NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Medicines optimisation

Date of Quality Standards Advisory Committee post-consultation meeting:
18 December 2015

2 Introduction

The draft quality standard for medicines optimisation was made available on the NICE website for a 4-week public consultation period between 5 October and 2 November 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 38 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Overall stakeholders welcomed the quality standard and its quality improvement areas.
- Some stakeholders pointed out that there was no hospital pharmacist with medicines reconciliation experience in the quality standard advisory committee.
- Suggestion that the quality standard needs to better explain why it is needed.
- The document needs to reflect the patient journey.

- Suggestion to add information about the role of the nurses in reporting adverse effects to prescribers.
- Concern that the quality standard is missing the children's perspective.
- Suggestion to reword the measures and make them more consistent with the statements.
- Concern that focusing on reduction in numbers of patient safety incidents is inconsistent with other national messages about improving reporting rates and may not encourage openness.
- Disappointment that the quality standard focuses on GP practices and acute settings while it misses the role played by community pharmacists in medicines reconciliation.
- Need to cover the complementary medicines user reviews delivered by community pharmacies.
- Concern that medicines optimisation principle 2 (evidence based choice of medicines) is not reflected within the quality standard and suggestion that it should be included in statements 1, 4 and 6.
- Some stakeholders highlighted that the quality standard does not include all the elements of medicines optimisation: helping patients to make the most of medicines by the Royal Pharmaceutical society.
- Concern that the quality standard does not mention the problem of inaccurate lists of medicines transferred between sectors and medicines often get missed off.
- Suggestion to refer to 'healthy' life expectancy in the introduction.
- Suggestion to mention patient safety under the "patient experience and safety issues" section.
- Suggestion to add a link to quality standard 85 Medicines management in care homes to explain why care homes are not included in this quality standard.
- The quality standard does not include anything specific to the actual taking of medicines.
- Need for the quality statements to be more outcome focused.
- Claim that the multi-morbidity definition is incorrect.

- Suggestion to have an estimate of the scale and implications of not taking medicines as intended and who is affected.
- Need to determine a management strategy for medicines optimisation followed by review and audit.
- Difficulty to obtain information from primary care in protecting people from avoidable harm. Suggestion to use the RCGP patient experience questionnaire.
- Suggestion to reword the quality measures.
- Concern that some long term conditions (such as osteoporosis) do not appear on the list. Suggestion to include a sentence to guide the readers to the broader definitions of long term conditions.
- Suggestion to take account the wording used in published government guidance on improving the use of medicines.

Consultation comments on equality & diversity

- Important to recognise the right of all competent adults to accept or refuse treatment.

Consultation comments on data collection

- Possible to collect the data.
- Some stakeholders suggested it is possible to collect the data at a national level. For example with the use of the Secure Anonymised Information Linkage system or the nurse-led monitoring profiles.
- Suggestion to clearly define what should be measured so outcomes can be measured using standardised tools
- Local collection can lead to variation in the way organisations collect data.
- Need to specify ‘local’.
- Labour intensive and costly to collect the data.
- The measures are not patient outcome based.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People have the opportunity to be involved in making decisions about their medicines.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- In general, stakeholders supported the statement and patient involvement as a key improvement area.
- Suggestion that statement should read ‘people should have the opportunity…’
- Suggestion to involve the pharmacist or nurse practitioner.
- Suggestion to extend the new medicine service to any new medicine the person has started and for the medicine user review to be also undertaken outside of the pharmacy.
- Need to give people evidence based information including risks and benefits of taking the medicine.
- Patient decision aids can be used to support a shared consultation approach.
- Define patient decision aids.
- Ask patients if they feel sufficiently involved as part of existing patient surveys.
- Suggestion that the patient’s decision on drug treatment should be included in their care plan and medication adherence should be measured against the plan.
- Need to emphasise the role of carers for patients with support needs.
- Suggestion to include informed refusal in the rationale.
- Concern that it is difficult to get the patient’s treatment goals in a typical 10 minute consultation.
- Question whether the fields of the friends and family test can include the appropriate questions for this statement.
- Emphasis on the needs of people with epilepsy.

Consultation comments on equality & diversity

- Suggestion that people with mental capacity issues should be offered advocacy.
- Identify patients with communication issues and offer aids to facilitate decision-making.
- Suggestion to make explicit that family members or carers can be involved in decision making when necessary.

Consultation comments on adherence

- Concern that the statement does not address the issue of non-adherence.
- Support healthcare professionals in understanding adherence and shared decision making.
- Need for a standard definition of adherence.
- Suggestion that medicine user reviews and new medicine service can support patients in making choices around drug therapy and improve adherence.

Consultation comments on measures

- Outcome measure should include patient desired outcomes.
- Suggestion to include additional outcome measures on adherence which could include tracking of GP follow-up appointments relating to medication review or the monitoring of treatment switching.

Consultation comments on data collection

- Possible to collect the data but it can be very time consuming and need to be clear on who is going to collect the data.
- Several stakeholders expressed concern that it will be difficult to measure accurate adherence rates. This is especially so in general practice surgeries and in the community where patients are self-administering.
- Many factors can influence adherence rates not just decision making involvement.
- Concern that for some conditions the optimal use of medicines is the use that the user finds optimal (For example non-curable and asymptomatic conditions).
- Need for clarity on method used when collecting patient reporting outcomes, frequency of data collection and the way data will be utilised.

- Suggestion to include quality outcome frameworks in primary care.
- Need for IT involvement to capture evidence in an efficient manner.
- Suggestion that electronic prescribing would aid data collection.

Consultation comments on barriers to implementation

- Need for interpreters or patients advocacy for people with language or mental capacity issues.
- Provide training for healthcare professionals and education materials for patients.
- Need to be specific on what aspect of patient satisfaction we want to achieve e.g. in joint working or effect of medication.
- Financial incentives (for example CQUIN) to reward organisations for success
- Put in place a referral system for patients with adherence issues.
- Suggestion to provide guides on ‘questions to ask your doctor’ with possible answers to empower patients.

5.2 Draft statement 2

Health and social care providers monitor reported medicines-related patient safety incidents to inform cross-sector action and best practice in the use of medicines.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- In general, stakeholders supported this statement as a key area of quality improvement.
- Sharing safety incidents within a no-blame culture can lead on the delivery of training on managing risks.
- Query if this standards fits with the work undertaken by NHS England and the MHRA.
- Stakeholders highlighted the role of the medication safety officer and medication safety subgroup to review accuracy and classification of incidents.
- Need for an electronic reporting incidents system.
- Suggestion to analyse data at a national level to highlight incident trends.
- The review results should be used to develop risk minimisation strategies.

- Need to define who will have overall responsibility in ensuring that all stakeholders participate.
- Concern that the statement is more focused on reporting than learning.
- Concern that the statement is not focusing on under-reporting.
- Difficult to monitor patient safety incidents in the community.
- Need for clear information governance arrangements.
- Include a categorisation of review levels of incidents of different hard outcome/potential.
- Need to inform drug manufacturers of adverse events.
- Unclear how incidents will be shared between providers.

Consultation comments on definitions

- Good to see a broad definition ‘patient safety incidents’ related to medication use.
- Need a clear definition of ‘monitor’ and ‘review’.
- Need to define ‘safety incidents’ as adverse drug reactions are not always safety incidents.
- Suggestion to link the definition of medicines related patient safety incidents to the NRLS definitions.

Consultation comments on measures

- The measure is appropriate and easy to measure.
- Suggested outcome measures: a) increase in overall number of reports, b) decrease in occurrence of high severity incidents, c) increase in proportion of low severity.
- Suggestion to reword the process measure to ‘the percentage of medicine-related patient safety incidents that get reviewed’.
- The outcome measure does not link well to the quality statement.
- Suggestion to focus on moderate – high harm incidents.

Consultation comments on data collection

- Possible to collect the data.

- Suggestion to collect local data on prescribing safety incidents.
- Need to be clear on who is going to collect the data.
- Suggestion to collect data by type of incident.
- Suggestion to focus on evidence of procedures in place and their utilisation.
- Concern that the data collection will not evidence sharing and learning.
- It will not be possible to collect the data as reporting rates are not related to incident rates.

Consultation comments on barriers to implementation

- Prescription errors should be entered in datix and can be reduced with the use of electronic prescriptions similar to EPMA.
- Learning outcomes to be fed to the patients.
- Ensure all medicines related patient safety incidents are reported.
- Adoption of a fair blame culture is not easy to implement.
- Need for a medicines safety officer.
- Healthcare professionals need a better understanding of error theory.

5.3 Draft statement 3

People who take medicines receive information on how to identify and report medicines-related patient safety incidents.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Stakeholders agree that this is a key area for quality improvement as it related to patient involvement and medication safety.
- Need for a referral system when a patient voices concern about their medicines.
- Suggestion to have a national patient leaflet on identification of incidents.
- Information on how to report incidents within the patient information leaflet in the medicines packaging.
- Concern about inappropriate reporting from the public.
- Query on whether the information given to patients should be specified.
- Query on how to assess ‘potentially avoidable’.

- Query on how safety incidents will be collated, checked and analysed and if any comparisons will be made.
- Suggestion to use nurse-led medicines monitoring profiles.
- Query on whether patients could access existing reporting mechanisms such as Datix.
- Suggestion to make people aware of the yellow card reporting scheme.
- Risk of reducing a patient's confidence in their health care professional and the service
- Suggestion to include how the medicines error is dealt with.

Consultation comments on equality & diversity

- People whose first language is not English.
- People with communication difficulties may not be able to understand how to identify and report incidents.

Consultation comments on measures

- Several stakeholders suggested that the outcome measure should be about patient reported safety incidents.
- Suggestion that the measure should be about the process being implemented rather than being in place.
- Concern that the outcome measure is vague.

Consultation comments on data collection

- Concern that it will not be possible to collect the data.
- Difficult to measure and implement.
- Data sources are vague.
- Suggestion to use current processes such as PALS.

Consultation comments on barriers to implementation

- The increase in incident reporting will have a resource implication.
- The public needs to be assured that learning will improve quality of care.

- Current patient and professional culture.
- Suggestion for a national awareness campaign.
- Need to explain to patients the difference between medicines-related patient safety incidents and the yellow card scheme.
- Suggestion to involve patient in root cause analysis.

5.4 Draft statement 4

People admitted to an acute setting, or transferred within acute settings, have a reconciled list of their medicines within 24 hours.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Suggestion that the statement should be more specific about the use of a checklist.
- Suggestion to reword the statement to read ‘reconciled and prescribed within 24 hours’.
- A pharmacist or registered pharmacist technician should be responsible for the reconciliation process.
- Add a discharge summary and medicines list as an additional safeguard.
- Suggestion that the reconciliation should be carried by a trained and competent professional.
- Make clear that a healthcare professional will carry out the reconciliation process.
- Suggestion that a list of medicines should travel with the patient.
- Suggestion to include medicines reconciliation at discharge.

Consultation comments on equality & diversity

- People whose first language is not English.
- People’s ability to understand medicines reconciliation may differ.

Consultation comments on definitions

- Include in the definition of ‘reconciled list’, talking to the person to find out how they take their medicines and any problems they are experiencing. Also, include a

review of the patient's own drugs that they have brought with them and an indication of other medicines at home.

- The definition should include which category of incidents will be reduced.

Consultation comments on 24 hours

- Stakeholders suggested defining "24 hours". If it is 24 hours according to the clock, it will be very difficult for Trusts to achieve without electronic prescribing.
- A stakeholder claimed that the 24 hours timescale is currently impossible.
- Need to make it explicit that reconciliation is a requirement within 24 hours of admission and that it applies 7 days a week.
- Concern that 24 hours may be too long to be without some medicines.

Consultation comments on measures

- Appropriate and measurable structure and process measures.
- Suggested outcomes: improved patient care, efficient use of medicines, reduction of waste, accurate records.
- Suggestion the outcome to be about reduction of incidents that are due to a medicines reconciliation failing.
- Outcome measures do not reflect medicines reconciliation.
- Suggestion to exclude day case and very short stay from the denominator.

Consultation comments on data collection

- Data is currently collected in hospitals via the patient safety thermometer.
- Possible to collect the data with an integrated IT system.
- Query where this data will be captured from.
- Concern that local collection with no guidance will result in different methodologies and no consistency or comparative potential.
- Challenging volume of data to collect on a regular basis.

Consultation comments on barriers to implementation

- Electronic prescribing would enable this metric to be accurately measured.

- There needs to be fast access to patient records by both primary and secondary care to reconcile medicines within 24 hours especially at weekend when most surgeries are closed.
- Central patient records for all sectors would be a step forward in meeting the requirements of this statement.
- Some patients may not want their GP informed about their chronic condition.
- Patients using blister packs may not recognise any medicine changes.
- Adequate resources are needed to ensure a 7 day service.
- Currently it is not a requirement to report medicines reconciliation. This needs to be a contractual obligation.

5.5 Draft statement 5

People discharged from an acute care setting to primary care have their medicines documented in the discharge summary and reconciled in the GP list within 1 week of the GP practice receiving the information.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- In general, stakeholders supported this statement.
- Need to be more specific about the use of the checklist.
- Suggestion to explain in the statement that a healthcare professional should carry out the reconciliation.
- Suggestion that community pharmacists should also undertake reconciliation after discharge.
- Need for the hospital pharmacist to communicate with the community pharmacist.
- Primary care should receive an accurate list of the patient's medicines.
- The GP may not be the most appropriate person to carry out the reconciliation for people who are discharged to a residential home or staying with family.
- Concern that a week is too long for people with compliance aids.
- Enough medication should be prescribed to last the patient for a week.
- Suggestion for a national standard framework to report changes made.

Consultation comments on statement

- Suggestion for the statement to include all settings.
- Suggestion to read code this statement in the GP clinical system using a nationally standardised read code.
- Suggestion to align the statement with the Royal Pharmaceutical Society guidance.

