NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Consultation report

Indicator area: Acute myocardial infarction

Consultation period: 23 November – 21 December 2020

Date of Indicator Advisory Committee meeting: 22 June 2021

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Summary of indicators included in the consultation

| ID | Indicator | Evidence source |
|-----------------|---|---|
| IND2020 -101 | The proportion of patients with STEMI who were reperfused among those eligible (onset of symptoms to diagnosis <12 h) | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology Acute coronary syndromes. NICE guideline NG185 |
| | | (2020), recommendation 1.1.3 |
| IND2020 -102 | The proportion of patients with STEMI who had arterial access for primary PCI in 60 minutes or less from | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology. |
| | a centre with catheterisation facilities. | <u>Acute coronary syndromes. NICE guideline NG185</u> (2020, recommendations 1.1.3 and 1.1.6. |
| IND2020 -103 | The time between the first medical contact and arterial access (absolute value) for patients with STEMI undergoing primary | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology. |
| | PCI. | Acute coronary syndromes. NICE guideline NG185 (2020), recommendation 1.1.3. |
| IND2020 -104 | The proportion of patients admitted with acute myocardial infarction with assessment of left ventricular ejection fraction before discharge. | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology. ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (2015) European Society of Cardiology |
| | | Acute coronary syndromes. NICE guideline NG185 (2020), recommendations 1 1 27 and 1 2 26 |
| IND2020 -105 | The proportion of patients with acute myocardial infarction prescribed a P2Y ₁₂ inhibitor at discharge. | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology. |
| | | ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (2020) European Society of Cardiology. |
| | | Acute coronary syndromes. NICE guideline NG185 (2020), recommendations 1.1.11, 1.1.24, 1.1.25, 1.2.17, 1.2.20, 1.2.21, 1.4.1 and 1.4.13. |
| IND2020 -106 | The proportion of patients with acute | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- |

| | myocardial infarction discharged on dual antiplatelet therapy. | segment elevation(2017) European Society of Cardiology.ESC Guidelines for the management of acute coronary syndromes in patients without persistentST-segment elevation(2020) European Society of Cardiology. |
|-----------------|--|--|
| | | Acute coronary syndromes. NICE guideline NG185 (2020), recommendation 1.4.1. |
| IND2020 -107 | The proportion of patients with acute myocardial infarction discharged on high- intensity statin therapy | ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST- segment elevation (2017) European Society of Cardiology. |
| | intensity statin therapy. | ESC Guideline for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (2020) European Society of Cardiology. |
| | | Acute coronary syndromes. NICE guideline NG185 (2020), recommendation 1.4.1. |
| | | Cardiovascular disease: risk assessment and reduction, including lipid modification. NICE guideline CG181 (2016), recommendations 1.3.2 and 1.3.20. |

General comments

The following is a summary of general (non-indicator-specific) comments:

- One individual commented that the indicators seem reasonable and suggested an additional indicator based on the NICE recommendation for preventative PCI in patients with STEMI and multivessel coronary artery disease.
- One stakeholder recommended that a GP indicator suitable for QOF should be developed focussing on management of raised cholesterol. They also recommended alignment to the ESC targets for reduction of LDL-cholesterol. Other stakeholders suggested that measuring LDL-cholesterol level a month or two after leaving hospital in primary care is an area for quality improvement and highlighted the importance of recording LDL-cholesterol at admission, as well as ezetimibe at admission and discharge.
- One stakeholder raised concern about the proposed indicators overlap with existing quality standards for primary PCI developed by the BCS in 2017 and supported continuation of the existing quality standards. They particularly highlighted the importance of radial access rates and cardiac rehabilitation referral rates and their influence on prognosis. They also proposed additional quality measures for measurement of secondary prevention medication.

IND2020-101: Reperfusion within 12h of symptom onset

The proportion of patients with STEMI who were reperfused among those eligible (onset of symptoms to diagnosis <12 h)

Indicator type: CCG level indicator.

Rationale

All patients with ST-segment elevation myocardial infarction (STEMI) presenting 12 hours or less after onset of symptoms should undergo coronary reperfusion therapy.

Specification

Numerator: The number of patients in the denominator who received reperfusion therapy.

Denominator: The number of patients with STEMI eligible for reperfusion (<12 hours from onset of symptoms to diagnosis)

Exclusions: Patients with contraindication to reperfusion treatment.

Summary of consultation comments

- One individual commented that time data is not well recorded within the myocardial ischaemia national audit project (MINAP) dataset.
- Consultation comments indicate that the wording of the indicator is not clear as some stakeholders commented on the challenges of an indicator measuring revascularisation within 12 hours of symptom onset. The proposed indicator does not measure the time of the intervention.

Specific questions included at consultation

Question: Date and time of diagnosis is not recorded in the MINAP database. Should admission date and time be used as a proxy measure for diagnosis?

There was a mixed response to this question.

- One individual agreed with our proposal as "in practice patients presenting with chest pain should be having an ECG as soon as possible so this would be a reasonable alternative".
- Another stakeholder commented that the time of diagnostic ECG is the time of diagnosis. This can be pre-hospital for STEMI.

Question: What contraindication to the use of primary percutaneous coronary intervention (primary PCI) or fibrinolysis as the reperfusion strategy in patients with STEMI presenting within 12 hours of onset of symptoms are used in clinical practice and should be used to exclude people from this indicator?

- Stakeholders listed some exclusions but suggested these would be rare.
- They also highlighted that in some cases revascularisation may be more risk than benefit even if patients are diagnosed within 12 hours of symptoms.
- One individual highlighted the limitations of identifying contraindications using the proposed data source.

