

Literature Review complex systems change initiatives and evaluation approaches for the AFFINITY National Falls & Bone Health Project October 2019

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Introduction

This document is the **literature review** of the systems change and systems change evaluation literature. The literature included in this review is particularly relevant to informing the evaluation of AFFINITY Project¹. The AFFINITY Project operates in a complex context. A range of approaches to evaluating change initiatives in complex contexts can be identified in the literature and the most relevant are described in this document.

The literature review is one of three documents prepared by the Centre for Effective Services in partnership with the AFFINITY Project team and other AFFINITY stakeholders, intended to inform the approach taken to any future evaluation of the Project. The three documents are:

- A literature review on implementing complex system change initiatives and evaluating systems change
- 2. An evaluation framework to inform any future evaluation(s) of the AFFINITY Project
- 3. A review of data collection and monitoring systems and associated gap analysis.

A range of different literature was reviewed that covered a number of different topics including:

- Learning from other jurisdictions on implementing national bone health, falls prevention and falls reduction strategies
- Implementing complex system change initiatives
- Approaches to evaluating complex system change initiatives
- Examples of systems of change initiative evaluations relevant to the AFFINITY Project.

The literature reviewed included articles from peer reviewed journals; reputable text books by leaders in the field of evaluation and evaluation design; grey material; and government publications.

The findings from this literature review show that the strategies aimed at preventing falls, reducing the number of falls and ameliorating the harm from falls among older people are generally multifaceted endeavours, involving different settings, health care professionals, community members and older people themselves. Policies and practices are typically nested in or interwoven with other policies and practices, which have the potential to mutually support each other, if harnessed effectively. These types of system change initiatives are not linear, predictable, or controllable and do not always produce neat, sequential and contained outcomes. As such, experimental evaluation

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¹ For the remainder of this document the term 'AFFINITY Project' or 'Project' is used for brevity.

designs are often not appropriate as cause and effect are difficult to isolate and measure. Therefore, evaluation approaches should be tailored to the specific initiative and its unique theory of change. The literature shows us that evaluations should pay close attention to the context within which the initiative is situated and that maintaining a focus on the whole initiative is important; this can be done while focusing on evaluating specific parts of the initiative.

Background to the literature review

The HSE is committed to conducting an evaluation of the AFFINITY Project. As part of this commitment, the HSE conducted a market sounding exercise in February 2019 to secure support to inform the evaluation procurement process for the evaluation of the project at a later date. The key needs identified were as follows:

- To prepare an evaluation framework
- Data collection and monitoring systems
- To support the drafting of evaluation procurement documentation.

In response to this market sounding exercise, the Centre for Effective Services (CES) was contracted to work with and support the AFFINITY Project team to address these needs.

This literature review was undertaken to inform and support the AFFINITY Project in developing their evaluation approach for the Project and specifically to:

- Identify learning from the implementation of falls reduction and bone health strategies internationally
- Better understand the literature on implementing complex system change initiatives
- Explore the literature on evaluation approaches for evaluating complex system change initiatives
- Identify the learning from existing evaluations of complex system change initiatives in several different sectors and environments.

This review is structured over four parts, as follows:

- Part 1: Overview of the AFFINITY National Falls and Bone Health Project and international approaches to falls prevention and bone health promotion
- Part 2: Understanding complex systems and efforts to exert change
- Part 3: Understanding the evaluation of systems change initiatives
- Part 4: Examples of systems change initiatives

PART 1: Overview of the AFFINITY National Falls and Bone Health Project and International Approaches to Falls Prevention and Bone Health Promotion

1.1 The AFFINITY National Falls and Bone Health Project(2018 – 2023)

In 2008 the HSE, the National Council on Ageing and Older People and the Department of Health and Children jointly launched the Strategy to Prevent Falls and Fractures in Ireland's Ageing Population (HSE, National Council on Ageing and Older People and Department of Health and Children, 2008). The AFFINITY Project was initially launched in 2013 and refocused in 2016 to take account of various structural and other changes in the HSE. In 2017 the AFFINITY National Falls and Bone Health Project (2018-2023) was established.

The aim of the AFFINITY National Falls and Bone Health Project (2018-2023) is to coordinate the development of a comprehensive, nationwide evidence-informed approach to reducing harm from falls for Ireland's population as it ages. The intent is to increase awareness of the preventable nature of falls and to empower older people, communities and health and social care providers to reduce the risk and rate of falling where possible, to reduce the severity of injuries and to promote the best possible outcomes for people who have suffered a falls-related injury.

The AFFINITY Project intends to achieve this aim by providing an overarching framework for the implementation of a system wide approach to prevention of falls and harm from falls in Ireland. This implementation framework seeks to: respond to the significant variations in content, governance and coverage of programmes to prevent harm from falls around Ireland, highlight limited access to fracture liaison services, implement a standardised approach to evaluating impact and outcomes, introduce a standardised suite of data that captures process and outcomes across the system, and shift efforts to prevention of, rather than reaction to, falls. Work under the AFFINITY Project focuses on:

- Promotion of healthy ageing, bone health and falls prevention activities in well, older people,
 e.g. promotion of evidence-informed community-based exercise programmes that address
 balance and strength.
- Building community capacity for identifying and responding to those people within or moving into the at-risk group for falls
- Development of an integrated pathways for assessment and treatment of those who have fallen
- Evidence of prevention for older persons at high risk of falls such as in continuing care / residential and acute services
- Lifelong optimisation of bone health and fracture liaison services for secondary fracture

prevention.

The following principles underpin the AFFINITY Project and implementation framework:

- Person-centred approach
- Aligned with Integrated Care Framework for Older Persons
- System-wide population health approach across the lifespan
- Informed by the principles of implementation science, including:
 - o evidence in its multiple forms
 - evaluation
 - o co-design
 - continuous improvement supported by data.

To date, the following progress has been made under the AFFINITY Project:

- Governance structures have been established under the Integrated Care Programme for Older Persons (ICPOP)
- A working group has been established, and this has developed a project plan including deliverables, work breakdown structure, timelines etc.
- A Stakeholder Analysis and Communication Plan has been developed
- Links and collaborations have been established both nationally and internationally with, for example, Age Friendly Ireland; clinical programmes including National Clinical Programme for Older People (NCPOP), Trauma and Orthopaedics, and Emergency Medicine; and with programmes in New Zealand and Scotland
- A logic model has been developed for the Project.
- A Service User panel has been established to ensure co-design.

The need to agree metrics to measure and monitor the progress and achievement of outcomes, address cost effectiveness and the budgetary impact of recommendations, and to recommend priorities for focus and action have been identified among the key priorities for the project.

1.2 AFFINITY and the international policy and practice context

Bone health and falls prevention among older people has been promoted at the international level by the World Health Organisation (WHO) Active Ageing Policy Framework (2002), the WHO Agefriendly World website, the WHO Global Report on Falls Prevention in Older Age and associated recommendations (2007), and the Global Network for Age-friendly Cities and Communities.

With regard to preventing falls, the WHO Report of Falls Prevention in Older Age (2007:37) states that:

"An effective falls prevention strategy will need to acknowledge the cultural reality of the society in which it is to be implemented. The culture that surrounds all individuals and communities' shapes and influences all of the determinants of active ageing. Cultural values and traditions determine not only how a given society views older people and the ageing process, but also the types of prevention, detection and treatment services that are most likely to be successful in a particular country and culture."

This suggests that falls prevention occurs within a complex system; stand-alone interventions tackling only one part of the system in which older people are embedded may therefore have limited success. The WHO report delineates a range of determinants of falls, each of which interacts with and impacts upon the other determinants, such as cultural, gender, behavioural, personal, social, physical environment, social environment and economic conditions. The WHO report suggests that the success of falls interventions involves changing the beliefs, attitudes and behaviour of older people themselves, the health and social care professionals who provide services, and the wider communities in which older people live. For example, the report notes that the effectiveness of a fifteen-week balance and exercise class depends on the older person going to the sessions, undertaking the exercises as prescribed, and continuing to practice after completion of the course; this may in turn depend on the support received at home and in the community to enable continued practice (WHO, 2007).

At the European level, bone health and falls prevention among older people is promoted by the A2 Action Group of the European Innovation Partnership in Active and Healthy Ageing (EIPAHA). EIPAHA is an initiative launched by the European Commission to foster innovation and digital transformation in the field of active and healthy ageing. The primary objective of the A2 Action Group is to launch validated and operational schemes for early diagnosis and prevention of falls. Additionally, the group supports the development of regional programmes for early diagnosis and the prevention of falls. This action group brings together organisations representing almost 100 multi-stakeholder commitments from regional and national administrations, local authorities, research centres, academia, industry (including SMEs) and advocacy organisations from across the EU. The Prevention of Falls Network for Dissemination (ProFouND) is an EC-funded initiative dedicated to the dissemination and implementation of best practice in falls prevention across Europe. ProFouND aims

to influence policy and to increase awareness of falls and innovative prevention programmes, amongst health and social care authorities, the commercial sector, NGOs and the general public.

The approach to bone health and falls prevention promoted by the WHO and the European Commission recognise complex systems in which falls occur and the variety of stakeholders implicated in prevention of falls. Western countries are more likely to have bone health and/or falls prevention strategies or policies at a national level. These also recognise the complex system in which falls prevention takes place.

1.3 Some approaches in other jurisdictions to bone health and fall prevention

1.3.1 Canada

In Canada, the 2005 *Report on Seniors' Falls in Canada* and the second report in 2014, from the Public Health Agency of Canada (PHAC) provide policy makers, researchers, community programmers and practitioners with current national information on falls among older people. PHAC has played a strong coordinating role within falls prevention among seniors in Canada, seeking to increase the capacity of those who work with seniors to plan, implement and evaluate evidence-based injury prevention programmes. PHAC has focused on public education, community-based programming and policy development and have developed numerous publications aimed at helping seniors and their families to reduce the occurrence and impact of falls. PHAC has advanced the Age-Friendly Communities concept in Canada to facilitate healthy and supportive environments for older adults.

The Canadian Fall Prevention Education Collaborative (CFPEC) is a centre for falls prevention education. They offer resources and up-to-date evidence on falls prevention and have developed the Canadian Fall Prevention Curriculum (CFPC), which they offer training around Canada to healthcare professionals.

