front-line teams
- Use of high-level change levers
- Engaging with patients and the public

To ensure data reports are relevant the audit has made great inroads into moving from the traditional cross-sectional data collection periods to continuous data collection to generate real-time analysis of the results (270). This informs concise and engaging quality improvement reports to encourage continuous improvement cycles. Quality improvement initiatives are supplemented by a 'good practice repository' and teaching opportunities align with the national programme in Wales (269). A best practice tariff (BPT) in NHS England, which enabled respiratory teams in some Trusts to qualify for enhanced tariffs (271), influencing NICE standards of care, and aligning incentives with the QOF have been delivered as high-level change levers. In the first 16 months of the NACAP process measures for COPD have improved in compliance with NICE standards (272). However, data quality challenges at a GP practice level limits the applicability of evidence. Take for example spirometry recording – this varies from 0% to 95% across GP practices demonstrating significant variation in the quality of data recording at practice level (268). Furthermore, the audit can only pick up the data that has been recorded, which potentially excludes a relatively high number of health records. When

this is aggregated to Health Board or nationally the findings are heavily caveated. These limitations have inevitably reduced the 'trustworthiness' of the findings, which is a barrier for clinician-level acceptance of the evidence for change (273). Better alignment with quality improvement and financial incentives have recently been introduced by the audit team, however translating this to a change in practice by the generalist in primary care is difficult, particularly when – even in the event of initiatives being prioritised at all – there is often scarce resource and available capacity to undertake the necessary changes (168), particularly during and following the pandemic.

Other similar large-scale respiratory initiatives have also chosen to be described (274–278). One of the most comprehensive and impactful large-scale programmes relating to respiratory guideline implementation was in Finland between 1994-2004. Their structured national asthma programme consisted of implementing guidelines for earlier diagnosis and inhaled corticosteroids as first line therapy, stronger collaboration between primary and secondary care, clinical networks, and easier access to specialists, guided self-management and education for patients. The programme primarily focused on implementing new knowledge, especially in primary care. This appeared successful resulting in significant reductions in asthma morbidity, hospital admissions, reducing asthma related hospital stay duration by half, and 36% reduction in costs of asthma for social security (277,279,280). Similar, large-scale programmes have also been implemented in other countries. In France between 2002-2005, the asthma programme had five objectives:

- 1) Information for patients and the public regarding preventative strategies and self-management.
- 2) Improved quality in asthma care through treatment of severe acute asthma, follow up of chronic patients, management of asthmatic children in the school environment, and detecting new cases.
- 3) Education around inhaled therapies.
- 4) Better management and detection of occupational asthma.
- 5) Development of system to collect epidemiological and economic data (281).

The wider clinical impact is still not publicly available (276), but some impact data are starting to come forth; the *Sophia Asthme* (SA) chronic disease management programme of the French National Health Insurance, found that subjects exposed to the programme were significantly

more likely to be dispensed and sustain controller medications (275). However, despite these national guidelines, between 62-68% of patients with severe asthma in France do not receive the right care (282).

In Ireland in 2000, 400 people with asthma were interviewed using similar methodology to the Asthma Insights and Reality in Europe (AIRE) survey. They reported high usage of acute services, suggesting the level of asthma control and management in Ireland falls short of recommended national and international (Global Initiative for Asthma (GINA)) guidelines (283). Several projects in Quebec mapped asthma-related morbidity and then targeted interventions to improve treatment. Their programme underwent continuous evaluation of standards of care (284). However, Canada has admitted failings and inadequate management of chronic respiratory disease due to poor implementation of these practice guidelines (285). Portugal introduced the Global Alliance against Chronic Respiratory Disease (GARD) structure; the WHO in 2007 created an organisational structure to oversee the GARD strategy. Portugal's programme focused on three areas: (i) equipment – nebulisers, spacers, and spirometers with supporting guidelines to primary care and hospitals; (ii) training – for doctors, nurses, and technicians; and (iii) research (286). Similar GARD activities have been commenced in over 40 countries (287), yet little evidence exists demonstrating impact of these programmes.

An asthma prevention programme implemented between 2000-2003 in Poland, resulted in increased number of new diagnoses (0.99 to 2.19 per 1000 inhabitants) and in year two of the programme, there was a significant reduction in the number of hospital admissions from asthma exacerbations (1.48 to 0.84 per 1000), and a significant reduction in the duration of hospital stays (p=0.001) (288). In 2009, Poland introduced POLASTMA – the Polish National Programme of Early Diagnosis and Therapy of Asthma (274). The strategy used to accomplish specific goals was broken down into tasks, activities, and tools, with a large focus on:

- 1) Distribution and communication of information to primary care and broader society.
- 2) Training of healthcare professionals.
- 3) Increasing the availability of diagnostic testing facilities.

The clinical impact has not been reported.

South Australia showed a statistically significant decline in the risk of readmission for asthma within 28 days of admission following implementation of a National Asthma Campaign (289). A Program for Control of Asthma (ProAR) was introduced into 3 low-income settings (Salvador, Bahia, and Brazil) in response to their increasing prevalence of severe asthma. The programme facilitated better referrals with better multidisciplinary working through focusing on education and medication, and ensuring patients were only referred to primary care when asthma control was maintained. In total, the programme enrolled only 2385 patients, but it reduced the rate of hospital admissions in this group by 74%. The programme was considered feasible, effective, and reduced costs for both people with asthma and the health system (290). Similarly, a substantial drop in hospitalisation and mortality from asthma was observed in Costa Rica between 2000-2011 because of adherence to guidelines recommending inhaled corticosteroids as first line therapy (291). In Tonga, the introduction of a self-management plan and community-based education reduced emergency care from 66% to 18%, hospital admissions from 19% to 3%, sick days from 29% to 4%, severe asthma attacks from 54% to 18% and mean increases in peak flow by 22% (p<0.001) for those enrolled in the study (292).

Clinical management and prescribing guidelines have not previously been published in Wales for asthma and COPD on a national scale, therefore evidence in the application of an implementation framework or centralised implementation strategy does not exist. However elsewhere, the Canadian Thoracic Society (CTS) introduced a framework for guideline dissemination and implementation in 2013 describing three spheres of action (238): guideline production, implementation infrastructure and knowledge translation, which was based on the Canadian Institutes of Health Research KTA process (183). Strategies included a web-based repository and communication forum to facilitate collaboration and communication amongst stakeholders. The CTS also offer a practical guide to guideline implementation and logistical support/assistance in securing peer-reviewed funding. Similarly, the Practical Approach to Lung Health in South Africa (PALSA) intervention for respiratory guideline implementation describes a 1-week cascade training programme for nurse trainers (293). The intention is to upskill health professionals to guideline standards as the burden of respiratory disease is high and growing. The American Thoracic Society published a joint report with the European Respiratory Society in 2012 describing integrated and coordinated efforts in COPD guideline development, dissemination, and implementation strategies (222).

They also report financial interventions appear to be effective levers for behaviour change, such as contractual and financial incentives to adopt guidelines (172). The 4E methodology, considers Education (guidelines and academic detailing interventions), Engineering (organisational/managerial interventions, such as prescribing indicators), Economics (financial incentives for prescribing), and Enforcement (enforced regulations by health authorities) (294). At the time of implementing the respiratory guidelines in Wales, most of these levers were outside the scope of the work, and beyond the jurisdiction of the *Programme*. However, these also existed through other Programmes, such as the financial returns offered through the Quality Outcomes Framework (QOF) (295,296) and reminders delivered through ScriptSwitch (297). For instance, QOF was relaxed in 2018 to reduce the administrative burden on GPs, who would retain the payments for maintaining chronic disease registers, without formally recording objective measures of quality, such as a measure of obstructive spirometry to confirm the diagnosis (Table 5. 2). For ScriptSwitch, at the time of writing, this was yet to be programmed to set reminders against the specifications of the guideline. The All-Wales Medicines Strategy Group (AWMSG) provide national prescribing indicators and (most recently) inhaler carbon footprint reports that may be used to measure impact of guideline adherence in the future by demonstrating variation by Health Board region or GP practice (298). AWMSG advises Welsh Government about the use, management and prescribing of medicines in Wales through an advisory committee comprising NHS consultants, GPs, nurses, pharmacists, health economists, pharmaceutical representatives, and lay members. The annual prescribing indicators are focused to three priority areas to improve safety and efficiency. The respiratory programme would do well to have inhaler prescribing listed here in the future. A more detailed narrative relating to COPD/asthma guidelines is presented in Chapter 6.

These experiences demonstrate that population health for respiratory disease can be improved by undertaking a coherent multi-strategic national approach. However, success – or the ability to confidently measure success – is variable.

Active QOF indicators 2018-19 for COPD	Inactive QOF indicators 2018-19 for COPD		
COPD001 The contractor establishes and maintains a register of patients with COPD.	 COPD002 The percentage of patients with COPD (diagnosed on or after 1 April 2011) in whom the diagnosis has been confirmed by post bronchodilator spirometry between 3 months before and 12 months after entering on to the register. COPD003 The percentage of patients with COPD who have had a review, undertaken by a healthcare professional, including an assessment of breathlessness using the Medical Research Council dyspnoea scale in the preceding 15 months. COPD005 The percentage of patients with COPD and Medical Research Council dyspnoea grade ≥3 at any time in the preceding 15 months, with a record of oxygen saturation value within the preceding 15 months. 		

Table 5. 2: The change of QOF indicators emphasising the shift away from objective delivery of quality metrics (299).

Implementation Strategy Constructs

Systematic reviews of implementation strategies undertaken by Mazza, Fischer, Michie, and Powell (79,161,169,172) have been assessed and grouped into common themes. The reason for selecting these reviews is they provide a broad assessment of multiple implementation strategies in healthcare. The systematic reviews undertaken by the four authors are the most widely reported in the literature and address the mechanistic, ecological, and social lenses, as depicted by Greenhalgh and Papoutis (31). Therefore, efforts to examine studies reporting discrete strategies, such as training, audit and financial incentivisation, for example, and in specific settings and contexts was not undertaken to avoid replication of the work already undertaken by the authors above. Building on the high-level framework in parallel with tailoring an implementation process model, the implementation strategy domain incorporates functional strategy constructs generated by the four systematic reviews undertaken by Mazza, Fischer, Michie, and Powell. The intention here, was to generate common themes and patterns from published systematic reviews of implementation strategies to inform the broader framework. These themes were validated for its 'Welsh-ness' by undertaking thematic analysis of interviews with potential guideline users currently working in NHS Wales that perhaps limits the applicability of the framework to Wales alone.

Whilst Mazza *et al.*, (161) and Powell *et al.*, (169) explore broad strategies in healthcare, the taxonomy by Michie *et al.*, (172) examines behaviour that relates to the adoption of practices. Whilst Fischer *et al.*, looked specifically at guideline adherence (79). Michie *et al.*, developed a comprehensive taxonomy of 93 behaviour change techniques. Initially, the COM-B model highlighted the intrinsic factors, which determine a person's behaviour (172). A person's behaviour (B) is determined by the product of their capability (C) to do it, the opportunity (O) for them to do it, and their motivation (M). The contrasting illustration of COM-B applied in court: Does this person have the capability (or capacity) to commit murder? Was there the opportunity? Was there a motive? The researchers expanded this to include the determinants for each aspect of the COM-B model; the physical and psychological capability; reflective and automatic motivation; and physical and social opportunity. Michie *et al.*, later expanded the COM-B model to included external factors that influence behaviour. These include nine intervention functions, such as training, coercion, restrictions, and incentivisation, which can also be perceived as the environment within which a person works. A further seven policy

categories, including guidelines, communication and marketing, and regulation. Fundamentally, what this tells us is that behaviour, a core output of implementation, is multifaceted, dynamic, and complex. However, Powell's Expert Recommendation Strategy Change (ERIC) study used a modified Delphi process involving surveys and live polling of 71 implementation experts to generate a final compilation of 73 discrete strategies (169). The researchers then matched 47 different ERIC strategies to overcome 39 specific barriers, emphasising wide heterogeneity of relationships between implementation barriers and implementation strategies to overcome them. The analysis of implementation strategies in this chapter applies this study because it has the broadest and most relevant reflection of implementation strategies to guideline implementation. The categories for each of these is summarised in Table 5. 3. Analysis of the ERIC study is presented in Table 5. 4.

Mazza <i>et al</i> . (161)	Fischer <i>et al.</i> (79)	Michie <i>et al.</i> (172)	Powell <i>et al.</i> (169)(264)
 Professional interventions Financial interventions Provider interventions Patient interventions Organisational interventions Provider orientated interventions Patient orientated interventions Regulatory interventions 	 Quality assurance Information and communication technology Distributing materials Identification of barriers Educating groups and individuals Feedback of compliance data Providing reminders 	 Reward and threat Repetition and substitution Antecedents Associations Learning Feedback and monitoring Goals and planning Social support Comparison behaviour Self-belief Comparison of outcomes Identity Shaping knowledge Regulation 	 Planning Educating Financing Restructuring Managing quality Policy context

Table 5. 3: Taxonomies of implementation and behaviour change techniques from four relevant studies.

The analysis in Table 5. 4 using the list of broad implementation strategies detailed by Powell *et al.*, (169) demonstrates that the strategies can be abridged to the two key strategy domains, in addition to a column determining the person or group that should be responsible for the strategy (implementation actor):

- (i) The implementation interventions.
- (ii) The drivers to implement them.
- (iii) The actors to implement them.

Each actor has a role in influencing adoption of the implementation tools to increase fidelity with evidence-based practices. Fundamental to this structure, however, is defining the actors across the programme. In this context, actors are the decision-makers, implementers, and the recipients, of the strategy. Key roles have specific responsibilities to ensure the system and people are equipped and ready to adopt new ways of working. However, the actors extend beyond the implementation strategy, as they are essential for the implementations process, evaluation, and dissemination.

Implementation Strategy	Implementation Driver	Implementation Intervention	Primary Implementation Actor
Access new funding	X		Implementation team
Alter incentive/allowance	X		Executive
Structures Alter patient/consumer fees	X		Executive
	X		
Assess for readiness and identify barriers and facilitators	A		Implementation team
Audit and provide feedback	X	X	Intervention development team
radit and provide recuback	A	Λ	/Implementation team
Build a coalition	X		Implementation team
Capture and share local	X	X	Opinion leader
knowledge			Spinion round
Centralise technical assistance	X		Implementation team
Change accreditation or	X		Executive
membership requirements			
Change liability laws	X		Executive
Change physical structure and		X	Executive
equipment			
Change record systems		X	Executive
Change service sites	X		Executive
Conduct cyclical small tests of	X		Implementation team
change			
Conduct educational meetings		X	Intervention development team
Conduct educational outreach visits		X	Power layer
Conduct local consensus	X		Dayyon layon
discussions	Λ		Power layer
Conduct local needs assessment	X		Power layer
Conduct ongoing training	71	X	Intervention development team
Create a learning collaborative	X	A	Implementation team
Create new clinical teams	X		Organisation
	X		
Create or change credentialing and/or licensure standards			Organisation
Develop a formal implementation	X		Implementation team
blueprint			
Develop academic partnerships	X		Implementation team
Develop an implementation	X		Implementation team
glossary		***	
Develop and implement tools for		X	Intervention development team
quality monitoring	X		Corremance and an
Develop and organize quality monitoring systems	Λ		Governance group
Develop disincentives	X		Executive
Develop educational materials	Α	X	Intervention development team
	X	Λ	-
Develop resource sharing agreements	^		Governance group
Distribute educational materials		X	Intervention development team
Facilitate relay of clinical data to		X	Opinion leaders
providers		^	Opinion leaders
Facilitation	X		Power layer
Fund and contract for the clinical	X		Executive
innovation	71		Litoutive
Identify and prepare champions	X		Implementation team
		İ	

Identify early adopters	X		Implementation team
Increase demand	X		Opinion Leaders
Inform local opinion leaders	X		Implementation team
Intervene with patients/consumers	71	X	Implementation team
to enhance uptake and adherence		21	implementation team
Involve executive boards	X		Executive
Involve patients/consumers and	X		Implementation team
family members			
Make billing easier	X		Executive
Make training dynamic		X	Product development team
Mandate change	X		Executive
Model and simulate change	X		Power layer
Obtain and use	X		Implementation team
patients/consumers and family	7.		
feedback			
Obtain formal commitments	X		Implementation team
Organize clinician	X		Implementation team
implementation team meetings			1
Place innovation on fee for	X		Executive
service lists/formularies			
Prepare patients/consumers to be	X	X	Intervention development team
active participants			_
Promote adaptability		X	Intervention development team
Promote network weaving	X		Implementation team
Provide clinical supervision	X		Opinion leaders
Provide local technical assistance	X		Executive
Provide ongoing consultation	X		Implementation team
Purposely re-examine the	X		Commissioning group
implementation			
Recruit, designate, and train for	X		Implementation team
leadership			-
Remind clinicians		X	Intervention development team
Revise professional roles	X		Executive
Shadow other experts	X		Power layer
Stage implementations scale up	X		Implementation team
Start a dissemination organisation	X		Implementation team
Tailor strategies	X		Implementation team
Use advisory boards and	X		Commission group
workgroups			group
Use an implementation advisor	X		Implementation team
Use capitated payments	X		Executive
Use data experts	X		Implementation team
Use data warehousing techniques	X		Implementation team
Use mass media		X	Implementation team
Use other payment schemes	X	23	Executive
Use train-the-trainer strategies	Λ	X	
_	W.	Λ	Power layer
Visit other sites	X		Opinion Leaders
Work with educational	X		Intervention development team
institutions			

Table 5. 4: List of implementation strategies identified in the ERIC study (169) categorised by an 'X' into the two proposed implementation strategy domains – the implementation interventions and

implementation drivers, with a column to determine who within the organisational structure is responsible.

The high-level framework presented in Chapter 3 (Figure 3. 7) is thus expanded to include the strategy domains. For completion, the framework also includes the implementation process domains (Figure 5. 1). Implementation interventions are the tangible assets experienced by the target population. The term [implementation] 'interventions' is selected over 'tools' or 'innovations' as it provides a broader concept that relates specifically to the implementations process (273). Secondly, as implementation has been determined as an active *make-it-happen* exercise, the strong verb 'driver' is chosen, like to that used by Fixsen *et al.*, for their Active Implementation Framework (AIF) (37). The term 'driver' (over 'action') insinuates targeted, mission-related, and focused activity. Implementation interventions are developed specifically to deliver evidence-based practice, whereas implementation drivers help ensure the target population adopts them.

The 'programme' therefore represents the actors and the governance structure within which they sit. It is recommended the implementation team is suitably trained in implementation methodology and accountable for facilitating the activities within and the transition through the phases of implementation (300). Blasé *et al.*, consider implementation teams accountable for change and delivery, which results in more efficient, higher quality implementation (301). Furthermore, developing implementation teams has parallels with team science; implementation teams must maintain clear expectations; promote effective communication; and establish a shared mission and goals (170), detailed in the implementation plan.

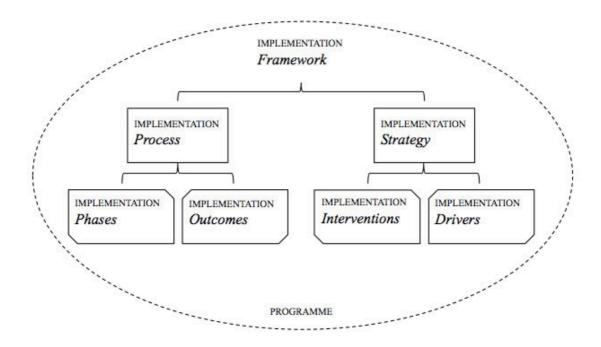


Figure 5. 1: Implementation process and strategy domains proposed in this study as a higher-level framework to offer easy recall to implementers.

Adjusting the Framework for Guideline Users in Wales

Whilst a comprehensive taxonomy of implementation strategies has been devised, and there appears to be consistency across systematic reviews of the literature (79,161,169,172), there is little published on tailoring approaches to implementation strategies for NHS Wales - a discrete political and clinical ecosystem that has subtle but important differences to even its closest neighbour, NHS England (see Chapter 2).

Semi-structured interviews were undertaken over a period of 5 weeks. The interview participants came from different Health Boards (representing 5 of the 7 Health Boards in Wales) and from rural settings to cities (Table 5. 5). With consent the interviews were recorded and transcribed verbatim.

Interviewee	Title and Health Board
reference	
Interviewee 1	Practice nurse, Hywel Dda UHB
Interviewee 2	Practice nurse, Betsi Cadwaladr UHB
Interviewee 3	Practice nurse, Cardiff and Vale UHB
Interviewee 4	Community nurse, Powys Teaching UHB
Interviewee 5	Specialist hospital nurse, Hywel Dda UHB
Interviewee 6	Practice nurse, Aneurin Bevan UHB
Interviewee 7	Practice nurse, Cardiff & Vale UHB

Table 5. 5: Job title and organisation of interview participants.

First Phase Thematic Analysis

The initial round of analysis identified several areas related to a preliminary list of broad clusters (Figure 5. 2). The clusters were then abridged to align with the LTSI (92) (Table 5. 6).

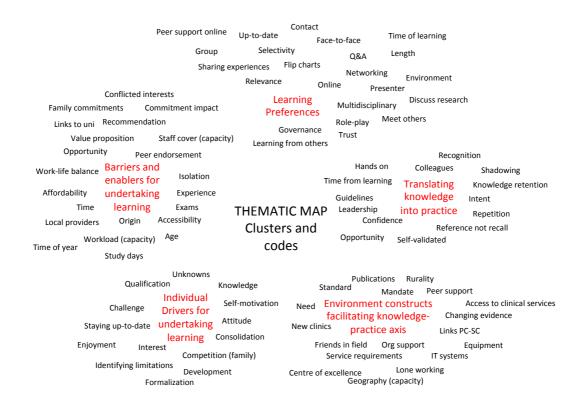


Figure 5. 2: Initial summary of themes, clusters and codes following first round thematic analysis.

Cluster 1: The drivers to learn		
Areas		Potential Themes generated from initial analysis
1.	Knowledge	Consolidation, applicability
2.	Motivation	Staying up-to-date, patient care, interest
3.	Opportunity	Organisation, accessibility, learning preferences
4.	Capacity	Workforce, time, personal
5.	Validation	Credits, trust, endorsement
6.	Influence	Family/friends, presenters/opinions leaders, industry/third parties
7.	Network	Isolation, peer support

Cluster	Cluster 2: The enablers to apply learning		
Areas		Potential Themes generated from initial analysis	
1.	Needs	Personal, service	
2.	Standards	Benchmarking, guidelines	
3.	Environment	Peers, leadership, culture, confidence	
4.	Integration	Services, relationships	

Table 5. 6: Summary of the areas and potential themes relating to cluster 1 (the enablers to learn) and relating to cluster 2 (the enablers to apply learning) following second round analysis.

In the next section, themes are selected from the list in Table 5. 6 based on suitability and the collective address of the topic. These are then presented in the final phase of thematic analysis to generate a final list of themes that align with the strategy categories presented by the ERIC study (Table 5. 2). These are then considered the most relevant features of the strategy and the framework is updated accordingly.

Cluster 1: The Drivers to Learn

Theme 1: Staying up to date

The primary motivating factor to participate in learning, for the nurses interviewed, is the desire to remain up to date. This is largely driven by an internal perspective of standards rather than driven through external mechanisms, such as audit or performance management, for example.

"Even though I do them every day of the week, you think, well, maybe I should have another update just to see, you know, is there a better way, has anything changed?

(Interviewee 4)

The necessity to undertake learning outside working hours was deemed acceptable by nearly all the nurses interviewed, particularly those employed by GP practices. Supplementing this is the enjoyment and satisfaction from doing a good job. Several interviewees commented about the enjoyment associated with learning and delivering good quality care:

"Oh yes, quite happy doing that [outside of work], because I think it is part of our job, isn't it, part of our responsibility to keep us up to date, isn't it?"

(Interviewee 5)

Four of the seven interviewees reinforced the value of consolidation, through attending educational events where what they learnt they already knew. One candidate considered it reassuring:

"It wouldn't be right if you sat there and thought 'Oh, that's news to me."

(Interviewee 1)

Whereas one would assume there is little value in taking the time to attend training and learning about things that are well known, it appears the process of consolidation is well rehearsed and reassuring to nurses. The quest for reassurance through consolidating knowledge is also balanced with the desire to expand on knowledge through learning new things. The interviewees were quite clear the scope of their learning, and they would only participate if it was relevant to their role:

"It's reinforcing your knowledge, and it'll make you feel more confident in your practice that you're doing what you should be doing."

(Interviewee 3)

Most interviewees acknowledged that study days are more than learning new things; they are an opportunity to reinforce knowledge, staying up to date and confidence building. Working in isolation was repeated as a driver to seek learning opportunities. The nurses interviewed were either lone workers in primary care or working independently within a larger service or hospital. Learning from others, especially to reassure and consolidate safe practice was clearly a motivating factor.

"The big issue at the moment is lone working, in this kind of sense, you know, because we've all individually had incidents or something peculiar happen, you know?"

(Interviewee 4)

Peer support ranges from external colleagues of the same profession to a broad spectrum of relevant clinicians within the organisation. Educational events are a common place to network and to develop relationships, important particularly for those working in isolation.

A common thread was to distinguish between the interviewee's perspectives on learning transfer and its application into practice. Distinguishing between the true practical nature of learning versus its value for qualification merit.

"I think it's – my motivation is always to try and improve my patient care. I don't really care about ticking the boxes, particularly."

(Interviewee 3)

There is awareness amongst respiratory nurses that as the evidence base changes so will recommendations for best practice. Change increases demand for new knowledge and it is identified as an independent factor that increases implementation impact. An awareness of working in isolation is a motivational driver for guideline adherence for nurses.

"I'm familiar with the protocols, the prescription guides and the management protocols and everything so I follow them to the letter."

(Interviewee 2)

Receiving updates to national guidelines were deemed a valued resource by all interviewees, particularly where the information is provided by a trusted source. Specifically, for managing patients with asthma and COPD, for example, it is changes to inhalers and understanding which of these should be prescribed at what stage influences the desire for new knowledge.

"Oh definitely. Things change so much, the inhalers are all changing, there's lots of changes and you just want to make sure that you're giving the patient the best, don't you?"

(Interviewee 2)

"The updated guidelines, obviously. COPD has been tricky. Because, you know, there have been so many changes over the years. But it is tricky for patients, because one minute, they are on that, and the next minute, you're saying, 'Right, you haven't exacerbated now for years and years, we'll change you to a dual bronchodilator.'

(Interviewee 1)

Coinciding with new inhalers introduced to the market, several interviewees highlighted that a common source for updates was learning opportunities offered by the pharmaceutical companies. Where the most common changes to asthma and COPD guidelines are new inhaled

therapies, offering learning where there is a demand for it, also perhaps offers a perfectly legitimate opportunity for product placement. One interviewee noted:

"Obviously the evening sessions, if I go, if drug companies are trying to wine and dine and educate and inform us then I obviously do that with my cynical hat on but obviously that's in our own time."

(Interviewee 7)

Theme 2: Capacity (Personal and Organisational)

All interviewees highlighted the importance of acquiring the support from the management team and local clinical leads. Opportunity in this case was to ensure they had clinical support, but also the financial resource and permission to partake in formal structured educational activities, especially where this impacted their clinical time. Common barriers include the time away from practice, cost of training, and to undertake training that is not deemed mandatory. Insufficient number of staff available to continue clinical services reduced the opportunity for current staff to attend formal educational activities during working hours. This is emphasised by a nurse who works in a rural Health Board, that likely has a smaller staff pool reserve.

"The support is there for education, but it's releasing the staff to go on these things, you know?"

(Interviewee 4)

Organisational capacity also impacts larger hospital-based staff. This interviewee emphasises the importance of the value proposition, particularly the perspective of the local manager. Here, the decision by the manager is determined by the immediate requirements of the service, rather than the broader long-term benefit to the organisation.

"Because I'm based in a rural hospital my manager will be looking at how that would benefit the hospital, rather than how that would benefit the Health Board."

(Interviewee 5)

Access to mandatory training is well supported, as this is a key indicator for managers to demonstrate compliant health teams. However, opportunities for non-mandatory training appears to be a challenge, with interviewee 5, a hospital-based nurse, in particular emphasising how little her manager knows about what matters clinically.

I've only been in post just over a year, but I've never had a recommendation for any respiratory updates from my manager at all."

(Interviewee 5)

All interviewees highlighted the importance of getting support from senior clinicians. Clinical leads see the value and outcome of learning, as their service will benefit directly in the long term from a more qualified or competent clinical team. However, the organisation must contend with the short-term impact of staff absence, which can only be relieved should sufficient staff numbers exist to ensure services continue as normal.

"I suppose what enables that is that both that your senior partners and the practice manager are on board with that really, both with study time and or funding."

(Interviewee 7)

The cost of training is also a factor that impacts organisational capacity. What is clear from the interviews is that nurses are pragmatic and clearly understand the decision-making process for authorising their requests. Understanding this enables them to judge the appropriateness of learning opportunities and helps them to judge the probability of their request being granted.

"Well, it needs to be really relevant; it needs to be affordable, both in terms of sort of some kind funding and the time it's going to take. I think courses need to be relatively short if they can be, so that you can – you're not away from the surgery a lot of the time."

(Interviewee 3)

Interviewee 3 articulates the factors one must consider when assessing the feasibility of undertaking an educational activity based on the capacity of the organisation with respect to

cost and the impact of being away from clinic. However, interviewee 2, like others, again demonstrates a compromise by offering their own personal time. This relieves the impact on the organisation's capacity, subsequently reducing the barriers for managerial support.

"Every module that I've wanted to go on I've gone on and like I say, the only downside is a lot of it is in your own time. They will give you money for it, your time, but it is on a day off."

(Interviewee 2)

Initially, organisational capacity and personal capacity were listed as separate themes. However, following extended synthesis of the data, they have subsequently been incorporated under the same 'capacity' theme. The reason for this is because capacity for all interviewees was related to their time, not for example, mental/cognitive/intellectual or an ability to do something. Furthermore, their time spans across the work hours (organisation time) and outside of work hours (personal time). In this respect, there is no delineation between work and home when it came to learning.

"Yeah, I don't get time, obviously my days are filled up, so I don't tend to have time in work, I tend to do it at home really."

(Interviewee 6)

However, one interviewee emphasised the pressure to do additional work during her personal time, which for one course she 'resented bitterly'. Another added the reluctance of their families when considering her commitment to learning.

"I'm a little bit reluctant, and the family are a bit reluctant, because we don't really want me to have that level commitment."

(Interviewee 3)

Theme 3: Accessibility

For respiratory nurses at the time of interviewing, each reported limited learning opportunities in respiratory, which impacted their ability to stay up to date. All interviewees commended the

use of e-learning because of the ease of access and immediacy of knowledge transfer. Online learning also increased opportunities as it negated the organisational barriers relating to time away from clinic.

"I think the availability of it. How easy is it to get hold of? For me, online is so much easier because I can do it wherever I am at my own time. It's not easy trying to get any time out of work to do CPD. And is it easily accessible?"

(Interviewee 5)

All interviewees explicitly highlighted a desire for better connection with their peers and clinical support. This is easier through face-to-face learning, but online access was considered acceptable as it provides more flexible opportunities to learn. However, several interviewees expressed caution with online learning due the amount of inaccurate information.

"Yeah, that tends to be our biggest issue, as well. Can you access it?

Where do you access it? That's going to be a huge benefit, to know that it's a recognised site and what information you're going to get is accurate.

Because of the huge amount of information that's inaccurate."

(Interviewee 5)

"Where do you find it? How appropriate is it? Who's doing the training?

That sort of thing. Because there's lots of CPD out there, but some of it

you're not quite sure whether to trust or not."

(Interviewee 1)

Theme 4: Influencers

Family and friends were identified as motivators for learning by all interviewees, as well as close and extended friends, particularly where they too share the same profession. This is also driven by the desire to network and discuss issues with their peers for support.

"Yes, I mean I think I've got quite a good informal network of nursing friends, or practised nurses, who, we meet often, we talk about work things."

(Interviewee 3)

The provenance of the learning opportunity also influences participation. This subsequently has a direct impact on the applicability of changing clinical practice.

"If I went to a training day and I wasn't convinced about the level of training then I'd be dubious about putting it into practice. I'd want to know more."

(Interviewee 5)

In summary, the drivers to learn cluster has four key themes – staying up to date, capacity (personal and organisational), accessibility, and influencers. These themes include several codes that will subsequently guide the implementation strategy focusing on the education domain of the 4E methodology for guideline implementation. The next section explores the barriers and facilitators to applying learning to practice.

