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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: Peripheral arterial disease

Pilot period: 1st April 2010 – 30th September 2010

Potential output: Recommendations for NICE Menu

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Piloted indicator(s)

1. The practice can produce a register of people with peripheral artery disease.
2. The percentage of patients with peripheral artery disease (diagnosed after 1 April 2010 for the purposes of piloting) who have had the diagnosis confirmed by a record of resting ankle brachial pressure index (ABPI) measurement or referral for specialist assessment.
3. The percentage of patients with peripheral artery disease with a record of aspirin or an alternative anti-platelet therapy or an anti-coagulant in the last 15 months (unless a contraindication or side-effects are recorded).
4. The percentage of patients with peripheral artery disease who have a record of blood pressure in the previous 15 months.
5. The percentage of patients with peripheral artery disease in whom the last blood pressure reading (measured in the last 15 months) is 140/90 or less.
6. The percentage of patients with peripheral artery disease in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less.

Number of practices participating in the pilot ¹ :	26
• 20 in England/2 each on NI, Scotland and Wales respectively	
Number of practices withdrawing from the pilot:	10
Number of practices where staff were interviewed:	21
• (18 in England, 2 in Scotland, 1 In Northern Ireland)	
Number of pilot practice staff interviewed	45
• (19 GPs; 16 PMs; 6 PNs; 4 others)	

¹ 10 English practices withdrew from Pilot 2. 5 practices withdrew for internal reasons (i.e. the practice merged with another practice and could not focus on the pilot as they would have wished or there was a change in practice manager who had other priorities), 1 practice for external reasons (i.e. barriers with piloting governance procedures that caused delays in practice visits) and 1 practice for a combination of internal and external reasons respectively. No reason was given by the remaining 3 practices that withdrew.

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

Clarity

Indicator wordings 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).

Reliability and Feasibility²

Feasibility	Reliability	Implementation
2	2	2

Comments	Response	NHSIC Summary
To be decided whether we look into the issues of co-morbidity and double counting people who have had for example their blood pressure measured elsewhere.	This is an aspect of QOF in general that needs looking at. Need to discuss with DH for policy steer	Not specific just to this indicator, but this is a 'new' clinical area and we should establish the correct policy on double counting.

Acceptability

"I think it's an important area and I think it's one that actually probably does get missed. Whether it's appropriate to raise its head through QOF when you're doing a lot of the stuff anyway, I'm a bit more dubious about that one. But there's an awful lot of people with vascular disease which I think get missed. So I would say 50/50 on that one to be honest". (Pilot practice GP, Warwickshire, practice 44)

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

General comments/ Specific comments: Indicator 1

- There was disagreement about the value of a separate QOF PAD register and set of indicators. Almost half (n=9) of practices recommended that none of the indicators should be included in QOF because:
 - Low incidence and prevalence of PAD: The views expressed by these practice staff echo that of the evidence, as presented to AC in December 2009.³
 - Many patients with PAD were felt to be already on an existing QOF register.
 - Duplication/double payment.

“I would be surprised if there were very many people who had only a bit of PAD who weren’t already on one of the other registers, who weren’t already known on the scheme of heart disease or the diabetes or the stroke register, but there would be course be some I suspect.” (Pilot practice GP, Bristol, practice 46)

However, other practices (n=7) recommended that PAD should be included in QOF because:

- High risk of a major cardiovascular event or cerebral vascular event.⁴
- Potential under-use of care at present.
- Low workload associated with low incidence/prevalence.