In Ontario, Canada, the Local Health Integration Networks (LHINs) and Public Health Units (PHUs) partnered to develop an Integrated Provincial Falls Prevention Framework and Toolkit (Local Health Integration Collaborative, 2011). The framework and toolkit aim to improve the quality of life for Ontario seniors aged 65 years and over, and to lessen the impact of falls on the health care system by reducing the number and impact of falls. The framework and toolkit bring together leading practices, programmes and resources in a coordinated, consistent approach to measure the

effectiveness of falls prevention interventions in Ontario.

A Fall Prevention Across the Lifespan Development Framework was produced in December 2016 by the Healthy Living Division of the Region of Waterloo Public Health and Emergency Services' (ROWPHE) to enhance capacity to prevent falls and fall-related injuries in the Waterloo Region. The Development Framework seeks to address the many risk factors of falls and fall-related injuries that affect individuals across all stages of the lifespan beginning with the 0-5 age group through to 55 years and older. Under a public health approach, it proposes that fall prevention interventions should target modifiable risk factors, i.e., risk factors that can be changed, through strategies related to education, safe and supportive environments, and healthy public policy. An accompanying compendium was developed to serve as a supplementary document to the Development Framework, examining some unique issues, risk factors, and implications of falls that are characteristic of the different stages of the lifespan. For those aged over 55 years, the compendium reports data on the top four causes of fall-related emergency department visits in the Waterloo Region for those aged 55+ (2007-2009), and fall risk factors for older adults, and it suggests implications for individuals and learning for educational, environmental and policy interventions. The compendium also provides links to a range of resources, including:

- Fall Prevention Month Provincial Campaign
- Fall Risk Assessment
- Canadian Fall Prevention Curriculum
- Fall Prevention Community of Practice
- Canadian Physical Activity Guidelines
- Canada's Low-Risk Alcohol Drinking Guidelines
- Eat Well and Be Active Educational Toolkit
- Eating Well with Canada's Food Guide
- Strategies and Actions for Independent Living
- Home Safety Checklist
- Age-Friendly Communities
- Queensland Stay on Your Feet
- Steps to Safer Stairs: A Kit for Improving Stair Safety

1.3.2 Australia

The Australian Commission on Safety and Quality in Health Care (ACSQHC) Falls Best Practice Guidelines (2009), provide the evidence base for fall injury prevention among older people in

hospital, community care and residential care settings, nationally. An implementation plan has not yet been developed for the guidelines across all settings. However, preventing falls and harm from falls is an agreed national standard for the accreditation of health care organisations. The National Safety and Quality Health Service (NSQHS) Standards were developed by the ACSQHC. The Standards are mandatory in Australia for hospitals to acquire accreditation. The primary aims of the Standards are to:

- Protect the public from harm
- Improve the quality of care provided by health care organisations.

Specific to falls care is Standard 10 Preventing Falls and Harm from Falls (ACSQHC, 2012). Standard 10 is the guide to develop systems to:

- Prevent falls including screening and/or assessing patients for falls risk
- Have multifactorial falls prevention strategies in place to reduce the incidence of patient falls and to minimise harm.

At a regional level, in New South Wales (NSW), the *Prevention of Falls and Harm from Falls Among Older People: 2011-2015* (Centre for Health Advancement, 2011) was developed; the policy was active until 2018. This policy described actions undertaken by NSW Health to support the prevention of falls and fall-related harm among older people. Actions were centred in three key domains: health promotion, NSW Health clinical services and NSW Health residential aged care services, both multipurpose services and State Government Residential Aged Care Facilities. The policy aimed to reduce the incidence and severity of falls among older people and reduce the social, psychological and economic impact of falls on individuals, families and the community.

The policy is now obsolete and the Clinical Excellence Commission (CEC) delivers falls prevention activities through the *Leading Better Value Care* initiative. The Office of Preventive Health supports Local Health Districts to implement physical activity programmes for older people and the *Stepping on Falls Prevention Programme*, a seven-week community programme aimed at preventing falls, encouraging active living and maintaining independence in older people. The CEC's *Falls Prevention Programme* aims to reduce the incidence and severity of falls among older people and reduce the social, psychological and economic impact of falls on individuals, families and the community. CEC provides State-wide leadership, coordination and collaboration and provides resources and support for the implementation of local health districts and networks falls prevention plans. It also provides leadership for the NSW Falls Prevention Network, in order to disseminate and promote research,

share falls prevention knowledge, expertise and resources through forums and meetings. *The Falls Prevention Programme* works in collaboration with the Ministry of Health, the Agency for Clinical Innovation, Ambulance NSW and local health districts to promote a comprehensive, systemic approach to falls prevention and to reducing fall injuries within NSW.

1.3.3 North America

In the USA, the Injury Centre at the Centers for Disease Control (CDC) developed the *Stopping Elderly Accidents, Deaths and Injuries* (STEADI) initiative and toolkit. The toolkit includes a suite of materials, for example, clinical algorithm, fact sheets and training videos, to help health care providers discuss fall risks with older adults and incorporate effective fall prevention into their practices. It also includes materials health professionals can give to the older people they work with (CDC, 2017). *STEADI* includes the following core elements:

- Screening to identify older adults with an increased falls risk
- Assessing to identify modifiable risk factors, such as medication review, functional ability test, measuring visual acuity, orthostatic blood pressure, podiatry review, and home hazard evaluation
- Intervening to reduce fall risk using evidence-based strategies, e.g., strength and balance programme, medication management, occupational therapy, and corrective eyewear.

The STEADI toolkit has formed the basis for New Zealand's Stay Independent: Falls Prevention Toolkit for Clinicians (bpac^{nz}, 2017).

In May 2016, a legislative brief from the National Conference of State Legislatures noted that states have adopted legislation that includes supporting older adults in their homes, communities and clinical settings in an effort to prevent falls. California, for example, supported the concept of "'aging in place' by requiring that recommendations be made, and funding allocated for home modifications intended to keep seniors safely in their homes and reduce the risk of falling" (Scotti, 2016:1). Elsewhere, legislation in New Mexico established a state-wide community-based adult fall risk awareness and prevention programme. This programme requires coordination throughout the community, including among health care providers, area agencies on aging and other community organisations, to encourage fall risk awareness and prevention strategies (*ibid*).

1.3.4 England

In England falls prevention is a theme addressed by Public Health England (PHE), an executive agency, sponsored by the Department of Health and Social Care. PHE provides government, local

government, the NHS, Parliament, industry and the public with evidence-based professional, scientific expertise and support. PHEs focus has latterly been on making the economic case for falls prevention and they have released a tool to assess the return on investment for four falls prevention interventions for older people where there was supporting evidence around the clinical and cost-effectiveness of such interventions. The Excel-based tool is used to report the return on investment for the included interventions in order to support investment in falls in an area. The tool is aimed at people involved in local policy setting and commissioning, as well as those delivering falls programmes in local government. The tool is supported by a structured literature review to identify cost-effective interventions to prevent falls in older people living in the community (PHE, 2018). The review identified six types of interventions: exercise (13), home assessment and modifications (4), multifactorial programmes (12), medicines review and modification to drugs (5), cardiac pacing (2) and expedited cataract surgery (2). These 26 studies provided cost-effectiveness results for 38 different interventions. The interventions were compared to a range of comparators including no intervention, usual care and other interventions.

Public Health England (PHE) and the National Falls Prevention Coordination Group (NFPCG) (made up of organisations involved in the prevention of falls, care for fall-related injuries and the promotion of healthy ageing) developed seven 'strength and balance quality markers', published in July 2019. These quality markers are intended to be used as criteria supporting local areas in carrying out self-audit for quality improvement.

PHE has identified some good practice in England, including:

- Get Up and Go: A Guide to Staying Steady, a guide for the public and patients on how to prevent falls produced by Saga in partnership with the Chartered Society of Physiotherapy and PHE (2015).
- PHE's Everybody Active, Every Day: An Evidence-Based Approach to Physical Activity (2014) is a
 physical activity strategy co-produced with over 1,000 partners, including health professionals,
 local authorities, research specialists, educationalists, charities and fitness experts. It represents
 an evidence-based approach for national and local action to address physical inactivity.
- The Royal College of Physicians' *National Audit of Inpatient Falls: Audit Report* (2015) contains recommendations aimed at reducing inpatient falls.

PHE and members of the National Falls Prevention Coordination Group (NFPCG) released their *Falls* and *Fracture Consensus Statement Supporting Commissioning for Prevention* (2017a). The statement

was due for review in January 2019. The Statement advocates a whole-system approach to prevention which takes in: risk factor reduction across the life-course; case finding and risk assessment; strength and balance exercise programmes; healthy homes; high-risk care environments; fracture liaison services; and collaborative care for severe injury.

The NFPCG is made up of organisations involved in the prevention of falls, care for falls-related injuries and the promotion of healthy ageing. It was formed with the aim of coordinating and supporting falls prevention activity in England. To support and encourage effective commissioning and provision, NFPCG member organisations committed to increase public and professional awareness; ensure the co-production of services with older people, their families and carers; support the effective use of data and evidence; work with partners to develop and inform quality standards and guidance; inform skills development for patients, their carers, health and care professionals and the wider workforce; disseminate best practice; and inform relevant national policy and strategy. The statement is accompanied by a resource pack (PHE and NFPCG, 2017b) which includes key guidelines, such as:

- Prevention of Falls in Older People: American Geriatrics Society/British Geriatrics Society Clinical
 Practice Guideline, 2010
- Occupational Therapy in The Prevention and Management Of Falls In Adults: Practice Guidelines: College of Occupational Therapists, 2015
- Clinical Guideline for The Prevention and Treatment of Osteoporosis: National Osteoporosis
 Guideline Group, 2017
- The Management of Hip Fracture in Adults: NICE² CG124, 2014
- Osteoporosis: Assessing the Risk of Fragility Fracture: NICE CG146, 2017
- Falls in Older People: Assessing Risk and Prevention: NICE CG161, 2013
- Midlife Approaches to Preventing the Onset of Disability, Dementia and Frailty: NICENG16, 2016
- Multi-morbidity: Clinical Assessment and Management: NICE NG56, 2016.

