

The impact of Keep Well: An evaluation of the Keep Well programme from 2006 to 2012

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The impact of Keep Well: An evaluation of the Keep Well programme from 2006 to 2012

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Executive summary

Background

Keep Well is a Scottish Government funded prevention programme implemented by local NHS Boards. It was initiated in 2006 with the stated aim of contributing to a reduction in health inequalities in Scotland by providing health checks targeting those at particular risk of preventable serious ill health, predominantly heart disease, and offering appropriate interventions, services and follow-up. This was termed 'anticipatory care'. NHS Health Scotland was involved in the development of the programme at the outset and supported delivery of the programme until March 2014.

The relative divergence of improvement in cardiovascular disease (CVD) outcomes by socioeconomic status was of political concern. It was felt that a CVD screening programme that specifically targeted, reached and engaged those who were not engaged with health services, and which supported them to undertake modification to identified CVD risk factors (smoking cessation, weight loss and statin therapy), could increase the rate of improvement in the most deprived socioeconomic groups. This would contribute to a reduction in the inequalities in CVD mortality between the most and the least well off.

There were several 'waves' of Keep Well which each brought on new areas and/or general practices and had slightly different requirements: Wave 1 (2006), Wave 2 (2007), Well North (2008), Wave 3 (2009) and Wave 4 (2009). As the programme evolved it incorporated other population groups and initiatives. A process of 'mainstreaming' began in April 2012 with the aim of making targeted health checks part of 'normal, permanent practice' by 2014. In 2013, the Chief Medical Officer announced that central funding for Keep Well will cease in 2017.

Prior to mainstreaming, those targeted by Keep Well were adults aged 45–64 years living in areas of concentrated deprivation (the 'core eligible population'). Some NHS Boards widened the eligible population and specifically targeted other vulnerable groups (e.g. Gypsy travellers). With mainstreaming, the Keep Well guidance broadened the eligible age range for the core population to 40–64 years and also required that specific population groups ('vulnerable groups') were consistently included in the eligible population.

This report presents the findings from a 'pragmatic' evaluation of the impacts of the Keep Well programme. The work was commissioned by the Keep Well Extension Board¹ in December 2011 and funded by the Scottish Government. It presents a picture of how the Keep Well programme theory² has been elaborated by local NHS

¹ The Keep Well Extension Board was set up to agree arrangements for mainstreaming Keep Well from April 2012 and comprised the Scottish Government, local Health Boards and three special Health Boards – NHS Education Scotland (Chair), NHS Health Scotland and NHS National Services Scotland.

² A programme theory is the articulation of how the actions of a programme interact with the people they reach to generate the intended or actual outcomes. This is often depicted graphically in the form of a flow diagram or logic model.

Boards over the years and provides a narrative about Keep Well's history and evolution, and what is known and not known about the programme's impacts, and why.

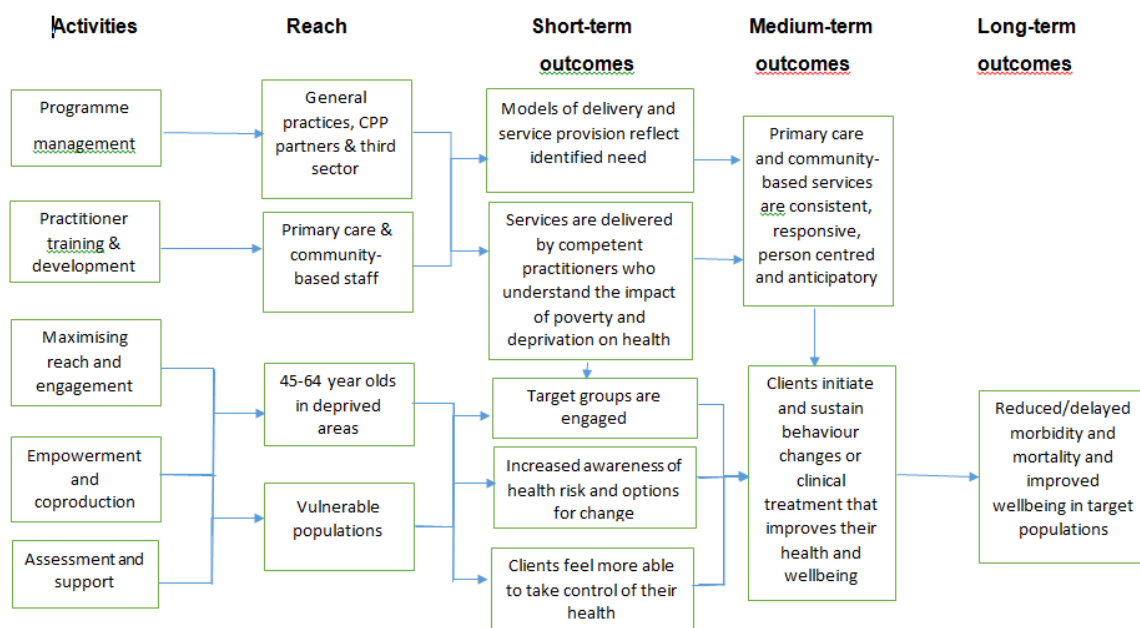
Methods

The evaluation includes two new studies: a qualitative study of variation in implementation and approaches to Keep Well across NHS Boards ('local variability study'), and quantitative analyses of trends in cardiovascular-disease-related mortality, hospitalisations, diagnoses and prescribing in Wave 1 general practices using available health service data ('outcomes analysis'). The local variability study was undertaken using semi-structured interviews with stakeholders in each NHS Board. The outcomes analysis compared trends in the period before and after the introduction of Keep Well, both in Wave 1 practices and in practices that did not participate in Wave 1. This evaluation has also brought together the findings from existing evaluations of engagement and outcomes undertaken by NHS Boards and nationally. This evaluation focuses on the programme prior to mainstreaming in 2012.

Results

Implementation of Keep Well

Each wave of Keep Well was accompanied by national guidance and annual performance reporting on completed health checks. NHS Health Scotland had a programme management role nationally which included provision of support to Boards in operationalising the guidance documents. However, as Keep Well was rolled out across Scotland, each of the waves was accompanied by slightly different guidance. In different areas, the programme's theory came to be defined in a variety of ways and NHS Boards adapted the programme to local circumstances. The local variability study used interviews with those involved in Keep Well's implementation locally to generate a simple generic programme theory that broadly reflected the Keep Well programme as a whole.



Within this, three theories of change were found to exist across the Boards:

- Theory 1: Changing the way care is organised and delivered.
- Theory 2: Empowerment and co-production.
- Theory 3: Focusing on clinical risk factors.

In general, within each NHS Board, one of these theories appeared to have driven local planning for Keep Well more than the others.

A number of outcomes for Keep Well were suggested during stakeholder interviews which were not part of the original programme theory, and are not possible to explore with available data. These include improved relationships and trust between practitioners and patients, and increased self-efficacy.

Engagement in Keep Well

The Wave 1 evaluation found that Keep Well in Wave 1 areas had identified and engaged with target population groups both in terms of their deprivation status (50–70% of attendees were from the most deprived quintile of data zones across the pilot sites) and in terms of their cardiovascular risk status (there was a high prevalence of CVD risk factors among attendees and over 20% had an ASSIGN³ score of 20% or more; i.e. had a 20% chance of developing CVD over 10 years). Local evaluations were more variable in their findings about the deprivation and CVD risk status of attenders but this could be due to the different geographical areas and the problems

³ ASSIGN scores give an estimated risk of developing CVD over 10 years. Further details at <http://assign-score.com/>

in accurately measuring deprivation and identifying those living in deprivation in more rural and less densely populated areas.

The impacts of Keep Well

The Keep Well programme encouraged innovation in the ways primary care sought to contact and engage deprived populations and those likely to be at high risk of CVD. In terms of collaboration between primary care and other services there is little evidence from local evaluation studies that this improved as a result of Keep Well. Despite this, interviewed stakeholders reported that Keep Well had improved working relationships between agencies and raised the profile and understanding of health inequalities locally.

There is weak evidence from local evaluations of patient and staff satisfaction with the programme and some evidence of small-scale, self-reported behaviour change, although the evidence of this derives from studies at a high risk of bias. One local evaluation found evidence of Keep Well resulting in appreciable increases in the diagnoses of chronic disease; however, this was not replicated in other areas. The new analysis of available data undertaken for the outcomes analysis suggests that there has been no discernable change in prescribing, although the limitations of the data mean that a change of less than 10% would not have been identified. Existing local evaluations suggest that referral practices were patchy, and there is evidence of considerable variation between practices and in terms of the proportion of those referred who attended and subsequently engaged with the referred service.

The impact on behaviour change is unclear from existing local studies, as is the extent to which any changes are maintained over time. One before-and-after local study showed small improvements in CVD risk factors, but there was no comparison group and substantial loss to follow up, and so it is uncertain if these improvements were due to Keep Well. No existing evaluations were identified that explored the contribution of Keep Well to improving self-efficacy, or sense of control, or to improved relationships and trust between patients and practitioners, although stakeholders suggested these were possible outcomes.

In terms of longer-term population health impacts on CVD deaths and illnesses, the analyses undertaken in this evaluation did not find that the introduction of Keep Well made a discernable difference. The new analysis of routine health service data comparing KW with non-KW practices following the introduction of Keep Well in Wave 1 practices found no appreciable differences in the trends in the diagnosis of coronary heart disease (CHD), hypertension (high blood pressure) or diabetes; incident hospitalisations for CHD or stroke; or in mortality for CHD or stroke. These analyses do, however, have a number of limitations which mean that small changes (less than a 1–2% change in hospitalisations or mortality) may not have been detected.

No existing evaluations were identified that explored unintended outcomes resulting from Keep Well.

Conclusions

This pragmatic assessment of the existing evidence of Keep Well's impacts has not been able to demonstrate an appreciable impact of the programme on its intended outcomes. It is therefore important to consider the lessons for any future primary care-based prevention programmes seeking to address health inequalities.

Learning

Three main lessons are identified. These relate to 11 recommendations.

1. Problematic theory underlying the intervention

The underlying programme theory for Keep Well, that a reduction in CVD would be achieved through identifying high-risk individuals and then providing brief advice on changing risk behaviours (diet, physical activity, smoking and alcohol) and prescribing a range of relevant medications, may be flawed. The evidence base for such a health check approach (targeted or otherwise) at the time of programme development was equivocal and where it was supportive was drawn from single interventions in a trial environment rather than effectiveness evidence from targeted health checks. This evidence has become less supportive over time. Where such a high degree of uncertainty is present, and where (as in Keep Well) the intervention does not lend itself to short-term process measures as valid proxies for the desired outcomes, a substantial programme such as Keep Well should be implemented in the context of a controlled trial, with comparison groups, considering options such as cluster randomisation or stepped wedge designs.

2. Variations in implementation

Keep Well was originally set up as a national programme for inequalities-targeted CVD prevention delivered in primary care. The roll-out of the programme across Scotland allowed local Health Boards considerable scope to extend and vary this according to local circumstances. This allowed the programme to be implemented in ways that were sensitive to local needs. As a consequence, Keep Well implementation across Scotland was highly variable in its form, focus, delivery setting and expected outcomes. While there are advantages in local flexibility, the disadvantages include difficulties in evaluating impact and uncertainty about the evidence supporting specific local approaches. In future, careful consideration is required about the acceptable variation of interventions in different settings and areas.

3. Barriers to an effective assessment of impact

Within Scottish Government, the Health and Social Care Directorates recognise more often than others the need for, and benefits from, robust evaluation of the impact of policy interventions. However, even within the scope of health policy evaluation, too often it is not possible to draw firm conclusions about whether or not the policy was effective. At the outset of Keep Well, a decision was made that it was not appropriate or feasible to design implementation as a trial or to use designs such as cluster randomisation or stepped wedge methods. This made it unlikely that there would ever be a robust impact evaluation. Nor was there an early developmental phase to test its application within deprived populations or practice settings, to pilot data collection methods or to agree a stable data set before health checks started. As a result, it has not been possible to assess the impact of the programme without limitations due to differences between the intervention and comparison groups, and contamination of the intervention group with individuals who were not eligible for the intervention. There are lessons for other national programmes about designing them in a way that allows impact evaluation to be built in from the start, where there is uncertainty about the effectiveness of the intervention in new contexts.

Recommendations

Recommendation 1: Where a future programme has a clear aim to address health inequalities, there is a need to assess whether it is sufficiently aligned with the principles for effective policies to reduce inequalities outlined by Macintyre (2007). Interventions which are most likely to be effective are those which involve reductions in poverty and inequality, which regulate the environment (including health risks such as tobacco, alcohol and food) and which do not rely solely on individuals to act on advice or depend on individuals' own resources (i.e. individual agency). It is unlikely that an intervention that is dependent on individual agency to take up an opportunity related to health behaviour change or risk factor reduction will be effective in reducing inequalities, even though the intervention is targeted towards those living in the most deprived areas.

Recommendation 2: Where there is uncertainty about the transferability of an effective intervention within new populations and/or contexts, an early developmental phase should be included before programme implementation. This will test the transferability of the intervention to a new population or setting, and whether it is likely to work in the same way and achieve the same results with a different population.

Recommendation 3: Screening programmes need to be considered in the light of the balance of potential risks as well as benefits. These include over-diagnosis (the identification and treatment of conditions which would not have caused the individuals harm), and iatrogenic harm (where diagnosis and treatment causes

side effects, anxiety or other harms and inconveniences). These should be assessed at the start and processes put in place to identify and manage such risks.

Recommendation 4: While acknowledging that there needs to be scope to tailor a programme to local circumstances, variability needs to be carefully managed. The agreement of what constitutes the core essentials of a programme (its active ingredients) need clearer definition at the outset with a realistic minimum data set for performance monitoring and reporting agreed to enable rapid feedback for improvement purposes. Evaluation of impacts of different delivery models is particularly important so that the more effective aspects can be identified and the learning shared.

Recommendation 5: Where interventions are to be evaluated, robust data collection and sharing arrangements need to be in place before implementation begins.⁴

Recommendation 6: The Scottish Government should continue to embed a culture of evaluation in all its Directorates and utilise the opportunities that new policy initiatives bring for evaluations of impact, as recommended in a UK Government Cabinet Office paper (Haynes et al., 2012).

Recommendation 7: New programmes should introduce a more formalised early stage of evaluability assessment⁵ to agree primary and secondary outcomes, key evaluation questions and design options. This will help identify opportunities for evaluation and might also include the development of a shared evaluation framework and funding to guide and support local programme evaluations.

Recommendation 8: Interventions that are not based on strong and generalisable effectiveness evidence (i.e. where the impacts have been measured in the entire eligible target population and not just those who have received the intervention) should be implemented in the context of scientific research (such as cluster randomised or stepped wedge trials).

Recommendation 9: Where NHS Boards decide to continue the Keep Well programme, they should do this in a way that incorporates or allows for the evaluation of outcomes; for example, by ensuring access to appropriate data, by identifying a comparison group, and following up those invited and those in the comparison group over time.

⁴ In future this may be made easier by the current SPIRE project (Scottish Primary Care Information Resource; www.spire.scot.nhs.uk/) which includes clear principles to guide data sharing between primary care and national NHS agencies.

⁵ Evaluability assessments are intended to inform decisions about whether and how to evaluate new policies and programmes by weighing the value of the evidence that an evaluation would provide, in terms of informing future decisions, against the likely cost and practicality of gathering that evidence.

Recommendation 10: Political, civil service and NHS Board decision-makers need to be supported to acknowledge uncertainty about evidence for interventions. Where interventions of uncertain effectiveness are incorporated into policy, it is important that this uncertainty is recognised and that the intervention is implemented in the context of research and robust outcome evaluation. Overconfidence that particular interventions will successfully improve outcomes may lead to over-commitment to programmes of uncertain effectiveness.

Recommendation 11: Decisions on the continuation and funding of health improvement (and other) programmes should be timed to take account of evaluation findings, whenever possible. In this case, the interim report was used to inform Scottish Government's decision. This provided insight into the likely conclusions but lacked the detailed findings and considered conclusions that come with the final report. In future there should be an explicit statement from programme funders about how evaluation findings will be used. This will also help to ensure that the evaluation questions meet the utilisation requirements from the outset.

Contents

Chapter 1: Introduction, history and background of the Keep Well programme	13
1.1 Introduction	13
1.2 History and background of the Keep Well programme	14
1.3 Funding for Keep Well	19
1.4 Cardiovascular disease epidemiology	19
1.5 Evaluation of Keep Well Wave 1	20
1.6 Annual performance data	20
Chapter 2: The impact evaluation	22
2.1 Purpose of this evaluation	22
2.2 Evaluation aim	22
2.3 Evaluation approach	22
2.4 The evaluation components	25
2.5 Other linked work undertaken in NHS Health Scotland	25
Chapter 3: Evidence relating to cardiovascular disease screening programmes	27
3.1 Evidence informing the design of the Keep Well programme	27
3.2 Relevant evidence emerging since Keep Well began	27
3.3 Targeted health check programmes	28
3.4 Prescribing guidelines	28
3.5 Unintended outcomes of CVD screening programmes	29
3.6 Ongoing debate	30
3.7 Cardiovascular disease-focused health checks in England	30
3.8 Cost-effectiveness evidence	30
Chapter 4: Variation in local delivery of Keep Well	32
4.1 Introduction	32
4.2 Methods	32
4.3 Findings	33
4.3.1 The range of outcomes that Keep Well programmes in different areas are trying to achieve	33
4.3.2 Revised programme theory for Keep Well and observed variation	37
4.3.3 How Keep Well was implemented in the different parts of Scotland	40
4.3.4 The feasibility of incorporating practice characteristics into the outcomes analysis arm of this evaluation.	44
4.4 Discussion	44
Chapter 5: Evidence from previous Keep Well evaluations	46

5.1 Introduction	46
5.2 Methods.....	46
5.3 Findings.....	47
5.3.1 Target groups are engaged	47
5.3.2 Models of delivery and service provision reflect identified need.....	50
5.3.3 Services are delivered by competent practitioners who understand the impact of poverty and deprivation on health.....	50
5.3.4 Increased awareness of health risk, including diagnosis of disease, and options for change	50
5.3.5 Clients feel more able to take control of their health.....	51
5.3.6 Primary care and community-based services are consistent, responsive, patient centred and anticipatory.....	52
5.3.7 Patients initiate and sustain clinical treatment or behavioural changes that improve their health/wellbeing	53
5.3.8 Reduced or delayed morbidity and mortality, and improved wellbeing in target populations	55
5.4 Unintended outcomes	56
5.5 Discussion.....	56
Chapter 6: The outcomes analysis study	58
6.1 Introduction	58
6.2 Methods.....	58
6.3 Results.....	60
6.4 Discussion.....	67
Chapter 7: Learning, conclusions and recommendations.....	70
7.1 Discussion.....	70
7.2 What should we learn from the experience of Keep Well?	72
7.3 Conclusion	76

Chapter 1: Introduction, history and background of the Keep Well programme

1.1 Introduction

Keep Well is a targeted health check programme based in primary care. It was initiated in 2006 to address inequalities in health, and specifically cardiovascular disease (CVD), using health checks delivered in primary care for adults aged 45–64 years living in areas of deprivation. The rationale for Keep Well was that, through targeted screening to a defined population considered likely to be at high risk of developing preventable disease, and particularly CVD, evidence-based interventions could be utilised to prevent the onset of disease or delay the progression of established disease.

An evaluation of the first ‘wave’ of Keep Well reported in 2010 providing learning about the reach and engagement of the programme and aspects of implementation.

This document presents the final report from the impact evaluation of the Keep Well programme. It brings together a portfolio of evaluation studies and projects to provide a narrative about the Keep Well programme, its history and evolution, what is known and not known about its impact and why. The learning and implications from this evaluation are intended to support and inform local and national decisions about similar policies and programmes in the future.

The implementation of Keep Well was not designed in a way that would allow a robust evaluation of the impact of the programme on health outcomes (for example, by recruiting control groups). This early decision was taken because such design requirements were seen as substantially increasing the cost of the programme and delaying the roll-out.

This has meant that any impact evaluation was necessarily retrospective and problematic. This evaluation has combined qualitative interviews with those involved in delivering the programme and a synthesis of findings from research and evaluation studies to date with an analysis of routine data available on outcomes.

The rest of this chapter provides some background to the Keep Well programme, including the aims and logic underpinning the programme at its conception. It also describes how the programme was implemented and how it evolved.

Chapter 2 describes the aims of the evaluation. It summarises the rationale for the approach taken and the various components of the evaluation. The relevant evidence relating to cardiovascular risk factor screening is briefly described in Chapter 3.