“It’s such a high risk area if you’ve got peripheral arterial disease...I think it is worth looking after these people properly because they’re just time bombs...unless they have bad symptoms, there’s a risk that these patients could slip through the net if they don’t fall in one of the other chronic disease groups.” (Pilot practice GP, Essex, practice 55)

A minority of practices recommended that only the register and ABPI indicators should be included in QOF because:

- Most patients with PAD are already on an existing QOF register such as stroke or CHD and as such were targeted for the

³ The NICE AC Briefing report on PAD stated that there was an annual population incidence of 0.20%

⁴ The NICE AC Briefing report on PAD state ‘Patients diagnosed as having PAD, including those who are asymptomatic, have an increased risk of mortality from CVD (fatal myocardial infarction and fatal stroke). The relative risks of all cause mortality are two to three times that of age and sex matched to groups without PAD.’

aspirin, blood pressure and cholesterol indicators under these co-morbid QOF conditions.

Specific comments: Indicator 2

- The majority of practices do not perform ABPI in practice. There would be associated training needs for in-house ABPI.
- There were concerns about inappropriate overuse of referral for ABPI in patients suspected of PAD or mildly symptomatic vascular disease where there was no subsequent surgical treatment option.
- Some clinicians discounted the role of ABPI in diagnosing PAD, preferring their own clinical judgment.

Specific comments: Indicators 3,4,5,6.

- The indicators in relation to aspirin, blood pressure and cholesterol were all deemed appropriate quality issues for people with PAD but people also on CHD, diabetes, CKD, hypertension and CVA QOF registers are being targeted already as part of QOF indicators in those domains.

Acceptability recommendation

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

Implementation

Assessment of piloting achievement:

Indicator 1 - The practice can produce a register of people with peripheral artery disease

	Baseline	Final	Number of practices uploading data at both baseline and final
Population	139744	86839	
Number of practices uploading data	21	13	13
Mean practice denominator ⁵	49.7 (1044)	54.1 (703)	
Mean score ⁶	-	-	
To what extent is the baseline representative of the national baseline?	N/A		

⁵ The average number of people across practices eligible for inclusion in the indicator population

⁶ The average achievement across practices for the indicator

Assessment of piloting achievement:

Indicator 2 - The percentage of patients with peripheral artery disease (diagnosed after 1 April 2010 for the purposes of piloting) who have had the diagnosis confirmed by a record of resting ankle brachial pressure index (ABPI) measurement or referral for specialist assessment.

	Baseline	Final	Number of practices uploading data at both baseline and final
Population	139744	86839	
Number of practices uploading data	21	13	
Mean practice denominator ⁷	0.57 12/21	2.54 33/13	
Mean score ⁸	0.0% ⁹ (1 day window)	12.1% 13/33*100	
To what extent is the baseline representative of the national baseline?	N/A		

⁷ The average number of people across practices eligible for inclusion in the indicator population

⁸ The average achievement across practices for the indicator

⁹ Due to technical issues with the business rules in pilot 2 the baseline is not a true baseline and cannot be used for thresholds and payments. It will be in future pilots. The denominator here is those newly diagnosed and the numerator is of those newly diagnosed, those that have had an ABPI or referral.

Assessment of piloting achievement:

Indicator 3 - The percentage of patients with peripheral artery disease with a record of aspirin or an alternative anti-platelet therapy or an anti-coagulant in the last 15 months (unless a contraindication or side-effects are recorded).

	Baseline	Final	Number of practices uploading data at both baseline & final
Number of practices uploading data	21	13	
Mean practice denominator ¹⁰	53.6	54.1	
Mean score ¹¹	75.6.%	77.5%	
To what extent is the baseline representative of the national baseline?	No national baseline data. However, relevant live QOF underlying achievement scores are: QOF CHD 9 (The % of patients with CHD with a record in the previous 15m that aspirin, an alternative anti-platelet therapy or an anti-coagulant is being taken [unless CI or SE are recorded]) 94.6%		

¹⁰ The average number of people across practices eligible for inclusion in the indicator population

¹¹ The average achievement across practices for the indicator

Assessment of piloting achievement:

Indicator 4 - The percentage of patients with peripheral artery disease who have a record of blood pressure in the previous 15 months.