Specific programmes such as the *FallSafe* project have also been implemented by the Royal College of Physicians and have been funded by the Health Foundation. The *FallSafe* project aimed to 'close the gap' between the evidence base for effective care and the care that patients receive. The *FallSafe* project involved educating and supporting 17 registered nurses from acute, rehabilitation and mental health wards (the *FallSafe* leads) to lead their local multidisciplinary teams in reliably delivering these assessments and interventions through a 'care bundle' approach. Every four-to-

² National Institute for Health & Care Excellence provides national guidance and advice to improve health and social care in the UK.

eight weeks, over nine months, a new element of the care bundles was introduced, and delivery of the full bundles was then sustained for six months. Compliance with the elements of the care bundles was measured each month. Outcomes were assessed by reported falls rates, which were adjusted by the proportion of staff who were certain that falls had been reported. All resources used in the project are now available for download (RCP, 2015).

Falls prevention has also been considered as a case study in applying the 'All Our Health' approach to prevention and the promotion of population wellbeing, published by PHE in 2015. All Our Health is a framework to support healthcare professionals working with patients and the population to prevent illness, protect health and promote wellbeing. It focuses on caring for individuals and local communities, as well as larger populations such as cities and regions, supporting all ages of life with the aim of improving health and reducing health inequalities, and presenting evidence and guidance to show the impact healthcare professionals can make through the topics aligned to the public health outcomes framework.

In terms of measuring patient/service user outcomes, the *Public Health Outcomes Framework* (PHOF) includes indicators on injuries due to falls in people aged 65 and over and indicators on hip fractures in people aged 65 and over (PHE, 2013). Mortality rates from accidental falls are reported in the Health and Social Care Information Centre Indicator Portal.

The Everyday Interactions Measuring Public Health Impact Toolkit (PHE and RSPH, 2017) is used by healthcare professionals to record and measure their public health impact in a uniform and comparable way. The impact pathways produced cover ten public health priorities, one of which is falls.

The toolkit helps healthcare professionals to measure **what they do** in their interactions with patients, what data can be collated and also the possible impacts from these interactions. For example, when using the falls prevention pathway, a health care professional records that an individual has been identified as being at low-to-moderate risk of falls and has been offered a strength and balance exercise programme. Over time, these records can be collated, to demonstrate the number of individuals who have been offered the exercise programme over the previous 12 months. The impacts in the models link to national indicators, and for falls include: reduced hospital admissions from falls at 65 and over; reduced incidence of hip fractures in people 65 and over; reduced mortality rates from accidental falls; increased life expectancy at 65 in men and women;

improved mental health and reduced prevalence of depression due to social isolation; and improved quality of life for older people.

1.3.5 Scotland

In Scotland, the *Reshaping Care for Older People (2011 - 2021)* Government initiative is aimed at improving services for older people by shifting care towards anticipatory care and prevention.

Reshaping Care for Older People: A Programme for Change 2011-2021 sets out a vision that:

"Older people are valued as an asset, their voices are heard, and they are supported to enjoy full and positive lives in their own home or in a homely setting" (COSLA et al., 2011:1).

A logic model to help with monitoring public services and to bring together evidence of change is currently in development. This initiative sits alongside other strategies and guidelines in Scotland including:

- Framework for Adult Rehabilitation in Scotland
- SIGN³ Guideline Management of Osteoporosis
- SIGN Guideline Management of Hip Fracture in Older People
- NICE CG161 Falls Assessment and Prevention of Falls in Older People.

The Scottish Government's Chief Health Professions Officer has supported a national falls programme since 2010. The falls programme has become one of the Allied Health Professional (PH) led national programmes that contributes to the new *Active and Independent Living Programme* (AILP) in 2019. The *AILP* is a three-year AHP-led national improvement programme to maximise the contribution that AHPs will make to the health and wellbeing of the population of Scotland. The programme aims to:

- Ensure that the AHP contribution to nationally identified priorities is fully realised
- Be aligned and integrated with other relevant national and local programmes
- Identify and take action to address AHP specific issues.

The falls programme Lead works in partnership with a network of Community Falls Leads and other key stakeholders to support Health and Social Care Partnerships to adopt falls and fracture prevention approach outlined in *The Prevention and Management of Falls in the Community. A Framework for Action for Scotland 2014-15* (The Scottish Government, 2014).

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³ Scottish Intercollegiate Guidelines Network (SIGN) develops evidence-based clinical practice guidelines for the NHS in Scotland.

The falls programme focuses on community settings. It raises the profile of falls and fracture prevention and facilitates sharing of learning, experience and knowledge in the falls and bone health community in Scotland. In addition, a number of varied workstreams address priority topics identified in mapping activities. The Programme is structured under four stages, outlined in the NHS Quality Improvement Scotland Resource *Up and About* (2010):

- Supporting health improvement and self-management to reduce the risk of falls and fragility fractures
- 2. Identifying individuals at high risk of falls and/or fragility fractures
- 3. Responding to an individual who has just fallen and requires immediate assistance
- 4. Co-ordinated management including specialist assessment

Up and About: Pathways for the Prevention and Management of Falls and Fragility Fractures presents an overview of the various aspects of fall and fragility fracture prevention and management and attempts to demonstrate how they link to provide comprehensive, co-ordinated and personcentred care (NHS Quality Improvement Scotland, 2010).

The Managing Falls and Fractures in Care Homes for Older People- good practice resource is a resource pack to help staff in care homes assess how well falls prevention and management and the prevention of fractures is being addressed in their service (Care Inspectorate and NHS Scotland, 2016). The resource pack can also act as an educational tool for new or existing care home staff and provides practical help, guidance and tools, and signposts to other resources available online. Tools include a falls data spreadsheet to gather and analyse information about falls in the care home. The spreadsheet is accessible on the internet, along with instructions for its use.

Falls prevention in acute settings is addressed under the *Scottish Patient Safety Programme* (SPSP), a national initiative that aims to improve the safety and reliability of health and social care and reduce harm, whenever care is delivered, and under NHS quality improvement. The *'Musculoskeletal (MSK)* and *Orthopaedic Quality Drive - Spread and Sustainability of Five High Impact Work Strands'* has identified five priority work strands, each with a clinical evidence/best practice base, to have the greatest impact. The work strands are:

- 1. AHP MSK Redesign getting patients on the right pathway
- 2. Fracture Pathway Redesign patients only attend fracture clinics if there is a clinical need
- 3. Enhanced Recovery optimising patient recovery after joint replacement

4. Hip Fracture Care Pathway - optimising care of frail older people

5. Demand and Capacity Planning and Management - supporting strategic and operational

decisions

Each work strand has a clearly defined aim, a definition of what success will look like with 'how much

by when' for improvement, details of the potential impact of the work strand, information for NHS

Boards to help them determine what they should do now and what support is available and a 'driver

diagram' with the key components and measures of success.

1.3.6 **New Zealand**

Live Stronger for Longer: Prevent Falls and Fractures is a collaborative initiative by Accident

Compensation Corporation (ACC), the Ministry of Health, Health Quality and Safety Commission

(HQSCNZ), District Health Boards (DHBs), GPs, health professionals, home carers and community

groups who deliver services to older people. The aim is to better coordinate efforts and create a

system that is easy to use and helps to reduce the incidence and severity of falls and fractures. The

falls and fractures outcomes framework and data dashboard support this work by bringing together

information on four domains:

Domain 1: Reduction in ACC claims for falls

Domain 2: Fewer serious-harm falls.

Domain 3: Improved recovery

Domain 4: Integrated care

Reducing Harm from Falls was a national programme led by the HQSCNZ, working in partnership

with a wide range of stakeholder organisations, between 2012 and 2018. Work on the programme

began in mid-2012 with the aim of reducing the harm that people experience following a fall,

particularly older people receiving care in hospital, residential care, or their own home.

The programme was designed to meet the needs of those experiencing the greatest harm from falls

and focused on people aged 65 years and over. Initially, the programme focused on hospital settings.

Hospital settings provided an opportunity to develop and test interventions supported through

systematic data monitoring. The focus on hospitals was followed by a modest extension into aged

residential care facilities in 2013. In 2015 the programme was extended to include primary care and

community settings.

The programme has developed and promotes a range of resources and activities. These include

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information for patients, the 'April Falls Quiz', clinician toolkits, newsletters, and the '10 topics' in reducing harm from falls (updated in 2019). Resources available from the Health Quality and Safety Commission include:

- The Stay Independent: Falls Prevention Toolkit for Clinicians is an aid for Primary Care Teams for the assessment of an individual's risk of falling, including practical strategies to reduce this risk.

 The toolkit is based on the STEADI falls campaign developed by the United States Centers for Disease Control and Prevention (CDC), and has been adapted for use in New Zealand by bpac^{nz} in association with the Health Quality and Safety Commission (bpac^{nz}, 2017)
- The falls prevention module for the *Releasing Time to Care- The Productive Ward* toolkit. This has been customised for the New Zealand environment by the HQSC and adapted from the version developed by Queensland Health in Australia. The New Zealand falls module is an addition to the suite of Releasing Time to Care tools currently used in hospitals. It draws on the guidance, evidence-based tools and resources developed through the national reducing harm from falls programme (HQSCNZ, 2016).
- An updated New Zealand Evidence Base (2019) on reducing harm from falls, available at https://www.hqsc.govt.nz/our-programmes/reducing-harm-from-falls/recommended-resources/2019-evidence-base/

The programme developed a theory of change and was evaluated in 2016. An evaluation of the programme in 2016 suggested that the programme was meeting its stated objectives and achieving its intended results. The evaluation also offered recommendations on the role of the Health Quality and Safety Commission going forward to continue to support a sustained focus on reducing harm from falls across care settings (Appleton-Dyer *et al.*, 2016).

1.4 Lessons from international approaches to bone health and falls reduction

- The prevention of falls, reduction of falls and amelioration of harm from falls among older people is a multi-faceted endeavour, involving different settings, health care professionals, community members and older people themselves.
- Policies and practices are nested in or interwoven with other policies and practices, which have the potential to mutually support each other, if harnessed effectively.
- Approaches include the provision of resources for professionals, such as guidance, training,
 workshops and eLearning, as well as interventions for older people, and modifications to care

and community settings.

• Some international data and research suggest that such interventions can be very successful. However, outcomes data suggests that even with good efforts and intentions rates of falls can increase over time. For example, in Canada self-reported falls among older people increased between the 2005 and 2014 Public Health Agency Reports on Seniors' Falls in Canada. This suggests a nuanced view of the relationship between efforts and outcomes is important in order to get a more complete understanding of the impact of policies, initiatives and interventions.