The local variability study component of the evaluation is the focus of Chapter 4. This study describes how the implementation of Keep Well varied between the different territorial NHS Board areas in Scotland and as it evolved over time.

The findings from previous outcomes-focused evaluations of the Keep Well programme undertaken by NHS Boards, or commissioned by NHS Health Scotland, are summarised in Chapter 5. These findings are presented in relation to the outcomes identified.

Chapter 6 reports the findings from the analyses of routine administrative data before and after the implementation of Keep Well. The analyses use the best available data and indicators of the impact of Keep Well on diagnosis, treatment, hospitalisation and mortality.

Chapter 7 synthesises the findings of this report to draw conclusions about the success of the Keep Well programme and the implications for future policies and programmes for both local and national decision-makers.

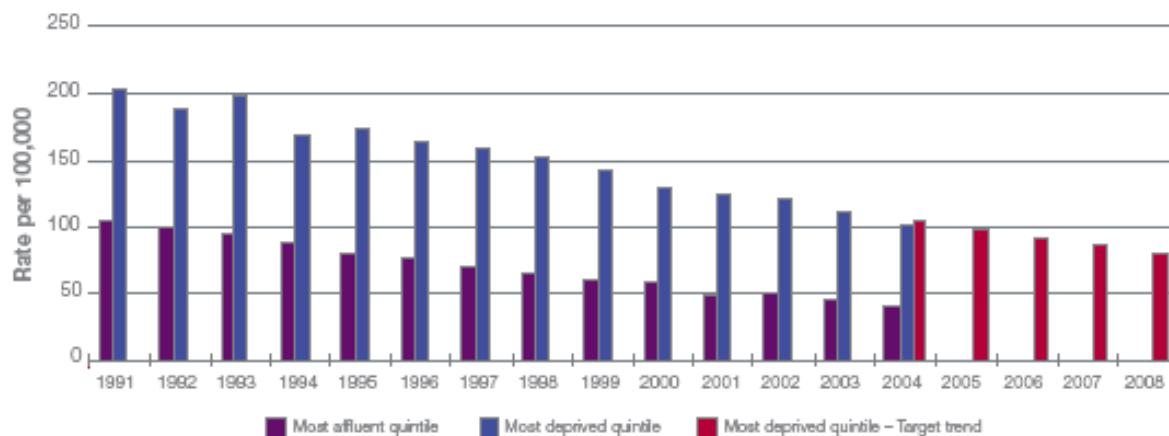
1.2 History and background of the Keep Well programme

The Keep Well programme was initiated in 2006, under the initial title of Prevention 2010 (P2010). It was developed in response to recognition and concern about the higher incidence and prevalence of CVD and higher levels of risk factors for CVD among socio-economically disadvantaged people. There was evidence of effectiveness of a range of preventive interventions (including statins, hypertension medication and smoking cessation support) and evidence of lower delivery/uptake of such preventive interventions among socio-economically disadvantaged people. In the light of this, there was professional and political will to address health inequalities by delivering effective interventions in a targeted way in deprived communities in order to prevent the onset of disease or delay the progression of established disease.

Tudor-Hart's seminal work in the 1970s highlighted the potential value of proactively seeking out those at high risk of disease (Tudor-Hart, 1970). He found that those requiring the greatest encouragement and effort to attend a health check were those with the greatest needs. The Keep Well programme was informed by Tudor-Hart's work, although it was not able to offer the same continuity of care and follow-up.

The approach adopted was similar to the earlier (but at that time ongoing) national heart health demonstration project Have a Heart Paisley, a community-based CVD prevention programme located in one deprived area in Scotland (Blamey et al., 2004; Sridharan et al., 2008). P2010 (later renamed Keep Well) was established as part of a package of initiatives to address the 'inequalities gap' highlighted in the Scottish Government plan for the NHS, *Delivering for Health* (Scottish Executive, 2005). Evidence for these 'unacceptable differences in healthy life expectancy' between the most and least affluent communities in Scotland were presented for CVD (Figure 1).

Figure 1: CHD mortality (under-75s)



Scottish Executive, 2005

The Scottish Executive stated that:

‘the most significant thing we can do to tackle health inequalities is to target and enhance primary care in deprived areas.’

This would be achieved by ensuring:

‘that people at greatest risk of ill health are actively identified and offered opportunities for early detection, advice and treatment, enabling earlier identification, prevention and treatment for conditions such as high blood pressure, type 2 diabetes and high cholesterol.’ (Scottish Executive, 2005).

P2010 was the programme set up to deliver this. Its stated aim was to contribute to a reduction in health inequalities by providing health checks targeted at those at high risk of preventable serious ill health, particularly CVD. Thus, P2010 was developed on the premise that earlier identification and management of specific risk factors and early disease in those most at risk of premature death from CVD would help to increase the rate of health improvement in the most deprived areas, and thereby contribute to a reduction in health inequalities.

This logic was detailed in the initial programme theory (Figure 2) which was developed by NHS Health Scotland and the Managed Public Health Network⁶. The target population was those living in deprived areas aged between 45 and 64 years without pre-existing CVD. The intended outcomes are illustrated in this logic model and include, in the short-term, reaching and engaging with the target population and achieving compliance with treatment. In the medium term (by two years), expected outcomes related to risk factor modification and patient satisfaction. In the longer

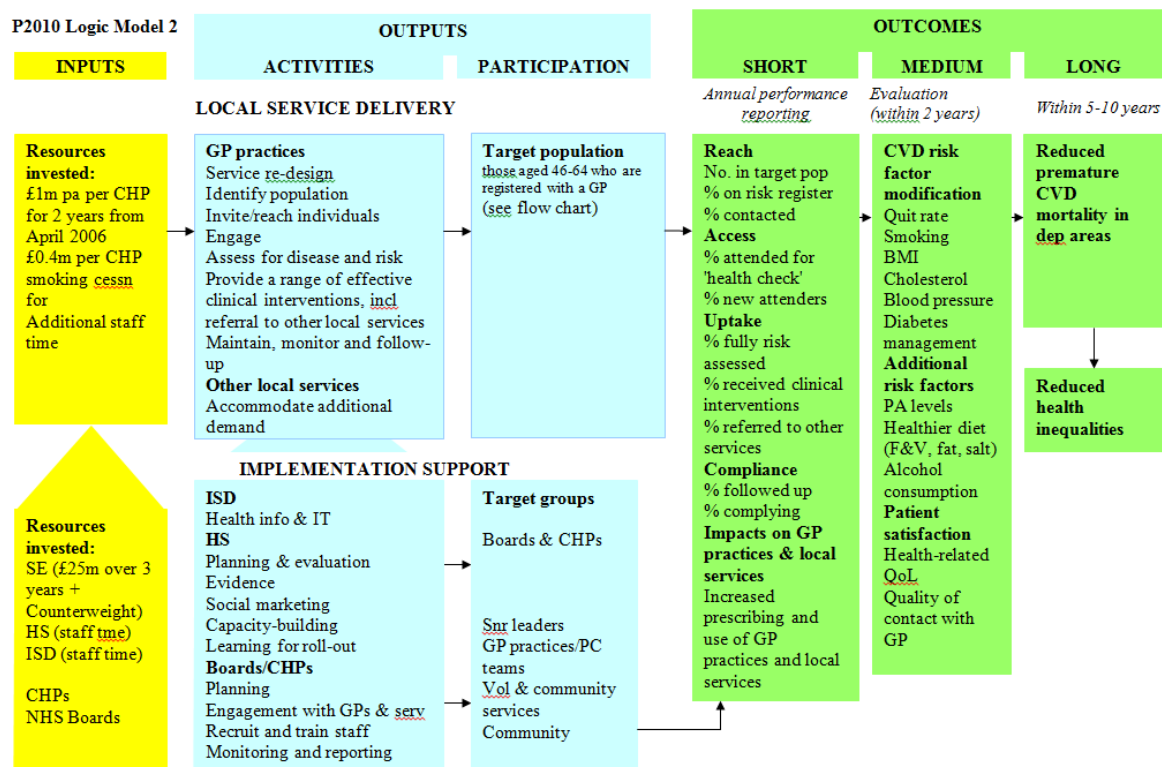
⁶ The Managed Public Health Network is now known as the Scottish Public Health Network (ScotPHN).

term, the goal was to reduce premature CVD-related mortality and, ultimately, reduce health inequalities.

Figure 2: Original Keep Well (P2010) logic model (2006).

(Source: Health Scotland. Prevention 2010. *Logic Modelling to Guide Planning, Monitoring and Evaluation*. Edinburgh: Health Scotland; 2007.

www.healthscotland.com/documents/1645.aspx)



BMI, body mass index; CHP, Community Health Partnerships; F&V, fruit and vegetables; HS, NHS Health Scotland; ISD, Information Services Division; PC, primary care; QoL, quality of life.

Keep Well began in 2006 and 2007 in five pilot areas. These were selected because they represented Community Health Partnerships (CHPs) with the highest proportion of their population living in the most deprived datazones (defined using the Scottish Index of Multiple Deprivation [SIMD]⁷). These five pilot sites were within four territorial NHS Boards (NHS Greater Glasgow and Clyde, NHS Lanarkshire, NHS Lothian and NHS Tayside). This was known as Wave 1.

The original project specification (Scottish Executive, 2006) stated that Keep Well was to focus on:

⁷ The Scottish Index of Multiple Deprivation (SIMD) identifies small area concentrations of multiple deprivation across Scotland. It assigns a score to datazones with a median population of around 750 people. It has seven domains (income, employment, education, housing, health, crime, and geographical access). Scores for each domain are combined into an overall score for each datazone which are then ranked from the most deprived to the least deprived. See www.scotland.gov.uk/topics/statistics/SIMD/

- CVD and its main risk factors, especially blood pressure, cholesterol, smoking and diabetes; this will have benefit in relation to other serious conditions
- evidence-based interventions, to make the greatest difference to health outcomes in the short term
- improving reach, access and methods of engagement within primary care services, thereby addressing the inverse care law (availability of good medical care tends to vary inversely with the need for it in the population served) (Scottish Executive, 2006).

The project specification also stated that the core intervention should include:

- tackling intermediate clinical risk factors – identifying, treating and controlling high cholesterol and high blood pressure.
- tackling lifestyle risk factors through smoking cessation services, *Counterweight* (addressing diet and physical activity), brief interventions on alcohol.

Wave 1 was followed by three further waves over the next four years, each of which added geographical areas to the programme. Keep Well evolved with each wave (see Table 1), with additional interventions and target populations included. Each NHS Board area was allowed to operationalise the programme in different ways according to their local population characteristics and available services. Approaches to delivery did not necessarily include general practices.

Table 1: The evolution of Keep Well

Wave 1, 2006–2008 (note additional funding was announced in May 2008 to extend Wave 1 to 2010)	<p>Five areas were selected to deliver services in local authority areas with the highest number of people living in the most deprived 15% of the population (using SIMD). The areas selected in Wave 1 were Glasgow North, Glasgow East, Edinburgh, Dundee and Lanarkshire.</p> <p>The aim of the extension announced in 2008 was to deliver services that would further enhance national and local understanding of what works and inform the creation of a strong policy base for potential future mainstream design and delivery of effective, efficient and sustainable anticipatory care approaches in disadvantaged communities.</p>
Wave 2, 2007	<p>The second wave included seven areas and continued to focus on deprived communities within selected Community Health Partnerships. Aberdeen, Fife, Glasgow South West, North Ayrshire and East Ayrshire focused on primary prevention in line with Wave 1, and Inverclyde and West Dunbartonshire focused on optimising secondary prevention.</p>
Well North, 2008–2010	<p>Well North was an adaptation of Keep Well for delivery in remote and rural areas. It comprised six strands of work across separate geographical areas in the Western Isles, Orkney, Shetland, Highland and the Moray area in Grampian. Each of these focused on different aspects of service delivery to disadvantaged populations as considered appropriate to the local area.</p> <p>The Well North branding was discontinued in April 2012 when the process of mainstreaming Keep Well nationally began.</p>

<p>Wave 3, 2009</p>	<p>NHS Borders, NHS Forth Valley and NHS Dumfries & Galloway were invited to develop proposals for Wave 3. However, as with Well North, a range of new approaches was considered necessary given the specific geographic and demographic characteristics of these areas.</p> <p>NHS Borders delivered Keep Well in general practices and in some selected workplace settings, and linked Keep Well with an existing lifestyle support programme.</p> <p>Within NHS Forth Valley, Keep Well built on an employability project in one area, a gender-sensitive project in another area and a regeneration initiative in a third area.</p> <p>NHS Dumfries & Galloway took a unique approach using a community-based mental health and wellbeing screening tool to help target their approach, and delivered the Keep Well consultations through community-based organisations and workplaces.</p>
<p>Wave 4, 2009</p>	<p>Following the publication of <i>Equally Well</i> and the <i>Equally Well Implementation Plan</i>, Wave 1 Keep Well areas were asked to submit proposals for expansion (known as Wave 4) and were instructed that proposals for expansion funding should include:</p> <ol style="list-style-type: none"> 1. Anxiety and depression screening as part of the Keep Well health check 2. Identification of new target populations (e.g. black and minority ethnic, homeless people, mental health users, Gypsy travellers or others) 3. Identification of new geographic areas 4. Identification of new settings (e.g. offenders, community pharmacy, workplace) 5. Pre-screening/ASSIGN.⁸ <p>This involved new geographic locations or populations within the original Wave 1 NHS Board areas. A further two years of funding was allocated to extend work in NHS Greater Glasgow & Clyde (in all participating Community Health Partnership [CHP] areas), NHS Lothian (West Lothian CHP), NHS Tayside (Angus, and Perth & Kinross CHPs) and NHS Lanarkshire (Hamilton and Motherwell CHPs).</p>

In 2011/12 a process of ‘mainstreaming’ the Keep Well programme began across NHS Boards in Scotland with the aim of making targeted health checks part of ‘normal, permanent practice’ by 2014 (NHS Health Scotland, 2010a). As part of this mainstreaming process, the eligible age range was widened to include 40- to 64-year-olds in the 15% most deprived areas of Scotland, and 35- to 64-year-olds in defined vulnerable populations outwith those areas (minority ethnic groups and Gypsy travellers, offenders, homeless people and those with caring responsibilities). In addition, the health checks were to be repeated every five years.

⁸ ASSIGN scores identify people, who are currently free of CVD, most likely to develop it over ten years. A score of 20 or more implies high risk and recommends risk-lowering medication and/or other medical help. <http://assign-score.com/>

1.3 Funding for Keep Well

The Scottish-Government funded NHS Boards to implement the Keep Well programme. The cost varied annually and grew as Keep Well was rolled out to more areas and general practices but totalled £11.3M in 2012/13, with each NHS Board's allocation of this dependent on its size.

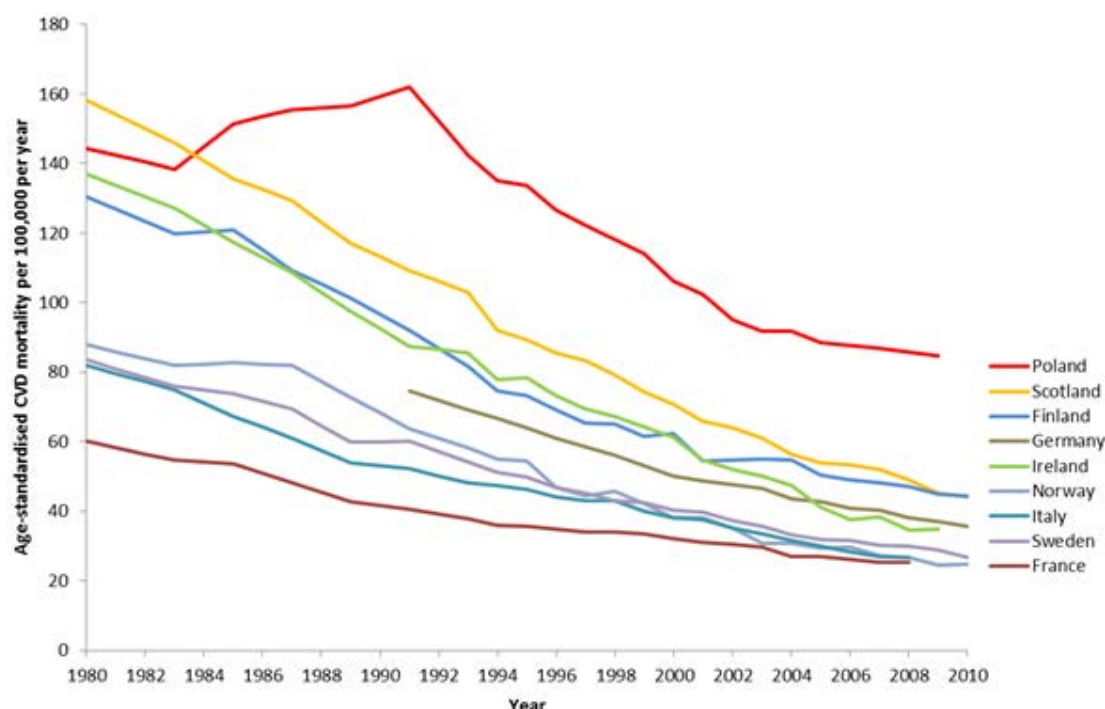
1.4 Cardiovascular disease epidemiology

The original intention of Prevention 2010 was to reduce inequalities in mortality through a faster reduction in CVD mortality in the most deprived areas. In Scotland, CVD mortality has been in decline since the 1970s (Figure 3) although relative inequalities have increased from 1997 to 2011 for those aged 45–74 years (Scottish Government, 2013). A similar decline in mortality has been witnessed across Europe with the result that Scotland has retained its position as the nation with the highest cardiovascular mortality (Whyte and Ajetunmobi, 2012).

Figure 3: Trends in age-standardised cardiovascular disease mortality among those aged <64 years in Scotland and selected European countries, 1980–2010.

(Source: ScotPHO. *European Health for All Database*.

www.scotpho.org.uk/comparative-health/scotland-and-european-hfa-database)



These trends are important in considering how to interpret some of the evaluation data contained within this report. There is a strong downward secular trend in CVD mortality (and indeed in many of its known risk factors) (Hotchkiss et al., 2014). This

means that any analysis using ‘before and after’ comparisons to assess the impact of Keep Well on CVD mortality or its risk factors needs to take into account these secular trends, which are likely to be due to a range of factors, in addition to any impact of Keep Well. A further consideration is that the relative contribution of CVD to the overall burden of ill health in Scotland is decreasing and as a consequence it is likely that the cost-effectiveness of interventions related to CVD will also be affected.

1.5 Evaluation of Keep Well Wave 1

When the plans for P2010 were being developed by the Scottish Executive, an experimental approach to the design of its evaluation was raised, discussed and rejected on the grounds that it would be too costly and would limit the rapid commencement of the programme.

An evaluation of Wave 1 was commissioned in 2007 and began shortly after Keep Well Wave 1 commenced delivery. It was funded from April 2007 to September 2010. The agreed focus of this evaluation was in relation to reach, engagement, implementation and service redesign. Its findings informed the ongoing implementation and evolution of the programme (Mackenzie et al., 2010). The evaluation team explored the possibility of undertaking some analysis of outcomes but found that methodological and data issues meant that a robust analysis was not possible (Mackenzie et al., 2010; McLean et al., 2011).

Specifically, the Wave 1 evaluation developed the programme theory and built knowledge and understanding about agreed aspects of the programme in order to inform programme development (Mackenzie et al., 2010). The ability of the programme to reach and engage with target population groups, and especially those considered hard to reach, was of particular interest to NHS Boards and national policy leads and was explored in detail as part of the evaluation.

1.6 Annual performance data

All the local NHS Boards were expected to report on an annual basis using a core set of performance indicators. The Information Services Division (ISD) worked with the local Health Boards involved in Wave 1 and Have a Heart Paisley to agree the core data set (focused on short-term outcomes) and the IT requirements for data collection, but consistent recording, coding, extraction and analysis of this core data encountered many challenges. The core data set was updated for the mainstreaming period. However, this data set on implementation, reach and short-term outcomes was of inadequate quality for use in this evaluation. Annual HEAT target data, available from ISD, provide the total number of health checks carried out each year.⁹

⁹ Between April 2009 and April 2012, the programme was subject to a Scottish Government Health Efficiency Access and Treatment (HEAT) target to ‘Achieve agreed number of inequalities targeted cardiovascular health checks during 2009–10’ (substituted with 2010–11 and 2011–12 in subsequent years). NHS Boards reported the number of health checks delivered on a monthly basis as required for monitoring performance against HEAT targets.

