QIPP Prescribing Comparators:

Feedback on proposals for retaining, amending or retiring 2013/14 comparators.

August 2014

Contents

Introduction

This document details the feedback received on proposals for retaining, amending or retiring the 17 current (2013/14) QIPP prescribing comparators. The proposals were outlined in a document - QIPP Prescribing Comparators: Proposals for retaining, amending or retiring the 2013/14 comparators – that was made available on the Health and Social Care Information Centre website in March 2014. Full details of the current QIPP Prescribing Comparators are available in the document QIPP Prescribing Comparators (2013/14): Descriptions and Specifications (December 2013)

The invitation for feedback was also disseminated to stakeholders via the Medicines and Prescribing Centre (NICE) Associates network, Pharmaceutical Advisers Group (PAG) and Association of British Pharmaceutical Industry (ABPI). The proposals were also forwarded to individuals and national groups at NHS England, Department of Health and Public Health England with an interest in the use of antibiotics.

This document and the proposals document should be read alongside the publication 'Key therapeutic topics – Medicines management options for local implementation (last updated 29 January 2013), produced by the Medicines and Prescribing Centre (MPC). MPC has subsequently undertaken a consultation on the Key Therapeutic Topics (KTT) to be included in the next edition of the publication.

Summary of Proposals

It was proposed that:

- 14 of the current 17 comparators are retained unchanged.
- 1 comparator (Cephalosporins & quinolones % items) is amended and/or supported by a further comparator.
- 2 comparators are retired.
    - Renin-angiotensin system drugs (ACE inhibitor % items)
    - Wound care products (Wound care products: NIC/item)

Summary of Feedback and Outcome of Consultation

A total of 27 individuals / organisations provided feedback on one or more of the comparators. The feedback received was considered by a group comprising of representatives from Department of Health, NHS England, MPC, Business Services Authority and HSCIC who were involved in the development of the comparators as part of the Department of Health QIPP (Quality, Innovation, Productivity and Prevention) medicine use and procurement work stream.

Comparator	Outcome of consultation
Laxatives ADQ/STAR PU	Comparator is to be retained.
ACE inhibitor % items	Comparator is to be retained and reviewed following the update to the Key Therapeutic Topics publication.
Low cost lipid modifying drugs	Comparator title and specification is to be further reviewed following the update to the Key Therapeutic Topic publication which will incorporate the recent NICE guidance published after this consultation closed.
Lipid modifying drugs: Ezetimibe % items	Comparator title and specification is to be further reviewed following the update to the Key Therapeutic Topic publication which will incorporate the recent NICE guidance published after this consultation closed.
Omega-3 ADQ/STAR PU	Comparator is to be retained.
Hypnotics ADQ/STAR PU (ADQ based)	Comparator is to be retained.
Antidepressant (selected): ADQ/STAR PU (ADQ based)	Comparator is to be retained.
Antidepressants: First choice % items	Comparator is to be retained. The anti-depressants considered to be 'first choice' (numerator) will be reviewed following the update to the Key Therapeutic Topics publication.
Antibacterial items/STAR PU	Comparator is to be retained.
Cephalosporins & quinolones % items	Comparator is to be retained and further reviewed following the update to the Key Therapeutic Topics publication and further discussion with antimicrobial strategy groups.
3 days trimethoprim ADQ/item	Comparator is to be retained and reviewed following the update to the Key Therapeutic Topics publication.
Minocycline ADQ/1000 patients	Comparator is to be retained.
Hypoglycaemic drugs	Comparator is to be retained and further reviewed following the feedback received and the update to the Key Therapeutic Topics publication. Consideration will also be given to changing the title of the comparator from 'hypoglycaemic drugs' to a more appropriate title. The development of additional comparators for diabetes will be explored.
Long-acting insulin analogues	Comparator is to be retained and further reviewed following the feedback received and the update to the Key Therapeutic Topics publication. The development of additional comparators for diabetes will be explored.
NSAIDs: Ibuprofen & naproxen % items	Comparator is to be retained.
NSAIDs ADQ/STAR PU	Comparator is to be retained.
Wound care products: NIC/item	Comparator is to be retired. The comparator will continue to be available via the Information Services Portal up to and including Q4 2014/15.

Anonymised details of the feedback, along with responses, are provided from page 6 onwards. In addition, the following general points can be made:

- There continues to be a need for prescribing comparators and their use is valued by a range of users.
- The intention is to continue to develop meaningful comparators to support the topics included in the Key Therapeutic Topics (KTT) publication.
- The proposals related to the comparators developed to support the KTT publication current at the time of this consultation. It was necessary to review the comparators ahead of an update to the KTT publication as 18 months had passed since the last review of the comparators. Since this consultation, the Medicines and Prescribing Centre, NICE has consulted on the topics to be included in the KTT publication and the publication is to be updated over the next few months. Therefore the comparators will be further reviewed to reflect the updated KTT publication and also the future arrangements for the development and maintenance of the comparators (see 'Next steps and timescales' below).
- The purpose of the comparators is to highlight variation in prescribing across organisations and support local discussion and decisions, with the aim of reducing variation and a movement of the mean in the appropriate direction over time. The comparators are intended to support organisations and prescribers in reviewing the appropriateness of current prescribing, revise prescribing where appropriate and monitor implementation. For some of the comparator topics more detailed work, probably involving patient-level audit, may be required to understand whether current practice – as highlighted in the comparator – is based on recommended practice. The need for this may apply irrespective of the current level of prescribing and the comparator value.

Thank you to all who responded and provided feedback. All comments received have been helpful in reviewing the comparators and ensuring the comparators continue to be fit for purpose whilst discussion regarding the future development of the comparators takes place (see 'Next steps and timescales') and the KTT publication is updated. The feedback has been discussed with MPC to help inform the update to the KTT publication.

Next steps and timescales

The feedback received has been helpful in evaluating the usefulness of the comparators and informing the way forward in placing the work within the new NHS structures and priorities.

Whilst QIPP is a term still in use, the Department of Health QIPP programme ended in March 2013. The comparators were originally developed and introduced to support the Department of Health QIPP (Quality, Innovation, Productivity and Prevention) medicine use and procurement work stream. Additions, revisions, and retirements to the QIPP Prescribing Comparators were implemented in February 2012, May 2012, August 2012 and August 2013 following discussion and feedback within the QIPP medicine work stream wider reference group, QIPP partners group and with Strategic Health Authority, Primary Care Trust prescribing leads and industry partners.

Discussions are currently taking place regarding the future development and maintenance of the comparators and the appropriate governance arrangements. Following discussions involving DH, NHS England, NICE (MPC), BSA and HSCIC, the Key Therapeutic Topics and prescribing comparator development work will be integrated into the NHS England medicines optimisation work stream and new governance arrangements will be established over the next 6 months.

Timescales for introducing revisions to comparators or further retirements will be announced at a later date. Dependent on timing, changes to comparators may be introduced alongside the current comparator for a period of time to allow continuity of monitoring of prescribing during the financial year.

Feedback on proposals for retaining, amending or retiring the current (2013/14) comparators

Proposals for retaining 14 of the 17 current QIPP prescribing comparators

Yes = agree with proposal to retain comparator No = disagree with proposal i.e. retire (or amend) comparator.

Laxatives

Comparator	Laxatives ADQ/STAR PU	Comparator description	Number of average daily quantities (ADQs) for laxatives per Laxatives (BNF 1.6) COST based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**7**		No comments received with responses	
No	**5**	1	Don't see the value in this indicator, it can never be a high priority and would rather it was retired with newer comparators related to patient orientated outcomes introduced such as in respiratory/diabetes.	Whilst Laxatives remains as a Key Therapeutic Topic a supporting comparator will be made available. Comment has been forwarded to the Medicines and Prescribing Centre, NICE.

		2	Using the daily prescribed amount of laxative adjusted for disease and age biases as a prescribing indicator probably doesn't reflect how laxatives are prescribed on repeat prescription in primary care and how they are used by patients (with the possible exception of routinely administered laxatives in a formal care setting). An alternative way of improving the quality of prescribing would be to ask prescribers (both GPs and nurse prescribers in Community Nursing Teams) to audit the prescribing of laxatives using the NICE clinical guideline for faecal incontinence (CG49) which sets out a suite of criterions for audit which implies that changing the 'culture' surrounding laxative prescribing and use may need a deeper analysis and insight. Auditing a sample of between 20 and 50 patients currently being prescribed laxatives against these audit criteria which support the use of alternative strategies for managing faecal incontinence without using laxatives will lead to improved quality of clinical management. Hydration and a balanced diet, higher in insoluble fibre offer better alternatives to managing incontinence long term by supporting large bowel-function, this should be something which is supported across primary and community health and social care services. A more effective way of controlling the volume of laxative prescribing would be to audit the routine inclusion of laxatives on repeat prescribing in GP clinical systems. The inclusion of a measure of amount prescribed per day in the QIPP Prescribing Comparator set isn't likely to lead to a focus on the quality of clinical management of faecal incontinence – showing a change in this by reducing the Average Daily Quantity (ADQ) prescribed would simply involve reducing the prescribed amount and wouldn't reflect on the quality of prescribing of laxatives per se.	Comments noted for future developments subject to availability of data. The aims and purposes of the comparators has always emphasised that they need to inform, and be used be used in conjunction with, local audit of prescribing. The comparator aims to highlight variation, with a view to further investigation locally to ensure laxatives are used appropriately. They do not provide a target to reduce prescribing.

