**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**INDICATOR DEVELOPMENT PROGRAMME**

**Consultation report**

**Indicator area:** Heart failure

**Consultation period:** 17 April - 16 May 2019

**Date of Indicator Advisory Committee meeting:** 4 June 2019

**Output:** New indicators for general practice

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# Introduction

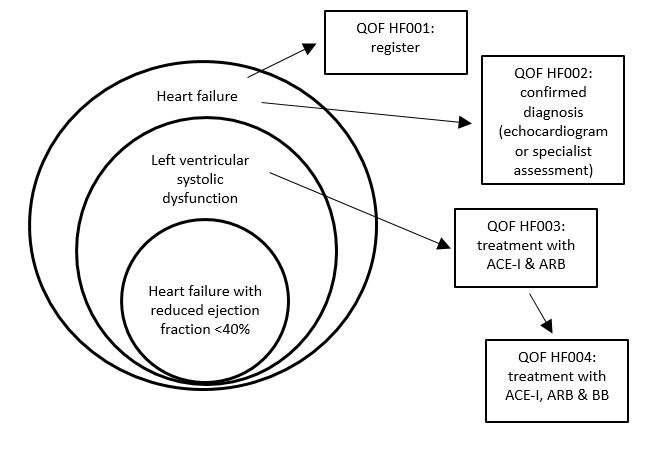
The [QOF review](https://www.england.nhs.uk/publication/report-of-the-review-of-the-quality-and-outcomes-framework-in-england/) recommended refreshing and renewing indicators with a focus on personalised care, addressing over- and under-treatment, and ensuring the best outcomes for patients.

In February and April 2019, a working group convened to consider what matters most to people with heart failure and how best to help them achieve their best outcomes. The group had representation from:

* British Society for Heart Failure
* BMA’s GPC
* North East Quality Observatory Service
* NHS Digital
* NHS England
* Guideline Development Group / RCGP
* NICE including IAC members

The results of these discussions were presented for public consultation in April 2019. The Indicator Advisory Committee is asked to consider this feedback and advise on inclusion on the NICE indicator menu.

# Summary of indicators currently included in QOF



# Summary of indicators included in the consultation

|  |  |  |  |
| --- | --- | --- | --- |
| **NICE Consultation ID** | **Existing QOF indicator** | **Proposed new indicator** | **Evidence source** |
| N/A | HF001: The contractor establishes and maintains a register of patients with heart failure | N/A | N/A |
| IND69 | HF002: The percentage of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2006) which has been confirmed by an echocardiogram or by specialist assessment 3 months before or 12 months after entering on to the register  NICE menu ID: NM116. | The percentage of patients with a diagnosis of heart failure (diagnosed on – date of implementation) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before or 3 months after entering on to the register. | [Chronic heart failure in adults](https://www.nice.org.uk/guidance/ng106) (2018) NICE guideline NG106, recommendations 1.2.3 and 1.2.4 |
| IND70 | HF003: In those patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, the percentage of patients who are currently treated with an ACE-I or ARB.  NICE menu ID: NM89 | The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ACE-I or ARB. | [Chronic heart failure in adults](https://www.nice.org.uk/guidance/ng106) (2018) NICE guideline NG106, recommendation 1.4.1. |
| IND71 | HF004: In those patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction who are currently treated with an ACE-I or ARB, the percentage of patients who are additionally currently treated with a beta-blocker licensed for heart failure.  NICE menu ID: NM90 | The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with a beta-blocker licensed for heart failure. | [Chronic heart failure in adults](https://www.nice.org.uk/guidance/ng106) (2018) NICE guideline NG106, recommendation 1.4.1 |
| IND72 | N/A | The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months | [Chronic heart failure in adults](https://www.nice.org.uk/guidance/ng106) (2018) NICE guideline NG106, recommendations 1.7.1 and 1.7.3. |

# IND69 Confirmed diagnosis

*The percentage of patients with a diagnosis of heart failure (diagnosed on – date of implementation) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before or 3 months after entering on to the register.*

**Rationale**

Earlier diagnosis in primary care allows treatment initiation, potentially avoids emergency admission to hospital, and improves patient outcomes ([Taylor et al. 2019).](https://www.bmj.com/content/364/bmj.l223) The NHS Long term Plan ([NHS England 2019](https://www.longtermplan.nhs.uk/)) promises greater access to echocardiography to improve the early detection of heart failure.

The new indicator reduces the timeframe for confirming diagnosis after entry on the register to help ensure that people with heart failure receive the right diagnosis and receive timely treatment that can control symptoms, improve quality of life and help reduce premature mortality.

**Summary of consultation comments**

Stakeholders made the following positive comments in relation to this indicator:

* General support for this indicator.
* Suggested tightened timeframe would have a beneficial effect on the identification and treatment of patients with heart failure.

Stakeholders outlined the following concerns about the indicator:

* Increasing echocardiography in order to detect HF may result in significant cost and increased time pressure within practice and have negative impact on detection rates as a result.
* An indicator solely reliant on echocardiogram or specialist assessment is not representative of the NICE guideline / clinical practice; using NT-proBNP for diagnosis should also be considered for inclusion.
  + Suggestion for alternative wording: the percentage of patients with suspected HF referred for confirmation of diagnosis by echocardiogram or specialist assessment within 2 weeks (if NT-proBNP levels >2,000ng/l) or within 6 weeks (if 400-2,000ng/l).

**Considerations for the advisory committee**

The committee is asked to consider:

* Potential for increased significant costs and time pressure.
* Including NT-proBNP for diagnosis
* Potential to improve patient outcomes by facilitating earlier diagnosis.

# IND70 Pharmacological treatment (ACE-I or ARB)

*The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ACE-I or ARB.*

**Rationale**

There is good evidence ([NICE NG106](https://www.nice.org.uk/guidance/ng106)) that prescribing ACE-I/ARB as well as beta-blockers for heart failure with reduced ejection fraction below 40%, can improve symptoms, reduce hospitalisation rate and improve survival.

The latest NICE guideline (NG106) defines heart failure with reduced ejection fraction (HFREF) as heart failure characterised by a left ventricular ejection fraction (LVEF) of less than 40%. The new indicator will support the recording of LVEF through including the LVEF recording in the indicator denominator code clusters.

This indicator focusses on ACE-I or ARBs only to help ensure the denominator size is large enough at practice level to not be subject to random variation in achievement.

**Summary of consultation comments**

Stakeholders made the following positive comments in relation to this indicator:

* Support for splitting the 2 indicators and looking at people with heart failure due to left ventricular systolic dysfunction rather than the subgroup prescribed ACE-I/ARB.

Stakeholders outlined the following concerns about this indicator:

* Difficulty of using 2 terms: left ventricular systolic dysfunction (LVSD) and heart failure with reduced ejection fraction (HFREF)
  + complexity of 'read codes' and QoF rules requiring entering two codes to annotate HFREF (one for HF and one for reduced LV function)
  + lack of awareness of this requirement in many practices - the dominator and the indicator become invalid
  + echocardiograms often reported with a range of ejection fraction or described as mild, moderate or severely impaired, as opposed to a precise figure
  + suggestion that HFREF code should be added on the register if:
    - LVEF available and <40%
    - No LVEF available on echocardiogram but described as having moderate, moderate to severe or severe LV systolic impairment
    - A HF specialist team has labelled patient as having HFREF and decided to start ACEi/ARB and BB (this may include some patients with LVEF <45%)
* Lack of clarity on terminology may result in patients not being managed appropriately.
* Several stakeholders suggested that ARNI (Sacubitril valsartan) should be specifically highlighted in addition to ACE-I and ARB.
* One stakeholder raised concerns that separating the indicator for treatment with beta-blockers from co-prescribing with ACE-I/ARB could slow the achievement of optimal patient therapy by adding an additional step to the treatment pathway.