PART 2: Understanding Complex Systems and Efforts to Exert Change

2.1 The literature on complex systems and efforts to exert change

The AFFINITY Project is analogous to other systems change initiatives nationally and internationally in that it addresses an issue with a multitude of determinants. The AFFINITY Project operates in and across complex systems comprised of interrelated and interdependent individuals and groups working together, or in parallel, in a variety of settings on activities that influence the prevention of harm from falls among older people. Together, this makes up a complex, dynamic whole that changes as the constituent parts interact and influence each other.

"Firstly, the dominant understanding of health and social care is through the lens of complex and adaptive systems" (Barry et al., 2018:4)

The New Philanthropy Capital (NPC) in their guide to systems change (Abercrombie *et al.*, 2015:6), note that the problems addressed by social systems change initiatives involve "individuals whose capabilities, beliefs and attitudes may play a part in the difficulties they experience. However, and more importantly, their problems are also a function of how institutions behave, of policy decisions, of the way markets operate, and even of public attitudes and cultural norms".

According to the Abercrombie et al. (2015), systems have the following characteristics:

- Systems are composed of multiple components of different types, both tangible and intangible.
 They include, for example, people, resources and services, as well as relationships, values, and perceptions.
- Systems exist in an environment, have boundaries, exhibit behaviours, and are made up of both interdependent and connected parts, causes and effects.
- Social systems are often complex and involve intractable, or 'wicked', problems. (Abercrombie et al., 2015)

For the purposes of this literature review, we understand systems change as Abercrombie *et al.* (2015) and Foster-Fishman *et al.* (2007:197) do:

"an intentional process designed to alter the status quo by shifting the function or structure of an identified system with purposeful interventions"

Systems change may require dramatic shifts in attitudes and ways of working. By changing underlying structures and their supporting mechanisms, such as values, routines, policies, allocation of resources, power structures and relationships, systems change aims to bring about enduring

change. It follows that systems change initiatives and interventions do not always produce neat, sequential and contained outcomes; rather they can be seen as an ongoing process of innovation, reflection, and learning resulting in change (Foster-Fishman *et al.*, 2007).

Systems, particularly social systems, are in a constant state of flux as people and the contexts in which they operate interact, change, develop, evolve and respond to each other. Systems change initiatives therefore are typically not well-bounded, stand-alone programmes, nor do they take place in stable environments. Systems change initiatives are instead complex, involving multiple people with different roles, and taking place in nuanced, interconnected environments. Change initiatives influence their systems, and in turn are influenced by the components of that system (the people and contexts that comprise the system). Coffman (2007:1) described systems initiatives as notoriously hard to measure because:

"they involve multiple programmes and players and feature outcomes at multiple levels (individual, family, community, and state). They involve numerous public or private funding streams administered through different agencies and decision-making structures. They require aligning goals and coordinating actions across programmes with different political cultures. And, they tackle difficult deep-rooted problems such as gaps in services and outcomes based on race, income, culture, and language. Finally, all efforts to improve systems are long-term efforts that evolve over time in response to the political, economic, and social contexts around them."

It is generally accepted that systemic change in human services is not linear, predictable, or controllable; social problems are resilient and not easily addressed using traditional means. Efforts to tackle such problems are therefore moving beyond traditional, mechanistic strategic models and more "emergent" approaches that better align with the complex nature of the problems being addressed are being adopted (Preskill et al., 2014).

Healthcare systems in particular have been described as being particularly complex. In fact, Braithwaite (2018:1) states that:

"No other system is more complex: not banking, education, manufacturing, or the military. No other industry or sector has the equivalent range and breadth, such intricate funding models, the multiple moving parts, the complicated clients with diverse needs, and so many options and interventions for any one person's needs. Patient presentation is uncertain, and many clinical processes need to be individualised to each patient. Healthcare has numerous stakeholders, with different roles and

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interests, and uneven regulations that tightly control some matters and barely touch others. The various combinations of care, activities, events, interactions, and outcomes are, for all intents and purposes, infinite."

If we consider the AFFINITY Project with regard to Weaver's (1948, cited in Ling, 2012) early definitions of simple, complicated or complex phenomena, it would best be described as a complex intervention (as contextualised to healthcare by Ling (2012)):

- Simple interventions depend on one (a coherent set of) known mechanism with one (or a
 coherent set of) output, the benefits of which are understood to lead to measurable and
 expected outcomes. In healthcare, these interventions could be biological (a drug), psychosocial
 (a behavioural therapy) or service delivery-based.
- Complicated interventions are composed of a number of interrelated parts, which are all required to operate in a predictable way in order for the success of the intervention. The processes are broadly predictable, and outputs arrive at outcomes in well-understood ways. "A television is complicated but has predictable and stable outcomes (it does not transform itself over time into a toaster)" (Ling, 2012:80).
- Complex interventions have multiple components which may act independently and
 interdependently (Campbell et al., 2007). They are characterised by feedback loops, adaptation
 and learning by both those delivering and those receiving the intervention, they have a portfolio
 of activities and desired outcomes which may be re-prioritised or changed, and they are both
 sensitive to starting conditions and outcomes tend to change, possibly significantly, over time.

2.2 Lessons from the literature on complex systems and efforts to exert change

- Systems change is not linear, predictable, or controllable
- Social problems are resilient and not easily addressed using traditional means
- Systems change initiatives and interventions do not always produce neat, sequential and contained outcomes
- Systems change can be seen as an ongoing process of innovation, reflection, and learning resulting in change.

PART 3: Understanding the Evaluation of Systems Change Initiatives

3.1 Overview of evaluation

Evaluation is a planned investigation of a project, programme or policy used to answer specific questions. It is carried out in a systematic and robust way, using reliable social scientific methods. The results can tell you what works, what does not work, how things could be improved and/or whether the project/programme provides value for money.

Evaluations provide information that address the issues that matter and meet stakeholder needs and priorities. They develop information that is timely and meaningful for decision-makers and communicate findings in a form that is usable for their purposes.

While there are similarities between research, evaluation and monitoring there are also key distinctions between them. Blome (2009) lays out some of these differences:

Research	Evaluation	Monitoring	
Produces generalisable	Judges a project, programme Involves the routine collect		
knowledge	or policy on merit/worth	of information	
Is a scientific enquiry based on	Is a systematic enquiry of	Utilises information given to	
intellectual theory	policy and programme	make amendments to service	
	interests of stakeholders;	delivery and	
		project/programme plans	
Takes place in controlled	Provides information for	Can make the evaluative	
settings	decision makers on specific	on specific process easier and produce	
	programmes;	more robust results	
	Takes place in settings of		
	changing actors, priorities,		
	resources and timelines.		

3.1.2 Evaluation Types

Different types of evaluation may be adopted depending on what the project/programme leaders and/or funders want to find out. The following table lays out the uses of different types of evaluation:

Area of Interest Types of Evaluation

What is the need for this service?	 Needs analysis 		
Are we reaching the people who will benefit most?	Process evaluation		
How do we get something to work on the ground?	Process or Implementation		
	evaluations		
Are our clients showing improvements?	Outcome evaluations:		
What is the relationship between X and Y?	Experimental, quasi-		
	experimental and non-		
	experimental designs; and		
	programme theory designs.		
Is our service responsible for any of these changes?	Outcome evaluations:		
What is the effect of X on Y?	Experimental designs,		
	programme theory designs		
	Systematic Reviews		
How much do we cost? Are we being efficient?	Cost-effectiveness		
How much does the change in outcomes save in the	Cost-benefit Analysis		
longer term?			
What do these changes mean for people's day to day	Process evaluation		
lives?			
We need an insight into the face behind the figures.			

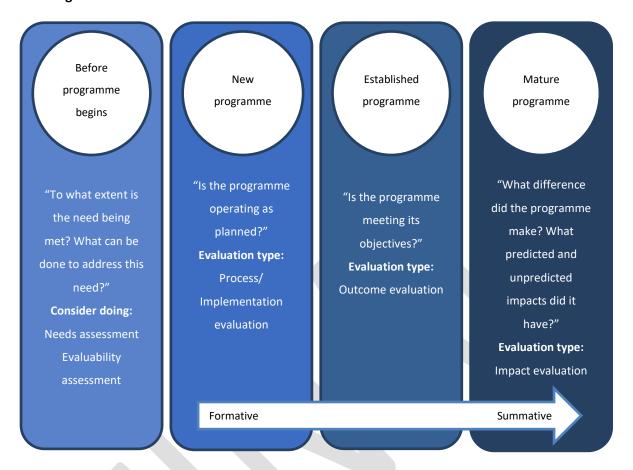
A **formative evaluation** takes place before a programme begins or when a new programme begins. It supports programme improvement. Needs assessments and process/implementation evaluations are formative evaluations.

A **summative evaluation** takes place when a programme is established or mature. It judges the overall merit, worth and significance of a programme. Summative evaluations are used to inform decisions about whether to expand, replicate or scale up a model. Outcome or impact evaluations are summative evaluations.

- The specific form and scope of an evaluation depends on:
- Its purpose and audience
- The nature and scale of the initiative or programme
- Resources and capacity
- Stage of implementation

• Political and organisational context

Timing of Evaluation:



Evaluation studies can fulfil a range of purposes and answer a range of evaluation questions. Some examples are provided below.

Evaluation Purposes Evaluation Questions

Implementation	Is the service being delivered as intended?		
	What can be improved?		
Outcomes	Are the clients showing improvements in outcomes?		
	What is the relationship between X and Y?		
Impact	What do these changes mean for people's day to day lives?		
	Is the service responsible for any of these changes?		
Relevance	What is the (continuing) need for this service?		
	Is it reaching people who will benefit most from this?		
Efficiency	Could it be done more efficiently?		
Cost-effectiveness	How much does it cost?		
	How much does the change in outcomes save in the longer term?		
	Is it sustainable?		

3.2 The literature on evaluating systems change initiatives

Systems change initiatives are complex and can be difficult to evaluate. Traditional approaches using experimental designs are often not appropriate to evaluating systems change initiatives because they are not always feasible to conduct, particularly where the intervention is designed to be open to all (which would not allow for a control group). Coffman (2007:31) emphasises that:

"Rigor applied to systems initiatives means being clear about the evaluation's outcomes, methodology and measures. Rigor does not only mean using experimental designs that use control groups or conditions. In fact, these designs typically are not feasible within systems initiatives. This is particularly true when the goal is developing inclusive systems with open-ended participation opportunities."