Data on five indicators¹⁰ have been collected quarterly from NHS Boards by NHS Health Scotland since April 2012. In 2012/13, NHS Boards reported that 85.5% of health checks were delivered to individuals residing in the two most deprived SIMD quintiles (SIMD 1=70.8%, SIMD 2= 14.7%).

Table 1 shows the total number of health checks carried out each year through the Keep Well programme and reported by NHS Boards. From 2009 to 2012 this was part of the Boards' performance management reporting on HEAT targets.

Table 1: Total number of Keep Well health checks¹¹

Cumulative to 2009	2009/10	2010/11	2011/12	2012/13	2013/14	Total
50,784	29,433	41,107	47,773	39,644	42,993	251,734

¹⁰ National indicator 1: number of people who attend appointments (as % of local target and by SIMD quintile).

National indicator 2: number of first health checks undertaken for carer (as % of local target).

National indicator 3: number of those attending a health check with ASSIGN risk score of 20% or more (as % of all health checks).

National indicator 4: number of people who have had at least one new chronic disease problem (CHD, diabetes, hypertension) identified within 3 months of their most recent health check (as % of all health checks).

National indicator 5: number of people who have been referred from health check providers and who attended the referred service at least once (as % of all health checks).

¹¹ Sources:

Cumulative to March 2009 – Keep Well Management Reports to NHS Health Scotland.

2009/10 – ISD Published Figures July 2010.

2010/11 – ISD Published Figures July 2011.

2011/12 – ISD Published Figures July 2012.

2012/13 – Reported by NHS Boards to NHS Health Scotland.

2013/14 – Reported by NHS Boards to NHS Health Scotland.

Chapter 2: The impact evaluation

2.1 Purpose of this evaluation

This study was requested by the Keep Well Extension Board (KWEB) in 2011 as part of their mainstreaming plans and was funded by Scottish Government. It was commissioned in response to an increasing recognition of the need for evidence about the impact of the programme on health outcomes in order to inform future policy and investment decisions in an increasingly tight economic climate.

This impact evaluation was originally planned and scheduled to inform the Scottish Government's decision about the future of the Keep Well programme, and it was agreed that outputs from the study should be available at the start of 2014/15. An interim evaluation report was published in May 2013 which highlighted that firm conclusions were unlikely to be drawn in the final report due to a range of evaluation challenges (NHS Health Scotland; 2013). Thereafter, the Scottish Government's decision-making timescale changed. In November 2013, the Chief Medical Officer wrote to all NHS Boards informing them of the decision to reduce and then cease central funding and support for the Keep Well programme. Ring-fenced national funding is therefore scheduled to end in 2016/17 and the Scottish Government expects that NHS Boards will prioritise locally in terms of services to be retained through existing resources thereafter. As a result, the purpose of this evaluation has changed; it will no longer inform national policy on the future of the Keep Well programme. However, it should still be useful to NHS Boards in informing decisions about the future of local funding and support for their own Keep Well programmes or similar health-check programmes. It also has wider implications for other similar health-check programmes.

2.2 Evaluation aim

The aim of this evaluation was to assess the implementation and impact of Keep Well (prior to mainstreaming in 2012) using available data.

2.3 Evaluation approach

At the outset of this evaluation, the KWEB and the Scottish Government recognised the difficulties in trying to evaluate the impact of Keep Well on health outcomes, given that an impact evaluation had not been incorporated into the original design of the intervention. It was therefore agreed by KWEB and the Scottish Government that a pragmatic approach should be adopted, which minimised the need for new data collection and used routinely available data to keep the costs of the evaluation as low as possible.

The constraints within which the evaluation had to operate were as follows:

Lack of a comparison population (counterfactual)

In order to attribute any observed changes in a programme's main outcomes to the programme itself, it is standard evaluation practice to use a counterfactual – a group

of practices or individuals with the same or similar characteristics but not exposed to the programme. This would have shown what would have happened to the beneficiary population in the absence of Keep Well and given the same downward secular trends.

However, the way the Keep Well programme was established and implemented did not allow for data to be collected on comparable individuals, practices or populations who would have been eligible for, but were not offered, the intervention. As a result, Keep Well practices (i.e. general practices which became loci for the intervention) were notably different to practices which had not delivered Keep Well, in terms of the deprivation status of their practice populations and other potential factors such as their capacity and willingness to be involved. This made comparisons between Keep Well and non-Keep Well practices difficult. In addition, some Health Boards did not use general practices as a means of delivering the programme and, while this may have been contextually appropriate in different areas, it further limited the possibility of identifying suitable comparison populations.

Programme variability between NHS Boards, practices and over time

The way that Keep Well was delivered was highly variable between (and even within) NHS Boards. The complex evolution of Keep Well since its inception in 2006 was briefly described in Chapter 1. Each wave of the programme introduced a new cohort of general practices, sociodemographic groups and/or geographical areas to the intervention. In addition, each new wave incorporated learning from previous waves and so advocated a slightly different approach to Keep Well. New policy initiatives also meant that additional components were added to the programme or health check over time.

Even within each wave, NHS Boards and to a lesser extent, general practices, had considerable flexibility in how the programme could be implemented, the models of delivery adopted and the information to be collected. NHS Boards were encouraged to be flexible and innovative in their implementation of the programme and to adapt their programmes in response to emerging learning. The variation in the delivery of the programme has been explored further in the local variability study component of the impact evaluation (Chapter 4).

Data

There were substantial difficulties in agreeing a suitable, core data set at the outset of the programme reflecting different views of the extent of data required as well as specific local requirement. Even once agreed, consistent recording, coding, extraction and analysis of this core data set across participating practices and NHS Boards encountered numerous challenges, and the requirements for reporting changed constantly over the life of the programme.

Participating NHS Boards collected some information from the outset on programme delivery, such as the numbers of invitations issued and health checks carried out, and basic demographic information on those receiving health checks. Detailed clinical information about individuals was collected at health checks and held in practices; however, although a few NHS Boards have been able to produce local reports based on these data, they have not been widely used for programme monitoring or evaluation. The obstacles to the use of these data include variation in the technical capacity of NHS Boards to extract these data from practices; changes to general practice IT systems during the life of Keep Well; different contractual arrangements between NHS Boards and general practices; and concerns about patient confidentiality which were increased by a lack of clarity about the legal and regulatory basis for such data sharing. In addition, despite the efforts of a national information steering group, there was a lack of consistency between NHS Boards in relation to data definitions and coding, limiting the comparability of the data collected, and wide variability in the completeness of recording clinical data.

These differences between areas, alongside variation in local analytical capacity, meant that NHS Boards had different data available for analysis and produced analyses that were often not directly comparable. Following the health check, referrals were often made to local partner organisations (e.g. for exercise programmes), but most of these partners have not been able to provide consistent data on the outcomes of those referrals. The most comprehensive and ambitious attempt to collect such referral data was in NHS Greater Glasgow and Clyde through the development of an online tracking tool, but this did not prove to be a cost-effective method of collecting data (Scoular, 2012).

Definitions of success

Although the national vision for Keep Well was to reduce health inequalities in CVD outcomes, different NHS Boards and stakeholders defined success in different ways, and held different views about how success could be achieved. In addition, the introduction of a performance management (HEAT) target that focused on the quantity of completed health checks emphasised the number of checks delivered rather than the outcomes achieved. Together, these had implications for how the programme theory was understood and implemented locally. This was explored as part of the local variability (LV) study.

Potential time lags between implementation and change in outcomes

There is a potential time lag between the time of implementation of the intervention and changes in CVD in the target population. The time lag may arise because of the time it takes to set up the intervention from the point of funding, the time taken to engage individuals and channel them through services to modify their risk, and the potential lag between changes in individual risk and changes in CVD outcomes.

Relatively few practices have been delivering the programme for more than five years and many patients have received the intervention much more recently.

2.4 The evaluation components

There were two main components to this impact evaluation: a local variability (LV) study and an outcomes analysis (OA). The evaluation focuses on the period prior to the mainstreaming of Keep Well because insufficient data were available for the period after April 2012.

Study 1: Local variability study

This was a qualitative study exploring the variations in implementation of the Keep Well programme across Scotland prior to April 2012 using information on approaches and intended outcomes in each of the territorial NHS Board areas. These data were gathered during 2012 through a series of interviews with key informants in the NHS Boards, supplemented with analysis of key documents relating to Keep Well implementation within each NHS Board (see Chapter 4).

Study 2: Outcomes analysis

This study has examined the impact of the introduction of Keep Well health checks on trends in CVD-related mortality, hospitalisations, diagnoses and prescribing among Wave 1 general practices before and after the initiation of the programme and compared with changes in non-Keep Well practices during the same period. It also used information gathered as part of the LV study to consider whether the impacts were greater in practices which had delivered Keep Well to a greater proportion of their patients (see Chapter 6).

2.5 Other linked work undertaken in NHS Health Scotland

Other pieces of work have been undertaken within NHS Health Scotland which have informed this evaluation, and specifically our understanding of the evidence and the gaps in evidence. These projects, described below, have informed Chapters 3 and 5 of this report.

Evidence-informed programme theory

As part of the LV study, the logic, or programme theory, for Keep Well was revised. Available evidence relating to the components of this theory was identified and mapped on to this programme theory to provide an indication of where evidence exists to support or challenge the programme theory as well as identifying gaps in current evidence.

A synthesis of existing Keep Well evaluations of impact

This was undertaken by the NHS Health Scotland evaluation team and the Keep Well evaluation project team. Evaluations included those which were available to NHSHS by March 2013 and which addressed the reach or outcomes of the

programme. Evaluations which focused on the process of implementation or delivery of the programme were excluded. Given the challenges in retrospectively evaluating impact at a national level (described above), the purpose of this synthesis was to explore the extent to which existing local and national evaluation work had detected changes in outcomes in the short, medium or long term.

Chapter 3: Evidence relating to cardiovascular disease screening programmes

3.1 Evidence informing the design of the Keep Well programme

When Keep Well was established there was a growing concern at the deprivation-related inequalities in health outcomes in Scotland, and CVD outcomes were often used as a proxy for these inequalities. There was a general move towards global risk assessment for CVD and the influence this had in supporting behaviour change across the risk factors. There was a widely held view that early intervention would have the greatest impact on subsequent development of disease.

Keep Well was considered a new and relatively novel approach to health improvement. However, the greatest uncertainty was felt to relate to the effectiveness of approaches to engaging those populations most likely to be at high risk of premature ill health and least likely to access preventive health care. The evidence was considered much stronger in relation to improving health through the modification of individual risk factors for CVD through brief advice, behaviour change (diet, physical activity, smoking and alcohol) and prescribed medication (lipid lowering, blood pressure lowering and antiplatelet therapy).

The Keep Well programme was thus developed, drawing on evidence regarding modification of individual CVD risk factors which would subsequently inform the SIGN 97 guidance on risk estimation and the prevention of CVD (SIGN 97) (Scottish Intercollegiate Guidelines Network, 2007). An interdisciplinary group, facilitated by NHS Health Scotland, summarised the key messages in an evidence guide for Keep Well practitioners (NHS Health Scotland, 2006). This was updated to reflect subsequent evidence (NHS Health Scotland, 2010). The most uncertain aspect of the programme, relating to reaching and engaging those target populations considered to have worse health and poorer access to health care, became the main focus of the Wave 1 evaluation.

3.2 Relevant evidence emerging since Keep Well began

When Keep Well began, some evidence that CVD screening was ineffective had already been published (OXCHECK, 1997; Ebrahim and Smith, 1997). However, this was discounted because many of these studies predated the introduction of statins which were considered highly efficacious for the primary prevention of CVD (Cholesterol Treatment Trialists, 2005).

Since Keep Well was initiated, two relevant bodies of evidence have been growing: multiple risk factor interventions for the primary prevention of CVD; and screening for CVD through universally provided health checks (i.e. open to everyone).

In 2011, the Cochrane Collaboration updated their 1997 (Ebrahim and Smith, 1997) systematic review of randomised controlled trials of multiple risk factor interventions for the primary prevention of CVD (Ebrahim et al., 2011). It included all relevant

randomised trials that have evaluated an intervention aiming to reduce more than one risk factor in people without evidence of CVD (55 trials with 163,471 participants). It found that such interventions resulted in small reductions in risk factors including blood pressure, cholesterol and smoking, but had little or no impact on the risk of CHD mortality or morbidity in general populations. The authors acknowledge, however, that interventions for high-risk individuals with hypertension or diabetes may be effective.

A review of lifestyle interventions in patients with existing CVD concluded that secondary prevention was effective in reducing CVD related mortality (De Waure et al., 2013).

In terms of screening for CVD, a systematic review of the effectiveness of general health checks (defined as screening for more than one disease or risk factor) found no evidence that these reduced mortality (Krogsbøll et al., 2012). This review included 14 trials involving 182,880 people. Nine of the trials studied the risk of death and included 155,899 participants. No effect of the health checks on the risk of death or on the specific risk of death from CVD or cancer was found. No effect was found on the risk of illness, although one trial found an increased number with chronic disease. No effect was found on hospital admissions, referrals to specialists or absence from work. Two of four trials found an increased number of people using anti-hypertensive drugs, although none of the trials compared the total number of new prescriptions.

The quality and generalisability of the evidence included in these reviews is variable. However, the lack of consistent, high-quality evidence to support such interventions would suggest that an appropriate approach to Keep Well would have been experimental in nature.

3.3 Targeted health check programmes

There is evidence that those who are socio-economically disadvantaged are likely to be under-diagnosed with hypertension, diabetes and hypercholesterolemia, and that they are less likely to be engaged in interventions to reduce risk (Sridharan et al., 2007). However, robust evaluations of tailored interventions in socio-economically deprived groups are lacking.

It is well recognised that interventions which are structural or regulatory are best placed to reduce health inequalities (Macintyre, 2007); and interventions which impact on the entire population to reduce each individuals risk by a small amount (as opposed to a high-risk approach which attempts to reduce the risk of a smaller number of people by a large amount) are best placed to make the largest difference to the (mean) health of the population (Rose, 1992).

3.4 Prescribing guidelines

When Keep Well began, evidence supported the use of statin therapy for the primary prevention of CVD (Cholesterol Treatment Trialists, 2005). Since then the safety of

this treatment for primary prevention has been increasingly debated (Abramson et al., 2013; Huffman et al., 2013), particularly in the light of recent clinical guideline update which recommends statin therapy at lower CVD risk thresholds (NICE, 2014). Supporters cite evidence that all-cause mortality in people taking statins (with no pre-existing CVD) is reduced, indicating that any unintended life-threatening effects are outweighed by the beneficial effect on CVD. Indeed, the updated Cochrane review (Taylor et al., 2013) of the use of statins for primary prevention of CVD reversed the conclusion of an earlier review (Taylor et al., 2011) in finding that the use of statins compared well with other treatments used for preventing CVD events, and that no excess of adverse events occurred in those people without evidence of CVD who were treated with statins. However, opponents suggest that this evidence is not strong (Ray et al., 2010) and that the range of harms considered should not be limited to those that are life-threatening (Abramson et al., 2013). There has also been debate about whether side effects are under-reported in trials (Goldacre et al., 2014).

Low-dose aspirin was widely used for the primary prevention of CVD in the early years of the Keep Well programme. However, in 2009 prescribing guidelines reflected growing review level evidence that the harms of such treatment for primary prevention were of a similar magnitude to the benefits (Drugs and Therapeutics Bulletin, 2009). The guidelines recommended that low dose aspirin should not be started routinely for this use and that those already taking this treatment should decide whether or not to continue after discussion with their healthcare professional.

3.5 Unintended outcomes of CVD screening programmes

Keep Well, as a programme which seeks to identify and treat those at risk of CVD through the invitation of a population who are asymptomatic and without known illness, can be considered as a screening programme. However, the programme was not set up with this in mind and it has not been implemented with the regulatory structures that would normally surround screening. Indeed, Keep Well has been understood and implemented very differently across Scotland. These differences are described in detail in Chapter 4.

The original intention of Keep Well was to systematically identify and call individuals, to screen them for chronic disease and for lifestyle and biological risk factors, and to provide treatment to those identified as at high risk of ill health, and particularly CVD, in order to reduce or delay subsequent disease. Keep Well can therefore be loosely defined as a screening programme.

All screening programmes have the potential to harm as well as benefit because, in identifying those with previously undetected disease, people not in need of treatment may also be wrongly identified and may be harmed as a result (Wilson and Jungner, 1968). Within CVD screening, the potential harms include wrongly identifying participants as being at risk (false positives) resulting in unnecessary treatment with medication, side effects from medication and the possibility of

increased anxiety from being labelled 'high risk'. If people at risk are not identified (false negatives) there is a risk of false reassurance or delays in patients seeking help when symptoms develop.

There is also a theoretical risk that health inequalities in CVD may increase as the interventions being offered are more likely to reach and be successful with those individuals who are least disadvantaged (Capewell and Graham, 2010; Krogsbøll et al., 2012; Thompson and Tonelli, 2012; Mackenzie et al., 2010). Inequalities in risk factors can widen when an intervention's effects are influenced by an individual's knowledge, motivation and behaviour (e.g. behaviour change programmes) (White, Adams and Heywood, 2009). The reliance in such programmes on an individual's material or psychological resources benefits those with more resources and is therefore likely to increase inequalities.

Krogsbøll and colleagues reported that important harmful outcomes, such as the number of follow-up diagnostic procedures or short-term psychological effects, were often not studied or reported (Krogsbøll et al., 2012). Other authors have also noted that unintended effects are not comprehensively reported in systematic reviews or trials (Armitage, 2007; Goldacre et al., 2014).

3.6 Ongoing debate

Relevant debates continue regarding the effectiveness evidence relating to health checks and CVD screening, to the efficacy of drugs such as statins, and to the balance of risk and benefits of drug therapy for the primary prevention of CVD (Thompson and Tonelli, 2012; McCartney, 2013).

3.7 Cardiovascular disease-focused health checks in England

Unlike the targeted approach of Keep Well in Scotland, NHS England has implemented a programme offering free health checks to all adults aged 40–74 years every five years. Like Keep Well, this programme was justified using evidence and guidelines intended for the primary prevention of CVD in the context of individual clinical encounters rather than as part of a screening programme. Public Health England now oversees the programme and has described their approach to the evidence as 'pragmatic'. In 2013 Public Health England stated that 'despite the lack of a systematic, established evidence-base that demonstrates the impact of the NHS Health Check programme, the existing relevant evidence, together with operational experience accruing on the ground, is compelling support for the programme' (Public Health England, 2013). However, the case for the programme has been the subject of debate (Krogsbøll et al., 2013; McCartney, 2013).

3.8 Cost-effectiveness evidence

Targeted approaches to screening interventions are theoretically more cost-effective than population-wide screening (Lawson et al., 2010a; Loubiere et al., 2003; Schuetz et al., 2013). A preliminary cost-effectiveness estimate of Keep Well health checks was undertaken by the University of Glasgow for NHS Greater Glasgow and Clyde.

An economic model was developed which used available data from Glasgow to estimate baseline risk scores, with an effect size estimated using adjusted risk reduction probabilities based on secondary literature and expert opinion on the effectiveness of interventions. This did not find that Keep Well (at £31,000 per QALY) was cost-effective using standard thresholds (£20,000 to £30,000/QALY) (Lawson et al., 2010b) and concluded that Keep Well may not be a cost-effective method of reducing risks associated with CVD in the target population. The authors note that a number of additional assumptions were required in the absence of adequate data and that this introduced uncertainties. They undertook a sensitivity analysis as a result in which these assumptions were varied to give a best case (£7,762/QALY) and a worst case (£72,762/QALY) as well as the base case.

In contrast to the base case reported for Keep Well by Lawson et al. (2010b), NHS England's Health Check programme was found to be cost-effective in two economic modelling reports, which found a cost-effectiveness ratio of about £3,000/QALY (Department of Health, 2008; Schuetz et al., 2013). This more optimistic cost-effectiveness estimate is likely to be due to a lower cost estimate for each health check as well as more optimistic assumptions on intervention compliance and the health gains attributable to the programme. In addition, the modelling methods used in the Department of Health's 2008 report have been criticised for being simplistic (Cobiac et al., 2012), which could account for the contrasting results.

Chapter 4: Variation in local delivery of Keep Well

4.1 Introduction

The local variability (LV) study explored variations in the way that Keep Well has been implemented across Scotland, using information gathered through a series of stakeholder interviews within NHS Boards and documentary analysis. The study intended to:

1. identify the range of outcomes that Keep Well programmes in different areas are trying to achieve
2. review and strengthen the programme theory¹² for Keep Well
3. provide information about how Keep Well was implemented in the different parts of Scotland
4. explore the feasibility of incorporating practice characteristics into the outcomes analysis arm of this evaluation.