Consultation comments on measures

- The outcome measure needs to be more specific to the statement.
- The process measure could be challenging to measure at GP practice level.
- Query on how the outcome will be measured.

Consultation comments on data collection

- Possible to collect data if electronic prescribing and discharge systems exist.
- Possible to collect the data through QOF.
- One stakeholder was unsure whether the data could be collected and asked how the reconciliation would be adjudicated.
- Suggestion to separate the discharge summary and the medicines reconciliation into two separate measures to give more meaningful data.
- Challenging to measure the denominator and may capture people who are not relevant.

Consultation comments on barriers to implementation

- Need for extra resources in primary care as appointments with GPs within one week are difficult to make.
- Suggestion to make this a requirement of the GP contract.
- Sometimes the discharge summary lists medications which should only be prescribed in hospitals.

5.6 Draft statement 6

People taking multiple medicines or taking medicines for long-term conditions have a discussion with their healthcare professional about the need for and purpose of a structured medication review.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- Suggestion to include some detail and timescale about the review.
- Suggestion to record how many medications stopped and started.
- Add to the rationale that stopping medications can have savings and help the environment.
- Cost of inappropriate use of inhalers.
- Suggestion to include community pharmacists.
- The patient's beliefs and values should be taken into consideration.
- Suggestion that nurse-led profiles can facilitate the review.
- Need to make a clear that the review should be completed and not just the discussion about the review purpose.
- Suggestion to reference tools such as STOPP/START.

Consultation comments on statement wording

- Suggestion to change 'their healthcare professional' to 'a healthcare professional'.
- Suggestion to amend the statement to ensure evidence based choice of medicines is reflected within its structure.

Consultation comments on definitions

- Suggestion to define multiple medicines and long term conditions.

Consultation comments on equality & diversity

- Some people are not able to have this discussion.

Consultation comments on measures

- Need for an outcome measure.
- Suggestion to measure structure medication reviews have taken place as the numerator.

Consultation comments on data collection

- Suggestion for the numerator to record patients receiving an appointment related to a medication review.
- Need for an integrated patient record to avoid duplication and gaps.
- Needs to be recorded and measured through QOF.

Consultation comments on barriers to implementation

- Suggestion to make clear who will perform the medication review to avoid duplication.
- Need to explain the triggers for the review.
- Suggestion to use patient decision aids.
- To overcome the barriers there is a need for a culture shift across the health sector.

5.7 Draft statement 7

Health and social care providers adopt a multidisciplinary approach to communicating complete and accurate information about the use of a person's medicines when people move between care settings.

Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

- Essential to have a multidisciplinary approach to communicating information to ensure there is no conflict between treatments for different conditions.
- Suggestion to include outpatient attendances.
- Several stakeholders described this statement as not necessary and similar to statement 5.

- Suggestion that the statement needs to be clear about what information needs to be transferred.
- Need to focus on whether the process has been implemented rather than whether it is in place.
- Concern that written protocols cannot ensure the adoption of a multidisciplinary approach.
- Need to use a standardised layout.
- Suggestion to identify who will have a leading role in this process.
- Need to include a timeframe.
- The rationale also needs to reference social care.

Consultation comments on measures

- Outcome measure not directly related to the statement.
- Unclear whether a reduction in medicines-related incidents will be a meaningful measure of approved quality.

Consultation comments on data collection

- Suggestion for all GPs to use the electronic prescription system, EMIS, and to be accessible by secondary care.
- Problems with information governance.
- Not possible to collect the data for this statement.
- Data needs to be up to date and clear.

Consultation comments on barriers to implementation

- Different IT systems within the NHS that are not able to easily communicate with each other.
- Need to define the population that is likely to benefit.
- Willingness of organisations to work together.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Provide patients with the indication for their medicines and information about side effects.
- Medicines reconciliation at discharge from hospital. This should also include the discharge information and acceptable timescales.
- Reporting of medicines-related patient safety incidents with an emphasis on near misses.
- Explore people's experiences of medicines and their beliefs about them to identify barriers to adherence. This should be done before initiating medication, especially for long-term conditions.
- Recommend the use of electronic prescribing to reduce errors and improve optimisation.
- Primary care should receive an accurate list of medicines that a patient needs to continue on discharge. The list should indicate which medicines have been discontinued and for what reason, what has been started and for what indication, any follow-up monitoring etc.
- Updated list of medications from GP to the specialist clinics at least twice a year to prevent incidents of drug interaction, prescribing errors etc.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments
1	North Bristol NHS Trust	General	There does not appear to have been a hospital pharmacist, especially one with medicines reconciliation experience included on the QS Advisory Committee and NICE project team. As NBT have the best results for an Acute Trust in England and Wales (by QIPP measurements) it would have been useful for the group to have used our experience – but we would still welcome any further liaison over this (see QS2 below for further contact details) Many of the quality statements have a stated outcome "(reduction of / number of) reported medicines-related patient safety incidents" Medicines optimisation has many other outcomes, and indeed reduction of occurrence of incidents may not always be an outcome. Medicines optimisation is a focus on the patient through every stage. Following the principles of medicines optimisation should improve patient care, allow more efficient use of medicines, reduce wastage of medicines, increase patient understanding of their medicines, ensure updating of information, ensure safe transfer of information and reduce harm to patients, improve patient experience and quality of life. There should be clear mention of the 4 Principles of MO –as per the DH sponsored Medicines Optimisation framework – summary below i.e. This MUST include improved outcomes and aligned measurement and monitoring of MO. This fundamental framework is the basis for all Medicines Optimisation work nationally!
2	North Bristol NHS Trust	General	This defines Medicines Optimisation but not "why this quality standard is needed" in addition to other publications by various professional bodies. The quality standard is needed to ensure a consistent approach throughout the UK/NHSE, preferably using standard measures. This would allow a consistent approach and understanding, as well as the ability to share data and improve practice. The standard of data would not be affected by movement of staff and patients throughout sectors (primary secondary care etc.) or geographical movement.
3	North Bristol NHS Trust	General	Looks like an appendix at the start of the document
4	UK Clinical Pharmacy	General	Question 1: Yes but needs to be more prescriptive

ID	Stakeholder	Statement number	Comments
	Association		
5	UK Clinical Pharmacy Association	General	Question 2: Yes
6	Merck Sharp & Dohme	General	MSD fully support Quality Standards to drive uniform quality care across the NHS. Please find our comments below.
7	Great Western Hospitals NHS Foundation Trust	General	There does not appear to be any hospital pharmacists or technicians on the QS Advisory Committee and Project team. Specifically one involved or experience of medicines reconciliation
8	Great Western Hospitals NHS Foundation Trust	General	Medicines optimisation is about the patients journey and this does not appear to be reflected in the document. A move away from process and specific outcomes
9	Royal College of Paediatrics and Child Health	General	This document appears to have been written from an adult perspective only. Whilst it can be assumed that parents are valid representatives, there are difficulties when considering different values and preferences for a child. A parent has a duty of care to their child, and circumstances may arise when parental preference must be over-ridden.
10	Medicines Use and Safety Team NHS Specialist Pharmacy Services	General	Lack of consistency and confusion throughout the document about process and measurement and outcome
11	Medicines Use and Safety Team NHS Specialist Pharmacy Services	General	Concern that focussing on reductions in numbers of patient safety incidents is inconsistent with other national messages about improving reporting rates to NRLS. You can easily reduce numbers of incidents by stopping reporting…. It would be better to focus on the reductions in incidents due to a particular cause as a proportion of total incident reporting. This way you can reduce the proportion of incidents due to a particular cause by increasing overall reporting. This at least keeps the message consistent.
12	Northumbria Healthcare NHS Foundation Trust	General	This quality standard does not include all the elements within *Medicines Optimisation: Helping patients to make the most of medicines. Good practice guidance for healthcare professionals in England. May 2013* (document endorsed by Medical Royal Colleges, RPS and RCN). Question 1 in the consultation asks if the draft standard accurately reflects the key areas for quality improvement. It certainly reflects some of the most basic/fundamental areas of practice that needs to change/improve (and are otherwise often overlooked). The standard contains very few useful metrics – perhaps reflecting the narrow focus adopted? Medicine incident reporting is frequently mentioned – limited use in the context described.
13	Swansea University	General	Generally, the document is interesting and worthwhile. I hope these comments will be useful. Please contact me if I can any further.
14	Swansea University	General	Should this refer to 'healthy' life expectancy?
15	Swansea University	General	'Local' is underspecified. Should there be a recommendation as to systems used? There is potential to collect these data on national levels e.g. with the Secure Anonymised Information Linkage (SAIL) system in Wales. Should there be some provision to use these systems?

ID	Stakeholder	Statement number	Comments
16	Swansea University	General	It would be useful to add: If patients are prescribed medicines, nurses will check regularly that they are not experiencing any adverse effects, document this, and report to prescribers. Prescribers will ensure that patients receive the maximum benefit and minimum harm from medicines.
17	Swansea University	General	With a regular monitoring system in place using nurse-led monitoring Profiles, it would be possible to collect the data electronically and merge it with primary care data for analysis at national level. The existing reporting systems miss too much.
18	Swansea University	General	I should be happy to discuss developing my suggestion, above.
19	NHS England	General	Under "Patient experience and safety issues" patient experience is mentioned but there is no mention of patient safety which is a fundamental principle of Medicines Optimisation.
20	NHS England	General	The key question is missing here i.e. does the proposed Quality Standard accurately reflect the four principles and seven elements of Medicines Optimisation as described in the RPS document "Medicines Optimisation: Helping patients to make the most of medicines". Each Quality statement should directly address one of these principles or elements.
21	NHS England	General	It might strengthen the response to this question to add a link to QS 85 Meds Management in Care Homes to explain why care homes are not covered in this particular QS. This would then reflect what is said in the introduction of the QS document.
22	NHS England	General	Although it is reasonable to focus the QS around medicines optimisation of diagnosed long term conditions as listed by the Dept Health there are some clinically recognised conditions that fit the definition that do not appear on the list. Conditions such as osteoporosis is an example and we would have some concerns that readers of this QS might focus their attentions solely on the list to the exclusion of other conditions that equally left treated sub optimally will inevitably lead to poor outcomes for patients. A sentence to guide readers that to the broader definitions of LTC may be helpful. The addition of links to other NICE clinical guidelines may also be useful such as CG 161 where routine medication review for older persons living in the community is a recommendation.
23	Dispensing Doctors' Association	General	Question 1: No, we do not believe it does reflect the key areas for quality improvement. For dispensing GPs, the key problem is that the lists of medicines transferred between sectors are not always accurate; drugs are often missed off. Some are not needed in hospital, for example, creams and PRN medications.
24	Dispensing Doctors' Association	General	Question 2: It would be extremely labour intensive to collect all of the data and we believe that it would produce more costs than benefits.
25	Dispensing Doctors' Association	General	Question 3: Statement 1 We support the aim of this. Statement 2 We support this. However, there is a lot of important pieces of information about relating to safety incidents which needs to be identified and it requires somebody to edit the information before it is sent out to providers. Statement 3 We support this.

ID	Stakeholder	Statement number	Comments
			Statement 4 This is a wonderful aspiration. However, it really does not accord with what is going on in the service. There is no recognition of how the GPC out-of-hours services works. The IT is nowhere near comprehensive enough to assist. This also assumes that the acute Trust will have an accurate and appropriate list. It would be sensible to set out in the discharge summary why a patient's medication is being changed. Statement 5. We support this. With regard to the discharge summary, this sometimes lists medications which should only be prescribed in hospitals, for example, some chemotherapeutic agents. Often discharge summaries do not appear within a week of the patient having left hospital and what does appear is not always of much use to be recorded in primary care. Many of the basics have yet to be got right before this could be introduced. Statement 6. We support this but it comes with a large cost. It is a wonderful aspiration, but there is a lack of clarity about who is responsible for undertaking this work.
26	Thames Valley and Wessex Chief Pharmacists Network	General	We fully support all of the quality statements as aspirational goals in areas of need for medicines optimisation.
27	Thames Valley and Wessex Chief Pharmacists Network	General	Nearly all the suggested measures require local data collection. This will create an industry of data collection processes that will be developed in different ways in different organisations making any attempt to benchmark almost impossible. If the data collection must be local, there needs to be a clear definition of what should be measured and how to make the measures meaningful and to support commissioners when comparing provider performance.
28	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	General	GMMMG is happy to support this quality standard and would be happy to endorse it jointly with NICE.
29	Bath and North East Somerset CCG	General	There are no standards about providers/ commissioners prioritising use of evidence based medicine for the standards to be complete and complement the Medicines Optimisation model set out by the professional body (principle 2 there should be some reference to these domains
30	GlaxoSmithKline	General	The quality standard uses a definition of medicines optimisation that refers to 'safe and effective medicines use.' This draft however does not include anything specific to the actual taking of medicines (medicines taking experience or the choosing clinical effective medicines).
31	GlaxoSmithKline	General	We note that having reviewed the full list of quality statements against the four principles of medicines optimisation, it appears that principle 2 (Evidence based choice of medicines) is not reflected within the standard. We have commented that it should be included within quality statement 6. Consideration could also be given to how it can be incorporated within quality statements 1 and 4 as well.
32	GlaxoSmithKline	General	The overarching purpose The Royal Pharmaceutical Society document 'Medicines Optimisation: Helping patients to make the

