1.	**Project reference:**	**Final report date:**	
	SPHR-FUS-COM-NDP	30/06/2017	
2.	**Project title:**		
	NHS Diabetes Prevention Programme: process evaluation of the demonstrator phase and consensus building for a common evaluation framework and data-set for programme implementation		
3.	**SPHR lead investigators on project:**		
	Prof Falko Snienhotta, Fuse Prof Ashley Adamson, Fuse		
	Other SPHR collaborators:		
	Dr Ruth Bell, Fuse Dr Linda Penn, Fuse Dr Angela Rodrigues, Fuse Dr Anna Haste, Fuse Prof Carolyn Summerbell, Fuse Prof Martin White, Cambridge		
	Names and roles of others involved in project (e.g. include fixed term contract researchers and external collaborators / partners):		
4.	**Project start date:**	**Project end date:**	**Duration:**
	01.09.2015	31.03.2016	19 months
5.	**Project objectives originally outlined in proposal:**		

The aims of this demonstrator phase formative evaluation of the NHS Diabetes Prevention Programme (NHS DPP) are to provide evidence from local health economies in England on how to maximise implementation and effectiveness of the NHS DPP, and to identify opportunities for national evaluation of the programme going forward. Evaluation of effectiveness is explicitly not an aim of this project and may be conducted in a subsequent national outcome evaluation in conjunction with NHS DPP national roll-out.

Background to the project

Type 2 diabetes (T2D) is a common, progressive and debilitating disease that affects people's duration and quality of life (1). The prevalence of T2D is increasing rapidly and is estimated to reach five million in the UK by 2025; with T2D related costs to the NHS estimated to reach 17 billion by 2035 (2). This presents a major public health challenge. In

2012 NICE guidance (PH38) for risk identification and interventions to prevent T2D in individuals at high risk was published (3). This guidance was informed by systematic reviews of the evidence including a review and meta-analysis of RCT evidence that showed pooled effect hazard ratios for T2D incidence in intervention trials with diet and exercise combined of 0.49 (95% CI 0.36 to 0.65)in adults with impaired glucose tolerance. More recently a pragmatic diabetes prevention trial that was conducted in a primary care setting showed 36.5% reduction in T2D incidence in the intervention versus comparator group (4). Sub-group analyses of a diabetes prevention study delivered by telephone with supporting self-help devices, suggests an alternative pragmatic approach that achieved similar risk reduction (hazard ratio 0.59 (95% CI 0.42 to 0.83) in the group with intensive support (5).

The NHS DPP was announced in the NHS Five Year Forward View (6) and is being led by a partnership between NHS England, Public Health England (PHE) and Diabetes UK (D-UK). The NHS DPP aims to prevent or delay the onset of type 2 diabetes in high risk individuals and thus reduce their risk of diabetes related complications and other illness with subsequent reduction in treatment costs further down the pathway of care. The NHS DPP is underpinned by research evidence and NICE guidance (PH38). The development, evaluation and implementation of the NHS DPP is planned in phases, starting with a demonstrator site phase.

In this phase the selected NHS DPP demonstrator sites are expected to implement a number of processes and strategies as detailed in the draft NHS DPP service specification (7) in order to test their feasibility and acceptability in practice, including: identification of eligible participants, risk assessment, risk communication and recruitment of eligible participants, delivery of behavioural interventions, post intervention assessment, data-collection and integration with general practice. Formative evaluation of the NHS DPP demonstrator sites will include all selected sites (Birmingham South and Central CCG, Bradford City CCG, Durham County Council, Herefordshire CCG/LA, Medway CCG/LA, Salford CCG/LA, Southwark Council and CCG). We are aware of variability in stages and methods of programme delivery across demonstrator sites; thus their contribution will fulfil different evaluation objectives. Flexibility and an iterative approach in the conduct of this evaluation will ensure that early findings feed into later evaluation procedures as the work progresses. This evaluation strategy requires close collaboration within the research team and effective access to and communication with the NHS DPP demonstrator site teams and NHS DPP Management Group. The NHS DPP management group have identified a key contact person at each demonstrator site, who will be the first contact for the research team. The evaluation design and study management is structured to facilitate the need for flexibility, collaboration and effective communication.

The evaluation of demonstrator site activities will be further informed by wider evidence and experience, including stakeholder discussions to ensure a constructive and comprehensive formative evaluation of the NHS DPP demonstrator phase in readiness for the next phase of NHS DPP implementation and further evaluation opportunities.

Objectives

The objectives of this NHS DPP demonstrator phase formative evaluation are defined as follows:

 To examine demonstrator site strategies, processes and stakeholder perspectives on the proposed NHS DPP, including potential barriers and enablers to implementation of the programme.