4.2 Methods

Phase one of the LV study began in April 2012. The purpose was to understand the differences in implementation and approach in the different NHS Boards (objectives 1–3). Semi-structured interviews took place with Keep Well stakeholders in each NHS Board area. Two public health advisers from the evaluation team within NHS Health Scotland undertook these interviews, either face to face during a visit to the NHS Board or by teleconference. The number of stakeholders participating in each interview ranged from one (the Keep Well manager or other senior manager within that NHS Board) to ten (the local Keep Well steering group or a group of stakeholders brought together by the Keep Well manager for the purpose). Participants were advised that the focus of the interviews was to be the programme prior to mainstreaming (i.e. before April 2012).

The semi-structured interviews were based on a draft logic model previously developed by a group of Keep Well managers based on the original P2010 logic model (Figure 2). As part of the interviews, participants were invited to describe whether and how their local Keep Well programme departed from this model. The interview schedule is in Appendix 1 and the draft logic model used in the interviews is included in Appendix 2.

Interviews began with a discussion about the background to the Keep Well programme in each area. Stakeholders were then asked to articulate the main intended outcomes for the Keep Well programme in their NHS Board. This was

¹² A programme theory (or logic model) is a way of demonstrating how the activities that comprise an intervention are understood to contribute to possible or actual outcomes. Programme theories can be drawn in different ways but they all aim to show the logic between activities and expected results.

intended to explore stakeholders' understanding of the most important outcomes for their programme. The draft version of the revised Keep Well programme theory was then presented and used to structure the remaining discussion.

Aspects of the programme theory were systematically explored and stakeholders expressed where this reflected or differed from their local approach; they also stated what changes would be required to make the logic model reflect their local understanding of the theory underpinning their particular Keep Well programme. One NHS Board requested that the programme theory that had been developed locally for their Board area was used as the basis for the discussion.

As a result of these interviews, 14 short reports summarising the key findings for each NHS Board were written and 14 individual Keep Well programme theories were identified that reflected the views and opinions expressed by those interviewed in each NHS Board. These may not reflect wider views within each Health Board; however, by interviewing local stakeholders for the Keep Well programme it was assumed that the views expressed broadly reflected the dominant approach and understanding of the programme in each locality.

Synthesis of the data gathered from the interviews was subsequently undertaken by the evaluators. An attempt was made to aggregate the local programme theories in order to achieve a revised programme theory that better reflected the programme across Scotland.

Phase two began in April 2013 and focused on establishing whether data was available at the level of general practice in order to allow a 'typology' study (of practices) to be included in the outcomes analysis (objective 4). This analysis, if feasible, would involve Wave 1 practices only as this would be an extension of the outcomes analysis. The aim of the analysis would be to explore whether those general practices which had delivered Keep Well to the greatest proportion of their practice populations experienced greater improvements in CVD-related outcomes than others. Consideration was given to the availability of data on different characteristics of general practices involved in Wave 1. Routine data sources and the information available directly from Keep Well managers were explored.

4.3 Findings

4.3.1 The range of outcomes that Keep Well programmes in different areas are trying to achieve

When asked to articulate the intended outcomes for the programme locally, most NHS Board representatives included several outcomes. These were a mix of short-, medium- and long-term outcomes. All those interviewed understood the programme to be part of their Health Board's contribution to addressing health inequalities, although some recognised a tension in the primary focus of the programme between health improvement and health inequalities. A substantial proportion of interviewees explicitly stated that they did not think that CVD mortality changes would be likely in

less than 10 years. Explanations for this included the nature of the need that is identified (much of which is social and not clinical), the age of many of the participants (the vulnerable groups can be as young as 35) and that many of the participants may take some months following a Keep Well health check before deciding to make changes to their health behaviours.

At interviews in four of the NHS Boards, the discussion highlighted how the intended outcomes had evolved and broadened with experience. One Health Board described their current intention to develop an integrated anticipatory care programme which tackles inequalities in a range of preventable morbidities (including, but not limited to, CVD-related morbidities) through both primary and secondary prevention.

Two NHS Boards stated that there had not been detailed local discussions about the outcomes for the programme when it first started as these were considered to be explicitly laid out in the P2010 /Keep Well guidance.

Six Health Boards stated that their intended outcomes included reducing CVD events in the target population or reducing the inequalities gap in CVD, and seven stated that the emphasis locally was on identifying CVD risk in the target populations and reducing this risk through supported health behaviour change. Two Health Boards explicitly stated that their intention was to focus more on lifestyle-related change than clinical treatments such as prescribed medication. Interviewees expressed the importance of reducing risk factors in people who are not currently high risk, particularly vulnerable adults who are unlikely to have high ASSIGN scores because of their lower age at the health check. Another Health Board was explicitly focusing on changing social determinants of health rather than health behaviours.

Two Health Boards mentioned that their intended outcomes included increasing awareness of CVD risk and options for change as an outcome; four Health Boards specifically identified improving early detection of disease as an outcome; and one Health Board stated that their intended outcome from the outset was for a high-quality CVD screening service which enables clients to access advice, screening and follow-up as required to improve CVD outcomes for all adult residents in their Health Board area. Two Health Boards described their main outcome as reduced inequalities in health, with CVD inequalities being just one aspect of this.

One Health Board stated that improved quality of life and increased healthy life expectancy was an intended outcome, with two other Health Boards expressing this slightly differently as increased productive life expectancy. One further Health Board reported that wellbeing was their key long-term outcome, as they considered that this would contribute to improved CVD outcomes over time.

Six Health Boards described one of their intended outcomes in terms of increasing clients' sense of control over their health or clients being more involved with their practitioner in the decision-making process about their health. One further Health Board stated that building self-efficacy or empowering their clients was an important

outcome, particularly for vulnerable populations. An understanding of the importance of this appears to have grown over the life of the programme.

Two Health Boards highlighted that the programme theory for the work with defined vulnerable groups (i.e. those population groups considered more at risk of ill health or with poorer access to health care, e.g. homeless people) was probably somewhat different to that of the core population (i.e. those living in deprived circumstances, defined variously). It was more likely to rely on building relationships, improving clients' confidence and self-efficacy, and addressing a range of needs which may not directly impact on CVD risk in the short to medium term.

Three Health Boards also highlighted the importance of outcomes related to building a supportive community that advocates for and supports individuals to improve their health.

Successfully reaching and engaging the target populations was explicitly stated as an outcome by three Health Boards and was considered especially important with vulnerable populations. This was expressed slightly differently, however, as achieving improved relationships with general practices, and greater trust with those who do not normally engage with healthcare providers and other services. These Health Boards described Keep Well as the start of a journey rather than an intervention in itself. While the interaction was important, the referral and support provided after the check was considered to be what made the difference to people's lives.

Appropriately trained staff, particularly in primary care, who understand the health impact of inequalities, are knowledgeable about local services and are able to signpost appropriately, was articulated as an outcome by five NHS Boards.

Seven Health Boards specifically articulated that shifting the culture of primary care to a more preventive/anticipatory care approach was an intended outcome. Embedding the Keep Well approach into routine care was specifically mentioned by three Health Boards in order to make it sustainable in the longer term. Seven other Health Boards were aiming to improve partnership working and the connections between services (within the NHS and between primary care and social care, voluntary and community organisations as well as with other local initiatives). This was not always an explicit outcome, and it was acknowledged by three Health Boards that Keep Well was one facilitator of this along with other national and local developments and policy initiatives, such the Quality Strategy, the Christie report and the integration of health and social care. One Health Board explicitly mentioned standardised policies and procedures across practices as an intended outcome and another highlighted the need to achieve improvements in organisational systems in the most deprived areas.

One Health Board highlighted their assets-based, participative approach to reducing inequalities, building on successful community development initiatives, as their means to achieving their intended outcome of a reduction in inequalities.

Unintended effects and outcomes

As part of the NHS Board interviews, the potential for unintended outcomes was discussed. Many of the stakeholders involved commented that they had not previously considered unintended outcomes. A number of possibilities were highlighted, but these had not been investigated by any of the Health Boards; it is not known, therefore, whether or not these have occurred in practice.

In the short term, as a direct result of the health check, possible unintended outcomes that were suggested included increased anxiety, disempowerment, dependency on health practitioners and the inappropriate medicalisation of an individual's problems. The potential for a suboptimal health check that does not provide the client with all the relevant information was also mentioned. There is also the possibility that the relationships between staff and patients change as patients' perceptions of the role of their general practice changes (either positively or negatively). The individual may react negatively to the check or may not accept the available support, a referral or clinical treatment. The possibility of individuals with mid-range risk not being followed up or offered further support was also highlighted by one Health Board.

In terms of staffing, the possibility that the training provided to staff may make them more attractive to other employers was raised. In some areas it was considered that this had led to a high staff turnover, which was a challenge to programme delivery. The potential for staff to have negative views of the Keep Well programme and not to engage in it was also raised at a number of the interviews.

At the organisational level, the possibility that general practices or other important partners did not engage in the programme was highlighted. Again, some Health Boards had experience of this.

In the medium term, there is the possibility that initiated changes in lifestyle behaviours are not maintained and that prescribed medication is not continued. It was also highlighted that there may appear to be an increase in CVD incidence if more cases are identified through screening.

On a more positive note, Keep Well may contribute to improved pathways and easier access to non-clinical services. There may be ripple effects with families or in the wider community as people who have engaged with Keep Well share their experiences.

In the long term, unintended outcomes might include poorer health as a result of increased anxiety or harm from medication. Some interviewees predicted an increase in the use of acute services by those identified as high risk and a greater

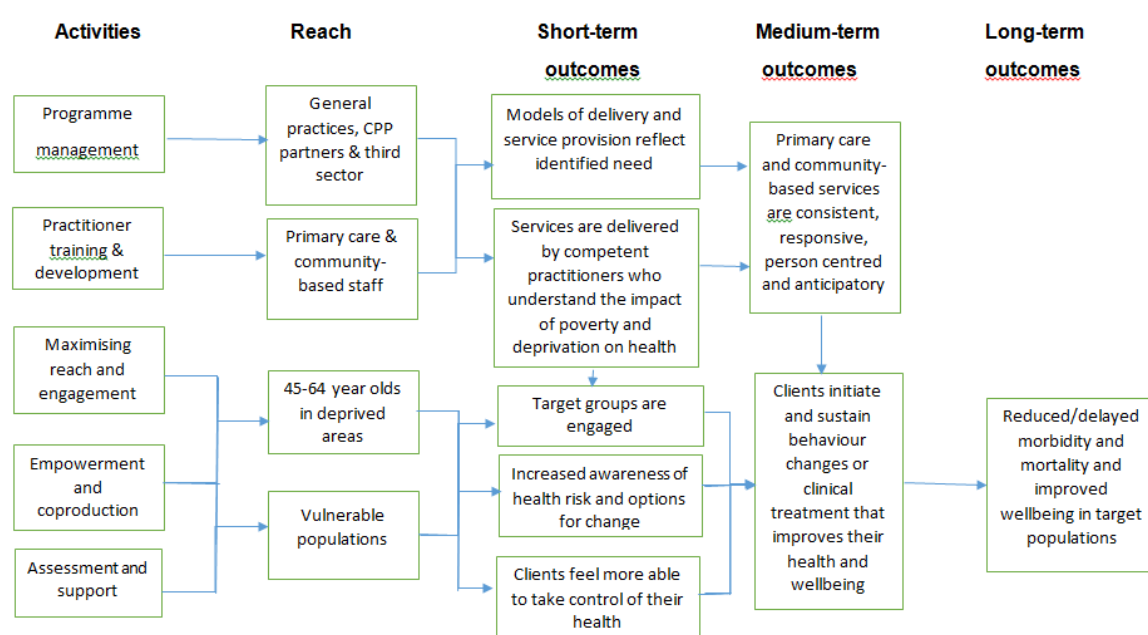
demand for NHS primary services for those requiring monitoring for a long-term condition identified as a result of the Keep Well programme. It was also suggested that inequalities may increase rather than decline if those people who are most in need or at risk do not access the services.

4.3.2 Revised programme theory for Keep Well and observed variation

Once the revised Keep Well programme theory was introduced to the discussion, it became clear that different Health Boards were content with different parts of it. There was general acceptance of the long-term outcome of reducing CVD-related inequalities (although three Health Boards wished this to be expressed more generally as health inequalities rather than being specific to CVD). Many stakeholders felt that Keep Well had evolved into a much broader inequalities programme which could address a range of needs in populations at high risk of a range of social and health issues. Most Health Boards agreed that making the culture of care more inequalities-sensitive, person-centred and anticipatory was a long-term outcome of Keep Well, though many acknowledged that Keep Well is just one facilitator of this, with many other initiatives working to achieve the same outcome. However, those Health Boards with centralised Keep Well services considered it less plausible that a centralised service was likely to have a substantial impact on the culture of primary care compared with those programmes delivered through existing primary care teams.

In order to address objective one, to review and strengthen the programme theory for Keep Well, the findings from the interviews were synthesised into a simple generic programme theory that broadly reflected the Keep Well programme as a whole. The resulting programme theory is shown in Figure 4.

Figure 4: Revised, simplified programme theory for Keep Well



This generic and simplified model conceals wide-ranging variation in how the different Health Boards understood the mechanism by which the programme would achieve its objectives. Further work was undertaken to explore this variation.

The discussions about the draft programme theory (see Appendix 2) in the 14 interviews were compared. There was broad agreement on the long-term outcomes for Keep Well, but there were clear differences in the emphasis that different Health Boards gave to these. For example, some Health Boards felt that reducing CVD mortality in the target populations was the main long-term outcome, whereas others felt strongly that increased healthy life expectancy or improved wellbeing were the primary intended outcomes for their programme. For one Health Board, improved wellbeing was the route by which improved health, including CVD outcomes, would be achieved. There was greatest disagreement with the long-term outcome related to hospitalisations, with many feeling uncomfortable with this as a long-term outcome. A reduction in the use of acute services by the target population was considered more likely.

In terms of short-term outcomes, there was some consensus that Keep Well was seeking to maximise engagement with those in the target population groups, ensuring that they have a positive experience of their health check and feel more able to take control of their health, that long-term conditions are detected and diagnosed earlier, and that health risks are identified and support offered to clients to make changes to improve their health.

Many respondents cited improved skills and knowledge about inequalities and health as short-term outcomes for staff. This was considered necessary for improved outcomes for the target groups, along with knowledge of local services to which people could be referred to meet their identified needs.

In terms of organisational outcomes, it was clear that most of the Health Boards were seeking to achieve improved collaboration and partnership working within and outside health services, and, for those with general practice-based delivery, improved relationships with general practices. In the longer term the majority of Health Boards highlighted the importance of quality of service provision, collaboration and partnership between services (including the community and third sector) and the need to reorient current service provision to make it more anticipatory and inequalities-sensitive.

There was greater divergence in the articulated medium-term outcomes. For example, improving trust between clients and practitioners, and improving clients' sense of control over their health and choices relating to their health, were expressed by six Health Boards as important outcomes necessary to achieve the longer-term outcomes, particularly with the most vulnerable population groups. These Health Boards were most likely to offer support for clients after the health check in the form of health coaching or other support irrespective of health risk.

Some Health Boards emphasised most strongly the identification of CVD risk, the early detection of existing disease and the appropriate onward referral or signposting to address identified CVD risk factors.

From the findings of these interviews we proposed that there are three broad theories that sit within the generic programme theory, which illustrate the different ways that NHS Boards understand the mechanism by which Keep Well is expected to contribute to the intended long-term outcomes. These are detailed below.

Theory 1: Changing the way care is organised and delivered

One theory is that Keep Well contributes to changes in the way that agencies work, how they collaborate to deliver services and how practitioners deliver care. This theory recognises that many agencies play a part in providing support for individuals to make changes. It also suggests that consistent and holistic service delivery, collaborative working between health and social-care agencies and the community and third sectors (and their staff), and clear processes are more likely to result in successful identification and engagement with those in greatest need.

In the NHS Boards in which this theory appeared most dominant, practice or community-based staff were often directly involved in delivery of Keep Well. In those NHS Boards where a small central team delivers Keep Well, this theory was considered to contribute less to the achievement of the long-term outcomes.

Theory 2: Empowerment and co-production

This theory relates to the importance of Keep Well in developing trusting and supportive relationships between individuals and services, particularly for those people currently disengaged with health and other services. This theory suggests that by changing the nature of the consultation, and providing ongoing support after or outside of the health check, individuals can be supported to develop a greater sense of control over their lives. They can be helped to make choices jointly with their practitioners about aspects they wish to change and embark on change to improve their wellbeing.

Three NHS Boards highlighted the importance of the community. In these Health Boards, community development approaches and the building of social capital were important components of the theory of change.

This theory was considered relevant to the most vulnerable and at-risk in the target groups, recognising that, for many, developing greater trust in services and a greater sense of control of one's life were necessary first steps in the process towards long-term health improvement. A minority of Health Boards, however, felt that addressing complex and entrenched social problems was beyond the scope of Keep Well. They felt that Keep Well practitioners did not have the skills and resources required and that other specific projects were required.

Theory 3: Focusing on clinical risk factors

This theory, which most closely resembles the original P2010 theory, is that the health check identifies health risks and triggers appropriate drug treatment (e.g. statins or anti-hypertensive medication) and/or referral to services regarding specific risk factors (smoking, diet, etc.). In this way, individuals have the opportunity to reduce their risk factors, contributing to the long-term outcomes of reduced CVD morbidity and mortality in the target groups.

These three theories can therefore be considered nested theories that sit within the more general programme theory described previously. These may coexist within Health Boards but more often it appeared that one of the theories was more dominant and had driven the planning and development of the programme in that locality.

4.3.3 How Keep Well was implemented in the different parts of Scotland

Keep Well was implemented differently across Scotland. Two important areas of variation were the way that Health Boards identified people to be invited to the programme and the models for delivering the programme.

Targeting

Keep Well was established as a CVD primary prevention programme targeted at those who are high risk, initially defined as those people aged 45 to 64 (who are not already included in practice stroke, diabetes or CVD disease registers) living in the areas of greatest concentration of multiple deprivation (the 'core population'). Some Health Boards widened their criteria for eligibility and a number of Health Boards specifically targeted some population groups which they considered vulnerable, for example Gypsy travellers. However, this varied by NHS Board and over time, and sometimes resulted from specific additional funding or specific projects. Some Health Boards, in addition to providing guidance on eligibility, gave practices the autonomy to invite those they thought should be invited based on their local knowledge. When the Keep Well mainstreaming phase began in 2011, the accompanying guidance stated that a number of vulnerable groups were to be routinely included in the eligible populations. These were:

- Carers (aged 40–64 years)
- South Asian ethnic subgroups (aged 35–64 years)
- Black and Afro-Caribbean ethnic subgroups (aged 35–64 years)
- Offenders, both in prisons and in the community (aged 35–64 years)
- Gypsies/Travellers (aged 35–64 years)
- Homeless individuals (aged 35–64 years)
- Those affected by drug or alcohol misuse (aged 35–64 years).

In Wave 1 (from 2006), the most deprived areas in Scotland were identified for the first five pilot sites using the SIMD. This is an area-based measure of deprivation which is often used as a proxy indicator of individual deprivation. However, there

may be some relatively affluent residents in the area and many people living in deprivation do not live in areas of concentrated deprivation. As a result, SIMD is more useful for identifying deprivation in urban areas, which are more densely populated and tend to have more concentrated deprivation, rather than in rural areas, which are more heterogeneous and less highly populated, and deprived households are likely to be more scattered.

Within Wave 1 pilot areas, different approaches were taken to targeting: some practices invited all patients in the eligible age band to engage with Keep Well, whereas others selected only those identified as living in deprived area. As Keep Well evolved – and learning from Wave 1 was incorporated – all Wave 1 practices moved to the latter approach. However, as other waves of Keep Well were launched, different approaches were adopted. In terms of identifying those likely to be eligible for Keep Well, approaches included use of SIMD datazones (both nationally and locally defined), Carstairs score,¹³ Council Tax banding, partnership working with communities and community planning partners, working with local employers (especially those with low-paid staff) and opportunistic engagement either through general practices or in the community. One Health Board took a whole-population approach and invited all adults between 40 and 80 years old in recognition of the difference in CVD outcomes between that NHS Board and the rest of Scotland.