ID	Stakeholder	Statement number	Comments
			most of medicines' is to support patients getting the best use of their medicines. The quality statements are process measure based but do not contain any specific patient outcome based measures. Will NICE consider reviewing the Quality Standard to ensure outcomes based measures are included?
33	GlaxoSmithKline	General	To deliver a real step change in the delivery of the medicines optimisation agenda will require a culture shift across the whole health sector. What implementation plans are NICE developing to ensure this Quality Standard is not tokenistic or seen as merely a tick box exercise?
34	Luton & Dunstable Hospital NHS Foundation Trust	General	Not all the quality standards are clear and concise nor are they designed to drive measurable achievements. Most are process orientated rather than outcome focussed and based on the assumption that delivery of a process is a good surrogate measure for outcome.
35	British Medical Association	General	Overall the quality standard seems to overlook the important role that community pharmacists should play in the safe and effective use of medicines.
36	The Royal College of General Practitioners	General	A thoughtful and sensible document, it would be helpful to have some estimate of the shape, size and scale of the problem and the implications from fairly trivial to life threatening. (PS)
37	The Royal College of General Practitioners	General	The epidemiology: who is affected in the "patient" population - old, frail, confused, mentally ill and people who fail to comply because of misunderstanding, perversity and manipulation but also because of inadequate information and guidance. It is a multi-faceted problem and is often perceived as patient failure rather than professional failing. (PS)
38	The Royal College of General Practitioners	General	The problem is a combination of mistakes: ignorance of interactions, unforeseen interactions (unknown unknowns), omissions and human failure and mistakes. (PS)
39	The Royal College of General Practitioners	General	The essence is the coming together and sharing between clinician/prescriber, the pharmacist, the patient and carer. They need to determine a management/caring strategy and of regularly auditing, the effectiveness, problems, costs and benefits and making changes together in an open minded way. It is also being prepared to sacrifice therapeutic efficacy against patient choice and life style. (PS)
40	The Royal College of General Practitioners	General	The aim is to improve the quality of the patient's life and secondly of the quantity (QALY). (PS)
41	The Royal College of General Practitioners	General	The objective is to provide maintenance care of chronic conditions, palliative care of progressive disease and, on occasion, curative care. (PS)
42	The Royal College of General Practitioners	General	The means are about a tailor-made package of medication, life style, surgery, behaviour, choice and tolerance of alternative medicine and refusal. (PS)
43	The Royal College of General Practitioners	General	The process requires a plan, action, review and audit. (PS)

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44	The Royal College of General Practitioners	General	It is going to be difficult to obtain information on the following, particularly for primary care. There is currently a study being undertaken for the Department of Health to understand the incidence and causes of avoidable significant harm in primary care. Obtaining this information is challenging and time-consuming, and while it is one of the objectives of the study. This is not to say that it is not worth having these indicators; there needs to be an acknowledgement that it would not be straightforward to obtain the data. (TA)
45	The Royal College of General Practitioners	General	The RCGP have produced e-learning materials which are hosted on the RCGP website, and have been well evaluated by participating GPs: http://www.rcgp.org.uk/learning/online-learning/ole/prescribing-in-general-practice.aspx (TA)
46	Tees, Esk and Wear Valleys NHS Foundation Trust	General	The Quality Standards broadly seem to reflect the key issues from the NICE MO guidance and would help contribute towards improved MO. Some concerns overall regarding some of the expected outcomes and some of the measures – especially the ability to collect them as part of routine practice. If we're striving to make medicines optimisation part of everyday practice then it's essential that we make the recording as simple as possible and not create challenging systems to collect evidence. There is a tension throughout the outcome measures between increasing reporting and reducing incidents – we need to be clear nationally what we are aiming for. There's a danger in this mixed message as it may not encourage openness.
47	Department of Health	General	Where the quality measure structure states that 'Evidence of local arrangements to ensure that….' we feel there should not be an emphasis on local arrangements. We suggest that it could read 'Evidence that demonstrates that…..'
48	Department of Health	General	Please take note of currently published government guidance on improving the use of medicines: https://www.gov.uk/government/publications/action-plan-for-improving-the-use-of-medicines-and-reducing-waste. This guidance has specific points for action relating to a number the areas covered in this draft such as 'Engaging people in decisions about their medicine and improving communications between health and social care professionals and patients'. We feel all quality standards should take account of wording used in this document.
49	Royal College of Physicians	General	Typographical error - The definition of multi-morbidity is not correct. 'When 1 or more noncurable long-term conditions are diagnosed, this is termed 'multimorbidity'
50	Royal College of Paediatrics and Child Health	General	Equality and Diversity. It is the right to all competent adults to accept or refuse treatment without fear of adverse response. This is not a matter of recognizing cultural differences, just one of recognizing that we are treating people.
51	Swansea University	Equality and diversity	Need to add: All documentation should comply with the Welsh Language Act 1993.
52	North Bristol NHS Trust	General	***Questions about the quality standard*** **Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? **Yes** **Question 2** If the systems and structures were available, do you think it would be

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			possible to collect the data for the proposed quality measures? **Definitions need to be made explicit so outcomes can be measured using standardised tools.** **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? S**ee below**
53	Epilepsy Action	General	**Question 2 - Does the draft quality standard accurately reflect the key areas for quality improvement?** Yes
54	Epilepsy Action	General	**Question 2 – If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?** Yes
55	Guild of Healthcare Pharmacists	General	Question 1: Yes, the 7 quality statements pick up the key areas within the overarching NICE Medicines Optimisation Guidelines (NG5). All of the recommendations in NG5 can be incorporated into the 7 standards.
56	Guild of Healthcare Pharmacists	General	Question 2: Possibly, but one area of concern would be the consistency in what is actually collected between different organisations if the data are to be used to benchmark or compare different service providers
57	Walgreens Boots Alliance	General	Question 1: No. We find this draft QS hugely disappointing in its focus only on general medical practices (GPs) and acute settings. There appears to be little or no recognition of the role played by community pharmacists in medicines optimisation and, worryingly and in particular, in medicines reconciliation after patients change setting. It is unclear whether this QS would be binding in Wales, but, either way, it is disappointing that no recognition has been given to the Discharge Medicines Reconciliation (DMR) service now provided by community pharmacies in Wales. An independent evaluation of the DMR service shows that it delivers real benefits in identifying and resolving post-discharge medicines anomalies by sending community pharmacies copies of discharge summaries. Replicating this service in England would be a key area for quality improvement. http://www.cpwales.org.uk/Contractors-Area/Pharmacy-Contact---Services/DMR/DMR-Evaluation_Final-Report_13082014.aspx The draft QS (Standard 6) focuses only on the structured medicine reviews, normally delivered in GP practices and ignores the complementary medicines use reviews (MURs) delivered by community pharmacies in England and Wales. Last year over three million patients in England had a structured discussion with a pharmacist about how they use their medicines and whether they are experiencing any problems with them. Discussing with patients how, when and why they should use medicines as prescribed (or why they choose not to do so) is just as important as a clinical review focusing on whether medicines are still needed. Medicines can be useless if patients fail to take them properly.

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			http://psnc.org.uk/funding-and-statistics/nhs-statistics/mur-statistics/
58	Gloucestershire Hospitals NHS Foundation Trust	General	Question 1: Yes, the 7 quality statements pick up the key areas within the overarching NICE Medicines Optimisation Guidelines (NG5). All of the recommendations in NG5 can be incorporated into the 7 standards.
59	Gloucestershire Hospitals NHS Foundation Trust	General	Question 2: Possibly, but one area of concern would be the consistency in what is actually collected between different organisations if the data are to be used to benchmark or compare different service providers
60	Luton & Dunstable Hospital NHS Foundation Trust	General	Question1: Mostly although it does not cover the full range of medicines optimisation
61	Luton & Dunstable Hospital NHS Foundation Trust	General	Question 2: The current definitions do not support data collection that is reproducible or comparable between organisations. The definitions are often vague and open to differing interpretation. Realistically much of this data is currently not easily collected. This effectively means this quality standard as it is currently formulated does not support continuous improvement (on-going measurement of performance in a standardised format, both within and across organisations, which can support identification of successful interventions and encourage their adoption and embedding).
62	Luton & Dunstable Hospital NHS Foundation Trust	General	Question 3: See comment on statement 1 re: adherence.
63	Royal College of Physicians	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so, we have liaised with the British Thoracic Society (BTS) and wish to fully endorse their submission. We have also liaised with our experts in clinical pharmacology and would like to make the following comments based on the consultation questions: Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? Question 2 If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Question 3 For each quality statement what do you think could be done to support improvement and help overcome barriers?
64	East Lancashire Hospitals NHS Trust	1	Patients may wish to be supported in decision making around choices in drug therapy following initiation in hospital after a period of reflection. Post-discharge Medicines Use Review (MURs) and New Medicine Service (NMS) offer this opportunity and are proven tools for improving medicines adherence. We feel that this framework for follow-up support should be included in the standard e.g Refer to Pharmacy (www.elht.nhs.uk/refer). We know locally in Lancashire the number of post-discharge MURs for 2014 was around 400 for the whole County. This is a very small proportion of the overall discharges from secondary care.
65	North Bristol NHS Trust	1	Outcome a) Patient medication adherence rates." Need a standard measure of adherence.

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			Definition of adherence should include what the patient has decided they want to do. The patient's prescription should match what they have decided. Measure adherence to the plan. Time needs to be made available to ensure HCP can liaise with patients and discuss actual adherence to their current prescription and discuss plan. Need to document any agreed plan. In secondary care adherence can be measured by recording missed doses (and reason for these e.g. patient choice or supply issues). Patient medication adherence rates could be difficult to measure once the patient leaves hospital. Community pharmacists can monitor frequency of requests for repeat medication but this will not necessarily reflect whether the medications have been taken. Need to consider where self-administration fits into this standard. Self admin in the acute setting can promote adherence via education. b) Patient satisfaction can be easily measured but need an agreed standard method. Rob Horne at Brighton & Sussex has worked on satisfaction validated questionnaire and Health beliefs.
66	Royal Bournemouth and Christchurch NHS Foundation Trust	1	General: Agree that a key area for quality improvement. However, involving patients in a decision around a key medicine for a chronic illness is different compared to, for example, the raft of medicines that are prescribed in a high acuity area. The involvement of the pharmacist or nurse practitioner would be key to augmenting decisions made by consultants. Will be difficult to measure accurate adherence rates as a Quality measure. Will this measure therefore be meaningful? Pt satisfaction rates – subjective data – will give a good flavour as to how an organisation is performing and could be drilled down to prescriber level. Electronic prescribing would aid data collection. Possible barriers include language – need for interpreters or patient advocacy. Issues around the elderly population – at risk patients including those with capacity issues should have advocacy.
67	Merck Sharp & Dohme	1	MSD support "Shared decision making" and believe that patients should be involved in the decision making process related to medicines and their care. This is in line with individualised patient care, which was considered essential in the draft clinical guideline for type 2 diabetes; for example, patients who drive for a living or operate heavy machinery may not want to be initiated, or continue on therapy associated with a high risk of hypoglycaemia, such as sulphonylurea. Patient adherence is listed as the only outcome used to asses shared decision making. MSD would recommend the inclusion of additional outcomes to assess patient involvement in decision making. This could include the tracking of GP follow-up appointments related to medication review, or the monitoring of treatment switching. Quality Statement 1 also refers to patient satisfaction rates. How will these data be collected? To drive continuity across different health care settings additional clarity relating to the: method/ instrument to be used when collecting patient reported outcome(s), frequency of data collection and by who, and the way in which these data will be reviewed/ utilised to drive improvement in care should be described.

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68	British Thoracic Society	1	**People have the opportunity to be involved in making decisions about their medicines.** This is virtually impossible to do in a ward or an outpatient setting and would be very difficult to reconcile local data collection in general practice surgeries and in community and therefore it would be impossible to calculate medicine adherence rates. Moreover we need to recognise that adherence to treatment and reconciliation about prescriptions are not always linked as many individuals will choose or will take treatment on a prn basis as directed by their doctor / clinician so medicines reconciliation will not answer the prn usage. In section D it would be impossible to get an idea of patient satisfaction as we are not specific about what it is. Is this satisfaction in the joint working, satisfaction that the medicines are actually doing what they are actually prescribed for. This is fraught with danger and needs to be re-considered.
69	Medicines Use and Safety Team NHS Specialist Pharmacy Services	1	Patient adherence rates where patients are self-administering are difficult /impossible to measure with any degree of reliability.
70	Northumbria Healthcare NHS Foundation Trust	1	This quality statement is very important but is too woolly. Suggest "patients should be actively involved in shared decision making about their medicines". It should be part of routine prescribing practice. The role of others e.g.carers in shared decision making should be emphasised for those patients who lack capacity and/or need support. Patient medication adherence rates are notoriously difficult to measure. To support improvement: training for healthcare professionals; events to promote within the professions; develop marketing materials to promote engagement to the public and patients; financial incentives (e.g. CQUIN) to reward organisations for action/success – may be necessary to help offset costs required to deliver this (time for quality conversations is a big barrier). Developing more intuitive clinical decision aids might also help overcome this problem.
71	NHS England	1	The fundamental principle of medicines optimisation is that patients achieve the best possible **outcomes** that **THEY** are looking for from taking their medicines. Then opening statement makes no mention of working with patients to achieve the **outcomes** that **they** consider important. Outcomes should include achievement of patient desired outcomes.
72	Epilepsy Action	1	For people to get the best from their medicines, they need to be involved in all decisions about their medicines. Many people with epilepsy, with the support of their families and carers where appropriate, are already involved in decisions about their long-term care in the community. However, in our experience, their input has not always been seen as valuable. Anecdotal evidence suggests that families and carers have sometimes been discouraged from voicing their concerns, even though the person with epilepsy themselves has had no memory of breakthrough seizures or previous treatments tried. The draft quality standard should allow people with epilepsy and their families and carers to have a voice, and be consulted about any changes being made to their medicines regime.