Considerations for the advisory committee

The committee is asked to consider:

- Amending eligibility for the denominator to use time of admission instead of time of diagnosis, as time of diagnostic ECG is not recorded in the MINAP dataset. <u>NICE's guideline on acute coronary syndromes</u> recommends reperfusion by fibrinolysis or primary PCI in people with acute STEMI presenting within 12 hours of onset of symptoms. The <u>European Society of Cardiology (ESC) Acute Cardiovascular Care</u> (ACVC) 2020 update of the QIs for acute myocardial infarction (acute MI) specify measurement of reperfusion for patients admitted less than 12 hours after onset of symptoms.
- Amending the denominator to include all patients diagnosed with STEMI and excluding from the numerator ineligible patients who did not undergo reperfusion treatment due to presenting too late to benefit (MINAP data field).
- The limited opportunity to improve performance as eligibility depends on the time between onset of symptoms and diagnosis.
- The risk of having limited fields within MINAP for recording contraindication to primary PCI.

IND2020-102: Timely reperfusion

The proportion of patients with STEMI who had arterial access for primary PCI in 60 minutes or less from time of presentation at a centre with catheterisation facilities.

Indicator type: CCG level indicator

Rationale

All patients with ST-segment elevation myocardial infarction (STEMI) presenting 12 hours or less after onset of symptoms should undergo coronary reperfusion therapy. Coronary angiography with follow-on primary PCI is the preferred reperfusion strategy for people with STEMI if it can be delivered within 120 minutes of the time when fibrinolysis could have been given. <u>ESC guidance</u> recommends wire crossing in 60 minutes or less from the time of STEMI diagnosis for patients presenting at a primary PCI hospital.

Specification

Numerator: The number of patients in the denominator who had arterial access for primary PCI in 60 minutes or less from time of presentation.

Denominator: The number of patients with STEMI treated with reperfusion by primary PCI.

Exclusions: Patients diagnosed with STEMI >12 hours from onset of symptoms. Patients with contraindication to primary PCI. Patients not directly admitted to a centre with catheterisation laboratory facilities.

Summary of consultation comments

- One stakeholder commented on the misalignment with the standard used in the <u>national audit of PCI (NAPCI)</u> which uses a call-to-balloon time of less than 150 minutes in more than 75% of cases. There is an additional standard in the national audit that measures PCI centre door to balloon time, and this defines achievement as a door to balloon time less than 60 minutes in more than 75% of cases.
- One stakeholder highlighted the updated ESC-ACVC QI for timely reperfusion that considers different time targets according to the type of reperfusion and the availability of PCI facilities.
- Observation of variation and inaccuracy in recorded reperfusion time was noted by stakeholders. One stakeholder suggested that time should be recorded from electronic devices such as an ECG.
- One stakeholder highlighted the difference between "door to artery" and "artery to balloon" and noted that "door to artery" corresponds to the quality of organisation of the cardiology department.

Specific question included at consultation

Question: Time of arterial access is not recorded in the MINAP database. Should time of reperfusion treatment/balloon inflation be used as proxy measure for this?

There was a mixed response to this question:

- One stakeholder commented that there is more data available for using time of reperfusion treatment compared with alternatives. They suggested a composite where date and time of the procedure is used unless the reperfusion time is earlier.
- Another stakeholder commented that time of arterial access is not routinely recorded but time of procedure (as local anaesthetic use time) and time of balloon inflation is recorded in the <u>PCI dataset</u>. They also highlighted that reperfusion time will not be applicable to all patients as some will not have successful reperfusion.
- One stakeholder noted that artery to balloon time is variable dependent on patient profile and interventional cardiologist.

Considerations for the advisory committee

The committee is asked to consider:

- Amending the indicator to measure date and time of balloon inflation instead of arterial access as this is not recorded in the MINAP or PCI datasets.
- The variation in time from artery to balloon that can be due to patient profile as well as the interventional cardiologist.
- Amending the indicator timeframe to less than 60 minutes door to balloon time to reflect updated ESC ACVA QIs and the NAPCI.

IND2020-103: Time between first medical contact and arterial access

The time between first medical contact and arterial access (absolute value) for patients with STEMI undergoing primary PCI.

Indicator type: CCG level indicator

Rationale

All patients with ST-segment elevation myocardial infarction (STEMI) presenting 12 hours or less after onset of symptoms should undergo coronary reperfusion therapy as quickly as possible. Coronary angiography with follow-on primary PCI is the preferred reperfusion strategy for people with STEMI if it can be delivered within 120 minutes of the time when fibrinolysis could have been given.

Specification

Reported as median time between first medical contact (FMC) and arterial access among patients with STEMI undergoing reperfusion with primary PCI.

Summary of consultation comments

- One stakeholder again commented on the limitations of recording of time data. They commented that data for time of first responder and ambulance was previously poorly recorded and noted that the presence of an ambulance responder does not necessarily mean the diagnosis is made. They note the presence of data fields relating to where the diagnostic ECG performed in the MINAP dataset.
- Another stakeholder noted that the longer delay to reperfusion comes from the call to door time and it is important to differentiate between accountability of ambulance/emergency/cardiology departments. They note that close coordination is mandatory. They also note that it is important to consider geographical areas and transportation difficulties that may impact on timing of reperfusion. To overcome this, they suggest including measurement of reperfusion using fibrinolysis.

Specific questions included at consultation

Question: First medical contact (FMC) is defined by the ESC guidelines as the time point when the patient with acute myocardial infarction is initially assessed by a trained emergency medical service personnel who can obtain and interpret the ECG and deliver initial interventions. For the UK, is it more appropriate for this indicator to measure from arrival at hospital than the prehospital setting?

There was a mixed response to this question:

- One stakeholder agreed with this proposal as they suggest that a diagnosis should be made on admission. They commented that an ambulance responder does not necessarily make a diagnosis and note that MINAP contains data fields for the location of the diagnostic ECG.
- Another stakeholder suggested that FMC in the UK is generally the time of the first call for help from the patient which is typically a 999 call. They noted that FMC would differ between patients who present directly to hospital or those who have an MI whilst already in hospital.