Delivery models

In some areas, a centralised Keep Well model was used, comprising a small number of Keep Well staff (nurses or healthcare support workers) working on a peripatetic basis to deliver the checks in various locations (general practices, workplaces, community agencies) throughout the Health Board. The central team could also identify and engage eligible patients. In other areas, existing general practice- (or community-) based staff were trained and supported to deliver Keep Well health checks (and, in some instances, follow-up support) as part of their current role. Some general practices took on most of the Keep Well programme (engagement, health assessment and follow-up). Other areas adopted a mixed model depending on local characteristics and the extent to which local practices engaged with the Keep Well programme. One area used a partnership approach to engage their target group, which involved working with employers, community planning partners and community organisations to identify individuals likely to be at high risk.

¹³ The Carstairs index was originally developed in the 1980s using 1981 census data. It is an area-based measure of deprivation that was widely used before SIMD was introduced. It is composed of four indicators at postcode sector level that were judged to represent material disadvantage in the population (lack of car ownership, social class, overcrowded households and male unemployment).

Explanations for the variation observed

Keep Well has been characterised by extensive variation despite its status as a national programme. The possible reasons for this were explored during the interviews and the following potential explanations were identified:

- **Performance management and outcomes:** There are differences and similarities in views about outcomes and theories of change which have been described above. In addition, some Boards reported concentrating specifically on delivering the services required in the original guidance rather than making explicit statements about the long-term outcomes that they were seeking to influence. This reflected a concern that they might be measured against any explicit outcomes. Also, several areas noted the potential influence of other national and local programmes and strategies in the longer term (e.g. *Equally Well*, the *Quality Strategy*) and expressed difficulty in separating the contribution of Keep Well to common long-term goals from other policy initiatives. Finally, the influence of a performance management target¹⁴ on throughput, which was in place from 2009, was also reported to have driven a focus on delivering required services rather than focusing on desired outcomes.
- **Date of engagement with Keep Well:** Each of the four waves of Keep Well was associated with slightly different guidance documents with slightly different emphases. This is reflected in the different approaches NHS Boards took to implementation.
- **History:** In some areas the Keep Well programme built on existing or planned health improvement or community development projects. Where this occurred, the Keep Well programme tended to reflect the approaches and ethos of the original project. Where this did not occur (i.e. where the programme began in direct response to the Keep Well guidance), the approaches more consistently reflected the respective Keep Well guidance documents.
- **Funding:** In some NHS Board areas, the Keep Well programme was entirely funded by Scottish Government Keep Well monies, whereas in other areas additional local or national monies were used to support all or part of the programme. This may have allowed some areas to offer additional services, such as health coaching after the check.

¹⁴ The Scottish Government's Health, Efficiency, Access and Treatment (HEAT) target for heart disease was 'to achieve the agreed number of inequalities-targeted cardiovascular health checks during the specified year.' The target number of health checks was agreed between the Scottish Government and each NHS Board.

- **Leadership and structure:** Most NHS Boards experienced consistent, high-level support and commitment to the Keep Well programme. Others had less obvious support but did not find this to be problematic. Where changes in NHS Board structures impacted on consistent management of the Keep Well programme, there were associated challenges for the programme.
- **Post-check support:** The follow-up support offered to Keep Well participants varied by NHS Boards in terms of form and focus. For example, some NHS Boards were able to provide health coaching for those with identified health or social needs who wished to engage after the health check. Others were able to refer to defined services on specific issues, such as smoking cessation or weight loss. Some developed links with established local initiatives, to which they could refer clients. One NHS Board introduced annual checks for those identified at high risk of CVD (ASSIGN ≥ 20) who were not on a disease register.

Views of Keep Well

During the interviews, participants expressed their enthusiasm for the programme. Participants in 11 of the 14 NHS Board interviews expressed strong views that their programme was making a difference to people at high risk of a range of health or social problems. Examples were cited, from personal experience and from local surveys, of the impact of Keep Well on individuals, often in terms of changes not directly related to CVD; for example, improved relationships with health services and involvement in voluntary work or with a community organisation, although changes in diet and physical activity were also mentioned. For many, and especially those in the vulnerable groups, this was seen as a necessary first step towards a longer-term health benefit. Three Health Boards reported, based either on anecdote or the results of local evaluations, that participants often did not embark on change immediately after the Keep Well health check, but that this could happen several months later. One interviewee estimated that around half of the needs identified at the Keep Well checks were social rather than health needs. Another interviewee highlighted the value of the 'therapeutic encounter' that Keep Well provided. Keep Well was widely considered to be an important mechanism, or 'hook', for engaging with the most 'underserved' in their population and for linking with a range of health, social and third sector partners.. As such, it was viewed as an important part of local health inequalities strategies. There was also a strongly held view that Keep Well had increased the profile, understanding and recognition of the importance of addressing health inequalities within their NHS Board.

4.3.4 The feasibility of incorporating practice characteristics into the outcomes analysis arm of this evaluation.

Keep Well managers in the four NHS Boards which delivered Wave 1 (NHS Greater Glasgow and Clyde, NHS Lanarkshire, NHS Lothian and NHS Tayside) were able to provide the following information:

1. Practice codes for all those practices registered to deliver Keep Well in Wave 1 between 2006 and 31 March 2010.
2. The total practice population for each of these practices as measured as near as possible to 31 March 2010.
3. The number of individuals in each of these practices who received a Keep Well health check on or before 31 March 2010.

Three of the four Wave 1 areas (NHS Greater Glasgow and Clyde, NHS Lanarkshire, NHS Lothian) were able to provide these data items linked to the practice code which allowed linkage to the routinely collected data for the practice. This made it possible to analyse Wave 1 practices in these areas by the proportion of their total practice population who received a Keep Well check to explore whether the outcomes changed more in the practices that had reached the greatest proportion of their population. The results of this typology analysis are reported as part of the outcomes analysis in Chapter 5.

4.4 Discussion

It is clear from this study that the Keep Well programme was characterised by substantial variation; quite different approaches were adopted by the local NHS Boards. It is also clear that there are a number of reasons for this. Importantly the variation observed is associated with different understandings of the mechanism by which the intended long-term reduction in health inequalities is most likely to be achieved. This has similarities to the findings from the Keep Well Wave 1 evaluation (MacKenzie et al., 2010) that the understanding of the concept of 'anticipatory care' varied between stakeholder groups. The Wave 1 evaluation recommended a resolution to these differences but it appears that Health Boards have developed the programme in a way that makes sense to local stakeholders and local circumstances rather than one which involved a consistent national approach.

One of the original objectives was to develop a revised national programme theory for the Keep Well programme. Each of the 14 local programme theories was examined in an attempt to do this. The result (Figure 4) was a high-level summary that masks considerable local variation. Three nested models were proposed which attempt to describe the three main mechanisms that appear to have driven local planning and implementation of the programme. These may coexist within a Health Board, but it is likely that one of these theories drove the planning and implementation of the programme in that locality.

In some areas Keep Well was incorporated into existing health improvement programmes. There are benefits from this, such as the potential to limit expenses

incurred in setting up the programme and more rapid implementation through existing staff and structures, but it may lead to the programme being diluted or altered in the process of merging programmes, resulting in a programme substantially different in terms of approach and intended outcomes to that which was originally intended by the Scottish Government.

Variations in the intervention, the programme theories and the range and variability of intended outcomes, most of which cannot, at present, be robustly measured, make a retrospective evaluation of programme impact extremely difficult. It also means that the relevant evidence base is different for the various approaches. Furthermore, it means that identifying the most appropriate outcomes against which Keep Well's success or otherwise should be measured is open to challenge and debate.

It is clear from this study that within NHS Boards and among practitioners delivering Keep Well there is enthusiasm and support for the approach, and it is widely considered to be an important part of the Health Board's work on health inequalities. This view has been formed both from first-hand experience with clients who have reported various benefits from their engagement with the programme (not just related to their health) and from managers who believe that the programme is an effective route to engaging those who are traditionally hard to engage. The programme has also been seen as a means of delivering and integrating other health improvement initiatives.

There were several limitations to this study. First, there is likely to be a selection bias, as those stakeholders who took part in the interviews are likely to have had interests in the Keep Well programme either through their employment status or the commitment they have made to implementing the programme in their area. As a result, interviewees may have offered more positive views on its impact than those who did not volunteer to be interviewed. Furthermore, this study took place in 2012, after the mainstreaming phase was introduced, and asked questions about the history and evolution of the programme. Recall bias may well have influenced the interviews, as well as the possibility that the interviewees were not involved in the programme during the period being discussed (prior to 2012). The finding that many interviewees either felt that any impact of the programme on CVD outcomes would not be seen for at least 10 years, or did not feel that it was likely that the programme's contribution to a reduction in CVD-related inequalities could be evidenced, may reflect their understanding of the programme, or it may reflect the widespread debate about the programme and the challenges in evaluating its impact which occurred in 2011 and 2012.

Chapter 5: Evidence from previous Keep Well evaluations

5.1 Introduction

This impact evaluation was established as a 'pragmatic' evaluation which set out to use available information to evaluate the impacts of the Keep Well programme. The challenges in undertaking a retrospective impact evaluation of an evolving programme which was not established with comparison groups have been rehearsed in Chapter 2. Given the many limitations and challenges in assessing the impacts of the Keep Well programme, work was undertaken as part of this evaluation to bring together the evidence that already exists in relation to the Keep Well programme from nationally commissioned evaluations and from the substantial bodies of research and evaluation work relating to Keep Well that were undertaken within NHS Boards.

5.2 Methods

Keep Well programme managers in all NHS Boards were asked to provide the evaluation team at NHS Health Scotland with evaluations that addressed outcomes of their local Keep Well programmes. The national Keep Well programme management team in the Programme Design and Delivery directorate of NHS Health Scotland also provided the evaluation team with the Keep Well evaluations on their database.

Evaluation studies of the Keep Well programme undertaken locally or nationally were included if they reported on reach and engagement or on the achievement or otherwise of one or more outcomes. Studies that only addressed process or implementation issues, with no data on reach and engagement or longer term outcomes, or which only provided descriptive reports of service provision, were excluded. Evaluations relating to specific aspects of the service, settings or population groups were excluded unless it was considered that their findings added useful information to this review. Papers that did not provide adequate detail of the methods utilised were also excluded. Included studies were all completed prior to March 2014.

The evaluations identified were reviewed by two members of the Keep Well evaluation project team. Many of the submissions received were not formal evaluations, but included literature reviews, case reports, performance data, audits and descriptive reports about current service provision. Twenty five studies were identified for inclusion. The table in Appendix 4 lists these studies and provides information on the study design, the aims/questions that frame the studies, a brief summary of results and some points regarding methodological quality that should be taken into account when interpreting their findings.

These evaluations were reviewed in relation to the outcomes in the LV study described in Chapter 4.

5.3 Findings

These findings are presented for each of the outcomes in the simplified Keep Well logic model (Figure 4).

5.3.1 Target groups are engaged

Maximising reach to the target (most at risk) population is important in order to optimise the potential to provide support and clinical interventions to those who have the capacity to benefit.

Reach of invitations

The Keep Well Wave 1 evaluation (Wang et al., 2010a; McLean et al., 2011b) analysed data from the five pilot sites. 'Reach' was defined by the authors as receiving an invitation to a health check. The evaluation found that in four of the five pilot sites a large proportion of the target group (range: 76% to 98%) were reached through the various contact methods used, although this was lower in areas of greatest socio-economic deprivation (range: 37% to 73%). In the fifth pilot site, reach findings were uncertain: they appeared to be low (34%) from the electronically collected data but the manually recorded data indicated a much higher reach figure (82%) (McLean et al., 2011b).

Attendance at health checks

Attendance data were analysed from the five Wave 1 pilot sites (Wang et al., 2010a; McLean et al., 2011b). The evaluation found that attendance was 61.3% overall (52% in Dundee, 54.8% in Lanarkshire, 68% in Lothian and 70.4% in Glasgow).

More women attended health checks than men, and older people were more likely to attend than younger people within the defined age group (age 45 to 64 years) with those over 60 most likely to attend (attendance rates of 77.8% in Glasgow, 60.4% in Dundee and 55.8% in Lanarkshire).

Although the programme targeted the most socio-economically deprived, general practice populations are heterogeneous so some people living in more affluent areas were able to attend. In all areas the percentage attending reduced with increasing deprivation, although the absolute numbers of targeted individuals was greater in the most deprived quintile (for example, 14,495 in most deprived SIMD quintile [73.7% of the total targeted] compared to 553 people in least deprived SIMD quintile [2.8% of the total targeted] in Glasgow). Glasgow had the highest percentage of patients attending from the most deprived 15% of datazones (70.0% of total attendees), with somewhat lower percentages in Lothian (62.5%), Lanarkshire (51.6%) and Dundee (50.1%) (Wang et al., 2010a; McLean et al., 2011b). It is possible that the high rate in Glasgow reflects the relatively concentrated deprivation there; however, it is also possible that there were practice characteristics or the organisation of Keep Well in Glasgow that improved the ability to engage the most deprived people. For example, the approach adopted by Glasgow and Lanarkshire, in which all patients between 45

and 64 years of age in Keep Well general practices were invited, may have influenced the engagement rates. Dundee's approach targeted only those living in the areas of greatest deprivation.

Another paper from the Wave 1 evaluation explores the relationship between attendance and deprivation at practice level (Wang et al., 2010c). It reports that engagement with patients was found to rise with increasing practice deprivation before falling for practices located in the most severely deprived areas, but it was still higher than in the less deprived practices. The authors suggest possible explanations for this at the individual patient, staff and organisational levels, but note that further exploration is merited as this was a relatively small-scale study of Wave 1 practices, and there were some uncertainties about the quality of some of the data used.

NHS Ayrshire and Arran analysed the data gathered through the delivery of Keep Well within their general practices between August 2008 and March 2012 (Hair and Wyper, 2013). They reported that 90.3% of those attending a health check resided in the most deprived 15% of datazones. They also reported that, unlike the findings in other areas, more men than women received a health check over this period (53.3% vs. 46.7%).

A cross-sectional study undertaken by NHS Lothian reported that 42% of the eligible population resided in the most deprived quintile. The study explored uptake of Keep Well as a proportion of those eligible in each SIMD quintile and found that uptake was lower among men, ethnic minorities and those in the most deprived quintile: 56% of those eligible attended from the most deprived quintile compared to 69% of those eligible from the least deprived quintile, although this difference lessened with increasing age (Tomlinson and Ramsay, 2011).

Some rural NHS Boards felt that SIMD was not useful in identifying those living in deprived circumstances. NHS Forth Valley (Lindsey, 2011) found that while only 12% of those who received Keep Well health checks in 2010 resided in the most deprived quintile of SIMD datazones, 55% were in homes in Council Tax bands A–C. This reflects the views of other rural Health Boards who have considered means other than SIMD for identifying deprived individuals (Allan, 2012; NHS Borders, 2011).

In terms of CVD risk, the Wave 1 evaluation found that those attending the Keep Well health check had high cholesterol levels (63% had cholesterol ≥ 5.0 mmol/l; 27% ≥ 6 mmol/l), high systolic blood pressure (31% ≥ 140 mmHg) and high levels of obesity (28.6% were classed as obese). The authors found that the prevalence of some risk factors was higher than reported by respondents to the Scottish Health Survey in 2008 (Wang et al., 2010b). In terms of CVD risk scores, approximately 21% of attendees in Glasgow, Dundee and Lanarkshire with no pre-existing heart disease were at high risk ($\geq 20\%$) of developing CVD in the next 10 years (Wang et

al., 2010b). It appears that the Keep Well approach, at least in Wave 1 areas, identified and engaged with a high-risk population group. However, the level of missing data (Glasgow 9.5%, Dundee 15%, Lanarkshire 26.6% and Lothian 57%) raises questions about the extent to which this data is representative of all health checks, particularly in the Lothian pilot site (McLean et al., 2011b).

Local evaluations have reported differing findings in terms of global CVD risk of attendees. NHS Forth Valley (Ekogen, 2011) found that around 9% of attendees had an ASSIGN score of 20 or more compared to around 30% reported by NHS Fife (Robinson, 2011a), although the Fife figure reflects only 69% of attendees for whom ASSIGN was recorded. The Forth Valley figure (Ekogen, 2011) may reflect the lower proportion of attendees living in a deprived SIMD datazone (because SIMD is a component of the ASSIGN calculation), although attendees were also low risk in other respects (for example, only 19% were smokers). In West Lothian (NHS Lothian, 2012) an analysis of data for all patients attending Keep Well over an 11-month period in 2010/11 found that 13.6% of attendees had an ASSIGN score of 20 or more. A small study of a Keep Well homeless pilot in Ayrshire and Arran (NHS Ayrshire and Arran, 2012) found that only 10% had an ASSIGN score of 20 or more, but this is likely to reflect the younger age of this population group (mean age = 41 years). The pilot found that those attending the homeless service did have substantial need in relation to mental health and addictions.

There is some evidence that opportunistic and outreach approaches result in small numbers of engagements but may have a part to play in reaching some people who would not otherwise be engaged, as well as supporting patients following their health check (Turner et al., 2010; Carver et al., 2010; Scoular, 2012; Sinclair and Alexander, 2012). However, the role of outreach workers varied across different NHS Boards and over time. As well as improving attendance, outreach workers can provide important insights into the factors associated with non-attendance for health checks (Scoular, 2012), provide time and skills to support patients and provide information of relevant local services (Carver et al., 2010). In Lanarkshire, outreach approaches increased attendance at Keep Well health checks by 11% (from 58% to 69%) in 2010 (Sinclair and Alexander, 2012). The authors suggest that the 'hard-to-reach' comprise at least 2 groups: the 'hard-to-contact' and the 'hard-to-engage' and that outreach approaches in Lanarkshire have been most successful with the former group. The Wave 1 evaluation reported, however, that the majority of patients contacted as part of outreach work remained unengaged in the Keep Well programme (Turner et al., 2010). If Tudor-Hart's finding (Tudor-Hart, 1970) that the individuals who require the greatest effort to attend for a health check are the individuals with the greatest health needs also holds for Keep Well, outreach could play an important part of a wider engagement strategy (Sinclair and Alexander, 2011), although the health needs of those engaged through outreach have not been explicitly reported in identified studies to date.

In general, previous national and local evaluations have found lower health check uptake among men, younger people and the most deprived, despite the targeted nature of the intervention. The extent to which those receiving checks were found to be at high CVD risk varied across the areas.

5.3.2 Models of delivery and service provision reflect identified need

Here we present evidence relating to whether or not the Keep Well programme resulted in models of local service delivery that meet identified needs in the local populations.

One evaluation was identified that found variations in ‘organisational systems, engagement efficiency, clinical management and, most crucially, in recognising and responding to need’ of the Keep Well intervention within an NHS Board (Scoular, 2012). This variation does not appear to be based on identified need, but rather on specific challenges to effective delivery including data sharing and IT issues, engagement of GPs and connections between relevant agencies.

Scoular (2012) highlights the opportunities that the NHS Greater Glasgow and Clyde (NHS GG&C) evaluation findings identify for responding more effectively and efficiently to the considerable ‘clinical, social and psychological need’ in the Keep Well population.

5.3.3 Services are delivered by competent practitioners who understand the impact of poverty and deprivation on health

One paper (Carver et al.; 2012) was identified that explores the extent to which staff have an understanding of inequalities as well as the necessary skills and competencies to deliver the Keep Well health check and any follow-up. The authors reported that staff interviewed in Lothian described changes to their practice and increased awareness of local services and of CVD risk, and of the impact of health inequalities on their patients. They also reported that they used these improved skills in a range of consultations, not just those of Keep Well. Respondents also highlighted some negative issues including high staff turnover due to low job security, increased workload for those working in practices and concerns about becoming deskilled because of the repetitive nature of the health checks.

5.3.4 Increased awareness of health risk, including diagnosis of disease, and options for change

Evidence for this outcome includes the changes experienced by the patient as a result of the health check in terms of them being more aware of their personal CVD risk and of the options to change their health behaviours. It also includes the identification and diagnosis of chronic conditions as a result of the Keep Well health check. This includes diagnoses of diabetes, CHD, depression, hypertension and stroke.

Awareness of CVD risk

Six Keep Well evaluations report on awareness of CVD risk and options for change in some form (Hooke et al., 2011; Clarke et al., 2010; NHS Lothian, 2012; Cunningham and Easton, 2012; Fyfe et al., 2011; NHS Borders, 2011) but do not always use this terminology (for example many use the term 'patient education'). The largest study (Hooke et al., 2011) includes data from 1035 patients but the response rate was low. Other studies included had small sample sizes or low response rates, were small qualitative studies or relied on secondary observations from those delivering Keep Well, rather than on direct responses from patients. These studies report that responders appeared to become more aware of the benefits of changing their behaviours as a result of Keep Well. The studies also report that, although respondents often found it difficult to recall the specifics of the Keep Well health check, they reported that they learnt more about their own health status in general and about their options for change as a result of attending.