Cluster 2: Drivers to apply learning

This cluster explores the factors that influence the application of what is learnt into clinical practice. This especially means the tangible elements that must exist for a learnt, or new practice to be implemented within the local practice. Whilst this shares many themes as cluster 1, it focuses more on the application of learning rather than the learning process itself. As with cluster 1, this cluster reflects the complexities surrounding personal and individual capacity to ultimately apply what is learnt into practice, the hallmark of the collective endeavours of undertaking training as part of an implementation strategy.

Theme 1: Service Needs

The first theme identifies needs of their service as a core enabler to apply what has been learnt in a training or educational event into practice. This theme includes its subcomponents – the personal needs of the practitioner, and the needs of the service. Personal needs may be their needs as a practitioner within the organisation, or intrinsic needs relating to value, productivity and self-worth. There was also an assured response when discussing the merits of what as being learn and applying this into practice.

"It's implementing what you've learned, isn't it, and applying it back to practice, that's the thing."

"You know, it's like identifying something that could run a little bit smoother, and then looking at ways of trying to develop that, isn't it?"

(Interviewee 4)

Where there was desire expressed by all interviewees for new or better services. Several interviewees highlighted the additional value learnt skills or new knowledge provides to the service and the people they work with.

Theme 2: Standards of Care

With increasingly independent practitioners as all interviewees highlighted working in isolation, the ability to maintain or raise the standards of care is difficult.

"We've got no way of sort of assessing ourselves and that, really."

(Interviewee 4)

"Well, you want to try and reach a standard and have it, sort of, a universal standard, don't you?"

(Interviewee 1)

At the time interviews were conducted, several guidelines existed for managing people with asthma and COPD. However, the nurses interviewed highlighted these are slightly different and can sometimes feel contradictory, which leads to some confusion around which ones to follow and which recommendations to adhere to.

"Which ones do you follow? The BTS, SIGN, and NICE are different. Which ones are the best ones to follow? It's all a little bit confusing."

(Interviewee 5)

"Yeah. And I mean, to be honest with you, COPD has been tricky. Because, you know, there's been so many changes over the years."

(Interviewee 1)

Theme 3: Support

This theme includes four core aspects of the environment that facilitate the application of learning into practice. This includes mentorship/leadership, culture (of the organisation), and personal confidence (within the environment).

"We're going to get together every three months to go through everything. Because we're so far apart, just geographically, from each other, we don't get the opportunity to speak to each other that often, so we thought it would be a good idea to do that."

(Interviewee 4)

In terms of applying new interventions into practice, one interviewee highlighted the support and alignment of colleagues, peers, and leads. Mentorship/leadership are the clinical leads in the organisation, typically consultant level doctors that have decision-making control and interest in the topic or disease. Irrespective whether the nurse was GP practice based, hospital, or in the community, this was a consistent belief for all interviewees.

"And she's [respiratory Consultant] excellent clinical support for them up there. They get quite a lot of information and training with her."

(Interviewee 4)

One interviewee highlighted the importance of forming positive relationships with staff in rural areas [where she works], as there is often low turnover of staff and therefore practitioners remain in post for many years.

"It takes time for you to build up that professional trust – and I think, like I say, it's coming into these small practices and make small, subtle changes."

(Interviewee 4)

She then provides some invaluable insight into techniques, which reduce barriers to change and facilitate better working relationships:

"So, what we try to do, is bring them in to the meeting, so we'll invite a person in, invite someone to come along, and say, come on, sit in and join in, and it's actually quite a healthy way to do it, because you've HCAs to GPs in the same room, if you know what I mean, and everybody contributes; and like the therapists, the pharmacists, whoever. We've even had GP's students. We've had all sorts of people come along to the links meeting and they've been very successful because you can have these open spaces about things, you know?"

(Interviewee 4)

Theme 4: Organisational infrastructure

Confidence applying new things into practice is integral for change. However, confidence seems to diminish the further between training and the application of newly learnt skills into practice.

"I would come out of the classroom or come out of the study or whatever thinking yes I've got it all in my head and then coming into work and actually trying to implement it I found because I didn't use that very quickly, I felt really rusty and very unsure because I was going from being really quite expert in most of what I was doing to suddenly feeling quite novice again."

(Interviewee 7)

Without the necessary infrastructure and clinical expertise to support new services, however, are major barriers to change.

"Because we don't have a respiratory ward, either. Our respiratory patients fill up the whole hospital in different wards. The nursing skills aren't there. If you put a respiratory patient in a surgical ward, they don't have the respiratory skills to deal with the patient. A lot of education is needed."

(Interviewee 5)

In summary, the drivers to apply learning cluster has four key themes – service needs, standards of care, support, and organisational structure. These themes include several codes that will subsequently guide the implementation strategy focusing on the education domain of the 4E methodology for guideline implementation. Final phase analysis is undertaken in the next section to deduce themes across both clusters into factors which have most relevance for a guideline strategy across NHS Wales.

Final Phase Thematic Analysis

In the final analysis, the codes were condensed into common themes relevant to the proposed strategy, deduced to a list in Table 5. 6. Themes are not discrete as they link to other themes demonstrating interrelatedness between clusters (Figure 5. 3). Furthermore, each theme has a causal effect on other themes. For example, influencers are a key theme as a driver to learn; they also influence personal and organisational capacity, provide support, help set the standards of care, identify service needs, and help practitioners stay up to date.

Cluster 1: the drivers to learn	Cluster 2: the drivers to apply learning
Theme 1: Staying up to date	Theme 5: Service needs
Theme 2: Capacity (personal and	Theme 6: Standards of care
organisational)	
Theme 3: Accessibility	Theme 7: Support
Theme 4: Influencers	Theme 8: Organisational infrastructure

Table 5. 7: The final list of themes relating to cluster 1 and cluster 2 following the final round of thematic analysis.

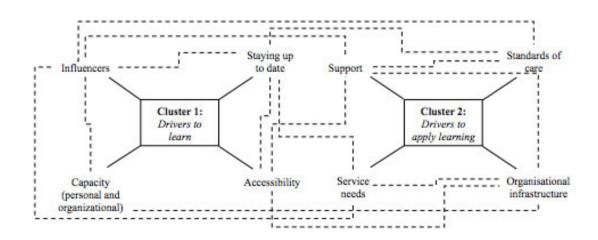


Figure 5. 3: Interconnections between the themes for the two clusters identified through the final phase of thematic analysis.

Implementation Interventions & Drivers

Interviews were conducted with participants with a special interest in respiratory care and potential guideline adopters; therefore, this offers valuable insight into the requirements for the implementation strategy for NHS Wales. Developing the implementation strategy is considered an early phase of the implementation process (Figure 4. 3). This is to ensure implementation interventions are developed that fit with the target population, within their environments and contexts. Whilst it was hoped other professional groups would be included (e.g., GPs), their recruitment into the study was impacted by their lack of availability. A more targeted recruitment campaign was necessary. Whilst this may limit the generalisation of the findings, it is however acknowledged through several discussions with senior medical colleagues that indeed, nurses are becoming increasingly responsible for the chronic disease management of asthma and COPD patients – and are therefore suitably adequate for this purpose. Reassuringly, the themes generated that have informed the implementation strategy are consistent with findings from other studies (79,169,302,303).

The themes generated from the interviews are finally coded against the list of implementation strategies proposed by the ERIC study (Table 5. 8). The findings help determine the necessary characteristics of implementation interventions, that can be applied to NHS Wales.

Themes	Intervention category
Influencers	Informative, instructional
Staying up to date	Informative, instructional
Capacity	Usable
Accessibility	Accessible
Support	Helpful
Standards of care	Informative
Service needs	Relevant
Organisational infrastructure	Relevant

Table 5. 8: Themes generated from interviews with healthcare professionals that are coded against intervention categories compiled by the ERIC study (169).

The selection of implementation interventions is fundamental to the implementation strategy (304). In the early phase of implementation, the feasibility of the implementation interventions must be assessed to determine suitability of the strategy against the context of organisational capacity. Implementation interventions can be adapted through testing with early adopters in preparation for large-scale implementation efforts (see phases one and two of the implementation process, Chapter 4, Figure 4. 2). A system to educate, communicate, and offer data feedback is a fundamental feature of implementation success (79) and requires learning across the entire system, requiring different methodologies as each layer of the organisational structure will have varying capacity to assimilate the necessary information. The strategy should consider interventions that are teachable, learnable, doable, and assessable in practice, as determined by Blasé *et al.* (37).

The primary motivating factor for nurses to participate in learning is the desire to remain up to date. This is largely driven by an internal perspective of standards rather than driven through external mechanisms, such as audit or performance management. The excerpts highlight the nurses' intuition about the standards of the care they provide. Whilst this has merit and emphasises the motivation to deliver their best, it also perhaps unveils a major issue around quality performance in Wales. It accentuates the values of practitioners with a genuine intrinsic motive to learn to ensure they do the right thing, but unexpectedly, the pressure to deliver to local objectives or indicators (e.g., Key Performance Indicators (KPIs)) is essentially absent. To reinforce this observation, all nurses emphasised the necessity to undertake learning outside working hours. Supplementing this appears to be the enjoyment and satisfaction through doing a good job. Several interviewees commented about the enjoyment associated with learning and delivering good quality care. The enjoyment of learning is an important intrinsic motivating factor to do it. However, how does this translate to practitioners without these attributes, or level of interest in a particular subject? The sample of nurses here are likely to be particularly motivated to learn and more likely to respond to questionnaires or interviews; so, they may not be representative of all practice nurses.

To "follow them to the letter" was a universal sentiment from the interviews as a marker of intent to follow best practice and to adhere to guideline recommendations. There is awareness amongst nurses that as the evidence base changes so will recommendations for best practice. Change increases demand for new knowledge and it has been identified as an independent factor that increases implementation impact (169). For the management of patients with asthma

and COPD, for example, it is the changes to inhalers and understanding which should be prescribed at what stage - influences the desire for new knowledge. Coinciding with new inhalers introduced to the market, several interviewees highlighted that a common source for updates was learning opportunities offered by the pharmaceutical companies. Where the most common changes to asthma and COPD guidelines are new inhaled therapies, offering learning where there is a demand for it, also offers pharmaceutical companies a direct opportunity for product placement. Remarkably, the strategy applied by the pharmaceutical industry should therefore be considered a template for others to follow, as the principles of implementation are applied effectively! Educational sessions offered by the pharmaceutical industry use prominent local and national key opinion leaders who teach about new things that practitioners want to learn about, a recommendation from the ERIC study (169). Receiving updates to national guidelines were deemed a valued resource by all interviewees, particularly where the information is provided by a trusted source. In these circumstances, educational events are aimed at a flexible time and duration that suits busy clinicians, perhaps outside the clinical setting, and with complimentary food and drink. This is an attractive way for clinicians to get new knowledge that does not have the same barriers relating to cost and impact on work time.

Accessibility to learning opportunities is dependent on a multitude of factors that facilitates learning. For respiratory, there were little available courses offered across Wales, reducing the opportunity to stay up to date; this was articulated by all interviewees. There is clear flexibility and pragmatism around accessing learning. This is largely influenced by individual circumstances, learning preferences, available time, and local opportunities. An increasing alternative to traditional fixed-time and fixed-place (classroom) learning is e-learning. All interviewees commended e-learning because of the ease of access and immediacy of knowledge transfer. Online learning also increased opportunities as it negated the organisational barriers relating to time away from clinic. Their major concern around e-learning, however, is limited contact with others and ability to ask questions verbally. All interviewees explicitly highlighted a desire for better connection with their peers and clinical support. The perception is that face-to-face training more adequately meets this requirement. A common barrier to accessing online learning materials is technical problems, most often associated with out-dated NHS computer and Internet systems perhaps also contributing directly to more out-of-hours learning.

One of the main barriers to healthcare professional knowledge is the lack of awareness and lack of familiarity with a guideline and its recommendations (79). Coinciding with increasing knowledge transfer through educational events is the need of health care professionals to keep up with increasing volumes of evidence that accumulates over time (305). Other barriers include a lack of agreement of guidelines, self-efficacy, skills, outcome expectancy and staff motivation. Subsequently, common strategies include dissemination and education (303,306), as well as audit and feedback (307) to address barriers relating to healthcare professional's attitudes. Cochrane reviews show that interactive educational meetings and workshops are moderately effective in improving compliance to clinical guidelines (308). Events that have a higher attendance, and greater contextual 'seriousness' of the topic, are associated with greater guideline compliance (259).

Acquiring learning credits (e.g., CPD points) appeared to be secondary to participating in learning within the group interviewed. Furthermore, several interviewees highlighted the benefit of undertaking skill-based training. Four of the 7 nurse interviewees reinforced the value of consolidation, through attending educational events. Consolidation can be considered "the action or process of making something stronger or more solid" (58)(para 2). There may be little value in taking the time to attend training and learning about things that are already known, but it appears the process of consolidation is reassuring, especially as the nurses interviewed reported increased isolation at work. Moreover, the quest for reassurance through consolidating knowledge is also balanced with the desire to expand on knowledge through learning new things. The interviewees were quite clear that they would only participate if the educational sessions were directly relevant to their role. The emphasis on consolidation perhaps highlights minimal opportunity for nurses to assess the quality of their practice, particularly those that work outside of a hospital setting. Most interviewees mentioned working in isolation as their driver to seek learning opportunities. Most are either lone workers in primary care or working independently within a larger service or hospital. Learning from others, especially to reassure and consolidate safe practice was clearly a motivating factor. Educational events are a common place to network and to develop relationships. Peer support ranges from external colleagues of the same profession to a broad spectrum of relevant clinicians within the organisation. Several quotes emphasise limited connectivity with peers and mentors, which leaves nurses, particularly vulnerable to potentially undertaking out-dated or even harmful practices. However, most interviewees acknowledged that study days are more than learning new things; they are an opportunity to reinforce knowledge, staying up to date and confidence building.

All interviewees highlighted the importance of acquiring the support from the management team and local clinical leads. Opportunity for learning in this case was to ensure they had clinical support, but also the financial resource and permission to partake in formal structured educational activities, especially if this ever impacted their clinical time. Common barriers include the time away from practice, cost of training, and to undertake training that is not deemed mandatory. Insufficient numbers of staff available to continue clinical services reduced the opportunity for current staff to attend formal educational activities during working hours. This has been made more acute by increasing staff shortages in the Respiratory workforce (British Thoracic Society (BTS) workforce report (309)) and post-COVID-19 backlogs. One responder highlighted that rural Health Boards and smaller practices have a smaller staff-pool reserve. Organisational capacity also impacts larger hospital-based staff. Another interviewee emphasised the importance of a clear value proposition, when presenting the opportunity and request for study leave to their manager. However, it was noted that the decision by the manager is determined by the immediate requirements of the service, rather than the long-term benefit to the organisation. In contrast, access to mandatory training is well supported, as this is a key indicator for managers to demonstrate compliant health teams. Opportunities for nonmandatory training appear to be a challenge, with one interviewee, a hospital-based nurse, in particular emphasising how little their managers know about what matters clinically. This puts more responsibility towards self-driven learning and doing so during a time that does not impact the day-to-day service. Perhaps reasons why nurses feel isolated and accept having to access learning outside of working hours.

All interviewees highlighted the importance of getting support from senior clinicians. Clinical leads see the value and outcome of learning, as their service will benefit from a skilled clinical team. However, the organisation must contend with the short-term impact of staff absence, which can only be relieved should sufficient staff numbers exist to ensure services continue as normal. Cost is important when determining the value proposition, feasibility, and appropriateness of undertaking a particular educational activity. What is clear from the interviews is that nurses are pragmatic and clearly understand the decision-making process for authorising their requests. Understanding this enables them to assess the appropriateness of learning opportunities and helps them to judge the probability of their request being granted.

Fundamentally, the value proposition is a balance between the relevance and benefit of learning to the service (qualified by the clinical lead), against the financial cost and investment of time by the organisation (determined by the manager). Interviewee 2, like others, demonstrates a compromise by offering their own personal time, subsequently reducing the requirement for managerial support.

Initially, organisational capacity and personal capacity were listed as separate themes but after extended synthesis of the data, they were incorporated under the same 'capacity' theme. This was because capacity for all interviewees was related to their time, not their cognitive/intellectual capacity. Furthermore, their time spans (i) across the work hours (organisation time) and (ii) outside of work hours (personal time). In this respect, there is no delineation between work and home when it came to learning. This offers a unique perspective into the commitment of nursing roles; largely determined by the dynamic nature of new and emerging evidence and best practices, and the responsibility of the practitioner to maintain standards of care that are safe and current. The decision to undertake any form of learning is a judgment on the relevance, benefit to the service, and their capacity (of time) and readiness to undertake it.

Readiness for change can be viewed at an organisational level and at the individual level (310–313). Implementation of new interventions necessitates change within the target organisation. Implementation science recognises that people – the target population – must be ready for change. Readiness is the optimal conditions within the target population that creates the capability, opportunity, and motivation (172) to adopt something new.

A period of preparation is considered necessary for readiness in anticipation for a change in practice or participation in a new programme or training. Assessment of readiness helps to identify potential barriers and challenges to implementing change within an organisation. Various tools help to determine the readiness of adopters and or the organisation. *Ready, Set, Change!* Is a decision support tool that assesses individual psychological (e.g., attitudes, beliefs) and individual structural (e.g., skills, knowledge), organisational psychological (e.g., collective commitment, collective efficacy) and organisational structural (e.g., resources, staff time, policies) (314). The Organisational Readiness for Implementing Change (ORIC) measure is a psychometric assessment based on Weiner's theory of organisational readiness for change (143). Weiner proposes that possible contextual factors, such as organisational culture,

resources, and structure, and past experiences, for instance, influence change valance and the assessment of information. Shea et al., concluded that a valid measure of organisational readiness for change reduces the probability of failed efforts to implement change (312). Weiner compartmentalised organisational readiness as a shared team property, defined as "a shared psychological state in which organisational members feel committed to implementing organisational change (143). Furthermore, Weiner asserted that whilst individual readiness for change has been the subject of extensive research, this is not the case for organisational readiness for change. Weiner et al. have since undertaken a systematic review of measure of readiness for implementation, concluding that current measures are unevenly distributed, exhibit unknown or low psychometric quality, and demonstrate mixed pragmatic properties. They suggested that those which show promise require further systematic testing to demonstrate usefulness in research and practice (315). Since Weiner's earlier work, several studies have explored organisational readiness to develop. The Organizational Readiness for Implementing Change Measures (ORCA) was developed as a tool (310). The ORCA survey comprises three scales corresponding to the core elements of the PARiHS framework. This includes (i) strength and extent of evidence for the clinical practice changes represented by the Quality Improvement (QI) program, (ii) quality of the organisational context for the QI program, (iii) capacity for internal facilitation of the QI programme. Whilst the tool received general support for its reliability it failed to conform in its entirety to the PARIHS framework as intended. However, it has since been applied successfully in other studies. Hagedorn and Heideman demonstrated that ORCA was able to measure differences in organisational readiness between sites when implementing hepatitis prevention services (316). However, in a systematic review of organisational readiness, Gagnon (like Weiner) concluded that very few, valid and reliable organisational readiness for change instruments could be applied in healthcare but suggested the Texas Christian University Organizational Readiness for Change (TCU-ORC) instrument (311). The self-scoring tool assesses motivation for change, resources, staff attributes, and organisational climate presents the best evidence for psychometric validity according to Gagnon; a statement consistent with the later analysis undertaken by Weiner et al. (315).

All interviewees, without prompting, highlighted the difficulties achieving the right 'work-life balance'. One interviewee emphasised the pressure to do additional work during her personal time, which for one course she "resented bitterly". This perhaps relates to interviewee 4 suggesting the implications lead to "burn out". This highlights the fine balance between the

demands to stay up to date as a professional and protecting personal time. Another added, not only their "reluctance", but also the reluctance of their families when considering her commitment to learning, suggesting past-problems, and considering the views of family members are part of the decision-making process. A study exploring teaching and learning for healthcare professionals found that the main drivers for further study were knowledge expansion, personal interest, and career progression but barriers were work commitments, cost, family commitments and distance from course location (317). Family and friends were identified as positive motivators for learning by all interviewees by increasing their desire to participate in learning. Others extend personal influencers to close and extended friends, particularly when from the same profession. This is also driven by the desire to network and discuss issues with their peers for support.

The provenance of all training is factored into the decision-making process. It also matters who organises, hosts, and presents in training activities. Several interviewees mentioned the amount of inaccurate information found online. Kitsen *et al.* identify the quality of the evidence base as one of three factors that determine the probability of implementation success (2). Furthermore, the clinical community demand empirically proven interventions before they would be even considered for use in practice. Opinion leaders are known, respected, well-qualified senior clinicians that influence the practice and behaviour of others (261). Their experience and confidence in delivery were attributes influencing expected learning experience and knowledge retention amongst the interviewees. The provenance of the learning opportunity also influences participation; nurses take a critical analysis of learning opportunities to ensure it is good use of their time and value to their practice and organisation.

The second cluster highlights the factors that influence the application of what is learnt being out into clinical practice. Whilst this shares many themes as cluster 1, it focuses more on the application of learning rather than the learning process. As with cluster 1, this reflects the complexities surrounding personal and individual capacity to ultimately apply what is learnt into practice – the goal of any clinical implementation strategy. The first theme identifies 'need' as a core enabler to apply what has been learnt in a training or educational event into practice. This theme includes its subcomponents – the personal needs of the practitioner, and the needs of the service. Personal needs may be their requirements as an employee, or intrinsic needs relating to value, productivity and self-worth. There was also an assured response when discussing the merits of what is learnt and applying this into practice. Several interviewees

highlighted the additional value their new skills offered to the service and the people they work with.

In terms of applying new interventions into practice, one interviewee highlighted the support and alignment of colleagues, peers, and leads. Mentorship/leadership are roles of the clinical leads in the organisation, typically Consultant-level doctors that have decision-making control and interest in the topic or disease. Irrespective whether the nurse was GP practice-based, hospital, or in the community, this was a consistent belief for all interviewees. The culture to apply evidence-based practice and learned practices are integral for service change and meeting the necessary standard. Support from the organisation is clearly an essential factor to applying new skills into practice. Building strong relationships are necessary to facilitate effective team working. For nurses, team building is an essential component of their practice as they are increasingly working independently and in isolation. One interviewee highlighted the importance of forming positive relationships with staff in rural areas, as there is often a low turnover of staff with practitioners in post for many years. She then provides some examples of techniques to reduce barriers to change and facilitate better working relationships. The inclusive nature of offering staff multidisciplinary working is an effective technique (170,318). Confidence in applying new things is integral for change. However, confidence diminishes the longer between training and the application of newly learnt skills into practice. Kitson et al., argues that implementation is dependent on the relationship between three key factors – the nature of the evidence, the quality of the context, and facilitation (2). Facilitation is a multifaceted process of enabling and supporting target groups as a strategy to overcome barriers of implementation and to leverage opportunities for engagement. Facilitators work with key stakeholders to encourage widespread adoption by addressing barriers, knowledge and understanding of the interventions and help to adapt interventions for local contexts (319). Facilitators include key influencers such as lead healthcare practitioners, local opinion leaders, or relevant managers and executives that actively mobilise the environment to accept and adopt an intervention. Early adopters are identified through product engagement and adoption, feedback, and other organic mechanisms such as word of mouth and requests to participate.

Stakeholder alignment is critical to the implementation process (137). Stakeholder engagement supports effective study design, data analysis and research prioritisation (320) and improves perceived relevance and uptake of research findings (321). Stakeholder engagement should be integrated throughout the implementation process through interactive communications

between responsible groups (82). Stakeholders have views and opinions that influence adoption to maximise value and return of efforts (322); therefore, they must be actively involved in the decision-making and development process detailed within the implementation plan. End-user engagement and coproduction (e.g., healthcare professionals, patients) is necessary to ensure the implementation interventions are feasible and acceptable for adoption. Patient engagement is ideally considered throughout all phases of health implementations (321,323) and is deemed an ethical necessity (324) and a positive process through improving the transparency and accountability of research organisations (325). The conceptual model for stakeholder engagement, provides a comprehensive support tool for determining the and 'what' and 'how' for effective stakeholder engagement activity (321).

Engagement with the guideline implementation strategy is expected to follow the pattern depicted by Rogers (104) – early adopters accepting and using the guidelines, followed by late adopters and some not changing at all; a pattern which may explain in part the variation in the standards of care observed. The national audits have emphasised the magnitude of the problem for people with asthma and COPD (326). Nevertheless, an implementation strategy to encourage more nurses to adhere to guideline recommendations is necessary to standardise proficiency and the care offered nationally. The interviewees reported very little external pressure to learn. Instead, learning choices and preferences are driven by their internal interest and desire to remain up to date, rather than organisational necessity or audit findings. With COPD and asthma this most commonly relates to guidelines and inhalers, however, all interviewees had difficulty accessing local established specialist training.

Based on this analysis and the recommendations from the ERIC study (169) the implementation strategy function of the framework can be developed (Figure 5. 4). In principle, implementation interventions should be informative, instructional, usable, accessible, helpful, and relevant. Implementation drivers are governed by the four target layers to ensure all stakeholders are aligned, the interventions are trialled and adapted accordingly, and assurance there is adequate capacity and readiness across the organisation to adopt the interventions.

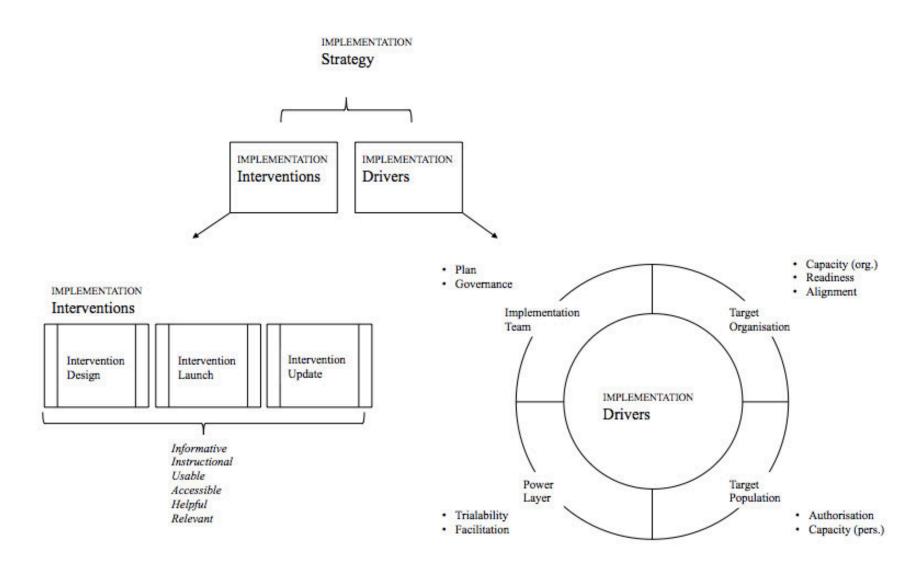


Figure 5. 4: Updated criteria for the design, launch and updating of implementation interventions following thematic analysis and comparison with the ERIC study (169).

Strengths

Whilst the literature either excludes implementation strategies altogether or mixes implementation strategies and implementation processes (207), this study allocates each of these to independent domains within the framework. This is notably the first attempt to do this and considered by the author to be an essential feature of implementation practice to dissociate to largely independent functions of implementation. It therefore maintains the structured and systematic process (to guide implementation), whilst allowing for a flexible, principle-based approach to selecting strategies (that form the implementation drivers). The range of implementation strategies reported in the literature will inevitably continue to grow, displaying varying levels of impact in different contexts. In principle, multi-interventional strategies are considered superior to single interventions (154,155,175) and these should be tailored to the programme aims and the local requirement (35,113,170).

For this study, the implementation strategy domain of the framework is developed specifically for the target population in Wales through ethnographic observation; that is deemed highly appropriate when assessing complex issues (91). For the cohort of nurses interviewed, data saturation (327) was achieved despite relatively low numbers of interview participants. The qualitative analysis of the interview data provides a deeper understanding of social and cultural contexts that would be challenging to capture through quantitative research or generalised from the literature. The interview data provided rich insight on a complex phenomenon such as the influences on learning behaviours, and crucially, the experiences and opinions of individuals that helped shape the strategies described in the next chapter. Undertaking research through utilisation and reporting of qualitative methods generates knowledge production that increases trustworthiness, transparency, relevance, and rigor in research findings (328). Further, the application of a structured thematic analysis framework (93) formed the identification, organisation, and interpretation of patterns and themes. By immersing in the content to develop a deep understanding of the local context, individual perspectives, motivation, opportunities, and challenges, this offers in-depth familiarisation of the data that has not been published elsewhere on this topic in Wales. Reporting the data with quotations offers a systematic and transparent analysis of the data that should serve to increase validity and reliability of this methodology to tailor the framework and guide the planning for guideline implementation in Wales.

Limitations

The lack of insight from different professions is important – as both guidelines are not just aimed at nurses. The strategy for national respiratory guidelines in Wales was determined by thematic analysis of semi-structured interviews intended to be with healthcare professionals that have direct interest and responsibility for patients requiring respiratory care, thereby representing the target population for the strategy. However, those responding to the invitation to take part in the study was limited to nurses, despite a broad and repeated recruitment campaign via email to GPs. After several reminders no other professions responded. The reasons for this are unclear, however the zero-response rate from GPs may be because of the researcher's limited direct access to this group and their willingness and capacity to engage with this process at the time.

Undertaking a simple survey may have been a more feasible approach to garner wider representation to supplement interviews with nurses. Only doctors from primary care were targeted due to the involvement of specialist respiratory doctors in the development of the guideline content, which was considered a potential bias. Therefore, respiratory doctors (secondary care) were excluded.

When conducting qualitative research and attempting to generalise the findings, there are several disadvantages of interviewing only one professional group:

- 1. Limited perspective: Interviewing only one professional group may provide a narrow perspective on the research topic. Different professional groups often have varying experiences, knowledge, and viewpoints. By excluding other groups, valuable insights and diverse opinions may be missed (329).
- 2. Bias and generalisability: Interviewing only one professional group increases the risk of bias in the findings. The experiences and perspectives of a single group may not accurately represent the entire population or target audience, leading to limited generalisability of the results (251,328).
- 3. Incomplete understanding: By focusing solely on one professional group, important factors or dynamics that influence the research topic may be overlooked. Different groups may have unique challenges, approaches, or contributions that could significantly impact the overall understanding of the phenomenon under study (330).

4. Missed opportunities for comparison: Comparing multiple professional groups allows for a richer analysis of similarities, differences, and patterns. By interviewing only one group, the opportunity to explore variations across different groups and identify potential factors that contribute to those variations is an opportunity missed (330). Furthermore, focusing solely on Welsh nurses in this case may abdicate generalisability of the framework to contexts outside of NHS Wales.

An in-depth focus through application of qualitative analysis helps to determine specific meanings, occurrences, behaviours, thoughts, and circumstances associated with the research topic (328). However, since this involves investigating a select group of people, findings cannot be generalised to the broader population. To consider whether qualitative findings are applicable and valid to other situations or populations there must be a judgment based on the context in which the research was conducted. Qualitative findings can be usefully indicative of what one might find in similar situations and contexts, and of how different aspects/elements studied may relate to one another. However, findings cannot be generalised based on qualitative data alone (331). Some argue that generalisation should be left to quantitative, probabilitybased research, although generalisation is also limited to population samples (329). Although, the goal of most qualitative studies is not to generalise but rather to provide a rich, contextualised understanding of some aspect of human experience through the intensive study of specific scenarios and cases. To strengthen the generalisation of the findings, Polit and Beck suggest using techniques such as planned replication, sampling strategies, systematic reviews, reflexivity and higher-order conceptualisation, thick description, mixed methods research, and using for example, the RE-AIM framework within pragmatic trials (332). In this study the results of the thematic analysis are used to qualify systematic reviews of both quantitative and qualitative studies within the literature. This is consistent with an exploratory mixed methods sequential observational study design (85) demonstrating real-world representativeness, albeit limited to a single professional group.

To enhance the generalisability of these findings recruiting multiple professional groups, policy makers, and patients would ensure a broader representation of personal, local, and national perspectives that could potentially increase the validity of the conclusions. Fundamentally, interviewing only those requiring – *to 'adhere'* – to the guidelines offers a single perspective of guideline implementation. Preceding that, as defined in chapter 1, *'adoption'* of the guideline is necessary by policy leads/managers to formally endorse a guideline as policy. Governance

is incorporated into the early stages of the implementation process (phase 1), which should offer some reassurance. Furthermore, a national directive from the Welsh Government policy team specifying the requirements of a national approach (detailed in chapter 1) offers sufficient confirmation of intent to adopt that should be satisfied by organisation (Health Board) confirmation during the pre-implementation phase.

