

# Developing and evaluating packages to support implementation of quality indicators in general practice: the ASPIRE research programme, including two cluster RCTs

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## Scientific summary

The ASPIRE research programme, including two cluster RCTs

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# Scientific summary

## Background

Clinical evidence that can improve patient outcomes does not reliably find its way into everyday care. The gap between evidence and practice limits the health, social and economic impacts of clinical research. Dissemination of evidence-based practice via clinical guidelines is necessary but seldom sufficient by itself to ensure implementation. The general practice context presents particular challenges – especially given limited practice organisational capacity, increasing workload and complexity of care, and competing priorities. Furthermore, many implementation studies focus on one condition. This limits confidence in applying research findings; it is uncertain how an intervention developed for one clinical condition will work for another. It is also impracticable and inefficient to invent and evaluate an implementation strategy for every new guideline.

## Aim and objectives

We aimed to develop and evaluate an implementation package that could be adapted to support the uptake of a range of guideline recommendations and sustainably integrate within general practice systems and resources. We undertook this through five linked work packages, which are also summarised in *Figure a*.

Work package 1 identified and developed ‘high-impact’ quality indicators where a measurable change in clinical practice can lead to significant patient benefit.

Work package 2 measured and analysed levels of adherence to high-impact indicators.

Work package 3 developed an implementation package that is adaptable to target different indicators. This included theory-guided interviews to understand adherence to multiple indicators in primary care (work package 3a) and systematic, stakeholder-guided intervention development (work package 3b).

Work package 4 evaluated the effects and cost-effectiveness of the adapted implementation package in targeting the implementation of high-impact indicators. This included a cluster-randomised evaluation (work package 4a) and economic modelling (work package 4b).

Work package 5 comprised an in-depth process evaluation examining implementation package delivery and mechanisms of action.

## Work package 1: identifying and developing ‘high-impact’ quality indicators

We reviewed existing national clinical guidelines and quality indicators and used a four-stage consensus development process to derive a set of ‘high-impact’ indicators relevant to primary care. Prioritisation criteria included burden of illness, potential for significant patient benefit, scope for improvement on current levels of achievement, the extent to which following a recommendation is directly within the control of individual practice teams, and the feasibility of measurement using routinely collected data. We screened 2365 recommendations to produce a shortlist of 102. These were considered by a consensus panel of 11 members, including primary care professionals, commissioners and patient representatives. We derived a set of 18 indicators (five single, 13 composites – comprising 2–9 individual recommendations) for field testing.