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73	Guild of Healthcare Pharmacists	1	Should there be evidence that the process has actually been implemented rather than the process being in place? Also, should this quality statement include recognition that sometimes individuals are unable to be involved in the decision making, but that carers may be on their behalf?
74	Guild of Healthcare Pharmacists	1	Outside of the research arena, 'medication adherence rates' is probably impossible to measure. Also it is a fairly tenuous link to the statement since many factors will affect adherence rates not simply whether or not the patient was involved in the decision
75	Guild of Healthcare Pharmacists	1	Delivery of consistent message/quality information will be important and how will this be quality assured? It may be appropriate to ask the patient what their goals of treatment are. In a 10 minute consultation, it is unlikely that this will be deliverable.
76	College of Mental Health Pharmacy	1	Where the statement states "This may include decisions not to take specific medicines." there should be mention about refusal of potentially life-saving medicines. That is, informed refusal. A risk:benefit analysis must be discussed with the patient.
77	College of Mental Health Pharmacy	1	There is no accurate and meaningful way of properly measuring adherence in clinical practice. Attempting to do so at this level will not be accurate.
78	Thames Valley and Wessex Chief Pharmacists Network	1	• It is hard to think of a way to have evidence of local arrangements since shared decision making would usually take place as a discussion within a patient care consultation. • Medication adherence rates are extremely difficult to measure and adherence rates are dependent on many different factors, so hard to show effect. • We thought that the easiest way to measure the success of this would be to ask patients whether they felt they were sufficient involved, e.g. as part of existing patient surveys/Friends & Family tests.
79	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	1	No Comment
80	Pharmicus	1	Shared decision making needs to be at the forefront of every decision made involving prescribing. The opportunity to discuss this with the clinician initiating the medicine with further advice available. There should also be a periodic opportunity to revisit these shared decisions, ideally as part of medication review. The importance of all clinical staff involved utilising robust evidence-based medicines principles in helping with these decisions is paramount. Consideration should be given to also recommending that certain medicines are not needed, can be stopped etc. Finally, clinicians need strong support to not feel pressured to prescribe a medicine just because a patient feels that it is needed, where the evidence base would not support using such a medicine.
81	Gloucestershire Hospitals NHS Foundation Trust	1	Should there be evidence that the process has actually been implemented rather than the process being in place? Also, should this quality statement include recognition that sometimes individuals are unable to be involved in the decision making, but that carers may be on their behalf?

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82	Gloucestershire Hospitals NHS Foundation Trust	1	Outside of the research arena, 'medication adherence rates' is probably impossible to measure. Also it is a fairly tenuous link to the statement since many factors will affect adherence rates not simply whether or not the patient was involved in the decision
83	Gloucestershire Hospitals NHS Foundation Trust	1	Delivery of consistent message/quality information will be important and how will this be quality assured? It may be appropriate to ask the patient what their goals of treatment are. In a 10 minute consultation, it is unlikely that this will be deliverable.
84	Janssen	1	The skills and experience of pharmacists should be emphasised if an effective Medicines Optimisation approach is to be implemented. This should be recognised in the statement such that it reads: "When medicines are being discussed at any point in the care pathway, involve a pharmacist with relevant clinical knowledge and skills. The skills level should be such that the process is truly patient focussed and shared decision can be made allied to the evidence base."
85	Janssen	1	NICE should acknowledge and support healthcare professionals (HCP) role in understanding adherence and shared decision-making so that the patient gets the maximum value from the medicine and that the NHS obtains the maximum value from the medicine in return.
86	Janssen	1	This recommendation could go further and highlight that patients are signposted to and encouraged to engage with appropriate education related to their condition on a systematic basis to improve uptake rates
87	NHS Sheffield CCG	1	Adherence rates need honest feedback from the patients and will be difficult to collate and interpret.
88	Royal Pharmaceutical Society	1	This is the most important statement as people must be involved in decisions about their medicines. This should be a true shared decision making process where people are supplied with evidence based information including both risks and benefits of taking the medicine. Data collection should not be onerous or a tick box exercise but could be achieved via patient surveys. Having the right discussion with people about their medicines requires time. Pharmacists, as experts in medicines, are ideally placed to discuss medicines with patients. This could be supported by extension of the New Medicine Service (NMS) to any new medicine that a person is started on a medicine and also extension of the Medicine Use Review to Service (MUR) to encompass other long term conditions and also to enable an MUR to be undertaken outside of the pharmacy, for example in a Care Home or patient's own home.
89	Royal Pharmaceutical Society	1	It is not always possible to involve the patient directly in decisions about their medicines. Where this is not possible, a family member or the patient's carer should be involved in such decisions and also in medicine reviews. This is not made clear within the suggested quality standards and should be made explicit.
90	GlaxoSmithKline	1	This quality statement relates to people having the opportunity to be involved in making decisions about their medicines, with the data source being local data collection. We recognise this is linked to principle 1 of medicines optimisation: Aim to understand the patient experience.

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			Achieving this will ensure patients are more engaged and able to make choices, including shared decisions about treatment. GSK has identified some key questions that we believe need to be addressed in order to effectively achieve this statement: • How will this quality statement be measured? • How will the quality statement drive improvement in medicines adherence and how will the outcomes be tracked?
91	Luton & Dunstable Hospital NHS Foundation Trust	1	Adherence doesn't accurately reflect opportunity to be involved in decision- making. No clear definition or measure for adherence. Adherence must reference the jointly agreed plan between clinician and patient. The standard does not describe how adherence can be reliably measured in a standardised and reproducible manner. Patient satisfaction is multi-faceted and not necessarily directly correlated in all groups to active involvement in decision-making.
92	Department of Health	1	We suggest that this should read- People should have the opportunity to be involved in making decisions about their medicines. We feel that patient adherence rates would be very hard to measure. It might be helpful to know what the best practice standards or baseline measurements would be and how you would recommend measuring patient medication adherence rates. Similarly, it might be useful to understand how you would measure patient satisfaction and again what baseline standards are. Further clarity on the following sentence might be helpful- "People who take medicines and those who choose not to have the opportunity to be involved in making decisions about their medicines in line with their values and preferences." It would be helpful to have a definition of what a patient decision aid is for the purpose of this exercise.
93	Royal College of Speech and Language Therapists (RCSLT)	1	Patients with communication problems should be identified and aids put in place to facilitate decision making.
94	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	1	Question 1: BHIVA and HIVPA comments: Yes but not fully as although it reflects patient's involvement in making the decision, it does not address the issue of non-adherence which is part of what the standards are looking to address. So although the patient may be involved at the beginning of treatment with the decision, this will not necessarily predict that they will have improved adherence once they start taking the medicines.
95	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	1	Question 3: a) Insist on patients receiving patient focussed education materials so they can be fully informed in their decisions. So the information is provided in simple language for example simplified patient information leaflets about the disease and the medicines so that they can take these away and digest them pre making any decisions. b) Support needs to be given to improve adherence outcomes by putting in place some form of referral system for patients with adherence issues. These could be identified at the medication usage review stage and referral made at this point or at the beginning after initial discussion. Bearing in mind the short consultation times a GP has when starting a new medication, suggest to have a system that the patient is either given a longer appointment to enable them to be involved in decision making or referred to pharmacist within the practice or at local pharmacy where there is some service

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			provision for new medicine patients.
96	British Thoracic Society	1	Question 2: This 'Quality Standards for medicine optimisation' seems generally satisfactory but data collection may be very burdensome for the health service. For example it could prove difficult to collect data. For example, Quality statement 1 (Shared decision-making) has an outcome of patient medication adherence rates which is to be gathered as 'local data collection'. It would be very difficult to get accurate data on adherence.
97	Swansea University	1	Data collection could/ should include QOFs (quality outcomes frameworks) in primary care. How will medication adherence rates be measured? Asking patients is notoriously unreliable, and electronic devices are expensive.
98	Walgreens Boots Alliance	1	Question 2: Quality Statement 1: We have experience of collecting patient medication adherence data and patient satisfaction data, especially through our work on the Community Pharmacy Future (CPF) project. http://www.communitypharmacyfuture.org.uk/ Although simple and validated tools are available for these purposes, they can be time-consuming for patients and pharmacy teams to administer and to collect and upload relevant data. Where we have used these within service evaluations, there is also a "fatigue factor" to be considered, and patients can be reluctant to repeat regularly basic activities that have no obvious direct benefit to them. This would be especially true if the activity was going to be repeated over many years. In terms of customer and patient satisfaction surveys, we have considerable experience built up over many years in carrying out this kind of work. However, there can be considerable difficulties in drawing out specific responses around particular services, for example, where these are being delivered as part of a wider health consultation or in settings where multiple services may be being delivered at the same time. In our view, collecting such data might be possible, but it would come at a considerable time penalty to both healthcare staff and patients. It is possible that, in future, some of this data might be collected by patient themselves through greater use of dose reminder apps and related technologies. However, there would then be issues around how this patient-generated data could be shared with the NHS in a standardised format.
99	Royal College of Physicians	1	Question 1: Our experts agree that this draft quality standard accurately reflects the key areas for quality improvement. It is true that 'Healthcare professionals can use patient decision aids to support a shared decision-making approach in a consultation'. However, it is not clear how valid decision aids will be introduced into practice, and whether this quality statement will allow marketing in another guise.
100	Royal College of Physicians	1	Question 2: If the systems and structures were available it would be possible to collect the data for the proposed quality measures by asking patients or observing consultations - but this would not be easy. The proposed outcome of adherence rates implies that adherence is desirable, but this may not be so. For many conditions 'that cannot, at present, be cured but controlled by medication and/or other treatment/therapies' – symptomatic conditions – the optimal use of medicines is the use that the user finds optimal. And for asymptomatic conditions, then the adverse effects or inconvenience of taking medicines 'as intended' may outweigh (or

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			appear to outweigh) the benefits of taking them unfailingly. Indeed the rationale for quality statement 6 makes this explicit.
101	Royal College of Physicians	1	Question 3: Our experts believe that providing guides such as 'these are questions you might ask your doctor' and providing the possible answers would support improvement, overcome barriers, and empower patients.
102	Tees, Esk and Wear Valleys NHS Foundation Trust	1	Q1. Yes Q2. Would need to develop a process and code to go in each clinical system that show this QS. If it's easy for clinicians to do this, then it may be possible, but the ability to record this "activity" may not reflect the quality of the discussion. In a mental health setting this may depend upon the stage in the patient's journey around whether this conversation will be had. Medication adherence would be possible for in-patients if EPMA in place (although this measures administration and not adherence). Difficult (if not impossible) for community based patients. Could this link to readmissions related to medication adherence (if recorded accurately). Patient satisfaction rates – would need to amend the standard q's in patient surveys (especially at a national level), but if worded correctly it may be useful. The question may cause confusion in MH (or other) settings. Differences between in-patient and community based patients is again an issue. Current processes are in place which can allow patient involvement though there would need to be IT involvement in order to capture evidence for this standard in an efficient manner. Need to be mindful that mental health settings have to consider capacity and treatment may need to be under Mental Health Act without patient consent. Measurement of patient adherence would be a challenge under current arrangements on an in-patient setting as no electronic system for recording administration is in place. Rates of adherence will not necessarily correlate with quality of patient involvement and non-adherence can have many reasons. Q3. Robust available relevant information (available at a national level without payment – e.g. choice and medication). National initiatives around patients surveys. National campaigns and change in mindset. Changes to national patient survey questions. Availability of NICE endorsed patient decision aids for mental health conditions.
103	NHS Dorset Clinical Commissioning Group	1, 2, 3 & 7	Dorset CCG medicines team supports this quality standard and is encouraging initiatives to meet this.
104	Bath and North East Somerset CCG	1 & 2	There are lots of questions which are left unanswered with this Statement: a. who is expected to do this? Contracts will need to be changed to achieve this - Commissioners NHS E in particular will need to change Standard NHS contact and Community Pharmacy contract b. Where is the concordance data anticipated to be collected - contractual issues here need to be considered c. Will NHS E need to change the Friends and Family test to include the appropriate Qs and will NHS E need to change patient

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			survey Qs
105	Bath and North East Somerset CCG	1 & 2	Possibly needs clear contract changes see comments for Statement 1Question1 and clarity of who is expected to collect and review the data
106	Bath and North East Somerset CCG	1 & 2	Contract changes as defined in response to Statement 1Question 1 plus inclusion in the Medicines Optimisation Dashboard from NHS E - needs to baseline data to establish then the % standards expecting people to get to - "QoF style" contract for some aspects of community pharmacy contract
107	North Bristol NHS Trust	2	**Structure** Need a clear definition of "monitor" and "review." Nationally there is a risk scoring classification = near miss/ insignificant/ minor /moderate /major and catastrophic. Role of medication safety officer (MSO) is to promote and increase reporting and the accuracy of reports as per: NHS/PSA/D/2014/005: "Improving medication error incident reporting and learning" (March 2014) MSOs and Medication safety subgroup review accuracy of the report and scoring/ classification to ensure appropriate. Decide if actions highlighted by manager are also appropriate and if an RCA should be undertaken. Very few incidents would have cross sector implications. NBT has good links with CCGs so reports can be dealt with in a prompt way. In addition, electronic Accident & Incident Monitoring System (e-AIM's) forms are recorded and reviewed so that trends can be identified and changes to improve safety can be made. **Process** Numerator – need definition of "reviewed" – is this just receiving? or looking at by a member of staff or a group? Or as per MSO above? Denominator – the <u>total</u> number of reported medicines-related safety incidents. **Outcome** Increase in overall number of reports Decrease in occurrence of incidents of high severity (major / catastrophic) Increase in proportion of low severity **Data source** Local - Should have monthly summary report to identify trends and themes NRLS – can this pull out local data? What types of reports are available? **Service providers** – community pharmacists are a reporting resource

ID	Stakeholder	Statement number	Comments
			Patient reporting – why is this listed as a separate standard? Jane Smith (NBT Medication Safety Officer) and Principal Pharmacist, Service Development and Governance, North Bristol NHS Trust would be very happy to be contacted to further discuss any comments – particularly related to Medicines reconciliation or Investigating incidents – from her experience of Medication safety Officer for NBT and lead for the Quality Improvement work including Medicines Reconciliation on Admission and Discharge, re-use of Patients Own Drugs and Missed doses. **Contact: jane.smith@nbt.nhs./uk 40788 443 7780 / 0117 - 414 - 2278)**
108	Royal Bournemouth and Christchurch NHS Foundation Trust	2	General: This is a key area for safety improvement. Sharing knowledge around medicines issues is paramount to improved safety of medicines use. Locally, prescribing errors and errors in monitoring are not monitored in a formalised way (although many other medicines related issues are). Individual patient level info needs to be shared between all carers inc community pharmacists. Electronic methods to do this are essential.
109	Merck Sharp & Dohme	2	The importance of monitoring AE/ patient safety relating to medicines is crucial. MSD welcome a platform/ method to share key safety learnings across the NHS. To fully understand the "process" described on page 12 of 37, it would be beneficial to understand what resource(s) are required for data collection, and how this will be conducted to calculate the denominator and numerator. For example, will medicines be reviewed as a class or individual agents? How will safety be defined, for example this could be safety leading to discontinuation? Reporting process for patient safety incidents, forming the denominator is not clear. MSD are concerned that if the denominator is not consistently reported/ under reported then the observed measure would be biased (numerator).
110	Medicines Use and Safety Team NHS Specialist Pharmacy Services	2	Process: what does the term review mean? What are you reviewing for? As part of the monitoring process the incidents should be reviewed for potential safety triggers and trends and then this information used to develop risk minimisation strategies that can be shared and adopted more widely
111	Medicines Use and Safety Team NHS Specialist Pharmacy Services	2	Outcome: the outcome measure proposed ie the number of incidents reported does not link well to the quality statement which talks about monitoring & review
112	Northumbria Healthcare NHS Foundation Trust	2	This quality statement is only useful if it results in change. This isn't being assessed. Measures too crude to be useful, particularly if numbers are small. Monitoring/review ≠ action/improvement. Challenge will be to get all stakeholders to participate. Who has overall responsibility for ensuring that a heath/social care system is working together on this? This should be defined.
113	Swansea University	2	As above, 'safety incidents' need to be defined. Not all problems are 'safety incidents' e.g. xerostomia or loss of fertility are sometimes adverse drug reactions, but they are not 'safety incidents'.