Summary

The compilation of implementation strategies by the ERIC study can be grouped into the two-implementation strategy domains presented (169): implementation drivers and implementation interventions. The domains represent the how (implementation drivers) and the what (implementation interventions). This is like the 'usable innovations' and 'drivers' as the function components within the Active Implementation Framework (37). Furthermore, this structure was chosen because its relevance here to the implementation of national guidelines and supplemental ('usable') implementation interventions that support the guideline recommendations. Implementation strategies are inherently entwined as part of successful implementation, which makes this framework unique.

The aim of the implementation strategy is to overcome the barriers to guideline adoption relating to personal factors, guideline-related factors, and external factors (79). The components of the strategy make up a package of implementation interventions that was originally aimed at a range of target groups that directly influence the likelihood of guideline adoption within the target organisation. However, as only primary, and secondary care nurses could be recruited for qualitative analysis, some care must be considered when generalising these findings, despite validating these findings against published systematic reviews. The structure of the implementation strategy incorporates the implementation drivers to increase the rate of adoption of the implementation interventions.

Fundamentally, healthcare professionals are unable to comply with guidelines they are not aware of, unless it is by pure accident! As with all product launches, guidelines must be marketed effectively to the target audience and rapidly to ensure they are aware of the guideline in advance of its publication. If this does not happen, by the time they find out more about the guidelines, read them, and synthesised the evidence, and structure their services to adhere to them, the guidelines may be out-dated (77).

One of the greatest challenges to any organisational training programme is transferring the newly learned skills, behaviours and competencies into the workplace and doing so with fidelity i.e., practitioners engage with the training and subsequently apply what is learnt into practice exactly as it was intended. Nurses in Wales indicated that transfer of learning knowledge into practice is limited by the organisation structure, not only their time and

motivation to undertake learning. Thematic analysis here also identified that, an interest in the topic, networking, and time, are key drivers for undertaking any form of education whilst organisational support, and time, are key enablers to applying what is learnt into actual practice.

The next chapter applies this framework to the implementation of respiratory guidelines across NHS Wales. This includes the activity undertaken within each phase of the implementation process, the implementation outcomes generated at each phase and a description of the implementation strategy applied based on the domains proposed in this chapter. Lessons from this study will inform the necessary changes to the revised framework.

Chapter 6

Case Study 1: Implementation of National Respiratory Guidelines for Asthma & COPD

Chapter Objectives:

- 1. Demonstrate the structured application of an implementation framework for new COPD and Asthma across NHS Wales.
- 2. Adapt the implementation framework where it is deemed ineffectual or limited in its application to novel national clinical guidelines.
- 3. Propose further modifications to the framework in preparation for application in a different setting.

Introduction

This chapter reports on the application of the framework (see Figures 3. 7, 4. 2, 4. 3, 5. 4) into the design and implementation of national clinical guidelines for two common respiratory diseases: asthma and COPD. These two guidelines are considered jointly because they were designed and implemented using the same framework and are delivered within the same programme, at the same time, with the same implementation team, governance structure, target audience, and implementation strategy. The clinical impact of the guidelines is not reported here — but whether the implementation framework can be used to successfully introduce respiratory guidelines across a large target population over a wide geographical area. The results are presented against the three (early, mid, or late) periods of the implementation process (163). For each period, the domains: Implementation Phase, Implementation Drivers, Implementation Interventions, and Implementation Outcomes also guide the report. The Standards for Reporting Implementation Studies (StaRI) framework checklist (333) was applied to structure this report (Appendix D) as it recommends a balanced description of both the intervention and implementation. The Implementation Research Logic Model (IRLM) framework (334) was also employed.

Context

Wales has a higher prevalence of asthma (6%) and COPD (2%) than the UK (335). However, a third of people 'with' asthma and a quarter of people 'with' COPD appear to be misdiagnosed (336,337). Several respiratory guidelines have been used in Wales, but none explicitly recommended specific makes or brands of inhalers (338–341). Furthermore, local guidelines have not included structured supplemental education aligned with audit as proposed by Fischer et al. (79). Over recent years there has been a proliferation of new inhaler therapies and guidelines in both COPD (338,340) and asthma (339,341). Moreover, the most influential guidelines in Wales, such as those published by NICE (339,340), GOLD (338), BTS (342), ERS (343) and GINA (341) suggest prescribing classes of inhalers at a particular disease stage of which there are many available options. This has created confusion for some Healthcare Professionals (HCPs), and likely fertile ground for pharmaceutical companies to influence prescribing behaviour through targeted local meetings; an observation also observed from interviews with nurses across Wales.

Multiple audits in Wales demonstrate significant differences in prescribing patterns between GP practices and between Health Boards, despite a similar prevalence of asthma and COPD, which is consistent with other UK studies (344,345). As an attempt to reduce inappropriate variation, internal Health Board guidelines were developed for COPD, first in Cardiff and Vale UHB in 2012, and subsequently across most of the remaining Health Boards. Local guidelines for COPD management and subsequently for asthma started being created by gaining consensus from interested respiratory consultants in several different Health Boards in Wales between 2012-2015. Following the publication of the Respiratory Health Delivery Plan by the Welsh Government, a key focus became the delivery of national prescribing guidelines for both COPD and asthma in Wales (52). These were initially focussed on limiting the available options and rationalising devices at different steps. However, there are several advantages to having a national guideline. First, a national market is significantly larger than that of a Health Board and so it was agreed by the programme the potential to further reduce costs using national procurement. Second, there was agreement amongst all Health Board Finance Directors that 50% of any savings generated by guideline adherence would be reinvested back into respiratory medicine, which was considered a key lever to promote guideline adoption by hospital departments (although, at the time of writing, this has yet to happen). In 2017, Bangor University (Wales) undertook a modelling economic analysis if the proposed All Wales Guidelines were fully implemented in Wales. If only 58% adhered to the asthma guideline and 75% adhered to the COPD guideline there would be potential savings of £7.2 million. These savings are much greater than the rebates offered by several pharmaceutical companies and could be utilised to improve local services. These guidelines represent a unique opportunity to reduce variation in prescribing, control costs and raise funds to support developments in respiratory medicine. They are thus firmly underpinned by the principles of prudent medicine (6).

Audit Findings

The continuous UK National COPD and asthma audits have repeatedly highlight issues around the management of patients over the past decade. It is known that clinical history and examination alone will miss many patients later diagnosed through abnormal spirometry (346). In 2004, QOF was introduced, and this incentivised spirometry in Primary Care (347). However, there continues to remain a concern over the accuracy of GP registers (337). In 2014,

the National Primary Care COPD audit uncovered the true extent of the problem in Wales (326). Fewer than 15% of registered COPD patients had a diagnosis confirmed by a post bronchodilator spirometry FEV1/FVC ratio of <0.7. Approximately 32% of those with post bronchodilator spirometry had FEV1/FVC ratios not compatible with a diagnosis of COPD yet were still on the register. Poor recording could imply that as many as 58% patients might have had a confirmed diagnosis but there is no evidence to support this estimate. The next publication of the National Primary Care COPD audit (2017) still showed significant problems with COPD diagnosis in Wales (326). Only 54% of patients diagnosed in the past two-years had a recorded FEV1/FVC ratio <0.7. In other words, nearly a half of patients newly diagnosed with COPD did not meet the international diagnostic criteria for COPD. Even after checking diagnostic (Read) codes, 24% of these patients were still given the wrong diagnosis according to their spirometry. The COPD and Asthma audit in 2020 indicated that of patients diagnosed with COPD in the past 2 years (n=9,395) only 11.5% had a record of the gold standard diagnostic test for COPD, with only 44.2% having any record of spirometry.

Whilst spirometry has remained a core activity in Primary Care across the UK for over two decades, there remains a marked variability and inconsistency in the use of spirometry to diagnose COPD. In their meta-analysis, Yamada *et al.*, applied a conceptual framework-based perspective on the use of diagnostic spirometry for asthma and COPD in primary care. Using global data, they explored enablers and barriers and mapped these to potential strategies using elements of behavioural change techniques (348). Barriers and enablers overlapped for asthma and COPD. Notably, the researchers identified more reported barriers than enablers. Key barriers to the use of spirometry in primary care can be divided into three factors – (i) practitioner, (ii) resource, (iii) and patient factors (349) (Table 6. 1)

Practitioner	Resource	Patient
A lack of conviction on the value or usefulness of spirometry (350) and/or a lack knowledge of clinical practice guidelines that recommend spirometry in the diagnosis of COPD, and general awareness of the utility of spirometry (351–353).	Insufficient resources or expertise to estimate the adequacy of ventilation to testing rooms that may need to be reconfigured or vacated for a period between testing patients (354,355).	Cost and reluctance to undergo spirometry (350)
Limited expertise in performing and obtaining good quality spirometry data (356). The specialty of the clinician in both primary and secondary care (350).	Together with staff re-engagement and retraining, the costs associated with these COVID-19 safe protocols can be prohibitive for primary care services (354,355).	Long waiting lists, out-of-pocket expenses and excessive travel time/distances (348)
lack of confidence in interpreting spirometry (352)	Lack of access to a well-maintained spirometer (350,356).	Reluctance to undergo spirometry due to inconvenience (350)
Unnecessary parameters in the spirometry report (357)	Lack of trained staff (350,358)	Spirometry underutilisation is associated with older age (359)

Over-reliance and/or 'overconfidence' in clinical-only diagnostic skills (360)	Increased time required for spirometry (350,358) Logistical challenges when clinical visits last just 10 to 15 minutes for patients with multiple comorbidities (361)	Spirometry underutilisation is associated with not having received respiratory care (362)
Mislabelling in hospital discharge summaries being carried forward into a primary care diagnosis (357)	Post-bronchodilator testing adds 20 min and requires administration of the bronchodilator (363)	Spirometry underutilisation is associated with having fewer comorbidities (362)
Attitude of nihilism viewing the spirometer as a means of convincing the patient to stop smoking rather than a tool to aid accurate diagnosis (350,364,365)	Difficulty integrating spirometry into patient flow (350,356).	Access to care and the severity of the disease (366).
Massive fall in the number of tests performed from prolonged disruptions due to COVID-19 that have led to the deskilling of staff with probable loss of confidence in performing spirometry (354,355)	Increased cost to providers (358)	

Table 6. 1: Key barriers to the use of spirometry in primary care

A multi-centre, cross-sectional study of 83 primary care clinics, reported 'severity of COPD' (348) on 899 patients before spirometry but these were accurate for only 30% of patients following spirometry. Disease severity in 41% of patients was underestimated. Physicians also underestimated severity compared with patients' self-assessment. Spirometry changed the physicians' clinical impressions and treatments for approximately one third of these patients. The study concluded that without performing spirometry, physicians are likely to underestimate COPD severity or inadequately characterise their patients' lung disease. Over 75% of these GPs owned or rented spirometers and, in most cases, practice nurses or health care assistants perform spirometry tests in their practices. Whilst the survey did not elicit the level or quality of training or the standard of proficiency attained, less than a quarter of the GPs stated they had undergone accredited training, and more than a quarter had no training to interpret spirometry tests at all.

Another UK survey found that only 20% of primary care nurses who always used spirometry to diagnose COPD had undertaken any form of formal accredited training (367). However, a UK audit of nearly 10,000 cases of people admitted to hospital with an exacerbation of COPD found that spirometry had been recorded within the last 5 years in 74% of their primary care records (270), illustrating the wider application of spirometry and thus highlighting the need to standardise proficiency of those providing this service. Since COVID-19, the provision of spirometry has dramatically changed, and many professionals (particularly in Primary Care) report a deskilling and even further reduction in confidence in both performing and interpreting spirometry (368).

Whilst there remains variability in spirometry standards across Primary Care, evidence shows a direct correlation between spirometry education and spirometry standards in both performance and interpretation. Trained nurses performed better than 'usual care' GPs, with spirometry standards for acceptability and reproducibility met in 76% and 44% of cases, respectively (364). White *et al.*, studied the level of agreement between GPs and specialists in the assessment of quality and interpretation of spirometry. In 312 spirometry test results from six general practices there was significant disagreement in the interpretation of the quality of the tracings, the diagnosis, and the severity of airflow obstruction. In another study by Poels *et al.*, 28.6% of incorrect test manoeuvres were not recognised by GPs, and only 66% of their interpretations agreed with that of an expert panel (369). A survey of 137 GPs who participated

in a spirometry evaluation in the Netherlands identified that 69% required on-going support, although recent training partially diminished this need (370).

Feasibility of spirometry training in Wales has already been investigated. In 2005, Bolton et al. surveyed the availability, staff training, use and the interpretation results of spirometry in 72% of General Practices (352). Eighty-four percent of GP Practices had a spirometer and of these, 86% used it. However only 58% felt confident in use and 34% confident in interpretation of spirometry. As expected, spirometry was performed more often if staff were confident in using it and interpretation and was related to the period when they undertook more training. The authors concluded that despite incentives to perform spirometry, the lack of adequate training in performance and interpretation suggests use in Primary Care is confounded so the diagnosis of COPD is likely to be made on imprecise clinical grounds. Another study reviewed the medical records of patients in the Lombardy region of Italy, who were diagnosed with COPD by their GPs over a four-year period. The researchers found that more x-rays were prescribed than spirometry and that adherence to COPD guidelines is suboptimal (317). Interestingly, having more COPD patients and more dedicated visits correlated with more correct clinical practice. National surveys of Australian (371) and Spanish (372) general practices have both highlighted the need to increase the number of spirometry tests being performed, improve training and knowledge, and improve quality assurance practices, specifically spirometer calibration and maintenance to meet acceptable standards. Barriers to objective testing for airway disease in primary care are complex; therefore, a successful intervention must leverage multiple behaviour change techniques (348). Understanding these barriers, interventions that have been suggested to promote the use of spirometry in primary care (Table 6. 2).

In summary, spirometry is vital in COPD for diagnosis and asthma for treatment across both Primary and Secondary care, and largely determines whether a patient should be prescribed an inhaler at all. Since 2005 most GP practices in Wales had a spirometer but the level of proficiency and confidence in the use of spirometry was poor despite QOF incentivisation for over 5 years. Therefore, the RHIG Programme chose to standardise the application and interpretation of spirometry as a core feature of the All-Wales national guidelines.

Theme	Intervention
Training	More training in the value, performance, and interpretation of spirometry. Further training may be web based, but will likely also involve hands on training on the set up and operation of the spirometer (338,362)
	Additional educational outreach visits by pulmonary function technicians (362)
	Professional development for doctors and practice nurses (373)
	Spirometry workshops in primary care (374,375)
	Ongoing supervision of operators after completion of training (374)
	Factors shown to improve spirometry test quality include the quality and duration of spirometry training (374,375)
	Incorporation of written and practical spirometry assessments with feedback to practitioners (375)

Quality Improvement	Increased quality assurance initiatives (375)	
Support from experts	To increase the primary care physician's access to spirometry, more advice on the choice of spirometers and economics of spirometry can be provided (376)	
	Several studies have highlighted the need for a more cohesive approach between general practice staff and appropriately trained respiratory professionals (377)	
	Close interaction with, and strict technical support by, specialist centres may be the optimal way to provide quality spirometry in general practice (377,378)	
Digital tools	Integrating lung function testing reminders into electronic health records and/or developing decision support technology and algorithms to increase awareness and instil confidence in clinicians to test and more accurately assess patients (373)	
	A potential way forward is developing prediction tools that risk stratify patients (379)	
Alternative clinics	Establishing diagnostic 'hubs or hublets' to provide a good-quality diagnostic spirometry service at a local network level in the community (378,380)	

	Open access spirometry clinics (381)
Technical Use of spirometers that display flow volume curves (382)	
	Emphasis on end-of-test criteria (375,382,383)
	Overall healthcare professionals were positive about the potential of AI to support clinicians in quality assessment and interpretation (384)
Capacity	Allowing time within the daily routine of the practice to perform spirometry (383)

Table 6. 2: Themes and interventions to address barriers to spirometry in primary care.

Implementation Strategy

This case study describes the application of an implementation strategy using the phases depicted within the implementation framework. This comprises a focus around the Education factor of the 4E methodology (294). At the time of introducing the strategy, economic factors were delivered through the QOF, and the RHIG All-Wales Programme distributed a spirometer and calibration syringe to every GP practice (engineering). National standards were set and published by the Delivery Plan, and these were assessed by the bi-annual NACAP audits (perhaps its closest function to enforcement). Therefore, key enablers were already in place. The educational interventions were digitalised to increase the potential to engage a wide population of stakeholders across Wales (9). This included:

- 1. The publication of National asthma and COPD guidelines for NHS Wales (Figure 6. 1 and 6. 2) endorsed by the All-Wales Medicines Strategy Group (AWMSG), Health Boards and the Third Sector.
- 2. Digital links to the guideline available through a range of healthcare traffic sites, such as the AWMSG website, local Health Board intranets and referenced in local pathways.
- 3. Hard copy posters placed in GP practices, wards, and outpatient areas, providing clinical guidance and easy access to the online resources.
- 4. Access to a digital learning platform featuring supplemental education for healthcare professionals via email hyperlinks and QR (Quick Response) codes on the posters.
- 5. Learning events held frequently and recorded for wider access, including videos on the digital platform featuring local and national opinion leaders.
- 6. Facilitation of the interventions through local champions (Power Layer).
- 7. Integration of patient-facing information and learning tools that align with guideline recommendations.

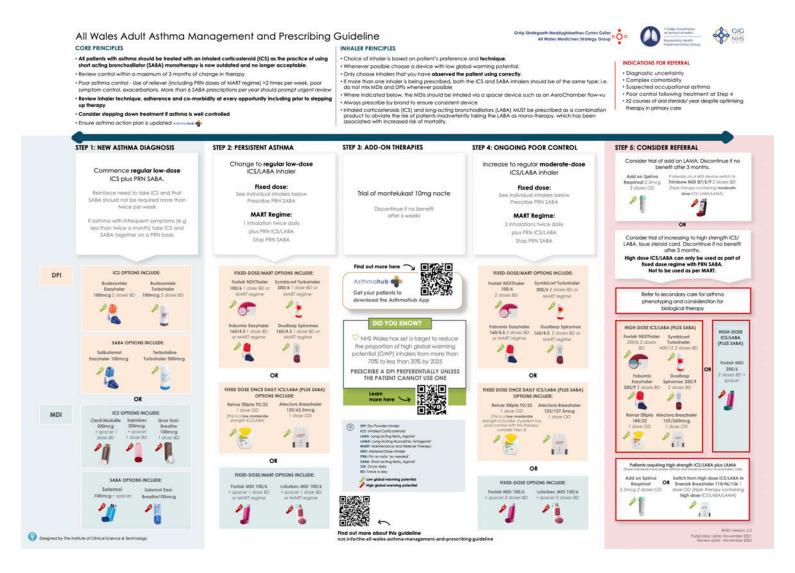


Figure 6. 1: The current All-Wales Asthma Guideline, including key management principles, specific inhalers recommended, and QR codes providing quick access to additional information and supplemental learning.

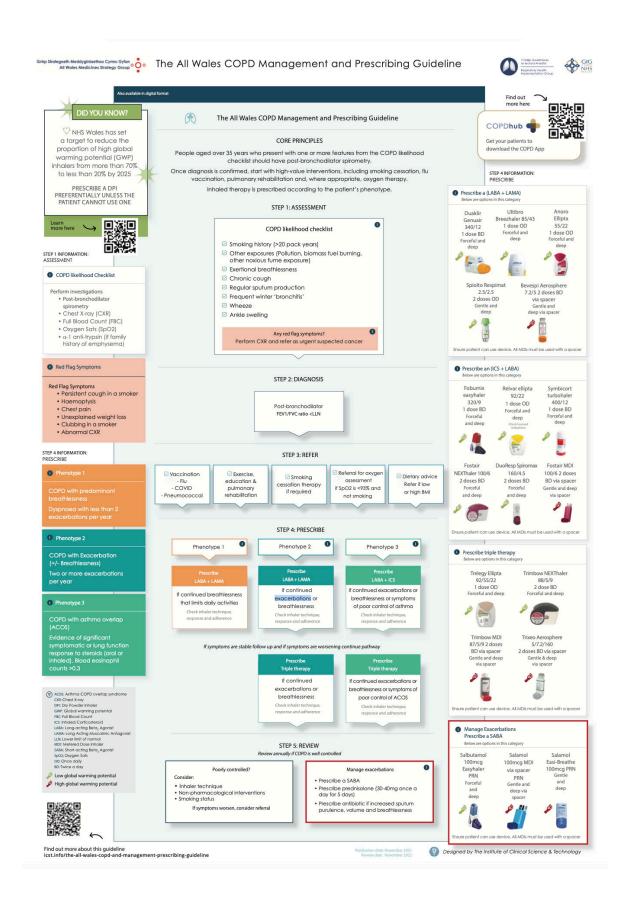


Figure 6. 2: The current All-Wales COPD Guideline, using the same design principles as the asthma guideline (Figure 6. 1).

Printed educational materials are a commonly used passive method to raise awareness of guidelines. It is relatively cheap and straightforward provided you have the postage details of the target population(s) (385). A recent publication evaluating 84 studies exploring the efficacy of printed materials concluded that distributing printed materials to HCPs improved their practice (260). Analysis of 32 randomised control trials within this study demonstrated moderate-certainty evidence. However, when used independently the evidence supporting use of printed educational materials alone is not as strong as that for other teaching / financial interventions — but does have value in as part of a multi-faceted implementation strategy. Printed materials have the potential to improve patient care by promoting best practice and discouraging behaviours that offer no benefit or harm (265).

The guideline was developed through input from experts and endorsed by national regulatory bodies and local governance groups. The guideline was designed as a single page, high quality colour poster in A3 size that can be printed as a poster or accessed digitally. To avoid over burdening the user with excess information, QR codes and hyperlinks positioned against core topics allows users to access more information and education at their own discretion. Placing the QR code in the camera frame of any smart phone generates a pop up on screen of a web link that when selected accesses the attached information, here supplemental education, or information regarding prescribing the patient self-management App. The patient self-management app was an additional intervention added to the strategy to support a key feature of the guidelines. It can be accessed through the AppStore, and Google Play, and supplements other forms of patient education and support (advice in clinic appointments, hardcopy learning materials, and patient support groups) that already exist.

Methods

Study Design

This is a descriptive observational case study (386) assessing the process to delivering a national strategy for guideline implementation using a formal implementation framework. The framework was applied equally in all Health Boards across Wales. The study details the activity undertaken against each phase of the implementation process measuring implementation outcomes at each phase. Implementation outcomes are the transitional points between the phases as described in Chapter 4.

Data Collection

Data were retrieved from anonymised user activity and assessments from the Learning Management System (LMS) and stored on a password-protected computer in Excel. Further information through questionnaires and interviews were received with the appropriate consent but no individual identifiers were used. Data were collected at each phase of the implementation framework as an output of the implementation strategy. As the guideline is implemented on a national scale a comparative study examining Group A versus Group B for example, was not feasible. Furthermore, one could only observe the engagers.

Data Analysis

Analysis was based on population-level engagement and implementation outcomes against the three periods (early, middle, late). Basic quantitative analysis was undertaken in Excel.

Ethical Issues and Approval

This study was presented to the research ethics committee in Hywel Dda University Health Board and was deemed a service evaluation. For all datasets, a description of its use and application to research was provided to the Caldicott Guardian, and where digital platforms were used, the terms and conditions and privacy policy was made explicit.

Recruitment and Characteristics

For the implementation strategy, three broad groups represent the target population (Table 6. 3).

- Group 1: Representing the target organisation this includes high-level system-wide decision makers including executives and service leads.
- Group 2: The guideline adopters including prescribing clinicians, nurses, and other Allied Healthcare Professionals (AHPs) who manage asthma/COPD.
- Group 3: Practitioners targeted to undertake the educational programme specifically to increase their proficiency of performing and interpreting spirometry.

Application of Clinical Guidelines	Completion of Education
General Practitioners (GPs)	 Practice nurses
Practice nurses	 Specialist nurses
Hospital doctors	
 Specialist nurses 	

Table 6. 3: Target populations for the three discrete implementation interventions, by group

The target number to determine the degree of penetration and adoption was estimated using publicly available data. For total numbers of health professionals, the StatsWales website (335) was used. Patient target data were estimated using publicly available disease (asthma/COPD) register denominator data generated from GP practices (335).

Inclusion and Exclusion Criteria

Inclusion criteria for healthcare professionals were kept as broad as possible and included anyone:

- 1. With an NHS Wales email address.
- 2. Registered to work in a GP practice in Wales or Hospital in Wales.

Pre-Implementation Period

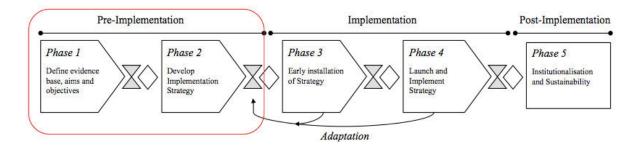


Figure 6. 3: Implementation process with highlighted pre-implementation period and the two phases:
1. Define evidence base, aims and objectives; and 2. Develop an implementation strategy.

The pre-implementation period consists of two phases (Figure 6. 3). Phase 1 is a largely scoping phase to define the evidence base and to establish programme level aims and objectives. Phase 2 uses this plan to develop a feasible implementation strategy. The target organisation for the strategy is deduced to three groups based on the alignment and governance structures that currently exist (Figure 6. 4).

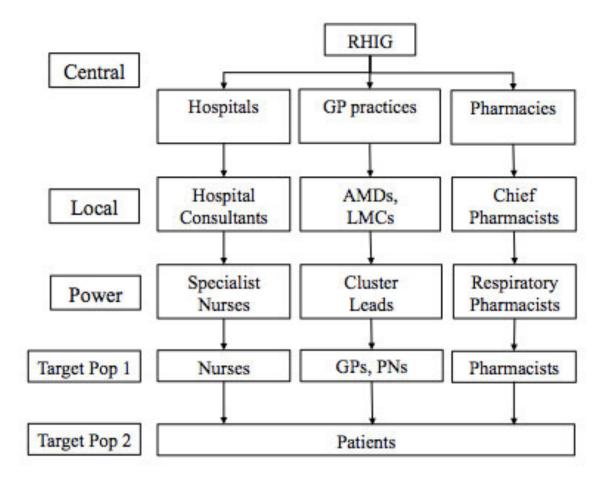


Figure 6. 4: Organisational structure for implementation: RHIG (Respiratory Health Implementation Group); Target Organisation 1, 18 District General Hospitals across the seven Health Boards in Wales, Target Organisation 2, 400 GP practices; and 3, Pharmacies including GP, Hospital and community.

Acceptability of the Guidelines

Acceptability for the proposed national COPD and Asthma guidelines was presented to the Programme during formal meetings, and The Respiratory Delivery plan was published by Welsh Government offering national endorsement and policy sponsorship (10). A survey (see Appendix E) was circulated to local Health Board clinical decision-makers, prescribers, and potential adopters of the guideline across primary and secondary care. The survey was adapted from the Acceptability of Intervention Measure (AIM) questionnaire (387) to ensure the answers were simple YES/NO, and to reduce the time required to complete and submit it to encourage participation. A link to the survey was sent from the NHS email of the National Clinical Lead for the programme between August-September 2017. The email was directed to:

- 1. All 54 Respiratory Consultants across NHS Wales.
- 2. All local Health Board communication leads to disseminate to primary care networks and any other formal representative groups.

The online survey, compiled using SurveyMonkey, included just three closed questions. The survey was anonymised, and respondents were divided into two groups determining whether there was support "for" or "against" developing national guidelines.

Wales-based Respiratory Consultants and Specialist Nurses developed the guidelines. They were based on current literature and reiterated by consensus (loosely based on the Delphi Consensus methodology) and national feedback. Their development and selection process of inhalers is considered a Phase 1 activity but falls outside the scope of this Thesis, as the focus here is the implementation of the evidence. Phase 2 of the implementation process involves translating the programme plan into an implementation strategy, which had never been attempted for respiratory care on a national scale in Wales. A strategy was agreed, and implementation interventions were assessed initially with a small sample of the target population to assess their relevance and acceptance (13).

Implementation Period

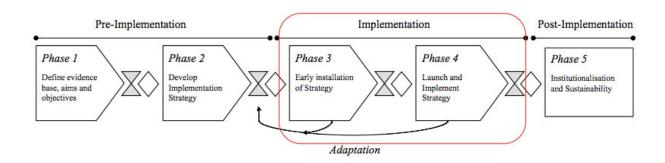


Figure 6. 5: Implementation process with highlighted implementation period and the two phases within it; 3. Early installation of the strategy, and 4. Launch and implement strategy.

Three A3-colour copies of the guideline with an accompanying letter from the National Clinical Lead was sent to all 400 General Medical Services (GMS) practices across Wales immediately following publication. HCPs were also sent digital links to the guidelines and educational films to provide contextual background and rationale for their development. Promotional materials including flyers, QR code stickers and posters were sent to surgeries, all hospitals, and many pharmacies.

To assess organisational capacity to adopt the guidelines, a simple survey was emailed to all 7 Health Board Chief Pharmacists asking whether their organisation is, or intending to, adopt the guidelines. Their response may have involved internal discussions between clinical leads and Medicines Management. To assess target population adoption with the guidelines (HCPs managing COPD and asthma patients), a short questionnaire was sent through various communication channels. These included GPs and practice nurses, all Respiratory Consultants and specialist Respiratory Nurses across all Health Boards (Table 6. 4). This survey was distributed via common external communication routes to reduce potential selection and response bias. In addition to the guideline adoption question, job title and Health Board were compulsory to assess distribution of responses based on profession and geography. To reach Respiratory Consultants and specialist nurses, the survey was sent through the Welsh Thoracic Society (WTS) mailing list and directly to the NHS email lists. Practice nurses were emailed through each Health Board Primary Care support team. For GPs, the survey went via the National Director for Primary Care and the Associate Medical Directors (AMDs) for Primary Care within each Health Board and GPC Wales via the Local Medical Councils (LMCs). To increase the likelihood of responses by GPs, the survey was also sent to the Medical Directors for of the 7 Health Boards, asking them to support their staff participation.

Target population	Estimated number
GP	400 (based on number of GP practices)
Practice nurse	400 (based on number of GP practices)
Respiratory Consultant	56 (Stats Wales)
Specialist nurse	54 (x3 nurses per District General Hospital, based
	on the number employed under KEL)

Table 6. 4: Estimated local organisational leads that would decide the department/service choice of guidelines for asthma and COPD.

To assess fidelity with the guideline recommendations, an end-of-learning questionnaire was issued to all who engaged with the supplemental education programme. This included 8 questions relating to the course content to determine how the training was accepted within the target population (See Appendix F). The questions were based on the Kirkpatrick model for evaluating training programmes (388). This was used because it provided a structured measure of the reaction to the learning experience, learning transfer, and an indication how this influenced behaviour. A change in measures from national audits was anticipated to determine outcome; the fourth domain of Kirkpatrick's model.

Adaptation of the Implementation Strategy

The implementation strategy was later adapted to offer a supplemental implementation intervention to support guideline behaviours. A freely available, bilingual, NHS Wales self-management App was developed to support patients with asthma and COPD. This was developed to align with the guideline recommendations to encourage greater fidelity with the evidence base. Several commercially available Apps were assessed, but several key features were considered essential that warranted a new App tailored to NHS Wales. For example, there is a requirement under the Welsh Language Act 1993 for patient facing interventions to be available in both Welsh and English (389). Furthermore, specific inhalers would need to be aligned to the guideline recommendations. The app would also need to comply with the implementation framework to ensure effective facilitation and alignment between App information, guideline-related training for healthcare professionals, and local procedures.

To assess the feasibility of the App, we surveyed healthcare professionals who would be responsible for recommending the Apps to their patients. The survey was developed using the Intervention Appropriateness Measure (IAM) template developed by Weiner *et al.* (387). The survey (Appendix G) asked whether healthcare professionals perceive a self-management App to be appropriate for patients with asthma and COPD under their care. The survey also asked what features healthcare professionals consider to be most useful and what outcome they would expect to see from widespread patient adoption. The survey was conducted during a British Lung Foundation training and study day held in Llanelli in September 2019. After a short contextual presentation by the author, the digital polling tool Slido was used to conduct follow-up polls (390). Digital collection facilitated the accumulation of data, and the survey required a response to a series of three multiple-choice questions displayed on the large presentation screen in real time. Questions were developed from a combination of the Stoynov (391) framework and that produced by Nguyen *et al.* (392).