Question: We propose the use of time of reperfusion treatment/balloon inflation as a proxy measurement for arterial access. Is this an acceptable measurement?

Stakeholders agreed.

- One stakeholder agreed that balloon time is most important from a patient perspective.
- One stakeholder commented that there is more data available for time of wire passage but again suggested a composite where date and time of procedure is used unless the time of wire passage is earlier.
- Another stakeholder commented that time of arterial access is not routinely recorded but time of procedure, for example as local anaesthetic use time and time of balloon inflation is recorded in the PCI dataset.

Considerations for the advisory committee

The committee is asked to consider the impact of FMC differing between types of presentation, for example 999 call, presentations directly to emergency departments and patients who have an acute MI in hospital. Defining FMC as admission date and time limits accountability to the emergency department and does not cover the whole pathway to the point of reperfusion.

IND2020-104: Left ventricular fraction recorded in notes

The proportion of patients admitted with acute myocardial infarction with assessment of left ventricular fraction before discharge.

Indicator type: CCG level indicator.

Rationale

Assessment of left ventricular function by measurement of left ventricular ejection fraction (LVEF) allows identification of patients who would benefit from specific investigations, review and treatment. Left ventricular function should be assessed before discharge in all people who have had STEMI or non-ST segment elevation myocardial infarction (NSTEMI).

Specification

Numerator: The number of patients in the denominator with a numerical value of LVEF recorded before discharge.

Denominator: The number of patients discharged from hospital following an admission with acute myocardial infarction.

Exclusions: Patients who died in hospital.

Summary of consultation comments

One individual commented that MINAP does not record exact values of LVEF, but that they had accepted category as a surrogate in their work. They state that ejection fraction is a key measure as it determines recommended treatment and advice. Another stakeholder notes that recording of category only makes it impossible to differentiate between patients with LVEF less than or more than 40% and gives additional reasons why it is important to record a quantitative value, including treatment and in the development of further quality indicators.

Considerations for the advisory committee

The committee is asked to consider amending the indicator to collect data on category of LVEF rather than a quantitative value.

IND2020-105: P2Y₁₂ inhibitor on discharge

The proportion of patients with acute myocardial infarction prescribed a $P2Y_{12}$ inhibitor at discharge.

Indicator type: CCG level indicator.

Rationale

P2Y₁₂ inhibitors prasugrel, clopidogrel or ticagrelor are prescribed after an acute myocardial infarction along with other anti-platelet medications such as aspirin to prevent further atherothrombotic events.

Specification

Numerator: The number of patients in the denominator prescribed a P2Y₁₂ inhibitor at discharge.

Denominator: The number of patients discharged from hospital following an admission with acute myocardial infarction.

Inclusions: Patients prescribed ticagrelor, prasugrel or clopidogrel.

Exclusions: Patients on long term anticoagulants. Patients with contraindication to P2Y₁₂ inhibitor use. Patients who died in hospital.

Summary of consultation comments

- One stakeholder noted the update to this indicator in the ESC-ACVA quality indicators detailing the choice in intensity and duration of the P2Y₁₂ inhibition. They noted the wording of the ESC quality indicator is for "adequate P2Y₁₂".
- One stakeholder was unsure that both IND2020-105 and IND2020-106 are required as dual antiplatelet therapy (IND2020-106) includes P2Y₁₂ inhibitors.

Specific question included at consultation

Question: Is this indicator feasible considering the number of medications and contraindication to these included in the indicator specification?

Stakeholders agree that this is feasible although one individual response noted the challenge in defining those not eligible, as reasoning is not recorded in the MINAP dataset.

Considerations for the advisory committee

The committee is asked to consider the appropriateness of not including any assessment of the 'adequateness' of $P2Y_{12}$ inhibition. Definition of adequate $P2Y_{12}$ inhibition on discharge is based on selection of medication, dose and length of duration. It is not possible to identify these parameters using the MINAP database.

IND2020-106: Dual antiplatelet therapy on discharge

The proportion of patients with acute myocardial infarction discharged on dual antiplatelet therapy.

Indicator type: CCG level indicator.

Rationale

Dual antiplatelet therapy should be offered to people with acute STEMI or NSTEMI and continued for up to 12 months after an MI (unless contraindicated).

Specification

Numerator: The number of patients in the denominator discharged on dual antiplatelet therapy.

Denominator: The number of patients discharged from hospital following an admission with acute myocardial infarction.

Exclusions: Patients treated with chronic anticoagulants are excluded. Patients with contraindication to P2Y₁₂ inhibitors or aspirin. Patients who died in hospital.

Summary of consultation comments

One stakeholder noted the challenge in defining those not eligible, as reasoning is not recorded in the MINAP database. They noted that a small minority are on $P2Y_{12}$ and oral anticoagulant and would be coded as not indicated.

Considerations for the advisory committee

The committee is asked to consider excluding patients on chronic oral anticoagulation from this indicator. It is not clear if they can be identified using data recorded in the MINAP database however they may not be eligible for dualantiplatelet therapy.

IND2020-107: High-intensity statins on discharge

The proportion of patients with acute myocardial infarction discharged on highintensity statin therapy.

Indicator type: CCG level indicator.

Rationale

All patients should be offered a statin after an acute MI, unless there is a high risk of adverse events or potential drug interactions. <u>NICE's guideline on cardiovascular</u> <u>disease</u> recommends starting atorvastatin 80 mg in people with cardiovascular disease.

Specification

Numerator: The number of patients in the denominator discharged on high intensity statin therapy.

The ESC defines high intensity statin as atorvastatin ≥40 mg or rosuvastatin ≥20 mg.