However, the low response rates, small sample sizes and reliance on proxy reports all mean that these studies do not provide strong evidence of improvements in understanding about CVD risk and are likely to overestimate the extent to which patients are more informed about their health as a result of Keep Well.

Identification and diagnosis of chronic disease

Three studies (Scoular, 2012; Robinson, 2011a; NHS Borders, 2011) report changes in the identification and diagnosis of chronic disease as a result of Keep Well health checks. The Fife study (Robinson, 2011a) suggested that, among health check attendees, recording on chronic disease registers increased by a third following the health check; however, this study included only 52% of health check data. Other evaluations found that the number of new diagnoses following a Keep Well health check was small, with the greatest proportion of diagnoses being for hypertension (high blood pressure), followed by diabetes, CHD and stroke. The largest of these studies, undertaken by NHS GG&C (Scoular, 2012), did not detect a significant change in the rate of new diagnoses of chronic disease as a result of the introduction of Keep Well (based on a comparison of data from Keep Well and non-Keep-Well practices). Scoular notes that 'the analysis suggests that the rate of new "disease" registrations arising directly from Keep Well is likely to be modest in scale.'

Ludbrook and Douglas (2011) estimate the rate of detecting new cases of hypertension and diabetes at 4% of Keep Well attendees using available data in NHS Grampian, with a higher proportion of attendees being identified with CVD risk factors.

5.3.5 Clients feel more able to take control of their health

Studies are included here that report on patient experience of the health check in general as well those that consider whether Keep Well increases patients' feeling of control over their health.

Patient experience

Six local evaluations of Keep Well address patient experience of the health check as an outcome (Hooke et al., 2011; NHS Borders 2011; Clarke et al., 2010; Cunningham and Easton, 2012; Ekogen, 2011; NHS Ayrshire and Arran, 2012) but these vary in terms of their focus, populations and scale. The largest study was the NHS Ayrshire and Arran Patient Satisfaction Report (Hooke et al., 2011) with 1035 patients in total (27% response rate with a 3:2 female to male ratio). Other studies have a small sample size, are small qualitative studies or have relied on secondary observations from those delivering Keep Well as opposed to those of the participant. In overall terms, these studies found that patients reported positive experiences of the Keep Well check both in terms of how the health professional delivered and managed the consultation itself and in relation to the more logistical elements (e.g. location and length of the check). However, high levels of non-response to many surveys mean that they may be more likely to include participants who had a positive experience; in addition, in satisfaction surveys, patients may be reluctant to report negative experiences. These are important sources of bias which make interpretation of these findings difficult.

There are a number of other factors and variables that may impact on patient experience which no evaluation studies identified to date have examined (e.g. impact of the type of health professional in delivering the check and whether a high ASSIGN score impacts negatively on perceptions of the experience of the health check). In addition, the development of trust and positive relationships between the client and the health practitioner during the health check has not been explored to date, although it was suggested as a possible outcome by some interviewees in the LV study.

Increased feeling of being in control of one's own health

The health professionals interviewed as part of the Well North study (Fyfe et al., 2011) reportedly felt that Keep Well encouraged patients to take 'greater responsibility' for their health and lifestyle, but this reflects the views of practitioners rather than direct reports from patients. It is unclear whether patients would feel more able to take control of their own health in the absence of ongoing support.

5.3.6 Primary care and community-based services are consistent, responsive, patient centred and anticipatory

The Glasgow Keep Well evaluation (Scoular, 2012) identified large variations in the delivery of the Keep Well health check across general practices delivering the programme. Patients clearly received a different service depending on which practice they attended. If all practices had been delivering consistently at the level of the best performing practice, the author suggests that it is possible that more patients would have benefited from appropriate advice, treatment or referral.

5.3.7 Patients initiate and sustain clinical treatment or behavioural changes that improve their health/wellbeing

This outcome includes evidence of outcomes related to the initiation and maintenance of behavioural changes, or clinical treatment, as well as evidence of subsequent improvements in health or wellbeing (including improvements in risk factor status).

Prescribing

In terms of prescribing, three studies report findings (Scoular, 2012; Tomlinson and Ramsay, 2011; Noakes, 2012). The NHS GG&C study (Scoular, 2012) assessed daily doses of all dispensed statin¹⁵ prescriptions over a five-year period before and after introduction of Keep Well in each of the Wave 1 and Wave 2 primary prevention sites and in one Community Health and Care Partnership (CHCP). Practices which subsequently became Keep Well practices had a higher rate of statin-prescribing from the start, probably as a result of their more disadvantaged populations. The study found that statin prescribing increased progressively in all areas over the five-year period from 2005 to 2010. While the increase was steeper in Keep Well practices, it was modest, not found in all areas and most pronounced in one CHCP area (which had considerable, concentrated deprivation).

A cross-sectional analysis of health check attendees in Lothian (Tomlinson and Ramsay, 2011) found that the overall proportion of people receiving statin medication in Keep Well practices was very similar to those in non-Keep Well assessed groups, although a higher percentage of people with diabetes or CVD who had a Keep Well assessment received statin medication. The authors suggest that this indicates that Keep Well has resulted in appropriate increases in prescribing for high-risk primary prevention patients.

A study in Tayside explored changes in statin-prescribing associated with Keep Well (Noakes, 2012). Like the NHS Lothian study, it found that statin prescribing in the Keep Well practices did not change overall, but that it did increase among those individuals who engaged in the Keep Well programme.

Referrals

The NHS GG&C evaluation (Scoular, 2012) used a tracking tool to measure referrals and reported a large number of referrals to health improvement services as a result of Keep Well. However, there was extensive variation in referrals across practices. Uptake of referrals by patients was found to be highly variable both by practice and by referral service. Referrals were high in the first year of Keep Well Wave 1 but declined sharply in subsequent years.

¹⁵ Statins are prescribed to those people identified as at high risk of CVD.

Other studies reported on referrals (NHS Borders, 2011; Hooke et al., 2011; Robinson, 2011a) though these were reported variably (as formal referrals, as all types of signposting and referrals, or as onward referral to an established health coaching programme rather than to a specific service). Robinson (2011a) reports that most referrals in Fife were made to weight management services and that 94% of those referred expressed an intention to attend, compared to only 50% of those referred to smoking cessation or alcohol services. Only the Glasgow study (Scoular, 2012) was able to offer results on uptake.

Health behaviour change

Five studies (Robinson, 2011a and b; Hooke et al., 2011; NHS Borders, 2011; Scoular, 2012) reported that patients said that they had made changes to their health behaviours (diet, physical activity, weight, smoking and alcohol consumption) immediately following, or up to six months after, the health check. Half of the 350 respondents (response rate at baseline 32%) to the Fife survey (Robinson, 2011a) reported making positive behaviour changes as a result of Keep Well; however, this group represented only 4% of all those undergoing health checks during this period. At three months, 72% of the original group were re-interviewed and 68% of those reported maintaining one or more behaviour changes. These findings were based on a selected sample which makes selection bias likely. In addition, self-reported changes may be over-optimistic and may be attributable to influences other than Keep Well.

Two studies (NHS Lothian, 2012; Robinson, 2011b) addressed reported post-health check behaviour change up to a 12-month point. The majority of patients who responded to the surveys reported that attendance at a Keep Well consultation positively influenced the maintenance of behaviour change, with over half of participants in the studies reporting that they had maintained these changes. The Fife study (based on a 64% response rate at 12 months from a sample of 328) found that some individuals reported that behaviour change began up to three months after the check, but the reasons for this are unclear (Robinson, 2011b). Maintenance of behaviour change was reported as being associated with higher educational achievement (Highers or more) and a sense of control. The Lothian study undertook a telephone survey of 129 participants, 12 months after their Keep Well health check (NHS Lothian, 2011). Participants were asked about the changes they had made and the support they received in the previous year. Half of the respondents reported making improvements to their diet, and 75% of these said that these had been influenced by Keep Well. Two-thirds reported having lost weight and 60% of these said that Keep Well had influenced them to do this. The Lothian study found an association between receiving information, support or advice and behaviour change in relation to diet (70% vs. 43%, $p < 0.5$), weight (93% vs. 70%, $p < 0.05$), physical activity (74% vs. 43%; $p < 0.05$) and alcohol consumption (73% vs. 27%, $p < 0.5$). These studies are based on small samples, low response rates, 'before and after'

designs without comparison groups and self-reported findings, all of which mean that the results are likely to overstate the effects. These therefore provide only weak evidence about the impact of Keep Well checks on behaviour.

The NHS GG&C evaluation (Scoular, 2012) examined referrals to two services. Using programme data it reported that, of 1077 referrals to smoke-free services, 23.8% of referred patients attended (range across practices: 92.3% to 7.4% uptake), compared with an 84.9% uptake of 630 referrals to Live Active (range across practices: 95.5% to 44.4% uptake). Using matched data for 220 patients who took up their referral to smoke-free services, it reported that 12.3% were successful in stopping smoking. In terms of the Live Active service, 407 patients who took up their referral sustained their engagement with the programme for 12 months or more.

No studies were identified that report on behaviour change beyond 12 months after the Keep Well health check.

Change in CVD risk

The only evaluation identified which explored changes in CVD risk to any significant extent is the NHS GG&C study (Scoular, 2010). In August 2008, Wave 1 practices reviewed patients who had originally attended a Keep Well health check at least 12 months previously, with the intention of assessing the extent of any changes in risk factors and risk scores between reviews. A total of 4282 patients (31% of those who attended the first review) attended second reviews (2184 in East Glasgow and 2098 in North Glasgow) after at least 12 months. The data collected at first and second reviews in relation to systolic blood pressure, plasma total cholesterol, smoking and body mass index (BMI) were compared. Small but significant declines were observed between baseline and review in systolic blood pressure (mean fall 1.0 mmHg, 95% confidence interval [CI] –1.6 to –0.5 mmHg). Small reductions were also observed between baseline and review in plasma total cholesterol (0.07 mmol/l, 95% CI –0.1 to –0.41) and in smoking prevalence (from 41.2% to 39.4%). Conversely, BMI showed an overall increase (0.26 kg, 95% CI 0.07 to 0.45). These changes are susceptible to secular trends (as there is no comparison group) and selection bias (because of the low proportion [31%] of patients who attended second reviews). Because of this even these small benefits are likely to overstate any impacts.

5.3.8 Reduced or delayed morbidity and mortality, and improved wellbeing in target populations

A retrospective cohort study from Fife (Humphries, 2013) used record linkage to compare the mortality of those who are eligible and attended Keep Well with those who are eligible but did not attend. The analysis showed better survival in those who attended the health check. However, people who do not respond to invitations are likely to differ from attenders in a range of characteristics, some of which may make them more likely to have poorer survival. This is well documented in existing literature. As a result, these findings do not offer reliable evidence of the impact of Keep Well.

One small exploratory study was identified that examined the changes in wellbeing scores before and after a Keep Well health check and subsequent health coaching (Allan, 2012). This was a small-scale study with no information on response rate or follow-up and no comparison group. Three separate tools were used to measure wellbeing and all were found to improve after the intervention. However, the findings are likely to be influenced by response bias and, without a comparison group, it is difficult to assess the validity of the findings. The author acknowledges the need for further research.

5.4 Unintended outcomes

Some Keep Well evaluation reports have highlighted concern expressed by healthcare staff that the engagement methods used, and particularly knocking on patients' doors, are potentially intrusive (Carver et al., 2012). Concern was also expressed by staff that health checks might increase anxiety among patients.

The Wave 1 evaluation (Mackenzie et al., 2010) reported that staff had concerns about the impact of the Keep Well programme on their relationships with some patients.

However, no evaluation evidence has been identified that explores whether these concerns have been realised.

5.5 Discussion

This chapter has explored the evidence from Keep Well evaluations, undertaken locally in NHS Boards and commissioned nationally, that have addressed a range of outcomes.

Strengths and weaknesses of this study

These studies reflect local perspectives and local knowledge which are important to understand the way in which Keep Well has had an impact. In addition, local studies have access to more detailed local data that are not available nationally. Individual follow-up data are a particularly important example of this. However, the time available for follow-up is still limited (a maximum of seven years) and it is possible that longer follow-up may reveal a greater impact. The lack of comparison populations within the design of the programme's implementation, the evolving nature of the programme, and the range of data issues that limited access to comprehensive data sets for the programme challenged the extent to which local Health Boards could undertake evaluations locally. The resource limitations to support evaluations added to this challenge. In addition, the evaluation approaches, which often included self-completion surveys, mean that response and recall bias are very likely to have influenced the findings. Response rates were often very low, which meant that conclusions could only be based on highly selected samples unlikely to represent the Keep Well target population locally. The self-report nature of many of the findings and the lack of comparison groups also limit the extent to which any findings can be attributed to the Keep Well programme. As a result, the evidence

that has been gathered through local evaluations is, in general, relatively weak evidence of programme effectiveness. However, NHS Boards continue to evaluate their work on Keep Well, refine their approaches and build on their learning to date. As a result, the findings in this chapter will quickly become out of date.

Gaps in this evidence

These studies have tended to focus more on short-term outcomes, including health check attendance, patient satisfaction and behaviour change, than on longer-term outcomes and very few have considered unintended outcomes. In addition, some of the outcomes for Keep Well that were cited by NHS Boards in the LV study have not been explored in evaluations to date. These outcomes include increased trust between patients and practitioners, and an increased sense of control, or self-efficacy, for patients.

Implications

There is some evidence of patient and staff satisfaction with the programme. Findings of small scale behaviour change are from studies that are at high risk of selection and response bias and are therefore unreliable. One study (Humphries, 2013) reported large numbers of new chronic disease registrations but these findings were not replicated in other areas. One local study (Scoular, 2012) found some improvements in CVD risk factors, though there was no comparison group and there was very substantial loss to follow-up.

The focus of Keep Well has changed over its life, with the focus moving from CVD-related inequalities to a broader focus on health inequalities generally. A range of potential outcomes have been hypothesised, but these have not been systematically studied to date and there is no reliable evidence from the evaluations that have been identified that Keep Well has influenced these.

Chapter 6: The outcomes analysis study

6.1 Introduction

One of the most important gaps in understanding of the Keep Well programme is the extent to which it has impacted on health outcomes. This section summarises three reports commissioned from the University of Glasgow that examine the national impact of Wave 1 of Keep Well on trends in the prevalence of CHD, hypertension (high blood pressure) and diabetes; trends in prescribing of medication relevant to CVD; trends in hospitalisations for CVD; and trends in CVD mortality (Geue et al., 2014a; Geue et al., 2014b; Lewsey et al., 2014). These outcomes were chosen to reflect the available data on outcomes in the original programme logic model (Figure 2) and can therefore be considered as the key measures of the overall success of the intervention where CVD outcomes were the main focus of Keep Well.

6.2 Methods

Our approach was to compare trends in Wave 1 Keep Well practices before and after the introduction of the intervention, with trends in all other practices in Scotland.

Data sources – prevalence data

Prevalence data (consisting of the crude number of individuals divided by the total practice population), drawn from general practice registers and submitted as part of the quality and outcomes framework (QOF) performance management and payment system for primary care, were obtained from the Information Services Division (ISD) of NHS National Services Scotland and were used to assess trends in the number of people recorded as having CHD, hypertension and diabetes. Data were available obtained annually (for the 31 March each year between 2004 and 2011) for each general practice.

Data sources – prescribing data

Prescribing data were obtained for the period January 2002 to June 2011 for all general practices in Scotland from ISD. We included prescriptions used in the primary prevention of CVD, categorised into statins (used to lower cholesterol and CVD risk), antihypertensives (used to treat high blood pressure) and antiplatelets (used to prevent clotting of the blood). The names and categories of all of the included medications are provided in Appendix 5. The data for each drug were provided as defined daily doses (DDDs), a defined quantity of drug which represents a standard daily individual dose by general practice and month. Total general practice (denominator) populations for each practice and each year were also provided by ISD from the Community Health Index (CHI) database. We provided ISD with data on which general practices implemented Keep Well at each time point to allow ISD to code the prescriptions data for us without disclosure.

Data sources – mortality and morbidity data

Coronary heart disease and stroke mortality and annual incident hospital discharge rates per 100,000 for those aged 40–65 years for the period January 1999 to August 2013 by month for Keep Well and non-Keep Well practices were obtained from ISD, together with estimates of practice population denominators. Incident events were defined as hospital admissions with no admission for the same diagnoses within the preceding 10 years. CHD was defined using ICD9 codes 410, 411, 412, 413 and 414 and ICD10 codes I20, I21, I22, I23, I24 and I25. Stroke (broadly defined as cerebrovascular disease) was defined using ICD9 codes 430, 431, 432, 433, 434, 435, 436, 437 and 438 and ICD10 codes I60, I61, I62, I63, I64, I65, I66, I67, I68, I69 and G45.

Analytical approach – prevalence

The analysis of the QOF data was limited to descriptive trends over time for Keep Well and non-Keep Well practices for the three registers, and a descriptive analysis of the trends before and after the introduction of Keep Well (achieved by allocating each practice's QOF data to the relevant number of months before or after the introduction of Keep Well). No statistical analysis was possible because of the small number of data time points and the data were not available at individual level to facilitate other approaches. Full details are available in a separate technical document (Geue et al., 2014a).

Analytical approach – prescriptions

Prescribing data were summarised using higher-level drug classifications. In particular, antihypertensive drugs, statins and antiplatelets were examined. In order to calculate rates per 100 population per prescription month, data on annual practice population were obtained from ISD.

Defined daily doses per 100 population for each broad drug category (statins, antihypertensives and antiplatelets) were calculated at each time point for the practices aligned, according to the number of months before and after they started implementing Keep Well. This was followed by statistical modelling of changes in prescribing before and after the introduction of Keep Well for practices implementing Wave 1 of the programme. The modelling was repeated for non-Keep-Well practices and the results were compared. Full details of the methods utilised are provided in a separate technical report (Geue et al., 2014b). Briefly, Box–Jenkins Autoregressive Integrated Moving Average (ARIMA) models were created for each drug category to account for autocorrelation and seasonality in the data. Practices recruited after Wave 1 did not have sufficient time to recruit participants within the time frame of the available data and so were not included.

A further analysis examined the possible effect of level of engagement on prescription rates. Data from 66 Wave 1 Keep Well practices were included (data

from practices in NHS Tayside did not include practice codes and could not be matched to the practice-level data on prescription rates and so were excluded). An explanatory variable was included in the model for the proportion of the final number of Keep Well checks that had been completed by March 2010. Generalised Estimating Equations (GEE) were used to analyse practice prescriptions data over time. The relationship between the proportion of Keep Well checks completed and change in prescriptions was modelled, adjusting for trends in prescribing over time, and presented as rate ratios.

Analytical approach – mortality and morbidity

Full details of the analytical approach used for the mortality and morbidity data are provided in a separate technical report (Lewsey et al., 2014). In summary, hospitalisations and deaths from CHD and stroke by calendar month were obtained for the period January 1999 to August 2013, together with practice-population denominators for the 40- to 65-year-old age group. Trends in mortality and morbidity rates were then graphed for Keep Well and non-Keep-Well practices, with practices aligned to the point of intervention. The strong secular downward trend in morbidity and mortality affecting all practices was first removed to facilitate analysis. A Box–Jenkins ARIMA approach was then used to estimate the intervention effect, taking account of secular and seasonal trends.