		3	Really not convinced this should remain a key focus (certainly not top 20) within prescribing	Whilst Laxatives remains as a Key Therapeutic Topic, a supporting comparator will be made available. Comment has been forwarded to the Medicines and Prescribing Centre, NICE.
		4	not high value indicator in terms of cost of patient outcomes, not high priority, rather it was retired with newer comparators related to patient orientated outcomes introduced such as in respiratory/diabetes	Whilst Laxatives remains as a Key Therapeutic Topic, a supporting comparator will be made available. Comment has been forwarded to the Medicines and Prescribing Centre, NICE.
		5	This indicator is of low priority and therefore could be replaced by something more useful	Whilst Laxatives remains as a Key Therapeutic Topic, a supporting comparator will be made available. Comment has been forwarded to the Medicines and Prescribing Centre, NICE.
	Outcome			
	The current comparator is to be retained.			

Lipid lowering drugs including ezetimibe

Comparator	Low cost lipid modifying drugs	Comparator description	Number of prescription items for generic statin preparations listed under category M in part VIII of the Drug Tariff as a percentage of the total number of prescription items for all statins, plus the total number of prescription items for combination of simvastatin/ezetimibe, plus total number of prescription items for ezetimibe alone.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**12**	1	Support the proposal to retain this comparator in order to highlight variation in prescribing across organisations and support local discussion and decisions regarding QIPP. We note the imminent publication of NICE lipid modification (update) guideline - currently available in draft form at: http://www.nice.org.uk/guidance/index.jsp?action=download&o=66547 Given the proposed changes in prescribing guidance, recommend (in line with the proposal for comparators in Type 2 diabetes) an immediate review of this comparator post-publication to ensure best practice is supported. In particular, implementation of the new guidance may require healthcare professionals to prescribe more high-intensity statins and this could potentially increase the proportion of non-generic statins prescribed. We would encourage guidance being released to ensure that local measures of this QIPP comparator do not inappropriately deter a healthcare professional from prescribing the most clinically appropriate statin.	Comments noted. The comparator will be reviewed in conjunction with the update to the Key Therapeutic Topic publication which will incorporate the recently updated NICE guidance (CG181, July 2014). The purpose of the comparators is to highlight variation. It is not intended that they are used to set or encourage targets, or to deter the prescribing of the most clinically appropriate treatments. These messages will be reinforced in all communications.

No	**2**	1	The availability of a number of generic statins presents an opportunity for population wide cardiovascular risk management and a reduction in the risk threshold for primary prevention and national screening programme for the over 40's to reduce both observed health inequality drive by cardiovascular mortality, morbidity due to a damaged myocardium following an MI and more significant cost of routine interventional cardiology to restore cardiac circulation. The challenge of achieving reduced cv risk at population level is governed more by the willingness of large numbers patients to take long term lipid modifying therapy than by the cost of the medicine being prescribed. Also there are higher risk, secondary prevention groups (patients with acute coronary syndrome, people with CKD, familial hyper-cholesterolaemia and post CAGB/stent) for whom there is accumulating (NICE appraisal and clinical guidelines) evidence for intensive lipid lowering to prevent or delay the need for further interventional cardiology. The money saved in prescribing cost needs to be balanced by the cost of interventional cardiology (e.g. average opportunity cost of a cardiac stent insertion is £10K). As the two remaining branded lipid lowering drugs are due to become available generically in the very near future shouldn't the focus now shift from the cost of these medicines to the value they can bring at population and high risk cohort level. And prescribing indicators should shift toward a focus on outcome by better supporting long term adherence with them so that the benefits shown in clinical trials are translated into practice.	Comments noted. Current data does not provide information on the indication or the patients treated. Also information on adherence is not available although improved information on medicine waste may potentially provide some indication. The title and the specification for the comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topic publication which will incorporate the recently updated NICE guidance (CG181, July 2014) published after this consultation.

		2	**Ezetimibe is not a comparator for statins in the care pathway** A number of documents including CG67[5] and TA132[1] clearly place ezetimibe after initial statin therapy in the care pathway. Patients in need of lipid lowering therapy should be initiated on a generic statin, with the option to titrate or switch to an alternative statin if cholesterol levels are not achieved. Ezetimibe is an option for those patients: • Who are intolerant or contraindicated to first line statin, as monotherapy. • As dual therapy for patients still not achieving recommended cholesterol levels, despite being prescribed the maximum tolerated statin dose. Ezetimibe is not positioned by NICE or promoted by [responder] to compete with statins in the patient pathway, and for this reason, including it as a denominator in the 'low cost lipid modifying drugs' QIPP comparator and retaining the QIPP comparator 'lipid modifying drugs: Ezetimibe % items' is clinically inappropriate and is not consistent with current practice and NICE guidance. The inclusion of ezetimibe is therefore completely irrelevant and unreasonable in this context. Extracted from correspondence. See appendix 1.	The title and the specification for the comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topic publication which will incorporate the recently updated NICE guidance (CG181, July 2014) published after this consultation. The comment regarding the inappropriateness of including ezetimibe in the denominator for this comparator is noted and will be considered in the further review of the comparator. Where possible, appropriate and meaningful comparators will continue to be developed and maintained to support and reflect the topics and content of the KTT publication.
	Outcome			
	The comparator title and specification will be further reviewed following the update to the Key Therapeutic Topic publication which will incorporate recent NICE guidance (CG181, July 2014) published after this consultation.			

Comparator	Lipid modifying drugs: Ezetimibe % items	Comparator description	Number of items for ezetimibe and ezetimibe/simvastatin combinations as a percentage of the total number of prescription items for all statins, plus the total number of prescription items for combination of simvastatin/ezetimibe, plus total number of prescription items for ezetimibe alone.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**12**	1	Support the proposal to retain this comparator in order to highlight variation and achieve a movement of the mean in the appropriate direction in prescribing across organisations to support local discussion and decisions regarding QIPP.	Concur with the comment that the purpose of all the comparators is to highlight variation and to support and encourage local discussion audit and review to ensure that prescribing is in line with NICE guidance
No	**2**	1	Some patients don't respond well or have poor toleration to statin therapy. Also older patients have significant muscle wastage on statin therapy leading to falls or fail to tolerate high statin doses and yet need to have their plasma cholesterol reduced more than has been achieved on a low statin dose. To achieve a lower percentage of ezetimibe than is currently seen may involve prescribers having to switch patients (or following prompts from electronic point of prescribing decision support programmes installed on their clinical systems). This may result in significant reduction in the quality of prescribing if there is a good rationale for the patient being prescribed ezetimibe in the first place, i.e. they have been titrated up to a higher statin dose but have been intolerant and yet need further reductions on their plasma cholesterol to lessen their CV risk. A better focus for clinical commissioners is the implementation of the NICE Commissioning Guideline for the integrated commissioning for prevention of cardiovascular disease CMG 45 http://www.nice.org.uk/usingguidance/commissioningguides/integratedcommissioningforpreventionofcvd/CardiovascularDisease.jsp	Comments noted. The purpose of the KTTs and comparators is to highlight variation. It is not intended that they are used to set or encourage targets, or to deter the prescribing of the most clinically appropriate treatments.

		2	See appendix 1	Comments noted. Responses to specific comments: 1. The proposals related to the comparators developed to support the KTT publication current at the time of this consultation. It was necessary to review the comparators ahead of an update to the KTT publication as 18 months had passed since the last review of the comparators. Since this consultation, the Medicines and Prescribing Centre, NICE has consulted on the topics to be included in the KTT publication and the publication is to be updated over the next few months. The comparator will be further reviewed to reflect the updated KTT publication which will include recent NICE guidance and also the future arrangements for the development and maintenance of the comparators (see 'Next steps and timescales' below). The feedback generated through this consultation has informed the appropriateness of the comparators in the short term and the arrangements for continuing the work in the new NHS structures. 2. Where possible, appropriate and meaningful comparators will continue to be developed and maintained to support and reflect the topics and content of the KTT publication. 3. The aim and purposes of the comparators are not to promote or encourage the setting of targets and inappropriately reduce prescribing of ezetimibe. It is inappropriate to use the comparators in this way. The comparators are to highlight variation and support local audit and review of prescribing in line with the KTT publication and NICE guidance. 4. As with all these comparators it is not possible to identify eligible populations. Within the context of the comparators it is considered that the volume of prescribing of lipid lowering drugs using a 'percentage item approach' (rather than a 'per population' approach) is a reasonable proxy for clinical need/eligible patients at organisational level.

				The NICE costing template is a tool to assist local planning and is not a national estimate of need. However if the comparator is interpreted and used appropriately, the variation highlighted can be used to support the implementation of NICE guidance and clinical evidence. The current comparator is appropriate for the current Key Therapeutic Topic. However as detailed above (point 1) the comparator will be reviewed.
	Outcome			
	The comparator title and specification will be further reviewed following the update to the Key Therapeutic Topic publication which will incorporate recent NICE guidance (CG181, July 2014) published after this consultation.			