Denominator: The number of patients discharged from hospital following an admission with acute myocardial infarction.

Exclusions: Patients who died in hospital. Patients with contraindication to highintensity statin therapy.

Summary of consultation comments

One stakeholder supported the proposed inclusion of this indicator and suggested that this should be developed into an indicator suitable for inclusion in QOF.

Specific questions included at consultation

Question: Prescription of high-intensity statins or named formulations/doses are not collected by the MINAP dataset. Should the data field of 'statin on discharge' be used as a proxy for high-intensity statin?

Question: NICE guidance recommends that a statin of high-intensity and low acquisition cost be used when a decision has been made to prescribe a statin. There is a misalignment between the definition of a high-intensity statin in the indicator specification based on the ESC guidance and that in the NICE guidance. Would rewording of the indicator to measure prescription of a statin on discharge, not restricted to high intensity, alter the intent of the indicator?

There were mixed responses to these questions:

- Two stakeholders commented that high intensity statin on discharge should be used. One stakeholder noted that <u>NICE's guideline on cardiovascular disease: risk assessment and reduction, including lipid modification</u> recommends use of a high intensity statin. They also reference evidence that patients do not adhere to statins. They suggest that better patient care and improved outcomes would be achieved by driving uptake of high intensity statins and more intensive lowering of cholesterol. They note that supporting discharge on statin may further increase lower intensity statin use. Another stakeholder comments on the corresponding recommendation by the ESC for high-intensity statin use based on the PROVEit study in 2004. They also comment "there is much more to do in this field than just prescribing a statin".
- One individual commented that "most centres will default to high intensity stain post-acute MI so using it as a surrogate is reasonable". Another stakeholder agreed it is reasonable to assume this.

97.7% of participants in the MINAP audit received a statin on discharge in the summary report from 2019. Do you think this is an area for quality improvement in England?

Respondents agreed that this is not an area for quality improvement.

- One individual agreed that attainment is high and is "not sure measuring it adds to quality improvement".
- One stakeholder instead reiterated the importance of high-intensity statins.
- Another suggested that LDL-cholesterol level post discharge is an area for improvement.

Considerations for the advisory committee

The committee is asked to consider:

- Whether prescription of a statin on discharge is part of established practice and is therefore not an area for quality improvement.
- The unintended consequence of potentially increasing the use of lowintensity statins because the intensity of a prescribed statin is not included the MINAP database. Use of a statin of high intensity is recommended by NICE and the ESC.

Appendix A: Consultation comments

Question 1: Do you think there are any barriers to implementing the care described by this indicator?

| ID | Proforma question no. | Stakeholder organisation | Comment | NICE response |
|----|-----------------------------|-----------------------------------|--|---|
| 1 | 1 | British Cardiovascular Society | Largely the BCS is supportive of the indicators selcted, subject to the points below. The first indicator (revasc within 12 hours of symptom onset of STEMI) is dependent upon when the patients present in relation to symptom onset. This is largely outside the control of the delivery system so not a marker of service quality. Patients presenting after 10 or 11 hours of chest pain may miss the 12 hour window even though the NHS has responded as fast as possible. Related to this is a slight difficulty with always knowing for sure an accurate time of onset of symptoms. This is often an approximation in the records, often to the nearest hour. This could be a source of potential inaccuracy in this indicator. | Thank you for your comment. Patients presenting too late for reperfusion would be excluded from the denominator. |

Question 2: Do you think there are potential unintended consequences to implementing/using any of these indicators?

| D | Proforma | Stakeholder organisation | Comment | NICE response |
|---|----------|-----------------------------------|---|--|
| | question | | | |
| | no. | | | |
| 2 | 2 | British Cardiovascular Society | Our concern about using these indicators would be if it lessened the emphasis on existing quality standards for primary PCI. These have previously been worked on by colleagues from the BCS (in 2017). They overlap with the metrics proposed but are not exactly the same. We would support the continuation of the quality standards in the figure below: | Thank you for your comment. The quality standards for PCI from the BCS were referenced in the indicator |

| | | | | · · · · · · · · · · · · · · · · · · · |
|---|---|-----------------------------------|---|--|
| | | | Quality Standards for Primary Percutaneous Coronary Intervention Andrew Archbold, Consultant Cardiologist David Hildick-Smith, Consultant Cardiologist Simon Ray, Consultant Cardiologist Huon Gray, Consultant Cardiologist, On behalf of the Cardiac Services Clinical Reference Group | advisory committee meeting in June 2021. The indicator on door to balloon time for patients undergoing primary PCI has been |
| | | | Quality standards for PPCI | aligned with the standard from the |
| | | | 1. Call to balloon time <150 mins in >75% cases | BCS. |
| | | | 2. PPCI centre door to balloon time <60 mins in >75% cases | |
| | | | Adjusted 30-day PPCI mortality rate (excluding cardiogenic shock and out of hospital cardiac arrest cases) | |
| | | | Secondary prevention rates: dual anti-platelet therapy, beta-blocker, angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), & statin in >90% eligible cases | |
| | | | 5. Radial artery access in >70% cases | |
| | | | 6. Referral to cardiac rehabilitation in >70% cases | |
| 3 | 2 | British Cardiovascular Society | We would wish to particularly highlight the importance of radial access rates and cardiac rehab referrals rates since these influence prognosis. Other secondary prevention medications should also be recorded as a quality metric (such as prescription of ACEi/ARB/Entresto or B blockers, as per existing NICE guidance. It may also be appropriate to record prescription rates of SGLT2i and/or aldosterone antagonists in PPCI patients with severely impaired LV function as well) since all of these have an impact on survival. | Thank you for your comment. Additional areas for indicators proposed by stakeholders have been logged for potential further indicator development. |