ID	Stakeholder	Statement number	Comments
114	NHS England	2	Although the Quality Statement is titled 'learning' from patient safety incidents, the statement itself, or the outcomes section, does not mention learning (particularly at a local level) and seems more concentrated on reporting which in itself is not enough.
115	NHS England	2	It is good to see a long list of the broader definitions of patient safety incidents related to medication use. This may allow some scope to consider some common consequences such as falls in older people.
116	Guild of Healthcare Pharmacists	2	A key issue that is not picked up in the statement is the under-reporting of patient safety issues as this statement only focuses on those incidents that have been reported
117	Guild of Healthcare Pharmacists	2	The measure is appropriate and easy to measure
118	Guild of Healthcare Pharmacists	2	One of the key issues here will be to ensure incidents are reported in the first place. Adoption of a fair blame culture will be extremely important but not necessarily easy to implement. There is a key role of a dedicated Medicines Safety Officer within this quality statement but it is disappointing that many organisations do not have such a post in response to the MHRA safety update.
119	Thames Valley and Wessex Chief Pharmacists Network	2	• We were unclear on the definition of the word "reviewed" with respect to medication incidents. • It would be helpful to include some categorisation of review levels for incidents of different harm outcome/potential. Otherwise there is a danger of tick-box review because the numbers are too high to fully review all incidents e.g. by RCA. • For the outcome, it does not state whether the number of incidents are expected to rise or fall. It is well recognised that the **proportion** of moderate-high harm incidents within the total is the best way to monitor effectiveness of reporting and medicines safety performance.
120	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	2	Q2 a single system across health economies should be encouraged to ensure sharing of learning – Information Governance arrangements need to be clear.
121	Pharmicus	2	Safety incidents need to be widely shared within a no-blame culture so learning can be shared amongst all. Sharing of learning is essential to allow suitable bespoke training on managing and mitigating risks to be delivered. Systems for recording, and analysing, safety incidents need to be easy to use and part of routine, daily working, not an additional system to log into otherwise this is a barrier to end-users completing reports about safety-related incidents.
122	Gloucestershire Hospitals NHS Foundation Trust	2	A key issue that is not picked up in the statement is the under-reporting of patient safety issues as this statement only focuses on those incidents that have been reported
123	Gloucestershire Hospitals NHS Foundation Trust	2	The measure is appropriate and easy to measure
124	Janssen	2	Although there is reference to reporting across 'local care settings' and further reference to 'cross sector action' there is no

ID	Stakeholder	Statement number	Comments
			mention of informing manufacturers of adverse events associated with their medicines; Manufacturers need to be kept informed of such matters so appropriate action can be taken.
125	Royal Pharmaceutical Society	2	It is important that all medicines related patient safety incidents are recorded and learnt from. Incidents are not always shared across providers, although they will be shared within a provider organisation, and it is not clear how provider organisations will be encouraged to do this. Such data should also be collated and analysed at a national level to identify trends and patterns, leading to effective national actions (potentially to be implemented at a local level). In order for such incidents to be recorded the systems that enable recording should be simple, quick and easy to use, potentially embedded into current primary care (including pharmacy), hospital and other systems currently in use.
126	GlaxoSmithKline	2	This quality statement is focussed on learning from medicines related patient safety issues. Whilst it correctly identifies important roles for health and social care providers, service providers and commissioners, it does not take into account the need to inform manufacturers. Healthcare providers should also report any safety related incidents with medicines to the MHRA and encourage reporting to the manufactures. The process for how this information is managed and then exchanged between these two parties is outlined in the EMA Good Pharmacovigilance Practices (GVP) modules derived from the Pharmacovigilance legislation . Specifically Module VI (Management and reporting of adverse reactions to medicinal products) refers to the reporting of safety incidents by manufacturers to regulatory authorities and the vice versa – this ensures that incidents are reviewed in a national/global context and not just in a specific hospital/clinical setting and opens the communication channels between HCPs, regulators and manufactures .
127	Luton & Dunstable Hospital NHS Foundation Trust	2	What does ‘monitor’ and ‘review’ mean? Review can mean anything from a quick look to a full root cause analysis. The data collection proposed will not evidence sharing and learning which is the point of the standard. Why is the number of errors reported an outcome? In isolation it tells you nothing. A reference to medication safety officers in this standard would be appropriate
128	The Royal College of General Practitioners	2	Unlike the comments in respect to deaths and severe harm above, it would be possible to collect information locally about prescribing safety incidents. It may be useful to consider the approach undertaken in a GMC-funded practice study. Full details of this are available at: http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf (TA)
129	Department of Health	2	Many providers already have guidance in place and it would be helpful to know if this quality standard fits in with the work

ID	Stakeholder	Statement number	Comments
			already undertaken for example the NHS England and the MHRA medication safety work ' National Medication Safety Network / NRLS' It would be helpful to have clarity on the listed terms that fall under medicine-related patient safety incidents. For example, within dispensing errors, does this include labelling errors. It might be helpful to give examples otherwise it may be subjective Under the quality measure process, we found the process description confusing. We suggest wording could read 'the percentage of medicine-related patient safety incidents that get reviewed' It would also be helpful to know what would be considered best practice in terms of the proportion of medicine-related patient safety incidents that should be reviewed (i.e. should these be 80%, 90% or 100% for example)
130	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	2	Question 1: It reflects the need to report the errors but would be good to look at what happens next, on putting in place system that will then minimise the incidents by improving best practice
131	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	2	Question 2: Yes
132	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	2	Question 3: Reporting all prescribing errors: a) Presentation at monthly morbidity meeting, which form part of governance, audit and quality b) Prescription errors should be entered in Datix which are reviewed in a root cause analysis c) Electronic prescriptions similar to EPMA will reduce prescription errors d) A good reporting system should have an "incident management person" coordinating incidents and putting into process systems to inform and educate people how to improve practice e) Ensure patients are fed back the outcomes following the incident in standardised non jargon language
133	British Thoracic Society	2	Question 2 **Health and social care providers monitor reported medicines-related patient safety incidents to inform cross-sector action and best practice in the use of medicines.** This is a very laudable but difficult to collect data. Does this need to be more specific e.g. the number of allergic reactions in patients receiving Penicillin who are known to be Penicillin allergic. It is difficult if we do not know the number of safety incidents to really determine what the denominator is. Perhaps an alternative would be evidence of procedures in place to monitor and educate when errors take place and their evidence of their utilisation.
134	Gloucestershire Hospitals	2	Question 3: One of the key issues here will be to ensure incidents are reported in the first place. Adoption of a fair blame culture

ID	Stakeholder	Statement number	Comments
	NHS Foundation Trust		will be extremely important but not necessarily easy to implement. There is a key role of a dedicated Medicines Safety Officer within this quality statement but it is disappointing that many organisations do not have such a post in response to the MHRA safety update.
135	Royal College of Physicians	2	Question 1: The evidence that 'Monitoring reported medicines-related patient safety incidents can help identify trends and causes of incidents' is lacking. It is very difficult to monitor patient safety incidents in the community even if there is harm, and almost impossible otherwise. The structures for sharing 'among providers across local care settings' will not help to protect against rare events that are only perceived nationally. The efficacy of computer alerts is a function of their rarity, and generating more alerts risks reducing efficacy.
136	Royal College of Physicians	2	Question 2: Our experts believe that it would not be possible to collect meaningful data on the proposed quality measure since reporting rates are unrelated to incidence rates.
137	Royal College of Physicians	2	Question 3: Better understanding of error theory by healthcare professionals would support improvement and help overcome barriers.
138	Tees, Esk and Wear Valleys NHS Foundation Trust	2	Q1. Yes Q2. Yes, but measure isn't a good reflection of QS. Number of reviewed incidents may not accurately reflect improvements made with lessons learned. Q3. Improvements at a national level. MHRA, yellow card improvements. Cross-sector learning forums to be supported – MSO network is helping. Often the commissioner leads review (or checking of) incidents. A huge improvement would be if all IT systems could generate incidents and ADR reporting directly from the clinical system. Local forums that replicate the National Reporting and Learning System. Training on use of Datix for those completing the entries to improve consistency.
139	Medicines Use and Safety Team NHS Specialist Pharmacy Services	2&3	Link the definition of medicines related safety incidents more closely to the NRLS definitions. Avoid use of the term "near miss" which is prone to misinterpretation.
140	Epilepsy Action	2 & 3	We note that the Yellow Card Scheme has only had 600,000 reports in over 50 years. In our experience, few people with epilepsy are aware of this scheme, and so it's likely that any of their medicines-related patient safety incidents, will not have been reported. Going forward, having people who take epilepsy medicines cared for by healthcare providers who monitor reported medicines-related patient safety incidents, and who respond accordingly and share learning with other local care providers, should ensure best practice and safety in the use of medicines. This is particularly relevant for women with epilepsy who are, or are considering, becoming pregnant due to the risks to the unborn child of taking certain epilepsy medicines. It is also important

ID	Stakeholder	Statement number	Comments
			for women not wanting to become pregnant, as some forms of contraception interact with epilepsy medicines, and some epilepsy medicines interact with contraception, making an unplanned pregnancy a high risk. Ensuring people with epilepsy receive information on how to identify and report medicines-related patient safety incidents through the Yellow Card Scheme is paramount to good practice. We would also recommend that data collected on medicines-related patient safety incidents is analysed at a national level to highlight incident trends.
141	Swansea University	2,3 & 4	List of quality standards. It would help readers to be reminded of the definition of 'patient safety incidents'. 24 hours is too long for people with some conditions to go without essential medicines e.g. anti-epileptics (below).
142	North Bristol NHS Trust	3	**Statement** "receive information on how to identify and report" There should be a leaflet / booklet available nationally rather than duplication of effort and local variation. At NBT, cards with a help line number are given on discharge to all patients. A national booklet could have a section to add a sticker with local contact details. In addition, PILs are given out. Also need to consider patients whose first language is not English. There are apps available for reporting – do these meet MHRA requirements of a medical device (CE standards)? SOPs for counselling, e.g. high risk drugs such as NOACs, should include information on reporting. If a patient voices a concern, there needs to be a system of referral between sectors (could be electronic prompt as "PharmOutcomes" or "Refer to Pharmacy") so that the concern or report is dealt with and the patient is listened to. For example, when a query mentioned in outpatient clinic is about a long term medicine prescribed by GP or a query about medicines started in hospital after they have been discharged. **Outcome** The number of medicines-related patient safety incidents reported by patients. (Out of the total number of reported incidents?)
143	Royal Bournemouth and Christchurch NHS Foundation Trust	3	General: I think this is laudable but we need to get the reporting of medicines related safety incidents "solid" among healthcare professionals first. As noted above, this data is not routinely captured local in our patch – it could be. I have a fear also that if not managed well, we will see a deluge of possibly inappropriate reporting from the public. Any system needs to be simple and electronic but with access points (for those who do not have access to electronic means) in community e.g. local pharmacies.
144	Medicines Use and Safety Team NHS Specialist Pharmacy Services	3	Outcome: the outcome measure does not link with the QS. Wouldn't it be better for the outcome measure to be "the number of safety incidents self-reported by people taking the medicine?"
145	Swansea University	3	These could be expanded with references to avoid misinterpretation. How is 'potentially avoidable' assessed? What criteria would be used?

