UNIVERSITY OF MANCHESTER NATIONAL PRIMARY CARE RESEARCH AND DEVELOPMENT CENTRE AND UNIVERSITY OF YORK HEALTH ECONOMICS CONSORTIUM (NICE EXTERNAL CONTRACTOR)

Development feedback report on piloted indicator(s)

QOF indicator area: Cardiovascular disease - primary prevention

Pilot period: 1st October 2010 – 31st March 2011

Potential output: Recommendations for NICE Menu

Contents

Piloted indicator(s)	2
Assessment of clarity, reliability, acceptability, feasibility, and implem	entation 2
Clarity	2
Reliabilityand Feasibility	2
Acceptability	4
Implementation	4
Assessment of piloting achievement	4
Changes in practice organisation	
Resource utilisation and costs	5
Barriers to implementation	5
Assessment of exception reporting	6
Assessment of potential unintended consequences	6
Assessment of overlap with existing QOF indicators and potential ch existing QOF indicators	
Overall recommendation	6
Appendix A: Indicator details	8
Appendix B: Details of assessment criteria for piloted indicators	

Piloted indicator(s)

1. In those patients with a new diagnosis of hypertension (as of 1 October 2010) (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an agreed risk assessment tool) of ≥20% in the previous 15 months, who are currently treated with statins (unless there is a contraindication).

Number of practices participating in the pilot: 30

Number of practices withdrawing from the pilot: 3¹

Number of practices where staff were interviewed: 29

Assessment of clarity, reliability, acceptability, feasibility, and implementation

Clarity

Indicator wording as stated, rated as clear and unambiguous by the RAM panel

The NHS IC has confirmed that they have been able to write Business Rules (and/or an Extraction Specification)

Reliability² and Feasibility

Indicator	Feasibility	Reliability	Implementation
1	4*	4*	4*
1 (with change to LIS applied)	2/3	3	2/3

Primary Care Quality and Outcomes Framework Indicator Advisory Committee Thursday 9th June 2011 Agenda Item 3.1: Primary Prevention of CVD (development feedback)

¹ 3 practices withdrew late in the pilot. 2 were still able to give comments about the indicators.

² NHSIC provide guidance on whether the piloted indicators are, from a business rule perspective, suitable to become 'live' indicators. A notional 'scoring' system is used:

^{1.} No problems to implement in live with other indicators

^{2.} Minor re-work before it can go live with other indicators

^{3.} Major re-work but do-able without recourse to anyone outside of the process

^{4.} Major considerations to be made before the indicator can go live - possibly need to speak to CFH / suppliers

^{5.} Not feasible

* Need to discuss with CFH and suppliers. Feedback seems positive and functionality expected to be included in the logical interface specification by April 2012

Comments	Response	NHSIC Summary
Need to establish time frames - The rules would need to be structured to look for a risk score of greater than or equal to 20% at some point in the period.	In pilot diagnosis of hypertension after 01/10/2010 and identify the first cvd risk where >=20 3 months before or 3 months after the diagnosis This requires new functionality	Discussions with CFH have been positive and it is expected that the additional functionality can be developed and included in the logical interface specification (LIS) that the suppliers use in time for April 2012.
Are all the correct diseases excluded?	Confirmed to exclude PVD and Familial Hypercholesterolemia and Chronic Kidney disease although not stated in the definition	
Is this a cumulative indicator or reset every year?	Decision was to reset each year	May give cross-year problems
How are we managing scores from the different tools – do all the tools give a reliable comparable result of >= 20%?	Consensus was that tools gave similar scores	May effect reliability
Is it appropriate to add age exclusion? Is the current age limit used in the CVD PP business rules of 30-74 years appropriate for all the CVD risk assessment methods? Clinical guideline 67 recommends the following: For the primary prevention of CVD in primary care, a systematic strategy should be used to identify people aged 40-74 who are likely to be at high risk.	Age range will be added to the final indicator.	May effect reliability

Acceptability

General comments

All except one practice thought this indicator was an improvement on the current PP1 and should be introduced into QOF. The one practice that was less keen cited workload issues.

Specific comments indicator 1

This indicator was overwhelmingly described as "good valuable medicine" and as "proactive care that patients like."

Acceptability recommendation

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of acceptability* that would preclude these 2 indicators from being implemented.

Implementation

Assessment of piloting achievement

	Baseline	Final	Number of practices uploading data at both baseline and final
Population	139561	147152	
Number of practices uploading data	16	18	16
Total Numerator	50	24	
Mean practice denominator ³	8.06 (129)	2.34 (43)	
Mean score ⁴	38.76%	55.81%	
To what extent is the b the national baseline?	aseline representative of	N/A	

In those patients with a new diagnosis of hypertension (as of 1 October 2010) (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an agreed risk assessment tool) of ≥20% in the previous 15 months, who are currently treated with statins (unless there is a contraindication).

³ The average number of people across practices eligible for inclusion in the indicator population

⁴ The average achievement across practices for the indicator

Please note that these are new diagnoses (i.e. relatively small numbers).