 To identify the optimal processes and strategies for successful implementation of the NHS DPP, in particular: promotion of the programme; identification of eligible participants; recruitment and retention of individuals in the behavioural intervention; engagement of primary care (particularly GPs); engagement of and alignment with relevant existing

	services; and mechanisms for the collection of high quality, usable data for monitoring and evaluation. To collect as much learning as possible to identify and report best practice in: o Promotion and recruitment (identification of eligible participants, targeting and hard to reach populations, referral, primary care engagement) o Retention and quality assurance o Delivery (including funding mechanisms and payment metrics (e.g. payment by results) To examine available evidence regarding long term success of diabetes prevention, including learning from the demonstrator sites and existing services, to build consensus on how to evaluate the long term outcomes of the NHS DPP including: o An evaluation framework o A common data-set o Eligibility criteria and cost-effectiveness
6.	**Briefly describe and explain the reason(s) for any changes to the project originally outlined in proposal:**
	We were aware that perspectives of people who were offered the intervention and who refused this offer and of people who dropped out of the intervention at an early stage would provide useful information to support the programme improvement and refinement. We attempted to conduct interviews with these stakeholder groups, but although one of the intervention key contacts was very helpful in providing us with contact details for four people in these categories and we scheduled telephone interviews with one person who had declined the offer and one person who had dropped out of the intervention at an early stage, neither of the scheduled interviews were completed as the respondents were not contactable. Difficulties in seeking to engage in interviews those who are not engaged in the programme should be realised for future evaluation. Original plans to request updates of information supplied at baseline by the demonstrator sites was revised to encompass discussion of discrepancies and gaps in the evidence across all the different evidence strands (including the NHS DPP specification and NICE PH38 guidance. This variation was necessitated by the speed at which the programme was being implemented and was considered advisable to avoid the confusion that would have arisen by including both baseline and updated information within an exercise that was designed to inform improvement in programme specification. We were provided with information about the NHS DPP minimum data set and we reviewed these data with regard to relevance for future phase evaluations, especially with regard to definitive outcome evaluation. We made recommendations with regard to additional data collection items for consideration by the management group and we clarified the reasons for this request in written and verbal response to an e-mail from the NHS DPP management Evidence Lead. On request we further developed the rationale for these additional data items and supplied this to the NHS DPP management group.
7.	**Brief summary of methods, findings against objectives, and conclusions (2-4 pages max):**
	Introduction To design our mixed methods evaluation we drew on the Medical Research Council (MRC) guidance for process evaluation of complex interventions to improve health and research recommendations and evidence gaps in NICE guidance (PH38) for risk identification and intervention in people at high risk of T2D. Methods used to answer the research questions included document review with critical appraisal, quantitative analyses of available data, qualitative research with interview studies and interactive focus-group discussions delivered through workshops, and questionnaire development and testing. Patient and public

involvement (PPI) informed some evaluation topics and we drew on expert opinion beyond the research team as required. We aimed to substantiate findings by using mixed methods.

In appreciating the importance of contemporaneous evaluation and the opportunity to impact service provision in real-time, especially in the context of this national scale and rapid programme roll-out, we sought to provide clear recommendations based on findings, in timely and concise executive summaries that were reported to the Department of Health.

Governance and ethics

We obtained NHS ethical approvals and Health Research Authority research governance agreements for stakeholder interviews (IRAS number 190418). We obtained ethical approval from Newcastle University Faculty of Medical Sciences ethics committee for stakeholder workshops and online questionnaires. All interview and workshop participants gave written informed consent to take part. To preserve the independence of our evaluation clear research governance procedures were established with the Department of Health.

Methods

Document review and critical appraisal

We reviewed and critically appraised programme documentation, as supplied by local health economies (from 03/2015 - 01/2016) in their applications to be selected as demonstrator sites. Information supplied by demonstrator sites was extracted and mapped against recommendations in NICE PH38 guidance (prevention of T2D in people at high-risk), the NHS DPP draft service specification, equality indicators and data collection and quality assurance measures. Standard procedures for coding and reporting behaviour change interventions were implemented.