6.3 Results

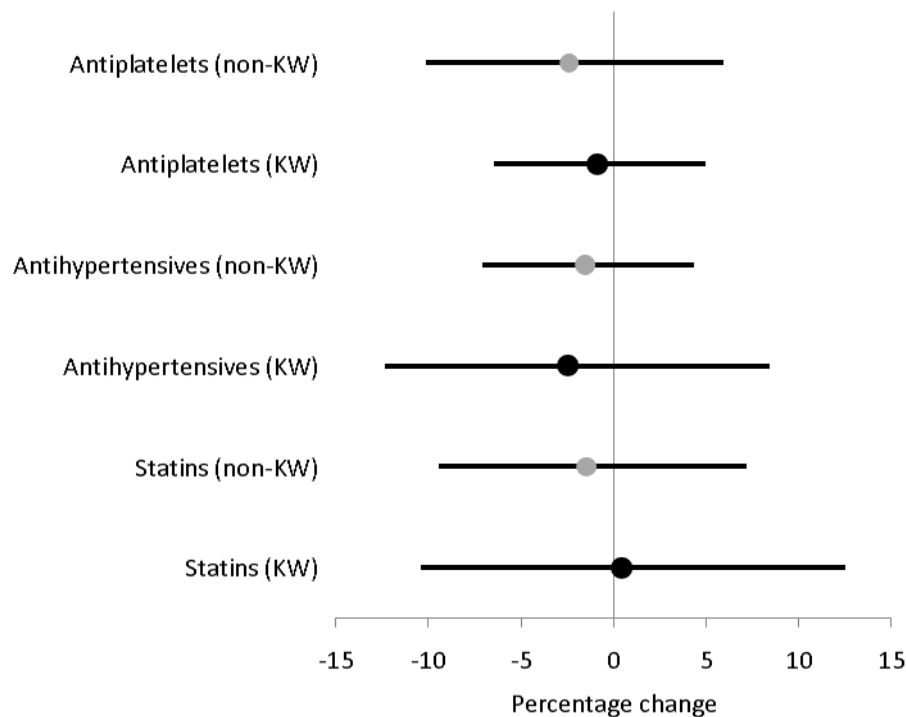
Trends in prevalence using QOF

The crude prevalence of CHD increased from around 4.4% to 4.9% between 2005 and 2006 in Keep Well practices and from around 4.3% to 4.6% in non-Keep Well practices, before slowly declining in parallel in both sets of practices. In contrast, there was little change over time in the crude prevalence of hypertension or diabetes, with diabetes being slightly more prevalent in Keep Well practices and hypertension less prevalent. The crude prevalence of CHD and diabetes was largely stable before and after the introduction of Keep Well, whereas the crude prevalence of hypertension decreased after the introduction of Keep Well.

Trends in prescriptions

Figure 5 shows the unadjusted trends in prescription rates in Keep Well and non-Keep Well practices before and after the intervention. In general, there was a very small decline in prescribing in the period after the introduction of Keep Well checks. Prescriptions for all three drug categories (statins, antihypertensives and antiplatelets) changed by less than 3%, although each of the estimates was very imprecise as indicated by the wide confidence intervals. Changes of similar magnitude were found in both Keep Well and non-Keep Well practices.

Figure 5: Percentage change (and 95% confidence intervals) in DDDs before and after the introduction of Keep Well Wave 1



The association between the proportion of Keep Well checks completed and prescription rates is shown for each of the three drug categories in Figures 6–8. Results are presented as rate ratios comparing the period before and after the delivery of health checks. None of the drug categories showed a clear trend in prescription rates with increasing coverage of health checks, although statin prescriptions were marginally higher among those practices in the two categories that had completed the greatest proportion of checks (Figure 6) and prescriptions for antihypertensive drugs were marginally lower in practices with the highest category of health checks delivered (Figure 7). Antiplatelet prescribing varied widely in relation to the proportion of checks completed and no clear association was discernible (Figure 8).

Figure 6: Rate ratios for statin prescribing among Keep Well Wave 1 practices by proportion of practice population engaged (reference category prescribing rate prior to Keep Well)

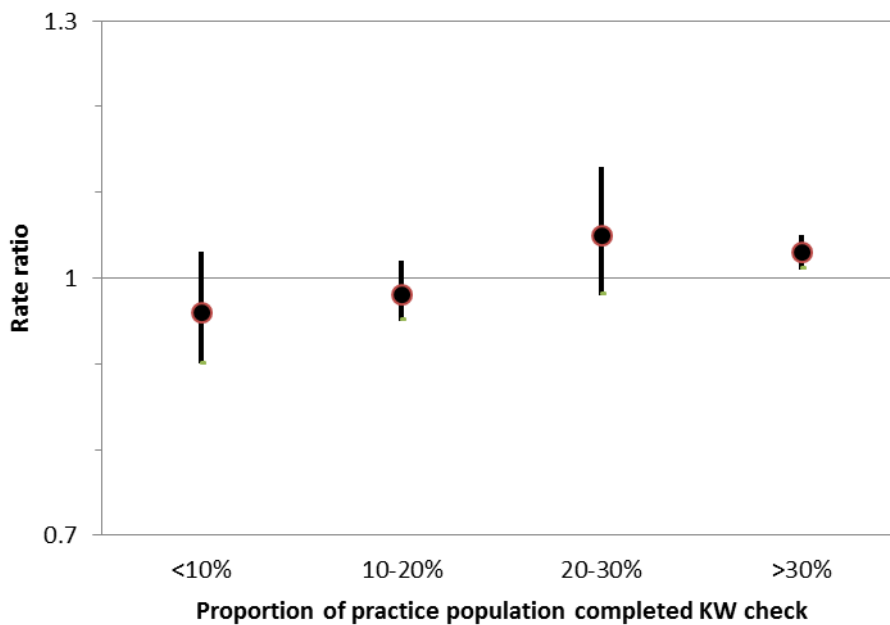


Figure 7: Rate ratios of antihypertensive prescribing among Keep Well Wave 1 practices by proportion of practice population engaged (reference category prescribing rate prior to Keep Well)

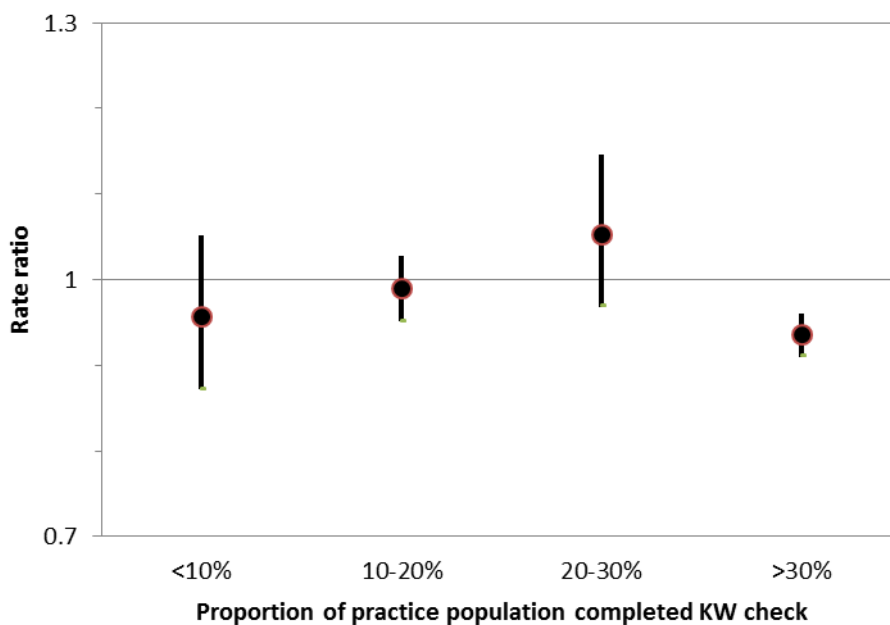
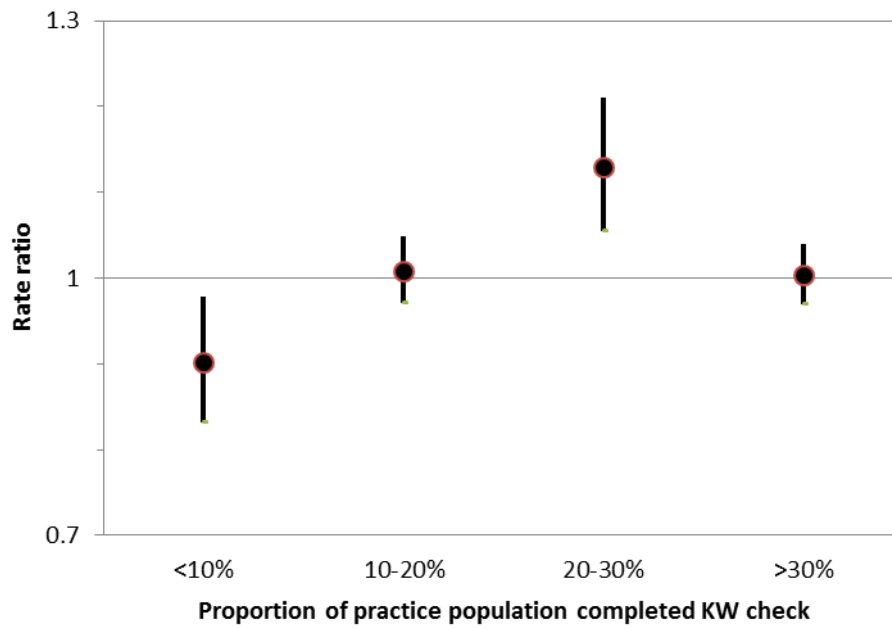


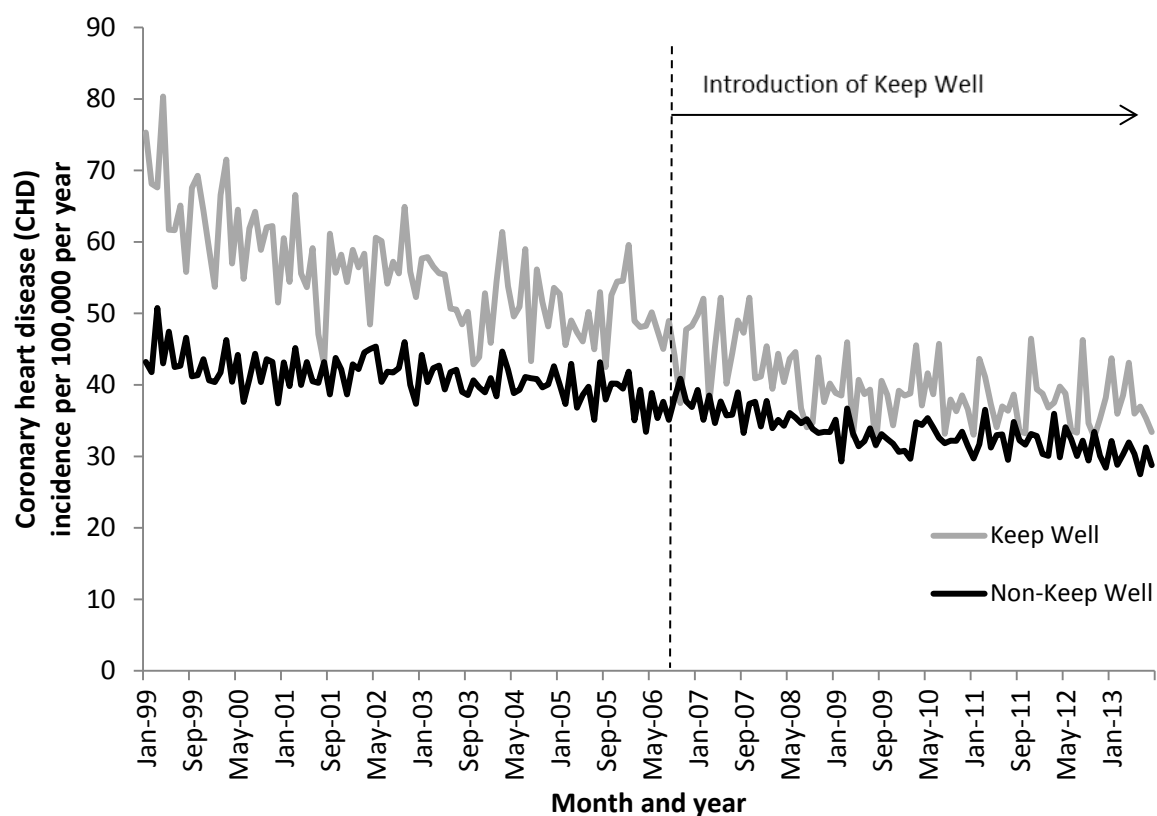
Figure 8: Rate ratios of antiplatelet prescribing among Keep Well Wave 1 practices by proportion of practice population engaged (reference category prescribing rate prior to Keep Well)



Trends in mortality and morbidity

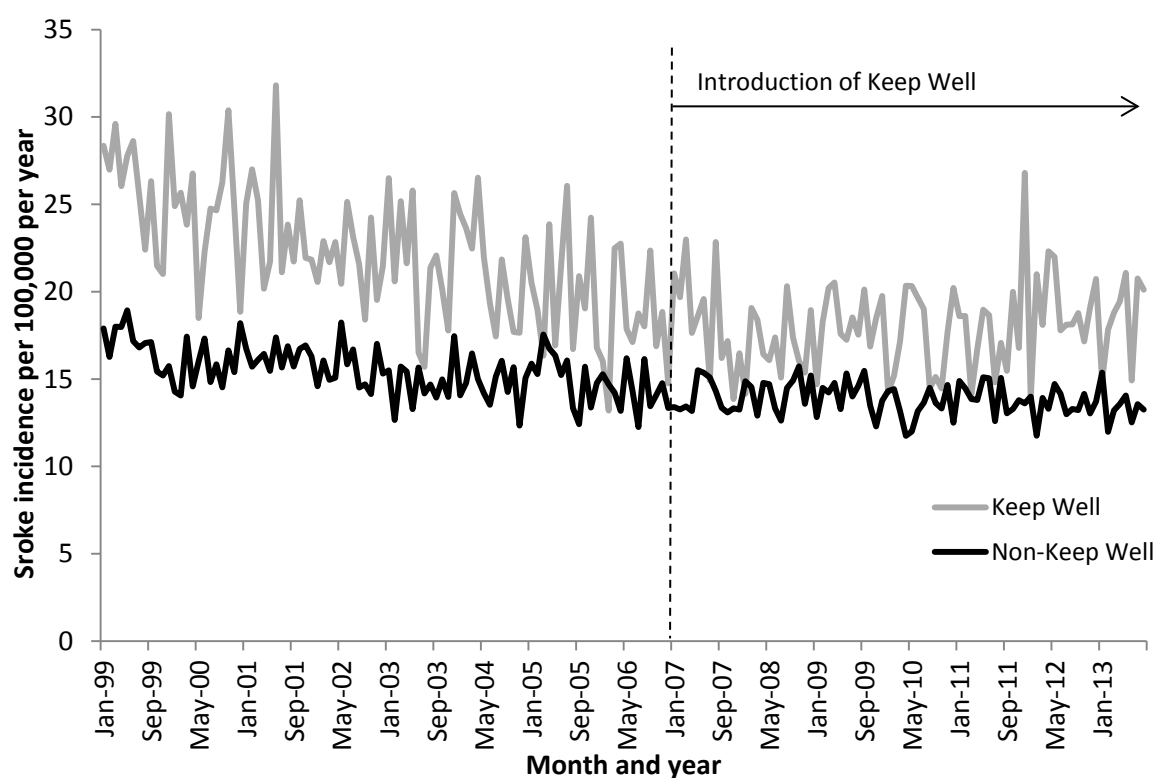
Figures 9 and 10 show the trends in incident hospitalisations for CHD and stroke respectively for Keep Well and non-Keep Well practices, with the starting point of the implementation of Wave 1 of Keep Well nationally indicated. Both CHD and stroke hospitalisations among this age group declined over time in both groups of practices. As expected, the incident CHD hospitalisation rates among the Keep Well practices were consistently higher (Figure 9). The ARIMA modelling estimated that, following the introduction of Keep Well checks, the incident CHD hospitalisation rate declined by 1.1% (95% CI –3.4% to 1.3%) in Keep Well practices after adjustment for seasonality and secular trends. The corresponding adjusted decline in non-Keep Well practices was 0.1% (95% CI –1.8% to 1.7%).

Figure 9: Incident CHD hospitalisation rates in Keep Well Wave 1 and non-Keep Well Wave 1 practices over time



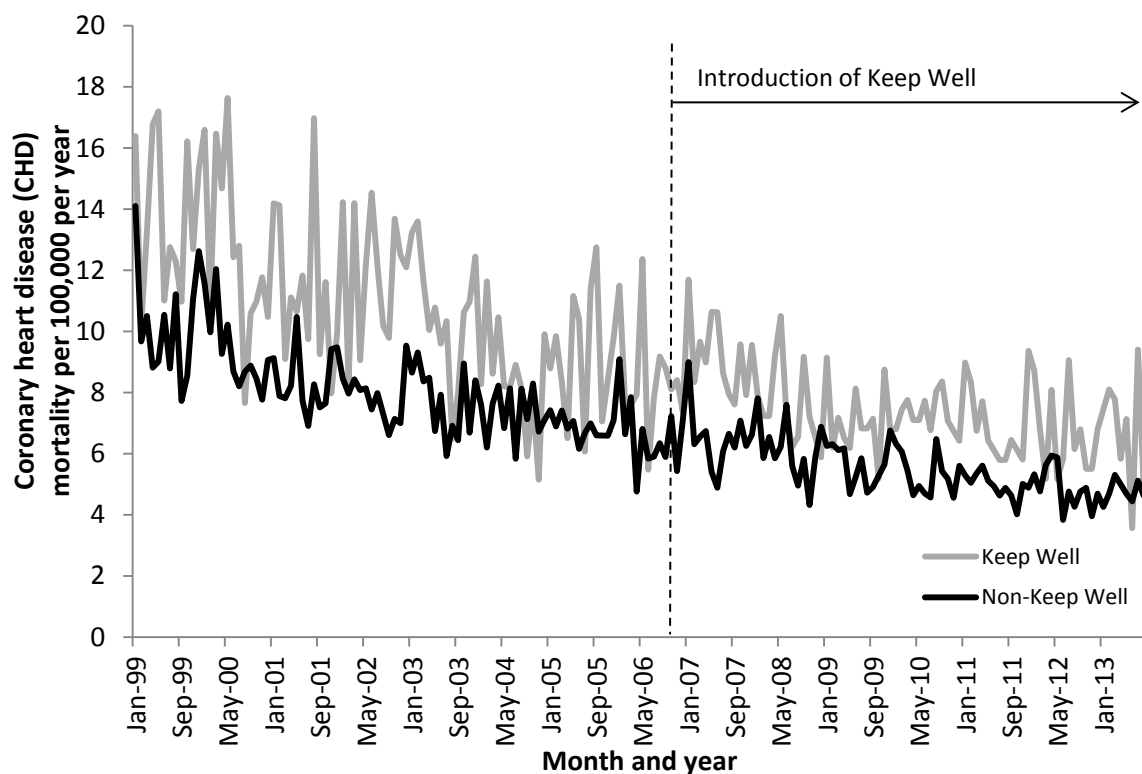
For incident stroke hospitalisations the trends are more variable, reflecting the small number of events in this age group. As for CHD, the incidence declines in both groups over time, with incident stroke hospitalisations in Keep Well practices being consistently higher (Figure 10). The ARIMA modelling estimated that, following the introduction of Keep Well checks, the incident stroke hospitalisation rate declined by 1.5% (95% CI –4.4% to 1.6%) in Keep Well practices (after adjustment for seasonality and secular trends). The corresponding decline in non-Keep Well practices was 0.1% (95% CI –1.5% to 1.3%).

Figure 10: Incident stroke hospitalisation rates in Keep Well Wave 1 and non-Keep Well Wave 1 practices over time



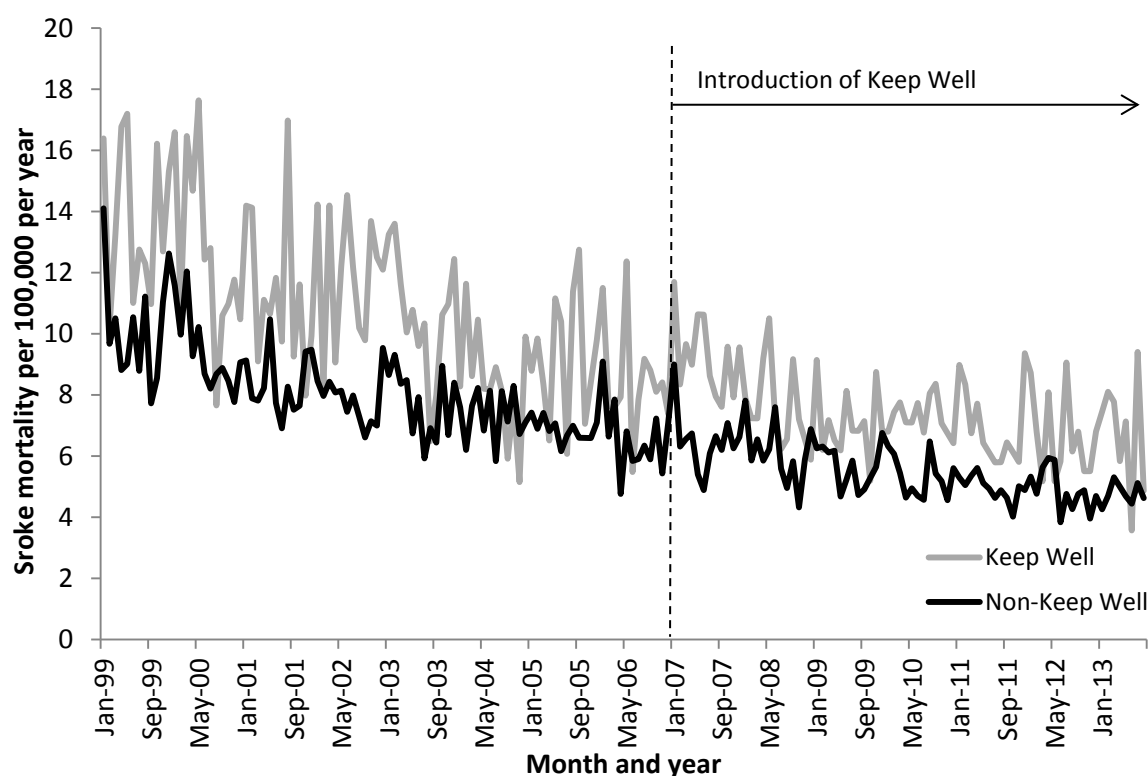
The descriptive data for mortality was more variable from month to month than incident hospitalisations because of the smaller number of events (Figures 11 and 12). As with hospitalisations, CHD mortality declined over time in both groups, with Keep Well practices having higher rates than non-Keep Well practices. Following the introduction of Keep Well checks, the CHD mortality rate increased by 0.4% (95% CI –5.2% to 6.3%) in Keep Well practices (after adjustment for seasonality and secular trends). The mortality rate in non-Keep Well practices decreased by 0.3% (95% CI –2.7% to 2.2%).