Omega-3 fatty acid supplements

Comparator	Omega-3 ADQ/STAR PU	Comparator description	Number of ADQs for omega-3 fatty acid compounds per Omega-3 fatty acid compounds (BNF 2.12 sub-set) ADQ based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**11**	1	Still a lot of this prescribed but often initiated by nurses in secondary care	
		2	yes working well to influence change	
No	**1**	1	Locally restricted Amber drug on traffic light tag	Noted. Interpretation of comparator values at CCG and practice level needs to consider local factors.
	Outcome			
	The comparator is to be retained.			

Hypnotics

Comparator	Hypnotics ADQ/STAR PU (ADQ based)	Comparator description	Number of average daily quantities (ADQs) for benzodiazepines (indicated for use as hypnotics) and "Z" drugs per Hypnotics (BNF 4.1.1 sub-set) ADQ based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**11**	1	Definitely *(retain)* – a lot more can be done in this area but it is often perceived as 'too hard basket'. I have run very successful benzodiazepine reduction clinics but it involves whole pathway analysis/review & engagement from all stakeholders	
No	**1**	1	The widespread prescribing of benzodiazepines for a wide spectrum of anxiety related disorders has very weak clinical justification and poor patient outcomes frequently result from toleration and dependence associated with inappropriate long term use. These medicines also have significant abuse potential and can result in harm as a result in accidental poisoning. Patients who have been prescribed these medicines for some time will have developed a degree of dependence and strategies to wean patients off these medicines in primary care have met with limited success due to the slow withdrawal that is most likely to lead to full abstinence. This is a complex issue and including this as a QIPP Prescribing Comparator will do little to resolve the over prescribing of benzodiazepines and improve the quality of care with anxiety syndrome disorders.	The comparator reflects these comments by highlighting variation in the volume of prescribing of hypnotics per weighted population.

			The NICE Clinical Knowledge Summary sets out four recommendations for individual review of their use and their slow withdrawal requiring individual clinical review and CKS Goals: 1. Assess suitability for withdrawal, 2. Manage withdrawal, including switch from short acting to long acting benzodiazepine, 3. Manage withdrawal symptoms, 4. Provide appropriate advice to people wishing to withdraw referral to specialist services if appropriate e.g. if the anxiety is the manifestation of a more serious mental health problem – substance misuse or severe mental illness. For these reasons, i.e. the complexities and need to carefully clinical management of withdrawal, this isn't appropriate for inclusion as an indicator which is most likely to impact on GP prescribing, as this may lead to a quick fix approach which is unlikely to succeed. Non-benzo prescribing strategies for managing anxiety related disorders need to be explored carefully before these medicines are prescribed, such as referral to Improving Access to Psychological Therapy (IAPT) services. This should be the first option if they have been commissioned locally. Commissioners should also consider commissioning a benzodiazepine withdrawal service on a payment by results tariff.	
	Outcome			
	The comparator is to be retained			

First choice antidepressant use in adults with depression or anxiety disorder

Comparator	Antidepressant (selected): ADQ/STAR PU (ADQ based)	Comparator description	Number of average daily quantities (ADQs) for selected antidepressant prescribing per Antidepressants (BNF 4.3 sub-set) ADQ based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**9**		No comments received with responses	
No	**3**	1	Similar rationale to the above *(hypnotics)* – there needs to be a change in prescribing culture toward treatment of depressive illness and the approach to treatment should be to enable a recovery from a depressive episode measured using recognised depression rating scales rather than to maintain treatment to achieve mood stabilisation with antidepressants when other psychological support is more appropriate. This indicator speaks to the rate of use of antidepressants rather than the appropriateness of their use. The involvement of community psychiatric nurses can support more appropriate targeting of antidepressants by GPs and in most cases of major depressive episodes pharmacotherapy with an antidepressant will be necessary, hence the rate of use will be dependent on the stage of the illness and is the rate of use will depend on stratification of the practice population. Those practices with a greater proportion of severely depressed patients will have a high rate of use of antidepressants. Healthcare query language tools can also be programmed using installed CHART software to run queries into practice clinical systems to begin the process of understanding what on-going support individual patients need. By implication using the rate of prescribing as an indicator is that a rate high is bad and a low rate is good, this is a spurious measure of the quality of care, as there needs to be a far better analysis of practice clinical data alongside	The comparator attempts to reflect these comments by highlighting variation in the volume of prescribing of antidepressants per weighted population. The aims and purpose of the comparator is not to set a target or suggest that low is good but to highlight the variation in the prescribing and support local discussion and audit/review regarding the appropriate use of antidepressants.

			prescribing analyses to gain some insight onto the quality of prescribing in depressive illness. Review of antidepressant prescribing is best done on a case by case basis using audit and the involvement of attached CPN in primary care is essential as without this specialist clinical input overzealous application of this metric will lead to premature withdrawal of anti-depressants simply to affect the rate of their use, which could adversely affect the quality of care and put depressed patients at risk of suicide.	
		2	Not a useful indicator since it measures volume of antidepressant prescribing and it is difficult to gauge what is good or not and may be reflective of other local services, e.g. access to behavioural therapies, etc. Feedback from prescribers is as above also.	As per above comments.
		3	Locally choice more of concern than ADQ. Mental health trust lead for higher doses	Other antidepressant comparator aims to address choice of antidepressant. Variation in volume of prescribing of antidepressants, as measured by ADQs per weighted population, is helpful to organisations.
	Outcome			
	Comparator is to be retained.			

Comparator	Antidepressants: First choice % items	Comparator description	Number of prescription items for '1st choice' generic SSRIs as a percentage of the total number of prescription items for selected 'other antidepressants'. NB: Proposal to retain this comparator stated that the drugs considered as "1st choice" will be reviewed as part of update of Key Therapeutics Topics.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**10**	1	but yes need to review what is considered first line	Comments noted and the choice of antidepressants included in the numerator will be reviewed in conjunction with the update to the KTT publication.
		2	I think this indicator should be renamed as the place in the pathway cannot be determined from prescribing data, but the preference for evidence based, cost effective choices should be encouraged.	Suggestion for an alternative name would be welcomed.
No	**3**	1	Will the first choices be swayed too frequently if there are category M price fluctuations?	The inclusion of medicines in the numerator ('first choice') is not solely based on cost but also effectiveness and safety. The choice of antidepressants included in the numerator will be reviewed in conjunction with the update to the KTT publication.
		2	The choice of anti-depressants should be limited available to prescribers as there are suitable and clinically significant differences between antidepressants depending on which neurotransmitter they affect. The Psychotropic Drug Directory http://psychotropicdrugdirectory.com provides a great opportunity to tailor treatment to ensure the best possible opportunity for long term adherence and for treatment to be optimised. Limiting choice based on cost is contrary to the opportunity to optimise antidepressant prescribing.	Comments noted. The comparator does not aim to limit choice but to highlight variation in the prescribing of anti-depressants considered to be first choice. The KTT publication highlights that choice of anti-depressant should normally be a generic SRRI taking into account side-effect profile.

		3	Unless the anti-depressants in question are those *exclusively* initiated in primary care by the patient's GP (and does not include anti-depressants initiated in secondary care) then this comparator should be retired.	It is not possible to identify prescriptions initiated in primary and secondary care. However this does not detract from the appropriateness of the comparator.
	Outcome			
	The current comparator is to be retained and will be reviewed following the update to the Key Therapeutic Topics publication and specifically around the 'first choice' antidepressants included in the numerator.			

Antibiotic prescribing - especially quinolones and cephalosporins

Comparator	Antibacterial items/STAR PU	Comparator description	Number of prescription items for antibacterial drugs (BNF 5.1) per Oral antibacterials (BNF 5.1 sub-set) ITEM based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**16**	1	'Blind' prescribing anti-bacterials for self-limiting viral conditions (as well as their agricultural use as 'growth promoters') will lead to high rates of antibacterial resistance. Excessively high rates of prescribing need to challenged but there are some circumstances when fast access to antibacterial therapy can be justified (eg exacerbations of COPD) and so messaging needs to take account of this and encourage more targeted use as a result of pathology testing.	Comments have been forwarded to the Medicines and Prescribing Centre, NICE.
		2	This is incredibly important for the 5 year strategy	
No	**0**		N/A	
	Outcome			
	Comparator is to be retained			

Three-day courses of trimethoprim for uncomplicated urinary tract infection

Comparator	3 days trimethoprim ADQ/item	Comparator description	Number of average daily quantities (ADQs) per item for trimethoprim 200mg tablets.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**15**	1	'Blind' prescribing anti-bacterials for self-limiting viral conditions (as well as their agricultural use as 'growth promoters') will lead to high rates of antibacterial resistance. Excessively high rates of prescribing need to challenged but there are some circumstances when fast access to antibacterial therapy can be justified (eg exacerbations of COPD) and so messaging needs to take account of this and encourage more targeted use as a result of pathology testing.	Comments noted and have been forwarded to the Medicines and Prescribing Centre, NICE.
		2	Introduce some commentary on fact that some patients may require longer courses of trimethoprim	Comments noted and have been forwarded to the Medicines and Prescribing Centre, NICE.
		3	yes working well to influence change	
		4	This is problematic because male/ female issues – but better to keep	Comments noted and have been forwarded to the Medicines and Prescribing Centre, NICE.
		5	Although local guidelines have longer treatment course for men – need to be aware when discussing with prescribers	Comments noted and have been forwarded to the Medicines and Prescribing Centre, NICE.