Question 3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|--------------------------|---------|--------------------|
| | no. | | | |
| 4 | 3 | British Cardiovascular | No | Thank you for your |
| | | Society | | comment. |

Question 4: If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|--------------------------|---------|--------------------|
| | no. | | | |
| 5 | 4 | British Cardiovascular | N/A | Thank you for your |
| | | Society | | comment. |

General comments

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|----------|-----------------------------------|---|--|
| | question | | | |
| | no. | | | |
| 6 | General | British Cardiovascular Society | We note the proposed new quality metrics and are broadly supportive of their use. We note that largely the metrics seem to be derived from the MINAP database, which is reasonable. BCS would promote also the use of data from the BCIS PCI database held by NICOR. This latter is more accurate and detailed, but omits (of course) all the STEMI patients who did not have a PCI. We would suggest harvesting data from both and, where there is discordance, having more faith in the BCIS/NICOR data. | Thank you for your comment. The BCIS PCI dataset has been considered as a data source for these indicators. |

| 7 | General | British Heart Foundation | We don't have anything substantial to share with you from a policy | Thank you for your |
|----|---------|--------------------------------|---|--|
| 8 | General | Individual 2 | Reading briefly through the indicators they all seem reasonable but there is one missing, which relates to the recent NICE guidance published on Nov 18th. This sensibly recommended that patients with ST elevation MI who have multivessel coronary artery disease have PCI to non-infract arteries (preventive PCI) during the index procedure or before hospital discharge. It would be sensible to have a performance indicator that measures adherence to this NICE recommendation to encourage the practice of Preventive PCI in STEMI It may also be necessary to revise the Tarriff for such treatment to encourage and properly remunerate such practice. Is it possible to propose that this indicator be added? | Thank you for your comment. Additional areas for indicators proposed by stakeholders have been logged for potential further indicator development. |
| 9 | General | Royal College of Nursing | Thank you for the opportunity to contribute however we do not have any comments to add this time. | Thank you for your comment. |
| 10 | General | Royal College of Physicians | The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the BCS. | Thank you for your comment. |

| ID | Proforma | Stakeholder | Comment | NICE response |
|----|-----------------|--------------|--|--------------------------------|
| | question | organisation | | |
| | no. | | | |
| 11 | IND2020- 101 | Individual 1 | In terms measuring and reporting there are no real barriers other than accurate data collection as time data is not well recorded within MINAP. Though may be better since my initial work. The indicator itself is a good measure of the PPCI service as a whole. One aspect to consider is how one will improve performance, identifying location of patient in relation to their nearest PPCI centre is not easy. Equally the confounder of time of symptoms to time of | Thank you for your comment. |

| | | | call would need assessing when determining how to improve attainment. We used admission date/time as proxy for time of diagnosis, in practice patients presenting with chest pain should be having an ECG as soon as possible so this would be a reasonable alternative. The issue on who is excluded is hard to address as MINAP currently has no frailty fields, it does include fields for those in whom PCI/angiography is contraindicated for various reasons and these were used in the creation of the QI. | |
|----|---|-----------------------------------|--|--|
| 12 | IND2020- 101 specification page 5 | European Society of Cardiology | it would be important to explain/discuss the selection of a threshold of 50 patients included by center. Using 30 patients per center would make it possible to include more centers, particularly centers with a low volume of activity, i.e. those where the quality is more variable (Of note, a relation between quality of care for AMI and volume of activity has been shown in a nationwide quality assessment in France (Circ Cardiovasc Qual Outcomes. 2013 Jan 1;6(1):50-7. doi: 10.1161/CIRCOUTCOMES.112.967133.). | Thank you for your comment. This is proposed as a CCG level indicator rather than at individual hospital/trust level. |
| 13 | IND2020- 101, acceptability page 5 | European Society of Cardiology | Acceptability, page 5: the 2017 ESC guidelines for STEMI consider that the risk of haemorrhage and uncontrolled hypertension might be a contra indication for reperfusion by thrombolysis, but these patients should be transferred for reperfusion by angioplasty. Therefore, these patients are eligible for reperfusion. | Thank you for your comment. |

Question 5: Date and time of diagnosis is not recorded in the MINAP dataset. Should admission date and time be used as a proxy measure for diagnosis?

| ID | Proforma question no. | Stakeholder organisation | Comment | NICE response |
|----|-----------------------------|-----------------------------------|--|-----------------------------|
| 14 | 5 | British Cardiovascular Society | No – typically diagnosis occurs pre-hospital for STEMI (some hours after admission for NSTEMI.) Time of diagnostic ECG being performed is the time of diagnosis. | Thank you for your comment. |

| 15 | 5 | European Society of | Time variables are mandatory and need to be recorded in | Thank you for your |
|----|---|---------------------|---|--------------------|
| | | Cardiology | registries/databases. | comment. |

Question 6: What contraindication to the use of primary percutaneous coronary intervention (primary PCI) or fibrinolysis as the reperfusion strategy in patients with STEMI presenting within 12 hours of symptoms are used in clinical practice and should be used to exclude people from this indicator?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|----------------------|-----------------------------------|--|-----------------------------|
| | 4.000.011 | | | |
| | no. | | | |
| 16 | 6 | British Cardiovascular Society | Patient wishes, Patient not for aggressive treatment (eg advanced frailty/terminal care), active GI bleeding, recent intracranial bleeding, patient dies before arrival to cath lab. There will also be cases who present, say, 11 hours after onset of symptoms where, on balance, revascularisation is felt to be more risk than benefit. These will all be rare | Thank you for your comment. |