**Considerations for the advisory committee**

The committee is asked to consider:

* Potential for over-treatment and misalignment with NICE guidance when referring to people with LVSDs as opposed to people with HFREF
* Potential for under treatment when referring to people with HFREF as defined by NICE guidance
* Including treatment with ARNI alongside ACE-I and ARB.

# IND71 Pharmacological treatment (Beta-blockers)

*The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with a beta-blocker licensed for heart failure*

**Rationale**

There is good evidence (NICE NG106) that prescribing ACE-I/ARB as well as beta-blockers for heart failure with reduced ejection fraction below 40%, can improve symptoms, reduce hospitalisation rate and improve survival.

The latest NICE guideline (NG106) defines heart failure with reduced ejection fraction (HFREF) as heart failure characterised by a left ventricular ejection fraction (LVEF) of less than 40%. The new indicator will support the recording of LVEF through including the LVEF recording in the indicator denominator code clusters.

This indicator focusses on beta-blockers only to help ensure the denominator size is large enough at practice level to not be subject to random variation in achievement.

**Summary of consultation comments**

Stakeholders made the following positive comments in relation to this indicator:

* Support for splitting the 2 existing QOF indicators.
* Support for prescribing beta-blockers as standard practice for people with heart failure due to left ventricular systolic dysfunction rather than the subgroup prescribed ACE-I/ARB.

Stakeholders outlined the following concerns about this indicator:

* Separating the indicator for treatment with beta-blockers from co-prescribing with ACEi/ARB could slow the achievement of optimal patient therapy by adding an additional step to the treatment pathway.

**Considerations for the advisory committee**

The committee is asked to consider:

* Potential for over-treatment and misalignment with NICE guidance when referring to people with LVSDs as opposed to people with HFREF
* Potential for under treatment when referring to people with HFREF as defined by NICE guidance

# IND72 Clinical review

*The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months.*

**Rationale**

The New York Heart Association classification allows people with heart failure a method of classifying and monitoring their condition, this classification can be used to guide future treatment and care.

The NICE guideline for heart failure (NG106) highlights the importance of medicines optimisation for people receiving treatment. [Taylor et al.](https://www.bmj.com/content/364/bmj.l223) (2019) found that while there have been gradual improvements in survival rates, the outlook for people after a new diagnosis remains poor. Conrad et al (2018) highlighted improvements in the initiation of pharmacological treatment but noted opportunities for improvement in medicines optimisation.

**Summary of consultation comments**

Stakeholders made the following positive comments in relation to this indicator:

* Support for an indicator that would facilitate regular reviews of functional capacity and medication in patients with heart failure.
* Annual review expected to improve medicines optimisation and patient outcomes.

Stakeholders outlined the following concerns about this indicator:

* The review should be carried out every 6 months in line with NICE guideline recommendations.
* Proposed wording may be interpreted as requiring only the review of medication to have taken place in the preceding 12 months.
  + Alternative suggestion: the percentage of patients on the register with heart failure, who had a review undertaken by a healthcare professional in the preceding 12 months, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication.
* There should be clear guidance about what action should be taken in the event of a deviation from the projected NYHA score.

**Considerations for the advisory committee**

The committee is asked to consider:

* Practicalities of measuring 6 monthly reviews.
* Opportunities to improve patient outcomes by optimising medication.

# General comments

* Most stakeholders agreed that the proposed changes are achievable and would improve the diagnosis and management of heart failure.
* Stakeholders highlighted the complexity of coding HF and consequent need for clear and pragmatic guidance for GPs and other staff involved in the management of patients with heart failure and the associated registries. They suggested that a set of advisory codes should be sent out with the QOF document.
* Several stakeholders suggested topics not included in this consultation that could be explored further.

# Suggestions for additional indicators

* Indicator on prescribing Mineralocorticoid receptor antagonists (MRA) should be added.
* Capturing the type of heart failure and supporting data points would be valuable. Metrics could include:
  + the quantitative measure of ejection fraction
  + NYHA1 classification
  + disease severity of heart failure
* 12-month medication review in patients with myocardial infarction (MI).
* Indicators looking at both systolic and diastolic dysfunction when assessing for HF.
* Proactive metrics for HF that address pre-diagnosis stage such as identifying people at risk of HF among those with multi-morbidity or older people.

# Appendix A: Consultation comments

Please note:

* British Cardiovascular Society (BCS) and British Society for Heart Failure (BSH) submitted the same comments.
* Alliance for Heart Failure, Roche Diagnostics Limited and Novatris submitted very similar comments.