		6	Could this also include 3 days nitrofurantoin?	Comments noted and have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the Key Therapeutic Topics publication. If nitrofurantoin is included in updated KTT publication then consideration will be given to incorporating nitrofurantoin into this comparator or another appropriate comparator.
No	**2**	1	Appreciate that 3 days can be effective but believe the dose and course length are far less relevant than the decision to prescribe at all if there is no firm justified need.	Comment noted. Consideration will be given to developing a comparator that supports the volume of prescribing / decision to prescribe.
		2	Unless this comparator can discriminate between the use of trimethoprim in UTI vs non-UTI settings then it should be retired	Prescribing data is unable to identify indication for use and therefore unable to differentiate between prescribing for UTI and non-UTI. Comment noted and work will be undertaken to establish the extent of prescribing of trimethoprim for non-UTI indications.
	Outcome			
	The comparator is to be retained and reviewed following the update to the Key Therapeutic Topics publication.			

Minocycline

Comparator	Minocycline ADQ/1000 patients	Comparator description	Number of average daily quantities (ADQs) for minocycline per 1000 patients.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**12**	1	Limiting excessive prescribing for acne should be challenged though severe acne is potentially disfiguring and can have significant consequences for patients confidence and self-esteem plus the rate of tetracycline resistance to *P acnes* is significant which can lead to slow response rates in severe cases.	
		2	keep until even lower prescribing – a patient safety issue – how is there any prescribing?	
No	**3**	1	don't see the value in this indicator, it can never be a high priority and would rather it was retired with newer comparators related to patient orientated outcomes introduced such as in respiratory/diabetes.	Whilst minocycline remains as a Key Therapeutic Topic, a supporting comparator will be made available.
		2	This is an indicator of low priority and could be replaced by something more useful.	Whilst minocycline remains as a Key Therapeutic Topic, a supporting comparator will be made available.
		3	The rationale for this indicator is unclear. Is it driven by financial concerns or drug toxicity concerns or concerns related to over-prescribing of systemic agents for acne? What evidence supports the view that increased prescribing of minocycline is undesirable?	Whilst minocycline remains as a Key Therapeutic Topic, a supporting comparator will be made available. The comparator is not driven by cost. Comment regarding supporting evidence has been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the Key Therapeutic Topics publication.
	Outcome			
	The comparator is to be retained.			

Type 2 diabetes mellitus

Comparator	Hypoglycaemic drugs	Comparator description	Number of prescription items for metformin and sulfonylureas as a percentage of the total number of prescription items for all antidiabetic drugs. NB: Proposal to retain the comparator stated that the comparator would be revisited following updates to NICE guidance and the Key Therapeutics Topics (KTT) publication.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**9**	1	Yes this may need re-visiting following update of NICE guidance	Comment noted
		2	*(but amend)* The current comparator could be improved to drive Quality in line with QIPP, NHS Outcomes Framework and RPS Medicine Optimization measures. The NICE Diabetes Type II guideline states that a patient should be started on Metformin, this is because it is the only hypoglycaemic drug that has been shown to have cardio-protective effects (UKPDS). Therefore, we propose that the comparator be amended to measure Metformin prescribing as the only numerator and include sulfonylureas within the denominator; total number of prescription items for all antidiabetic drugs.	Comment and suggestion noted. The comparator will be further reviewed in conjunction with the update to the KTT. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the Key Therapeutic Topics publication.
		3	review indicator ,has massive gaps where combinations are not included which is pointless, also best to monitor metformin alone exclude OSUs	Comment re: combinations and suggestion noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication.

		4	Support the proposal to retain this comparator in order to highlight variation in prescribing across organisations and support local discussion and decisions regarding QIPP. We welcome the commitment to review this comparator on publication of the new NICE guidance to ensure best practice clinically and cost effective prescribing is supported.	
No	**6**	1	Must revisit this and the LAIA indicator. Treatment modalities are changing all the time in this area and a thorough review is required	Comments noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication.
		2	Needs to be redefined or retired	Comment noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication.
		3	This indicator should be retired as it does not reflect evidence based practice. It would be better to determine the proportion of type 2 diabetics who should be being prescribed metformin (excluding contraindications/intolerances etc.). The problem with the existing comparator is that type 2 diabetic patients inevitably move onto dual and then triple oral therapies to optimise glycaemic control – this reflects NICE guidance but the comparator is essentially penalising Practices when additional agents are used and the % figure consequently reduces.	Comments and suggestions noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication.
		4	I think this indicator needs significant revision. Treatment options in this therapeutic area are changing quickly and the indicators needs to reflect this.	Comments and suggestions noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication.

		5	Would agree if denominator included all oral ant diabetic drugs only as opposed to including insulin as well	Denominator does not include insulins only BNF section 6.1.2 Antidiabetic drugs.
		6	Newer oral anti-diabetic drugs (NOADs) provide the opportunity to more carefully manage high and erratic plasma glucose levels. The targeting of these medicines is essential and therapeutic trials are needed involving a combination of different molecules with complementary modes of action to bring plasma glucose under control. There is a risk that imprecise use aimed at achieving QOF targets can put patients at risk of hypoglycaemia which can have significant consequence for patients. However uncontrolled diabetes as a result of limiting the availability of NOADs also puts patients at risk of micro-vascular complications of hypo-gylcaemia such as loss of sight, loss of kidney function and amputation. The availability NOADs shouldn't be subject to restriction especially as they offer opportunity of bringing diabetes under control if their use is tailored as a result of careful and precisely tailored treatment. The role of diabetic specialist nurse to support the initiation of these medicines in primary care is essential.	Comments noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication. The comparator does not exclude the use of NOADs but highlights the variation in their use albeit by measurement of prescribing of metformin/sulphonylureas as a percentage of all oral anti-diabetic agents.
	Outcome			
	Comparator is to be retained and reviewed following the update to the Key Therapeutic Topics publication and the feedback received. Consideration will also be given to changing the title of the comparator from 'hypoglycaemic drugs' to a more appropriate title. The development of additional comparators for diabetes will be explored.			

Comparator	Long-acting insulin analogues	Comparator description	Number of prescription items for long-acting human analogue insulins as a percentage of the total number of prescription items for all long- acting and intermediate acting insulins excluding biphasic insulins.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**9**	1	keep but perhaps could review content to ensure all NPH vs LA analogues	Comment and suggestion noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE.
No	**4**	1	The issue is now more about starting insulin at all in Type 2, especially in the relatively early stages of the disease. We should be looking at doses per registered patient rather than the type of insulin.	Comment and suggestion noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE. Consideration will be given to developing a comparator that supports the use the of insulin in addition to choice of insulin
		2	These medicines are an important addition to the armentarium available to the prescriber their use should be tailored to meet patient's needs, like the NOADs, and they should be appropriately positioned as per NICE TA53 but targeting higher use of these important medicines may lead to in-appropriate withdrawal which can put patients at risk of losing control of their plasma glucose.	Comments noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE.

		3	This indicator needs revision - the use of insulins is increasing and appropriate patient selection would be more useful	Comment and suggestion noted. The comparator will be further reviewed in conjunction with the update to the Key Therapeutic Topics publication. Comments have been forwarded to the Medicines and Prescribing Centre, NICE who are responsible for the KTT publication. Consideration will be given to developing a comparator that supports the use the of insulin in addition to choice of insulin
		4	Propose amendment around broader diabetes comparator. We welcome the opportunity to comment on the proposal to retain the current QIPP comparator on the use of basal insulins. While the comparator has had some success in driving analogue prescribing to levels expected by NICE, we are concerned with the wider issue that looking at prescriptions of medicines in isolation will not drive the improvement in care and outcomes that is critically needed for people with diabetes. Furthermore, driving changes in prescribing behaviour without assessment of patient outcomes may deliver savings in prescribing budgets, but will not address the greatest burden on NHS resources: the treatment of complications related to diabetes. The data exists to measure costs and outcomes in a more sophisticated manner and we believe this is currently happening in some isolated areas across the country. We would encourage the HSCIC to consider how such approaches can be developed further and implementation supported across the NHS. The key points *we* would like to raise through this consultation are as follows: 1. The stated aim of the comparator is to reduce unwarranted variation without giving an indication as to the appropriate level of prescribing. However, in many areas it is being used as a vehicle to drive local agenda's aimed at simply reducing prescribing budgets, with the message being that 'lower is better' in relation to insulin analogue use, rather than seeking	Comments and suggestions noted. The opportunities to utilise additional accessible and consistent data sources will continue to be explored. It is inappropriate for the comparators to be used in this way. The aims and purposes of the comparators, along with their limitations and appropriate use, will continue to be promoted. An aim of the comparator is to reduce unwarranted variation around a mean that reflects the appropriate use of the medicines.

			to ensure the right patients receive the right medicines. For example, in one area, a target has been set for the type 2 population, aiming for 75% NPH usage in new starters and those patients having difficulty with their current insulin. In another, there is a CQUIN to ensure a 14% usage of NPH. In addition to concerns around the development of rigid targets to support local implementation of the comparator, we are also aware of issues around coding on GP clinical systems which do not differentiate between those with type 1 and type 2 diabetes. This can prove challenging for GP practices with a young population, and therefore a high number of people with type 1 diabetes, when measuring against the delivery of the comparator. It is essential that any practices to support the implementation of the comparator locally do not compromise the care of people with type 1 diabetes.	Used in conjunction with the 'Use of NICE-appraised medicines in the NHS in England' publication, the comparator will continue to support the appropriate use of medicines. A degree of variation is expected.
			2. We understand that there is a need to ensure that the NHS is prescribing in line with NICE advice and would highlight the recent HSCIC publication, '*Use of NICE-appraised medicines in the NHS in England – 2012*'[i]. When the report was first published in 2010, it found that usage of long acting insulin analogues (LAA), insulin glargine and insulin detemir, was 15% above the expected usage levels. However this has substantially declined in subsequent years, with the 2011 report finding usage 7% above and only 3% above in 2012 – which is deemed 'at expected levels'. Following the current trajectory, retaining the current comparator is likely to drive analogue use down further to levels below those expected by NICE.	As above
			3. It can therefore be seen that, at a national level, there has been success in achieving prescribing of LAA's in line with NICE. However, as previously stated, looking at prescriptions of medicines in isolation will not drive the improvement in care and outcomes that is critically needed for people with diabetes.	There are aspirations, particularly concerning the management of diabetes, to link prescribing with indications and outcomes. As noted above, the use of additional accessible and consistent data sources will continue to be explored.