	Baseline	Final	Number of practices uploading data at both baseline & final
Number of practices uploading data	21	13	
Mean practice denominator ¹²	53.6	54.1	
Mean score ¹³	87.0%	92.7%	
To what extent is the baseline representative of the national baseline?	<p>No national baseline data. However, relevant live QOF underlying achievement scores are:</p> <p>DM11 (The % of patients with diabetes who have a record of the blood pressure in the previous 15m) 98.3%</p> <p>CKD 2 (The % of patients on the CKD register whose notes have a record of blood pressure in the previous 15m) 97.6%</p> <p>CHD 5 (The % of patients with CHD whose notes have a record of blood pressure in the previous 15m) 97.7%</p> <p>Stroke 5 (The % of patients with TIA or stroke who have a record of BP in the notes in the preceding 15m) 96.8%</p> <p>BP4 (The % of patients with hypertensions in whom there is a record of blood pressure in the previous 9m) 91.5%</p>		

¹² The average number of people across practices eligible for inclusion in the indicator population

¹³ The average achievement across practices for the indicator

Assessment of piloting achievement:

Indicator 5 - The percentage of patients with peripheral artery disease in whom the last blood pressure reading (measured in the last 15 months) is 140/90 or less.

	Baseline	Final	Number of practices uploading data at both baseline & final
Number of practices uploading data	21	13	
Mean practice denominator ¹⁴	53.6	54.1	
Mean score ¹⁵	59.9%	65.4%	
To what extent is the baseline representative of the national baseline?	<p>No national baseline data. However, relevant live QOF underlying achievement scores are:</p> <p>CHD6 (The % of patients with CHD in whom the last blood pressure reading measured in the previous 15m is 150/90 or less) 89.8%</p> <p>STROKE 6 (The % of patients with a history of TIA or stroke in whom the last blood pressure reading measured in the previous 15m is 150/90 or less) 88.1%</p> <p>DM12 (The % of patients with diabetes in whom the last blood pressure is 145/85 or less) 80.6%</p> <p>BP 5 (The % of patients with hypertension in whom the last blood pressure measured in the previous 9m is 150/90 or less) 78.7%</p> <p>CKD 3 (The % of patients on the CKD register in whom the last blood pressure reading measured in the previous 15m was 140/85 or less) 73.9%</p>		

¹⁴ The average number of people across practices eligible for inclusion in the indicator population

¹⁵ The average achievement across practices for the indicator

Assessment of piloting achievement:

Indicator 6 - The percentage of patients with peripheral artery disease in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less.

	Baseline	Final	Number of practices uploading data at both baseline & final
Number of practices uploading data	21	13	
Mean practice denominator ¹⁶	53.6	54.1	
Mean score ¹⁷	53.8%	79.8%	
To what extent is the baseline representative of the national baseline?	No national baseline data. However, relevant live QOF underlying achievement scores are: DM 17 (The % of patients with diabetes whose last measured total cholesterol within the previous 15m is 5mmol/l or less) 83.0% CHD 8 (The % of patients with CHD whose last measured total cholesterol measured in the previous 15m is 5mmol/l or less) 82.1% STROKE 8 (The % of patients with TIA or stroke whose last measured total cholesterol measured in the previous 15m is 5mmol/l or less) 77.3%		

Summary:

- Data for indicators 3-6 showed differential improvements from baseline to final: Aspirin (75.6% to 77.5%), blood pressure (87.0% to 92.7%), blood pressure control (59.9% to 65.4%) and cholesterol control (53.8% to 79.8%). However, scores are lower than for comparative live QOF indicators in related QOF domains as shown.

Changes in practice organisation

Specific comments: Indicator 1

(See Acceptability)

Specific comments: Indicator 2

- An ABPI takes 30 minutes to perform and the patient has to be lying down. This can block a treatment/consulting room.
- Changes to READ codes are required e.g. codes would be needed for amputees.