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Indicator** | **Stakeholder** | **Comment** |
| 1 | **General** | **Royal College of Nursing** | The Royal College of Nursing (RCN) welcome the consultation on the listed NICE QOF indicators. The RCN invited members who care for people with the listed conditions to review the draft indicators on our behalf. The comments below reflect the views of our reviewers. |
| 2 | **General** | **Royal College of Physicians** | The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the responses submitted by the British Association for Sexual Health & HIV (BASHH) and British Thoracic Society (BTS). |
| 3 | **General** | **Bayer PLC** | Bayer plc supports all proposed amendments to the heart failure indicators and the inclusion of new indicator IND72 |
| 4 | **General** | **Royal College of Nursing** | All the proposed changes should be easy to achieve and will improve the detection and management of heart failure. |
| 5 | **General** | **Elcena Jeffers Foundation** | There is a wish to know about self-care in general public education in life as different people has different diseases or ailments |
| 6 | **General** | **Boehringer Ingelheim Limited** | General comment. The consultation changes focus on a narrow range of therapeutic agents, with proven CV and HF benefits. Boehringer Ingelheim is in agreement with all approaches using evidence based medicine, particularly where an agent has demonstrated overall mortality benefits.Recent therapies within the class of diabetes have provided a useful addition to the compendium of agents that a physician can utilise to treat their patients with uncontrolled type 2 diabetes mellitus, but which have also demonstrated significant cardiovascular mortality improvements and hospitalisation for heart failure reductions vs standard of care. One such example is Empagliflozin, an agent from the Sodium Glucose co-transporter 2 class (SGLT2-i) which demonstrated a 32% RRR (2.2% ARR) of cardiovascular death death and 35% RRR of hospitalisation for Heart Failure (1.4% ARR) vs standard of care. Considering the co-existence of type 2 diabetes and within the context of patients who present to the physician with signs and symptoms of HF, these agents may be appropriate for consideration where these conditions co-present. https://www.nejm.org/doi/full/10.1056/NEJMoa1504720 |
| 7 | **IND69** | **Alliance for Heart Failure** | We welcome the drive for earlier specialist assessment given the clear benefits this has been shown to have for patients. Given the high risk of death or hospitalisation faced by heart failure patients, and the high demand on heart failure clinical services, we believe a change to this indicator could improve the speed and quality of patient referrals. We believe that, in alignment with the NICE guidelines on Heart Failure, the percentage of patients with a diagnosis of heart failure using NT-proBNP should be considered for inclusion. The Chronic Heart Failure: Diagnosis and Management (NG106) and Acute heart failure: diagnosis and management (CG187) guidelines both recommend the use of NT-proBNP in diagnosis and we therefore believe using an indicator which is solely reliant on echocardiogram or specialist assessment is not representative of clinical practice.  Please see the recommendations below which support the use of NT-proBNP: 1.     Chronic Heart Failure: Diagnosis and Management (NG106) 1.2.1 Take a careful and detailed history and perform a clinical examination and tests to confirm the presence of heart failure. [2010] 1.2.2 Measure N-terminal pro-B-type natriuretic peptide (NT‑proBNP) in people with suspected heart failure. [2018] 1.2.3 Because very high levels of NT‑proBNP carry a poor prognosis, refer people with suspected heart failure and an NT‑proBNP level above 2,000 ng/litre (236 pmol/litre) urgently, to have specialist assessment and transthoracic echocardiography within 2 weeks. [2018] 1.2.4 Refer people with suspected heart failure and an NT‑proBNP level between 400 and 2,000 ng/litre (47 to 236 pmol/litre) to have specialist assessment and transthoracic echocardiography within 6 weeks. [2018] Ref: National Institute for Health and Care Excellence (NICE). Chronic heart failure in adults: diagnosis and management (NG106) 2018. Available from: https://www.nice.org.uk/guidance/ng106 [Accessed 2 May 2019] 2.     Acute Heart Failure: Diagnosis and Management (CG187) 1.2.1 Take a history, perform a clinical examination and undertake standard investigations – for example, electrocardiography, chest X‑ray and blood tests – in line with chronic heart failure (NICE guideline CG108). 1.2.2 In people presenting with new suspected acute heart failure, use a single measurement of serum natriuretic peptides (B‑type natriuretic peptide [BNP] or N‑terminal pro‑B‑type natriuretic peptide [NT‑proBNP]) and the following thresholds to rule out the diagnosis of heart failure: - BNP less than 100 ng/litre - NT-proBNP less than 300ng/litre Ref: National Institute for Health and Care Excellence (NICE). Acute heart failure: diagnosis and management (CG187) 2014. Available from: www.nice.org.uk/guidance/CG187 [Accessed 2 May 2019] |
| 8 | **IND69** | **Alliance for Heart Failure** | Around 80% of Heart Failure cases in England are currently diagnosed in hospital despite approximately 40% of patients having symptoms that should have triggered earlier assessment in Primary Care.​1​ This is recognised in the NHS Long Term Plan and a focus is given in the document to people with heart failure being better supported by multi-disciplinary teams as part of primary care networks.​2​ Clinical Commissioning Groups (CCGs) should be encouraged to implement the recommendations in the NHS Long Term Plan and we believe that this could be supported by the inclusion of NT-proBNP testing which is also available in the point of care setting. 1. Bottle A., Kim D., Aylin P., Cowie M.R., Majeed A., Hayhoe B. Routes to diagnosis of heart failure: observational study using linked data in England. Heart. 2017;104(7):600–5. 2. NHS. The NHS Long Term Plan. 2019. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf [Accessed 2 May 2019] |
| 9 | **IND69** | **AstraZeneca** | AstraZeneca welcomes the decision to reduce the timeframe for confirming diagnosis after entry on the register. It is estimated that heart failure affects over 920,000 people in the U.K. and only 550,000 are registered with on their GP’s heart failure register1. Pharmacological treatments, devices, and exercise-based rehabilitation can improve outcomes for patients with heart failure and so early diagnosis is crucial for timely initiation of evidence-based treatments. In addition to a diagnosis of heart failure which has been confirmed by an echocardiogram or by specialist assessment, AstraZeneca proposes the inclusion of pro-B-type natriuretic peptide (NT-proBNP) to meet NICE diagnostic guidance in heart failure2, which would support uniform availability and awareness. 1.     https://www.bhf.org.uk/for-professionals/press-centre/facts-and-figures 2.     Chronic heart failure in adults: diagnosis and management, NICE guideline NG106 (Recommendation 1.2.2 https://www.nice.org.uk/guidance/ng106/chapter/Recommendations#diagnosing-heart-failure Last accessed May 2019) |
| 10 | **IND69** | **Boehringer Ingelheim Limited** | Do you think there are any barriers to implementing the care described? Whilst desire for increased echocardiography in order to detect HF is a welcome sign, this may represent significant cost and time pressure constraints within practice and the subsequent detection rates as a result subpar. In addition, there needs to be a clear directive set to primary care in identifying patients who may show signs or symptoms of HF and escalating them through to secondary care, so to prevent delay in management. |
| 11 | **IND69** | **Boehringer Ingelheim Limited** | Do you think there are potential unintended consequences to implementing / using the indicators? The impact on resources and full assessment of and clear identification needs to be mapped through primary to secondary care so that the optimal pathway can be developed. |
| 12 | **IND69** | **Boehringer Ingelheim Limited** | Do you think the proposed indicators will lead to improvements in care and outcomes for patients? We welcome the update to the HF indicators, particularly the benefits of detecting and identifying the earlier diagnosis of patients with heart failure. By reducing the timeframes for diagnosis, this is a positive step which will enable patients to commence treatment for this condition earlier, thereby minimising morbidity and mortality, whilst also reducing strain within the NHS. |