			Current QOF data indicates that 69.9% of adults with diabetes in England achieved the DM26 QOF indicator of HbA1c <7.5%, net of exceptions, in 2011-12, but this proportion dropped to 66.5% in 2012-13. This means a third of people with diabetes in England did not reach this NICE recommended target in 2012/13, resulting in a total of 900,000 people with diabetes across England not having good control of their HbA1c. Even more concerning is that the proportion of patients meeting DM27 (HbA1c <8%) and DM28 (HbA1c <9%) net of exceptions, similarly fell. The percentage of those with HbA1c above 9% increased from 11.4% in 2011/12 to 13.6% in 2012/13 – this equates to almost 367,000 people recording HbA1c above 9%, an increase of almost 90,000 in one year. We would reiterate the need to ensure that where people are focussing on medicines use, they are doing so in a holistic way to ensure that the right patients are receiving the right medicines. It is widely recognised that improved control of HbA1c will have a positive impact on long term micro and macro-vascular complications which have longer term financial benefits for the NHS[ii]. Current estimations suggest that, of the £10bn spent on diabetes, 80% is spent on treating complications, many of which are avoidable[1]. In addition to the possible detrimental impact on patient outcomes, considering medicines use in isolation is likely to incur additional costs elsewhere in the system. 4. We believe there is an opportunity for the QIPP comparators to support the medicines optimisation agenda and ensure it is embedded into the NHS. In 2013, the Royal Pharmaceutical Society published '*Good Practice Guidance for healthcare professionals in England*'[iii] which set out the principles of medicines optimisation. It states that: "*Medicines use today is*	It is recognised that prescribing comparators need to be integral to the medicines optimisation strategy and this is currently being considered.

			too often sub-optimal and we need a step change in the way that all healthcare professionals support patients to get the best possible outcomes from their medicines... Medicines optimisation is about ensuring that the right patients get the right choice of medicine, at the right time."	
			To ensure this is supported in the context of the comparators, measurement of medicine use must be linked to patient outcomes. Yet the current comparators continue to consider medicines use in isolation. We were pleased to see the HSCIC propose an indicator focussing on the cost related to percentage achievement of HbA1c targets in 2012; however it is not clear what, if any, progress has been made on this. We believe this would be an important step in the direction of supporting the medicines optimisation agenda.	See above. Delays in exploring the use of other data sources such as QOF has been delayed whilst the BSA modernise their information services (Information Services Portal). The intention is to revisit the proposal.
			5. As well as the medicines optimisation agenda, we also believe that more advanced comparators could be used to better support prescribing in line with NICE.[iv] If the NICE guidance was simply to prescribe NPH first line and LAA's second line, the current comparator would be the most appropriate to drive behaviours in line with this. However, there are a substantial number of exceptions which mean that for a proportion of people with type 2 diabetes, the right choice of first line insulin is an LAA. NICE recognises that LAAs are an essential part of the diabetes care pathway for certain patients, including "*those who do not reach their target HbA_{1c} because of significant hypoglycaemia."* We do not feel the current comparator adequately addresses the need to prescribe appropriately for the individual patient, particularly in areas where it is being implemented with hard measures as the examples above demonstrate.	The comparator aims to show variation and not drive prescribing towards local targets or in a particular direction nationally. The comparator allows for flexibility in prescribing, all suitable options to be considered and for patients to receive appropriate medicines.

			6. For the reasons stated throughout this response, we feel a more sophisticated measure, such as considering achievement of HbA1c levels in QOF and medicines usage in parallel, would help support the medicines optimisation agenda within the NHS whilst maintaining a focus on prescribing costs. We do not believe such a metric would be difficult to implement as 'outcomes' data, such as HbA1c measurements, are currently available at practice level. We also believe that, in the longer term, it would also be useful to work towards utilisation of end points such as hypoglycaemia admissions. We have worked with several CCGs to support them to integrate data such as hospital admissions, QOF and prescribing data with practice level information on patient outcomes and costs. We would be happy to discuss these programmes further with HSCIC and look into how we could progress such an initiative at a national level. 1 http://www.hscic.gov.uk/catalogue/PUB13413 1 The UKPDS and its global impact. Diabet Med. 2008 Aug;25 Suppl 2:57-62. 1 Hex et al. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabetic Medicine (2012). Available at: http://onlinelibrary.wiley.com/ doi/10.1111/j.1464-5491.2012.03698.x/abstract Last accessed 15 November 2013 1 http://www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf 1 CG87 Type 2 diabetes - newer agents (a partial update of CG66): short guideline http://www.nice.org.uk/nicemedia/live/12165/44318/44318.pdf *Initiate insulin therapy from a choice of a number of insulin types and regimens.* • *Begin with human NPH insulin injected at bed-time or twice daily according to need.* • *Consider, as an alternative, using a long-acting insulin analogue (insulin detemir, insulin glargine) if: − the person needs assistance from a carer or healthcare professional to inject insulin, and use of a long-acting insulin analogue (insulin detemir, insulin glargine) would reduce the frequency of injections from twice to once daily, or* o *the person's lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes, or*	Comments noted. See above responses. Invitation to explore further noted.

			○ *the person would otherwise need twice-daily NPH insulin injections in combination with oral glucose-lowering drugs, or* ○ *the person cannot use the device to inject NPH insulin.* • *Consider twice-daily pre-mixed (biphasic) human insulin (particularly if HbA1c ≥ 9.0%). A once-daily regimen may be an option.* • *Consider pre-mixed preparations that include short-acting insulin analogues, rather than pre-mixed preparations that include short-acting human insulin preparations, if:* ○ *a person prefers injecting insulin immediately before a meal, or* ○ *hypoglycaemia is a problem, or* ○ *blood glucose levels rise markedly after meals.* • *Consider switching to a long-acting insulin analogue (insulin detemir, insulin glargine) from NPH insulin in people:* ○ *who do not reach their target HbA1c because of significant hypoglycaemia, or* ○ *who experience significant hypoglycaemia on NPH insulin irrespective of the level of HbA1c reached, or* ○ *who cannot use the device needed to inject NPH insulin but who could administer their own insulin safely and accurately if a switch to a long-acting insulin analogue were made, or* ○ *who need help from a carer or healthcare professional to administer insulin injections and for whom switching to a long-acting insulin analogue would reduce the number of daily injections.*	
	Outcome			
	The comparator is to be retained and will be reviewed following the feedback received and the update to the Key Therapeutic Topics publication. The development of additional comparators will be explored.			

Comparator	NSAIDs: Ibuprofen & naproxen % items	Comparator description	Number of prescription items for ibuprofen and naproxen as a percentage of the total number of prescription items for all NSAIDs.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**11**	1	yes working well to influence change	
No	**1**	1	This class of medicines need to be reviewed as a result of increasing evidence of toxicity especially when used in the elderly where there use should be routinely covered by gastro-protection with a generic PPI. However they are also known to have toxic effects on kidney function and cardiovascular risk so the impression that ibuprofen and naproxen are safe should be discouraged and their use overall should be reviewed NICE TA 27 and CG 79 provide a strategy for limiting their use in osteoarthritis, the most common indication for their use.	Comments have been forwarded to the Medicines and Prescribing Centre, NICE. The KTT recommends that 'If an NSAID is needed, use ibuprofen (1200mg per day or less) or naproxen (1000mg per day or less)". Another comparator 'NSAIDs ADQs/STAR-PU' shows variation in the volume of prescribing of NSAIDs.
	Outcome			
	The comparator is to be retained.			