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|-----------------------------------|--|---|
| | no. | | | |
| 17 | IND2020- 102 | Individual 1 | We used time of reperfusion treatment as alternative to arterial access. The other option is date/time angio. I think the former was used as there was more data available and obviously also covered fibrinolysis. A composite could be used where date/time angio is used unless the reperfusion time is earlier. Again the main limiter for this variable was the recording of time data. | Thank you for your comment. |
| 18 | IND2020- 102 | European Society of Cardiology | The updated ESC-ACVC QI for timely reperfusion (aligned with the ESC guidelines) consider different time targets, according to the type of reperfusion (fibrinolysis or PCI) and | Thank you for your comment. This indicator is for |

| | the availability of PCI facilities on-site at the center (PCI on site or need for transfer). Consideration, page 5: same comment regarding the number of patients needed as for "reperfusion": 50 patients might exclude low volume centers. Feasibility: it is important to consider the potential issues regarding the accuracy of the times to reperfusion (J Am Coll Cardiol. 2008 Dec 9;52(24):2100-12. doi: 10.1016/j.jacc.2008.10.013). Variations/inaccuracy in the recorded reperfusion times (like door to artery time or artery to balloon time) have been observed with PCI (Acute Card Care. 2011 Dec;13(4):223-31. doi: | primary PCI only and excludes time between non- interventional centre and interventional centre. This is proposed as a CCG level indicator rather than at individual hospital/trust level. |
|--|--|---|
| | 10.3109/17482941.2011.628029.). | |

Question 7: Time of arterial access is not recorded in the MINAP database. Should time of reperfusion treatment/balloon inflation be used as proxy measure for this?

| ID | Proforma question no. | Stakeholder organisation | Comment | NICE response |
|----|-----------------------------|-----------------------------------|--|---|
| 19 | 7 | British Cardiovascular Society | Time of arterial access is not a familiar metric. It is not routinely recorded, even in BCIS PCI dataset, although start of procedure is recorded there (for example, local anaesthetic use time). Time of balloon inflation (or first device being passed across lesion) is the conventional measure, which is recorded in BCIS database. Of note, this is not the same as the reperfusion time because some patients will have perfusion from the outset, whilst others will never have successful reperfusion at all, due to limitations of the PCI technique. Patients thrombolysed (rare nowadays) will not fit this metric at all, since they never get arterial access. | Thank you for your comment. This indicator is for primary PCI only. Patients undergoing fibrinolysis would be excluded from the denominator. |
| 20 | 7 | European Society of Cardiology | Ideally, all times should be recorded from electronic devices (i.e. ECG) to assess quality. "Door to artery" time corresponds to the | Thank you for your comment. |

| | quality of organization of a cardiology department (= facilitate the access to PCI). Artery to balloon time depends on the quality of the | |
|--|---|--|
| | interventional cardiologist and on the patient's profile. | |

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|-----------------|-----------------------------------|--|---|
| | question no. | | | |
| 21 | IND2020- 103 | European Society of Cardiology | The longer delay to reperfusion (and greater room for improvement) comes from the "call to door" time, which is often under the responsibility of emergency departments. It seems important to differentiate between what falls under the accountability of the ambulance/emergency/cardiology departments. Nevertheless, close coordination between all caregivers is mandatory. For center benchmarking, it is important to consider geographical issues. Some centers cover a very large geographical area, maybe with transport difficulties (such as in mountainous areas) whereas in large cities, where distances are short, shorter times are expected. A way to (partially) overcome this issue is to include reperfusion with fibrinolysis. | Thank you for your comment. This indicator focuses on patients treated with primary PCI. Patients treated with fibrinolysis would be excluded from the denominator. |
| 22 | IND202-103 | Individual 1 | We used time of wire passage as alternative to arterial access. The other option is date/time angio. I think the former was used as there was more data available. A composite could be used where date/time angio is used unless the passage wire time is earlier. Again the main limiter for this variable was the recording of time data. Given the fact data on time for first responder and ambulance is available this could be used, but was poorly recorded when we did the work and also the presence of an ambulance responder does not necessarily mean the diagnosis is made, there are fields relating to where the diagnostic ECG performed for simplicity we chose arrival | Thank you for your comment. |

| | at hospital as there was more data and the diagnosis should be | |
|--|--|--|
| | made in that setting so measuring it from there made sense, I would | |
| | therefore say that using time of arrival is acceptable in this setting | |

Question 8: First medical contact is defined by the ESC guideline as the time point when the patients with acute myocardial infarction is initially assessed by a trained emergency medical service personnel who can obtain and interpret the ECG and deliver initial interventions. For the UK, is it more appropriate for this indicator to measure from arrival at hospital than the prehospital setting?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|-----------------------------------|--|-----------------------------|
| | no. | | | |
| 23 | 8 | British Cardiovascular Society | No, the measure that is used generally in the UK is the time of the first call for help from the patient (typically a 999 call). This is first medical contact outside hospital. For patients who present directly to hospital, it would be the admission time to A&E that should be used. For patients who have their MI whilst already in hospital, we use the time of the first diagnostic ECG being performed. | Thank you for your comment. |

Question 9: We propose the use of time of reperfusion treatment/balloon inflation as a proxy measurement for arterial access. Is this an acceptable measurement?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|----------------------|--------------------------|--|--------------------|
| | no. | | | |
| 24 | 9 | British Cardiovascular | See answer to question 7. | Thank you for your |
| | | Society | | comment. |
| 25 | 9 | European Society of | I agree: the most important time from the patient's perspective is the | Thank you for your |
| | | Cardiology | balloon time. | comment. |