| 13 | **IND69** | **British Cardiovascular Society (BCS)** | The percentage of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2019) which has been confirmed by an echocardiogram or by specialist assessment 3 months before or 3 months after entering on to the register. The BCS is pleased that the timeframe has been condensed, and feel that this change will have a beneficial effect on the identification and treatment of patients with heart failure. However, we have concerns that there are practical difficulties for general practitioners in coding patients with left ventricular systolic dysfunction (LVSD) or heart failure with reduced ejection fraction (HF-REF). There is difficulty with both terms being used. This might mean that some patients with heart failure are not managed according to the recommended standards. We would also like clarification that additional codes on the general practice electronic medical records are not necessary to place a patient on the practice’s heart failure register. The BCS would like to highlight particular issues with the differences between heart failure with preserved ejection fraction (HF-PEF) and heart failure with reduced ejection fraction (HF-REF). It is the latter where there are clear data that interventions can transform patient well-being and prognosis. Echocardiograms are often reported with a range of ejection fraction or even as mild, moderate or severely impaired, as opposed to a precise figure. We need to ensure that the vast majority (ideally all) of suitable patients are assessed for potentially life-saving medication. There is a need for clear and pragmatic guidance for GPs and other staff involved in the management of patients with heart failure and the associated registries. There is marked complexity of 'read codes' and QoF rules. Our understanding is that you also need to enter two codes to annotate HF-REF (one for HF and one for reduced LV function) and lots of practices are unaware of this. The rest of the indicators become meaningless unless we can ensure the denominator is valid. A set of advisory codes sent out with the QOF document. For example, we would propose recommendations for general practice, which are outlined below. HF-REF code should be added if : 1.LVEF available and <40%. 2.No LVEF available on echocardiogram but described as having moderate, moderate to severe or severe LV systolic impairment.  3.A HF specialist team has labelled patient as having HFREF and decided to start ACEi/ARB and BB etc (this may include some patients with LVEF <45%) Otherwise GPs may get confused and potentially deny patients treatment (or over treat) A footnote on coding as HFPEF may need to be added too: Label of HFPEF if LVEF >50% with symptoms and signs of HF, raised BNP and evidence of diastolic impairment on echocardiogram or labelled as such by specialist HF team. |
| 14 | **IND69** | **British Medical Association** | IND69: The percentage of patients with a diagnosis of heart failure (diagnosed on – date of implementation) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before or 3 months after entering on to the register.  We support the changes to this indicator. |
| 15 | **IND69** | **British Society for Heart Failure (BSH)** | The percentage of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2019) which has been confirmed by an echocardiogram or by specialist assessment 3 months before or 3 months after entering on to the register. The Board of the British Society of Heart Failure (BSH) is pleased that the timeframe has been condensed, and feel that this change will have a beneficial effect on the identification and treatment of patients with heart failure. However, the Society has concerns that there are practical difficulties for general practitioners in coding patients with left ventricular systolic dysfunction (LVSD) or heart failure with reduced ejection fraction (HF-REF). There is difficulty with both terms being used. This might mean that some patients with heart failure are not managed according to the recommended standards. The Board would also like clarification that additional codes on the general practice electronic medical records are not necessary to place a patient on the practice’s heart failure register.  The Board would like to highlight particular issues with the differences between heart failure with preserved ejection fraction (HF-PEF) and heart failure with reduced ejection fraction (HF-REF). It is the latter where there are clear data that interventions can transform patient well-being and prognosis. Echocardiograms are often reported with a range of ejection fraction or even as mild, moderate or severely impaired, as opposed to a precise figure. We need to ensure that the vast majority (ideally all) of suitable patients are assessed for potentially life-saving medication. There is a need for clear and pragmatic guidance for GPs and other staff involved in the management of patients with heart failure and the associated registries. There is marked complexity of 'read codes' and QoF rules. Our understanding is that you also need to enter two codes to annotate HF-REF (one for HF and one for reduced LV function) and lots of practices are unaware of this. The rest of the indicators become meaningless unless we can ensure the denominator is valid.  A set of advisory codes sent out with the QOF document. For example, the Board have proposed recommendations for general practice, which are outlined below:  HF-REF code should be added if : 1.LVEF available and <40%. 2.No LVEF available on echocardiogram but described as having moderate, moderate to severe or severe LV systolic impairment.  3.A HF specialist team has labelled patient as having HFREF and decided to start ACEi/ARB and BB etc (this may include some patients with LVEF <45%) Otherwise GPs may get confused and potentially deny patients treatment (or over treat) A footnote on coding as HFPEF may need to be added too: Label of HFPEF if LVEF >50% with symptoms and signs of HF, raised BNP and evidence of diastolic impairment on echocardiogram or labelled as such by specialist HF team. |
| 16 | **IND69** | **National Pharmaceutical Advisers Group (PAG)** | Reduction in timeframe to 3 months from 12 months to diagnosis and earlier starting of treatment should improve outcomes |
| 17 | **IND69** | **Novartis Pharmaceuticals UK Ltd** | We welcome the drive for earlier specialist assessment given the clear benefits this has been shown to have for patients. Given the high risk of death or hospitalisation faced by heart failure patients, and the high demand on heart failure clinical services, we believe a change to this indicator could improve the speed and quality of patient referrals. We suggest rewording the indicator as follows, to include upfront measurement of NT-proBNP in line with recently published NICE guidance1: “**The percentage of patients with suspected HF referred for confirmation of diagnosis by echocardiogram or specialist assessment within 2 weeks (if NT-proBNP levels >2,000ng/l) or within 6 weeks (if 400-2,000ng/l)**.” References: 1.     NICE. Chronic Heart Failure (CHF) in Adults: Diagnosis and Management, NICE Guideline 106. September 2018. Accessed May 2019: https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685 |
| 18 | **IND69** | **Roche Diagnostics Limited** | We believe that in alignment with the NICE guidelines on Heart Failure, that the percentage of patients with a diagnosis of heart failure using NT-proBNP should be considered for inclusion. The Chronic Heart Failure: Diagnosis and Management (NG106) and Acute heart failure: diagnosis and management (CG187) guidelines both recommend the use of NT-proBNP in diagnosis and we therefore believe using an indicator which is solely reliant on echocardiogram or specialist assessment is not representative of clinical practice.  Please see the recommendations below which support the use of NT-proBNP: 1.     Chronic Heart Failure: Diagnosis and Management (NG106) 1.2.1 Take a careful and detailed history, and perform a clinical examination and tests to confirm the presence of heart failure. [2010] 1.2.2 Measure N-terminal pro-B-type natriuretic peptide (NT-proBNP) in people with suspected heart failure. [2018] 1.2.3 Because very high levels of NT-proBNP carry a poor prognosis, refer people with suspected heart failure and an NT‑proBNP level above 2,000 ng/litre (236 pmol/litre) urgently, to have specialist assessment and transthoracic echocardiography within 2 weeks. [2018] 1.2.4 Refer people with suspected heart failure and an NT-proBNP level between 400 and 2,000 ng/litre (47 to 236 pmol/litre) to have specialist assessment and transthoracic echocardiography within 6 weeks. [2018] Ref: National Institute for Health and Care Excellence (NICE). Chronic heart failure in adults: diagnosis and management (NG106) 2018. Available from: https://www.nice.org.uk/guidance/ng106 [Accessed 2 May 2019] 2.     Acute Heart Failure: Diagnosis and Management (CG187) 1.2.1 Take a history, perform a clinical examination and undertake standard investigations – for example, electrocardiography, chest X-ray and blood tests – in line with chronic heart failure (NICE guideline CG108). 1.2.2 In people presenting with new suspected acute heart failure, use a single measurement of serum natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NT-proBNP]) and the following thresholds to rule out the diagnosis of heart failure:  - BNP less than 100 ng/litre - NT‑proBNP less than 300 ng/litre. Ref: National Institute for Health and Care Excellence (NICE). Acute heart failure: diagnosis and management (CG187) 2014. Available from: www.nice.org.uk/guidance/CG187 [Accessed 2 May 2019] |