To determine patient acceptability of the self-management Apps, a selection of the target population of patients were sent a closed multiple-choice selection survey following a trial of a Beta version of the App. The patient sample was identified through respiratory consultants approaching patients in clinic. Patients willing to participate were identified and contacted. The online survey using SurveyMonkey comprised of three questions. Inclusion criteria were patients with a diagnosis of asthma or COPD. There was a requirement that testers could speak

English or Welsh. Patients were first sent a summary of the App, containing similar information to that given to the healthcare professionals. They were then asked to answer three short questions around the general concept of the App and if they thought it would be beneficial to them. The results were anonymised.

Post-Implementation Period

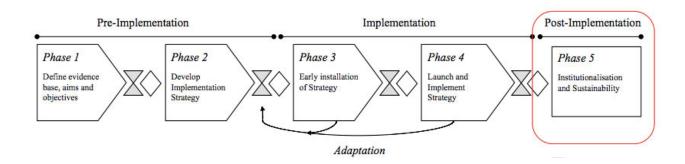


Figure 6. 6: Implementation process with highlighted post-implementation period and the single phase: Institutionalisation and Sustainability.

It was planned to measure adherence with the guidelines by the Institution(s) through assessing inhaler prescribing trends, diagnostic accuracy, hospital admissions and length of stay. However, the impact of COVID-19 precluded this phase, therefore these measures could not easily be collected or analysed during this study tenure owing to capacity and workload restrictions of the author generated by focused responsibilities towards supporting the COVID response. Several other studies have examined the impact of the COVID-19 pandemic on respiratory care (18,41,42,393).

Results

Acceptability of National Guidelines

There were 435 responses from a range of professionals across primary and secondary care (Figure 6. 7). There were similar numbers of responses from all Health Boards except Powys Teaching Health Board (PT) with only with 9 (2%). This is likely representative of the small number of prescribers in that region. For reference, the total number of respiratory consultants, one marker of inhaler prescribers by Health Board, and total number of COPD and asthma patients on GP practice registers, are presented in Table 6. 5. This demonstrates underrepresentation in Swansea Bay (SB) (9% respondents to 16% consultant representation and 18% patient population); whereas Hywel Dda (HD) suggests overrepresentation (18% respondents to 3% consultant representation and 12% patient population).

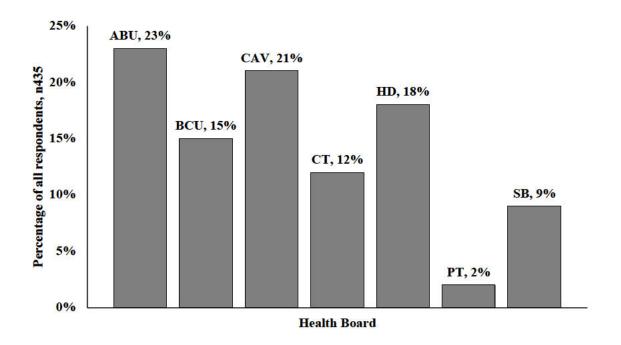


Figure 6. 7: The distribution and frequency of responders to the guideline questionnaire against the 7 Health Boards across NHS Wales.

ABU = Aneurin Bevan University HB; BCU = Betsi Cadwalader University HB; CAV = Cardiff & Vale University HB; CT = Cwm Taf Morgannwg University HB; HD = Hywel Dda University HB; PT = Powys Teaching HB; SB = Swansea Bay University HB.

Health Board (HB)	Proportion of Respiratory Consultants (%)	Proportion of Asthma + COPD Patients (registered with GP) (%)	Responses (%)
ABU	19	19	23
BCU	21	23	15
CAV	24	14	21
CTM	17	10	12
HD	3	12	18
PT	0	4	2
SB	16	18	9

Table 6. 5: HCP respondents against consultant and patient (asthma and COPD) percentage by Health board.

The majority of responses came from practice nurses (166 responses, 38.8%), followed by GPs (158 responses, 36.9%), and consultants (29 responses, 6.8%). Hospital registrars, primary care managers, hospital managers, primary care pharmacist and Finance Directors represented a small proportion of responders (17.5% in total). Seven responders selected to not disclose their job role (Figure 6. 8).

A total of 398 (93%) responders supported the prescribing guidelines. 2% did not support the guidelines and the remaining 5% did not know (Figure 6. 9).

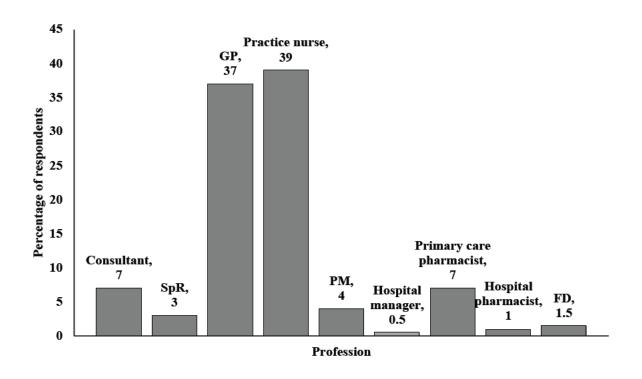


Figure 6. 8: Distribution of job professions of responders to the questionnaire.

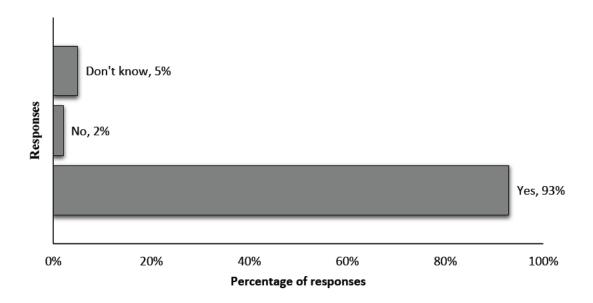


Figure 6. 9: Responses determining support (yes or no) to the proposed national prescribing guidelines.

Implementation Period

Adoption of Guidelines

Senior management representatives (Chief Pharmacists) from all seven Health Boards confirmed that their organisation was formally adopting the National Guidelines. As only 7 chief pharmacists were contacted, the question was sent in an email with responses easily tracked and there was no requirement for anonymisation. There were 246 responses from potential guideline users to the questionnaire distributed across the seven Health Boards. Most responses were from practice nurses (39%), followed by GPs (19%) representing primary care prescribers (Figure 6. 10). 31 responses were from Respiratory Consultants based in hospitals, representing 55% of all eligible Respiratory Consultants employed in Wales.

Most respondents were from CAV (30%), whilst the other Health Boards apart from PT and SB have a smaller response rate (Figure 6. 11). For PT a low number of responders reflects the small number of potential users (a small rural Health Board with no Respiratory Consultant presence), but it was unclear why such a low number of responses was received from SB.

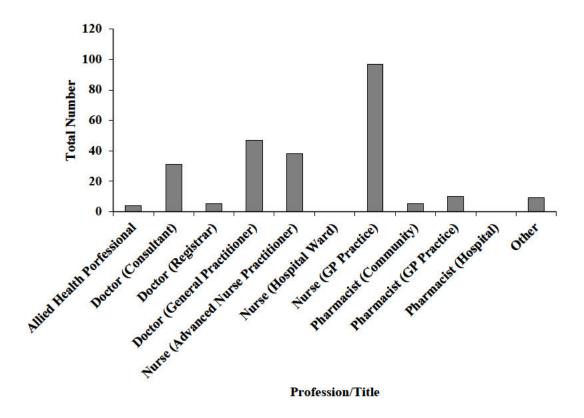


Figure 6. 10: Job distribution of survey respondents.

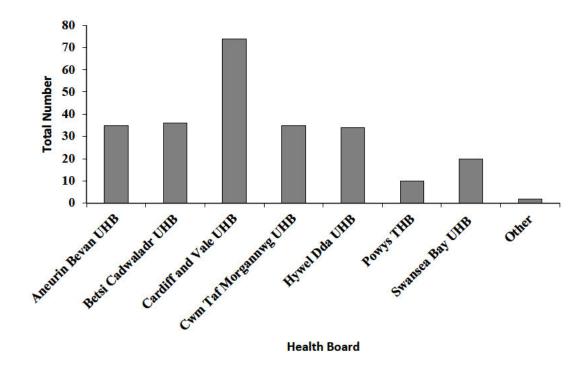


Figure 6. 11: The Health Board where the respondent worked.

78% of respondents report using the National COPD Guidelines (Figure 6. 12). Guidelines were most used by practice nurses. 80% of respondents report using the national asthma guidelines (Figure 6. 13). The remaining respondents report using other established guidelines.

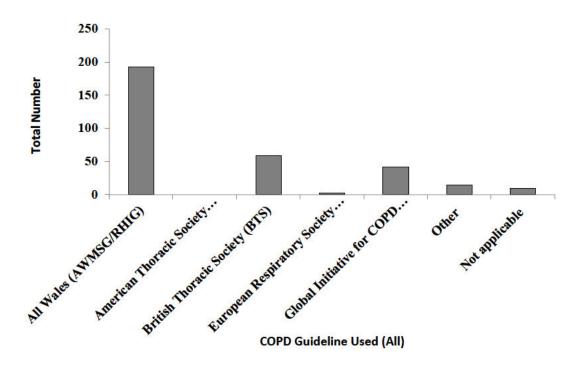


Figure 6. 12: Survey results to determine which COPD guidelines are used by healthcare professionals in NHS Wales.

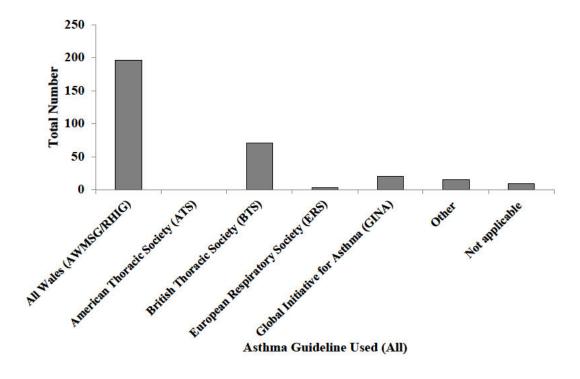


Figure 6. 13: Survey results to determine which Asthma guidelines are used by healthcare professionals in NHS Wales.

450 practitioners completed the supplemental training broadly representing the target for one person per GP practice completing (Table 6. 6), illustrated geographically in Figure 6. 14. However, when assessing completers against Health Board, some Health Boards have notably greater penetration than others; ABU has the greatest penetration (219%) versus 34% for CTM.

Health Board	Number of target practitioners	Actual number of practitioners completed	Penetration %
ABU	74	162	219
BCU	100	86	86
CAV	62	50	81
CTM	54	21	34
HD	47	23	49
PT	14	34	243
SB	49	62	127
Total	400	438	110

Table 6. 6: Number of practitioners that completed the spirometry competency programme once the decision was agreed to fund this training centrally.

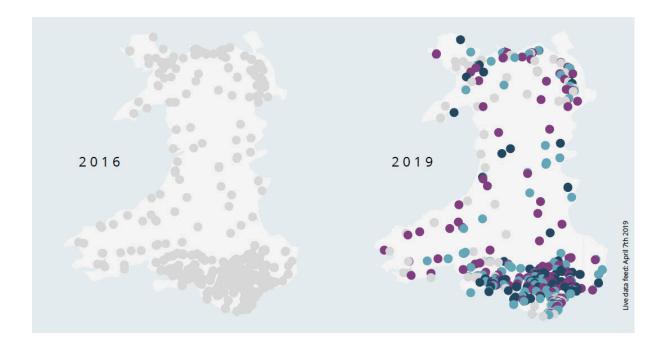


Figure 6. 14: Change in spirometry competency across NHS Wales between baseline (2016) and following the intervention (2019) (the colours representing the course level – foundation (practical-only), practitioner (practical and interpretation), and interpretation-only).

Following completion of the supplemental education (spirometry competency) programme, 365 candidates responded to the feedback questionnaire. Fifty per cent of candidates were very satisfied with the course assessments and a further 44% were satisfied. Less than 2% were dissatisfied. 67.5% of candidates were very satisfied with the topics covered during the course and a further 31% were satisfied. Less than 2% were dissatisfied (Figure 6. 15). Fifty-five per cent of candidates reported they enjoyed the course "a lot"; 36% enjoyed it "a little"; < 7% "didn't enjoy it much"; <3% "didn't enjoy it at all" (Figure 6. 16).

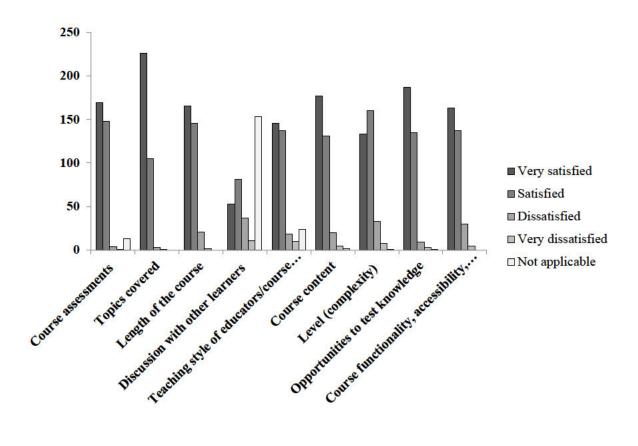


Figure 6. 15: Feedback on course assessments completed by candidates that completed the programme. Percentage of all responses against each selection.

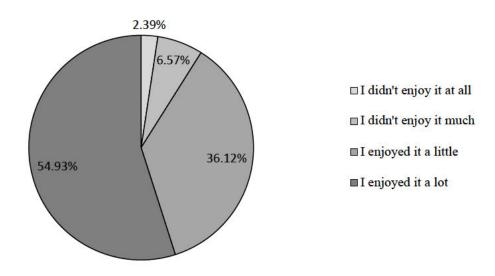


Figure 6. 16: Proportion of survey respondents who enjoyed the online learning a lot, or a little, against those who didn't enjoy it much, or at all.

73% of candidates were satisfied with the length of the course, 17% suggesting it is reduced in length, whilst 9% suggested it is increased (Figure 6. 17). 84% of survey responders reported undertaking the training to advance, develop, or stay up to date in my profession or field. Only 5% undertook the training to explore further career or study options, and less than 4% undertook the learning for pleasure or to satisfy intellectual curiosity (Figure 6. 18).

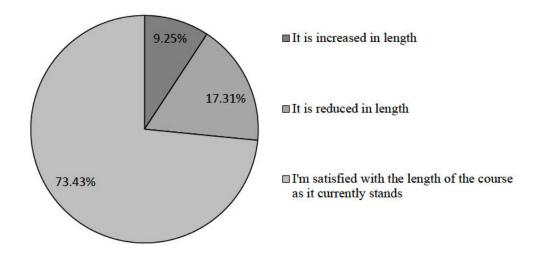


Figure 6. 17: Reaction to the length of the online course

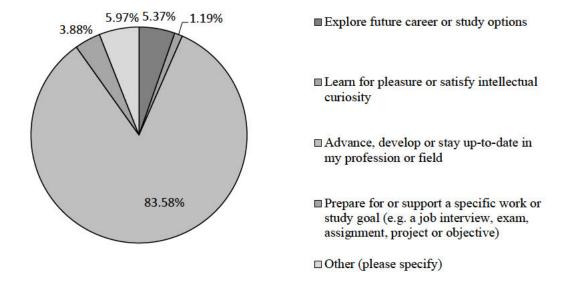


Figure 6. 18: Motivation to complete the learning

Adoption of spirometry standards was assessed through a survey question following completion of the programme. 60% of completers reported having applied what was learnt into practice, whilst a further 37% reported they were very likely to do so. Less than 1% of responders reported they were not likely to apply learning into practice (Figure 6. 19).

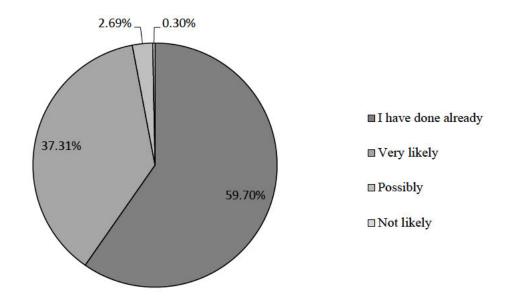


Figure 6. 19: Whether by the end of the course candidates had applied learning into practice.

Adaptation to the Implementation Strategy

Feasibility of an NHS Wales Self-Management App

70 healthcare professionals attended the live event, and of those, 49 took part in answering a simple survey using their smartphones. Around half of the people in the room were from primary care and half from secondary care. 86% responded that they considered an NHS Wales self-management App has the potential to improve self-management of chronic respiratory conditions for patients in Wales (Figure 6. 20). 92% responded that the app data would support their management of patients with chronic respiratory condition (Figure 6. 21).

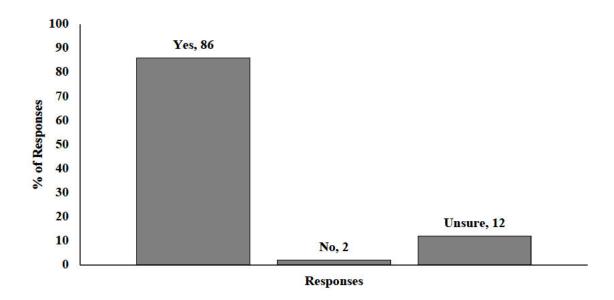


Figure 6. 20: The results to question 1: 49 survey responses "Does an NHS Wales patient app has the potential to improve the self-management of chronic conditions for patients in Wales?"

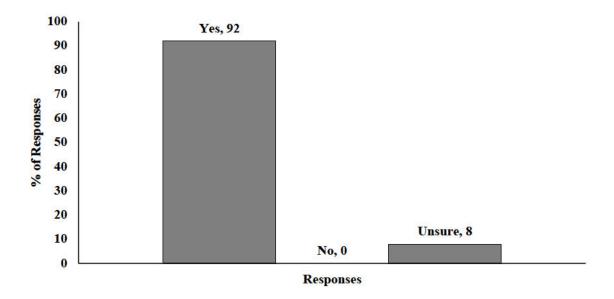


Figure 6. 21: The results to question 2: 49 survey responses "Does an NHS Wales patient app to benefit HCPs with more information?"

To ascertain the key functions of an App, a word cloud generator was used. HCPs could write down in a text box on their phone which elements of a patient app they deemed to be the most important and this would create word cloud on the screen (Figure 6. 22). 37 people gave their suggestions. 12 HCPs suggested that education was the most important element of a patient self-management app, 11 people said it was ease of use, with other suggestions receiving a varying number of votes. Some suggestions given meant the same things but were worded differently, so these were categorised together, for example, calendar reminders and calendar prompts. Questions also arose at the end of the session, primarily about how we will market the app; funding, and how easy it will be for older patients to use.

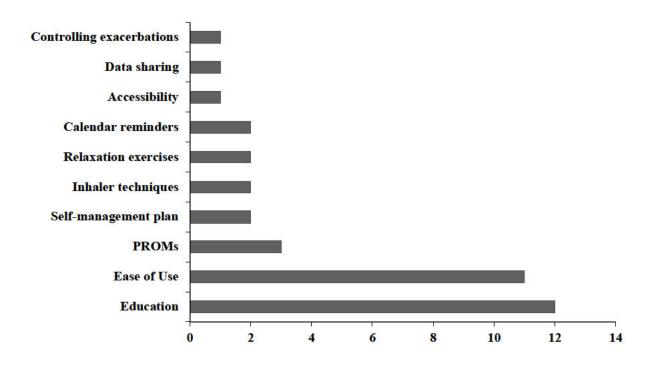


Figure 6. 22: The frequency of features perceived to be most important from the perspectives of the 37 from 70 HCPS who answered the survey.

A small sample of 5 patients assessed the feasibility of the App. All 5 patients answered that they would use the App, described to them in the summary. All 5 patients said they thought the App had the potential to improve the everyday management of their condition. Supplemental responses from HCPs and patients are summarised Table 6. 7. The results are specific to the App proposed, however in addition, the results have been compartmentalised based on the implementation strategy categories presented by the ERIC study, to generalise the responses that can inform the implementation framework (Table 6. 8).

Patient answers	Intervention category
The reassurance that it gives you	Supportive
Being able to use it as a reference tool	Helpful
Self-management plan	Instructional
Peak flow diary	Informative
Keeping track of appointments	Helpful
Logging symptoms	Informative
Inhaler technique	Instructional
Healthcare professional answers	
Education	Instructional
Ease of use	Usable
PROMs	Informative
Calendar reminders	Helpful
Inhaler technique	Instructional
Self-management plan	Instructional
Relaxation exercises	Instructional
Accessibility	Accessible
Controlling exacerbations	Instructional
Data sharing	Informative

Table 6. 7: Compilation of features for a self-management App as determined by patients in response. These have been coded against the implementation strategies compiled by the ERIC study (169).

Quality scales	Description
Functionality	Overall app performance
Usability	Ease of use, navigation, and error prevention
Design	Logical layout and visual appeal
Information	Education, credibility, quality
User perceived value	Continued use, recommendations and overall star ratings

Table 6. 8: Quality scales, adapted from the studies by Stoynov (391) Nguyan et al. (392).

Early Installation of App

In July 2020, following extensive testing by HCPs, the Apps were ready for testing by a further 8 patients. The patients were instructed to download the App and use it for a few days before filling in an online survey. Five of the 8 respondents answered they would continue to use the App for the day-to-day management of their condition. One answered no, whilst two were unsure. Using the Likert scale from 0 (Poor) to 100 (Fantastic) to rate user experience, the overall patient score for this phase of the app was 77%. 3/8 patients added a free-text option suggesting other improvements (Table 6. 9, 6. 10, 6. 11). Immediate changes made to the App included adding the Privacy Policy for storage within the App so that it is always accessible rather than directing patients to the App website. Information about CE marking and what is done with App user data was added to the Frequently Asked Questions section of the App. Other adaptations based on the survey feedback included a broader range of educational videos, the ability for GP/ Hospital appointments to appear on the homepage and for it to be made clearer how to change the information in your care plan such as you base Peak Flow reading.

Number	Answer	
1	"Educational Awareness and being able to access feedback Help through the	
	Available links The ease of using the App and pitched very well for COPD Patients."	
2	"The "Feeling unwell. What to do next" and "How to stay well" sections"	
3	"Peak flow monitoring and the videos are really helpful; I've recently changed my inhaler during lockdown and seeing the demonstration on how to use it effectively was far better than reading a leaflet. Really love the app and think it will make such a difference in keeping my asthma under control and remaining aware of self-care."	

Table 6. 9: The most important features of the App determined by user testers.

Number	Answer	
1	"The app runs slowly/buffers sometimes when switching between sections"	
2	"I put the wrong peak flow base score in and can't see where to change it. So it's	
	given me the wrong data in the asthma plan."	
3	"Please include more information on the rules around GDPR and CE marking"	
4	"A tile also having your appointment would be useful there so it's a constant	
	reminder (but might not always be relevant if you've not got one scheduled)"	

Table 6. 10: General improvements that users would make to the App.

Number	Answer	
1	"I would like to emphasise how great it is that this is available in Welsh – sometimes in the	
	medical world my first language isn't considered and so I'm really grateful this has been	
	developed in Welsh."	
2	"The weather section is a really nice touch."	
3	"It's really well thought out and covers a lot of really useful information – things I'd not	
	considered myself and hadn't been told by my GP. The app itself is really slick and user	
	friendly."	

Table 6. 11: Additional comments made by the App reviewers.

The results from the patient survey and clinician feedback resulted in the following adaptations to the App to increase its utility for the target population:

- Monthly Checker, for users to record their asthma control each month between their annual reviews. Here they can add information such as their GP visits, the number of oral steroids/antibiotics prescribed and how often they are taking their reliever inhaler to determine their Asthma/COPD Control that month.
- Reminder's feature, e.g., for GP appointments or to do a Peak Flow.
- GP/Hospital visits checklist to know what care to expect during their visit. Making sure they get the most out of them.
- Reducing the number of notifications e.g., only they have a reminder or need to do their monthly checker.
- More educational content including films.

Whilst no respondent reported that they do not normally read through privacy policies for digital platforms, they highlighted their main concerns on who accesses and sharing of their data, wanting it to be fully anonymised. 66% of respondents reported the privacy policy and Terms & Conditions (T&C) were made clearly available, however 16% did not notice and 16% felt they were not clear.

App Launch

In October 2021, version 2.0 of the App was formally launched with an event chaired by the British Lung Foundation/Asthma UK and presentations from a range of clinicians including a paediatrician, pharmacist, and a nurse (Appendix H). The virtual one-hour event was attended by 163 HCPs with an aim to encourage them to use the Apps as part of usual patient consultations and reviews. Analysis of total number of downloads from Google Play and AppStore demonstrates an increased rate of downloads (Figure 6. 23) and penetration across Wales, determined by GP practices where at least one patient has downloaded the App (Figure 6. 24) suggesting uptake in all geographical regions.

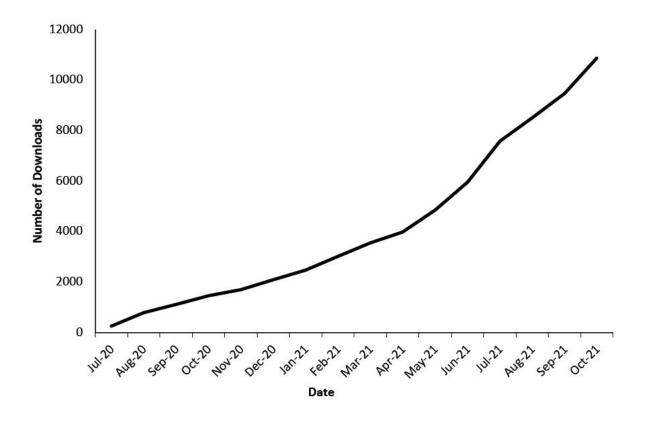


Figure 6. 23: Trend monitoring of App downloads between July 2020-October 2021.



Figure 6. 24: Distribution of user downloads against mapped GP practices in ABU, BCU, CAV, CTM, HD, SB, PT.

A total of 98 App users responded to the feedback questionnaire three months after launch. Responses to the layout, visual appeal, functionality, usability, and content are summarised in Table 6. 12, 6. 13, 6. 14. All respondents felt that the App supported their self-management. 69% felt the app assisted them in managing their condition, 23% did not feel it assisted them, whilst the other 8% could not answer as they have not used it for long enough, or they are managing their condition sufficiently without it.

Question	Answer out of 5 stars
Question 1: Out of five stars, how would you rate the layout of the app?	4.7
Question 2: Out of five stars, how would you rate the overall visual appeal of the app? This includes things like page screens, text & titles, imagery, and videos for example.	4.5
Question 3: Out of five stars, how would you rate the functionality of the app? (Overall app performance). This includes things like data entry, data presentation and loading times for example.	4.8
Question 4: Out of five stars, how would you rate the usability of the app? This includes its ease of use & navigation for example.	4.3
Question 5: Out of five stars, how would you rate the content of the app? This includes the education, instructional text, and informational quality for example.	4.8

Table 6. 12: The first 5 questions to assess the quality of version 2.0 of the Apps following adaptation.

Question	Answer out of 5 stars
Question 1: Out of five stars, how would you rate the design of the app?	4.0
(Visual appeal & layout)	
Question 2: Out of five stars, how would you rate the functionality of	3.9
the app? (Overall performance)	
Question 3: Out of five stars, how would you rate the usability of the	4.0
app? (Ease of use & Navigation)	
Question 4: Out of five stars, how would you rate the content of the	4.0
app? (Education, and informational quality)	

Table 6. 13: The first 5 questions to assess the quality of the Apps.

Number	Answer	
1	"The ability to set reminder to do a peak flow"	
2	"The ability to record how often a reliever inhaler was taken"	
3	"Sharing with their asthma nurse/GP directly"	
4	"Reduce the number of notifications"	
5	"Allow than one profile on the app"	
6	"Medication reminders"	
7	"Add notes to Peak Flow"	

Table 6. 14: Lists of aspects where the App could be improved to better manage the respondents' condition.

Discussion

Implementation interventions were selected and developed during the planning and scoping phase of the implementation process. The implementation strategy was developed for the implementation of asthma and COPD guidelines by acquiring AWMSG endorsement, distributing hardcopy colour posters of the guidelines to all GP Practices and hospital respiratory departments, with supplemental education for healthcare professionals and patients accessed through QR codes and links to a digital learning platform and patient self-management App, respectively. Local champions were identified to undertake facilitation activities to raise the profile of the guideline interventions and to ensure all spirometry training was offered to practitioners and the app used as a support tool during patient reviews. The implementation interventions were developed with consideration of the following limitations: (i) the time available to develop and implement the strategy; (ii) the jurisdiction and scope of the programme; (iii) the resources available. The interventions were considered through strategic planning within the national group and implementation team.

All 7 HBs in Wales formally adopted the National Guidelines for asthma and COPD. Around 80% of prescribers surveyed reported they are adhering to these guidelines. The questionnaire was intentionally short to increase response rate. Alternative adoption assessment instruments were considered but these were deemed excessive and too burdensome for this circumstance (the survey was circulated during the COVID-19 pandemic). For example, the validated questionnaire by Malo *et al.* is composed of 46 questions (394), whereas the American Hospital Association's national longitudinal survey of health information technology adoption tool has 31 items, most of which are irrelevant for this purpose (395). The Lean in Healthcare Questionnaire (LiHcQ) is shorter (16-items), but still focuses on measuring the perception of Lean adoption in healthcare and generic perceptions about service improvement (396).

Spirometry training was offered to all GMS practices and secondary care practitioners to support staff managing asthma and COPD patients in Wales. However, there was resistance from the General Practitioners Committee (GPC) Wales who subsequently wrote to all GP practices emphasising this was not mandatory, and practices were not expected to comply. Subsequent discussions between the Programme (RHIG) and GPC Wales identified the main barrier as the burden of spending two days away from the practice. The author submitted a request to the governing body for the standards of spirometry training (the Association of

Respiratory Technology & Physiology (ARTP) with a proposal to reduce the usual two days face-to-face training down to a half day workshop supplemented by online training, electronic assessments, and an electronic booking system to undertake the practical examination. The new training model was accepted as the delivery model for all of Wales and based on the acceptance and reach generated here it later became the official programme for the ARTP and offered UKwide (19). Key to negotiation was better alignment with primary care representatives and to consider the impact the training would have on their capacity to run clinics. This subsequently resulted in GPC Wales's representation within the Programme, as a key stakeholder and ultimately guideline endorser. In Wales, 450 practitioners completed the 6-month competency training for spirometry standards by the end of 2019, superseding the target set in the 2018 Wales Respiratory Delivery Plan. Proportionally, the greatest penetration of GP practices was for PT and ABU reflecting early adoption of innovations. Overall, the programme received excellent satisfaction scores, with 97% of candidates reporting they were applying or very likely to apply what was learnt into clinical practice. The main reason for doing the course for 84% of responders was to advance, develop or stay up to date – a consistent finding from indepth interviews with 7 nurses. Several others were mid-way through completing the training, but this was halted when COVID-19 hit.

Implementation Challenges

There were two major challenges to the implementation of these guidelines – removal of QOF during the implementation phase, and the COVID-19 pandemic. The programme was implemented driven by a several years where national audits demonstrated that spirometry quality was poor (337). A further examination of actual spirometry results indicated that around a quarter of patients had results inconsistent with COPD. Whilst discrepancies between the two methods stimulated debate within the Programme, in early 2017 there were already discussions between Primary Care Commissioners and GPC Wales regarding the value and administrative burden of the QOF. In 2018, as the spirometry standards and training were introduced, QOF was simplified, meaning GPs were able to opt out of a substantial part of the framework to free up more capacity to undertake clinical work. The only contractual requirement thus became managing chronic disease registers (397). Spirometry was removed from QOF indicators for both COPD and asthma and practices were no longer paid for these.

Acquiring a digital connection with primary care was strategically important, as a direct communication channel would enable the introduction of educational interventions (398). However, COVID-19 has had a major impact on the delivery of respiratory care worldwide. The pandemic coincided with the second phase of the implementation process. Through 2020 and 2021, most patients were isolating and not accessing healthcare services (18). Furthermore, the capacity to focus on asthma and COPD across primary and secondary care has compromised nearly all HCPs involved with their care as they focused on the COVID-19 response. Furthermore, at the time of writing, spirometry was deemed to be an Aerosol Generating Procedure (AGP) (399) and therefore largely unfeasible to perform, especially in primary care with few dedicated rooms and limited personal protected equipment. Fundamentally, spirometry, a key element of the COPD and asthma guidelines, and a focus of the implementation strategy (pre-pandemic), was stopped at the start of the pandemic and at the end of 2022, had not been restarted.