Ling (2012) argues that conventional designs like randomised control trials are inherently unable to deal with the complexity characteristic of systems change initiatives. He states that conventional approaches aim to understand the whole by seeing it as a combination of its parts, building up detailed pieces of evidence into an accurate account of costs or efforts and consequences to form judgements. He argues that while this may be appropriate for simple and complicated interventions, in more complex cases the underlying limitations of the approach, such as its unsuitability at dealing with the uncertainty inherent to complex situations, has become apparent. Attributing outcomes directly to activities can be particularly challenging in system change evaluations. Latham (2014:32) emphasises that system change is dynamic and characterised by "uncertainty, volatility and adaptation." She argues that:

"while traditional evaluation often assumes a linear and predictable chain of cause and effect...systems change initiatives unfold in a world where outcomes are highly unpredictable, control over events is fragmented, interests diverge, and there may be low levels of agreement on solution [sic] to problems (or even on problem definition). In addition, the organisational, political, economic and funding contexts are turbulent, with new opportunities and barriers arising often. Under these circumstances, it is folly to posit cause and effect, and to define outcomes against [sic] we will measure progress." (ibid: 32)

Given the unpredictable nature in which system change unfolds, cause and effect are difficult to measure. It is difficult to clearly attribute outcomes to the activities undertaken as part of the intervention. Patton (2011: 133) states that "under conditions of complexity, processes and outcomes are unpredictable, uncontrollable, and unknowable in advance" and he advocates for an

approach to evaluating systems change initiatives that is sensitive to this uncertainty. He argues that summative evaluations can be inappropriate for complex systems change initiatives, as summative evaluations require a fixed programme model which does not readily allow for ongoing development, adaptation and innovation (Patton, 2011). Choosing an evaluation design that recognises the complexity of an initiative is important. Patton (2011) suggests that two common approaches to dealing with complexity - denying it or attempting to control it - are both inadequate. Ling (2012) emphasises that complexity cannot be grafted onto more conventional evaluation approaches as it changes the questions that the evaluator should ask.

"For example, rather than asking 'what factors need to be present in order for this intervention to work' we might ask 'how do the factors interact with each other, how do these interactions change over time, and to what extent are these amenable to intentional change?'" (ibid: .84)

Latham (2014) on the other hand states that the mismatch between systems change and traditional evaluation can be overstated. She argues that once the practice of defining and operationalising outcomes and indicators is decoupled from the practice of assuming linear progress toward an ultimate outcome, traditional approaches can be useful. Even where the context and initiative are uncertain, volatile and nonlinear, system change concepts can be developed and tracked over time.

Theorists emphasise the need to select an evaluation approach that is appropriate to the particular initiative. Coffman argues that:

"Systems initiative evaluations should be tailored to their unique theories of change, assessing the outcomes and impacts connected to the parts of the system they are attempting to change."

(Coffman, 2007:16)

The evaluation should be directly informed by the unique characteristics of the intervention in question, and the changes that it seeks to bring about. As such, there is no 'one size fits all' approach to evaluating systems change initiatives. And indeed, Coffman (2007) emphasises that methodological choices should be based on the information the evaluation audience wants, the stage of development that the initiative is at, and practical considerations such as the evaluation timeframe and resources available. She identifies five main areas that systems change initiatives seek to address- context, components (programmes and services within the system), connections (linkages across system components), infrastructure and scale. She recommends different evaluation questions and methodologies depending on what area the evaluation seeks to address (Coffman, 2007).

	Context	Components	Connections	Infrastructure	Scale
Questions	 Has the initiative changed the political environment through its activities? Has the initiative produced changes to investment, policy, or practice that will enable changes in components, connections, infrastructure, or scale? 	 Did the initiative design and implement system components as intended? Did the components produce their intended impacts for beneficiaries? 	 Did the initiative design and implement connections and linkages as intended? Did the connections and linkages produce their intended impacts? 	 Did the initiative establish infrastructure or supports that are consistent with its objectives? Did the infrastructure or supports achieve their objectives for effectiveness, sustainability and quality? 	 Did the initiative enable system scale up with quality and fidelity? Did scale up result in broad impacts for beneficiaries at a system-wide population level?
Methodologies	Theory of change evolution Case studies Public polling Policy tracking Key informant surveys Coalition analysis Policy/bellwether interviews Media tracking	Programme evaluation methodologies (including experimental/quasi-experimental) Programme monitoring Quality assessments Efficiency analyses Customer surveys	 Programme evaluative methodologies (including experimental/ quasi- experimental) System mapping Network analysis Customer surveys 	 Theory of change evaluation Case studies Performance audits Management information systems Practitioner data collection 	Population-based demographic and service analysis Programme evaluation methodologies (including experimental/quasi-experimental) System/programme monitoring Results-based accountability

(Coffman, 2007:17)

The W.K. Kellogg Foundation (2007) proposes four different evaluation designs for evaluating system change initiatives: (1) exploratory, (2) predictive, (3) self-organising, and (4) initiative renewal. The evaluation design will depend on the evaluation questions the initiative leader wishes to answer. The Foundation proposes that exploratory designs look at components and dynamics, not delineated in the theory of change; predictive designs examine cause and effect relationships between structured interventions and predict outcomes; self-organising designs examine patterns of change emerging from self-organising dynamics within the initiative, and initiative renewal designs place the initiative in context and examine the interplay of multiple dynamics of change and their implications for the sustainability of the initiative. The Foundation argues that:

"By aligning the evaluation design with the different dynamics of system change, the evaluation can be more tailored to the nature of change within an initiative, resulting in evaluations that are timely, targeted, efficient, and useful." (W.K. Kellogg Foundation, 2007: 12)

Patton (2011: 131) also argues that every evaluation situation is unique and that a successful evaluation "emerges from the special characteristics and conditions of a particular situation - a mixture of people, politics, history, context, resources, constraints, values, needs, interests, and change". There is no universally applicable, 'one-size fits all' way to evaluate complex systems change initiatives. Evaluations should be tailored to the initiative that is being evaluated, the needs of stakeholders and wider context.

It is possible, and some would argue preferable, to adopt more than one evaluation approach simultaneously. Given the wide range of areas that complex systems change initiatives address, different evaluation approaches may be appropriate for addressing different aspects of the initiatives and for answering different questions. As noted, Latham (2014) advocates for a hybrid approach between traditional and developmental evaluation.

Other theorists emphasise the importance of mixed-method designs. Coffman (2007) argues that as most systems initiatives focus on more than one area, evaluations should feature a mix of design elements to address the multiple applicable evaluation questions. Hargreaves (2010) agrees that mixed-method design allows for exploring multiple perspectives in a system evaluation. The W.K. Kellogg Foundation (2007) emphasise that the evaluation designs they discuss are not rigidly distinct and recommend shifting evaluation design or using more than one design concurrently. Patton (2011) notes that when undertaking a developmental evaluation, evaluators must adapt their design as the initiative changes, responding with versatility and flexibility to changes as they unfold.

Evaluations, such as developmental evaluations, have been suggested (Patton, 2011; Latham, 2014) as appropriate for evaluating systems change evaluations as they focus on adaptation.

Developmental evaluation may occur at the beginning of a programme or in situations where the programme will continue to be developed and adapted on an ongoing basis. Developmental evaluation supports innovation and development, especially in complex and dynamic situations. It also helps people to get ongoing, real-time feedback about what is emerging and its implications for making a difference. Both argue that developmental evaluation is particularly appropriate for evaluating complex systems. Patton (2011) argues that the two main purposes of evaluating system change are:

- To support exploration and innovation before there is a programme model to improve and summatively test
- 2. To support on-going real-time decisions about what to change, expand, close out or further develop in situations where programme staff and funders expect to keep developing and adapting the programme.

This focus on adaptation is a key feature of developmental evaluation.

"Developmental evaluation.... centres on situational sensitivity, responsiveness, and adaptation, and is an approach to evaluation especially appropriate for situations of high uncertainty where what may and does emerge is relatively unpredictable and uncontrollable. Developmental evaluation tracks and attempts to make sense of what emerges under conditions of complexity, documenting and interpreting the dynamics, interactions and interdependencies that occur as innovations unfold."

(Patton, 2011:7)

Developmental evaluation is attuned to both linear and nonlinear relationships, intended and unintended interactions and outcomes and both hypothesised and unpredicted results (Patton, 2011). Latham (2014) emphasises that while a traditional evaluator takes a third-party objective stance, developmental evaluators become key actors at the strategy table, answering evaluation questions and often providing insight as the initiative unfolds. In developmental evaluations, the evaluator provides ongoing feedback to programme managers to inform adaptations of the programme. Ling (2012) does not explicitly argue for developmental evaluation but does argue for an evaluation approach that is sensitive to uncertainty and adaptation and that focuses on real time changes as they unfold:

"Rather than seeing an intervention as a fixed sequence of activities, organised in linear form, capable of being duplicated and repeated, we see an intervention as including a process of reflection

and adaptation as the characteristics of the complex systems become more apparent to practitioners. The evaluation aims in real time to understand these and support more informed adaptation by practitioners. It also provides an account of if and how effectively practitioners have adapted their activities in light of intended goals." (Ling, 2012: 84)

Ling (2012) argues that evaluations should more often be conducted in real time to support reflexive learning and informed adaptation. Evaluators can support learning as part of a formative role while building a data base for summative evaluation; in evaluating complex interventions the balance of roles might shift significantly towards a more formative role for evaluators (*ibid*).

Evaluations designed around a theory of change or logic model are referred to as programme theory evaluations (Mayne, 2015; Rogers, 2008; Birckmayer and Weiss, 2000). Coffman (2007:7) advocates for an evaluation design that is built around the system change initiative's theory of change and notes that "almost every systems-initiative evaluation" is now based on a theory of change. Theories of change illustrate how change is expected to occur, the role of the initiative in producing that change. Developing a programme theory for an initiative enables evaluation stakeholders to clarify what initiatives are doing in relation to their intended outcomes and impacts. Coffman (2007) argues that making these stakeholder ideas explicit and producing testable assumptions, for example through developing a logic model, is especially useful for complex initiatives where it is difficult to understand the many strategies at play. Coffman recommends building the evaluation around activities, outcomes and impacts identified in the theory of change and/or logic model. To take this approach, logic models must be constructed with rigour and identify the initiative's underlying assumptions and measurable ways to test them (Coffman, 2007).