| 19 | **IND69** | **Roche Diagnostics Limited** | We believe that there is a lack of awareness amongst healthcare professionals of the recommendations of NT-proBNP in the diagnosis of heart failure. In alignment with ensuring improved patient outcomes, we feel that the indicators should be reflective of NICE guidelines as they are recognised by many stakeholders for having clear and robust recommendations which are built on a solid evidence base. The inclusion of NT-proBNP in IND69 would support driving practice of NICE recommendations by incentivising their implementation. |
| 20 | **IND69** | **Roche Diagnostics Limited** | Around 80% of Heart Failure cases in England are currently diagnosed in hospital despite approximately 40% of patients having symptoms that should have triggered earlier assessment in Primary Care.1 This is recognised in the NHS Long Term Plan and a focus is given in the document to people with heart failure being better supported by multi-disciplinary teams as part of primary care networks.2 Clinical Commissioning Groups (CCGs) should be encouraged to implement the recommendations in the NHS Long Term Plan and we believe that this could be supported by the inclusion of NT-proBNP testing which is also available in the point of care setting.  1. Bottle A., Kim D., Aylin P., Cowie M.R., Majeed A., Hayhoe B. Routes to diagnosis of heart failure: observational study using linked data in England. Heart. 2017;104(7):600–5. 2. NHS. The NHS Long Term Plan. 2019. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf [Accessed 2 May 2019] |
| 21 | **IND69** | **Royal College of General Practitioners** | IND69: The percentage of patients with a diagnosis of heart failure (diagnosed on – date of implementation) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before or 3 months after entering on to the register. We support this change |
| 22 | **IND70** | **Alliance for Heart Failure** | Currently, there is no reference to ‘ARNi’ as a distinct drug class in the HF QOF menu. This means HCPs may not be accurately capturing use of ARNi treatment as opposed to other drug classes listed in the indicator menu. For example, while sacubitril/valsartan is technically included in the QOF dataset due to its ARB component (valsartan is an ARB), we believe this fact should be made explicit to avoid any confusion on this point. Consequently, we support the current wording of IND70 subject to the proposed inclusion of an additional indicator that makes reference to ‘ARNi’ as a discreet drug class (see below ‘proposed additional indicator’). We believe this will add sufficient clarification to the indicator menu to enable the precise capture of treatment regimens. In the event that our proposed new indicator (below) is not adopted, we propose clarifying IND70 to avoid any confusion on the classification of treatments as stated. In this case, we would propose IND70 is reworded as follows to avoid any confusion on this point: “The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ACEi, ARB or ARNi.” |
| 23 | **IND70** | **AstraZeneca** | Hospital admissions for uraemia that are related to use of angiotensin converting enzyme inhibitors are still commonplace, but many cases are preventable by testing of renal function. The most vulnerable patients are elderly people and those with heart failure, chronic renal impairment, or renovascular disease; acute deterioration of renal function often accompanies an intercurrent illness in such patients. Despite widespread recognition of this risk of treatment with angiotensin converting enzyme inhibitors many general practitioners still do not regularly monitor renal function even in the most vulnerable patients. AstraZeneca believes that the inclusion of renal function/biochemical testing for those patients on renin-angiotensin-aldosterone system inhibitors (RAASi) would reduce this cause of morbidity and admission to hospital and may reduce costs1. P A Kalra, M Kumwenda, P MacDowall, M O Roland et al. 1999. Questionnaire study and audit of use of angiotensin converting enzyme inhibitor and monitoring in general practice: the need for guidelines to prevent renal failure. BMJ 318 234-237. |
| 24 | **IND70** | **AstraZeneca** | Compared to people without diabetes, people with diabetes are more than 2.5 times more likely to experience heart failure. Every year diabetes causes more than 27,000 heart attacks and almost 100,000 cases of heart failure1. Type 2 diabetes mellitus (T2DM) is a highly prevalent disease and a major atherosclerotic cardiovascular disease (ASCVD) risk factor. An aggressive, comprehensive approach to ASCVD risk factor treatment in adults with T2DM reduces ASCVD events. SGLT-2 inhibitors have recently been demonstrated to significantly reduce heart failure in adults with T2DM. Three RCTs have shown a significant reduction in ASCVD events and heart failure with use of an SGLT-2 inhibitor. Although most patients studied had established cardiovascular disease (CVD) at baseline, the reduction in heart failure has been shown to extend to primary prevention populations.2 In patients with T2DM and additional risk factors for CVD, it may be reasonable to initiate this class of medications for primary prevention of CVD and reduction in heart failure.  Given that the recent review of QoF recommended modification of indicators to improve efficacy where there is good evidence, for example through a more targeted approach to population segments3, AstraZeneca would therefore like to see the heart failure pharmacological indicator evolve to include the percentage of patients with a current diagnosis of T2DM and who have additional risk factors for CVD, who are currently treated with SGLT-2 inhibitors.  1.     Diabetes UK: Us, diabetes and a lot of facts and stats. January 2019. ( https://www.diabetes.org.uk/resources-s3/2019-02/1362B\_Facts%20and%20stats%20Update%20Jan%202019\_LOW%20RES\_EXTERNAL.pdf – last accessed May 2019) 2.     Arnett et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease (https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000678- last accessed May 2019) 3.     Report of the Review of the Quality and Outcomes Framework in England. NHS England July 2018. (https://www.england.nhs.uk/wp-content/uploads/2018/07/quality-outcome-framework-report-of-the-review.pdf- last accessed May 2019) |
| 25 | **IND70** | **Boehringer Ingelheim Limited** | Do you think the proposed indicators will lead to improvements in care and outcomes for patients? These developments reflect positive evidence based changes that should improve outcomes for patients with Left ventricular systolic dysfunction. |
| 26 | **IND70** | **British Cardiovascular Society (BCS)** | The percentage of patients with a current diagnosis of heart failure with reduced ejection fraction below 40%, who are currently treated with an ACE-I or ARB. The BCS feel that the use of angiotensin-renin-neprilysin inhibitors (ARNIs), as well as ACEi/ARBs should be included in the outcome measures for QOF. The BCS would also like NICE to consider the use of mineralocorticoid-receptor antagonists (MRAs) in the quality marking framework, as this is a standard treatment with high quality evidence of benefit to a sub-population of patients with heart failure. |
| 27 | **IND70** | **British Medical Association** | IND70: The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ACE-I or ARB We support the changes to this indicator. Note that the word ‘failure’ is missing in the indicator wording. |
| 28 | **IND70** | **British Society for Heart Failure (BSH)** | The percentage of patients with a current diagnosis of heart failure with reduced ejection fraction below 40%, who are currently treated with an ACE-I or ARB. The Board of the BSH feel that the use of angiotensin-renin-neprilysin inhibitors (ARNIs), as well as ACEi/ARBs should be included in the outcome measures for QOF. The Board would also like NICE to consider the use of mineralocorticoid-receptor antagonists (MRAs) in the quality marking framework, as this is a standard treatment with high quality evidence of benefit to a sub-population of patients with heart failure. |
| 29 | **IND70** | **National Pharmaceutical Advisers Group (PAG)** | This indicator will provide greater sensitivity in identification of the proportion of patients with a diagnosis of heart failure that are being treated with an ACE/ ARB |