Updating the Implementation Framework

The implementation process is revised to include an adaptation function to promote agile responses to the target and need. Adaption here is a continuous cycle, which starts in the pre-implementation period and cycles throughout the implementation period. As the strategy is designed to be data-rich, with continuous checkpoints and measures of implementation outcome, it informs the transition between phases of scoping, intervention design, and implementation. Ambiguity around these phases was considered a challenge to the original model, therefore data collation and formal decision points were planned at key check points to mitigate risk of implementing interventions with little impact (Figure 6. 25).

The Taxonomy of Implementation Outcomes (ToIOM) better reflects the transition between periods, rather than phases. This offers more flexibility to implementation decision points. Furthermore, whilst the original model did not include a feedback loop, measuring implementation outcomes at the final phase helps generate formal review of the intervention and initiation of clinical outcomes. This helps determine whether the intervention generated the benefits proposed in the original protocol, or whether implementation failed and therefore a different strategy was required.

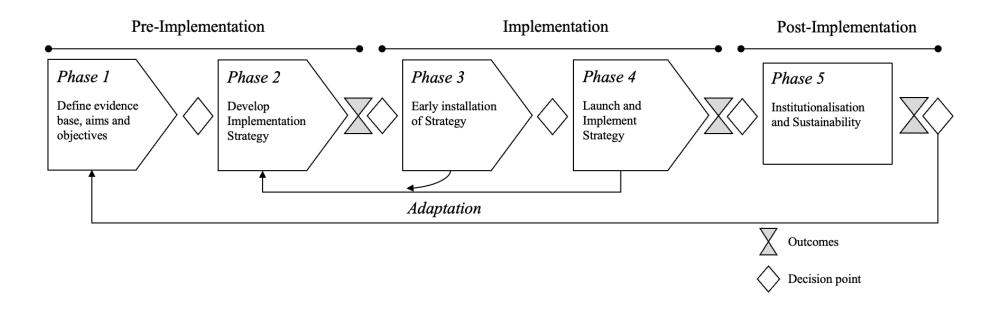


Figure 6. 25: Adaptation to the implementation process model following observations during the implementation of the asthma/COPD respiratory strategy.

Strengths

This is a real-world large-scale observational study, which encompasses implementation outcomes at each phase of the implementation process across Wales. Whilst impact was affected by many cofounding factors such as COVID-19 (from 2020) and changes to financial incentives linked to QOF (from 2018), it does demonstrate that when an implementation strategy is delivered through a simple structured implementation process, indeed, large-scale implementation can be achieved. This is the first reported study of guideline implementation in Wales utilising a structured implementation framework. Furthermore, these are the first national management and prescribing guidelines formally published in Wales for asthma and COPD.

A key strength of this study is its top-down perspective, utilising a national programme to introduce a large-scale pan-Wales guideline implementation strategy whilst supporting a bottom-up approach to service improvement (400). This focused implementation outcomes to an appropriately high-level, compartmentalising outcome measures to Health Boards, professional groups, and patient groups, rather than perhaps specific services, GP practices, or professionals. The benefit of this was the ability to demonstrate national impact and reach, however this may have missed closer observation of early adopters or pioneering services, late adopters, and laggards (104). Whilst some pilot testing was undertaken at GP practice level to measure process outcomes of the strategy, these data were excluded as poor data recording prohibited any meaningful analysis at the time. Additional qualitative exploration of service providers during this time may have been beneficial.

The application of the Kirkpatrick model provided a structured approach to assessing educational impact. Kirkpatrick model is a widely used framework for evaluating training programmes (388). The model is used primarily in the evaluation of medical training, followed by computer science, business, and social sciences (401). Bates considers the model a simple and systematic tool that can easily align with the learning objectives of the training (401). It can arguably be applied to any form of training and provides clarity and structure to the value of complex training programmes in a clear summary of the gap between the training objectives and its outcomes. Furthermore, its simplicity is also captured through little requirement for preor peri-training evaluation measures which reduces the planning and data capture load for

trainers/evaluators at times where participants are less accessible or a predominance to learning is desired (402).

Applying a digital implementation strategy (blended/online training, patient self-management app, QR codes on posters, etc.) provided objective measures of spread that would otherwise have been difficult to measure on this scale. Data could be tracked to region (Health Board) and profession, further measures were confined to GDPR limitations. There is some early evidence demonstrating the impact of the national programme. Stone *et al.*, compared quality of COPD care across all UK nations in an article published in Nature in 2022. They conclude that English, Scottish, and Northern Irish practices were significantly worse than Welsh practices at recording spirometric parameters in diagnosis and referrals to pulmonary rehabilitation (268). The authors emphasise the potential impact of the audit and nation-wide spirometry training but acknowledge some of the difference may be due to better and more consistent coding of parameters in the patient records. Nevertheless, this is the first independent comparison of COPD care between the four nations, demonstrating favourably towards the standards of care in Wales.

Limitations

The healthcare professionals and patients that agreed to assess the acceptability of the strategy were potentially representative of early adopters given their involvement with this study and what has resulted in a positive contribution to the work, therefore this has likely resulted in selection bias. A greater focus on those unlikely to engage or those that did not engage with the programme would likely uncover a more balanced perspective of the benefits of the programme and alterative barriers to engagement. However, although the findings may not be generalisable to the entire target population, its purpose is to act as a means of understanding whether implementation interventions are appropriate and what features would be desirable. Ultimately, it is fair to assume in the first instance, if early adopters do not adopt it – it is most likely to fail.

The role of the local executive and facilitation is to determine the adoptability of the local target population so that the strategy can be tailored to address unique local barriers. Local teams may decide to undertake additional activities such as local engagement events, supervision, escalation to the clinical board etc. This was observed in ABU and PT, resulting in greater

penetration during the implementation period. For this study however, observing local facilitator efforts was not formally measured – a missed opportunity and a suggestion for further research.

Whilst the Kirkpatrick model continues to be useful, widely used across sectors, and appropriate and applicable in a variety of contexts, it has limitations when applied to healthcare training, and a critical analysis reveals some potential shortcomings (403). For example, Cahapay identifies three themes to describe limitations in the application of the Kirkpatrick model were identified (404):

- (i) propensity towards the use of the lower levels of the model.
- (ii) rigidity which leaves out other essential aspects of the evaluation; and
- (iii) paucity of evidence on the causal chains among the levels.

Cahapay (395) concluded that when applying the model evaluators should consider methodologies to assess contextual inputs and to establish causal relationships among the levels. Bates (401) also argues the sequential linkage of the model is conceptually flawed, as it insinuates that the one level has causal impact to the next and so on. In other words, in a case where reaction to training is good, this implies behaviours will change leading to a positive result (outcome); a bias based on a positivist relationship. Furthermore, this also potentially induces an illusion of value, particularly when the response rate to level 1 is high. This is a limitation to the application of the model in this study – compounded due to challenges accessing outcome measures, leading to predominance towards the first two levels. For instance, the second level of the model assesses participants' acquisition of knowledge and skills. While this is important, it does not guarantee that learners will apply what they have learned in the clinical environment. The limitation to this function is highlighted by the study by Walker et al., participants' reactions to an online training course were encouraging, facilitating increases in perceptions of importance of weight the management for pregnancy and confidence to provide advice (405). Whilst qualitative analyses revealed an increase in participants' knowledge of communication strategies that they intend to apply in practice, quantitative measures demonstrated no change in participants' knowledge.

Badran et al., (406) evaluating the results of an educational programme for dental students and demonstrated effective application of the model yet emphasising the extensive period of analysis that is required to determine behaviour change and its effect in practice. In this study, the first level of evaluation showed an overall satisfaction score of 82.1%, the second level demonstrated an increase in the percentage of correct answers after the educational sessions from 68.3% to 80%, and significant agreement with responsible antibiotics usage (pvalue = 0.020, Effect size = 0.121). The third level showed that the percentage of correct answers 2 years later was 87.5%. The fourth level confirmed the success of the programme as 88.9% of participants reported using the knowledge gained from the programme when prescribing antibiotics. Whilst there is merit here reporting outcomes two years later, the replication of level two in this case, emphasises the complexity assessing objective outcomes of training. Students reporting using the knowledge do not necessarily constitute behaviour change and therefore an objective assessment of antibiotic usage is required. Recall bias also limits the accuracy of reported outcomes when assessing performance against established standards. Inevitably, responders will select the best answer that reflects good practice, rather than perhaps the behaviour they display in practice (407).

The third level of the Kirkpatrick model measures changes in behaviour resulting from the training. However, behaviour change is a complex process that can be influenced by various factors beyond training alone. The limitation to reported assessment of behaviour change is also influenced by a presumption of what behaviour should be displayed. Therefore, participants report a behaviour consistent with the learning objective but in practice display a different behaviour altogether. Evaluating behavioural change in healthcare requires considering factors such as practitioner and service capacity, resources, clinical guidelines, service infrastructure, referral processes, patient complexity, and interprofessional collaboration, for example, which may not be adequately captured by the model. Bates argues that the model fails to effectively address both the summative question – was training effective? (401), and the formative question – how can training be modified in ways that increase its potential for effectiveness? In this perspective the capacity of the training to fulfil the core ethical duty of beneficence is not addressed, and this is considered a major limitation to the model.

Furthermore, the Kirkpatrick model does not explicitly consider the influence of contextual factors on training outcomes, described earlier through the triangulated perspective of

implementation-complexity-social sciences. Healthcare environments are complex, and the effectiveness of training can be influenced by factors such as organisational culture, resources, and support. Ignoring these contextual factors may limit the model's ability to accurately evaluate the impact of training on healthcare practice. Furthermore, in this study, as the spirometry training was blended (in-person and online) the application of the Kirkpatrick model is also problematic as it does not dissociate the technical, functional, performance and system quality, the usefulness and usability of the web-based platform; therefore, adaptations to the model or the tools used should have been considered (408). To comprehensively evaluate healthcare training, it is essential to consider patient outcomes, contextual factors, and behavioural change in addition to participant satisfaction and learning outcomes, which is considered a major limitation of this study.

Augmenting the Kirkpatrick model with other evaluation frameworks or adapting it to incorporate these factors can enhance its usefulness in healthcare settings. The limitations described here consider a broad analysis of challenges to applying what is learnt (evidence-base) into practice (adoption). It is a welcome opportunity therefore to emphasise this too is the outcome for implementation science as a sensor check that the realities of generating patient-level outcome must be considered in context to a broader perspective of the organisation, service, practitioner, and the patient. For each, there are a multitude of factors that enable or prevent positive changes to outcomes. Whilst it is important to set out the ambition to deliver end-point results, training is only one aspect of the strategy, and may not influence change in isolation.

This section also highlights a broader discussion around the limitations to this study. Given the aims of the programme was to encourage adoption of the clinical guidelines, in fact what has been implemented is focused predominantly on the outcome of delivering a training strategy. Whilst this has obvious merit, it fails to consider other aspects of service-specific level change support that is necessary to increase capacity and capabilities to deliver evidence-based practices at a service level. As a national remit, the outcome is inevitable – some areas, services, people, will action recommendations with fidelity, indeed bringing about the intended benefits. Whilst for others this will not be the case and insignificant or no change is expected. This is a sobering observation and perhaps an important consideration in the application of implementation frameworks or indeed training evaluation models, such as Kirkpatrick. A large-scale programme such as this has an essential role in providing a structure for service delivery.

However, it does not change the practice at a service level alone. Achieving any change takes specific work in different settings, over an extended time period, and it usually involves spending money, diverting staff from their daily work, shifting deeply held cultural or professional norms, and taking risks (31).

Whilst a number of broad strategies exist in Wales, such as national audits and QOF, a more comprehensive analysis of the value and impact of each of these are necessary. Furthermore, this emphasises the complex nature of healthcare change that cannot be captured through analysis of clinical guideline dissemination strategies. In fact, this conundrum pushes beyond the envelope of the implementation science discipline. A more comprehensive horizon scanning exercise would have benefited this approach, such as that described by Greenhalgh and Papoutsi (31). The authors broaden the perspective of clinical practice to spread and scale-up through utilisation of many different theoretical lenses, such as implementation science, complexity science, and social science, each of which is based on a different logic of change (mechanical, ecological, and social, respectively). The authors highlight that the successful spread (replicating an intervention) and scale-up (building an infrastructure to support full scale implementation) consider mostly on one of these lenses but also to a smaller extent on the other two.

A representative sample of COPD and asthma patients was not necessarily achieved from the methodology applied here. A small selection of patients was selected based on the patient opting in within the small recruitment window. Limitations to small sample size and representation is described in chapter 4. Further app reviews were undertaken with a larger sample following launch of the apps. Whilst this offers a broader representation there may be bias given these patients potentially represent early adopters of technology (109). Furthermore, all survey respondents in both stages of app assessment were technology users as they used the app to provide feedback. This methodology excluded non-technology users and their perceptions and barriers to app usage to improve self-management (409).

The focus of implementation shifted to the COVID-19 hospital guideline in March 2020, however this had a considerable effect on implementation of COPD and asthma guidelines. Whilst the focus on COVID-19 at the peak was expected, there was a missed opportunity to directly assess service-level process outcomes and perceptions of asthma and COPD care in Wales relating to the guideline recommendations. Across multiple indices of good asthma care

Wales was improving at the greatest rate compared to the other home nations. However, the quality of care was impacted significantly by the pandemic (342). Whilst process and clinical outcomes have indeed been assessed elsewhere (18), the opportunity to examine guideline users and especially patient perceptions of care was missed within this piece of work. Future evaluation of clinical impact using inhaler prescription data, health care utilisation, and PROMs is needed to really assess implementation.

The missed opportunity also highlights the impact of diminished implementation capacity, where a shift in priority towards another intervention (e.g., in this case, the COVID-19 hospital guideline) has affected the work implemented others (e.g., asthma and COPD guidelines). This implies implementation capacity is an important factor for delivery, similarly to that of adopter capacity (40).

Summary

This case study reports the acceptance and adoption of the first national guidelines for COPD and asthma in Wales delivered through a structured implementation framework. We could find no evidence of clinical guidelines implemented through a central coordination using an implementation framework on a national scale in Wales. This approach appeared to affirm widespread acceptance and adoption of the guidelines by a sample population of respiratory guideline adopters across primary and secondary care in Wales.

The COVID-19 pandemic has had a major impact on the ability to measure adherence because respiratory care was affected and there was a marked transient increase in prescriptions of asthma reliever inhalers, as in March 2020 people were anxious about their respiratory health and access to the NHS (18,410). COVID-19 has had a significant impact on prescribing practice in Wales and elsewhere (18). However, prior to the COVID-19 pandemic NHS Wales saw a sustained reduction in inhaler spend of 11% (£9 million), and Wales saw the greatest upward trajectory in quality of care, when compared to all four nations (268,411). Post study period, on-going analysis of inhaler patterns does suggest sustained increases in the prescription of the inhalers recommended by the guideline suggesting some positive clinical impact and a strong signal of guideline adherence; however, this needs more time to review.

Furthermore, the removal of spirometry from the QOF for managing patients with asthma and COPD has likely had a negative impact on the implementation of these guidelines, despite the introduction of a supplemental educational programme for HCPs and patients. This highlights an important lesson for implementation. Cofounding factors outside the control and scope of implementation programmes will impact on the success of implementation efforts, emphasising the complexity of implementing innovations across the NHS.

At the time of writing, the guidelines have been updated to address current decarbonisation policy. Nevertheless, learning from implementation of the national respiratory guidelines through a standard framework should act as the template and foundation for future initiatives. The framework has been applied and through observation a more agile response to introduce (or disband) implementation interventions is deemed necessary. As a result, the implementation process component of the framework has been expanded to include an adaptation process between phase 2 and phase 4, but also as a core function during the sustainability phase to

ensure the interventions are used as intended and indeed delivering the benefits. The updated framework is next applied to a different context in Wales to determine its applicability to guideline implementation beyond asthma and COPD.

Chapter 7

Case Study 2: Implementation of National COVID-19 Guidelines

Chapter Objectives

- 1. Demonstrate the structured application of the implementation framework for novel COVID-19 hospital guidelines across NHS Wales.
- 2. Utilise the lessons from the National Respiratory Programme to develop an implementation strategy that can be implemented quickly in response to the pandemic.
- 3. Adapt the implementation framework where it is deemed ineffectual or limited in its application these guidelines.
- 4. Propose further modifications to the framework in preparation for formal validation.

Introduction

This chapter reports on the application of the framework (Figure 5. 4) in the design and implementation of a national clinical guideline for hospitals across Wales to manage COVID-19 from March 2020. The updated feature of the implementation process model (Figure 6. 25) is highly adequate for this context as it offers a flexibility to pivot the strategy to an unpredictable scenario that was indeed observed in early 2020 when COVID-19 first emerged. For this guideline, there is a greater focus on acquiring data to measure key outcomes such as facilitation impact, reach and penetration. Furthermore, the measures are assessed between periods rather than phases, which allows a more organic process to implementation that is necessary for large scale implementation efforts. In doing so, this demonstrates a flexible application of the framework that may be tailored to other guidelines in the future. The assessment here is not to determine the efficacy within guidelines as there is no 'before' and 'after' COVID-19 guidelines and comparison with other healthcare systems (e.g., NHS England) will be affected by multiple confounders on service design. Our aim is to determine whether the implementation framework provides an adequate structure to introduce novel national guidelines across an even larger target audience than that described in Chapter 6.

Chapter Structure

The results are similarly presented against the three (early, mid, or late) periods of the implementation process (163). For each period, the framework domains: Implementation Phases, Implementation Drivers, Implementation Interventions, and Implementation Outcomes, guide the report (Figure 5. 4). The StaRI checklist (333) and the IRLM (334) were also applied.

Context

The emergence of a highly infectious novel coronavirus (SARS-CoV-2) in December 2019 has given rise to the greatest challenge faced by our healthcare system in the last century. At the time of writing there was over 500 million infections and over 6 million deaths worldwide and rising (412). The pandemic led to the most rapidly evolving guidelines ever seen in science – on public health measures and medical management of individuals with COVID-19 (Coronavirus disease 2019). At the start of the pandemic, it was (correctly) surmised that a lack of clear guidance would lead to confusion amongst HCPs and create variation in care and outcomes. In response to this challenge many national and international guidelines were created and implemented at pace. We underwent a similar journey to ensure advice was offered rapidly to improve the quality and effectiveness of health services and care across Wales to promote the systematic uptake and application of research findings and other evidence-based practices into routine practice (59).

At its core is the question:

"How do we get what works to the people who need it, with greater speed, fidelity, efficiency, quality, and relevant coverage?" (74).

Contextualised and rearranged, in Wales we asked:

- How do we get timely, relevant information, instruction, and advice for the management of COVID-19 to clinical decision-makers, in an easily accessible format to help improve COVID-19 survival rates across the country?

Whilst large-scale programmes often take years to achieve widespread adoption of the innovations (1), the COVID-19 pandemic brought a different contextual backdrop: uncertainty, and urgency — which accelerated implementation success. This offers a unique learning opportunity into the potential for implementing large-scale innovations using a particular methodology that could be adapted rapidly.

Building on Lessons from Respiratory

The implementation strategy applied to the national guidelines for COVID-19 was influenced by the recent implementation of asthma/COPD guidelines, presented in Chapter 6. Thematic analysis identified common themes to developing educational guidelines (informative, instructional, usable, accessible, helpful, relevant) to support healthcare professionals, and these were immediately applied here. Given the rapid spread of COVID-19 in early 2020, Welsh Government wanted to standardise the guidance and learning around it. Whilst standardising the approach and continually learning from COVID-19, it was anticipated local adaptations to pathways would exist (based mainly on local resource, staffing, and even estate layout). The national guideline and learning repository were therefore designed as a reference and framework for hospitals to guide local decision-making. There was clearly an immediate requirement to initiate this work; therefore, wide stakeholder acceptance in this approach was not entirely feasible. However, senior government officials and Health Board Executives, agreed to base the strategy on the impact generated by the respiratory guidelines, which had recently demonstrated strong governance, utilising high quality education and online videos, wide acceptance by specialists and healthcare professionals, and delivery through penetration to the target population. The Wales Chief Medical Officer (CMO) wrote to all HB Chief Operating Officers (COO) encouraging its use (see Appendix I).

The first confirmed case of COVID-19 infection in Wales was on the 28th of February 2020 in a person who had returned from Northern Italy, which at that time was the epicentre of the western hemisphere pandemic. Two weeks later (10th March), Wales saw the first significant evidence that the virus was spreading, leading to Welsh Government to close all schools and leisure facilities on the 20th of March. The UK went into lockdown on the 23rd of March restricting people from leaving their home for non-essential travel. The COVID-19 guideline was formally launched on the 21st of March 2020, early in the pandemic, but at a time where COVID-19 infections were rising across Wales.

Methods

Study Design

This is a descriptive observational study (386) assessing the process of generating widespread utilisation of a national strategy for guideline implementation using the implementation framework updated in Chapter 6. The framework was applied equally in all Health Boards across Wales. This study details the activity undertaken against each phase of the implementation process measuring implementation outcomes at each phase. Implementation outcomes are the transitional points between the phases as described previously. The study is therefore designed and presented against the periods of implementation (Figure 7. 1 from Chapter 6).

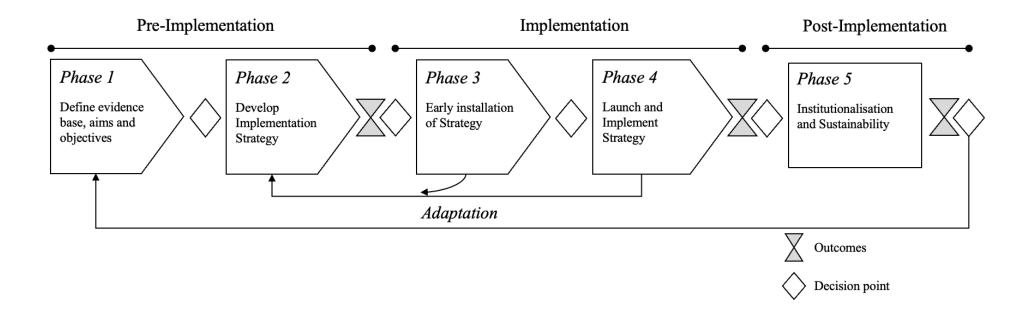


Figure 7. 1: Adaptation to the implementation process model following observations during the implementation of the respiratory strategy described.

Ethical issues and approval

As in Chapter 6, this study was categorised as a service evaluation. No patient or identifiable staff data was extracted or used for this analysis.

Recruitment and Target Population Characteristics

For the implementation strategy, three broad groups represent the target population.

- Group 1: Representing the target <u>organisation</u> this includes high-level system-wide decision makers including executives and service leads.
- Group 2: Guideline <u>adopters</u>, especially senior clinical decision-makers, such as consultant-level clinicians.
- Group 3: <u>Practitioners</u> managing patients admitted with COVID-19, such as nurses, junior doctors, relevant allied healthcare professionals, and medical students.

Inclusion and exclusion criteria

The guideline was implemented across six of the seven HBs in Wales. Powys Teaching (PT) was not included since it did not have any District General Hospitals (DGHs) within its boundaries. Data were collected from all DGHs, but not from smaller rehabilitation or community hospitals that did not have facilities for acute medical care and were therefore not sites for admitting patients with *acute* COVID-pneumonitis. An implementation organisational structure (Figure 7. 2) was established, facilitating central control through the Implementation Team. The Implementation Team could then manage locally positioned facilitators to increase widespread adoption by the target audience – that is, the clinical decision makers responsible for managing patients admitted with COVID-19. This is a structure that was formalised based on the pockets of success observed for respiratory guidelines, and recommendations from other studies examined in previous chapters. Reflecting the demands of COVID-19, we also included Emergency Department (ED), Respiratory, Intensive Care, and Palliative Care Consultants, which were estimated to be around 193 clinicians across Wales (413). The central guideline management team primarily supported facilitator activity, but could also respond quickly to any technical issues, user requirements and requests.

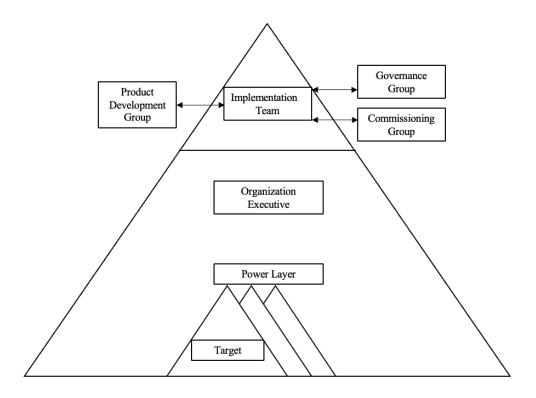


Figure 7. 2: Relationship between the guideline implementation team, the target organisation, and the target population, highlighting the bi-directional influence of the guideline facilitators (Power Layer).

Pre-Implementation Period

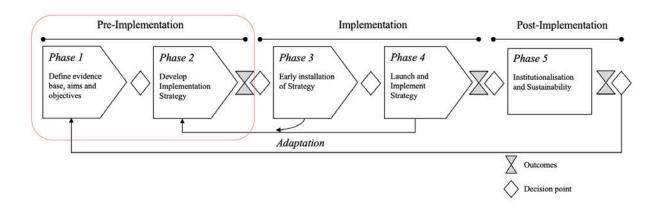


Figure 7. 3: Pre-implementation period of the implementation process.

The pre-implementation period consists of Phase 1 and Phase 2 (Figure 7. 3, represented above). Phase 1 is a largely scoping phase to define the evidence base and to establish programme level aims and objectives. Phase 2 uses this plan to develop a feasible implementation strategy.

The guideline features a universal pathway for assessment, triage and management of patients presenting to hospital with COVID-19. The guideline was designed so that HCPs could easily access and understand the basic principles of COVID-19 management, with supplemental detail that could change as new evidence emerged. The fixed component of the guideline represented flow through the system (Figure 7. 4). This was compatible with all hospital structures and therefore sufficiently flexible for local adoption across all Health Boards (HBs) in Wales.

The dynamic component of the guideline is accessed through QR readers on colour-printed guideline posters with web links, and through update emails of new clinical instruction as they emerged. Local experts from a variety of different professional groups provided contextual and instructional education, a factor that has shown to increase the rate of adherence substantially (258,261). Updates were delivered in a contemporary format, with information distilled into brief 3-5 minute videos with summaries, graphs and other visual aids incorporated during the editing process to promote ease of information transfer. We hosted these on a single, unique web-based platform to increase reach and accessibility – thereby facilitating a rapid response to the expected changes in clinical instruction. As per asthma/COPD guidelines, the guideline platform, features a repository of localised, and national pathways, instructional videos, and learning, with multiple-choice questions (MCQ) assessments at the end, to generate a COVID-Ready certificate. Access was aimed only to NHS Wales's staff, requiring an NHS Wales email and registration with clinical demographic information, to map implementation outcomes by profession and locality.

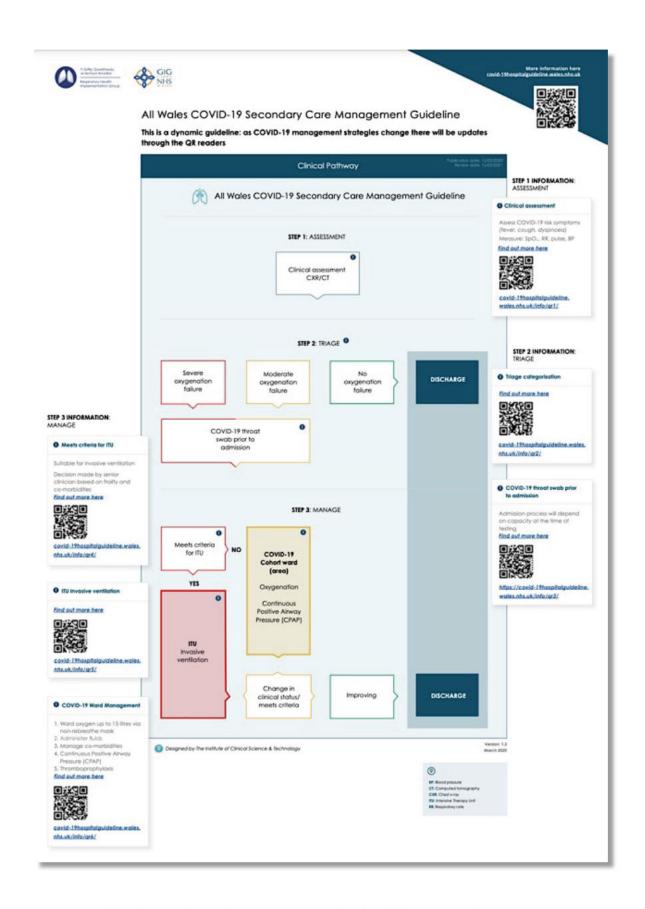


Figure 7. 4: All-Wales COVID-19 Secondary Care [Hospital] Management Guideline

Leading experts in respiratory, intensive, and palliative care developed the guideline content, with the National Respiratory Clinical Lead for Wales acting as the primary author and guideline content coordinator. The National Lead considered all decisions about what to include as updates for the guideline, then invited experts to deliver an update in a video format on specific topics. Many of these were practical in nature and depended on immediate need and changing evidence, e.g., how to deliver Continuous Positive Airway Pressure (CPAP) therapy, how to prone patients, or how to provide palliative support. Other videos outlined emerging evidence from clinical trials. Consultation amongst a network of clinical colleagues enabled consensus decisions around issues with a limited evidence base, such as target oxygen saturation ranges, or thromboprophylaxis. Video topics were categorised into the following:

- What makes the virus novel?
- Mode of transmission of SARS-CoV-2.
- PPE guidance for frontline teams.
- Other tips for staying well at work and in the community.
- On admission to hospital.
- Diagnosis and investigations.
- Treatment options for Acute COVID-19 (Figure 7. 5a).
- Managing a patient on a COVID-19 cohort ward.
- CPAP and ventilator equipment (Figure 7. 5b).
- Managing tracheostomy (Figure 7. 5c).
- Management of patients on ICU (Intensive Care Unit).
- Rehabilitation and discharge.
- All Wales Palliative Care Guidelines.
- Symptomatic approach to Palliative care.
- Communication during end-of-life care (Figure 7. 5d).
- Registering a death.

For all tutorial webpages relevant documents, reports, websites, links, and local pathways and resources were added as additional resources. These were tailored so that only relevant information was available by Health Board, which was determined during registration with the guideline platform.

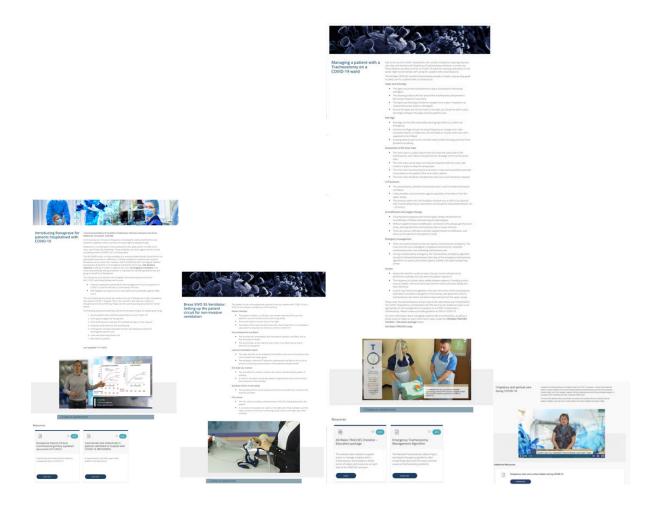


Figure 7. 5: a) notification about a new drug treatment and its efficacy when prescribed to patients with severe COVID; b) an example of a video tutorial and text instruction hosted on the guideline platform; c) tracheostomy experts demonstrate a standardised approach to safe tracheostomy care according to the TRACHES mnemonic; d) tutorial presented by a member of the chaplain team.

Opinion Leaders

The guideline features NHS Wales-specific instruction from respected subject-matter experts (opinion leaders) (Figure 7. 6, Figure 7. 7), which was a strategic decision to increase the likelihood of adoption of the guideline once it was launched. The primary target population for this guideline were Consultant-level doctors as they were senior decision-makers for the acute management of COVID-19 in hospitals. To reflect this and to promote acceptance of the guideline, we selected senior Consultant-level doctors, from a range of specialties, to present in most of the video tutorials. As the guideline was national and the remit was to generate widespread use across Wales, the strategy was to ascertain representation from each of the Health Boards to reduce the potential barriers to local (clinician-level) acceptance. However, there was a large preponderance from Cardiff reflecting the location of some super-specialities (e.g., Infectious Disease / Virology) but mainly the ease of travel to the Cardiff filming studios given clinical pressures and COVID-19 restrictions to travelling. Through capacity issues and unavailability for quick turnaround, Cwm Taf Morgannwg (CTM) had no representation on the guideline (Table 7. 1).