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			Monitoring errors. These will depend on the medicine. Do they include failure to check vital signs or laboratory tests? For people prescribed antipsychotics, would they include failure to document monitoring of posture and movement disorders or tongue tremor as an early sign of tardive dyskinesia. Missed doses. How long a delay is acceptable?
146	Swansea University	3	Should the information given to patients be specified? E.g. the PIS?
147	Swansea University	3	How will safety incidents be collated, checked and analysed? What comparisons will be undertaken?
148	Swansea University	3	What systems are in place for identifying potential problems? Our group has developed nurse-led medicines monitoring Profiles, which would be useful here, and could be implemented at little cost (Jordan et al 2015).
149	NHS England	3	The outcome measure should be patient safety incidents reported by 'patients'.
150	Guild of Healthcare Pharmacists	3	Should there be evidence that the process has actually been implemented rather than the process being in place? We are unclear as to what this statement actually means. How is it possible to educate patients on how to identify a patient safety incident (as these can be anything) other than saying 'this isn't right'? Further, when they do identify an incident all they can really do is report this to a healthcare professional, unlike ADRs which they can report directly through the yellow card scheme.
151	Guild of Healthcare Pharmacists	3	This needs to relate to something specific to patient reported safety incidents e.g. an increase in proportion of patient reported safety incidents. Simply reporting the number does not demonstrate that this quality statement has been implemented.
152	Guild of Healthcare Pharmacists	3	As part of the process it will be important to detail how incidents should be reported/to, whom/through, what the mechanism will be, and how the reports will be used/ acted upon. Could patients access already existing reporting mechanisms such as Datix/ NRLS?
153	Pharmicus	3	Consider including information for patients to report, using Yellow Card reporting scheme, within the patient information leaflet in medicines packaging
154	Gloucestershire Hospitals NHS Foundation Trust	3	Should there be evidence that the process has actually been implemented rather than the process being in place? We are unclear as to what this statement actually means. How is it possible to educate patients on how to identify a patient safety incident (as these can be anything) other than saying 'this isn't right'? Further, when they do identify an incident all they can really do is report this to a healthcare professional, unlike ADRs which they can report directly through the yellow card scheme.
155	Gloucestershire Hospitals NHS Foundation Trust	3	This needs to relate to something specific to patient reported safety incidents e.g. an increase in proportion of patient reported safety incidents. Simply reporting the number does not demonstrate that this quality statement has been implemented.
	Royal Pharmaceutical Society	3	People need to be made more aware of the yellow card reporting scheme which enables patients and health care professionals to report medicines related safety incidents. A simple suggestion would be for IT software to automatically suggest generating a yellow card report if a patient is recorded as having an "issue" e.g. allergy or 'unable to tolerate' any medicine, particularly for black triangle drugs.

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156	Luton & Dunstable Hospital NHS Foundation Trust	3	Should the outcome not reference patient-reported incidents since this is the point of the standard? Again a number is meaningless without context. Should the standard not also say something about dealing with the error rather than just noting it?
157	Department of Health	3	We feel this may be difficult to achieve from a patient perspective. There is a risk of reducing a patient's confidence in their health care professional and the service they are providing if they are being counselled on potential prescribing/dispensing errors. These should really be resolved before reaching a patient level. We feel the ownership shouldn't be on the patient to recognise some of these errors. However we do understand the need for transparency in this process and the need for a public reporting process for these types of errors, without the patient feeling as though they are compromising health care professionals. Our concern is that patients may be reluctant to take medicines if they are being counselled about the risk of potential errors. Need to be clear that medicine-related patient safety incidents are different form side effects so that a patient knows how to distinguish between which is which.
158	Royal College of Speech and Language Therapists (RCSLT)	3	Patients with communication difficulties may not be able to understand and remember how to identify and report medicine-related patient safety incidents.
159	British Thoracic Society	3	**People who take medicines receive information on how to identify and report medicines-related patient safety incidents.** Again this is very laudable but becomes very difficult to measure and the vagueness of data sources and data collection means this will be very difficult to implement.
160	Thames Valley and Wessex Chief Pharmacists Network	3	• A potential barrier to achieving this is the resource needed to manage the reports that are received. • The outcome statement is too vague and non-specific. The number of incidents could go up or down for a wide variety of reasons completely unrelated to the QS. To encourage reporting the initial outcome could be the number of patient-initiated reports received, but there must be a denominator to make it meaningful.
161	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	3	Q2 a single system across health economies should be encouraged to ensure sharing of learning – Information Governance arrangements need to be clear. Q3 – Public awareness and assurance that learning will improve care for others.
162	Gloucestershire Hospitals NHS Foundation Trust	3	Question 3: As part of the process it will be important to detail how incidents should be reported/to, whom/through, what the mechanism will be, and how the reports will be used/ acted upon. Could patients access already existing reporting mechanisms such as Datix/ NRLS?
163	Bath and North East	3	Question 3: not at all clear who is going to be tasked to do the local reporting, via what system and how this will be measured

ID	Stakeholder	Statement number	Comments
	Somerset CCG		
164	Royal College of Physicians	3	Question 1: The draft quality standard accurately reflects the key areas for quality improvement insofar as it relates to patient involvement and medication safety. However, it fails to explain how patients might be helped to identify medicines-related patient safety incidents or distinguish them from adverse drug reactions. Most errors will either be completely obvious or completely hidden. Our experts agree that patients should be instructed how to report errors.
165	Royal College of Physicians	3	Question 2: Our experts believe it would not be possible to collect the data for the proposed quality measures.
166	Royal College of Physicians	3	Question 3: Our experts agree that 'Reporting on and learning from medicines-related patient safety incidents can be more effective if it is informed by the people who take medicines.' This is an argument for involving patients in root cause analysis.
167	Tees, Esk and Wear Valleys NHS Foundation Trust	3	Q1. Yes Q2. Would be easy to put in a system, but there would be a significant challenge in collating these reports and following up – where does yellow card meet "incident"? The outcome measure would need to clearly identify that we were looking for an increase in incidents reported, but we'd need to be clear what we're doing with these. This standard could make use of current processes e.g. PALS. The actual measure linked to this standard does not specifically link to patient reported incidents as it is written. What happens to the information – more value if feeds into other systems for collating incidents to improve lesson to be learnt. Q3. Cultural barriers (patient, professional, barriers). Patients understanding. Access to systems. Where to report what to may become a challenge – yellow card, local discussion with clinician, which organisation to report to (primary care, MH, acute?) National campaign to raise awareness. Information to explain difference between this and yellow cards (MHRA).
168	East Lancashire Hospitals NHS Trust	4	We feel that the standard should include more specificity around use of a checklist approach to documentation of reconciliation
169	North Bristol NHS Trust	4	Definition of **Reconciled list** Reconciliation is NOT just a list of current medicines. As well as confirming what is currently prescribed for the patient and bought over the counter, reconciliation involves talking to the patient or their carer to find out exactly how they are taking their medicines (as 30-50% of patients do not take what their doctors think they are taking) and any problems they are experiencing and/or reasons for not taking. The reconciliation also involves reviewing Patient's Own Drugs (PODs) that they have brought with them, and an indication of other medicines still at home.
170	North Bristol NHS Trust	4	See comment above on definition of Med Rec **Statement**

ID	Stakeholder	Statement number	Comments
			"Within 24 hours" – need to confirm definition of "24 hours". Is it next working day i.e. patient admitted on Day 1, meds rec completed by Day 2 (as per NHS England and NBT definition) --- or exactly 24 hours according to the clock – which would be very difficult for Trusts without Electronic Prescribing. Need to also confirm if this includes weekends and all wards - Now 7 day working at NBT, with 2 pharmacists on the admissions wards 8am-7pm weekdays and 8am-2pm Saturday and Sunday, has helped capture more patients. Need to ensure service for patients admitted directly to speciality wards i.e. not through admissions ward. **Quality measures** Gold standard = ongoing monitoring using a run chart and quality improvement methodology with PDSA cycles and tests of change and spread – and measurement via ongoing sampling. **Process** Denominator – the number of people on medication and in hospital greater than 48 hours. Exclude day case and very short stay (24 - 48 hours) Other outcomes Improved patient care, efficient use of medicines, reduction of waste, accurate records Cost avoidance: QIPP benchmarking shows medicines reconciliation decreases length of stay. Reuse of patient's own drugs allows financial savings and decreases harm by reducing duplication errors, where a patient may have received a new supply and could potentially take both products. **Outcome** Reduction of medicines-related patient safety incidents Definition should include which category of incidents e.g. medicines reconciliation incidents and missed dose incidents – as other categories may not be affected **"What the quality standard means for patients, service users and carers"** The patient or carer MUST be involved in the medicines reconciliation process and, whenever possible, the patient's own medicines should be examined. Speaking to the patient, especially when using their own medicines as a prompt, will give insight as to how or if the medications are being taken. A written list, letter or prescription is helpful but this alone is not sufficient. At least two sources of information should be used. Involving the patient will also link to QS1. Definition of **Reconciled list – as above**

ID	Stakeholder	Statement number	Comments
			Reconciliation is not just a list of current medicines. As well as confirming what is currently prescribed for the patient and bought over the counter, reconciliation involves talking to the patient or their carer to find out exactly how they are taking their medicines (as 30-50% of patients do not take what their doctors think they are taking) and any problems they are experiencing and/or reasons for not taking – and also reviewing a Patient's Own Drugs (PODs) that they have brought with them, and an indication of other drugs still at home. After clarification of the definitions - Staff training and SOPs are very important to ensure consistent standards. Medicines Reconciliation needs a multi-professional approach and can involve input from Doctors, Pharmacy staff and Nurses - in liaison with patients. NBT have recorded a DVD which is shown to all new Doctors to the Trust - showing the steps they need to undertake in Medicines Reconciliation on admission – including an interview with a patient. Copies of the DVD have been purchased by many trusts in England and Europe.
171	Royal Bournemouth and Christchurch NHS Foundation Trust	4	General: The timescale of 24 hours is impossible with current (not 7 day) full service. Barriers include workforce issues. Electronic prescribing would enable this metric to be accurately measured. Without electronic prescribing manual data collection only way. Improvement in med rec could be achieved by adopting a national approach for doctors having access to SCR making the list of GP meds available at admission.
172	Great Western Hospitals NHS Foundation Trust	4	What about medicines reconciliation at discharge?
173	British Thoracic Society	4	**People admitted to an acute setting, or transferred within acute settings, have a reconciled list of their medicines within 24 hours.** This would be an ideal way to do this, however it is very difficult for patients who are admitted at weekends when general practices are not always open to get information to allow reconciliation within 24-hours. Of course we can ask relatives to bring in the patients prescriptions but it is not always possible for this to take place. Electronic systems to allow transfer of information are clearly are what are needed here and until those are in place it will be very difficult, though ideal to get such information within a 24-hour period.
174	Medicines Use and Safety Team NHS Specialist Pharmacy Services	4	Outcome: Shouldn't this be reduction of incidents that are due to a failing in medicines reconciliation
	Northumbria Healthcare NHS Foundation Trust	4	Very important standard – but terminology is ambiguous. The 'reconciled list' in the acute setting is typically that which is outlined on the inpatient treatment chart (i.e. drug chart or an equivalent for those prescribing electronically) taking into consideration what needs to be continued or not. Must make it clear that medicines reconciliation is not just a drug history. Suggest statement should be reworded to read 'reconciled and prescribed within 24 hours'. Why endorse having a separate list in admissions which then needs to be transcribed with its inherent risks of error – this itself is inefficient and will lead to omissions

ID	Stakeholder	Statement number	Comments
			of important medicines during the delay to transcription? Patients who are then transferred within acute settings will remain on the reconciled list of medicines (as it is the prevailing drug chart). Also needs to be more explicit that it is a requirement within 24 hours of admission and applies 7 days per week. Patients and/or carers MUST (where mental capacity allows) be involved in the process of medicines reconciliation – they are the only people to know what is actually being taken at home (or not). Medicines reconciliation at point of admission is already measured in many (most) hospitals. However there has been much variation of interpretation of this standard and the methodology used to measure it which has made benchmarking almost meaningless – hence reason for suggested clarity in definition above. Measurement is less straightforward at point of transfer but, with the changes proposed above, this would become redundant anyway. Medicines safety incidents are not always reported at such a granular level to be able to attribute cause to failure in reconciliation – also likely to be so common in some organisations that it won't be reported on all occasions.
175	Swansea University	4	Lists of medicines should travel with patients. Our monitoring Profiles might be useful here.
176	Swansea University	4	24 hours is too long to be without some medicines, including those for epilepsy or diabetes. Withdrawal symptoms may also appear for patients taking antidepressants with short half lives.
177	Swansea University	4	Professionals need to know which medicines cannot wait longer than 3, 6 or 12 hours. This should be in education programmes. Should experts compile a list to append to the standard?
178	NHS England	4	Medicines reconciliation is not defined. It should include information on how a patient takes their medicines rather than just a list. Outcome measures do not seem to reflect medicines reconciliation. Also need to confirm definition of '24 hours'
179	NHS Dorset Clinical Commissioning Group	4	Dorset CCG medicines team would support this quality standard and has already undertaken work acute trust providers to encourage this reporting
180	Guild of Healthcare Pharmacists	4	Measurable and appropriate. Currently this is already done in a large number of acute settings. We wish to point out that mental health settings have (in recognition of the differing patient needs) used a 72 hour target. Introducing a 24 hour target for all admissions and internal transfers is likely to be unachievable (and unnecessary) in this setting.
181	Guild of Healthcare Pharmacists	4	One of the key factors will be ensuring there are adequate resources in place to allow a 7 day service to be implemented. The evidence supports the input of a pharmacist into this process and therefore pharmacy services are likely to require resources to allow this to be delivered
182	Pharmicus	4	IT sharing enablement is a must for this to happen safely. Transcription errors can be introduced or existing errors reproduced where information is copied from a paper source.
183	Gloucestershire Hospitals NHS Foundation Trust	4	Measurable and appropriate. Currently this is already done in a large number of acute settings. We wish to point out that mental health settings have (in recognition of the differing patient needs) used a 72 hour target. Introducing a 24 hour target for all admissions and internal transfers is likely to be unachievable (and unnecessary) in this setting
184	Janssen	4	'Patients may be involved in reconciliation process…..'. Janssen suggest that this chance for involvement is routinely offered to patients.
185	NHS Sheffield CCG	4	Who should carry out this reconciliation? Could it be made clear this should be done by a healthcare professional