Ling (2012), too, advocates for basing evaluations of complex system change initiatives on a theory of change. He argues that in projects designed to accommodate the uncertainties associated with complexity, the theory of change will include attention to the importance of learning and adaptation and identify key dependences upon systems and subsystems that lie outside the formal structures of the intervention, such as the systems changing professional and service-user identity and improvement-audit loops. He recommends analysing key uncertainties and supporting reflexive learning (Ling, 2012).

Realist evaluation, first advocated by Pawson and Tilley (1997), is a form of programme theory evaluation. It is an evaluation approach based on testing the mechanisms through which change is

theorised to occur. Rather than attempting to view initiatives or programmes in a vacuum, realist evaluation looks at them within their context:

"Realist evaluation asks not, 'What works?' or 'Does this programme work?' but asks instead, 'What works for whom in what circumstances and in what respects and how?'" (Pawson and Tilley, 2004:2).

In realist evaluations, programmes are 'active,' and thus unable to be isolated or kept constant. Whereas with experimental designs the goal is to test whether a treatment, and the treatment alone, is effective; such designs do not take account of individual intentionality, e.g. individual motivation. Realist evaluation sees a programme as working through a stakeholder's reasoning. Factors such as unanticipated events, political change, staff/personnel changes, practitioner learning, organisational imperatives, etc., impact on the delivery of a programme. Realist evaluations recognise these wider conditions and view programmes as self-transformational, that is successful interventions can change the conditions that make them work (Pawson and Tilley, 2004).

Realist evaluation works by testing and refining theories and developing and testing conjectures about how programmes activate mechanisms among whom and in what conditions to bring about desired changes. The findings of realist evaluations always try to pinpoint the configuration of features needed to sustain a programme (Pawson and Tilley, 2008). Realist evaluation does not preference either quantitative or qualitative methods, but rather marries both, so that both processes and impacts can be investigated (Pawson and Tilley, 2004).

Ling (2012) emphasises the importance of context, arguing that evaluations of complex interventions must provide information about the complex systems which shape the context. He further notes that the realist evaluation approach has long been concerned with bringing in context, and that it has not been alone in this insistence (*ibid*). It is important that evaluations show how particular systems function and interact to provide contextualisation and deliver a sufficiently 'thick' description of the workings of systems and subsystems. Better understanding the system supports reflexive learning within the intervention and facilitates more informed decision making elsewhere (Ling, 2012). A 'thick' description describes not just the initiative, but its context, so that it can be better understood by an outsider and generate findings with broader application. Ling (2012) notes that when using a theory of change approach to evaluate complex interventions, the evaluation judgement should not aim to identify attribution, but clarify contribution. It is important to consider how reasonable it is to believe that the intervention effectively contributes to the intended goals. Realist evaluation has recently been used to evaluate complex health initiatives in Ireland. For

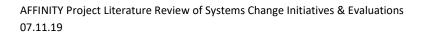
example, it has been used to examine the implementation of a national programme to standardise and improve services for people with diabetes (McHugh *et al.*, 2016). Realist evaluation is also being used to evaluate intensive home care packages (IHCP's) for people with dementia. IHCP's were one of a range of initiatives developed/implemented to address pressure on acute hospital beds. Realist evaluation was considered an appropriate methodology for the evaluation of the IHCPs as the intervention is "highly complex, large-scale and messy" (Keogh *et al.*, 2018:1). A realist evaluation methodology was also used in a process evaluation of the early implementation of a suicide prevention intervention in four European countries: Germany, Hungary, Ireland and Portugal (Harris *et al.*, 2013).

Systems initiatives are made up of many different components. Latham (2014:3) states that systems consist of many pathways, which are understood as the arrangements set up to deliver programmes and services. How these pathways function together to form the system is key. Latham argues that: "Systems should never be seen as a simple 'collection of parts' because parts never exist in isolation. Instead, parts exist in relation to other parts, and it is often these relationships - rather than anything intrinsic to the parts themselves - that determine how a whole system functions." (Latham, 2014:8)

Maintaining a focus on the 'big picture' or whole system is important. The W.K. Kellogg Foundation (2007) proposed initiative evaluations as a way of focusing on the big picture when evaluating systems change initiatives. They define an initiative as a complex system made up of a highly entangled collection of subsystems (W.K. Kellogg Foundation, 2007). They distinguish an initiative evaluation from a project evaluation, where a project evaluation focuses on a specific project and an initiative evaluation looks across projects and their meaning within the initiative as a whole. Initiative evaluations put project work in the perspective of the bigger picture and give unique information about relationships and patterns across the initiative not evident from a single project. They place importance on change over time and across locations and context (W.K. Kellogg Foundation, 2007). Ling (2012), too, argues that evaluations of complex interventions attempt to understand the systems within which the 'parts' operate, looking at the whole logically and causally prior to assessing the individual parts. When evaluating an entire initiative, it is necessary to determine the boundaries of the evaluation. Hargreaves (2010) emphasises that without boundaries, the scope of system-change evaluations become too unmanageable. The boundaries cannot be too broad or too narrow. The W.K. Kellogg Foundation (2007:6) point out that initiative evaluators seldom evaluate whole systems, yet they 'keep the "whole" in their peripheral vision" as they focus on the parts they are investigating.

3.2 Lessons from the literature on evaluating systems change initiatives

- An experimental design is often not appropriate as cause and effect are difficult to isolate and measure.
- Evaluation approaches should be tailored to the specific initiative and its unique theory of change.
- Mixed-method designs, and hybrid approaches may be useful.
- Evaluation approaches focused on adaptation, such as developmental evaluations can be useful.
- Programme theory approaches, e.g. logic models and theory of change, offer an alternative to 'traditional' experimental or quasi-experimental designs.
- Evaluations should pay close attention to the context within which the initiative is situated.
- Maintaining a focus on the whole initiative is important; this can be done while focusing on evaluating specific parts of the initiative.



PART 4: Examples of Systems Change Initiatives and their Evaluations

4.1 Overview of systems change initiatives

This section of the paper considers four health and social care programmes from different countries with a view to:

- Illustrating how systems change initiatives operate in the real world
- Drawing attention to certain key features of change initiatives
- Deriving lessons relevant to an evaluation framework for AFFINITY.

The examples have been chosen because, like AFFINITY, each:

- Aimed to tackle a complex (or 'wicked') issue for which there are multiple, interacting determinants
- Involved a number of intersecting workstreams or operated at different levels, from the macro to the local
- Targeted professionals and service users in different contexts
- Aimed to change the behaviour of professionals, as well as service users
- Aimed to affect multiple contexts.

The examples described in this section of the paper can all be described as complex interventions according to the criteria suggested by Pawson and Tilley (2004):

- The 'intervention' is a theory or set of theories
- The intervention involves the actions of people
- The intervention consists of a chain of steps
- These chains of steps or processes are often not linear and involve negotiation and feedback at each stage
- Interventions are embedded in social systems and how they work is shaped by this context
- Interventions are prone to modification as they are implemented
- Interventions are open systems and change through learning, as stakeholders come to understand them.

4.1.2 Good for Kids

The Good for Kids programme was implemented as one of a number of concurrent government initiatives in New South Wales (NSW), Australia, to reduce the prevalence of child overweight and obesity. It was developed in response to a number of local and international policy developments. Enhanced child obesity prevention policy and programme development also occurred at this time in the non-government sector.

The goals of the *Good for Kids* programme were to reduce the prevalence of child overweight and obesity in the Hunter New England (HNE) region of NSW and to build evidence for policy and practice related to the prevention of child obesity in NSW more broadly. The programme was funded by the NSW Ministry of Health and the HNE local health district, who also implemented the programme.

The focus of the overarching program was on children aged 2-12 years. Interventions in individual community settings targeted particular age groups within this range.

Like the AFFINITY Project, the programme emphasised awareness and capacity building, within a multi-setting approach. The multi-setting capacity building approach was based on the view that for healthy eating and physical activity to become the norm for children, the community settings with which they interacted needed to foster these behaviours. Some settings had the potential to reach almost all children in the target age group, for example schools; others had the potential to reach large numbers of children, for example preschool and long day care centres, general practices and community sports clubs; while others catered for smaller numbers or specific groups of children, for example community service organisations, HNE Health Service and Aboriginal Health Services.

4.1.2.1 Evaluation of Good for Kids (Wiggers et al., 2013)

Good for Kids was evaluated over the period of 2006-10. The evaluation was conducted by the funders, along with the Physical Activity, Nutrition and Obesity Research Group at The University of Sydney.

The evaluation involved the measurement of:

- Impacts: reach of the intervention and adoption of practices by participating organisations;
 community awareness of the programme and its key messages.
- Outcomes: prevalence of healthy eating and physical activity behaviours; prevalence of overweight and obesity.

The reach of the programme was determined by assessing the number of organisations in each community setting that participated in the programme intervention and by assessing the extent to which various organisational practices were adopted by community organisations.

Two separate **quasi-experimental studies** compared the prevalence of new organisational practices in schools and services in the HNE region with randomly selected samples in the rest of NSW.

Adoption of the programme's organisational practices in other settings were assessed through a

variety of designs, including pre-post and post-test only surveys. Repeated quasi-experimental studies were undertaken to determine the impact of the programme's social marketing campaigns on community awareness. This involved nine cross-sectional telephone surveys of a randomly selected sample of parents of 2-15-year olds in the HNE region and a randomly selected sample from the rest of NSW. Assessment of the prevalence of child healthy eating and physical activity behaviours was done through cross-sectional pre-post field surveys of randomly selected children attending services and schools in the HNE region and quasi-experimental telephone surveys of randomly selected samples of parents in the HNE and NSW regions. Measurement of children's height and weight were also undertaken during the field surveys.

The evaluation found that the capacity of community organisations to improve children's eating and physical activity behaviours was enhanced in all community settings that were the focus of the programme. In a number of instances, these changes occurred at differentially greater rates in HNE than elsewhere in NSW. A large proportion of parents in the HNE region were aware of the child obesity prevention messages that were promoted by the programme, these proportions were significantly greater than elsewhere in NSW. The field survey results suggested positive change over time in the prevalence of a number of healthy eating and physical activity behaviours in the HNE region. There were some statistically significant findings regarding consumption of certain foods, however, rates of overweight and obesity remained in line with NSW trends (Wiggers *et al.*, 2013).