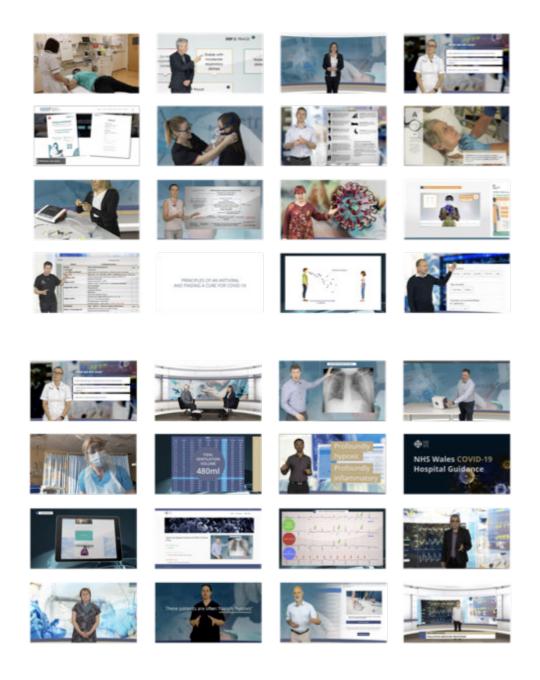


Figure 7. 6: Montage of video tutorials demonstrating range of opinion leaders who volunteered their time to film at the studio in Cardiff.



Figure 7. 7: The green-screen film studio in Cardiff. The National Clinical Lead for Palliative Care (faced blurred as permission not sought) presents a tutorial on the symptomatic management of patients with COVID-19, towards the end of life.

Profession	Number of Video Tutorials	Discipline	Number of Video Tutorials	Organisation	Number of Video Tutorials
Consultant	33	Respiratory	23	Cardiff & Vale UHB	35
Registrar	5	Intensive care	8	Betsi Cadwaladr UHB	7
Nurse	5	Infectious diseases	4	Swansea Bay UHB	3
Junior Doctor	3	Palliative care	4	Aneurin Bevan UHB	3
Medical rep	3	Medical technology	3	Other	3
Physio	2	Public health	2	Hywel Dda UHB	2
Scientist	1	Cardiology	1	Public Health Wales	2
Physiologist	1	Psychiatry	1	Cwm Taf UHB	0
Dietitian	1	Virology	1		
Chaplain	1	Dietetics	1		
Pharmacist	1	Dermatology	1		
		Geriatrics	1		
		Radiology	1		
		Immunology	1		
		Gastroenterology	1		
		Nephrology	1		
		Endocrinology	1		
		Chaplaincy	1		

Table 7. 1: A breakdown of opinion leaders represented within the guideline by profession, discipline, and organisation.

Implementation Period

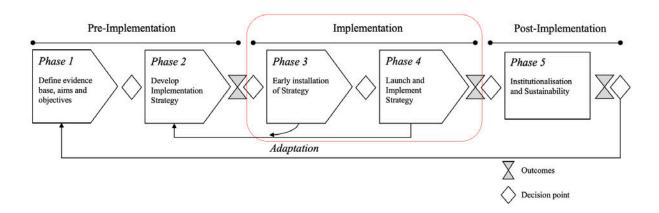


Figure 7. 8: Implementation period of the implementation process.

Guideline Dissemination

The website and resources were published and 1000 colour and laminated (for infection control) guideline posters were distributed to the 18 DGHs across Wales by the end of March 2020 when total (confirmed) COVID-19 inpatients and COVID-19 deaths were low. The webbased platform was hosted on the Welsh Clinical Portal (WCP) to make it easier for clinicians to access information and educational videos whilst at work. Links to the guideline platform were added to Health Board intranet sites and included in local Trust-wide communications to clinical teams. Posters were displayed in clinical areas, staff rooms, and offices for easy access and familiarisation (Figure 7. 9). Additional guidelines, pathways and posters were also printed and issued on request of managers and clinical staff across Wales. These were posted (and in some cases hand-delivered to build relationships with key stakeholders) within 24 hours of request. During the first wave alone, 7 approved clinical pathways and approximately 260 information pages regarding COVID diagnosis and management were freely available online to registered HCPs across Wales.



Figure 7. 9: The hospital guideline poster pack – printed and delivered to hospitals across Wales during the first wave. Within the pack, to accompany the hospital guideline, there were several supplemental pathways and posters, laminated for Infection Prevention and Control (IPC) purposes.

Communication

Most tutorials (151, 82%) were published within the first wave (March to end of June 2020) (Figure 7. 10). From initial publication in March 2020, to December 2021, there were 184 content updates to the platform: 18 of these updating the key instruction within the 6 QR links on the guideline pathway (Figure 7. 11). More than 180 pre-recorded video tutorials averaging 5-7 minutes from 45 clinical specialists totalling over 1000 minutes of video education from clinical specialists. There were 101 email campaigns (mail-out clinical updates and video synopses, to registrants) during the first wave (Figure 7. 12). The communication campaign delivered approximately three updates on average per week. In busy weeks, where changes and new evidence was emerging quickly, the updates were distributed more frequently – on some days, more than one update. Further communication channels included social media, Health Board communication channels, and mainstream news outlets. For example, the National Clinical Lead presented this work to the BBC to reassure the public that a coherent and coordinated approach was being taken to manage COVID-19 across all hospitals in Wales (Figure 7. 13).

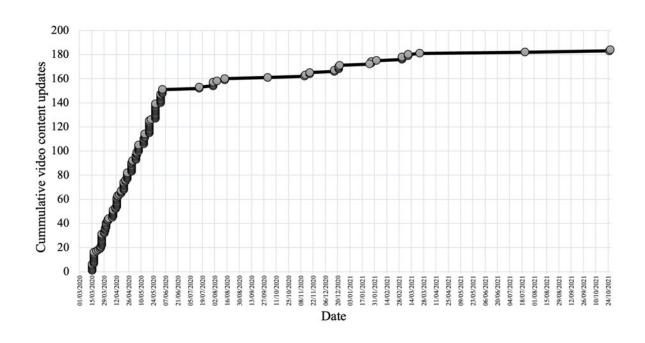


Figure 7. 10: A cumulative graph, showing the number of content updates published to the All-Wales Hospital COVID Guideline.

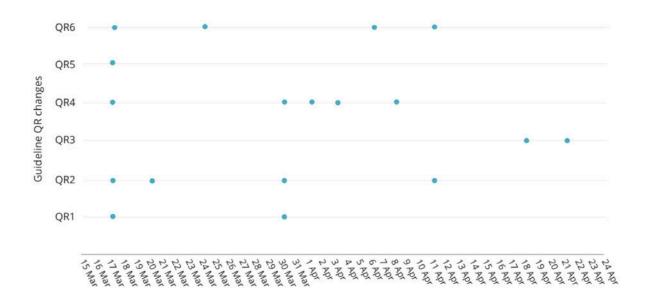


Figure 7. 11: The dates for the dynamic changes to the guideline QR links (see Figure 5.3).

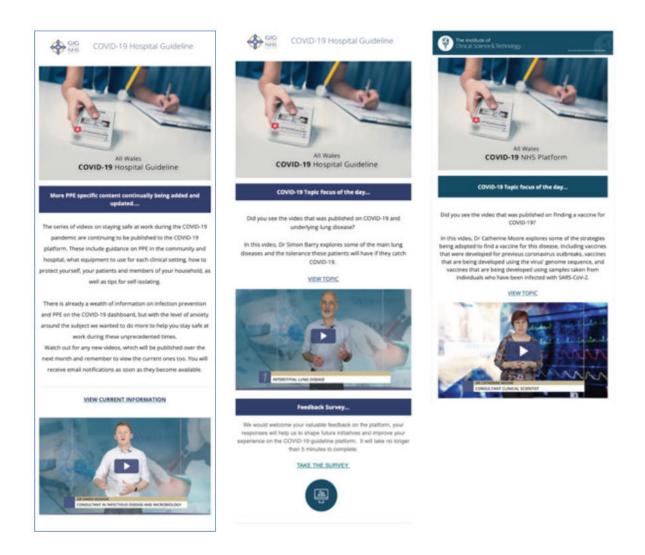


Figure 7. 12: Example of email communications sent to users of the All-Wales Hospital Guideline Platform. The email includes a descriptor of the message and direct links to the platform to read more or watch the video illustrated within the email.



Figure 7. 13: Media teams from BBC and Channel 4 joined the National Clinical Lead in the Cardiff studio to showcase the work being done. Permission to use the image granted.

Facilitation

Implementation software supported the implementation process. A Guideline Facilitator Dashboard (GFD) provided regional engagement and activity metrics to stimulate local efforts to promote its use. Facilitators (Power Layer) could also encourage new registrants directly from the dashboard through a mass email invite coming from them, nudging potential users to register with the platform. To better understand the potential influencers for guideline registrations we assessed facilitator activity, through logging the number of unique interactions by selected guideline facilitators by Health Board with the GFD.

Alignment

Implementation data were analysed, and reported in real-time by the Implementation Team, consisting of government, clinical, and executive members of the wider stakeholder group with direct decision-making responsibility. The Welsh Government received periodic implementation reports to support strategic decision-making. The BLF and Asthma UK, the BTS, and multi-professional clinical groups publicly endorsed and promoted the guideline. It also received acknowledgment in published BMJ articles (17), with international praise from social media posts from users (Figure 7. 14). It has also featured on the BBC Wales News as an innovative approach to COVID-19 management (414). This was a result of passive spread and active efforts by the Implementation Team to generate widespread alignment with multiple stakeholders to increase the net promotion of the guideline with potential users across NHS Wales.

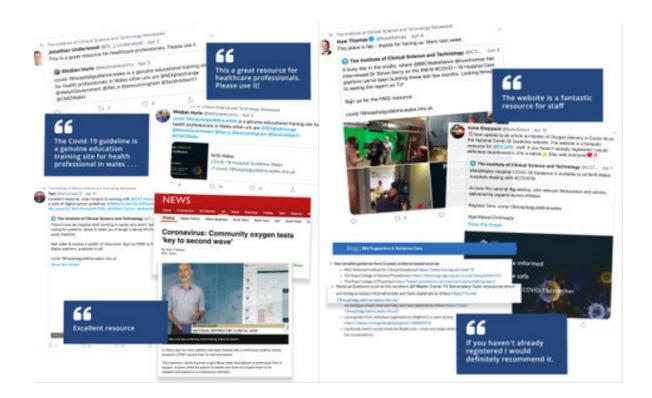


Figure 7. 14: Example montage of comments, posts and news articles from guideline users, clinicians, managers, leaders, and the public, from across the UK.

Data Collection

Guideline activity was analysed for the period comprising the first wave of the COVID-19 pandemic (21/3/20 to 15/8/20). We recorded registrations of HCPs within NHS for the first wave of the COVID-19 pandemic. An online anonymised registrant survey using SurveyMonkey (Appendix J) was emailed to all registrants on 08/06/20 with a further two reminders allowing a two-week response time. The survey comprised 11 multiple-choice questions, three open questions, a star rating for overall quality, and sliding scales regarding ease of use and by how much the guideline had influenced their practice.

Data Analysis

Penetration ratios were calculated by dividing the total number of HCP platform registrations within a Health Board, by Health Board size by population, staff employed, number of acute beds, and burden of COVID-19 admissions during the implementation period, (available from publicly available hospital data sources) (335,413,415). Data were curated in Microsoft Excel. Chi-squared testing was performed using GraphPad Prism (version 6.06).

Results

We were confident that all registrations were associated with guideline engagement for several reasons that were considered prior to implementation:

- *i)* The guideline was not hosted anywhere else (note for the Asthma and COPD guidelines (Chapter 6); these can be found on both the AWMSG website and the ICST educational website for Wales).
- *ii)* The guideline educational platform was a new website developed specifically for this guideline.
- *iii)* Registration with the guideline platform and to receive email updates required formal registration where we encouraged use of, and verification through, NHS Wales email accounts.

Registrants

Total registrants with the guideline platform reached 4521 during the first wave. Rates of new registrations slowed at the same time as the rate of patients admitted to hospital and dying from COVID-19 (Figure 7. 15). The pattern of user activity is also demonstrated by Google analytics of website traffic, which includes all activity, including for people who did not register (Figure 7. 16).

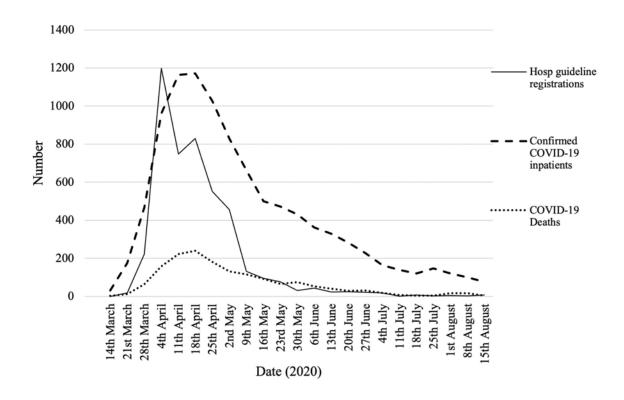


Figure 7. 15: The number of registrants and the number of COVID admissions and COVID deaths across Wales.



Figure 7. 16: Google Analytics of Guideline Platform traffic, throughout first wave of the pandemic.

Google analytics of website traffic also demonstrates international interest, Table 7.2 representing the top 10 users by country of the 73 countries. However, because access required registration and was clearly directed to staff in NHS Wales, the website bounce rate is relatively high (55%) despite the remarkably high average session duration (5:07mins) (Figure 7. 17).

		Acquisition			Behavior			Conversions		
Country		Users	New Users	Sessions	Bounce Rate	Pages / Session	Avg. Session Duration	Goal Conversion Rate	Goal Completions	Goal Value
		16,799 % of Total: 100.00% (16,799)	15,181 % of Total: 100.04% (15,175)	33,417 % of Total: 100.00% (33,417)	55.30% Avg for View: 55.30% (0.00%)	4.10 Avg for View: 4.10 (0.00%)	00:05:07 Avg for View: 00:05:07 (0.00%)	0.00% Avg for View: 0.00% (0.00%)	% of Total: 0.00% (0)	\$0.00 % of Tota 0.005 (\$0.00
1.	United Kingdom	15,822 (93.59%)	14,112 (92.96%)	32,164 (96.25%)	54.95%	4.19	00:05:15	0.00%	0 (0.00%)	\$0.00
2.	United States	546 (3.23%)	544 (3.58%)	552 (1.65%)	49.46%	1.55	00:00:19	0.00%	(0.00%)	\$0.00
3.	Netherlands	64 (0.38%)	64 (0.42%)	64 (0.19%)	98.44%	1.02	00:00:00	0.00%	0 (0.00%)	\$0.0
4.	Finland	60 (0.35%)	60 (0.40%)	60 (0.18%)	100.00%	1.00	00:00:00	0.00%	(0.00%)	\$0.00
5.	India	35 (0.21%)	35 (0.23%)	39 (0.12%)	74.36%	1.44	00:01:09	0.00%	0 (0.00%)	\$0.00
6.	Ireland	30 (0.18%)	27 (0.18%)	59 (0.18%)	71.19%	2.10	00:01:54	0.00%	(0.00%)	\$0.00
7.	France	27 (0.16%)	27 (0.18%)	27 (0.08%)	96.30%	1.07	00:00:28	0.00%	(0.00%)	\$0.00
8.	Germany	25 (0.15%)	24 (0.16%)	28 (0.08%)	78.57%	2.89	00:03:50	0.00%	(0.00%)	\$0.00
9.	Austria	23 (0.14%)	23 (0.15%)	23 (0.07%)	95.65%	1.43	00:00:45	0.00%	(0.00%)	\$0.00
10.	Maldives	20 (0.12%)	(0.13%)	45 (0.13%)	51.11%	2.91	00:05:11	0.00%	(0.00%)	\$0.0

Rows 1 - 10 of 73

Table 7. 2: Google Analytics demonstrating international interest. Here listing the top 10 of 73 countries.

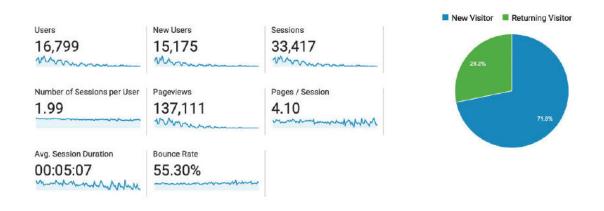


Figure 7. 17: User activity derived from Google Analytics throughout the first wave of the pandemic.

Registration rates with the guideline platform increased substantially from 28th March (Figure 7. 18) in response to a range of alignment and facilitation activity, including email campaigns, formal guideline on-boarding, and discussions promoting adoption with executive teams. Whilst common communication methods such as using WhatsApp and Twitter facilitated awareness, hospital Information Technology (IT) phishing issues, and not being in work (weekend) reduced activity (Figure 7. 19).

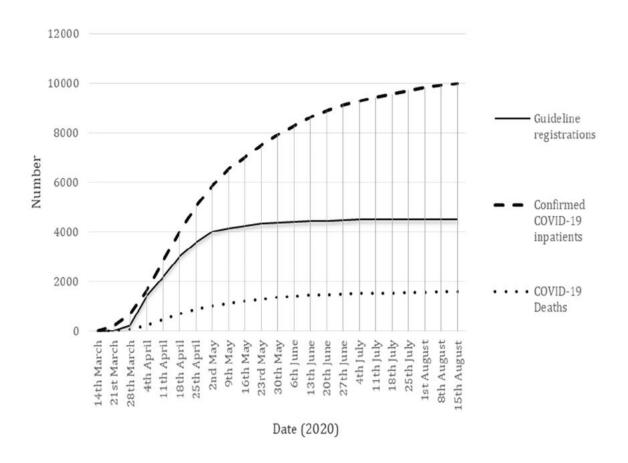


Figure 7. 18: Cumulative number and trend patterns for guideline registrants, confirmed COVID-19 inpatients, and COVID-19 deaths for Wales during the first wave of the COVID-19 pandemic.

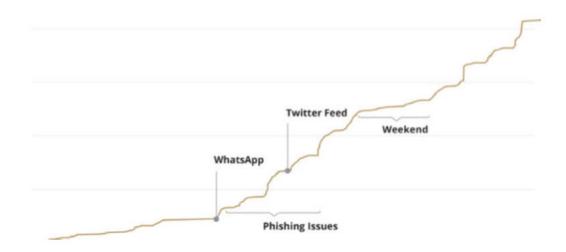


Figure 7. 19: Examples of implementation drivers (communications) and implementation barriers that impacted registration rate.

The registration rate by Health Board was assessed. Given the potential impact of sickness and staff transfers on this estimate of guideline uptake, additional sensitivity analysis was conducted to derive penetration ratios adjusting for number of whole time equivalent (WTE) clinical staff, and number of COVID-19 admissions (Table 7. 3). There was x3-fold variation in HCPs registering within Swansea Bay UHB for every COVID-19 admission. For the Health Board with lowest penetration, ABU, there was only one HCP registration for every two COVID-19 admissions.

	Penetration Ratio						
Health Board (HB)	Total Registrants/ Catchment Population	Total Registrants/ Total Healthcare Staff	Total Registrants/ Number acute beds	Total Registrants/ Number COVID-19 admissions	Consultant Registrants / Total consultants		
ABU	0.0007	0.03	0.23	0.44	0.30		
BCU	0.0009	0.04	0.31	0.41	0.36		
CAV	0.0026	0.09	0.67	2.81	0.43		
CTM	0.0019	0.05	0.40	0.67	0.39		
HD	0.0014	0.06	0.51	2.95	0.52		
SB	0.0033	0.11	0.96	4.18	0.74		

Table 7. 3: HCP uptake of the national guideline as shown by penetration ratio adjusted for size of Health Board using metrics shown. Rankings for each column in colour: green – highest; red – lowest penetration.

Penetration

The primary target (hospital Consultants) accounted for the greatest proportion of professionals registered with the guideline platform (23%). Uptake observed across allied health professionals (including physiotherapists, pharmacists, dieticians, and occupational therapists) accounted for 21.4%, and nurses 20.6% (Figure 7. 20).

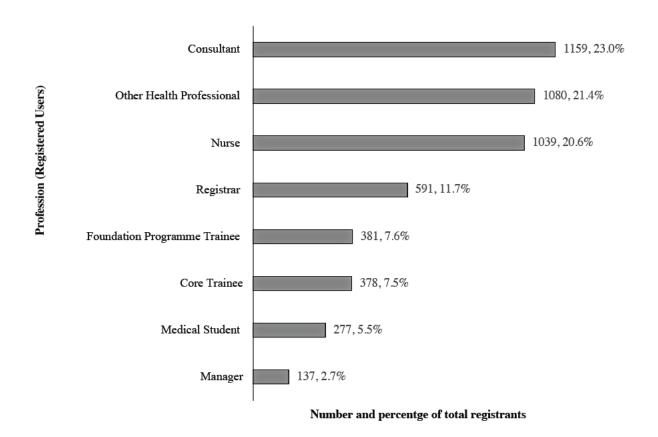


Figure 7. 20: Number and percentage of guideline registrants by profession.

From a maximum possible 2505 consultants employed in Wales at the time (413), 1131 (45%) registered with the guideline. Swansea Bay (SB) showed the greatest penetration, with 73.7% (325 of a possible total 440) of all consultants registered, followed by Hywel Dda (HD) with 51.9% (111 of 214) of total. Uptake by hospital consultant was lowest in Anuerin Bevan (ABU) at 30.5% (131 of 429 Consultants). This variation in consultant uptake between Health Boards was highly significant (Chi-squared testing, p<0.0001) (Table 7. 4).

We next evaluated total uptake for hospital Consultants involved in the management of patients admitted with COVID-19, including ED, Respiratory, Intensive Care, and Palliative Care. The uptake was estimated as a percentage of the known Consultant workforce in each of these specialities across Wales (Figure 7. 21).

Health Board (HB)	All Consultants employed. (Any specialty)	Guideline Registrants. (All consultants only)	Consultants likely involved in direct COVID care. (Emergency Department, Respiratory, Intensive Care, Palliative Care)
ABU	429	131 (30.5%)	36
BCU	502	183 (36.5%)	35
CAV	550	238 (43.3%)	55
CTM	370	143 (38.6%)	23
HD	214	111 (51.9%)	8
SB	440	325 (73.9%)	36
Wales	2505	1131 (45.1%)	193

Table 7. 4: Uptake by COVID-19 consultants and all consultants (any specialty) for each Health Board determined by a publicly available resource (413)

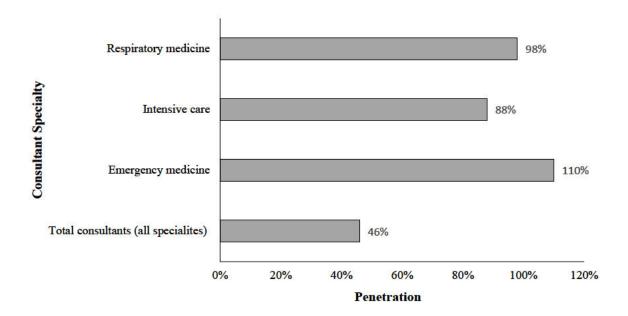


Figure 7. 21: Penetration of the target population across Wales determined by registration rates of consultants and specialism selected on registration. This is using information provided by StatsWales, a publicly available source of metrics for NHS Wales.

Capacity

To help estimate capacity to use the guideline, the impact of COVID-19 at the time of the guideline publication was assessed. This is presented in Table 7. 5, comparing the number and percentage of peak COVID in-patients by Health Board. ABU had the highest proportion of peak COVID-19 in-patients (37.4%) at the time of publication of the guideline, compared to other Health Boards (CAV, 10.4%, CTM, 6.3%, SB, 5.9%, HD, 5.7%, and BCU, 4.9%).

Health Board	COVID-19 inpatients around the time of the guideline launch (data from 22nd March)	Maximum COVID-19 inpatient count during the first wave	COVID-19 inpatients around the time of the guideline launch as percentage of peak
ABU	107	286	37.4%
BCU	12	243	4.9%
CAV	26	250	10.4%
CTM	13	208	6.3%
HD	5	88	5.7%
SB	12	202	5.9%

Table 7. 5: Table of figures representing inpatient numbers at time of guideline launch against its peak for each Health Board.

Facilitation

There were 972 interactions in total from 51 facilitators. Of these, SB had the most interactions (642, 67%). Furthermore, of the top ten facilitators accessing the facilitator dashboard by frequency, SB had the top three most accessed by individuals (410, 137, 109 times). CTM had three in the top 10 (106, 23, 8 times), CAV two (52, 27 times), and BCU and HD each with one (86 and 14 times, respectively). ABU had no single facilitator in the top 10 – the most accessed by a single facilitator in the Health Board was 9 times (Table 7. 6 and 7. 7).

Health Board (HB)	COVID-19 inpatients around the time of the guideline launch as percentage of peak	Total Number of Facilitators selected by the Health Board	Number of active facilitators determined by dashboard access	Total interactions with Facilitator Dashboard	Frequency of dashboard access by most active facilitator	Opinion Leaders in video
HD	5.7% (5)	9 (18%)	1 (9%)	14 (1%)	14 (2%)	2 (4%)
ABU	37.4% (107)	5 (10%)	1 (9%)	9 (1%)	9 (1%)	3 (5%)
CTM	6.3% (13)	8 (16%)	3 (27%)	137 (14%)	106 (16%)	0 (0%)
BCU	4.9% (12)	7 (14%)	1 (9%)	86 (9%)	86 (13%)	7 (13%)
CAV	10.4% (26)	8 (16%)	2 (18%)	79 (8%)	52 (8%)	35 (64%)
SB	5.9% (12)	14 (27%)	3 (27%)	651 (67%)	401 (60%)	3 (5%)

Table 7. 6: In order of guideline registrants by consultants (all) employed (top least registrants to bottom most registrants) variables relating to Guideline Facilitators and Opinion Leaders. Also, for reference, the number of inpatients (as percentage of peak) at the time of guideline launch.

Health Board (HB)	COVID-19 inpatients around the time of the guideline launch as percentage of peak	Total Number of Facilitators selected by the Health Board	Number of active facilitators determined by dashboard access	Total interactions with Facilitator Dashboard	Frequency of dashboard access by most active facilitator	Opinion Leaders in video
ABU	37.4% (107)	5 (10%)	1 (9%)	9 (1%)	9 (1%)	3 (5%)
BCU	4.9% (12)	7 (14%)	1 (9%)	86 (9%)	86 (13%)	7 (13%)
CTM	6.3% (13)	8 (16%)	3 (27%)	137 (14%)	106 (16%)	0 (0%)
CAV	10.4% (26)	8 (16%)	2 (18%)	79 (8%)	52 (8%)	35 (64%)
HD	5.7% (5)	9 (18%)	1 (9%)	14 (1%)	14 (2%)	2 (4%)
SB	5.9% (12)	14 (27%)	3 (27%)	651 (67%)	401 (60%)	3 (5%)

Table 7. 7: Results from Table 7. 6 ranked in order of penetration by consultants employed by the Health Board.

Knowledge Transfer

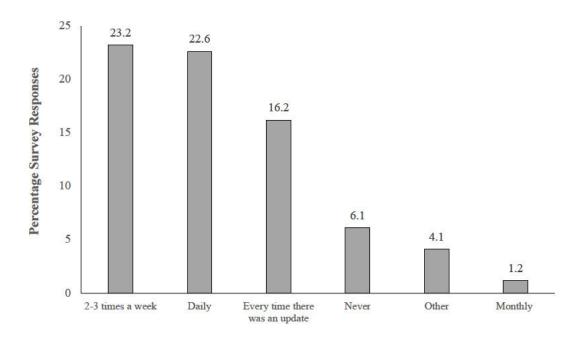
During the first wave alone, there were nearly 170,000 page views. Google analytics show approximately 40,000 individual login sessions, resulting in 32,200 video plays from registered users, an average of 4.2 page views per session lasting an average of 5.2 minutes (Figure 7. 17). This suggests close to 200,000 minutes of educational time and knowledge transfer. In total around 910 *COVID-Ready* Assessments (and award of certificates for CPD) were completed during the first wave. The majority of these (627, 69%) were from staff in SB coinciding in response to a letter circulated by the Medical Director for the Health Board mandating this for all clinical staff (Appendix K). Circulation of this letter was achieved through proactive efforts of the local facilitator.

Guideline Access

In total, 178 healthcare professionals responded to the survey representing 3.9% of the total number of registrants at the time. Of these responses 33.9% were consultants, with 23.1% nurses and 26% reported as 'other', which is relatively consistent with the distribution of guideline registrants by profession. 33.7% were invited to register with the guideline by an email generated by the facilitator dashboard; whilst a further 23.6% were notified directly by guideline facilitators and 12.9% department leads. Only 2.8% heard about the guideline through social media and 2.8% via the WCP. 17.9% were recommended it by a colleague.

Most respondents reported using the guideline weekly (26.6%), 23.2% using it 2-3 times per week and a further 22.6% used it daily (Figure 7. 22). Most respondents accessed the guideline most often whilst on duty at work (53.2%), whilst 26.3% accessed it most often from home, whilst not on duty, and a further 19.3% during work, whilst off duty. However, this does not distinguish those that may have viewed it from more than one place, only most frequently (Figure 7. 23). Most respondents accessed the guideline using a hospital computer (57.3%), 24.0% accessed using mobile phones, 20.5% using their personal computer, and 7.0% using a tablet device (Figure 7. 24a). Google analytics of website traffic suggests similar patterns, although browsing using mobile phones is notably higher than that reported by the survey respondents (Figure 7. 24b). Google analytics shows high average session durations through desktop and tablet access (6:35 and 7:09 minutes, respectively) compared to mobile viewing (2:59 minutes). Furthermore, mobile phone access included significantly less pages viewed per

session - 2.7 pages on average, versus 5.12 and 4.65 pages, respectively. In addition, the website bounce rate (percentage of people who land on the page the website but do nothing more) was greater for mobile phone browsing (64.87%) than desktop or tablet (48.46% and 50.43%, respectively) (Table 7. 8).



How often guideline was accessed

Figure 7. 22: Frequency guideline was accessed determined by survey responses.

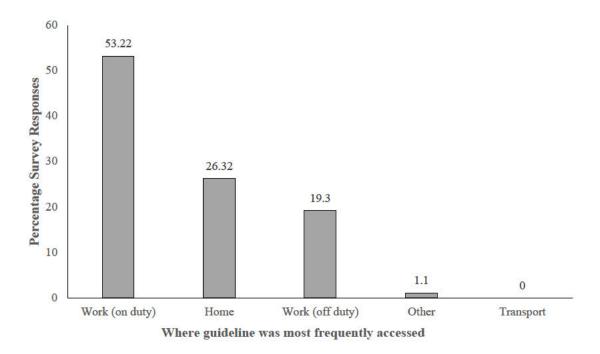


Figure 7. 23: Location where guideline was most frequently accessed determined by survey responses.

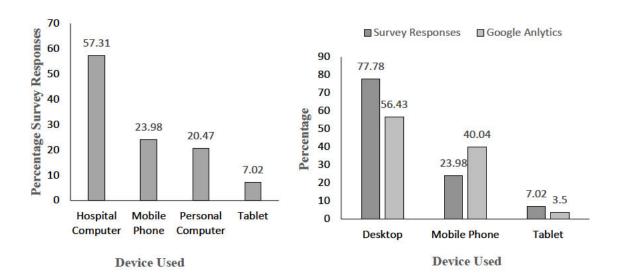


Figure 7. 24: a) Device used to access the guideline from survey responses; b) Survey responses (hospital computer and personal computer data aggregated to desktop) compared to Google Analytics.

Device	Bounce Rate	Pages per Session	Avg. Session Duration
Desktop	48.46%	5.12	6:35 mins
Mobile Phone	64.87%	2.70	2:59 mins
Tablet	50.43%	4.65	7:09 mins

Table 7. 8: Bounce rate, pages per session and average session duration according to Google Analytics.

Guideline Rating (User Survey)

The weighted average rating of the guideline platform was 4.01 out of a maximum of 5 stars. 34% of survey respondents voted 4/5 stars, 38% of survey respondents voted 5/5 stars (Table 7. 9). 81% reported they would like the email updates to continue. 68% reported they had encouraged others to use the guideline platform, whilst 28% had not (4% did not answer this question).

Stars (rating out of 5)	1	2	3	4	5	Weighted Average
Percentage of respondents	1.71%	6.86%	18.86%	34.29%	38.29%	4.01%

Table 7. 9: Rating by stars (out of a maximum of 5) reported by 175 survey responders. Proportion by star rating and weighted average.