¹⁶ The average number of people across practices eligible for inclusion in the indicator population

¹⁷ The average achievement across practices for the indicator

- Templates are required.
- In-house training on ABPI for nurses would be needed.
- There was disagreement over workload associated with ABPI due to its low incidence.

Specific comments: Indicators 3 - 6

(See Acceptability)

Resource utilisation and costs

(See Changes in practice organization)

Barriers to implementation

General comments:

If these indicators were to be implemented in practice, there would need to be clear templates, and a better understanding of the practicalities of measuring ABPI.

Specific comments: Indicator 1

- There is a lack of existing templates.

Specific comments: Indicator 2

- The indicator requires the reporting of new data items or concepts that are not routinely recorded as part of current practice.
- Information from secondary care on ABPI results is often unclear.

Specific comments: Indicators 3-6

- None, as for many patients, these issues are addressed through other QOF registers.

Assessment of exception reporting

N/A

Assessment of potential unintended consequences

Specific comments: Indicator 2

- There were some concerns about inappropriate overuse of referral for ABPI in patients suspected of having PAD or mildly symptomatic vascular disease where there was no subsequent surgical treatment option.
- ABPI was being conducted by some practices as part of quality payments for other initiatives, such as DESs, so there are potential issues of double payment need to be taken into account when cost effectiveness is assessed.

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

There is considerable overlap with indicators in the CHD, Diabetes and CVA domain and some overlap with indicators in the Hypertension and CKD domains.

Overall recommendations

Indicators 1-6

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

Suggested amendments to indicator

- It should also be noted that the wording of indicator 2 should be changed to make it clear that this is NOT a cumulative indicator as follows:

The percentage of patients diagnosed with PAD in the preceding 15 months whose diagnosis has been confirmed by a record of resting ankle brachial pressure index measurement or referral for specialist assessment.
- There is very limited evidence for anticoagulation in PAD and therefore indicator 3 should be: The percentage of patients with peripheral artery disease with a record of aspirin or an alternative anti-platelet therapy in the last 15 months (unless a contraindication or side-effects are recorded).
- It should also be noted that indicator 4- measurement of blood pressure, is a purely process measure and therefore now out of step with the general direction of travel for QOF.
- It should also be noted that BP level in indicator 5 is different from the audit target used in other QOF indicator sets and should be amended

to: The percentage of patients with peripheral artery disease in whom the last blood pressure reading (measured in the last 15 months) is 150/90 or less.

Appendix A: Indicator details

Recommendation(s) presented and prioritised by the Advisory Committee

- SIGN recommendation 2.8 Antiplatelet therapy is recommended for patients with symptomatic peripheral arterial disease
- SIGN recommendation 2.6: Hypertensive patients with peripheral arterial disease should be treated to reduce their blood pressure
- NICE recommendation 1.4.3: Offer drug therapy, adding different drugs if necessary, to achieve a target of 140/90 mmHg, or until further treatment is inappropriate or declined. Titrate drug doses as described in the 'British national formulary' noting any cautions and contraindications.
- SIGN recommendation 2.3: Lipid lowering therapy with a statin is recommended for patients with peripheral arterial disease and total cholesterol level > 3.5 mmol/l.
- NICE recommendation 1.4.19: Statin therapy is recommended for adults with clinical evidence of CVD.
- NICE recommendation 1.4.25: An 'audit' level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD, in recognition that more than a half of patients will not achieve a total cholesterol of less than 4 mmol/litre or an LDL cholesterol of less than 2 mmol/litre

Summary of Committee considerations (taken from the Committee minutes)