Comparator	NSAIDs ADQ/STAR PU	Comparator description	Number of average daily quantities (ADQs) for all NSAIDs (BNF 10.1.1) per Oral NSAID (BNF 10.1.1 sub-set) COST based STAR-PU.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**12**	1	The rate of use of these drugs should be challenged especially in older patients who are at risk due to slower GI transit time and previous history of peptic ulcer disease or gastro-oesophageal reflux disease. The recent PINCER thttp://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61817-5/abstract trial demonstrated that contraindication alerts on GP clinical systems are overridden often without adding gastro-protection which leaves patients at risk of serious complications such as a GI bleed.	
		2	Although feel CCGs with practices without local pharmacies (i.e. rural) may look poorer as patients default to their local GP if corner shop only sells small packs of ibuprofen 200mg.	Comments noted. Interpretation of comparator values at CCG and practice level need to consider local factors.
No	**0**		N/A	
	Outcome			
	The comparator is to be retained.			

Proposals for retiring 2 of the 17 current QIPP prescribing comparators

Yes – agree with proposal to retire comparator No – disagree with proposal to retire comparator i.e. retain

Renin-angiotensin system drugs

Comparator	ACE inhibitor % items	Comparator description	Number of prescription items for angiotensin converting enzyme (ACE) inhibitors as a percentage of the total number of prescription items for all drugs affecting the renin-angiotensin system excluding aliskiren.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**8**	1	Not cost advantage as all generic now	Focus for KTT and comparator is the evidence regarding effectiveness.
		2	Could potentially focus on reducing olmesartan	Comment has been forwarded to Medicines and Prescribing Centre, NICE.
No	**5**	1	We know ACEI have very positive effect on patient oriented outcomes eg reduced risk of MI compared with Sartans that only have surrogate markers	
		2	Locally Better care better value target of 75 % not hit yet	

		3	Still a high cost area where evidence is greatest for ACEI vs ARBs Review rather than retire	See Outcome (below)
		4	Still think it is useful	
		5	Still useful to retain until after Key Therapeutics Topic publication has been completed.	See Outcome (below)
	Outcome			
	The current comparator is to be retained and will be reviewed in conjunction with the update to the Key Therapeutic Topics publication.			

Wound care products

Comparator	Wound care products: NIC/item	Comparator description	Cost (NIC) per item for wound care products.

	Number of responses	Comments/feedback received		Response to comments/feedback
Yes	**11**	1	High tech dressings are cost effective if not changed too frequently – there cost goes up when they are removed from the wound too frequently though they are designed to stay in situ and contract with the second intension wound healing. Audit by tissue viability nurses especially of dressing use in care homes with untrained staff will achieve significant efficiencies – over-ordering needs to be challenged and not adding them to repeat prescriptions can help	
		2	Never used it anyway.	
		3	High cost and high growth area. Retain but review indicator in different format ie cost per 1000 patients not NIC/item	
		4	Most of our wound care is now through an alternative supply system so indicator is not used locally	
No	**2**	1	Useful to retain to allow benchmarking of local wound care choice and formulary. Also highlights an area of prescribing for QIPP work streams and retirement could impact negatively on QIPP agenda.	
		2	Still think it is useful	
	Outcome			
	The comparator will be retired at the end of 2014/15. Data will be available up to and including Q4 2014/15.			

Proposals to amend a QIPP prescribing comparator

Proposal that the **'Cephalosporins & quinolones % items'** comparator is amended. Options proposed:

1. Refining the selection of the cephalosporins included in the numerator to include only **2nd, 3rd and 4th generation cephalosporins** which are associated with greater risk of infection due to Clostridium. difficile. i.e. NOT include cephalexin, cefradine or cefadroxil in numerator.

2. Adding **co-amoxiclav** into the above numerator either as per the current comparator (if above proposal is not implemented) or an amended comparator as proposed i.e.

   Items for 'Co-amoxiclav, cephalosporins & quinolones' as a percentage of the total number of prescription items for selected antibacterial drugs (BNF 5.1).

   or alternatively/in addition to option 2:

3. Develop a further comparator to support the **'Cephalosporins & quinolones % items'** comparator (amended or not amended as per option 1) i.e..

   Items for co-amoxiclav as a percentage of items for co-amoxiclav and amoxicillin

Summary of Feedback received

Response	Option 1	Option 2	Option 3	
1	Yes	Yes	No	
2	No	No	Yes	
3	No	Yes	No	
4	No	Yes	Yes	
5	Yes	No	No	
6	Yes	Yes	Yes	
7	No preferences provided but general comments			See detailed feedback
8		Yes		
9	Yes	No	No	
10	No	No	No/Yes?*	*Comments suggested a preference for a separate indicator. See detailed feedback
11	No	No	Yes	
12	No	Yes	No	
13	Yes	Yes		
14	Yes	No	No	
15	No	No	No	
16	No	No	Yes	
17	Yes	No	Yes	
18	No	Yes	No	
19	Yes	Yes	No	
20	No	Yes		
Yes	8	10	6 or 7	*see above
No	10	9	10 or 9	*see above
Blank	2	1	4	
	20	**20**	**20**	

Options 1 and 2

Option 1 YES Option 2 YES	**Amend** current 'Cephalosporins & quinolones % items comparator **Add** co-amoxiclav to the amended comparator	4
Option 1 YES Option 2 NO	**Amend** current 'Cephalosporins & quinolones % items comparator **NOT** add co-amoxiclav to the amended comparator	4
Option 1 NO Option 2 YES	**Retain** current 'Cephalosporins & quinolones % items comparator **Add** co-amoxiclav to the amended	5
Option 1 NO Option 2 NO	**Retain** current 'Cephalosporins & quinolones % items comparator **NOT** add co-amoxiclav to the amended comparator	5
Option 1 ----- Option 2 YES	**No comment** on current 'Cephalosporins & quinolones % items comparator **Add** co-amoxiclav to the comparator	1
Option 1 ----- Option 2 -----	No preference provided. General comments only	1
		20

Options 2 and 3

Option 2 NO Option 3 YES	**NOT** add co-amoxiclav to the current comparator **Develop** a separate comparator for co-amoxiclav	4 (or 5)*
Option 2 YES Option 3 NO	**ADD** co-amoxiclav to the current comparator **NOT** develop a separate comparator for co-amoxiclav	5
Option 2 YES Option 3 YES	**Add** co-amoxiclav to the current comparator **Develop** a separate comparator for co-amoxiclav	2
Option 2 YES Option 3 -----	**Add** co-amoxiclav to the current comparator **No comment Develop** on a separate comparator for co-amoxiclav	2
Option 2 NO Option 3 NO	**NOT** add co-amoxiclav to the current comparator **NOT** develop a separate comparator for co-amoxiclav	5 (or 4)*
Option 2 ----- Option 3 -----	No preference provided. General comments only	1
		20 (20)

*response to option 3 = NO but comments suggested a preference for a separate indicator for co-amoxiclav i.e. YES to option 3

Detailed feedback

Responder	Proposal	Agree	Comments
1	1	Yes	Agree that co-amoxiclav should be included, and would prefer this to be as per option 1, so that it is in addition to cephalosporins and quinolones. Locally we see a strong correlation with recent use of co-amoxiclav following RCA from C. difficile cases. Our local work to reduce co-amoxiclav prescribing has been associated with both a reduction in C difficile cases and no significant rise in use of cephalosporins or quinolones.
	2	Yes	Comments as above
	3	No	
2	1	No	Strongly in favour of maintaining the *status quo* on this. The data still suggests that the CD risk with 1st generation cephalosporins is significant even if lower than that associated with 2-4th generation versions. The highest risk appears to be associated with the 3rd generation cephalosporins but I would not change anything at this stage.
	2	No	(See comments above/below)
	3	Yes	This appears to be the better approach, *i.e.* to leave the original comparator and add in a new one just for co-amoxiclav prescribing. Otherwise this will lead to confusion with prescribers and potentially undermine an already established pattern of disinvestment in cephalosporins and quinolones.
3	1	No	Understand the link between first generation & C difficile is not established
	2	Yes	Include **2nd, 3rd and 4th generation cephalosporins** (I understand the link between first generation & C difficile is not established) plus quinolones plus co-amoxiclav
	3	No	

Responder	Proposal	Agree	Comments
4	1	No	Research evidence shows all cephalosporin use can contribute to Health care associated infections so I would want to include all cephalosporins in the indicator.
	2	Yes	Have been adding co-amoxiclav into our data and are now working across the Area Team to share this data. We also plot the antibacterials/STAR-PU indicator against this combined indicator to show variations to prescribing practice at GP level. (If you would like to see this data, please mail me).
	3	Yes	Have not done this and it is an interesting idea. Would support the development of this indicator, but would choose the combination above if had to choose one co-amoxiclav indicator only.
5	1	Yes	
	2	No	Sensitivity patterns for co-amoxiclav v amoxicillin support its use, significantly affecting treatment success rates – seek microbiologist advice – not straightforward enough to include in the indicator
	3	No	As above
6	1	Yes	
	2	Yes	
	3	Yes	
7	1		Restricted use of quinolones and cephalosporin's to prevent C difficile has resulted in rise in piptazobactam and meropenem use according to IMS data – this may drive more resistance. A diversity of antimicrobials should be maintained.
	2		
	3		

Responder	Proposal	Agree	Comments
8	1		
	2	Yes	agree with adding co-amoxiclav to the antibiotic indicator (option 2).
	3		
9	1	Yes	Must also measure weighted prescribing of all antibiotics. Also assume this is in combination with quinolones? But assuming this is the case then I would completely agree that this measure should be adjusted to remove the 1st generation cephalosporins as compared to other antibiotics, they are as low a risk. Use of 4th generation in primary care must be close to zero and wonder what value they add to this numerator, other than perhaps to avoid any 4th generation sneaking in.
	2	No	Comparing the risk of different ABs or AB groups and their contribution to C.difficile in secondary care, I wonder what we're looking at co-amoxiclav at all. With cash current prices there may be some value in including this but I know this falls outside the argument for monitoring antibiotics. While I am not aware of enough evidence to promote co-amoxiclav unnecessarily (and wouldn't), I am not aware of enough evidence to restrict its use either. Wouldn't clarithromycin be a more important addition. Although primary care prescribing is low, the risk in C.difficle is much higher.
	3	No	Performance on this would be greatly influenced by the heavier weighting of amoxicillin in the denominator (or co-amoxiclav and amoxicillin). This would disadvantage those with average or just below average prescribing rates of co-amoxiclav but suitably low prescribing rates of amoxicillin. If the overall aim it to minimise the inappropriate use of antibiotics (including restricted agents) then this may encourage prescribers to prescribe more amoxicillin if they are performing badly in this indicator. Inclusion of any indicator in a national set may not be intended to achieve 'unchallenged status' at local level. But despite instruction not to use these are performance measures, I am certain the majority of PCTs and now CCGs will turn these into local indicators and include in prescribing incentive schemes.