In total, 207 registrants unsubscribed to the emails (4.6% of total registrants). This equates to 2.5% unsubscribes per email campaign, or 0.04% of all users per email campaign. Of the unsubscribers who entered their job title (n=189, 91% of un-subscribers), the most unsubscribes came from Medical Students - 21% (n=40), followed by 'Other Healthcare Professional' – 17% (n=33) and Registrars – 16% (n=31). There are only 272 Medical Students, and 15% of these have unsubscribed. There are 579 Registrars, 6% of these have unsubscribed. Compare this to consultants that have an unsubscribe rate of just 0.4%. Of the un-subscribers who entered their service (n=188, 91% of all un-subscribers), the most unsubscribes came from University Hospital Wales (UHB) (CAV) – 22% (n=41), followed by Morriston Hospital (SB) – 12% (n=22) and the Royal Gwent (ABU) – 11% (n=21). Of the total number of registrants, this equates to 3.5% of UHW users have unsubscribed, 2.5% of Morriston Hospital, and 8.5% of the Royal Gwent. Of the un-subscribers who entered their department (n=73, 34% of all unsubscribers), the most came from Medical Assessment Units (MAU) (16.4%, n=12), followed by Accident and Emergency (A&E) (15%, n=11) and COVID-19 Wards (12%, n=9). This equates to 5% of users who work on the medical assessment units have unsubscribed, 4% A&E, and 3% COVID-19 wards.

Post-Implementation Period

At the time of writing, the guideline continues to remain up to date and is available to healthcare professionals across NHS Wales throughout the second wave. Although formal implementation activity including email communications, social media, facilitation, and alignment activity has ceased as new registrants and guideline activity plateaued late in the first wave (Figure 7. 18). As per governance structure, the guideline content is monitored and updated through the Implementation Team.

Discussion

It was agreed by the implementation team that standard approaches to disseminating guidelines would not be effective in a rapidly changing scenario, such as that presented by the COVID-19 pandemic. To maximise the effectiveness of a national hospital COVID-19 guideline for NHS Wales, implementation science principles were adopted and lessons from implementation of asthma and COPD guidelines for Wales applied.

Central control through the implementation team was essential to ensure effective alignment and coordination of the strategy. The results suggest adopting such an approach has increased the rates of adoption of evidence-based practice provided by the guideline, which one would expect contributed to better outcomes for patients (416). Acceptability is the perception among implementation stakeholders that an intervention is agreeable, palatable, or satisfactory (13). Lack of acceptability has long been noted as a challenge to implementation (210). Typically, a paucity of evidence makes guideline design and clinical acceptance a significant barrier to wider adoption, but this was not the case with this guideline. This study demonstrated a rapid uptake of new registrants across the whole of Wales, mirroring the rise in new hospital cases and deaths. The consultant registration target surpassed estimates six-fold, with almost half of all consultants in Wales registering. Although limited in size, user responses to the survey gave excellent feedback, with an overall guideline rating of 4.1 out of a total rating score of five with over 80% of respondents requesting on-going email updates and nearly 70% of respondents endorsing the guideline by recommending it to others. Analysis of website traffic demonstrated sustained and significant engagement with the online resources, consistent with the role of this tool in informing clinical practice. The progressive rise in knowledge transferred during the initial phase of the pandemic, reflected new evidence and emerging recommendations to managing patients with COVID-19. The frequency of access is mixed, but most users accessed the information from work whilst on duty, using a work computer. Registration rate and platform activity was therefore lower on the weekend.

The implementation phase was initiated in three weeks from date of commissioning the guideline. The speed of delivery was vital to ensure it kept pace as the pandemic unfolded. It is therefore of interest that the Health Board with the lowest penetrance (ABU) was the region with the first surge of cases. COVID-19 affected different HBs asymmetrically and that early exposure to large numbers of cases before launch of the guideline reduced its effective uptake.

At the time of publication of the guideline, ABU already had 107 inpatients with confirmed COVID-19, representing 37.4% of their maximum number of inpatients at the peak of the first wave and a much higher proportion than for the other Health Boards, proportionally, this is three-fold or greater than the other Health Boards. Thus, even a short delay meant that the guideline lost traction since the window of readiness closed – that is, the extent to which organisational members are psychologically and behaviourally prepared to adopt an intervention (312). Readiness was low as the national guideline competed with local solutions already established to address the crisis. HCPs were more likely to view the guideline as undesirable, subsequently avoiding, or resisting its use (312). A corollory to this argument is that as the case load and death rate from COVID-19 reduced, the rate of new registrants reduced significantly. Overall, the clear conclusion was that one of the main drivers for guideline adoption was organisational readiness, a factor influenced by the timeliness of guideline implementaiton.

Whilst the guideline was available to everyone, the primary target group was senior decisionmakers with clinical responsibility for patients admitted with COVID-19. It is an accomplishment therefore, that 1159 consultants registered with the guideline – six-fold the intended target, which equates to 45% of all consultants appointed in Wales. This is a remarkable number given that many consultants, such as those in surgical specialities, pathology, mental health, and sub-specialities within medicine were not directly dealing with COVID-19 patients. It is reasonable to suggest that the guideline increased hospital capacity by preparing staff for their anticipated redeployment to COVID-19 wards. Evidence that consultants continued to find the guideline of value was that they are the professional group least likely to unsubscribe from email updates (0.4% of all consultants registered). This contrasts with medical students, who have the least decision-making responsibility, and were most likely to unsubscribe (15% of all medical students registered). Furthermore, medical students were the most likely staff group to move on from clinical placements requiring direct care of COVID-19 patients, therefore the information and updates would not be relevant to them. The un-subscribe rate is remarkably low for a typical communication campaign probably because the context of COVID-19 and little trusted evidence and instruction was available at the time, confirming the value proposition of this resource.

Despite endorsement and recommending guideline usage from Welsh Government, variation in penetration between Health Boards was observed, with over three times the number of staff

registering in SB compared to ABU. This appeared consistent across multiple indices of penetration accounting for differences in Health Board size. It is notable that SB employed a facilitator with previous expertise in implementation methodology and highly motivated to increase guideline adoption rates across the Health Board. They actively engaged in promoting guideline dissemination and utilised the facilitator dashboard significantly more frequently than the other facilitators used it. SB also mandated that all local HCPs managing COVID-19 patients register with the guideline and undertake the COVID-19 assessment, thus demonstrating good alignment with policy leads. No other Health Board offered a similar local mandate.

These observations coincided with better engagement and uptake within SB, particularly greater consultant penetration (74% of all consultants employed). Furthermore, SB had a significantly higher proportion of registrants undertaking the guideline assessment – translating to 68.9% of all assessments passed (627/910), demonstrating greater fidelity than all other Health Boards. However, the guideline facilitator was selected by the Health Board like for the other Health Boards, therefore the variation is largely circumstantial owing to little if any control by the Implementation Team. Whilst selection criteria were sent to each Health Board COO, the variation observed in guideline engagement highlights the necessity to manage this selection process closely to ensure the right people are appointed to do this essential role on a local level. This statistic highlights the value of carefully selected and active facilitators to encourage local-level innovation adoption (417,418). However, ABU had a similar number of facilitator interactions (9, 0.9%) to HD (1.4%), who had a considerably better relative uptake (by consultants employed, population, etc). Furthermore, ABU had more opinion leaders presenting on video than other Health Boards. This suggests variations in penetration accounted to more than these factors alone.

Impact

There was no existing exemplar way of working in what has become a sustained, global pandemic. Much of this is pioneering work based on evidence from previous viral outbreaks including SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome), but also management of ARDS (Acute Respiratory Distress Syndrome). The dynamic elements of the guideline have had 18 updates as the core clinical information has changed and are evidence-based and consistent with UK guidance such as NICE.

The purpose of the guideline was to improve clinical outcomes by standardising practice and reducing variation. It is of relevance therefore Wales had one of the lowest mortality rates in the UK for COVID-19 during the first wave of the pandemic (75.7 deaths per 100,000 people (confidence interval (CI) 72.7-78.6) versus 90.9 deaths per 100,000 in England (CI 90.1-91.8)) (419). In addition, the Intensive Care National Audit & Research Centre (ICNARC) report showed that intensive care survival rates for the first wave were more favourable in Wales when compared to the UK (61.7% compared to 59.6%, respectively), albeit not a statistically significant difference (420). These results are unusual since Wales has a significantly older population (421) and a higher proportion of people with co-morbidities than England (422), both known to be important factors for increasing the probability of death from COVID-19 (41,423). This data suggests that creating consistency and reducing variation by actively implementing a relevant national guideline may help to improve clinical outcomes, although there are cofounding factors that limits the strength of this relationship, such as lock down timings, adherence to isolating, and policy learnings from countries and cities closer to the epicentre of the pandemic.

Implementation Challenges

Barriers exist in the implementation of clinical guidelines (79). The three known barriers to the adoption of this guideline were:

- 1. NHS Wales IT issues: the guideline website was initially flagged as a phishing site as a security measure against new websites with 'COVID-19' in the URL (Uniform Resource Locator). This happened despite involvement of senior officials within NHS Wales Informatics Service (NWIS) who were made aware of the proposed URL, which demonstrates how easy problems can arise. Furthermore, the most common complaint from the target population was that the website did not always load on NHS computers, and for some, the videos would not play. This was a common complaint for staff using out of date versions of Internet Explorer.
- 2. It is likely that many potential users of the guideline did not access the platform because they had to register with it first; albeit by adding minimal personal information (name, profession, organisation as mandatory; specialism and department as optional). Google Analytics bounce rate is on the high side (55%) and especially high for mobile phone browsing (65%). This is likely because international users could not access the

- guideline and repository unless they worked for NHS Wales and formally registered with the website, at which point they leave the site. Whilst the alternative option to provide access open source (no registration) was considered, it was decided that minimal registration information was necessary to monitor metrics of engagement by Health Board and profession at the very least.
- 3. Of interest, nurse registrants remained a substantially lower proportion of the total nursing workforce in Wales (4.6%) when compared to consultant doctors (45%). However, they were not the primary target group and subsequently there was inadequate alignment within the nursing hierarchy to support usage and adoption of the guideline. Barriers to nurses (and other allied HCP) in accessing the guidelines included the following: first, nurses rarely use NHS emails so would not get notifications of updates, second, it was impractical for ward-based nurses to access the guideline via QR links as they are prohibited from using personal mobile devices whilst on duty. Third, some hospital firewalls blocked the video play function from generically logged on ward-based computers. This latter problem happened despite involving national IT specialists in the planning phase. Therefore, dissemination activity was greatest in those with greater access to NHS emails or–personal mobile devices. This observation emphasises the importance of considering technical practicalities in real world settings as potential barriers affecting user engagement and satisfaction (79).

Updating the Implementation Process Model

This study highlights that timeliness has a fundamental influence over the implementation process. It is proposed that timeliness has a causal relationship with contextual factors, e.g., a highly prevalent disease, a commonly used clinical procedure, high associated costs, and current variations in practice (267), which the contrast between the two guidelines demonstrates. The adapted implementation process model includes two high-level factors that limit or facilitate implementation impact that must be considered in any implementation programme. Leading up to phase four – implementation is time-limited; that is, ensuring the interventions are available at a time when they are needed. The magnitude of implementation impact (assessed during phase 4 and 5) is context-limited; that is the conditions of the environment within which the interventions are being exposed to (Figure 7. 25).

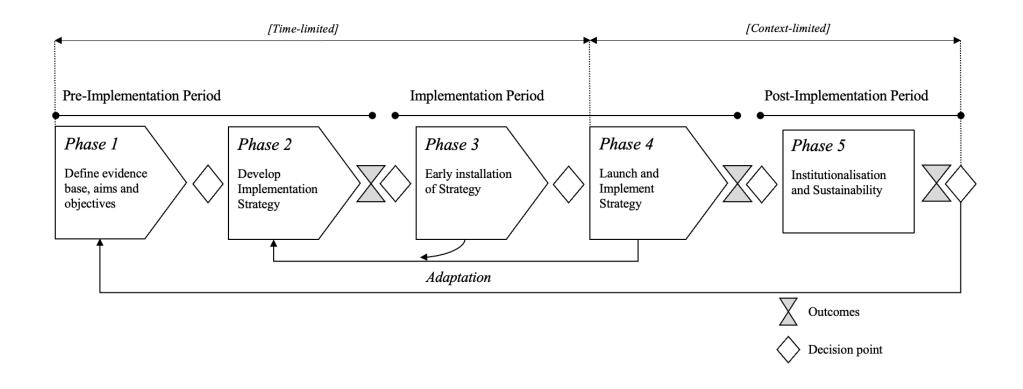


Figure 7. 25: Adaptation to the implementation process model, with the addition of time-limited and context-limited periods.

Strengths

This evaluation applies a structured approach to guideline implementation under highly unpredictable circumstances and testing a similar conceptual framework applied to COPD and asthma.

Some key features of the framework were amended to reflect the very different circumstance. Quantifying the impact of timeliness, i.e., the rate production and rate uptake was a key outcome not previously reported. Furthermore, we confirmed the applicability of tested strategies including use of opinion leaders, local facilitation, and local mandate to supplement national policy. We applied the same concepts of acceptance-adoption-adherence outcome classification. We showed that although acceptance and adoption can be measured, adherence is influenced by multiple cofounding factors. Here, adherence to the All Wales COVID-19 hospital guidelines was likely also influenced by local pathways (even geographical layout of hospitals), other national guidance including NICE (424) and WHO (425), lock down (426,427), background comorbidities and health inequality in Wales (428), clinical capacity, and capabilities (as some systems became overwhelmed) (429), as well as policy learnings from experiences of other countries (430,431).

The COVID-19 guideline was designed to be a dynamic tool that updated frequently. Whilst the core hospital pathway remained unchanged (printed and put up across all hospitals in Wales) the QR codes and corresponding email updates changed frequently as new evidence emerged and agreed recommendations were updated. This 'dynamic' design to guideline implementation offers a novel approach to guideline implementation that has not been reported in the literature. It addresses the challenge of recommendations becoming quickly out of date and irrelevant and provides the very latest evidence-base that is both attractive to users and theoretically beneficial to patients. However, frequent changes to guideline recommendations should be considered a potential risk impacting fidelity as users could become confused and overwhelmed. Furthermore, some changes may only be relevant to experts in the field with particular interest in the topic. Frequently changing patient management plans will increase the cost of dissemination and potentially have adverse impact to clinical outcomes as broad guideline recommendations surpass individualised patient care – even delaying highly focussed interventions. Clinical management for most established chronic diseases will not change

anywhere near as rapidly as was observed in the early stages of the COVID-19 pandemic. However, the principles applied in this guideline could be replicated for other emerging disease areas or future pandemics. A specific evaluation of this approach will require further exploration.

Limitations

The evaluation fails to capture the acceptance of the guideline by Health Board executive leaders. Despite good alignment and anecdotal support from many executive leads noted, for example, mandating the guideline by the Clinical Director in Swansea Bay, more granular analysis of their opinions would provide greater clarity regarding the institutionalisation and strategic positioning of the guideline for replication and refinement in the future. Qualitative assessment of their opinions through semi-structured interviews could have provided further insight.

High penetration of users in SB was a success. This was associated with facilitation and mandating training. However, further exploration into the weighted impact of facilitation and mandate, and other variables that were not routinely measured, such as local pathways or lack of them for instance, was not explored.

The benefits of facilitation are well known (319,417,418). but the impact of mandating training is mixed – mandatory training is compulsory learning deemed essential for safe and efficient service delivery and personal safety. It is designed to reduce organisational risks and to comply with local policies and/or government guidelines (432). Mandatory training is traditionally unpopular, and there is a perception it decreases motivation to learn resulting in passive learning and disinterest. Some education theory-related barriers to learning that may reduce the effectiveness of mandatory training include employee resentment, frustration, or anger due to a lack of control, lack of interest, perception of irrelevancy to their specific workplace context, and workplace time pressures (433).

Some educationalists argue more behaviour change, educational impact, and improved patient care are achieved through experiential, active learner, peer group learning (434). Furthermore, mandating requires some element of recourse that prohibits engagement with other activities or evokes induvial punishment, such as, impact on pay, progression, and development, a loss

of professional registration and indemnity claims related to work-related injuries, or ill health (435). Yet there were media reports and early papers on the high number of healthcare professionals becoming seriously unwell from the virus. It is also unclear what negative impact mandating training in SB had on subsequent behaviours towards the guideline. Comparing perceptions from SB against those from other Health Boards (where no mandate was in place) would have provided an in-depth exploration of key drivers to engagement or disengagement comparing two local implementation techniques (passive active learning v mandate).

Penetration data were limited by the accuracy of the information held on the StatWales website (335). The responses from different clinicians were variable: ITU Consultant responses were remarkably low, and we did not access the ITU clinical network for dissemination nor clinician numbers. We could not get reliable data on the total number of active A&E Consultants. It is also possible that responders supplied incorrect details (profession/Health Board) on registering.

Summary

Knowledge transfer is an essential component of implementation (60). However, during the first wave of the COVID-19 pandemic, demand was immediate, the evidence-base was initially weak, and subsequently subject to rapid changes. Therefore, a decisive and adaptive communication system was necessary to render the guideline usable, accessible, effective, and sustainable (436).

The evaluation shows the dissemination and implementation of a guideline can happen in a matter of days/weeks, provided the context and demand allows, and an effective implementation framework is applied. However, for one Health Board (the first affected at scale in Wales), even this was too late, and they were unable to engage. This emphasises the timely publication and dissemination within a window of organisational readiness, is paramount to guideline implementation success.

Successful implementation is dependent on the relationship between three key factors – the nature of the evidence, the quality of the context, and facilitation (2). We propose a fourth factor – timeliness. Timeliness is considered here: the optimal window of organisational readiness to adopt an innovation. The national experience suggests that when this window is missed it adversely impacts guideline penetration.

A key enabler was an active and experienced central implementation facilitator, which resulted in three quarters of employed consultants registering with the guideline in the most engaged Health Board. The dynamic features of the guideline have undergone 18 iterations highlighting the rapidly changing context. The platform now contains 30-fold the number of instructional videos from the six proposed in the original specification. This is largely testament to the implementation success and value proposition offered by the guideline.

The COVID-19 pandemic has exerted extreme pressures on governments and health systems around the world to react at a scale and pace far beyond their norms of practice. The problems and subsequent enquiries into Government handling, regional building of field hospitals, PPE (Personal Protection Equipment) procurement and vaccination strategies can only be understood in this context. It is unreasonable to expect organisations to replicate the speed of implementation of the guideline across other clinical areas, particularly without the urgency

imposed from COVID-19. However, this study suggests the implementation methodology underpinning this COVID-19 guideline is valid, replicable, and transferable to other disciplines.

Whilst measuring clinical outcomes, or the efficacy of the recommendations within the guideline was not the purpose of this study, it should be noted that the ICNARC report has demonstrated that ICU mortality in Wales was lower than the UK average for the first wave (420). In addition, Wales had a statistically significantly lower mortality rate from COVID-19 than the rest of the UK for the first wave according to the Office for National Statistics (419). Whilst several factors will influence this statistic, it supports the notion that the potential we have in Wales to deliver in a rapid and collaborative manner has been used to full effect in this huge project.

Chapter 8

Conclusions

Adaptations and Future Application of the Framework

Chapter Objectives

- 1. Present the adapted framework and modifications from application in two discrete settings demonstrated in the two case studies.
- 2. Reflect on the purpose and objectives of the study to highlight its limitations and necessity for future research.
- 3. Summarise the impact of this work and next steps.

Thesis Purpose and Value

The structured process of implementation is fundamental to the delivery of socially acceptable benefits because programme outcomes can only be realised once implementation has been successful (37). Whereas guidelines capture the evidence-base, implementation science is concerned with the structured process of widespread compliance with evidence-based practices (2). However, clinical practice is often incongruous with recommendations within clinical guidelines (76–78). Lack of clinician knowledge, understanding and awareness of guidelines are considered some of the main changeable barriers to guideline adherence (76,79).

The fundamental goal of my work was to develop a framework to apply a strategy for guideline implementation to achieve widespread acceptance and adoption of new respiratory guidelines by healthcare professionals across NHS Wales. We applied the broad literature of implementation frameworks, implementation theories, and implementation processes in healthcare (86) (Step 1), tested and adapted following application to the two distinct settings (Step 2) (Figure 8. 1). The emergence of COVID-19 impacted this effect for asthma and COPD guidelines, but it also offered an opportunity to apply the framework into an environment with a remarkably different context.

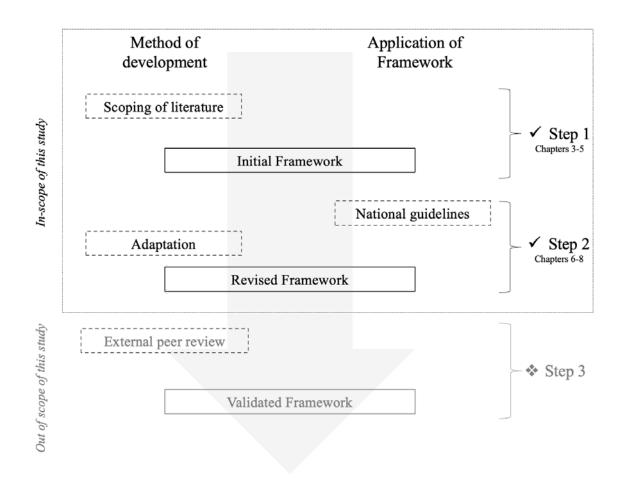


Figure 8. 1: Development and Application of the Implementation Framework based on Pfadenhauer's (26) validation of their CICI framework.

Developing an Implementation Framework

At a higher level the framework provides the necessary components for implementing clinical guidelines at a national level – the *Programme* within which it sits, the *Implementation Strategy* that determines what is being implemented, and the *Implementation Process* that guides how to implement the strategy. There is no other framework in the literature that presents it in this way. Furthermore, delineation of the implementation process and implementation strategy reinforces the clarity separating two fundamental features of any implementation programme. This framework encompasses the work of others from an academic and perspective and is intentionally simple and easy to remember from a practical perspective (Figure 8. 2).

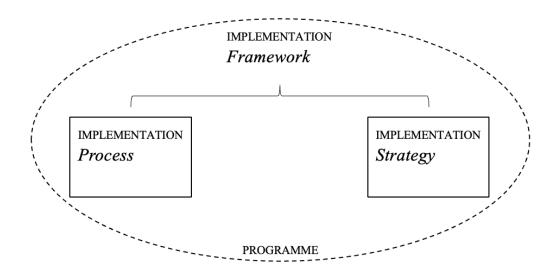


Figure 8. 2: the high-level framework, which highlights the three core categories – the programme, implementation strategy, and implementation process.

My main discovery was to distinguish the two functions of implementation practice that sits within a programme of work:

- 1. An implementation process, and
- 2. An implementation strategy

The overall framework applies a structured strategy comprising *implementation interventions* and *implementation drivers* with a coordinated process of *implementation phases* and *implementation outcomes* to generate widespread utilisation of clinical guidelines.

The high-level framework is expanded to include the additional domains deemed essential for implementation practice (Figure 8. 3). We applied these principles in implementing two sets of clinical guidelines in very different contexts and believe these principles can be applied to other contexts.

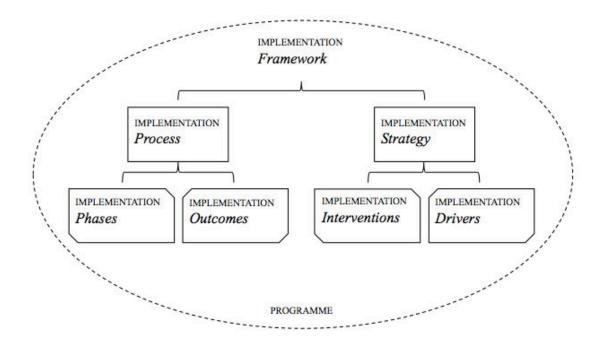


Figure 8. 3: Implementation process and strategy domains proposed in this study as a higher-level framework to offer easy recall to implementers.

Implementation Process

Synthesis of the literature deduced actions according to the periods of implementation — whether this was the work required before actual implementing happens (pre-implementation period), the actions of implementation (implementation period), and/or what happens after implementation has taken place (post-implementation period). Notably, there appears to be a predominant focus on the pre-implementation period, with very few frameworks/models addressing the entire implementation journey. Furthermore, assessment of classic theories was undertaken, emphasising the work of Rogers (104) in particular, because implementing at scale typically requires engagement from a large population of people. Rogers proposed groups of engagers neatly dispersed according to their likelihood to adopt an innovation. The implementation process within the framework is designed to leverage this observation by systematically addressing each group (early adopters, majority, late adopters, etc.) sequentially, to increase the potential for widespread adoption of the innovation over time (Figure 8. 4).

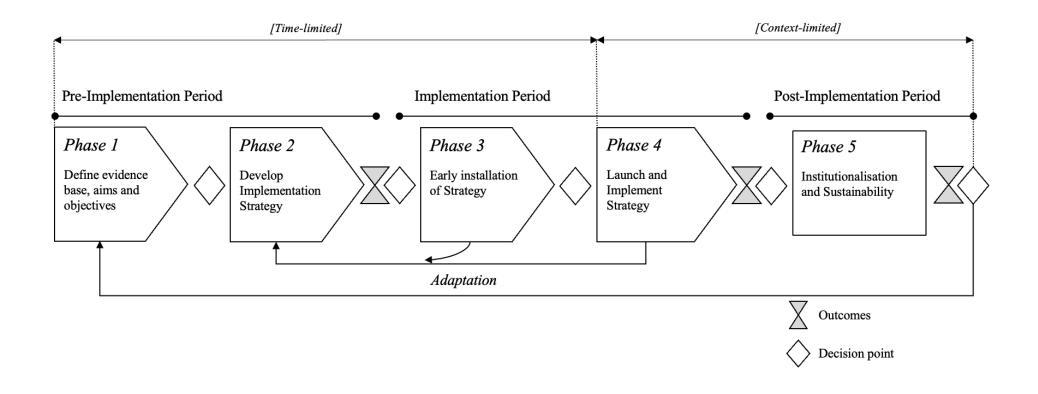


Figure 8. 4: Adaptation to the implementation process model, with the addition of time-limited and context-limited periods.

Context Matters, but so does Timeliness

Where the context is focused to a new disease with considerable political address and media coverage, the desire and urgency for the right information quickly is a necessity. For COVID-19 this is a unique scenario that contextual influence is unlikely to be matched, certainly in our generation. However, the implementation framework was applied, and a strategy delivered at a pace unrecognisable to a typical large-scale programme, and indeed the COPD/asthma guidelines.

Timeliness is proposed here as a key function of implementation, that should be viewed alongside the three proposed by Kitsen *et al.* Furthermore, time is a core factor according to the original work on diffusion by Rogers (104), however, seldom is it referenced as a barrier or enabler for implementation, only that, ten years between innovation and routine application in practice has been adequately termed the 'implementation gap' (437).

In his well-known paradigm the Diffusion of Innovations Theory, Rogers emphasises that in addition to communication channels and the social system within which innovations are spread – time is considered a core element when categorising adopters into categories of engagement. The innovation-decision time is the period between processing the cognitive action between first knowing about the innovation and forming an attitude towards it (positive, negative, or neutral), to the decision to adopt or reject the innovation, respectively. Whilst mass media and modern mechanisms using social media are initially important to diffusion of innovations (438), inter-personal and inter-professional networks become more influential later in the knowledge-adoption process to reduce uncertainty around an innovation. The knowledge-attitude-gap is the process of applying what is known into practice (439).

The decision-making process involves exposure to essential knowledge, persuasion, decision, implementation, and confirmation of the innovation. Innovativeness is the degree to which individuals within the target population perceive new ideas and are open to change. Furthermore, the rate of adoption is perhaps the most valued and desirable outcome of any diffusion activity, that indeed companies convert billions a year investment into multi-fold more in profits by influencing the behaviour of their target audiences (440). The rate of adoption relates to the number of people accepting an innovation over a given period. The

desire for most implementing organisations therefore is to increase the number of people adopting its innovation, in the least possible time.

The differentiation of contexts between the two case studies presented here highlights the difference in pace and urgency of implementation. However, for both cases, it is necessary because each context requires it. Some interventions require rapid deployment, which increases the potential for widespread acceptance, whereas others require more concerted efforts in the early phases to achieve wider acceptance and familiarisation.

Adaptations to the Framework

The framework has been modified based on observations of the COPD/asthma guideline implementation. The implementation intervention checklist was updated to consider the findings from thematic analysis of potential guideline adopters. This was deemed relevant to wider strategies and was therefore applied to the development of the strategy for implementing the COVID-19 guidelines. The implementation process was updated following lessons learnt implementing the COVID-19 guidelines. These are focused to three key areas:

- (i) The implementation outcomes are measured as transitional points between periods rather than phases, as the latter requires more flexible intervention-specific signals of progress that cannot be generalised.
- (ii) The process model was adapted to include a feedback loop at the final phase of implementation to initiate formal review of the intervention, adaptation to the strategy as required, and potential initiation of the measurement of clinical outcomes, given implementation has been achieved.
- (iii) The contrast between COPD/asthma guideline and for COVID-19 has considered timeliness to be a key driver for the implementation process. Furthermore, the implementation process model emphasises two high-level factors limiting implementation impact. That leading up to phase four where implementation should be considered time-limited; that is, ensuring the interventions are available at a time when they are needed. Whereas the magnitude of implementation (phase 4 and 5) is considered context limited. This is determined by the factors relating to the environment within which the interventions are introduced.

To introduce a new clinical guideline is complicated. Doing so on a national scale, spanning multiple organisations and professional groups adds further complexity, simply because, the value proposition must be relevant to all, and they must all accept them before they replace something else currently used.

Two major things differentiate the COPD/asthma guideline implementation to the COVID-19 guidelines. Firstly, the COPD/asthma guidelines were introduced where local alternatives were already in place. This was not the case for the COVID-19 guideline. Secondly, the COPD/asthma guidelines did not address a novel problem; therefore, the contextual lever for adoption did not exist in the same way as the COVID-19 ones. Kitsen *et al.* offer widely accepted reflections of the core factors which influence implementation. They conclude that context is considered one of only three major drivers to implementation. Whilst this was experienced through implementing COVID-19 guidelines and comparing this with COPD/asthma guideline implementation, it has been difficult to measure this objectively.

Thematic analysis of interviews with potential users of the guideline identified several themes, which aligned with the implementation strategies identified in other studies (155,169). Implementation interventions are designed from the results of the analysis of the questionnaires and the outcomes of thematic analysis listed against the recommendations from the ERIC study (169). In principle, to generate potential for widespread utilisation, implementation interventions should be:

- 1. Informative
- 2. Instructional
- 3. Usable
- 4. Accessible
- 5. Helpful
- 6. Relevant

Furthermore, several core drivers must exist which facilitate the potential for awareness and acceptance of the interventions:

- 1. The programme should consist of an implementation team, supported by an executive sponsor or mandate, which manage the governance process and structured plan against the implementation process.
- 2. A Power Layer should exist to act as an early adopter to trial interventions prior to them facilitating local utilisation.
- 3. The target organisation should be known and its current demands that may impact readiness to adopting a new intervention.
- 4. The target population must be given the authority by their organisation and have personal and professional capacity to utilise the intervention as prescribed (Figure 8. 5).

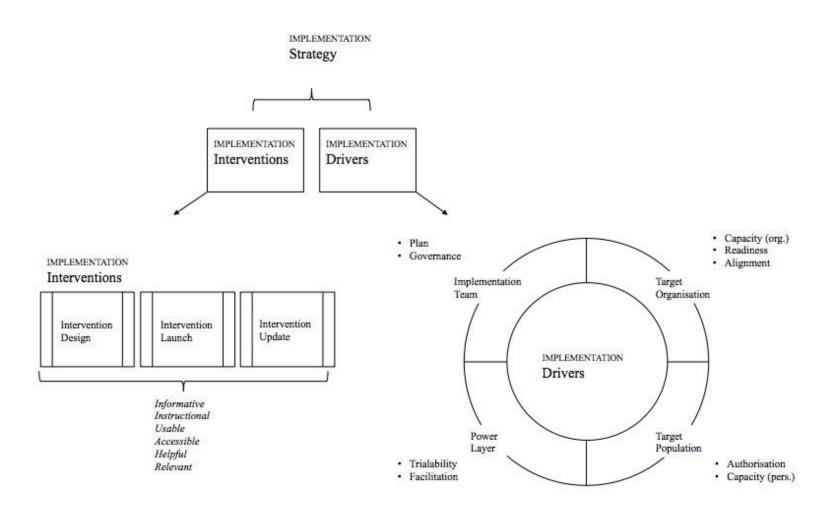


Figure 8. 5: Updated criteria for the design, launch and updating of implementation interventions and the drivers of an implementation strategy.