Figure 11: CHD mortality rates in Keep Well Wave 1 and non-Keep Well Wave 1 practices over time



For stroke mortality, there was a high degree of month-to-month variability, but an overall downward trend for both groups, with higher rates in Keep Well Wave 1 practices (Figure 12). Following the introduction of Keep Well checks, the stroke mortality rate increased by 6.7% (95% CI –2.6% to 16.9%) in Keep Well practices (after adjustment for seasonality and secular trends). The mortality rate in non-Keep Well practices decreased by 0.2% (95% CI –6.7% to 6.7%).

Figure 12: Stroke mortality rates in Keep Well Wave 1 and non-Keep Well Wave 1 practices over time



6.4 Discussion

Main results

These analyses provide evidence that following the introduction of Keep Well in Wave 1 practices, any difference between Keep Well and non-Keep Well practices is likely to be small in relation to the trends in the diagnosis of CHD, hypertension (high blood pressure) or diabetes; prescribing of statins, antihypertensives or antiplatelets; incident hospitalisations for CHD or stroke; or mortality for CHD or stroke.

Strengths and weaknesses of the analyses

The mortality, hospitalisation and prescriptions data used in these analyses have complete national coverage and are likely to accurately count the incidence of CVD and CVD-prescribing in Scotland with a low likelihood of missing cases or misclassification. The ARIMA models had relatively long time series available both before and after the intervention and were able to account for random variation, secular trends and seasonality, thereby facilitating an account of the trends in Keep

Well and non-Keep Well practices before and after the introduction of Keep Well Wave 1. The outcomes used were clearly linked to the original defined purpose of Wave 1 of Keep Well and allow the theory to be evaluated at different points across the interventions. The mortality data are not subject to changes in clinical practice and are clearly an important outcome measure of the programme.

The way in which Keep Well was implemented and the available data meant that intervention populations had to be defined in such a way that they included some individuals who were not eligible for the intervention. Similarly, the comparison group (the rest of the Scottish population) included people who had undergone health checks as part of subsequent Keep Well waves. The effect of both of these factors would be to dilute the measured impact of Keep Well, creating a bias towards a null result. However, the relatively high coverage of the eligible population within Keep Well Wave 1 practices formed a very small proportion of the Scottish population mean that the impact of this 'bias to the null' is likely to be small.

The hospital admissions data can fairly reliably exclude reductions of more than 1–2% as a result of Keep Well. However, because of the smaller number of deaths, the mortality results are less precise and cannot reliably exclude mortality reductions of less than 3–6%.

We were not able to get access to individual-level data nationally because information-sharing was not agreed with general practitioners. This meant that we had to define the eligible population at practice level (QOF prevalence data and prescriptions) or for specific age groups within practices (hospitalisations and mortality) rather than at individual level. This reduced the power of the study to detect any impact of the intervention by misclassifying untreated individuals as treated (and, to a lesser extent, vice versa). However, analyses at individual level (as have been performed in some local studies) provide information only on efficacy (i.e. potential benefits for those who actually received checks). In addition, they require the implausible assumption that those receiving the intervention do not differ in any important respect from those not receiving the intervention. As a result, such individual based analyses tend to overestimate the likely overall effectiveness of the programme. The approach taken here is therefore likely to give a more realistic estimate of the effectiveness of the programme as a whole.

The QOF data have particular limitations: these data are not adjusted for age or other patient characteristics which makes comparison between practices very crude (particularly because the entire practice population is used as the denominator population). In addition the definitions for coding individuals as prevalent cases have changed over time.

Information was available on the approximate dates on which each general practices start health checks as part of Keep Well Wave 1. However, the study included few data on the speed or intensity with which the intervention was implemented in each

practice. If some practices implemented the programme in a less vigorous way, this may have diluted the impact of Keep Well, but our analysis was not able to take account of this. The size of this potential bias is difficult to assess, so it is important to emphasise that these results can only relate to Keep Well as it was implemented in practice and with the coverage rates that were actually obtained, rather than to an ideal scenario with complete coverage.

The intervention group (Keep Well Wave 1 practices) was more deprived than the comparison group and so it may have been subject to a range of confounders (e.g. the impact of the economic downturn), concealing a true impact from Keep Well.

Interpretation

These results provide evidence that any effect of Keep Well on CVD hospitalisation, mortality or prescribing is likely to be very small. However, there are a number of possible explanations for these findings.

The limitations of these analyses are outlined above and the possibility remains that this study has underestimated the true impact of Keep Well. However, the results are consistent with wider literature that suggests that the effectiveness of a health check approach is limited.

It is possible that the overall level of health check coverage was not sufficient to produce a measurable effect. It is also possible that even though people received a check, they did not receive all the interventions that were originally planned. The fact that there was not consistent evidence of increased CVD recording or increased prescribing may provide support for this interpretation.

It is possible that while the individual components of the Keep Well check (drug therapy, lifestyle advice, etc.) are effective in trial situations, other factors including the challenges of programme delivery and the individual situations of people in deprived circumstances mean that their real-life effectiveness is much less.

These analyses include more than six years of follow-up, but it is also possible that clear benefits might only emerge later because of the time required to move from intervention to referral, support, sustained behaviour change and use of appropriate medications.

These interpretations are discussed further in the next chapter.

Chapter 7: Learning, conclusions and recommendations

This chapter brings together the information presented in previous chapters to describe what has been learned about the Keep Well programme, draws conclusions and makes recommendations for consideration, both locally and nationally.

7.1 Discussion

When Keep Well was first developed it drew on evidence regarding modification of CVD risk factors (NHS Health Scotland, 2006; NHS Health Scotland, 2010) and on growing evidence about the efficacy of statin therapy (Cholesterol Treatment Trialists, 2005). Evidence that CVD screening was ineffective had been published (OXCHECK, 1995; Ebrahim and Smith, 1997), but was discounted because that evidence predated the introduction of statins.

The relative divergence of improvement in CVD outcomes by socio-economic status was of political concern. It was felt that a CVD screening programme that specifically targeted, reached and engaged those currently not (proactively) engaged with health services, and which supported them to undertake modification to identified CVD risk factors (smoking cessation, weight loss, statin therapy), could increase the rate of improvement in the most deprived socio-economic groups and thus contribute to a reduction in the inequalities in CVD mortality between the most and the least well off. This was felt to mirror to a large extent the sort of approach that Tudor Hart had taken in Wales 20 years previously to address what he described as the 'inverse care law' (Tudor Hart et al., 1991). However, this approach involved engagement with practice populations on repeated occasions over many years, and the similarity to a single health check screening programme was limited.

Keep Well adopted a systematic CVD screening approach delivered primarily via primary care and targeted at the most deprived communities in Scotland. At the outset, the novel part of this approach was considered to be how to engage those hard-to-reach patients who did not use health services for preventive health care. Thus, the evaluation of Wave 1, and the focus of much of the programme management in the early years of the initiative was on reaching and engaging these groups. In fact, the Wave 1 evaluation suggested that Keep Well, at least in the pilot phase, was relatively successful in this respect. The learning from the early stages informed subsequent developments in the programme, and so the success in reaching and engaging target (deprived) groups actually appeared to improve over the period of the initiative as the approaches became more refined.

However, successful engagement of the target population does not ensure the intended outcomes of reduced CVD morbidity and mortality and reduced inequalities. The outcomes analysis reported here provides evidence that any impact is likely to be small. None of the evidence from local evaluations to date calls this conclusion into question.

There were, however, constraints to this analysis as outlined in the previous chapter: it was not possible to measure outcomes in comparable groups who did not receive the interventions so it was not possible to know by how much CVD morbidity and mortality would have changed without the Keep Well programme. In addition, an anticipated effect size has never been stated for Keep Well so it is not known how much faster health was expected to improve in the target populations. As learning emerged from the Wave 1 evaluation and from local evaluations, NHS Boards adapted their local Keep Well programmes accordingly, but without arrangements in place to robustly assess the impact on health outcomes. Indeed, Scottish Government encouraged these local variations in response to locally identified need and locally generated learning. This made it increasingly difficult to define the Keep Well 'intervention' and thus attribute any observed effects to the programme itself.

The original aim and target groups have expanded and evolved and NHS Boards understand the programme, and perceive success of the programme, in quite different ways. The local variability study shows that local areas had different views of the underpinning programme theory. Boards articulated various 'intermediate' outcomes that had not been part of the initial programme theory and had not been (and could not be) measured robustly with existing data. These included improved engagement with mainstream services, increased trust of health practitioners, improved self-efficacy, increased sense of control over one's own health, and improved mental wellbeing (NHS Health Scotland 2013a). While the long-term outcome of reducing inequalities was accepted by all those interviewed, NHS Boards had different theories about how their programme would achieve this. We have categorised these into three broad theories:

- Changing the way care is organised and delivered
- Empowerment and coproduction
- Addressing risk factors

Elements of all theories existed in most NHS Boards, but one of the theories appeared to have driven the planning and approach taken to Keep Well in each Health Board area more than the others. This evaluation has not been able to identify which, if any, of these theories is most effective; indeed, one lesson is that while this diversity allows more local flexibility it makes it more difficult to measure impact.

Outcomes at staff and organisational levels were also articulated by stakeholders within NHS Boards. These included improved staff knowledge and understanding of the impact of deprivation on health, increased staff confidence in supporting patients to make changes in their life, and primary care systems that are more able to engage those living in chaotic or challenging circumstances. All of these were felt by those interviewed to be important and likely to contribute to an improvement in health and wellbeing in the longer term; however, many of those interviewed felt that CVD-specific outcomes were unlikely to be affected specifically for many years.

It is notable that in the evaluations of Wave 1 (MacKenzie et al., 2010; McLean et al, 2011a; McLean et al, 2011b; Scoular, 2012) a large proportion of the data that would have been expected to have been collected as part of a Keep Well check (e.g. blood cholesterol levels and blood pressure) were missing in individuals who were coded as having received the intervention. This may be because, although health checks were carried out, the intervention was not always delivered to the extent and manner originally intended, reducing its potential effectiveness.

The view, implicit in the original programme theory, that people in the target population groups would prioritise and have the capacity to focus on CVD risk factor modification once they were engaged with services is likely, in many instances, to be overly simplistic. During the LV study, local stakeholders suggested that those living in difficult circumstances who engage with the Keep Well programme value the approach being taken and often require intensive support from a range of services. Nonetheless, the issues of greatest importance to them, and which had the greatest perceived impact on their wellbeing, were often not related to health but rather to social issues. Keep Well was not set up to address these issues, although many NHS Boards adapted their approach to provide more relevant referral and support.

Success, according to the original programme plans and funding commitment, was considered in terms of improved CVD outcomes in the target groups and subsequent impact on the inequalities in CVD outcomes. The outcomes analysis undertaken as part of this evaluation has used existing routine data on CVD-related morbidity and mortality to test these outcomes. These analyses provide moderately strong evidence against anything more than a small impact. However, given the evidence of no impact of such programmes from more robust studies and reviews, and the lack of any change in any of the outcomes measured here (Ebrahim et al., 2011; Krogsbøll et al., 2012), it seems reasonable to conclude that Keep Well has had a very limited impact, if any, on prescribing for CVD or on CVD outcomes.

7.2 What should we learn from the experience of Keep Well?

Despite substantial problems in carrying out a robust evaluation, the analyses described in this report show that Keep Well has had little or no impact on its original, primary goal – CVD outcomes – over the first six years of the programme. It is important that we learn from the Keep Well experience so that we are in a position to know more clearly what the impact of other interventions are likely to be in the future, and so that the interventions that we do implement are more likely to improve health and reduce health inequalities. The following learning points and recommendations seek to achieve these goals:

1. Problematic theory underlying the intervention

The underlying programme theory for Keep Well, that a reduction in CVD would be achieved through identifying high-risk individuals and then providing brief advice on changing risk behaviours (diet, physical activity, smoking and alcohol)

and prescribing a range of relevant medications, may be flawed. The evidence base for such a health-check approach (targeted or otherwise) at the time of programme development was equivocal and where it was supportive was drawn from single interventions in a trial environment rather than effectiveness evidence from targeted health checks. This evidence has only become less supportive over time. Where such a high degree of uncertainty is present, and where (as in Keep Well) the intervention does not lend itself to short-term process measures as valid proxies for the desired outcomes (a situation in which improvement science approaches might be suitable), appropriate substantial programmes such as Keep Well should be implemented in the context of a controlled trial, with comparison groups, considering options such as cluster randomisation or stepped wedge designs.

Recommendation 1: Where a future programme has a clear aim to address health inequalities, there is a need to assess whether it is sufficiently aligned with the principles for effective policies to reduce inequalities in health outlined by Macintyre (2007). Interventions which are most likely to be effective are those which involve reductions in poverty and inequality, which regulate the environment (including health risks such as tobacco, alcohol and food) and which do not rely solely on individuals to act on advice or depend on individuals' own resources (i.e. individual agency). It is unlikely that an intervention that is dependent on individual agency to take up an opportunity related to health behaviour change or risk factor reduction will be effective in reducing inequalities, even though the intervention is targeted towards those living in the most deprived areas.

Recommendation 2: Where there is uncertainty about the transferability of an effective intervention within new populations and/or contexts, an early developmental phase should be included before programme implementation. This will test the transferability of the intervention to a new population or setting, and whether it is likely to work in the same way and achieve the same results with a different population.

Recommendation 3: Screening programmes need to be considered in the light of the balance of potential risks as well as benefits. These include over-diagnosis (the identification and treatment of conditions which would not have caused the individuals harm), and iatrogenic harm (where diagnosis and treatment causes side effects, anxiety or other harms and inconveniences). These should be assessed at the start and processes put in place to identify and manage such risks.

2. Variations in implementation

Keep Well was originally set up as a national programme for inequalities-targeted CVD prevention delivered in primary care. The roll-out of the programme across

Scotland allowed local Health Boards considerable scope to extend and vary this according to local circumstances. This allowed the programme to be implemented in ways that were sensitive to local needs. As a consequence, Keep Well implementation across Scotland was highly variable in its form, focus, delivery setting and expected outcomes. While there are advantages in local flexibility, the disadvantages include difficult evaluating impact and uncertainty about the evidence supporting specific local approaches. In future, careful consideration is required about the acceptable variation of interventions in different settings and areas.

Recommendation 4: While acknowledging that there needs to be scope to tailor a programme to local circumstances, variability needs to be carefully managed. The agreement of what constitutes the core essentials of a programme (its active ingredients) need clearer definition at the outset with a realistic minimum data set for performance monitoring and reporting agreed to enable rapid feedback for improvement purposes. Evaluation of impacts of different delivery models is particularly important so that the more effective aspects can be identified and the learning shared.

Recommendation 5: Where interventions are to be evaluated, robust data collection and sharing arrangements need to be in place before implementation begins.¹⁶

3. Barriers to an effective assessment of impact

Within Scottish Government, the Health and Social Care Directorates recognise more often than others the need for, and benefits from, robust evaluation of the impact of policy interventions. However, even within the scope of health policy evaluation, too often it is not possible to draw firm conclusions about whether or not the policy was effective. At the outset of Keep Well a decision was made that it was not appropriate or feasible to design implementation as a trial or to use designs such as cluster randomisation or stepped wedge methods. This decision allowed a rapid and flexible implementation of the programme but made it unlikely that there would ever be a robust impact evaluation. Nor was there an early developmental phase to test its application within deprived populations or practice settings, to pilot data collection methods or to agree a stable data set before health checks started. As a result, it has not been possible to assess the impact of the programme without limitations due to differences between the intervention and comparison groups, and contamination of the intervention group with individuals who were not eligible for the intervention. There are lessons for other national programmes about designing them in a way that allows impact

¹⁶ In future this may be made easier by the current SPIRE project (Scottish Primary Care Information Resource; www.spire.scot.nhs.uk/) which includes clear principles to guide data-sharing between primary care and national NHS agencies.

evaluation to be built in from the start, where there is uncertainty about the effectiveness of the intervention in new contexts.

Recommendation 6: The Scottish Government should continue to embed a culture of evaluation in all its Directorates and utilise the opportunity that new policy initiatives bring for high-quality evaluations of impact as recommended in the UK Government Cabinet Office paper by Haynes et al (2012).

Recommendation 7: New programmes should introduce a more formalised early stage of evaluability assessment¹⁷ to agree primary and secondary outcomes, key evaluation questions and design options. This will help identify opportunities for evaluation and might also include the development of a shared evaluation framework and funding to guide and support local programme evaluations.

Recommendation 8: Interventions that are not based on strong and generalisable effectiveness evidence (i.e. where the impacts have been measured in the entire eligible target population and not just those who have received the intervention) should be implemented in the context of scientific research (such as cluster randomised or stepped wedge trials).

Recommendation 9: Where NHS Boards decide to continue the Keep Well programme they should do this in a way that incorporates or allows for the evaluation of outcomes, for example by ensuring access to appropriate data, by identifying a comparison group, and following up those invited and those in the comparison group over time.

Recommendation 10: Political, civil service and NHS Board decision-makers need to be supported to acknowledge uncertainty about evidence for interventions. Where interventions of uncertain effectiveness are incorporated into policy, it is important that this uncertainty is recognised and that the intervention is implemented in the context of research and robust outcome evaluation. Overconfidence that particular interventions will successfully improve outcomes may lead to over-commitment to programmes of uncertain effectiveness.

Recommendation 11: Decisions on the continuation and funding of health improvement (and other) programmes should be timed to take account of evaluation findings, whenever possible. In this case, the interim report was used to inform Scottish Government's decision. This provided insight into the likely conclusions but lacked the detailed findings and considered conclusions that come with the final report. In future there should be an explicit statement from programme funders about how evaluation findings will be used. This will also help

¹⁷ Evaluability assessments are intended to inform decisions about whether and how to evaluate new policies and programmes by weighing the value of the evidence that an evaluation would provide, in terms of informing future decisions, against the likely cost and practicality of gathering that evidence.

to ensure that the evaluation questions meet the utilisation requirements from the outset.

7.3 Conclusion

The Keep Well programme was launched in 2006 and evolved over the following seven years. Much effort has gone into delivering and evaluating the programme, both nationally and locally. Overall, the evidence suggests that it has been somewhat successful in engaging those living in concentrated areas of deprivation. However, the programme design and implementation plan precluded a robust impact evaluation; the extensive variation within and between NHS Boards, the flourishing of a wider range of intervention designs and intended outcomes in subsequent waves, and the associated lack of evaluations for these innovations has made this even more difficult.

If it is important for the public, policymakers and clinicians to know the extent to which programmes like Keep Well have been successful, then there is a need to rethink how health improvement and health inequalities interventions are conceived, designed, monitored and evaluated in the future. Preventative interventions are clearly desirable but those interventions should be effective and cost-effective. The available evidence for Keep Well does not support a conclusion that Keep Well was an effective intervention to reduce CVD or inequalities in CVD, and there is an absence of evidence for the wider range of interventions and outcomes which flourished subsequently.

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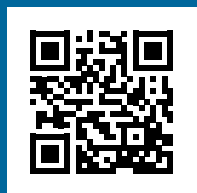
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