4.1.3 Personalised Integrated Care Programme (PICP)

In 2011 Age UK commenced its *Personalised Integrated Care Programme* (PICP), developing an innovative model of person-centred care for older people with multiple long-term conditions who are at the greatest risk of avoidable hospital admissions. The programme's three primary aims are to:

- Improve the health and wellbeing outcomes for older people with long-term conditions who experience high numbers of avoidable hospital admissions
- Improve older people's experience and quality of care and support by tailoring services to meet their needs
- Reduce cost pressures in the local health and social care economy, with a particular focus on acute care.

PICP adopted a phased approach, evolving iteratively over time in response to learning on the ground and the changing local and national context. Phase 2 began in 2015, piloting the model across England with eight local health and care partnerships. Each partnership, together with Age UK, tailored the model to its local context through a structured co-design phase, while seeking to

retain the fidelity of the core elements of model.

The Age UK *Personalised Integrated Care* model can be described as 'a social prescribing model'. How care is provided in the model has also been noted as being consistent with what Nesta describe as 'good help'. Like AFFINITY, the *PICP* has a multi-disciplinary focus, seeks to co-ordinate the care an older person receives, involves partnerships with local healthcare settings and seeks to put the older person at the centre.

4.1.3.1 Blended evaluation of Phase 2 (Fullwood, 2018)

The phase 2 evaluation was carried out by an independent consultant and assessed the programme from commencement in 2015. A whole-programme, mixed method approach was used to evaluate the programme. This included both a formative evaluation and quantitative and qualitative evaluations of the programme's impact and outcomes. The evaluation drew on a range of existing evaluative evidence, including two independent evaluations of the co-design phase; an independent qualitative evaluation of phase 2, involving semi-structured in-depth interviews and focus groups; an MSc thesis; and two independent local evaluations, one using a realistic evaluation design and one an interim evaluation. Fullwood's evaluation also analysed programme-level performance management data, included an analytical summary of changes in the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) scores and reviewed programme documentation. The range of evidence was assessed using a deductive content analysis methodology, which is an analytical framework tailored to the programme's theory of change. The analytical framework captured:

- Outputs, outcomes and impact, and how these have been achieved
- Lessons learned, including challenges, successes and enabling factors
- The quality of the evidence/methodology used

It was noted as a limitation by the evaluator that no process evaluation of phase 2 had been undertaken. The qualitative programme evaluation, local evaluations and programme-level documentation provided evidence of common features that worked well, common challenges and shared elements of effective practice. However, a robust comparative analysis of how the model was implemented and the impact and delivery of the service was not possible.

The evaluation found strong quantitative and qualitative evidence of a significant positive impact on the wellbeing of older people. There was qualitative evidence of the positive impact of the programme on the primary care workload by supporting older people who would otherwise have sought help for their GPs for underlying non-medical needs. The local health and care systems in all sites progressed towards new, more integrated and holistic models of care. Involvement in PICP was

effective in fostering agency and empowered older people to recognise and develop their own strengths and abilities. It helped clients to take action to enable them to live independent, fulfilling lives. The evaluation also showed that PICP was effective in enabling personalised care for older people and connecting people and services in the community through holistic social prescribing, thereby promoting the integration of statutory and non-statutory services and harnessing community assets to improve older peoples' wellbeing. PICP proved effective in empowering older people to identify their goals and preferences, and in planning care and supporting clients to help ensure these goals are achieved and preferences met (Fullwood, 2018).

4.1.3.2 PICP impact on hospital activity (Georghiou and Keeble, 2019)

The evaluation of the impact of the *PICP* on hospital activity for patients who had participated in the *PICP* was carried out by Nuffield Trust. It **compared** PICP clients with very similar **matched controls** from areas not covered by the *PICP*; these matched controls were selected using advanced methods.

The evaluation compared the use of A&E and outpatient services in the first nine, and for a large subset 16, months after the start of each client's PICP with the matched controls. Additional analyses were carried out to examine the impact of PICP on potentially preventable admissions, the causes of emergency admissions and variations in impact by subgroupings of clients.

The analysis used three data sources, including Age UK's *PICP* client data, an anonymised file with details of referral to the *PICP* programme, and NHS hospital activity data. The use of existing monitoring data allowed the evaluators to pseudonymously identify almost every *PICP* client within national hospital datasets and describe hospital activity for each of these clients for at least three years before the intervention start date and up to 16 months after. The evaluation was carried out using a retrospective matched control methodology, such that for every person referred to the *PICP*, the evaluators found one other individual who had not received the service and who shared or were closely matched on a range of characteristics, such as calculated risk of future emergency admission; sex; age; history of recorded diseases/conditions; and pattern of use of hospital services.

The evaluation found that in the first nine months after referral, the *PICP* group had 33 per cent more A&E visits and 35 per cent more emergency admissions than the matched control group. Outpatient attendances were also higher by 23 per cent. Overall hospital costs in the nine months after referral for the *PICP* group were £3,504 per person compared with £2,455 for the matched control group. In the *PICP* group, 37 per cent of admissions were considered to be potentially preventable with effective primary and community care compared to 34 per cent in the matched

control group. These effects continued for the group who were analysed up to 16 months after referral, suggesting that the higher level of admissions were not short-term effects but rather potentially lasting consequences of the service.

The aim of *PICP* is to improve the care older people experience through direct support and by reducing fragmentation in the care system, and to reduce local cost pressures. In terms of the latter aim, the results were disappointing. The evaluators noted that with Age UK's focus on each client's individual needs, it is likely that there was a corresponding increase in attention on potentially unaddressed health needs. A previous qualitative evaluation of the programme found that it had been helpful in discovering unmet needs among clients and noted instances when referrals were made to NHS services and social care. It is possible that the process of uncovering additional needs led directly or indirectly to increased hospital use, for a sustained period beyond the short duration of the service. They noted that while emergency hospital care can be destabilising for older people, the additional care may ultimately have been to the benefit of those affected over the longer term (Georghiou and Keeble, 2019).

The approach of this evaluation was to examine one particular outcome area using rigorous quasi-experimental methods. The findings demonstrate a risk of conducting an evaluation focused on one outcome area alone; particularly where the results are unexpected. Focusing the evaluation on only one aspect of a complex and multi-component programme may lead to judgements about a programme that do not sufficiently explore other areas that may provide more context to results. It is worth noting that this was not the sole evaluation of *PICP*, with the blended evaluation previously discussed commissioned to evaluate other important factors.

4.1.4 Food for Life

The *Food for Life Programme* (FFLP) is an England-wide healthy and sustainable food programme that evolved in schools and is being adapted for children's centres, universities, care homes, and hospital settings. It is a collaboration between charities, led by the Soil Association together with Focus on Food, Garden Organic, the Health Education Trust and the Royal Society for Public Health. Schools, councils and other agencies are local partners in this wider partnership. It is funded by the Big Lottery Wellbeing Fund. It is an ongoing programme that has had two major evaluations to date; one published in 2012, which evaluated the first five years of the programme (2007-11) and the second published in 2016, which covered the years 2013-15.

The school's element of the programme is a whole-school, multi-component intervention delivered

by national charities in England and Wales, with a related scheme in Scotland. A central thread that links the different components of the programme is the relationship between dietary health and sustainable food systems. Like the AFFINITY Project, the Food for Life programme involves multiple intersecting actors and recognises that contextual responses can help individuals change behaviours.

4.1.4.1 Food for Life Partnership Evaluation (Orme et al., 2010)

The University of West England, Bristol (UWE) and Cardiff University were commissioned by the Soil Association to carry out the first evaluation. The evaluation was outcome-focused and assessed a range of behavioural changes at the policy, organisational, group and individual level.

The evaluators noted several challenges to evaluating complex community-based initiatives like FFLP, including the multiple levels of change targeted by the programme; that longer term outcomes may be achieved at a point beyond the lifetime of the programme; adaptations in programme implementation in response to context; the multiple and diverse stakeholder goals; and the interconnectedness of the programme with other initiatives in related fields of activity. The FFLP partnership evaluation used a theory of change approach, testing the links between FFLP's activities and outcomes. The theory of change approach addressed the need to estimate the programme's effect on short- and long-term outcomes. A strategy was adopted to surface 'theories of change,' building the evaluation around how FFLP was thought to work. Theoretical links were identified between short term inputs, outcomes and contextual conditions. The measurement of FFLP's activities was as important as the measurement of outcomes, to enable a clear account of the relationship between the programme and the changes sought. The measurements were intended to test the plausibility of the changes theorised. This approach was used to evidence the contribution of the programme to the changes in outcomes, as it was not feasible to establish causality.

The central elements of the research design were a pre- and post-cross-sectional study of 111 flagship schools and process evaluation. The pre- and post-study involved assessing the position of schools at the point of enrolment (baseline) and after approximately 18-24 months (follow-up). The perspectives of sub-samples of pupils and other participants were used to provide direct evidence of outcomes for beneficiaries. The process evaluation consisted of programme delivery analysis and case study work with selected schools, caterers and their associated communities. The evaluation involved detailed questionnaires with lead staff at the baseline and follow up and semi-structured interviews with school leads. Programme documentation and official data sources were also analysed. A sub-sample of the schools participated in pupil and parent questionnaires.

The evaluation found that *FFLP* made a positive contribution to the achievement of a range of outcomes: benefit local and organic producers supplying *FFLP* schools; an increase in both awareness and non-school consumption of local, organic and MSC products; healthier eating attitudes among pupils; increased staff training; and improvements in facilities (Orme et al., 2010).

4.1.4.2 Second Evaluation of Food for Life Programme 2013-15 (Jones et al., 2016)

In 2013, *FFLP* secured funding from the Big Lottery Fund to support two further years of programme implementation and UWE's Public Health and Wellbeing Research Group were appointed as an independent evaluator. The funding allowed *FFLP* to deliver a further phase of the programme, extending its work beyond schools into early years settings, hospitals, workplaces, care homes and universities. UWE adopted a theory of change approach informed by realist evaluation, to estimate the programme's effects on interim and longer-term outcomes and looked at how and why *FFLP* produced outcomes. The theory of change approach was adopted to capture the value of a systemic approach. A focus was placed on both processes and outcomes to gain an understanding of whether *FFLP* worked, and of why and how it worked or did not work in particular contexts. The approach provided for capturing interim measures of progress in a developmental phase, where impact may not be measurable in the timescale afforded to the evaluation. Social Return on Investment (SROI) methodology was also used to show the value of FFL (Jones *et al.*, 2016).