Responder	Proposal	Agree	Comments
10	1	No	What is evidence that cephalexin does not increase risk of C difficile infection? The MM team has made excellent progress with raising awareness that cephalosporins should be used for select patients and therefore changing the drugs included could provide mixed messages and possibly drive prescribing of cephalexin?
	2	No	Agree with need to monitor co-amoxiclav prescribing since there are concerns of displacement to co-amoxiclav prescribing in view of concerns with cephalosporins and quinolones. Prefer to monitor co-amoxiclav prescribing as a separate indicator.
	3	No?	See above
11	1	No	1. BNF states orally first generation cephalosporin has similar antimicrobial spectrum to oral CEFACLOR which is second generation and hence would have a similar effect in altering the gut flora pre-disposing vulnerable patients to increased risk Clostridium difficile 2. All first generation cephalosporins(cefalexin, cefradine and cefadroxil) are oral preparations unlike the other generation where more than half are intravenous preparations which is more likely to be used in secondary care only 3. When Cephalosporins prescribing for the last 11 months in our CCG was analysed 93% of the prescriptions were for Cefalexin (first generation) and an overall of 94.2% were first generation compared to the other generations of cephalosporins. Hence if we take out first generation from the tag we are only measuring 5.8% of cephalosporin prescribing in primary care which will not be a true indicator of the level of cephalosporin prescribing as a class especially in the context of increased Clostridium difficile infections. DOH Antimicrobial resistance strategy (2013-2018) seeks to promote reduced use of antibacterial to preserve existing antibiotics and hence including first generation as part of all cephalosporin is important as it is more likely to be used in primary care and needs reducing.
	2	No	Current national targets are available only for cephalosporins and quinolones (<3.15%) on its own against which practices are monitored .Adding co-amoxiclav to this will make monitoring impossible unless new national targets are set for this new indicator. It is a known fact that cephalosporins and quinolones exposure is associated with increased risk of Clostridium difficile against which practices are monitored .Local hospital strategy which introduced co-amoxiclav as formulary choice for most indications in secondary care since the last 5 years has not observed any rise in Clostridium difficile
	3	Yes	This will be a more meaningful indicator to monitor individual primary care (CCG) where there are concerns of excess co-amoxiclav prescribing when comparing any reduction in cephalosporins and quinolones.

Responder	Proposal	Agree	Comments
12	1	No	no keep as all cephalosporins, prescribers don't always appreciate difference
	2	Yes	yes combine cephs/ quins with co-amoxiclav because they are used in similar 2nd line indications and where use in high in one group often means opposite group is low so this will help equalise this affect eg Herefordshire is low in cephs/ quins but high for co-amoxiclav hence currently working on all 3 groups with similar messages hence logical to combine
	3	No	Prefer option above
13	1	Yes	Support strongly
	2	Yes	Support strongly
	3		
14	1	Yes	My major concern is likely under-treatment of UTIs in the community reflected in increasing hospital admissions as seen in http://www.cqc.org.uk/sites/default/files/media/documents/state_of_care_annex1.pdf. In this context, discouragement of 1 gen cephs, which may be effective Rx for community UTIs, appears to be overdone 2,3-4 gen cephs are largely hospital use and are more associated with C. diff
	2	No	Discouragement of co-amoxiclav in community UTIs would lead to likely lead to further under treatment of community UTIs when, as already noted, there already is concern about more hospital admissions for complicated (& possibly undertreated) UTIs, as detailed in http://www.cqc.org.uk/sites/default/files/media/documents/state_of_care_annex1.pdf
	3	No	As above. My view is that these QIPPs with respect of total cephalosporins, fluoroquinolones and co-amoxiclav use are excessively blunt instruments. Lumping together usage that relates to UTIs and RTIs is not reasonable. In the case of UTIs, discouragement of antibiotics that are likely to work seems profoundly unwise, given that hospital admissions for UTI are rising, and that there is a reasonable hypothesis that this reflects inadequate prior Rx of UTIs in the community. By contrast, measuring % usage of quinolones, cephs and co-amoxiclav in community RTIs (where they are less likely to be warranted)and using this as a QIPP would be reasonable

Responder	Proposal	Agree	Comments
15	1	No	Increasing evidence suggests that favouring particular classes of antibiotic is a major risk for emergence of multiresistant infection. A diversity of antibiotics should be maintained. This includes the continued use of cephalosporins and quinolones as well as ureidopenicillins. For the control of C difficile it is the overall amount of antibiotic used that is important. The removal 2-4th generation cephalosporins and quinolones in many hospitals has driven more use of piptazobactam and then meropenem. There is a risk this will accelerate meropenem resistance. Diversity should be the comparator.
	2	No	As above coamoxiclav is just one of many antibiotics that risk the development of resistance
	3	No	Unsure of the meaning here. A new comparator should be developed based on the use of antibiotics in all the major classes.
16	1	No	Don't see any reason to change the selection of cephalosporins in the indicator. Their use should be limited anyway and excluding some of the products may see an increase in their use without any was of monitoring this. It would be useful to separate out cephalosporins from quinolones as individual indicators to encourage further reduction of cephalosporin use, whilst acknowledging there is a place for quinolones in selected indications.
	2	No	The inclusion of multiple items within a single indicator compromises the clarity of the message being communicated.
	3	Yes	Agree that the use of co-amoxiclav should be monitored but not compromised by including within the existing indicator that has been used to good effect to deliver change.
17	1	Yes	
	2	No	
	3	Yes	It would be useful to have this as a separate comparator. Co-amoxiclav is a broad-spectrum antibiotic and there is evidence that this is associated with *Clostridium difficile*. It would therefore be useful to monitor this antibiotic but separated out from cephalosporins and quinolones.

Responder	Proposal	Agree	Comments
18	1	No	Do not support the proposal to remove first generation cephalosporins from this group unless robust evidence can be furnished to demonstrate the relative safety of these drugs in comparison to the others in the group with respect to potential for selecting for Clostridium difficile infection. Removing first generation cephalosporins risks confusing the message for prescribers. If first generation cephalosporins are removed, the impact is likely to be increased cefalexin prescribing for UTI. There is clinical evidence of increased UTI recurrence after treatment with cephalosporins (see current IDSA guidelines for complicated UTI). This may lead to a risk of increased E. coli bacteraemia.
	2	Yes	strongly favour option 2: support the addition of co-amoxiclav to this group. For evidence, refer to Chilton C et al, J Antimicrob Chemother 2012; 67: 951–954. Aldeyab M et al, J Antimicrob Chemother 2012; 67: 2988–2996. Talpaert M, J Antimicrob Chemother 2011; 66: 2168–2174. Vernaz N, Journal of Antimicrobial Chemotherapy (2009) 63, 1272–1275
	3	No	Combining co-amoxiclav with cephalosporins and quinolones sends a clear and consistent message that broader spectrum second-line agents should not be used routinely in primary care.
19	1	Yes	Yes as we use cephalexin in line with HPA guidance, although don't have cefradine or cefadroxil on local formulary.
	2	Yes	As proposed indicator above – useful to see use of all these items – as find when do work on eg quinolone prescribing often see a subsequent increase in co-amoxiclav
	3	No	Wouldn't use co-amoxiclav instead of amoxicillin so denominator doesn't seem appropriate

Responder	Proposal	Agree	Comments
20	1	No	The 1st generation cephalosporins also have increased risk of c.difficile compared to other antibiotics.
	2	Yes	Yes I agree that by excluding co-amoxiclav from the numerator we are driving increased use of this in the community. I think it would be useful to list the indicators for: 1. Co-amoxiclav a) Facial cellulitis b) Animal/human bites c) Pyelonephitis d) Persistent sinusitis if first line treatment fails e) Acute exacerbation of COPD if co-morbid disease, severe COPD antibiotics in past 3 months, frequent exacerbations – see PHE guidance attached f) Infection post gynaecological surgery if non superficial 2. For ciprofloxacin – acute prostitis, acute pylonephitis, travellers diarrhoea if risk of severe illness. Ofloxacin – PID with metronidazole, acute prostatitis, chlamydia. Cefalexin – third line in UTI in pregnancy (first lien nitrofurantoin, second line trimethoprim giving folate in first trimester. Second line in lover UTI in children (first line trimethoprim or nitrofurantoin or amoxicillin if susceptible.
	3		This would be useful as several persistent RTIs may be given co-amoxiclav rather than doxycycline. This is mostly inappropriate except in sinusitis– references – see rationale within PHE guidance.
Outcome			
It is evident from the feedback that a consensus cannot be reached on the options presented. All comments are noted and have been forwarded to Medicines and Prescribing Centre, NICE who are responsible for the Key Therapeutic Topics publication, for their further consideration. The comments will also be shared with relevant persons and groups in NHS England, Department of Health and Public Health England for further consideration.			