| 30 | **IND70** | **Novartis Pharmaceuticals UK Ltd** | We support the inclusion of indicators which aim to capture treatment with appropriate therapies. As currently phrased, IND70, which aims to capture patients on recommended ACE inhibitor (ACEi) or angiotensin receptor blocker (ARB) therapy may not support full capture of such patients as intended. Angiotensin receptor neprilysin inhibitors (ARNi) are a distinct class of drug recently introduced in HF, however, there is no reference to ‘ARNi’in the HF QOF menu. For example, while use of the ARNi, sacubitril/valsartan1 could technically be included in the QOF dataset due to its ARB component (valsartan is an ARB), because it is considered as part of a distinct ARNi class we believe HCPs could miss accurately capturing its use. We would recommend explicitly including treatment with ARNi in the HF QOF menu to avoid any confusion on this point. Consequently, we support the current wording of IND70 subject to the proposed inclusion of an additional indicator that makes reference to ‘ARNi’ as a discreet drug class (see below ‘proposed additional indicator’). We believe this will add sufficient clarification to the indicator menu to enable the precise capture of treatment regimens. In the event that our proposed new indicator (below) is not adopted, we propose clarifying IND70 to avoid any confusion on the classification of treatments as stated. In this case, we would propose IND70 is reworded as follows to avoid any confusion on this point: “The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ACEi, ARB or ARNi.”  References: 1.     Novartis manufactures the heart failure medicine Entresto® (sacubitril/valsartan) |
| 31 | **IND70** | **Royal College of General Practitioners** | IND70: The percentage of patients with a current diagnosis of heart **failure** due to left ventricular systolic dysfunction, who are currently treated with an ACE-I or ARB - the word ‘failure’ is missing in the indicator text.  We support this change |
| 32 | **IND71** | **Alliance for Heart Failure** | We have concerns that separating the indicator for treatment with beta-blockers from co-prescribing with ACEi/ARB, as is proposed, couldslow the achievement of optimal patient therapy by adding an additional step to the treatment pathway and should therefore be avoided. This is particularly pertinent considering that the National Heart Failure Audit[1] has consistently highlighted the need to improve the proportion of HFrEF[2] patients placed upon ACEi/ARB and beta-blocker medication. We believe that implementing a composite measure of ACEi/ARB + beta blocker to incentivise optimal therapy as early as possible would improve patient outcomes. We would therefore recommend rewording this indicator as follows, to drive faster achievement of optimal first line pharmacological therapy[3]: “**The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated on optimal first line therapy consisting of ACEi/ARB and beta-blocker (licensed for heart failure).”** |
| 33 | **IND71** | **British Cardiovascular Society (BCS)** | The percentage of patients with a current diagnosis of heart failure with reduced ejection fraction below 40%, who are currently treated with a beta-blocker licensed for heart failure. The BCS is pleased that the prescription of beta-blockers are being recognised as standard practice for all patients with heart failure, rather than only those who are concurrently prescribed ACEi/ARBs. |
| 34 | **IND71** | **British Medical Association** | IND71: The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with a beta-blocker licensed for heart failure. We support the changes to this indicator. |
| 35 | **IND71** | **British Society for Heart Failure (BSH)** | The percentage of patients with a current diagnosis of heart failure with reduced ejection fraction below 40%, who are currently treated with a beta-blocker licensed for heart failure. The Board is pleased that the prescription of beta-blockers are being recognised as standard practice for all patients with heart failure, rather than only those who are concurrently prescribed ACEi/ARBs. |
| 36 | **IND71** | **National Pharmaceutical Advisers Group (PAG)** | This indicator will provide greater sensitivity in identification of the proportion of patients with a diagnosis of heart failure that are being treated with an ACE/ ARB |
| 37 | **IND71** | **Novartis Pharmaceuticals UK Ltd** | We have concerns that separating the indicator for treatment with beta-blockers from co-prescribing with ACEi/ARB, as is proposed, couldslow the achievement of optimal patient therapy by adding an additional step to the treatment pathway and should therefore be avoided. This is particularly pertinent considering that the National Heart Failure Audit1 has consistently highlighted the need to improve the proportion of HFrEF2 patients placed upon ACEi/ARB and beta-blocker medication. We believe that implementing a composite measure of ACEi/ARB + beta blocker to incentivise optimal therapy as early as possible would improve patient outcomes. We would therefore recommend rewording this indicator as follows, to drive faster achievement of optimal first line pharmacological therapy3: “**The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated on optimal first line therapy consisting of ACEi/ARB and beta-blocker (licensed for heart failure).”** References: 1.     NICOR, National Heart Failure Audit 2016/17 Summary Report. November 2018. Accessed May 2019: https://www.nicor.org.uk/wp-content/uploads/2018/11/Heart-Failure-Summary-Report-2016-17.pdf 2.     Heart failure with reduced ejection fraction 3.     NICE. Chronic Heart Failure (CHF) in Adults: Diagnosis and Management, NICE Guideline 106. September 2018. Accessed May 2019: https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685 |
| 38 | **IND71** | **Royal College of General Practitioners** | IND71: The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with a beta-blocker licensed for heart failure. We support this change |
| 39 | **IND72** | **Alliance for Heart Failure** | We welcome the drive for more regular review of patients with heart failure. We would recommend that the timeframe for carrying out these reviews is changed from “in the preceding 12 months” to “in the preceding 6 months”, as well as ensuring that patients’ clinical records are updated following review, to align with recently published NICE guidance[4]. Similarly, we propose the wording “undertaken by a healthcare professional” be amended to “undertaken by the primary care team working with the specialist heart failure multi-disciplinary team”. |
| 40 | **IND72** | **AstraZeneca** | Getting the most from medicines is vital for improving patient outcomes and maximising NHS resources. Patients who receive maximum therapeutic benefit of their medication through optimal medication adherence will result in significantly improved patient outcomes for mortality, quality of life, hospital admissions and cardiovascular events1. There is still huge variation in care for heart failure patients across the UK and so AstraZeneca welcomes the decision by NICE to include a new indicator for those patients with heart failure who have had a review of medication in the preceding 12 months.  AstraZeneca would also like to see this indicator evolve to include the percentage of myocardial infarction (MI) patients who have had a review of medication in the preceding 12 months. In the UK more than 100,000 hospital admissions and more than 200,000 UK hospital visits each year are due to heart attacks.2  Despite advances in treatment and prevention, particularly secondary prevention, MI remains a common and important cause of death and morbidity. UK mortality rates for CHD (of which MI is a preventable complication) are amongst the highest in Western Europe with more than 66,000 deaths per year2.  The NHS Long Term Plan identifies cardiovascular disease as a clinical priority and the single biggest condition where lives can be saved by the NHS over the next 10 years. The Plan sets the ambition for the NHS to help prevent over 150,000 heart attacks, strokes and dementia cases over the next 10 years. The National Institute for Health and Clinical Excellence (NICE), American Heart Association/American College of Cardiology (AHA/ACC) and the European Society of Cardiology (ESC) clinical guidelines recommend risk factor modification by optimisation of drug therapies for secondary prevention in patients who have suffered a myocardial infarction3,4,5,6. It has been estimated that between 30% and 50% of medications prescribed for long-term conditions are not taken as intended. Several studies show that there is a significant level of non-adherence to secondary prevention medicines in patients with Coronary Artery Disease (CAD)7. Primary care plays a significant role in the management of people with CHD including MI. GPs are involved in secondary prevention management, including optimisation of combined drug therapy, blood pressure and cholesterol control to reduce the risk of further MI or other manifestations of vascular disease. NICE clinical guideline 172 makes a number of recommendations that would support the development of a new or revised indicator for MI patients who have had a review of medication in the preceding 12 months. 1.     