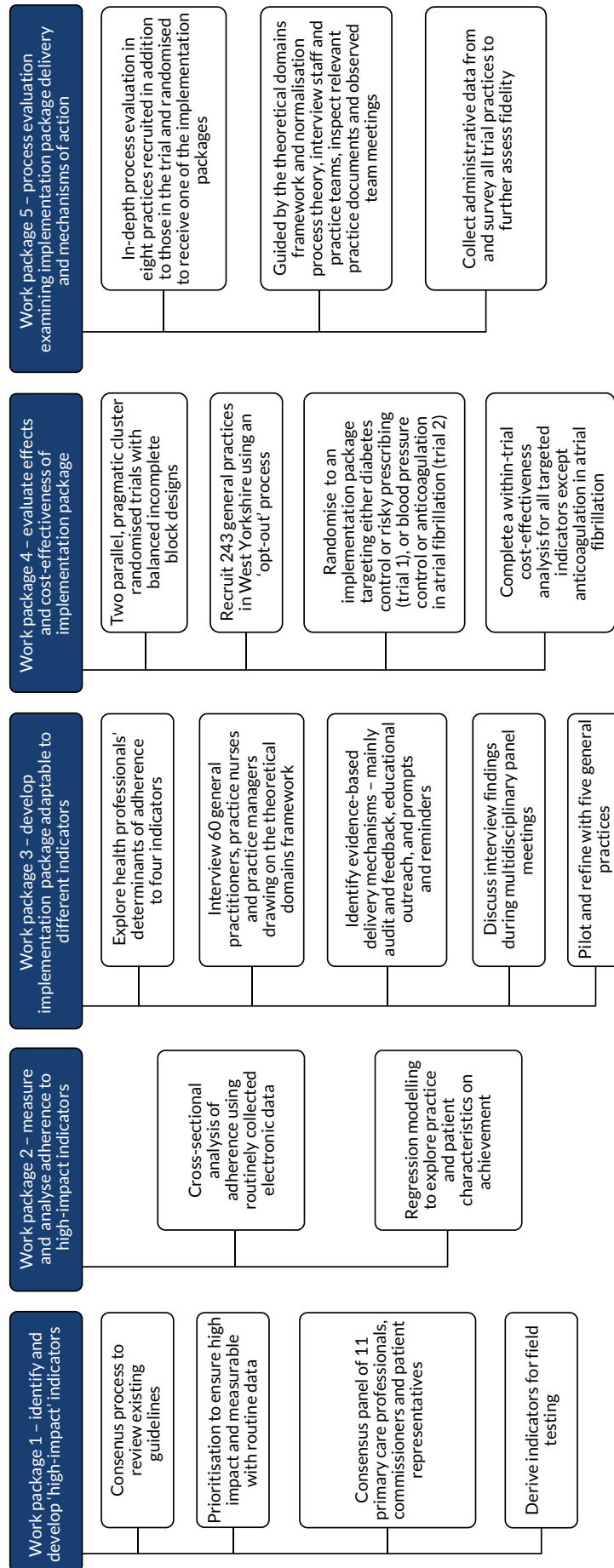


FIGURE a Research pathway diagram.

## Work package 2: analysing adherence to 'high-impact' indicators

We undertook a cross-sectional analysis of adherence to seven indicators using routinely collected electronic data from a sample of 89 general practices in West Yorkshire. The indicators spanned processes and intermediate clinical outcomes of care related to diabetes, hypertension, atrial fibrillation, myocardial infarction, chronic kidney disease and 'risky prescribing' combinations. Regression modelling explored the impact of practice and patient characteristics on indicator achievement.

Median practice achievement of indicators ranged from 43.2% (diabetes control) to 72.2% (blood pressure control in chronic kidney disease). Considerable between-practice variation existed for all indicators: the absolute difference between the highest and lowest performing practices was 26.3% for risky prescribing and 100% for anticoagulation in atrial fibrillation. Odds ratios associated with the random effects for practices emphasised this; there was a greater than 10-fold difference in the likelihood of achieving the hypertension indicator between the lowest and highest performing practices (odds ratio range 0.50–5.24). Patient but not practice characteristics were modestly and consistently associated with indicator achievement, particularly age, gender and comorbidity.

Practice and patient characteristics partly accounted for marked inappropriate variations in practice. This may, in part, reflect the limitations of using routinely collected data but it is also likely that much of the remaining variation is attributable to differences in clinical and organisational behaviour.

## Work package 3: developing an implementation package

We initially explored health professionals' perceived determinants of adherence to four indicators: achievement of recommended treatment targets for all of glycated haemoglobin, blood pressure and cholesterol in type 2 diabetes; avoidance of risky prescribing involving non-steroidal anti-inflammatory and anti-platelet drugs; achievement of anticoagulant prescribing for stroke prevention in atrial fibrillation; and achievement of recommended blood pressure levels in hypertension. We interviewed 60 general practitioners, practice nurses and practice managers in West Yorkshire, drawing on the theoretical domains framework. Data were analysed using framework analysis. We examined the degree to which determinants were indicator specific or potentially generalisable across indicators.

Professional role and identity and environmental context and resources featured prominently across all indicators, whereas the importance of other domains, for example beliefs about consequences, social influences and knowledge, varied across indicators. We identified five meta-themes that broadly underlined the need to align the design of interventions targeting general practices with higher-level supports and broader contextual considerations. These included the perceived nature of the job and norms of practice; internal and external sources of support; communication pathways and interaction; meeting the needs of patients; and perceptions of indicators. Our findings suggested that it was feasible to develop interventions to promote the uptake of different evidence-based indicators that share common features while also including content-specific adaptations.