ID	Stakeholder	Statement number	Comments
186	Royal Pharmaceutical Society	4	It is vital that patients admitted to hospital, or transferred to different wards, have their medicines reconciled within 24 hours. We believe that a pharmacist or registered pharmacy technician should be responsible for undertaking this reconciliation. Data is currently collected on this in some hospitals via the Patient Safety Thermometer but all hospitals should be encouraged to collect such data. Access to patients' records electronically enables medicines reconciliation to be undertaken more efficiently and effectively. 87% of hospitals now have access to the Summary Care Record and data shows an average of 30 minutes saved per patient in establishing their drug history. The Government and NHS England need to ensure all health professionals involved in a patient's care have appropriate access to the patient's records.
187	Luton & Dunstable Hospital NHS Foundation Trust	4	Within 24 hours or before the end of the end of the second day of admission? Assume this is meant to be 7 days a week but needs stating. Local data collection with no guidance will result in different methodologies (continual monitoring, snapshot, point prevalence, sampling etc) and therefore no consistency or comparative potential. Patients must be involved in med rec where physically/cognitively capable. Patient report of medicine taking essential part of medicines reconciliation – needs to reflect what patient is actually doing not what medical records document. What does reconciled on transfer within acute settings refer to? Patient has electronic prescription record which follows them throughout admission – what would be being reconciled?
188	Royal College of Paediatrics and Child Health	4	"Health and social care practitioners should recognise that people's ability to understand the issue of medicines reconciliation may differ, and therefore that the issue should be communicated effectively."
189	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	4	Question 1: should apply 7 days per week
190	Gloucestershire Hospitals NHS Foundation Trust	4	Question 3: One of the key factors will be ensuring there are adequate resources in place to allow a 7 day service to be implemented. The evidence supports the input of a pharmacist into this process and therefore pharmacy services are likely to require resources to allow this to be delivered
191	Bath and North East Somerset CCG	4	Question 1: currently there is no obligation to report Meds Rec. via any route - a contractual change would need to be made in the NHS standard contract to implement this
192	Bath and North East Somerset CCG	4	Question 2: Where would this data be captured? Would there be exception reporting allowed for short stays?
193	Royal College of Physicians	4	Question 1: Medicines reconciliation is a reasonable goal – provided it is agreed that there is evidence that medicines reconciliation reduces adverse events. However, reconciliation within 24 hours in hospital would imply that information from the community (GP and pharmacy) will be available within that time and that staff (usually pharmacists) will be available to conduct

ID	Stakeholder	Statement number	Comments
			the reconciliation.
194	Royal College of Physicians	4	Question 2: Our experts agree that if the systems and structures were available, it would be possible to collect the data for the proposed quality measures.
195	Royal College of Physicians	4	Question 3: Our experts stated that extra resources would be required in order to support improvement and help overcome barriers.
196	Tees, Esk and Wear Valleys NHS Foundation Trust	4	Q1. Yes Q2. Yes – we currently do (reported to commissioners), although not at 24 hours (med rec rate with no time limit). Transfer needs to be considered (does this mean to next door ward? – this may generate a large amount of work). Outcome of reduction in medication related patient safety incidents is a poor measure as a good med rec process will increase reporting. This measure does not look at the quality of med rec, simply the numbers. Refers to 'acute settings' Are long-stay facilities excluded from this standard? Still relevant for long-stay but turnaround time of 24 hours would be a challenge with current processes and responsibilities for medicines reconciliation often falling solely to pharmacy staff. Also, sources of information from primary care often necessary to complete medicines reconciliation but these are not available 24/7. Q3. Barriers include training for non-pharmacy professionals and culture that this is pharmacy responsibility. Budget for 24/7 working across the NHS and access to information. Improved IT system – SCR access (that has implied consent). IT systems between secondary care organisations as well as primary care. Also, challenge in recording that a med rec has been done within 24 hours (IT system vs. paper). SCR available but not useful in all settings e.g. patients who move around country-wide in-patient settings, prison transfers where GP access is limited. Central patient records (for all sectors) would be a great step forward.
197	Department of Health	4	Question 2: In reference to the healthcare professional that carries out the medicines reconciliation, we suggest that it might be helpful to align the wording as stated in 1.3.5 of the Medicines Optimisation NICE guidance. This specifies that it should be carried out by a 'trained and competent health professional. A 24 hour deadline may be difficult to achieve seven days a week. It might be useful to clarify what is meant by 'acute setting' and 'transferred within acute settings' Although we do understand the importance of collecting this data, it might be challenging to have to collect this volume of data on a regular basis.
198	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	4, 5 & 7	Question 2: Yes. The systems would have to be an integrated IT system such as ICE used in the NW where GP and secondary care access the same blood results online or PACs which is used around the UK to access radiology images regardless of where the investigation as undertaken. EMIS, which is the electronic prescription system used by GPs, should be used by all GPs and should be accessible by all of secondary care.

ID	Stakeholder	Statement number	Comments
199	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	4, 5 & 7	Question 3:Yes. a) Electronic records, access to GP and hospital systems by both GP and secondary care including pharmacists. Need to be able to access GP records to be able to reconcile medicines within 24 hours especially if this is at a weekend when most GP surgeries are closed. There needs to be an effective communication system both ways so there is quick access to patient's records. b) Hospital discharge summaries and discharge medication should be accurate and useful and ideally electronic (many institutions already do this) and these should be communicated promptly (email/electronically visible instantly) to the GP. c) Changes to chronic medication need to be reconciled as well not just new medicines d) More work needs to be done with patients who do not want their GP informed about their chronic condition (HIV specifically). e) Use of patient centred portals such as Patients Know Best will empower patients to self manage as well as involve all healthcare professionals in accessing the patient's information in a safe environment and timely manner through integration with laboratory systems. f) Use of specialist pharmacists in disease areas in the hospital to help with accurate drug histories and interactions with new medications etc., for both other disease areas within the hospital and in primary care g) Systems to ensure medicines supplied by home delivery companies are accurately recorded on hospital and GP systems to reconcile medication supply. h) Ensure specialist medicines are put on GP systems including HIV drugs, antipsychotics, depots, etc., for drug interaction purposes i) Special attention to patients who receive blister packs as they may not recognise any medicine changes
200	Epilepsy Action	4 & 5	Being taken to an acute setting following a seizure can be disorientating for people with epilepsy, who may not have any of their usual medicines on their person. We welcome the standard regarding having a reconciled list of their medicines within 24 hours. As long as a person with epilepsy has been prescribed enough of any newly prescribed medicine at discharge, they should have enough for the week it could take for their GP practice to be advised of any treatment changes, and to organise on-going prescribing. Adding a discharge summary and medicines list for the community pharmacist should be an additional safeguard. In creating a reconciled list, special attention should be paid to the person's specific brand and dosage of epilepsy medication to ensure consistency of supply.
201	Guild of Healthcare Pharmacists	4 & 7	One of the real barriers to the effective transfer of information is the number of different IT systems that are in use within the NHS and the lack of any ability for the different systems to communicate with each other. There is very little information that comes into hospital when a patient is admitted and this can compromise care. The Summary Care Record is a useful piece of information but it must be understood that this may not always be up to date and is only part of the information when undertaking medicines reconciliation
202	Thames Valley and Wessex	4 & 5	• The outcome statement is too vague and non-specific. The number of incidents could go up or down for a wide variety

ID	Stakeholder	Statement number	Comments
	Chief Pharmacists Network		of reasons completely unrelated to the QS. Perhaps this could be replaced with the proportion of total medication incidents that are related to inadequate medicines reconciliation, or the number/proportion of medication incidents prevented by medicines reconciliation. • A reduction in medication incident reporting is not recognised as a good thing for an organisation with a safety culture. The level of harm or specific cause should be included.
203	East Lancashire Hospitals NHS Trust	5	We feel that the standard should include more specificity around use of a checklist approach to documentation of reconciliation and this should be set within a Standard Operating Procedure. Prescribers with responsibility for ongoing prescribing care should be directly involved at some point in the process, to avoid failures in clinical assessment by inappropriately delegated non-clinical staff
204	North Bristol NHS Trust	5	Community pharmacists or pharmacists working within a GP practice should also undertake medicines reconciliation after discharge. Bristol CCG have employed practice pharmacists to undertake this and they liaise with the acute trusts if any issues arise. At NBT patients are supplied at least 2 weeks' medication at discharge and so review within 1 week seems reasonable. There is a CQUIN target for Trusts to inform the GP surgery within 24 hours of discharge. Some drugs are not prescribed by the GP e.g. chemotherapy, renal transplant drugs, clozapine, hospital-only drugs. It is still important to be aware of the totality of all medicines the patient is taking. **Outcome** Not specific Page 22 **"What the quality standard means for patients, service users and carers"** The patient or carer MUST be involved in the medicines reconciliation process (as above) Definition of **Reconciled list – as above**
205	UK Clinical Pharmacy Association	5	We have concerns that one week is too long especially for people with compliance aids.
206	Royal Bournemouth and Christchurch NHS Foundation Trust	5	General: Absolutely crucial. Barriers to timely update of GP records include letters being posted (electronic means would overcome this). Crucial that Community pharmacists informed of changes also. Barriers to GP records being updated and suggested monitoring recommendations of individual patients not being met include not having a clinical practitioner involved. Ideal position for pharmacist in GP surgeries. Could include outreach pharmacist from secondary care.
207	Great Western Hospitals NHS Foundation Trust	5	Pharmacist have a role to play – community pharmacist, pharmacists working in GP practices
208	British Thoracic Society	5	**People discharged from an acute care setting to primary care have their medicines documented in the discharge summary and reconciled in the GP list within 1 week of the GP practice receiving the information.**

ID	Stakeholder	Statement number	Comments
			No comments
209	Medicines Use and Safety Team NHS Specialist Pharmacy Services	5	Process: Measuring the numerator and denominator at GP practice level could be challenging
210	Medicines Use and Safety Team NHS Specialist Pharmacy Services	5	Outcome: Shouldn't this be reduction of incidents that are due to a failing in medicines reconciliation
211	NHS England	5	There is no mention of community pharmacies being informed of discharge medication or of the rationale for any changes being documented. Medicines which are not prescribed by the GP should also be included.
212	NHS Dorset Clinical Commissioning Group	5	Dorset CCG medicines team would support this quality standard and has already undertaken work with practices to ensure medicines reconciliation occurred as part of a quality improvement audit. To make this part of routine practice, and to collect and access the data it would have to be a requirement as part of the general practice contract, as GP practices are independent contractors. In commissioning any "enhanced" or local services the CCG can add quality requirements and data collection to the contract, but for independent contractors such as GPs and Community pharmacists this will have to be entered into the national negotiations.
213	Guild of Healthcare Pharmacists	5	There are probably two separate but equally important measures here, namely the discharge summary and the medicines reconciliation process within 1 week. If the two are combined it may not be easy to determine where particular issues lie since to meet the standard there must be a discharge summary AND this must be reconciled
214	Guild of Healthcare Pharmacists	5	The measures should be split into two separate ones to give more meaningful data. Assuming the same benefits are achieved as within the acute setting from having pharmacist input into this process would necessitate increased pharmacist resources to deliver a clinical service within the practice
215	College of Mental Health Pharmacy	5	This should be from ALL inpatient settings, not just from "acute" settings, as it makes no difference to the GP which setting the patient has come from. They still need to know that information in a timely manner regardless.
216	Royal College of Speech and Language Therapists (RCSLT)	5	If measures are in place to reconcile medicines in the GP list within 1 week of discharge, then acute care must ensure that in the case of thickeners enough is prescribed on discharge for the patient to last them a week.
217	Pharmicus	5	This would be easier to achieve with a national standard framework to report changes made. New medicines, stopped medicines and changes to medicines should be clearly identified and if all communications used a common layout then errors would be reduced due to increased familiarity with the data. It should also be fundamentally clear who is prescribing each medicine so that no duplication occurs. Again, IT sharing of patient information would again reduce errors and increase safety.

ID	Stakeholder	Statement number	Comments
218	Gloucestershire Hospitals NHS Foundation Trust	5	There are probably two separate but equally important measures here, namely the discharge summary and the medicines reconciliation process within 1 week. If the two are combined it may not be easy to determine where particular issues lie since to meet the standard there must be a discharge summary AND this must be reconciled
219	Janssen	5	As above – this should be routinely offered to patients
220	NHS Sheffield CCG	5	Who should carry out this reconciliation? Could it be made clear this should be done by a healthcare professional? As it stands this reconciliation could be done by a receptionist, who may not have the skills to pick up potential problems.
221	Royal Pharmaceutical Society	5	It is important that accurate medicines information is transferred when a patient is discharged from an acute setting into primary care and the RPS published guidance on this in 2012 (http://www.rpharms.com/previous-projects/getting-the-medicines-right.asp). We believe that medicines reconciliation should occur in primary care, as well as in secondary care, in fact whenever a patient is transferred between different care providers. To enable accurate information about changes to medicines to be shared, healthcare professionals in all settings should have write access to the patient record. Information on medicines supplied through other routes such as Homecare and clinical trials should also be noted on the shared patient record so everyone is aware of this and a complete list of medicines is maintained.
222	Luton & Dunstable Hospital NHS Foundation Trust	5	The process and related numerator statement have 2 conditions – this must be done AND that must be done. If this is not 100% will not support identification of which part of the dual process failed. Medicines related patient safety incidents are multi-factorial – the outcome has no specificity to the standard. Again where possible patients must be involved in the process
223	British Medical Association	5	For example, community pharmacy is an integral part of the medicines reconciliation process in primary care, but is not mentioned in Quality Standard 5. According to QS 5, GPs are solely responsible for reconciling the medicines of people discharged from an acute care setting to primary care within one week of receiving the information. However, when a GP is in the process of reconciling the GP list with the hospital discharge list, someone will still have to liaise with the community pharmacy which dispenses the patient's medicines. Additionally, the rationale of QS 5 is that it can prevent people from being prescribed medicines that were stopped while they were in hospital. However patients may have at home supplies of a medicine that has stopped and therefore continue to take it after discharge, if this has not be properly communicated to them at the hospital, whereas GPs often do not get the discharge summaries for weeks after a patient has been discharge. Finally, for people on repeat dispensing there may be numerous prescriptions available in the community pharmacy for them to continue to collect, unless the community pharmacist is told to cancel them. To avoid this, it should be stipulated that the hospital pharmacist must communicate with the community pharmacist and this should be recorded on the discharge summary. Otherwise, the already strained GPs will feel the responsibility to do this.