The time frame for the baseline upload was 12 months and for the final upload was 6 months.

Summary:

- Just over a third (39%) of patients were being recorded as having a statin pre pilot.
- The pilot did appear to focus GPs' minds and increase the % of people being prescribes a statin.

Changes in practice organisation

General comments

None

Specific comments indicator 1

None

Resource utilisation and costs

General comments

Almost all practices said that they were already doing the work described in this indicator and therefore this indicator represented little additional work for anyone in the practice.

Specific comments indicator 1

None

Barriers to implementation

General comments

There were two recurring themes:

Specific comments indicator 1

- a. Eight practices noted that patients cannot always tolerate statins and this might lead to some GPs prescribing more expensive tablets which might not be approved of by the PCT prescribing advisor or to higher exception reporting for this indicator.
- b. Six practices would value more guidance about which is the best risk tool to use. It was noted that a number of risk tools can be used to assess cardiovascular risk for the purpose of QOF including
 - Framingham
 - Joint British Society 2 (JBS2)
 - QRISK
 - (ASSIGN Scotland only)

In February 2010, NICE withdrew its guidance recommending a particular method of CVD risk estimation (Framingham) so that the decision could be left to local NHS organisations to use the method best suited to their requirements. However six practices preferred a more didactic approach.

Assessment of exception reporting

See above.

Assessment of potential unintended consequences

General comments

There is a possibility that patients may feel coerced into accepting statins when they might want to try lifestyle changes first or may not tolerate statins.

Implementation recommendation

There are barriers/risks/issues/uncertainties identified from the pilot in terms of implementation that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Assessment of overlap with existing QOF indicators and potential changes to existing QOF indicators

PP1. In those patients with a new diagnosis of hypertension (excluding those with pre-existing CHD, diabetes, stroke and/or TIA) recorded between the preceding 1 April to 31 March: the percentage of patients aged 30 to 74 years who have had a face to face cardiovascular risk assessment at the outset of diagnosis (within three months of the initial diagnosis) using an agreed risk assessment tool (8pts 40–70%)

NICE menu ID: NM06

If the new indicator is accepted, then current PP1 will need to be retired.

Overall recommendation

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot that would preclude the new indicator from being recommended for publication on the NICE menu of indicators.

Suggested amendments to indicator

There is a caveat about guidance and exception reporting that might be addressed through e.g. lower threshold setting to ensure patients do not feel coerced into taking statins.

The pilot date needs to be removed, an age range in line with PP1 could be specified within the indicator wording and the usual phrase "unless a contraindication or side effects are recorded" could be used as follows:

In those patients with a new diagnosis of hypertension (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an agreed risk assessment tool) of ≥20% in the previous 15 months: the percentage of patients aged 30 to 74 years who are currently treated with statins (unless a contraindication or side effects are recorded).

Appendix A: Indicator details

Recommendation(s) presented and prioritised by the Advisory Committee

NICE Clinical guideline 67 (Lipid	NICE recommendation 1.4.3
Modification)	Statin therapy is recommended as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. This level of risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an appropriate risk calculator is not available or appropriate (for example, older people, people with diabetes or people in high-risk ethnic groups).

Summary of Committee considerations (taken from the Committee minutes)

The Committee considered a briefing paper on the topic of statin therapy for the primary prevention of cardiovascular disease (CVD). The proposed recommendation was taken from clinical guideline 67 'Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease'

The Committee noted that there is strong clinical and cost effectiveness evidence for the use of statins in the primary prevention of CVD.

The Committee noted that people with hypertension are one of the major groups of people at risk of CVD and that indicator development should therefore focus on people newly diagnosed with hypertension who are at high risk of developing CVD. The Committee noted that statin therapy for people with diabetes, who are one of the other major groups of people at risk of CVD, is already currently incentivised in the QOF.

The Committee noted that indicator development could build on the current QOF indicator PP 1 which incentivises face to face cardiovascular risk assessment.

The Committee agreed that the topic of statin therapy for people newly diagnosed with hypertension at high risk of developing CVD should be progressed for further development.

NICE clinical guideline 67:	Recommend to progress for
recommendation 1.4.3	development

Pre-RAND indicators

- 1. In those patients with a new diagnosis of hypertension (as of 1 October 2010) (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have had a face-to-face cardiovascular risk assessment (using an agreed risk assessment tool) at the outset of diagnosis (within 3 months of the initial diagnosis) with a recorded cvd risk assessment score a ≥20%, the percentage of patients who are treated with statins (unless there is a contraindication)
- 2. In those patients with a new diagnosis of hypertension (as of 1 October 2010) (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have had a face-to-face cardiovascular risk assessment (using an agreed risk assessment tool) at the outset of diagnosis (within 3 months of the initial diagnosis) with a recorded cvd risk assessment score a ≥20%, the percentage of patients who are currently treated with statins (unless there is a contraindication)

Final indicator as piloted

In those patients with a new diagnosis of hypertension (as of 1 October 2010) (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an agreed risk assessment tool) of ≥20% in the previous 15 months, who are currently treated with statins (unless there is a contraindication).