We next used a staged process to develop an implementation package adaptable to the four indicators. We identified evidence-based delivery mechanisms: mainly audit and feedback, educational outreach, and prompts and reminders. Research team members independently mapped determinants of adherence (from the above interviews) to candidate behaviour change techniques, resolving discrepancies by discussion. We discussed key interview findings during a series of multidisciplinary panel meetings, each involving 5 to 10 primary care professionals, quality improvement specialists and service commissioners, and prioritised likely determinants and intervention content. We piloted and refined components of the implementation packages with five general practices. We downgraded our original plan for more extensive piloting of the whole implementation package because we prioritised starting the trials 3 months earlier to coincide with data collection for the 2015–16 Quality and Outcomes Framework year.

## Work package 4: evaluating effectiveness and cost-effectiveness

We undertook two parallel, pragmatic cluster-randomised trials with balanced incomplete block designs. We recruited general practices in West Yorkshire using an 'opt-out' process. We randomised practices to an implementation package targeting either diabetes control or risky prescribing (trial 1), or blood pressure control or anticoagulation in atrial fibrillation (trial 2). In trials 1 and 2, practices randomised to the implementation package for one indicator acted as control practices for the other implementation package, and vice versa. The implementation package was tailored to each indicator and included behaviour change techniques embedded within audit and feedback, educational outreach and computerised support. Respective primary end points assessed after 11 months comprised achievement of all recommended levels of glycated haemoglobin, blood pressure and cholesterol; risky prescribing levels; achievement of recommended blood pressure levels in people with hypertension or at increased risk of cardiovascular events related to other conditions (e.g. chronic kidney disease); and anticoagulation prescribing. An intention-to-treat analysis using two-level binary logistic regression models with patients nested within registered practices adjusted for both patient- and practice-level covariates. We completed a within-trial cost-effectiveness analysis for all targeted indicators except anticoagulation in atrial fibrillation.

We approached 243 eligible general practices and recruited 178. We randomised 80 practices to trial 1 (40 per arm) and 64 to trial 2 (32 per arm), with 34 no-intervention controls. The implementation package reduced risky prescribing (odds ratio 0.82, 97.5% confidence interval 0.67 to 0.99); the estimated number needed to treat to prevent one case of risky prescribing was 95. The package had no effect on other primary end points; the odds ratio for diabetes control compared with controls was 1.03 (97.5% confidence interval 0.89 to 1.18), for blood pressure control was 1.05 (97.5% confidence interval 0.96 to 1.16) and for anticoagulation in atrial fibrillation was 0.90 (97.5% confidence interval 0.75 to 1.09).

The risky prescribing implementation package was more expensive and on average more effective than usual practice. This yielded an incremental cost-effectiveness ratio of £2337 per incremental quality-adjusted life-year, falling below the National Institute for Health and Care Excellence preferred threshold of £20,000–30,000 per quality-adjusted life-year. Over 75% of simulations conducted for the probabilistic sensitivity analysis fell below this threshold. The blood pressure implementation package was also more expensive and non-significantly more effective than usual practice, yielding an incremental cost-effectiveness ratio of £3954. However, the uncertainty around this result was considerable and the intervention incremental cost-effectiveness ratio had just over a 50% chance of falling below the £20,000 per quality-adjusted life-year threshold in the sensitivity analysis. Modelling indicated that the diabetes implementation package was unlikely to have favourable cost per quality-adjusted life-year estimates.

## Work package 5: process evaluation

We conducted an in-depth process evaluation in eight practices recruited in addition to those in the trial and randomised to receive one of the implementation packages (two practices per package). Guided by the theoretical domains framework and normalisation process theory, we interviewed individual staff and practice teams, inspected relevant practice documents (e.g. meeting notes and policies) and observed team meetings. We also collected administrative data from and surveyed all trial practices to further assess fidelity. We analysed interview and observational data using a framework approach; this included constructs from the theoretical domains framework to compare planned versus actual intervention content and normalisation process theory to understand individual and group implementation processes. We compared trial fidelity data with in-depth practice case narratives to help to explain trial findings.