NICE recommendation  1.3.1 Offer all people who have had an acute MI treatment with the following drugs:  - ACE (angiotensin-converting enzyme) inhibitor - dual antiplatelet therapy (aspirin plus a second antiplatelet agent) - beta-blocker - statin.  2.     NICE recommendation 1.3.12 Offer aspirin to all people after an MI and continue it indefinitely, unless they are aspirin intolerant or have an indication for anticoagulation 3.     NICE recommendation 1.3.13 Offer aspirin to people who have had an MI more than 12 months ago and continue it indefinitely.  4.     NICE recommendation 1.3.17 Ticagrelor in combination with low-dose aspirin is recommended for up to 12 months as a treatment option in adults with acute coronary syndromes (ACS) that is, people:  - with ST-segment-elevation myocardial infarction (STEMI) – defined as ST elevation or new left bundle branch block on electrocardiogram – that cardiologists intend to treat with primary percutaneous coronary intervention (PCI) or  - with non-ST-segment-elevation myocardial infarction (NSTEMI) It is also worth noting that NICE Technology appraisal guidance (TA420) recommends that Ticagrelor, in combination with aspirin, is recommended within its marketing authorisation as an option for preventing atherothrombotic events in adults who had a myocardial infarction and who are at high risk of a further event. Treatment should be stopped when clinically indicated or at a maximum of 3 years. 5.     NICE recommendation 1.3.18 Offer clopidogrel as a treatment option for up to 12 months to:  - people who have had an NSTEMI, regardless of treatment - people who have had a STEMI and received a bare-metal or drug-eluting stent 6.     NICE recommendation 1.3.19 Offer clopidogrel as a treatment option for at least 1 month and consider continuing for up to 12 months to: - people who have had a STEMI and medical management with or without reperfusion treatment with a fibrinolytic agent. 7.     NICE recommendation 1.3.20 Continue the second antiplatelet agent for up to 12 months in people who have had a STEMI and who received coronary artery bypass graft (CABG) surgery 8.     NICE recommendation 1.3.21 Offer clopidogrel instead of aspirin to people who also have other clinical vascular disease, in line with Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events (NICE technology appraisal guidance 210), and who have: - had an MI and stopped dual antiplatelet therapy or - had an MI more than 12 months ago 9.     NICE Recommendation 1.3.27 After 12 months since the MI, continue anticoagulation and take into consideration the need for ongoing antiplatelet therapy, taking into account all of the following: - the indication for anticoagulation - thromboembolic risk - bleeding risk - cardiovascular risk - the person's wishes 10.  NICE recommendation 1.3.32 Continue a beta-blocker for at least 12 months after an MI in people without left ventricular systolic dysfunction or heart failure 11.  NICE recommendation 1.3.33 Continue a beta-blocker indefinitely in people with left ventricular systolic dysfunction 12.  NICE Recommendation 1.3.34 Offer all people who have had an MI more than 12 months ago, who have left ventricular systolic dysfunction, a beta-blocker whether or not they have symptoms. For people with heart failure plus left ventricular dysfunction, manage the condition in line with Chronic heart failure (NICE clinical guideline 108) 13.  NICE recommendation 1.3.35 Do not offer people without left ventricular systolic dysfunction or heart failure, who have had an MI more than 12 months ago, treatment with a beta-blocker unless there is an additional clinical indication for a beta-blocker. 14.  NICE recommendation 1.3.44 Statin therapy is recommended for adults with clinical evidence of cardiovascular disease in line with Statins for the prevention of cardiovascular events (NICE technology appraisal guidance 94) and Lipid modification (NICE clinical guideline 67). 15.  NICE recommendation 1.3.9 Renal function, serum electrolytes and blood pressure should be measured before starting an ACE inhibitor or ARB and again within 1 or 2 weeks of starting treatment. Patients should be monitored as appropriate as the dose is titrated upwards, until the maximum tolerated or target dose is reached, and then at least annually. 1.     Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. NICE guideline [NG5] 2.     UK Fact Sheet. British Heart Foundation April 2019. (file:///C:/Users/kkwc865/Downloads/bhf-cvd-statistics-uk-factsheet%20(5).pdf 3.     NICE. 2013. Myocardial Infarction: cardiac rehabilitation and prevention of further cardiovascular disease. Clinical Guideline 172. Online. Available from: http://www.nice.org.uk/guidance/cg172. Last accessed April 2018.  4.     O'Gara P.T et al. 2013 .ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. J Am Coll Cardiol. 2013;61(4):e78-e140. doi:10.1016/j.jacc.2012.11.019  5.     ESC. 2012. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. European Heart Journal 33, 2569–2619.  6.     ESC. 2011. ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. European Heart Journal 32, 2999–3054.  NICE. 2015. Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. NICE guideline (NG5). Available from http://www.nice.org.uk/guidance/ng5/chapter/introduction. Last accessed May 2019 |
| 41 | **IND72** | **Boehringer Ingelheim Limited** | Do you think the proposed indicators will lead to improvements in care and outcomes for patients? This is a positive step emphasising the routine review and management of patients with HF. A regular review and patients centered treatment approach should aim to improve the burden of morbidity and mortality associated with HF, which is quite significant.  In addition, and of important, regular therapy reviews and medicines optimisation enable decisions to be taken on the background of the changing pharmacological evidence base. Indeed, at present there a number of agents that have ongoing trials in HF. Some may come to market. The change in IND72 should allow patients to receive optimal individualised therapies now and in the future. |
| 42 | **IND72** | **British Cardiovascular Society (BCS)** | The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months . The BCS are cautiously pleased that a comprehensive care plan will be undertaken in general practice, but has concerns that this exercise should be clinically meaningful for patients and their carers, and that there should be clear guidance about what action should be taken in the event of a deviation from the projected NYHA score. Specifically if there was a deterioration in symptoms that this should alert review by heart failure team or change in treatment strategy. We also felt strongly that the following should be considered: -       That this should include assessment that an updated care plan for heart failure is in place -       Can we ensure that these data come from a single dedicated heart failure review for the patient? There is a danger that if these data were ‘pulled’ from separate consultations over a period of time that an appropriate individualised care plan for the patients may not be achieved. -       Should this include confirmation that the patient is taking an appropriate doses of the medications described in the pharmacological QOFs, as determined by clinical assessment (including measurement of heart rate, blood pressure and urea/electrolytes) -       That measurement of physiological parameters (including blood urea and electrolytes) is fundamental to the annual assessment. Whilst an annual assessment would represent great progress on what is currently in place, the NICE 2018 guidelines recommend 6 monthly review. Should we not aspire to this? |
| 43 | **IND72** | **British Medical Association** | IND72: The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months.  We support the changes to this indicator. |
| 44 | **IND72** | **British Society for Heart Failure (BSH)** | The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months  The Board of the BSH are cautiously pleased that a comprehensive care plan will be undertaken in general practice, but has concerns that this exercise should be clinically meaningful for patients and their carers, and that there should be clear guidance about what action should be taken in the event of a deviation from the projected NYHA score. Specifically if there was a deterioration in symptoms that this should alert review by heart failure team or change in treatment strategy. The Board also felt strongly that the following should be considered: -       That this should include assessment that an updated care plan for heart failure is in place -       Can we ensure that these data come from a single dedicated heart failure review for the patient? There is a danger that if these data were ‘pulled’ from separate consultations over a period of time that an appropriate individualised care plan for the patients may not be achieved. -       Should this include confirmation that the patient is taking an appropriate doses of the medications described in the pharmacological QOFs, as determined by clinical assessment (including measurement of heart rate, blood pressure and urea/electrolytes) -       That measurement of physiological parameters (including blood urea and electrolytes) is fundamental to the annual assessment.  Whilst an annual assessment would represent great progress on what is currently in place, the NICE 2018 guidelines recommend 6 monthly review. Should we not aspire to this? |