Qualitative interviews and interactive focus-group workshop discussions

We used individual semi-structured interviews and interactive focus group discussions to explore stakeholder experiences, including barriers and enablers to participant engagement and behaviour change, and feasibility and acceptability of the programme. Sampling frames to select and invite interview and focus group participants were used to obtain a spread of stakeholder experience. Semi-structured interviews (n=50) and focus groups (n=9) were conducted with four stakeholder groups (service users, intervention deliverers, referrers and local commissioners). Focus groups were delivered in a workshop setting with parallel (3 X 3) one hour sessions over the course of a day. Variation in focus group composition was organised to maximise interactive discussions. Workshop sessions focussed on referral and recruitment, intervention delivery, staff training, data collection and equality issues. All interviews and focus-groups were digitally audio recorded, transcribed and analysed using the Framework method. Qualitative data were collected, coded and checked by AR, AH and LP with use of NVivo 10 to facilitate data management.

Data to support further evaluation

We identified elements from document reviews and themes from qualitative research, relevant to data management and data items. We explored factors in incident risk-scores, using scores validated in a UK population (QDiabetes, Cambridge Risk Score, the Finnish Diabetes Risk Score, and the Diabetes-UK risk score), and compared with data items in the minimum-data-set and data routinely collected in primary care.

Findings

Programme specification (Document review and critical appraisal)

Organisational sections, identified within demonstrator site provider programmes, to facilitate mapping and evidence synthesis were: a) raising awareness and recruitment pathways; b) intervention components, design and delivery; c) inequalities and adaptation; d) quality assurance, monitoring and staff training.

In the demonstrator site documentation, referral to intervention was via primary care or NHS Health Checks in all sites and community based recruitment was included in two sites, but responsibilities for awareness raising and enrolment in behavioural interventions were unclear. Risk score use and blood testing were commonly reported, with the Diabetes UK risk score

and HbA1c blood test being the usual measures. The proposed programmes were less intensive and shorter than recommended in NICE guidance (PH38). Place of residence and gender impacted on intervention delivery in terms of choice of venue (accessibility) and availability of single-sex groups. Data items to evaluate programmes (age, sex, ethnicity, postcode, height, weight, HbA1c and physical activity levels) were specified by five sites, whereas dietary data were only specified by one site. Regular review of intervention delivery and training needs of deliverers were reported in some sites.

Qualitative interviews and interactive focus-group workshop discussions

Themes identified through demonstrator site phase qualitative research were: referral and recruitment challenges including the need for primary care (GP practice) engagement, self-referral and community based options, reasons for service refusal and withdrawal, and monitoring of recruitment demographics; intervention delivery quality such as, accessible venues and session times, consistency of staff training, mentoring and refresher training.

Data to support further evaluation

We identified data collection and management information as vital for efficient management and robust evaluation of the NHS DPP. We identified confusion between 'contacted' and 'referred' as well as 'recruited' and 'enrolled', in reference to intervention pathway data, with possible ambiguity and opportunity for miss-interpretation in data reported by demonstrator sites. We recognised the added value of including EQ-5D in the minimum data set for the NHS DPP first wave implementation. We identified accepted risk assessment data items that were not included in the NHS DPP minimum data set and explored the rationale for these additions.

Discussion

Main findings

Through qualitative research we identified a high level of interest in the NHS DPP and an appreciation of its potential, across all stakeholder groups, but allocation of responsibilities and resources required further consideration and clarification, especially with regard to sustainability of participants' behaviour change and fit with other services.

Uncertainties in the programme included: distribution of stakeholder responsibilities and resources, staff training, data collection, measurement protocols, data audit and management systems, fit with other services and sustainability of participant behaviour change. We identified a degree of confusion in intervention pathway data collection and some limitations in the data specified in the NHS DPP minimum data set for the first wave rollout.

Strengths and limitations of this evaluation

We applied a systematic approach to appraise the baseline documents, service specifications and change theory. Importantly, we appraised elements across the entire programme of activities from awareness raising to follow-up, avoiding a narrow focus on intervention delivery.

A strength of our qualitative research was the inclusion of all stakeholder groups, but the numbers in each group were limited by time and resource. We relied on the Management Group to supply us with key contacts in different localities, who then helped with our access to interview and focus group participants. This may have limited the interview participants and focus group compositions, but was unlikely to impact research credibility. Delivering focus groups in a workshop setting allowed several interactive discussions to be actioned within the time available for the project, but restricted the number of participants.

We developed methods through the conduct of this research, notably the method we used for review and appraisal of service specification and provider documents. We expect these methods to have utility for future projects.