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|-----------------------------------|--|--------------------------------|
| | no. | | | |
| 26 | IND2020- 104 | European Society of Cardiology | Acceptability: LVEF is usually measured by echocardiography and, in most cases, recorded as a percentage in the notes. Recording only categories (good, moderate, poor) makes it impossible to differentiate between patients with LVEF > or < than 40%. This is important for quality, because the use of betablockers, ACEI/ARB and aldosterone receptor inhibitors is not supported by the same level of evidence according to the LVEF (40% and not 30%). In addition, the <30% category is also important to determine future QIs, such as consideration for a lifevest for example. Thus, I would recommend recording the LVEF as a quantitative value. | Thank you for your comment. |
| 27 | IND2020- 104 | Individual 1 | MINAP does not record exact values only category, the QI is for a numerical value, we accept the category as a surrogate. The data is available and easy to interrogate, it's a key measure as the EF does determine whether patients are recommended for additional therapies, has impact on how long patients cannot drive for (important for QoL) | Thank you for your comment. |

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|-----------------|-----------------------------------|--|---|
| | question | | | |
| | no. | | | |
| 28 | IND2020- 105 | European Society of Cardiology | This indicator is feasible, but updated. Most of the patients are discharged with a P2Y12. A more important question is the choice of the intensity and duration of the P2Y12 inhibition. This point has been extensively described in the 2020 NSTE-ACS ESC guidelines. In the 2020 QI definition, another indicator was included to indicate the proposed duration of the dual antiplatelet therapy. | Thank you for your comment. The proposed indicator did not progress to the NICE menu. |

| 29 | IND202-105 | Individual 1 | This is straight forward in principle the key is in defining those not | Thank you for your |
|----|------------|--------------|--|---------------------|
| | | | eligible which is more challenging and largely based on the | comment. The |
| | | | recording of not eligible in the P2Y12 variable though no exact | proposed indicator |
| | | | reason is given in the database for this decision. There are variables | did not progress to |
| | | | for ticagrelor and thienopyridine, obviously recent evidence has | the NICE menu. |
| | | | meant changes in choice of P2Y12 between patients which makes | |
| | | | assessment slightly more challenging. It remains an easy QI to | |
| | | | assess and monitor. Though not sure both IND2020-105 and | |
| | | | IND2020-106 are required. | |

Question 10: Is this indicator feasible considering the number of medications and contraindications to these included in the indicator specification?

| ID | Proforma question no. | Stakeholder organisation | Comment | NICE response |
|----|-----------------------------|-----------------------------------|---|--|
| 30 | 10 | British Cardiovascular Society | Yes (record of % patients getting DAPT on discharge, excluding anticoagulation). This is perfectly doable. | Thank you for your comment. This indicator proposes measurement of P2Y12 inhibitor only. Indicator 2020-106 proposes measurement of DAPT and this was progressed to the NICE menu. |
| 31 | 10 | European Society of Cardiology | In the 2017 and 2020 ESC-ACVC QI sets, the corresponding QI was "adequate P2Y12" on discharge. "Adequate P2Y12" is not difficult to assess from existing variables and the selection between clopidogrel and prasugrel/ticagrelor denotes quality (Open Heart. 2016 May 23;3(1):e000384. doi: 10.1136/openhrt-2015-000384). | Thank you for your comment. The proposed indicator did not progress to the NICE menu. |

Indicator 2020-106

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|-------------------|-----------------------------------|---|---|
| | no. | | | |
| 32 | 2 IND2020- 106 | European Society of Cardiology | Question for consultation: In the 2017 and 2020 ESC-ACVC QI sets, the corresponding QI was "adequate P2Y12" on discharge. "Adequate P2Y12" is not difficult to assess from existing variables and the selection between clopidogrel and prasugrel/ticagrelor denotes quality (Open Heart. 2016 May 23;3(1):e000384. doi: 10.1136/openhrt-2015-000384). | Thank you for your comment. |
| 33 | 3 IND2020- 106 | Individual 1 | See above for comments on implementation. There are a small minority patients who will be on P2Y12 and oral anticoagulant, hopefully these would be coded as not indicated. | Thank you for your comment. Patients on anticoagulation have been excluded from this indicator. |

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|----------|--------------------------|--|--------------------|
| | question | | | |
| | no. | | | |
| 34 | IND2020- | Amgen Ltd. | As called out in the NHS Long Term Plan achieving improved | Thank you for your |
| | 107 | | outcomes in patients with cardiovascular disease is a key priority and within this, improving the management of raised cholesterol is also a key priority alongside atrial fibrillation and raised blood pressure. We fully support the development of a QI that will help drive improved patient outcomes by tackling raised cholesterol in | comment. |
| | | | We believe that the removal of cholesterol from most of the OoF | |
| | | | indicators in 2014/15 had a detrimental effect on the performance of | |

| | | | primary care in managing patients with raised cholesterol. This has been backed up in the PRUComm research [1] that showed the removal of CHD03 (The percentage of patients with CHD whose last measured total cholesterol (in the preceding 15 months) is 5 mmol/l or less) led to an almost 20% drop off in a year. Creating the quality indicator is a move in the right direction. We would also strongly recommend that this be developed into a full Quality and Outcomes Framework indicator and incorporated into the primary care remuneration mechanism. [1] IMPACT OF REMOVING INDICATORS FROM THE QUALITY AND OUTCOMES FRAMEWORK: RETROSPECTIVE STUDY USING INDIVIDUAL PATIENT DATA IN ENGLAND; Report to NHS England 28 June 2018. Policy Research Unit Commissioning and the Healthcare System. | |
|----|-----------------|--------------|--|---|
| 35 | IND2020- 107 | Individual 1 | MINAP only currently records statin use where as the QI is for high intensity statin, so one can only collect data on statin therapy. However, most centres will default to high intensity statin post AMI so using it as a surrogate is reasonable. I don't think rewording takes away from the indicator given previous observation. Although attainment is high and not sure measuring it adds to quality improvement. | Thank you for your comment. The proposed indicator did not progress to the NICE menu. |