Appendix B: Details of assessment criteria for piloted indicators

This appendix provides details for each of the assessment criteria used in the report to provide the basis of the pilot feedback, assessments and recommendations.

Clarity

Clarity measures whether the indicator wording is clear and unambiguous. This is assessed and rated by the RAM⁵ panel, in terms of the ability to write business rules (and/or an extraction specification) for the indicator. Clarity may also take into account the attribution of the indicator, that is whether it is applicable to primary care and performed within the practice.

Reliability

Reliability measures how closely multiple formats or versions of an indicator produce the same result. Each indicator undergoes compulsory reliability testing (how closely multiple versions of a test produce the same result).

Data elements obtained through automated search strategies of electronic health records are verified against and compared with a reference manual review strategy for obtaining the data elements, and a report is compiled. Reasons for any discrepancies between electronic extraction and manual reviews are then investigated and documented. This procedure is undertaken for each indicator in a small number of practices.

During the analysis, development and execution of the extraction software, issues are documented and a statement on the level of change required to subsequent business rules is prepared.

Acceptability

Acceptability measures how acceptable the activity is to both the assessors and those being assessed, for example that the activity is perceived as good clinical practice without any major barriers, risks or issues. Assessment might examine any conflicts with national guidance, variation in preferences of engagement with patients, concerns in relation to exception reporting, frequency of prescribing or undue focus on one area of care.

Feasibility

Feasibility measures the ability of the clinical practice to interpret an indicator's definitions and technical specifications and integrate them into both clinical practice and health information systems, and generate performance reports within a reasonable time frame and budget. A technical feasibility

Primary Care Quality and Outcomes Framework Indicator Advisory Committee Thursday 9th June 2011

⁵ In the initial stages indicators in development go through a rigorous two-stage consensus process: a modified RAND/UCLA Appropriateness Method (RAM). This is the only systematic method of combining expert opinion and evidence (Naylor, 1998) and feeds consultation with experts in each clinical area as appropriate in to the development process.

assessment will include the ability to extract data from the pilot practices using business rules, and/or an extraction specification via an extraction software provider (PRIMIS+) at the appropriate times, using the technical solution for each extract.

Assessment will also include an outline of any exception reporting codes necessary or subsequent changes to the business rules for indicators to operate functionally in live QOF.

Implementation

Implementation measures several factors which may have an impact on a practice and/or patient during the piloting of an indicator.

An assessment of piloting achievement measures the current baseline and any changes in baseline including the degree of confidence that the baseline is representative of the expected national baseline. The assessment will also report if the baseline has been supplemented with GPRD/THIN⁶ data.

Changes in practice organisation measures any necessary changes required to create, use, and maintain the capacity to report on an indicator. These changes might involve IT, staffing, workflow structure, processes, policies, culture, inter-organisational relationships, and physical or financial capital critical to the cost effectiveness analysis.

Resource utilisation and costs measures the resource impact the indicator has on a practice. This may require engagement and consultation with practices through qualitative face-to-face methods, for example work load diaries, interviews and focus groups or quantitative methods exploring the extracted data from the piloted indicators.

Barriers to implementation measure any major barriers which would make the indicator unreasonably difficult to implement in practices or in live QOF. This may include requirements to make fundamental changes to practice organisation, unfeasible data collection or any unacceptable impact of unintended consequences. Assessment might examine barriers encountered in data collection, whether there was a lack of existing templates, the completeness of data and any missing data, and whether the indicator requires the reporting of new data items or concepts that are not routinely captured as part of current practice.

The implementation assessment will also take into account the overlap with existing indicators, and the extent of any overlap. For instance, whether the indicator partly or completely duplicates activities covered by other indicators in the same or a separate clinical domain.

An assessment of exception reporting measures the susceptibility of an indicator to high levels of exception reporting. This may include engagement

⁶ The Health Improvement Network (THIN) is a partnership of organisations which develop primary care systems. The general practice research database (GPRD), developed by THIN, is a database of anonymised patient records from information entered by general practices in their clinical systems.

issues, relevance of the indicator to certain groups, contraindications, and the accessibility of patients (namely those who are housebound or in a nursing home). The rate of exception reporting for the piloted indicator will include the extent to which exception reporting levels are within the expected range.

Unintended consequences are unforeseen effects of QOF measurements on processes of care, patient outcomes, and/or the functioning of the wider healthcare system. They may be positive in nature, for example encouraging general quality improvement, or negative, such as diversion of effort, disruption to clinical or organisational workflows, susceptibility to monetary gain, potential harm to patients, inappropriate standardisation of care or local practice, and undue focus on process. This may require auditing of patient exception reporting and referral rates to other health and social care sectors, and exploration of the reasons for these at an individual level including patient socio-demographic variables if available.