Appendix 1: Response to proposals for 'Lipid lowering drugs including ezetimibe'

30 May 2014

By Email / Letter

Health & Social Care Information Centre

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Board Lane

Leeds

LS1 6AE

Dear Sir/Madam,

[Responder] response to 'QIPP Prescribing Comparators: *Proposals for retaining, amending or retiring 2013/14 comparators*'

[Responder] considers strongly that the QIPP Prescribing Comparator – *Low cost lipid modifying drugs* should be amended to remove ezetimibe from the denominator and that the QIPP Prescribing Comparator – *Lipid modifying drugs: Ezetimibe % items* should be **retired**. We set out our detailed comments below. In summary, the continued inclusion of ezetimibe as described in the QIPP prescribing comparator programme is totally inappropriate. The use of the comparators, particularly in conjunction with the NICE Key Therapeutic Topics (KTTs), undermines NICE guidance on ezetimibe and unfairly discriminates against ezetimibe, which is the only branded product to be singled out. Moreover, it is unfair and illogical to include ezetimibe as a comparator for statins in the care pathway when it is clear from NICE guidelines that ezetimibe is prescribed only after initial statin therapy or when statin therapy is inappropriate or contraindicated. Finally, [responder] is concerned about the process for developing the QIPP Prescribing Comparators, which ordinarily takes place after NICE has first reviewed and amended the KTTs. The issuing of QIPP Prescribing Comparators in advance of a NICE consultation on the KTTs is therefore premature and procedurally flawed.

TA132[1] ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia remains valid

Within the current KTTs,[2] the only description on ezetimibe refers to a lack of published evidence that ezetimibe reduces the risk of cardiovascular disease or mortality, and in the last

consultation on the KTTs, [responder] expressed our concern on the skewed evidence documented in the KTT. As NICE is aware, the results of an on-going cardiovascular outcomes trial (IMPROVE-IT) should become available in late 2014. TA132 will be reviewed once the results from IMPROVE-IT become available; therefore the positive recommendations for ezetimibe made in 2007 are the primary recommendations that must be followed by Clinical Commissioning Groups (CCGs).[3] The *Innovation, Health and Wealth* report, reiterating the NHS Constitution, makes it clear that all NICE-recommended treatments should be made available on formulary.[4] This is also the legal position pursuant to Regulations 7 and 8 of the National Institute for Health and Care Excellence (Constitution and Functions) Regulations 2013. The failure to include a summary of this key technology appraisal recommendation and provide clear reasons for not following it, is inconsistent with NICE's functions and contrary to its public law duties (see *R (on the application of Rose) v Thanet Clinical Commissioning Group)* [2014] All ER (D) 162 (Apr)).

Ezetimibe is not a comparator for statins in the care pathway

A number of documents including CG67[5] and TA132[1] clearly place ezetimibe after initial statin therapy in the care pathway. Patients in need of lipid lowering therapy should be initiated on a generic statin, with the option to titrate or switch to an alternative statin if cholesterol levels are not achieved. Ezetimibe is an option for those patients:

- Who are intolerant or contraindicated to first line statin, as monotherapy.
- As dual therapy for patients still not achieving recommended cholesterol levels, despite being prescribed the maximum tolerated statin dose.

Ezetimibe is not positioned by NICE or promoted by [responder] to compete with statins in the patient pathway, and for this reason, including it as a denominator in the 'low cost lipid modifying drugs' QIPP comparator and retaining the QIPP comparator 'lipid modifying drugs: Ezetimibe % items' is clinically inappropriate and is not consistent with current practice and NICE guidance. The inclusion of ezetimibe is therefore completely irrelevant and unreasonable in this context.

The implementation of the QIPP comparator at a local level is inappropriate

The overall aim of the 'lipid modifying drugs: Ezetimibe % items' comparator is to highlight CCGs and GP practices that have a variation from the mean and move them towards it. Whilst the KTT and QIPP Comparator documents do not state a 'target' for ezetimibe prescribing, at a local level CCGs are using this to identify 'outlier' GP practices, and reduce the use of ezetimibe. For example:

1) The [CCG] Prescribing Incentive Scheme (2012-2014)[6] introduced a prescribing incentive scheme in October 2012, which was active through to March 2014. This incentivised a target level of prescribing of ezetimibe of **2% or less**. No rationale was provided for the specific value, but the Scheme referenced its rationale as "*Included as an NPC QIPP indicator for 2012/2013*", along with "*NICE guidance*".

2) The [CCGs] Key Prescribing Performance Indicators (KPPI) 2013-2014[7]also incentivises a prescribing target for ezetimibe of ≤2% (relative to all statin + ezetimibe items). The documents states that "*The majority* [of the indicators] *are in line with nationally published recommendations from the National Prescribing Centre and Scottish Therapeutic Indicators*". Since February 2012, the NPC (now MPC) KTT chapter on ezetimibe has reproduced some of the recommendations for ezetimibe from relevant NICE guidance/guidelines (none of which contain a prescribing target). The document also states "[Prescribing incentive] *Schemes usually identify areas where practices are outliers within national benchmarks or where there is variation or clear room for improvement*".

Both schemes described above identify an arbitrary target prescribing level for ezetimibe that is justified on the basis of the QIPP Prescribing Comparators. We cannot understand how NICE or the HSCIC regard this approach as being clinically appropriate, as the introduction of these arbitrary targets is hindering the implementation of NICE guidance, TA132[1]. The evidence clearly points to the inclusion of ezetimibe in QIPP Prescribing Comparators is being used for improper purpose. We suggest that this is due, in part, to a lack of transparency over the process for developing a comparator for ezetimibe, in particular the uncertainty over variations in the eligible patient population for ezetimibe (see below).

If anything, the targets that CCGs are setting should be higher. For instance, the HSCIC report in January 2014[8], which provides an overview of the number of prescriptions of products approved by NICE, suggests the number of ezetimibe prescriptions is mainly in the region of 3 to 5%, although there is significant variation. Moreover, the NICE costing template that accompanied TA132[9] makes clear that a 2% figure is an estimate only of those patients that might benefit from ezetimibe monotherapy. It does not account for a potential 30% of patients who tolerate statins and who would be eligible for treatment with ezetimibe under NICE guidance. The costing template states:

> *"Although nearly all of the people with familial hypercholesterolaemia are likely to require treatment with lipid-lowering therapy, approximately 75% of people with non-familial hypercholesterolaemia are likely to require treatment (approximately 460,000 people). Therefore, a total of just over 470,000 people could be eligible for treatment with statin therapy.*
>
> *Approximately 2% of eligible patients are unable to take statins because of contraindication or intolerance. Therefore, approximately 10,000 people could be eligible for treatment with ezetimibe monotherapy.*
>
> *Of those people who are able to tolerate statins,* ***approximately 30% would be considered for an alternative statin or ezetimibe.*** *Approximately 140,000 people could be eligible for treatment with ezetimibe in combination with a statin."(Emphasis added).*

Assessment of variation

There is no attempt to differentiate between appropriate and inappropriate levels of variation. There is no evidence that associates the level of statin prescribing to an 'appropriate' level of ezetimibe prescribing. Prescribing levels should be based on the characteristics of individual patient populations and in accordance with NICE guidance: for example, in those areas with a higher incidence of cardiovascular disease or diabetes, NICE recommends consideration is given to lower cholesterol targets.[10] By NICE's own admission, statin monotherapy is not sufficiently efficacious for these targets to be achieved in all patients, implying an add-on therapy may be required (and recommended by NICE).[11] Such areas will therefore have a higher prescribing rate for ezetimibe (as a proportion of all lipid-modifying therapy use), relative to other patient populations, and this variation in practice may be clinically appropriate and warranted.

Such differences are not considered or accounted for in the proposed methodology and so it is not clear why the inclusion of ezetimibe in QIPP Prescribing Comparators is justified as a quality indicator. This is particularly the case when NICE acknowledges in the KTT chapter on ezetimibe that "*there are significant uncertainties involved in establishing an estimate of the eligible patient population*". The inclusion of a quality indicator based on such uncertainty is unreasonable, particularly given the potential knock-on effect to reduce significantly the prescribing of ezetimibe.

Please note that we will be sending a copy of this letter to NICE to bring this important matter to the attention of that body.

We would be happy to discuss any aspect of this letter with you and look forward to your response. We reserve all of our rights in relation to this letter and the development of the QIPP Prescribing Comparators (and associated NICE KTTs) as they apply to ezetimibe.

Yours faithfully,

[responder]

cc NICE

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