We had set out to devise an implementation package that could be adapted to target a range of high-impact indicators and that could also be delivered within existing resources and ways of working in general practice. Our process evaluation offers three main explanations for its limited impact. First, we observed losses in fidelity from delivery through to enrolment and enactment by practice teams; for example, although all practices received feedback reports, under half (67; 46.5%) accepted outreach visits. Second, the type and scale of targeted behaviour changes varied by indicator, such that practice teams may have perceived and exerted greater control over goal-setting and action-planning for risky prescribing. In some cases, receiving quarterly feedback reports that drew attention to perceived insufficient progress towards achieving targets (particularly in the diabetes and blood pressure control practices) seemed to activate a negative feedback loop and demotivate staff. Third, we had sought to ensure that targeted indicators were well aligned with existing clinical priorities; this inadvertently resulted in the implementation package being insufficiently differentiated from other improvement initiatives.

## Patient and public involvement

Our patient and public involvement panel comprised nine people from diverse ethnic, occupational and social backgrounds and with considerable collective lay experience in commissioning and governance of health care, national clinical audits, patient advocacy and community development. The panel met quarterly and contributed to all work packages and wider stakeholder events. In addition, we undertook further work on the role of patient and public involvement in implementation research.

### *Patient and public involvement contributions to Action to Support Practices Implementing Research Evidence*

The panel played an integral role in the development and conduct of the Action to Support Practices Implementing Research Evidence (ASPIRE) programme. Specific contributions included patient representation in consensus processes (e.g. the selection of research areas; work package 1), endorsement of an opt-out recruitment process (work package 2 and work package 4), feedback on the interpretation of emerging data (all) and assistance with relationship-building and dissemination.

### *The role of patient and public involvement in implementation research*

Patient and public involvement is generally an essential requirement for research funding. As an implementation research programme, ASPIRE generally focused on health professionals' behaviour. This is in contrast to clinical research, which generally focuses on patients. Discussions with our panel identified uncertainty about the role of patient and public involvement in implementation research and we decided to explore this issue further to inform relevant good practice guidance. Via a structured consensus process, our panel considered and rated 21 potential patient and public involvement roles in research. There were more disagreements relating to patient and public involvement roles in implementation research than in clinical research. The work informed a framework to guide the planning, conduct and reporting of patient and public involvement in implementation research.

## Conclusions

Our highly pragmatic and rigorous evaluation indicates the value of an implementation package targeting risky prescribing, given predictable population reductions in avoidable morbidity, deaths and hospital admissions. However, in broad terms, an adapted 'one-size-fits-all' approach did not work, with no improvement for other targeted indicators.

Our programme had several limitations. It was set in one geographical area; however, practice and patient population characteristics are otherwise likely to be sufficiently diverse and typical to enhance generalisability. We used an 'opt-out' approach to recruit general practices to the randomised trials. Subsequently, our trial practices may not have engaged with the implementation package as much as if

they had actively volunteered. However, this approach may also have ensured the applicability of our findings to 'real-world' quality improvement initiatives targeting all practices in a given locality.

There are challenges in designing implementation strategies that are sufficiently robust to bring about change in the face of difficult clinical contexts and likely losses to fidelity. Despite our systematic intervention development, we now believe that we could have conducted more feasibility and 'stress-testing' work prior to rolling out interventions within a definitive evaluation – and recommend this to others. Our programme has led onto other work, adapting our audit and feedback approach for other priorities and evaluating different ways of delivering feedback to improve patient care. We are also producing practical, evidence-based guidance and supporting materials to promote the implementation of National Institute for Health and Care Excellence guidance in general practice.

### ***Implications for practice***

Selecting priorities for implementation may be facilitated by a realistic appraisal of the likelihood of being able to bring about change for the targeted clinical practice, ideally ensuring that any goals for change are within the control of the professionals and patients who need to change behaviour. Specifically, we demonstrated a reduction in risky prescribing by a strategy exploiting routinely available data and involving repeated audit and feedback accompanied by persuasive messages, realistic goal-setting and action-planning. Implementation strategies may have small to modest effects but such effects can translate into worthwhile population health gains.

### ***Recommendations for research***

We recommend maximising feasibility and 'stress-testing' work prior to rolling out interventions within a definitive, pragmatic trial. We specifically recommend further implementation research addressing type 2 diabetes control, blood pressure control and anticoagulation for atrial fibrillation that builds on our experience and the wider body of research literature. Concerted strategies that target system, organisational and patient levels as well as general practices may be required to bring about significant change.

## **Trial registration**

This trial is registered as Current Controlled Trials ISRCTN91989345.

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