- The Committee highlighted the need to ensure that patients with PAD are correctly identified and investigated. The Committee considered that ankle brachial pressure index (ABPI) measurement should be used to assess PAD and requested that measurement of ABPI is considered for QOF indicator development.
- A recommendation supporting this indicator was not presented at the AC but it is noted that measuring ABPI is recommended : SIGN clinical guideline 89 (Peripheral Arterial Disease):
- Ankle brachial pressure index should be measured in all patients suspected of peripheral arterial disease.
- The AC recommended that this recommendation (Antiplatelet therapy recommended for patients with symptomatic peripheral arterial disease) should be carried forward for indicator development
- The AC recommended that this recommendation (Hypertensive patients with peripheral arterial disease should be treated to reduce their blood pressure) should be carried forward for indicator development
- The AC recommended that this recommendation (Offer drug therapy, adding different drugs if necessary, to achieve a target of 140/90 mmHg, or until further treatment is inappropriate or declined. Titrate drug doses as

described in the 'British national formulary' noting any cautions and contraindications) should be carried forward for indicator development

- The AC recommended that this recommendation (Lipid lowering therapy with a statin is recommended for patients with peripheral arterial disease and total cholesterol level > 3.5 mmol/l) should be carried forward for indicator development
- The AC noted that the 5 mmol/litre 'audit target' used in the current QOF indicators CHD 8 and STROKE 8 is consistent with NICE clinical guideline 67 on lipid modification. The AC agreed there was no need to review these indicators at this time. NICE clinical guideline 67 includes people with PAD. Therefore, the use of 5 mmol/litre 'audit target' for PAD would be consistent with AC recommendations for CHD 8 and STROKE 8.

Pre-RAND indicators

1. The practice can produce a register of people with peripheral artery disease.
2. The percentage of patients with newly diagnosed peripheral artery disease (diagnosed after 1 April 2010 for the purposes of piloting) who have a resting ankle brachial pressure index (ABPI) measurement recorded or who are referred for specialist assessment.
3. The percentage of patients with peripheral artery disease with a record of aspirin or an alternative anti-platelet therapy or an anti-coagulant in the last 15 months (unless a contraindication or side-effects are recorded).
4. The percentage of patients with peripheral artery disease who have a record of blood pressure in the previous 15 months.
5. The percentage of patients with peripheral artery disease in whom the last blood pressure reading (measured in the last 15 months) is 140/90 or less.
6. The percentage of patients with peripheral artery disease in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less.
7. The practice can produce a register of people with cardiovascular disease (any or any combination of the following conditions: coronary heart disease, atherosclerosis, congestive heart failure, peripheral arterial disease, peripheral vascular disease, stroke or TIA).
8. The percentage of patients with any or any combination of the following conditions (coronary heart disease, atherosclerosis, congestive heart failure, peripheral arterial disease, peripheral vascular disease, stroke or TIA) in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less.

9. The percentage of patients with any or any combination of the following conditions (coronary heart disease, atherosclerosis, congestive heart failure, peripheral arterial disease, peripheral vascular disease, stroke or TIA) in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less, who are currently treated with a Statin (unless a contraindication or side-effects are recorded).

10. The percentage of patients with any or any combination of the following conditions (coronary heart disease, atherosclerosis, congestive heart failure, PAD, peripheral vascular disease, stroke or TIA) who are currently treated with Statins.

Final indicators as piloted

1. The practice can produce a register of people with peripheral artery disease.
2. The percentage of patients with peripheral artery disease (diagnosed after 1 April 2010 for the purposes of piloting) who have had the diagnosis confirmed by a record of resting ankle brachial pressure index (ABPI) measurement or referral for specialist assessment.
3. The percentage of patients with peripheral artery disease with a record of aspirin or an alternative anti-platelet therapy or an anti-coagulant in the last 15 months (unless a contraindication or side-effects are recorded).
4. The percentage of patients with peripheral artery disease who have a record of blood pressure in the previous 15 months.
5. The percentage of patients with peripheral artery disease in whom the last blood pressure reading (measured in the last 15 months) is 140/90 or less.
6. The percentage of patients with peripheral artery disease in whom the last measured total cholesterol (measured in last 15 months) is 5.0mmol/l or less.

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 RAM¹⁸ 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

¹⁸ 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/THIN¹⁹ 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

¹⁹ 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.