| 45 | **IND72** | **National Pharmaceutical Advisers Group (PAG)** | Agree with rationale to add this new indicator to improve medicines optimisation which will improve control and outcomes. |
| 46 | **IND72** | **Novartis Pharmaceuticals UK Ltd** | We welcome the drive for more regular review of patients with heart failure. We would recommend that the timeframe for carrying out these reviews is changed from “in the preceding 12 months” to “**in the preceding 6 months**”, as well as ensuring that patient’s clinical records are updated following review, to align with recently published NICE guidance for chronic heart failure1. Similarly, we propose the wording “undertaken by a healthcare professional” be amended to “**undertaken by the primary care team working within the specialist heart failure multi-disciplinary team**” to ensure this aligns with existing NICE guidance. References: 1.     NICE. Chronic Heart Failure (CHF) in Adults: Diagnosis and Management, NICE Guideline 106. September 2018. Accessed May 2019: https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685 |
| 47 | **IND72** | **Resuscitation Council (UK)** | The proposed wording is potentially unclear: ‘*The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months*’. Some may interpret this as requiring only the review of medication to have taken place in the preceding 12 months, whereas we believe that you intend the full review to have taken place within this timeline. We suggest a change of wording for clarity: ‘**The percentage of patients on the register with heart failure, who had a review undertaken by a healthcare professional in the preceding 12 months, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication.**’. |
| 48 | **IND72** | **Roche Diagnostics Limited** | We believe that in alignment with the NICE guideline on Chronic Heart Failure, that the use of NT-proBNP in monitoring as part of the clinical review should be considered for inclusion in this indicator. Currently this indicator is reliant on an assessment of functional capacity and a review of medication which is not representative of clinical practice and the NICE guidance. Please see below for the recommendation of NT-proBNP in monitoring in the NICE guideline NG106. Chronic Heart Failure: Diagnosis and Management (NG106)   1.7.5 Consider measuring NT-proBNP (N-terminal pro-B-type natriuretic peptide) as part of a treatment optimisation protocol only in a specialist care setting for people aged under 75 who have heart failure with reduced ejection fraction and an eGFR above 60 ml/min/1.73 m2. [2018] Ref: National Institute for Health and Care Excellence (NICE). Chronic heart failure in adults: diagnosis and management (NG106) 2018. Available from: https://www.nice.org.uk/guidance/ng106 [Accessed 2 May 2019] |
| 49 | **IND72** | **Royal College of General Practitioners** | IND72: The percentage of patients with heart failure, on the register, who had a review, undertaken by a healthcare professional, including an assessment of functional capacity (using the New York Heart Association classification) and a review of medication in the preceding 12 months. New We support this change |
| 50 | **IND72** | **Vifor Pharma UK** | Vifor Pharma supports the introduction of indicator IND72 to regularly review functional capacity and medication in heart failure patients. Such reviews should include assessment for: - iron deficiency which affects 50% of heart failure patients with HFrEF, as documented  by the European Society of Cardiology - and for hyperkalaemia: mortality outcomes can be improved by optimisation of RAAS blockade therapies. However, hyperkalaemia can result from use of ACE inhibitors, ARBs and MRAs i.e. treatments that contribute to RAAS blockade regimes. Hyperkalaemia can be managed with new licensed treatments for hyperkalaemia allowing optimisation and continuation of life-preserving RAAS blockade treatments. |
| 51 | **Suggestions for additional indicators** | **Novartis Pharmaceuticals UK Ltd** | We propose that the drug class ‘ARNi’ should be recognised and captured in the QOF as a discreet category, in addition to ACEi and ARB, so as to make these separate treatment classifications explicit. Currently, by not including the wording ‘ARNi’ in the indicator menu we believe that some healthcare professionals may inadvertently fail to capture the use of this treatment in certain patients (due to the discreet classification of the drug). We therefore recommend proposing the following additional indicator to clarify this point: “The percentage of patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, who are currently treated with an ARNi.” |
| 52 | **Suggestions for additional indicators** | **Novartis Pharmaceuticals UK Ltd** | Novartis welcomes this consultation from NICE and the proposal to update the menu of heart failure indicators included within the QOF as a means of achieving improved outcomes for patients. Novartis plays an active role in developing, manufacturing and commercialising medicines in cardiovascular disease (CVD) and heart failure. Novartis manufactures the heart failure medicine Entresto® (sacubitril/valsartan).Due to the severity of prognosis and the high risk of death or hospitalisation faced by patients with heart failure, we believe it is essential that patients with suspected heart failure are appropriately diagnosed and treated as a matter of clinical urgency. The QOF indicator menu can serve as a valuable tool to ensure patients with heart failure are able to receive the appropriate, potentially life-saving care without delay. We therefore welcome the opportunity to respond to this important consultation. As well as the specific recommendations to the newly proposed indicators outlined below, we suggest the following general points to help improve overall management of patients living with heart failure. Data Integrity – It would be valuable to capture the type of heart failure and supporting data points within the QOF indicator menu. For example, more specific metrics to capture include a) the quantitative measure of ejection fraction b) NYHA1 classification and c) disease severity of heart failure. By tracking these metrics, healthcare professionals (HCPs) would generate a more robust data-set to actively manage patients with heart failure, potentially improving patient outcomes. Multi-morbidity / Elderly checkup crossovers – Currently, all of the measures contained in the QOF heart failure indicator menu are post-diagnosis metrics. In other therapy areas such as cancer, measures are more proactive, also covering the pre-diagnosis stage of the patient pathway. We therefore propose including proactive metrics for heart failure and incorporating these into existing activity undertaken in primary care. For example, screening for and tracking patients that show early indicators of heart failure (shortness of breath, oedema, chronic fatigue etc.) at multi-morbidity or polypharmacy checkups2. At a minimum this should include a NT-proBNP test as part of the regular blood tests taken. We propose specific synergies between the Heart Failure and Multi-morbidity and Frailty indicator menus below, for consideration. References:  1.     New York Heart Association scale – a scale used to classify the severity of heart failure symptoms into four categories, 1-4 2.     Jurgens C, Moser D, Armola R et al. Symptom Clusters of Heart Failure. Research in Nursing and Health. July 2009. Accessed May 2019: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234105/# |
| 53 | **Suggestions for additional indicators** | **Boehringer Ingelheim Limited** | General comment. Whilst importance has correctly been attributed to identifying and treating left ventricular systolic dysfunction, consideration of diastolic dysfunction and the new emerging evidence of morbidity, mortality and prevalence rates in patients must also be taken into account. Thus, our view is that the new indicators should look at both systolic and diastolic dysfunction in tandem when assessing for HF. Moreover, as an integral point of proposed indicator IND69 is to increase echocardiography screening. Emerging evidence around ‘preserved’ Heart failure –also known as diastolic heart failure (ie signs and symptoms of heart failure but with ‘normal or preserved’ ejection fraction) comprise approximately half of all patient cases of HF. Therefore, it must be borne in mind that even with a ‘normal’ ejection fraction at echocardiography- an individual may still have ‘preserved heart failure’ and should not miss out on optimal care. |