Question 11: Prescription of high-intensity statins or named formulations/doses are not collected by the MINAP dataset. Should the data field of 'statin on discharge' be used as a proxy for high-intensity statin?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|-------------------|--------------------------|--|--|
| | no. | | | |
| 36 | 11 | Amgen Ltd. | As stated in question 13 of this consultation, a significant percentage of patients (97.7%) are discharged from hospital on a statin, however this does not capture whether patients are appropriately discharged on a high intensity statins in line with NICE Guidelines | Thank you for your comment. The proposed indicator |

| | | | (ref CG181) and there is also evidence to suggest that many patients do not adhere to their statins [1]. The evidence linking a patient's risk reduction of suffering a CVD event to their level of cholesterol reduction is very clear. The Major lipid trials meta-analysis [2], demonstrated a clear liner relationship between the lowering of LDL cholesterol and a reduction in risk of CV events. If a quality indicator is aligned to a patient simply being discharged on any statin, then achieving quality care will be judged to have been successful if this has been achieved. This would however be a missed opportunity given the evidence is clear that better patient care and improved outcomes would be achieved by driving uptake of high intensity statins and more intensive lowering of cholesterol. It is also not in line with NICE guidelines. We believe this would represent a missed opportunity for further reducing cholesterol levels, and hence CV risk, in this high-risk group of patients if 'statin on discharge' is used as a proxy for high-intensity statin. As such we would suggest that 'high intensity statin on discharge' would be a far better data field to capture. [1] A longitudinal evaluation of cardiovascular risk factors, treatment patterns, and outcomes in patients with documented cardiovascular disease treated with lipid lowering therapy in the United Kingdom. Beaini et al. ESC 2020 abstract. [2] Major lipid trials meta-analysis; LDL-C levels vs rates of coronary events by Sabatine, M., Cleveland Clinic Journal of Medicine. 2016, 83 (3) 181-186 | did not progress to the NICE menu. |
|----|----|-----------------------------------|--|---|
| 37 | 11 | British Cardiovascular Society | Yes, reasonable to assume this | Thank you for your comment. The proposed indicator did not progress to the NICE menu. |

Question 12: NICE guidance recommends that a statin of high intensity and low acquisition cost be used when a decision has been made to prescribe a statin. There is misalignment between the definition of a high-intensity statin in the indicator specification based on the ESC guidance and that in NICE guidance. Would rewording of the indicator to measure prescription of a statin on discharge, not restricted to high intensity, alter the intent of the indicator?

| ID | Proforma | Stakeholder organisation | Comment | NICE response |
|----|----------|-----------------------------------|--|---|
| | question | | | |
| 38 | 12 | Amgen Ltd | As in our response to question 11, we believe it is very important to drive the use of high intensity statins in this group of patients to reduce their risk of suffering a further cardiovascular event as much as possible. Supporting discharge on any statin would not align to this and indeed may further increase lower intensity statin use. We would go a step further and recommend alignment to the more aggressive and target driven approach adopted by the ESC of ≥50 LDL-c reduction and/or an LDL-c level ≤1.4mmol/I [1]. This is in keeping with the evidence as described by Sabatine et al in point 2 above. | Thank you for your comment. The proposed indicator did not progress to the NICE menu. Additional areas for indicators proposed by stakeholders have been logged for potential further indicator development. |
| | | | European Heart Journal (2020) 41, 111188. | |
| 39 | 12 | British Cardiovascular Society | Yes. All statins are cheap nowadays so that's not really an issue. | The proposed indicator did not progress to the NICE menu. |
| 40 | 12 | European Society of Cardiology | Question for consultation: MINAP needs to record statin intensity at discharge. The use of high intensity statins (and not just "statins") is a high grade recommendation from the ESC since 2011, based on the PROVEit study (2004). In the current context of the confirmed | The proposed indicator did not progress to the NICE menu. Additional |

| | causality of LDL in atherosclerosis, the validation of ezetimibe on top of statins <10 days post AMI and the potential need for PCSK9i, MINAP should record not only the type and dose of statins, but also LDL-cholesterol at admission, and ezetimibe at admission and at discharge. A single center experience reported that post ACS, in a population discharged with 100% high-intensity statins combined with ezetimibe in 65%, less than half of the patients will reach the ESC LDL-c target during follow-up. Thus, there is much more to do in this field than just prescribing a statin. (Eur Heart J Acute Cardiovasc Care 2020 Dec;9(8):879-887 doi: 10.1177/2048872620912639.) | areas for indicators proposed by stakeholders have been logged for potential further indicator development. |
|--|--|---|
|--|--|---|

Question 13: 97.7% of participants in the MINAP audit received a statin on discharge in the summary report from 2019. Do you think this is an area for quality improvement in England?

| ID | Proforma question | Stakeholder organisation | Comment | NICE response |
|----|----------------------|-----------------------------------|--|--|
| 41 | 13 | Amgen Ltd | Albeit 97.7% is an average of all trusts across England, it is unlikely there will be significant variation from this. As such we do not believe there is much improvement in quality and patient outcomes to be gained by driving this further, nor is it likely to be easy getting the final 1% or 2% as the law of diminishing return takes place; huge amount of effort to gain just 1% or 2%. We would also draw your attention to our responses to questions 11 and 12. Being discharged on any statin is better than no statin, but it is critical that patients receive the correct statin i.e. a high intensity statin in keeping with the evidence to reduce the risk of a patient suffering a further cardiovascular event. | The proposed indicator did not progress to the NICE menu. |
| 42 | 13 | British Cardiovascular Society | Not really. If you are looking for improvement, you want to know what their LDL cholesterol level is a month or two after leaving | The proposed indicator did not progress to the NICE |

| | hospital and seeing if it is adequately controlled. This is info only available through primary care though. | menu. Additional areas for indicators proposed by stakeholders have been logged for potential further indicator |
|--|--|---|
| | | aevelopment. |