Implications for policy and practice

The decision by the NHS DPP Management Group to start with a demonstrator site phase was an innovative and potentially most productive initiative. However, the pace at which the first wave national programme was rolled out, set against the time needed to conduct meaningful appraisal, made it difficult to maximise 'learning from the demonstrator sites' to inform the first

	wave national programme although this was the stated aim of the demonstrator site phase and of our evaluation. ***Conclusion*** The high level of stakeholder interest in the NHS DPP, an appreciation of its potential and of the need to tackle the increasing prevalence of type 2 diabetes suggested a supportive environment for implementation of the national programme. The opportunity to lean from demonstrator site experiences, to inform the national programme, was limited by the pace of roll-out.
8.	**Plain English Summary (400 words max)** **Please provide a summary of the project, including background, findings and conclusions:**
	In preparation for 'Healthier You', NHS Diabetes Prevention Programme, areas across England were selected to become 'demonstrator sites'. These sites agreed to test certain policies and procedures that would inform roll-out of the national programme. We were commissioned by the Department of Health for England to evaluate the demonstrator site phase of 'Healthier You'. To do this we reviewed documents provided for demonstrator site selection, interviewed stakeholders (service users, intervention deliverers, health care professionals and local public health commissioners), invited stakeholders to workshops with interactive focus group discussions and reviewed recruitment and data collection procedures. We communicated findings from our evaluation, and recommendations based on these findings, in reports that were passed to the Department of Health for England and the NHS Diabetes Prevention Programme Management Group. We also spoke regularly with members of the NHS Diabetes Prevention Programme Management Group. We found interest in and support for 'Healthier You, but the opportunity to learn from the demonstrator site phase was limited by the pace at which the national programme was rolled-out.
9.	**Keywords** **Please provide up to 8 keywords that relate to the research undertaken in this study:**
	Type 2 diabetes Prevention National programme Lifestyle / behavioural intervention Formative evaluation Demonstrator site phase Healthier You
10.	**Dissemination – please detail planned or published articles in peer-reviewed journals (including web links):**
	Complete: presentations and abstracts Presentation: Falko Sniehotta, invited speaker to the PHE conference in Warwick 13-14th September 2016. Presented E-poster Presentation: Anna Haste at the PHE conference in Warwick 13-14th September 2016. Poster Presentation: Angela Rodrigues at the NIHR SPHR Conference in London 23rd March 2017. Oral Presentation: Anna Haste at the World Congress on the Prevention of Diabetes in Atlanta, USA 2-4th December 2016. Conference proceeding Publication: Haste, A., Rodrigues, A. M., Penn, L., Bell, R., Summerbell, C. D., White, M., Adamson, A.J., & Sniehotta, F. F. (2016). The NHS Diabetes Prevention Programme in England: Lessons learnt from process evaluation of the

	demonstrator site phase. Abstracts: 9th World Congress on prevention of diabetes and its complications. *Endocrine Practice, 22*(Supplement 6), 12-13. Oral Presentation: Angela Rodrigues at the UKSBM Conference in Cardiff 1st-2nd December 2016. Oral Presentation: Angela Rodrigues at the SSM Conference in York 14-16th September 2016.
11.	**Impact – please use this space to capture information (e.g. data, case studies, quotes, 'thank you' emails etc.) that can be used now and in the future to effectively and concisely demonstrate the impact of your project:**
	We supplied recommendations based on findings for each of the work packages in this evaluation as these work packages were completed. The NHS DPP Management Group agreed to provide responses to these recommendations. We discussed response categories, with the management group, as: (i) Implemented in advance of receiving these recommendations; (ii) Implemented as a result of these recommendations (iii) Implementation not currently planned (e.g. more evidence needed). We received draft responses to our recommendations for one work package. On request we then collated all the recommendations and supplied the collated set to the management group. We understand these responses have been agreed by the management group, and approved by the expert reference group, and we expect these to be returned to us shortly. In the meantime we can cite the addition of EQ-5D quality of life assessment to the NHS DPP minimum data set as a direct result of our recommendations.
12.	**Public and practitioner involvement and engagement - please summarise your progress to date in implementing your plan for PPIE. Please provide comment on your experiences, any changes made and lessons drawn:**
	Volunteers from VOICENorth (Valuing Our Intellectual Capital and Experience) attending their monthly event were approached for the PPI activities. A total of 11 members of the group attended the session (with an age range of mid-50s to late 80s. The members of the group were from various place across the north east of England representing a mixed socio-economic background. The following key findings were identified: (i) Involvement of members of the public in future documentation development to ensure readability and acceptability of leaflets, weekly handouts, questionnaires, food/PA diaries (e.g. less complex language, attractive layouts); (ii) Members of the public also suggested improving the documentation by using consistent terminology with clear definitions (e.g. IGF or 'high risk of diabetes') and well-known branding; (iii) The inclusion of online/digital documentation as part of the NHS DPP was also suggested by the members of the public.
13.	**Any other information:**
	N/A

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