Impact of the Strategy

The evidence from the two case studies presented in Chapters 6 and 7 indicates widespread adoption of the guidelines. Where clinical guidelines encapsulate a summary of evidence-based practices, implementation strategies (knowledge, education, training, incentivisation, prompts, etc.) act as support structures that help the environment to align with the recommendations within them. However, clinical guidelines are valuable but "useless if they are poorly implemented and too complex for adoption" by healthcare professionals (281)(pg.475). A strong consensus from clinicians was achieved to create national guidelines for asthma and COPD (when asked in a survey 98% were supportive of this endeavour). The guidelines simplify choice for prescribers and offer an easy-to-follow step-by-step approach. More recently, the COPD and asthma guidelines have been updated to include information on the green agenda in prescribing. This is having been achieved because the efforts to accepting national guidelines were achieved and all seven Health Boards formally adopting them. Supplemental educational packages to support nurses and other HCPs to deliver standardised care to patients with not only asthma and COPD but for other respiratory illnesses has been created, which align the guidelines with national audit via the RCP. Next, to bridge the gap between learning new practices and applying this in practice, a digital QI will be hosted on the same digital platform. Specific QI projects can be published and shared to promote best practice. Whilst this falls outside the scope of this study, it emphasises the potential impact of achieving widespread utilisation of a single digital platform for education and relevant clinical instruction to a particular target audience. To support patients (and prescribers), selfmanagement apps align to the guidelines, with videos about how to take the relevant inhaler correctly, address the green agenda and a range of self-management advice. They are free to use and bilingual for those who use Welsh as their first language. The newest iteration of the apps enables a simple survey to be undertaken every month on asthma control. At this stage the focus is to support patients with asthma and COPD, however, successful implementation will result in powerful data at a national level on how well controlled Welsh patients with asthma or COPD are.

In March 2020, a COVID-19 digital hospital guideline was developed within two weeks of approval. This required user registration and meant that we were able to rapidly disseminate to all registrant's new information as it became available. We hosted national guidelines such as

NICE and BTS as resources, but the predominant mode of delivering updates was through a video format with local experts distilling information into simple key management points. Through this mechanism we were able to measure user engagement. Since the log in requires users to declare who they are and where they work and other details, we know exactly who is accessing and getting the information at any time and what they are looking at. This allows us to update the guidelines in a targeted way to focus on what is needed. Following the successful utilisation of this guideline, a COVID-19 primary care guideline to support GPs diagnosing and referring COVID-19 patients was developed using the same approach. This meant that we had a strategic approach to managing COVID-19 in the community, with GPs referring those with evidence of organ dysfunction to specialists and the rest to multi-disciplinary teams.

A digital approach has helped to rapidly disseminate information to a wide target audience updates that would not have been as effective through standard guideline dissemination strategies. During the first wave of the pandemic, nearly 50% of all consultants of any speciality in Wales and nearly 100% of those from the key specialities (respiratory medicine, intensive care and accident and emergency medicine) were registered with the guideline platform. In addition, Welsh government provided ongoing support to run a national data collection on COVID-19 patients on the same platform. It is a retrospective collection, based on case notes and submitted by each hospital. It wasn't mandatory, but it had the prerequisite sponsorship from the CMO for Welsh Government, who wrote to all medical directors in the country stressing how important and necessary this was. Nation-wide data is now available from three waves of COVID-19. The data included mortality, comorbidities, vaccination status and other data on patients with COVID-19, including nosocomial infections. Some of the data collected on the latter was published in Thorax (393), where it was demonstrated that nosocomial COVID-19 infection had higher mortality rates than community-acquired cases.

Most recently, the framework was applied to implement a patient-facing App for Long-COVID. The COVID-Recovery App is a self-support tool, designed by a multi-professional team, that aligns with our national Long COVID-19 guideline for Wales. Patients can put their parameters in and the recovery goal they want to achieve, and the app directs them to achieve it. The App has amassed 12000 downloads in Wales to date and there continues to be 20-30 downloads per day on average, generating political support through launch by the Health Minister and endorsement from patient groups and the third sector.

This framework contributes to the literature as it focuses the entire implementation journey from proposal to institutionalisation. Most implementation frameworks have predominance towards the pre-implementation phase; that is, the period of discovery of the evidence base focused around the intervention(s), perhaps reflecting the pre-disposition of evidence-based practices and discovery of new medicines, treatments, and practices. However, the transition between the activity of implementation and the post-implementation phase is poorly understood and this study fails to offer any more insight, beyond acknowledging that indeed, this is observed in practice. Distinguishing the rate of engagement with the COVID-19 guideline, suggests clinical guidance is most relevant when it is new and that large, focused efforts are required to raise awareness to ensure it is used at a time when is indeed needed most. For the COVID-19 guidelines, the rate of access to the guideline learning was proportionate to the number of COVID-19 cases and admissions, but also to the number of email updates distributed to the target population. Another way of looking at it – the more novel COVID-19 was, so too was interest in the guideline and therefore the rate of engagement observed. However, once COVID-19 became business-as-usual, then so did hospital processes and subsequently the need to access the guideline dropped considerably. This likely reflects the transition into the sustainability phase, thereby reducing the requirement for concerted implementation activity or the requirement for de-implementation (441).

Limitations to this Study

For each of the chapters a detailed description of the limitations each component of the study has been described. A simple implementation framework does not nullify complexity of implementation practice in healthcare (27,31). Implementation is influenced by several essential disciplines that frequently merge, overlap, or contradict. Each may have their unique intricacies and nuances driven by independent academic rigor and application across all aspects of healthcare and beyond. Take, for example, behavioural science, team science, project and programme management, data science, social science, complexity science, evidence-based healthcare, quality improvement, political science, human resource, procurement, service redesign – each influences the practice of implementation. Michie et al., demonstrate this effectively in their Behaviour Change Wheel, which emphasises a behaviour system, influenced by intervention functions and policy categories (172). This acts as a useful checklist for planning most interventions in healthcare. However, it does not address the complexities of each function, nor the strategies to deliver effectively or to overcome the likely challenges to introducing new interventions. The work by Greenhalgh and Papoutsi broadens the perspective of the 'know-do gap' to include social and ecological lenses that perhaps illuminates the narrow scope of implementation science in its endeavour to comprehensively bridge this gap (27,31). The challenge assigning and measuring quantitative and qualitative signals of adherence to clinical guidelines on a national scale cannot be captured through the implementation lens in isolation. For further evaluations, from a guideline adoption perspective, this can be assessed against patient, clinician, and system level (36) (see table 8. 1). Some of these aspects, such as a longitudinal assessment of patient, clinician and process-specific indicators need to be addressed outside this work.

Patient	 Characteristics do not fit clearly with the guideline. Preferences cannot be reconciled with the guideline recommendations. Cannot tolerate/adhere to recommendation so an alternative intervention is pursued.
Clinician	 Does not recognise that a guideline exists for the clinical problem. Does not understand and correctly apply a guideline to the clinical situation. Disagrees with guideline and delivers care based on alternate evidence or personal practice experience.
System	 Includes guidelines from different societies that cannot be reconciled. Limits feasibility, availability, or affordability of the intervention. Limits time to apply guidelines within a busy setting with lack of necessary clinical support.

Table 8. 1: Common barriers to guideline adherence for patients, clinicians, and the system. Adapted from an article by Ryan (36)

Measuring impact of large-scale implementation programmes can be difficult, particularly where a controlled methodology cannot be applied. This research applies an exploratory mixed methods sequential study design, which was considered effective for greater versatility in discovering novel concepts and ideas (85). However, whilst this methodology has helped generate a specific framework for NHS Wales, others have applied methodologies parallel cluster or stepped-wedge designs to help determine a more robust objective assessment of cause and effect (99). The parallel study involves one cluster exposed to the intervention whilst the other remains unexposed, whilst the stepped-wedge design includes an initial period in which no clusters are exposed to the intervention before, at regular intervals (the "steps") one cluster (or a group of clusters) is randomised to cross from the control to the intervention under evaluation. This process continues until all clusters have crossed over to be exposed to the intervention. Data collection continues throughout the study, so that each cluster contributes observations under both control and intervention observation periods. This design has been applied at scale in other successful programmes that subsequently identified other factors that were not observed when interventions are exposed to the sample simultaneously (99). Applying a parallel cluster or stepped wedge methodology to this study, for example at Health Board, or primary care cluster level, would have added a more robust mechanism to compare implementation impact. However, as national policy was a key enabler for this study, it would be difficult to expose each cluster in a stepped design. Furthermore, it would be almost impossible for the most latterly exposed clusters to being completely blinded to this type of intervention.

The effect of this intervention might be confounded by temporal trend, particularly during COVID-19 pandemic where the evidence-base challenged quickly, and a proliferation of guidelines and local pathways were developed. Temporal trend was observed in Matching Michigan (234) through undertaking a controlled stepped wedge methodology (98); however, this remains a feasible explanation for the proliferation in engagement and plateau in engagement observed in the COVID-19 guideline case study (Chapter 7).

Whilst there are some clear lessons learnt from COVID-19 case study, they may not be applicable in other settings. The first challenge is to demonstrate an outcome that outperformed the secular trend. The second is the decline effect, where an initially promising intervention appears not to deliver equally successful results when attempts are made to replicate it in new settings. Matching Michigan may be an example of both (99). Whilst the rate of infections

declined to the rate seen in Keystone over the course of the programme, there was evidence of strong secular trend anyway towards decreased infections. Therefore, when designing and delivering interventions to improve quality and safety, risks of decline effects and difficulties in demonstrating added value over the secular trend might be averted by improved understanding of programme mechanisms and assigning tight performance metrics within the control of the programme delivery (234).

Whilst an aim of this study was to encourage widespread adoption of new clinical guidelines, the ability to accurately quantify the target population was challenging. Both case studies have attempted to do this through publicly available sources (e.g., StatsWales), which, one would expect to be accurate and up to date. However, anecdotally, through discussions with clinical leads (and KEL), these numbers do not reflect the actual numbers employed – for example, the number of intensive care consultants in HD are thought to be higher than that recorded by StatsWales. Whilst a judgment can be made regarding the penetration of engagers, this must be done with caution as it is limited by the quality and precision of its source.

Furthermore, to confidently assess adoption with fidelity requires more than subjective deduction based on user feedback and assessment scores of engagers. It does not accurately measure fidelity beyond the periods assessed. For example, acknowledging adoption of guidelines from a survey is one level, completion of a competency programme in diagnostic spirometry another, feedback from a survey indicating practices being applied is the next level. However, an objective assessment of quality over time is necessary to measure true adoption. The intention within the programme is to measure key KPIs such as spirometry recording, inhaler prescribing activity, and cost, for example. However, notably, each has its own challenges on a national level. Further, the study does not measure the social impact of the implementation efforts. Whilst it is accepted clinical outcomes cannot be measured immediately, and the likely opportunity to do so falls outside the scope and timeframe of this study, further assessment of clinical outcomes could be incorporated during the planning phase. Access to this information may be a challenge, however national datasets exist (442). In addition, for both case studies presented, only those engaged with the implementation strategy were observed and reported. Understanding barriers to those that did not engage would offer critical insight for improving the strategy to broaden engagement furthermore.

Future Research

Fundamentally – the guidelines exist, and they are being used. Therefore, one should now not consider these novel at all, nor is the implementation strategy an innovation anymore. Whilst, therefore, we consider that implementation of both guidelines has indeed reached the sustainability phase; what happens next? And what degree of implementation activity, or deimplementation is required to achieve institutionalisation, or dispansion of the interventions, respectively? Assessment of adherence and sustainability requires time. This naturally falls outside of the scope of this work. Yet it warrants further exploration as this must be considered integral for determining the degree of effort and investment required to achieve long term return and socially significant outcomes.

Regarding the formalisation of this framework, the final step is to validate the framework through a Delphi process, as a critical appraisal of the framework through peer review. Parker and colleagues set out to develop an implementation process model using Delphi questions via survey to 54 international experts in knowledge translation and implementation (137). The model was built upon elements of the CISG, which were originally drafted from domains of the Knowledge-activated Tools (KaT) Framework. Through a two-round modified Delphi study, participants commented on all aspects of the model, specifically focusing agreement on operationalised domains, subdomains and elements, structure and order, labels/terminology, and applicability to target users. Whilst the work has generated important lessons and agreement from international experts it has not yet matured into a useful model for implementers. However, the author intends to use the model to develop a user-friendly Implementation Support Tool.

This structured approach to the development and implementation of national innovations engaging a large and broad target audience would potentially be applicable to any disease area. There is also further scope to apply the framework to other clinical guidelines, at a national or local level, in different contexts or specialties, or for interventions beyond clinical guidelines. However, the true clinical impact of this approach is yet to be determined and until this is demonstrated on a national basis, can the true efficacy of this framework be proven.

Closing Remarks

At the core of implementation science is the question:

"How do we get what works to the people who need it, with greater speed, fidelity, efficiency, quality, and relevant coverage?"(74).

For the COVID-19 Hospital Guideline this was achieved through a rapid assimilation of high-quality digital communication tools that resulted in comprehensive penetration of the target population, coinciding with positive outcomes for patients in Wales. For the very different context of asthma and COPD, whilst widespread acceptance and reported adoption has been shown, their impact and value has yet to be ascertained.

As we move into the sustainability phase of the framework, we have demonstrated that applying a structured and centralised approach to implementing national clinical guidelines at scale is achievable.

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Appendix A: Initial letter to the Health Minister

Mark Drakeford AC / AM
Y Gweinidog lechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services





2 September 2014

Den Mr Jefferies

Thank you for your correspondence of 29 July in regard to the Respiratory Health Delivery Plan, inviting me to meet with you to discuss your proposition of putting Wales at the forefront of quality spirometry screening in the UK.

I am very interested to learn more about the approach you advocate, but rather than wait until a space becomes available in my diary, I would be grateful if you could meet with my respiratory health policy official to discuss your proposals. Please contact

who can be contacted on e-mail to arrange a mutually convenient date and time.

Yours siceregy, Mank Orealetans.

Mark Drakeford AC / AM
Y Gweinidog lechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Wedi'i argraffu ar bapur wedi'i ailgylchu (100%)

Printed on 100% recycled paper

Appendix B: Semi-structured questions for interviews with nurses

Research question: what factors influences clinicians to engage with the education programme

<u>SEMI-STRUCTURED INTERVIEW GUIDE – STAFF PARTICIPANTS</u>

Interview date:		
Interview time:		
Location:		
Staff Initials:		
Staff role:		
Interviewer:		

INTRODUCTION

The aims of the national education programme are to enable equitable and standardised access to healthcare education to facilitate national excellence and lean management of respiratory healthcare by supplementing national clinical guidelines for Wales. The objective of the programme is to educate clinical staff throughout Wales in conjunction with the key priorities set out by the Respiratory Health Implementation Group (RHIG). The programme will feature clinicians, patients and carers dealing with respiratory disease as part of an asynchronous, personalised formal and informal e-learning programme, using innovative and engaging interactive video and animation techniques.

I would therefore like to ask you a series of questions about the factors that you feel may help in understanding the expectations of respiratory practitioners and the best mechanisms for rolling this programme out across Wales. This interview should take around 30 to 45 minutes.

Your participation is entirely voluntary, and you are free to withdraw at any time. If you do not wish to answer any questions, then please say so. There are no right, or wrong answers and I am interested in your own personal point of view. Your identity will remain strictly confidential, and it will not be possible to identify individual members of staff from the results.

I will want to record our conversation so that I do not have to write everything down. Again, these recordings are strictly confidential and will not be linked with your name in any way.

Please complete the consent form provided.

QUESTIONS

Utilising the *learning transfer system* inventory:

1) ABILITY TO USE KNOWLEDGE AND EXPERTISE

a. Personal capacity for transfer

Question 1: Can you tell me a little about yourself and your work background?

- i. How long have you been in your current role, and in healthcare/NHS?
- ii. What specialities have you worked in?

Question 2: When did you last undertake CPD?

- i. What was it about?
- ii. Has it improved /changed practice/

Question 3: What enables you to do CPD?

Question 4: what prevents you from doing CPD?

- i. Openness to change yourself/your practice
- ii. When does most of your CPD occur during or outside of work hours

b. Perceived content validity

Question 5: What training requirements do you feel that you need to support the management of respiratory patients, in particular?

i. For example

c. Transfer of design

Question 6: How do you judge your IT skills?

i. Tablets/smart phones

d. Opportunity to use learning

Question 7: Is there anyone that socially influences your learning?

- i. Who? Managers, peers, family
- ii. How?

<u>Question 8:</u> In your current workplace can you think of any opportunities that you had to apply what you've learnt into practice?

- i. Could you give an example of when this has worked well
- ii. What are the limiting factors to applying new skills in practice?

2) MOTIVATION TO USE KNOWLEDGE AND EXPERTISE

a. Motivation to transfer learning

Question 9: What motivates you to undertake CPD?

i. Do you do CPD to improve knowledge/reinforcement or for the qualification/points

Question 10: What is your preferred way of learning?

i. Do you prefer to learn as a group, your peers, or as an individual?

- ii. Do you prefer to learn in a classroom environment, online, self-study etc?
- iii. Humour, opinionated/hard/relaxed

Question 11: With regards your preferred ways to learn, is this possible in your current role?

- i. If yes, are there any other ways you learn in your current role
- ii. If no, are there any alternatives?
- b. Performance outcomes and expectations
- c. Transfer effort performance expectations

3) WORK ENVIRONMENT DESIGNED TO SUPPORT USE OF KNOWLEDGE AND EXPERTISE

a. Personal outcomes

Question 12: How does your organisation view CPD?

- i. Does your organisation support you to do CPD?
- ii. Positive and negative example, if you can
- b. Supervisor/manager support
- c. Supervisor/manager sanctions
- d. Openness to change
- e. Feedback performance coaching

4) TRAINEE CHARACTERISTICS – SECONDARY ELEMENTS

a. Learner readiness

Question 13: How relevant is the NREP to your day-to-day job?

b. Performance self efficacy

Question 14: Do you feel confident about applying new abilities and skills into

practice?

i. Is this different after training

Thank you very much for your time and for being willing to talk to me. Your comments have

been very helpful and will be used together with those of the other participants to gain an

understanding of how these educational resources should be delivered. The identities of all

individuals will, however, remain strictly confidential.

**Arrange to send copy of report.

From your point of view, how did you feel about my asking you these questions?

Is there anything I could do to make it better for future participants?

Would you be willing to take part in follow up interviews post the intervention?

Would you be happy I contact you by email should I think of any follow up questions?

Thank you for your time and interest in this study

Provide contact details should you have any questions or concerns about the project.

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Appendix C: Participant consent form for interviews

Site number:		
Study Number:		
Identification Number:		
CONSENT FORM		
Title of Project:		
Name of Researcher:		
	Please initial bo	×
 I confirm that I have read and understand the info dated for the above study. I have had the opportur the information, ask questions and have had the satisfactorily. 	nity to consider	
 I understand that my participation is voluntary and to withdraw at any time without giving any reason, companion's medical care or legal rights being affe 	, without my or	
		1

Na	me of Participant	Date	Sigr	nature	
S.	l agree to take part in the abo	ve study			
7.	I agree to be contacted, by my in study focus groups at the st 12 months into the study				
6.	I give permission to be audio-ı				
5.	I understand that if at any ti sensitive information/ inapp relating to me or others that co and the information referred	propriate behavi	our/ bad practice		
4.	I understand that relevant sec collected during the study, m Swansea University or from th my taking part in this resea individuals to have access to n	ay be looked at ne NHS Trust, wh arch. I give pe	by individuals from ere it is relevant to		
3.	I understand that if I withdidentified data may still be retunless I withdraw my consent	ained and used			

Name of Person	Date	Signature
taking consent		

When completed: Original for researcher file; copy for site file

Appendix D: Standards for Reporting Implementation Studies (StaRI) Checklist

Standards for Reporting Implementation Studies: the StaRI checklist for completion



The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. BMJ Open 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

		Reported		Reported	
Checklist ite	m	on page #	Implementation Strategy	on page #	Intervention
			"Implementation strategy" refers to how the	~	"Intervention" refers to the healthcare or public health
			intervention was implemented		intervention that is being implemented.
Title and abstra	ct				
Title	1		Identification as an implementation study, and	description of	f the methodology in the title and/or keywords
Abstract	2		Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction			The second secon		Charles Processor Petrological Charles and Article Charles and Cha
Introduction	3		Description of the problem, challenge or deficiency in hea	Ithcare or pu	blic health that the intervention being implemented aims
			to address.		
Rationale	4		The scientific background and rationale for the		The scientific background and rationale for the
			implementation strategy (including any underpinning		intervention being implemented (including evidence
			theory/framework/model, how it is expected to achieve		about its effectiveness and how it is expected to
			its effects and any pilot work).		achieve its effects).
Aims and	5		The aims of the study, differentiating between implementation objectives and any intervention objectives.		
objectives					

Methods: descr	Methods: description					
Design	6		The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any			
			changes to st	udy protocol,	with reasons	
Context	7		The context in which the intervention was implemented.	(Consider so	cial, economic, policy, healthcare, organisational barriers	
			and facilitators that might	influence imp	plementation elsewhere).	
Targeted	8		The characteristics of the targeted 'site(s)' (e.g		The population targeted by the intervention and any	
'sites'			locations/personnel/resources etc.) for implementation		eligibility criteria.	
			and any eligibility criteria.			
Description	9		A description of the implementation strategy		A description of the intervention	
Sub-groups	10		Any sub-groups recruited for additional research tasks, and/or nested studies are described			
Methods: evalu	ation					
Outcomes	11		Defined pre-specified primary and other outcome(s) of		Defined pre-specified primary and other outcome(s) of	
			the implementation strategy, and how they were		the intervention (if assessed), and how they were	
			assessed. Document any pre-determined targets		assessed. Document any pre-determined targets	
Process	12		Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work			
evaluation						
Economic	13		Methods for resource use, costs, economic outcomes		Methods for resource use, costs, economic outcomes	
evaluation			and analysis for the implementation strategy		and analysis for the intervention	

Sample size	14	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as	
		appropriate)	
Analysis	15	Methods of analysis (with reasons for that choice)	
Sub-group	16	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic	
analyses		populations), and sub-groups recruited to specific nested research tasks	

Results				
Characteristics	17	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	Representativeness and outcomes of subgr	oups includin	g those recruited to specific research tasks

Fidelity/	22	Fidelity to implementation strategy as planned and		Fidelity to delivering the core components of
adaptation		adaptation to suit context and preferences		intervention (where measured)
Contextual changes	23	Contextual changes (if any) which may have affected outcomes		
Harms	24	All important harms or unintended effects in each group		
Discussion				
Structured discussion	25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General				
Statements	27	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Appendix E: Prescribing guidelines questionnaire to healthcare professionals

- 1. Which Health board are you from?
- 2. What is your job/position?
- 3. Do you support national prescribing guidelines for COPD and asthma in Wales?
- 4. Do you want to be involved with the guideline development group?

Appendix F: Training evaluation form

- 1. During this course, how satisfied were you with each of the following:
 - a. Course assessments
 - b. The topics covered during the course
 - c. The length of the course
 - d. Discussions with other learners
 - e. The teaching style of the educators/course presenters
 - f. The course content (e.g., videos, text, resources)
 - g. The level of complexity
 - h. Opportunities to test your knowledge (e.g., quizzes)
 - i. Course functionality, accessibility, and navigation
- Very satisfied
- Satisfied
- Dissatisfied
- Very dissatisfied
- Not applicable
- 2. How much did you enjoy your course experience overall?
- I enjoyed it a lot
- I enjoyed it a little
- I didn't enjoy it much
- I didn't enjoy it at all
- 3. What would be your preference regarding the length of this e-learning course?
- It is increased in length
- It is reduced in length
- I'm satisfied with the length of the course as it currently stands
- 4. What was your favourite part of the course, and why?
- 5. What was your least favourite part of the course, and why?

- 6. Which of the following best describes why you wanted to take this course? I wanted to take this course to...
 - a. Explore future career or study options
 - b. Learn for pleasure or satisfy intellectual curiosity
 - c. Advance, develop or stay up to date in my profession or field
 - d. Prepare for, or support, a specific work or study goal (e.g., a job interview, exam, assignment)
 - e. Other (please specify)
- 7. How likely are you to apply some of the lessons learnt in this course into your practice?
- I have done already
- Very likely
- Possibly
- Not likely
- 8. How likely is it that you would recommend this course to a friend or colleague? (score out of 10)

Appendix G: Questions to healthcare professionals about the self-management app

- 1) Do you think an NHS Wales patient interface, such as an app, has the potential to improve the self-management of chronic conditions for patients in Wales?
- 2) If healthcare professionals had access to very specific information about the patient in front of them, generated by the patient via the patient app, would this be beneficial?
- 3) What do you propose to be the most important elements of a patient self-management app?

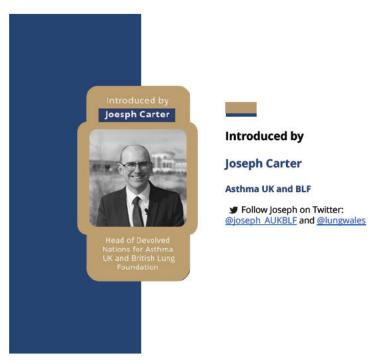
Audience Questions:

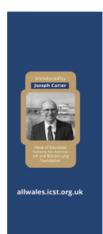
Everyone in the audience had the opportunity to ask questions through the sli.do website anonymously once the surveys were completed. Below are the questions that were raised.

- 1) What about those patients who are not digitally literate? For example, older patients.
- 2) There are many places in Wales that do not have digital access due to poor signal. Are there any plans to overcome this?
- 3) If patients cannot prioritise their medication or a flu jab, then why would they take other controls with their health?
- 4) Is this not taking away the value of human touch and support, will it be as effective? How can the app be free? How will it be tailored to specific age groups?
- 5) What about attrition rate and people dropping off?
- *6)* How will you market the app?

Appendix H: World Asthma Day slide deck







In the UK, around **5.4 million** people are currently receiving treatment for asthma. That's **one** in **every 12 adults** and **one** in **every 11 children**.

There are over 8,000 asthma attacks every day in the UK and 200 emergency hospital admissions a day

Every 10 seconds someone in the UK has a potentially life threatening asthma attack. Three people a die a day of asthma attacks - 2 of these are preventable

BUT

Two thirds of people do not receive all three elements of basic care







Presenting the All-Wales Asthma Guidelines

Dr. Katie Pink

Asthma Specialist

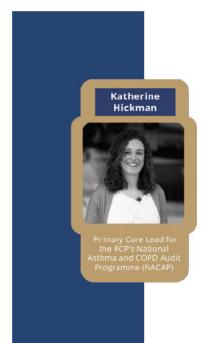
罗 Follow Katie on Twitter: @ktlouisepink











The NACAP Audit and All Wales QI project toolkit

Katherine Hickman

Primary Care Lead for NACAP, GP







The All Wales NHS Respiratory Apps

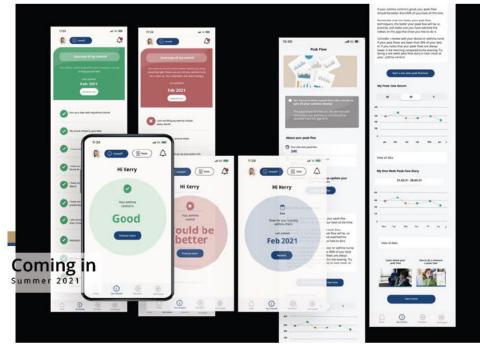
Julian Forton

RHIG Child Health Lead









Appendix I: Welsh Government letter to Health Boards promoting use of the national hospital COVID guideline



To: Chief Executives, Health Boards and Trusts Chief Operating Officers, Health Boards and Trusts

24 March 2020

Dear colleague

SECONDARY CARE RESPONSE TO COVID-19

The second meeting of the Acute Secondary Care Subgroup took place on 23 March. It was agreed that health boards in particular would like greater clarity on the priorities for implementation falling out of the national response to COVID-19. With regard to the requirements set down by the group, the following are priorities at this time:

1. The scale and complexity of the secondary care response requires national coordination and common approaches. Your designated COVID Coordinators (hospital) are responsible for implementing the in-hospital COVID pathway. This pathway is designed for implementation at scale across Wales. Your COVID Coordinator (hospital) will receive 1:1 support on how to discharge this role from the national COVID-19 Management Team hosted by the Institute for Clinical Science and Technology. The national COVID-19 Management Team will be in touch directly with your COVID Coordinators (hospital) this week. We request they participate fully in this process. Hard copies and digital versions of the pathway are available. These include links through to the relevant training and clinical guidance to implement the pathway for your ward based COVID teams. It is important that the COVID Coordinator (hospital) enrols the whole COVID team on the national system that can be accessed from pathway so that they can access the relevant training and any updates.





PopulationHealthcare@oov.wales

Yours sincerely

Dead Chain Lance

Prof Chris Jones Deputy CMO Welsh Government Andrew Sallows Delivery Programme Director Welsh Government Steve Curry Chief Operating Officer Cardiff and Vale UHB



Appendix J: Evaluation questions for the COVID-19 hospital guideline

- 1. Please select name of your hospital
 - a. Selected from drop down list
- 2. Please enter your job title
 - a. Selected from drop down list
- 3. How would you rate the quality of the COVID-19 hospital guideline platform?
 - a. Star rating
- 4. How easy did you find the guideline platform to use/navigate?
 - a. Star rating
- 5. If applicable, how do you think the guideline platform could be made easier to use?
 - a. Free text
- 6. How did you hear about the guideline platform?
 - a. Hospital COVID-19 management team
 - b. Department lead
 - c. Colleague
 - d. Email invite
 - e. Social media
 - f. Welsh Clinical Portal (WCP)
 - g. Other
- 7. During the peak period of the COVID-19 outbreak, how often would you say you were using the guideline platform?
 - a. Daily
 - b. 2-3 times per week
 - c. Weekly
 - d. Monthly
 - e. Every time there was an update
 - f. Never
 - g. Other
- 8. Where do you most often access the guideline platform?

- a. Home
- b. Work (on duty)
- c. Work (off duty, e.g., breaks)
- d. Transport
- e. Other
- 9. What device do you typically use to access the guideline platform?
 - a. Mobile phone
 - b. Tablet
 - c. Personal computer
 - d. Hospital computer
- 10. To what extent do you think the guideline platform has informed your clinical practice?
 - a. Sliding scale
- 11. Have you encouraged others to use the guideline platform?
 - a. Yes
 - b. No
 - c. Other
- 12. What were your primary motivations for using the guideline platform?
 - a. Free text
- 13. Were you aware the guideline was mandated in Wales?
 - a. Yes
 - b. No
- 14. Over the period of the COVID-19 pandemic, how would you rate the frequency of the guideline update emails?
 - a. Free text
- 15. Would you like the update emails to continue?
 - a. Yes
 - b. No
 - c. Other
- 16. Is there any other feedback relating to the guideline platform that you would like to make?
 - a. Free text

Appendix K: Letter from the Medical

Director at SB UHB mandating the

COVID-19 guideline

NHS Wales wishes to ensure that all health boards are delivering an equitable level of care and

to avoid significant variation in how patients across Wales are treated. It is supported by the

National Clinical Lead for Respiratory Disease and the Critical Care Network. An NHS Wales

Covid-19 response for hospital across Wales is being supported by a detailed training package

that can be found at https://covid-19hospitalguideline.wales.nhs.uk/.

Many have already completed this training (thank you for doing so) but the majority of doctors

at Morriston Hospital have yet to complete this. Given that most in-patients are currently being

admitted because of suspected or confirmed Covid-19, or may have this alongside another

clinical presentation, it is axiomatic that there is a mandatory requirement that all

doctors/dentists working in Morriston Hospital undertake this training. I should therefore be

grateful if all doctors and dentists based at Morriston Hospital complete this by Friday

24th April.

You will need to sign-up for the training using the website. The training takes about 90 minutes

and is supplemented by a series of questions at the end. Successful completion will allow a

certificate to be published. Feedback from doctors who have undertaken the training

programme is that it rates 9.0 to 9.5 out 10 for its quality so it does come with a high level of

recommendation.

If there are any problems accessing the site, please do not hesitate to contact me.

Dr Mark Ramsey

Unit Medical Director

Morriston Hospital, Swansea, SA6 6NL

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