The evaluation encompassed five workstreams: (1) the long-term impacts and durability of FFL in schools; (2) a review of local commissions; (3) a cross-sectional study of pupils' diets in *FFLP* local commissions; (4) exploration of new settings beyond schools; and (5) the social value of *FFLP* in local authority commissions. The overarching research questions across all the workstreams were:

- What are the impacts of Food for Life on healthy eating behaviours in a range of settings?
- How are these impacts achieved?
- How is the Food for Life approach sustained?
- What is Food for Life's wider social return on investment?
- How can Food for Life become embedded in a range of settings?

A mix of qualitative and quantitative research methods were used, including case studies across the workstreams.

Evaluating the long-term impacts and durability of *FFLP* in schools (workstream 1) involved a survey of schools and case study research. The evidence suggested that FFL remained relevant for schools and highlighted that for some schools' *FFLP* became fully embedded and part of their school ethos.

The review of local commissions (workstream 2) encompassed a review of commissioning documentation, scoping discussions with *FFLP* leads and semi-structured interviews with key stakeholders from each commissioned area. While commissioners expressed a high degree of satisfaction with FFLP, the commissioners and *FFLP* staff emphasised the need to further define the *FFLP* programme and demonstrate the public value of such programmes.

The cross-sectional study of pupils' diets in *FFLP* local commissions (workstream 3) compared schools engaged with *FFLP* with schools not engaged in the programme in the same local area using the validated Day in the Life Questionnaire. It found that pupils in *FFLP* schools are more healthily

New settings (workstream 4) were evaluated through case studies focused on organisation's piloting *FFLP*, informed by a theory of change approach. Data was collected for each case study using qualitative methods, primarily semi-structured interviews with key stakeholders. The case studies demonstrated clear potential for *FFLP* to work with people across their life course and the new settings programme had made good progress in establishing this in the sectors prioritised.

The SROI analysis of *FFLP* (workstream 5) covered two local commissions over two financial years and involved interviews and analysis of programme records. The SROI found that for every £1 of investment £4.41 of social value was created (Jones *et al.*, 2016).

4.1.5 Communities for Work

Communities for Work (CfW) is a Welsh voluntary programme that aims to increase the employability of long-term unemployed and economically inactive adults and 16-24-year olds not in employment, education and training and to help them to move into or closer to employment. It is jointly funded by the Welsh Government, the Department for Work and Pensions and the European Social Fund. It is delivered at a local level and participation is voluntary.

4.1.5.1 Evaluation of Communities for Work (CfW)

The programme evaluation was conducted in three stages between 2016 and 2018. The first report set out the theory of change and developed a logic model, which was developed through analysis of documentation and interviews with key policymakers and stakeholders (Newton, 2017). The logic model informed the rest of the evaluation.

The second report assessed how the programme was set up and was being implemented. This was done by surveying front-line delivery staff; conducting face-to- face interviews with key

stakeholders; and carrying out qualitative fieldwork using a variety of methods in cluster areas and reviewing the database of participants. The report made a number of findings and made recommendations related to the benefits and challenges of integration. It also looked at early outcomes, with the data suggesting that despite its many strengths CfW might struggle to deliver the levels of engagement and outcomes (Burrowes and Holtom, 2017).

The third report built on the theory of change to assess emerging outputs and impacts of the programme. This was assessed through a review of programme documents and research reports, an analysis of the database of participants, interviews with key stakeholders, and qualitative fieldwork in 10 *CfW* areas, contact with current and former *CfW* participants, and reviewing the portfolios of 60 participants (Burrowes and Holtom, 2018). The third report found that engagements of young people exceeded the level profiled whilst that of economically inactive and long term unemployed was somewhat below the level profiled. However, the evidence also suggested that the programme had yet to address more complex or entrenched barriers, with those with fewer barriers more likely to move into work and the programme sometimes struggling to effectively engage and support those with the most complex barriers (Burrowes and Holtom, 2018).

4.2 Lessons from these examples of systems change initiatives and their evaluations

4.2.1 What can we learn about systems change initiatives from these examples?

The literature suggests that there a number of dimensions along which systems change initiatives vary, these include:

- **Scale:** Systems change initiatives operate at different scales, for example, they can target a specific population, an entire subgroup in a population or the entire population.
- **Complexity:** Complexity can occur and may be experienced at either or both the system and the intervention level.
- **Stage:** Complex systems change initiatives are often implemented incrementally and there may not be implementation alignment between different components in the system.
- **Scope:** System change initiatives tend to have multiple components therefore clarity on what part or parts of the systems change initiative are to be evaluated is critical.
- Support: Different levels and types of support may exist for systems change initiatives, for
 example is there a legislative imperative to introduce change; is there a supportive policy
 context; is there public appetite for change; what is the mandate for change?

4.2.2 What can we learn about evaluating systems change initiatives from these examples?

We know from the literature that evaluating complex system change initiatives brings particular challenges, as these types of systems are not stable, have many moving parts and the processes and outcomes are often not known or are not predictable at the beginning. In this context.

"The randomised control trial (RCT) as the highest guarantor of change on the basis of the strongest evidence has lost some of its positionality in a growing awareness that process and system change does not happen on the basis of rationality or technical process alone" (Barry et al., 2018:4).

Therefore, particular attention should be paid to the following when planning for and designing a complex system-change evaluation:

- The evaluation of complex initiatives is not a one-off event, it is an ongoing, iterative process, and the outcomes of one evaluation will likely impact how the initiative operates into the future.
- Evaluation involves a range of different methods to gather a variety of perspectives; different types of data will be needed to answer different types of questions and at different time points.
- There are different theoretical perspectives that underpin different evaluation designs, for
 example, objectivism, which asserts that social reality exists independent of and apart from our
 awareness and that social realities can be discovered and measured; and constructivism, which
 argues that there is no objective reality; meanings are not fixed but emerge as a result of
 peoples' interaction with the world around them
- The design of the evaluation should be informed by the evaluation questions, the context and circumstances of the initiative; and the stage of implementation.

Summary of Evaluation Approaches Used Elsewhere

Programme	Evaluation Purpose	Evaluation Questions	Evaluation Types	Evaluation Approach	Evaluation Methods
Good for Kids (New South Wales)	To evaluate several key impacts and outcomes related to the reach and effects of the programme.	 Impacts What is the reach of the intervention and adoption of practices? What is the level of community awareness of the programme and key messages? Outcomes What is the prevalence of healthy eating and physical activity behaviours? What is the prevalence of overweight and obesity? 	Outcome/impact	Quasi- experimental studies comparing target community with the rest of NSW	Pre- post- and follow-up surveys
Personalised Integrated Care Programme- Age UK (U.K.)	To reflect on outputs, outcomes and impact, and on lessons learned, including successes, challenges and enabling factors, to gain an understanding of the why and how, as well as the difference the programme made.	Blended Evaluation of Phase 2 1. Did the health and wellbeing outcomes for older people with long-term conditions who experience high numbers of avoidable hospital admissions improve? 2. Did the older people's experience and quality of care and support improve by tailoring services to meet their needs? 3. Were cost pressures in the local health and social care economy, with a particular focus on acute care reduced?	Formative Outcome/impact	Programme theory, using theory of change	Review and analysis of existing evaluative evidence and performance management data

Programme	Evaluation Purpose	Evaluation Questions	Evaluation Types	Evaluation Approach	Evaluation Methods
Personalised	To assess one crucial aspect of the	Evaluation of Impact on Hospital Activity	Impact	Quasi-	Pre- and post-
Integrated	performance of the programme- its	1. Was the subsequent hospital use in		experimental-	surveys
Care	impact on hospital use. The blended	the PICP group lower than that of the		PICP group	
Programme-	evaluation covered other important	matched control group?		retrospectively	
Age UK	factors.	2. Were the costs lower for the PICP		compared to	
(U.K.)		group?		matched controls	
Food for Life	To test the theoretical linkages	Food for Life Partnership Evaluation	Process/	Programme	Pre- and post-
Programme	between programme activities and	(2010):	Implementation	theory, using a	cross-sectional
(FFLP)	outcomes	Are schools adopting the FFLP		theory of change	study of flagship
(UK)		approach associated with increased	Outcomes/Impact		schools
		school meal take up?			
		2. Are schools adopting the FFLP			
		approach associated with increases in			Process evaluation
		healthier eating amongst pupils?			consisting of
		3. Are schools adopting the FFLP			programme delivery
		approach associated with increases in			analysis and case
		pupil awareness of food sustainability			study work
		issues?			
		4. Do schools adopting the FFLP			
		approach influence parental			
		behaviours towards healthier &			
		sustainable foods?			
		5. Are schools adopting the FFLP			
		approach associated with			
		improvements in pupil behaviour &			
		attainment?			

Programme	Evaluation Purpose	Evaluation Questions	Evaluation Types	Evaluation Approach	Evaluation Methods
		6. Do FFLP-led school meal improvements provide new markets for local, organic and MSC producers?			
Food for Life Programme (UK)	To estimate the programme's effect on interim and long-term outcomes.	 Evaluation of Food for Life 2013-2015 What are the impacts of Food for Life on healthy eating behaviours in a range of settings? How are these impacts achieved? How is the Food for Life approach sustained? What is Food for Life's wider social return on investment? How can Food for Life become embedded in a range of settings? 	Impact Cost-Effectiveness	Programme theory using Realist evaluation design methodology	Mix of quantitative and qualitative methods including surveys, interviews, case studies, documentation analysis and a cross-sectional questionnaire SROI methodology
Communities for Work (Wales)	To elucidate the theory of change for CfW and develop the logic model underpinning the programme. To assess how the programme was set up and was being operated. To provide an indication of the programme's overall effectiveness.	 What is the theory of change for the CfW? How was the programme set up? How was the programme implemented? What is the overall effectiveness of the programme? 	Process/ Implementation Outcomes	Programme theory, using theory of change and logic model	Mixed methods including documentary analysis, surveys and qualitative fieldwork

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