ID	Stakeholder	Statement number	Comments
224	Department of Health	5	It might be useful to bear in mind that some patients are discharged to new settings i.e. residential home or staying with family members therefore their GP may not be the most appropriate person to carry out the reconciliation. The denominator measurement would be challenging to measure and may capture patients that are not relevant for example those discharged following an uncomplicated elective procedure requiring short term or 'when required' medicines. Further clarity may be needed on the expected outcome measure of reduction of medicines-related patient safety incidents.
225	Department of Health	5	It might be helpful to understand more about how the outcome of reduction of medicine-related patient safety incidents when a patient moves between care settings can be measured. For example, it may be subjective as to whether the error has happened as a result of a transfer or as a result of other reasons such as a transcription error.
226	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	5	Question 1-One week to reconciliation may be aspirational in some areas. Most discharge summaries are sent within 48-72hr from discharge and now routine – should be supported by electronic prescribing in providers – one week as a standard feels too long – within 48 hrs of receipt safer – thus 96hrs (4 days) of discharge may be more appropriate. Question 2 If electronic prescribing and discharge systems exist. Should community pharmacists also be included in this communication. See Refer to Pharmacy in East Lancs as one example. Q3 Data collectable if electronic systems are used to measure
227	Gloucestershire Hospitals NHS Foundation Trust	5	Question 3 The measures should be split into two separate ones to give more meaningful data. Assuming the same benefits are achieved as within the acute setting from having pharmacist input into this process would necessitate increased pharmacist resources to deliver a clinical service within the practice
228	Bath and North East Somerset CCG	5	Question 1: needs to be read coded onto GP clinical system using a standardised read code defined nationally
229	Bath and North East Somerset CCG	5	Question 2:if collected through QoF yes - would be more powerful and helpful also for reconciliation to happen in the community pharmacy from the discharge letter too - this would provide the opportunity for then signposting to services for helping delivering Quality Statement 1 and 3
230	Bath and North East Somerset CCG	5	Question 3:the standard needs to be clearer about being reconciled by an appropriate clinician - otherwise it may be done by inappropriate staff - will this then be linked to any QoF indicator? It should be to enable it happening!
231	Royal College of Physicians	5	Question 1: Medicines reconciliation is a reasonable goal.
232	Royal College of Physicians	5	Question 2: Our experts were unable to confirm whether it would be possible to collect the data for the proposed quality measures and asked how the reconciliation would be adjudicated.
233	Royal College of Physicians	5	Question 3: In order to support improvement and help overcome barriers it was felt that extra resources would be needed, as appointments with GPs within one week are often difficult to make for non-urgent matters.
234	Tees, Esk and Wear Valleys NHS Foundation Trust	5	As above. This is possibly going to drive GP receptionist tick box process. Quality is an issue. Is a week too generous? Question 1. Yes

ID	Stakeholder	Statement number	Comments
			Question 2. To be useful, the acute setting would need to provide discharge information in a timely manner. Question 3. Turnaround times for information from acute settings
235	Walgreens Boots Alliance	5 & 6	Question 3 Quality statement 5: We believe that this statement should be amended to read [changes underlined]: In order to support full medicines reconciliation across the whole of primary care, people discharged from acute care or any other healthcare setting that is not their normal permanent residence should have their medicines documented in the discharge summary and this information should be sent to the patient's registered GP and other relevant contacts identified by the person, their family members or cares, including their normal or nominated community pharmacy. Pharmacists should be responsible for ensuring that changes are reconciled and that any new or repeat medication prescribed after discharge is in line with the discharge summary. Community pharmacies should liaise with the prescribing GP to address any identified anomalies and ensure that a full discharge medication reconciliation is carried out. Medicines reconciliation should be carried out by trained and competent healthcare professionals, such as pharmacists, pharmacy technicians, nurses or doctors with the necessary knowledge, skills and expertise. The Royal Pharmaceutical Society has issued guidance on "Keeping patients safe when they transfer between care settings". It would be helpful if the Quality Standard made reference to this. http://www.rpharms.com/previous-projects/getting-the-medicines-right.asp? Full access to summary care records by community pharmacies would clearly be helpful in undertaking these reconciliations and plans should be put in place to ensure full roll-out of SCR access within the timescales set out by Health Departments. Quality statement 6: As well as documenting the number of patients who have had a structured medication review, there should be a clear and explicit link in documenting how many of these patients have also had a pharmacy-led medicines use review within the past 12 months. Where structured medication reviews lead to significant changes in prescribed medication, there should be a requirement that these are followed by a medicines use review or, if appropriate, a new medicines service intervention by a community pharmacist.
236	East Lancashire Hospitals NHS Trust	6	…….have a discussion with their healthcare professional about the need for and purpose of a structured medication review….. this description used in the standard is not clear enough – we need to specifically talk about the review itself. Frequency:- we feel that some indicators should be set out for reasonable frequencies of review
237	North Bristol NHS Trust	6	Should record and measure number of medications stopped and started. Establish when the next review should take place. STOPP

ID	Stakeholder	Statement number	Comments
			START Toolkit Stopping medications can have direct and indirect savings which can be used elsewhere in the health economy. Reducing the amount of wasted medicines can help the environment.
238	UK Clinical Pharmacy Association	6	This should be a bit stronger i.e. have a structured medication review (it says this in the rationale but I think it needs to be in the statement)
239	Merck Sharp & Dohme	6	Clarity needs to be provided on how this is going to be implemented – how regular will these medication reviews be? Is this additional to or in place of (existing measures for GP in the QoF framework) the regular review already recommended? Is there a potential that this could overlap with existing reviews? Due to resource implication associated with medication review, is there the potential to introduce bias into the care provided across geographical locations? The numerator defines the "need for and purpose of a structured medication review" - would it not be more accurate to record those patients who are receiving an appointment related to a medication review?
240	Great Western Hospitals NHS Foundation Trust	6	**Medication review** has a lot more to offer than is described here e.g. reducing waste, direct and indirect savings
241	British Thoracic Society	6	**People taking multiple medicines or taking medicines for long-term conditions have a discussion with their healthcare professional about the need for and purpose of a structured medication review.** This is an important area and the role of pharmacists here needs to be stressed. This is the opportunity to stress the importance of compliance concordance with a whole variety of different treatments but a particular area from a respiratory perspective is the use of inhalers. Inhaled corticosteroids and bronchodilators including long acting bronchodilators (cholinergic and sympathomimetic) are expensive and probably constitute one of the biggest spends in the NHS. Unfortunately many patients use inhalers very poorly and are wasteful of both the product and at risk of having potential side effects from their use. It will be important to stress the use of inhaled treatment and whilst there is an inhaler project taking place this should be formally acknowledged and documented in NICE given the financial implications of failure to use inhalers correctly.
242	Medicines Use and Safety Team NHS Specialist Pharmacy Services	6	Define multiple medicines? How many? Otherwise unmeasurable.

ID	Stakeholder	Statement number	Comments
243	Medicines Use and Safety Team NHS Specialist Pharmacy Services	6	Define long-term conditions, otherwise unmeasurable
244	Northumbria Healthcare NHS Foundation Trust	6	This quality standard should include the requirement for the medication review to be undertaken using shared decision making principles e.g. taking into consideration the patient's beliefs and values (emphasising role of carer/others in this process) (as stated in QS1). This statement appears to be about signposting for medication review rather than undertaking medication review. Is this correct? If it isn't then this should be clarified with substantial rewording of this section.
245	Swansea University	6	We think our nurse-led Profiles have potential here to facilitate review (Jordan et al 2015, Jordan 2015). Nurses often know the patients better than other professionals, and can assemble a list of potential problems (including vital signs' recordings) on 1 page to share with pharmacist and prescriber.
246	NHS England	6	Quality Statement talks about a "discussion" with their healthcare professional about the need for and purpose of a structured medication review. This actually needs to happen and not just be talked about. That review needs to include stopping as many medicines as is appropriate and recording the rationale for decisions made. Stopping medications can have direct and indirect savings which can be used elsewhere. There should be something about sharing decisions and their rationale with other relevant healthcare professionals.
247	NHS England	6	The statement would be strengthened by the addition of a timeframe and/or guide for the frequency for review such as that used in the Care Homes Meds Management QS (annual or less). The statement does not mention why this is omitted. The omission may make data collection hard to obtain also the relevance questionable as for someone living with a LTC more than 1 review in their lifetime will be necessary.
248	Epilepsy Action	6	We agree that people taking multiple medicines within the last 12 months (or even one for a long-term condition) have a discussion with their healthcare professional about the need for and purpose of a structured medication review. We would like a timescale to be set for this. NICE CG137 recommends: 1.20.4 For adults, the maximum interval between reviews should be 1 year but the frequency of review will be determined by the person's epilepsy and their wishes. **[2004]**
249	NHS Dorset Clinical Commissioning Group	6	Dorset CCG medicines team would support this quality standard and has already undertaken work with practices to attempt to improve the quality of medicines reviews undertaken as part of a quality improvement audit. To make this part of routine practice, and to collect and access the data it would have to be a requirement as part of the general practice contract, as GP practices are independent contractors. In commissioning any "enhanced" or local services the CCG can add quality requirements and data collection to the contract, but for independent contractors such as GPs and Community pharmacists this will have to be entered into the national negotiations.
250	Guild of Healthcare Pharmacists	6	There is no outcome measure associated with this statement. Without this, the statement lacks a purpose.
251	Thames Valley and Wessex Chief Pharmacists Network	6	• We felt that this should be more specifically aimed at primary care rather than hospital, where virtually all patients are on multiple medicines, but possibly for short term reasons.

ID	Stakeholder	Statement number	Comments
			• It might be helpful to state how many medicines the word multiple refers to.
252	Pharmicus	6	The minimum expectation should be a medication review, not just a discussion as to the need for and purpose of one.
253	Gloucestershire Hospitals NHS Foundation Trust	6	There is no outcome measure associated with this statement. Without this, the statement lacks a purpose.
254	Janssen	6	Will there be a recommendation as to how regularly the medication review should be undertaken?
255	Janssen	6	Identifying a regular timeframe for these reviews to take place would be extremely helpful? Although every patient is different it is important to document how often reviews should happen and how soon after any polypharmacy is started? What are the triggers to ensure that this process happens for those progressing onto polypharmacy?
256	NHS Sheffield CCG	6	This recommendation is stating people taking multiple medicines or taking medicines for a long term condition have a **discussion** with their healthcare professional **about the need for** and purpose of a structured review. Is there better / stronger wording that can be used? Also there is no indication as to how frequently the review should happen if the need is established. In practice it will be difficult to measure this and put it in to practice. If the discussion results in a need for a review then this would potentially require another appointment.
257	Royal Pharmaceutical Society	6	The draft quality standard does not accurately reflect the key area for improvement as it only requires a patient and healthcare professional to have a discussion about the need to have a structured medicines review. In order to ensure the safe and effective use of medicines, and to incorporate standard 1 'People have the opportunity to be involved in making decisions about their medicines', the standard should be altered to include a face to face medicines review. All patients should have an agreed process for review of long term medicines and these reviews should be more frequent where there are multiple long term conditions (LTCs) and at extremes of age. It is worth noting that NICE also have some built in medicines reviews to some of the TAGs they have published, which are ensuring patients get the benefit identified within the respective TAGs, but this benefit should be available to all patients. As part of undertaking the medicines review the quality statement should state that patients should not be taking unnecessary medicines. Many community pharmacies undertake Medicines Use Reviews and there should be better linking of information to ensure that all healthcare professionals involved in the care of the patient have access to information recorded about discussions with patients about their medicines. Again, if health care professionals involved in a patient's care had read and write access to the patient's record this would enable better sharing of information about the patient's medicines and any changes that are made to them.
258	GlaxoSmithKline	6	This quality statement is designed to ensure patients and healthcare providers engage in discussions and structured medical reviews. The statement is very process orientated but does not take into account the detail of the second principle of medicines

ID	Stakeholder	Statement number	Comments
			optimisation, evidence based choice of medicines. There is an opportunity to secure alignment with the NICE Medicines Optimisation Clinical Guideline (NICE Guideline 5) where there is a clear need to reduce the suboptimal use of medicines. The role of structured medication review was also highlighted and its potential to reduce suboptimal use of medicines. The Royal Pharmaceutical Society document 'Medicines Optimisation: Helping patients to make the most of medicines' states that the aim of the principle is to 'Ensure that the most appropriate choice of clinically and cost effective medicines (informed by the best available evidence base) are made that can best meet the needs of the patient'. GSK believes the quality statement should be amended to ensure that evidence based choice of medicines is suitably reflected within its structure.
259	Luton & Dunstable Hospital NHS Foundation Trust	6	Quality statement doesn't make sense – needs rewording. Written protocols are evidence of written protocols not evidence that structured medication reviews are actually happening and effective. Do we really need a) and b) – surely one statement to cover both. The quality measure is evidence a discussion has taken place about the possibility of a review- that is not evidence of quality. This quality statement as it stands is worthless. Needs to reference tools such as STOPP/START or similar
260	British Medical Association	6	Community Pharmacists would be invaluable assets in medication reviews and ensuring patients get the most of their medication.
261	Department of Health	6	It might be useful to understand how service providers are expected to demonstrate that this conversation has taken place. It might be useful to bear in mind that not all patients are able to have this discussion and/or they may not always be the one collecting their medicines in person. It may be really challenging to measure the number of people talking multiple medicines and the number of people taking medicines for long term conditions. Without very clear definitions, this might be very subjective. Definition may be needed to understand what a structured medication review is. We suggest that it may be more useful to measure how many structured medication reviews have actually taken place as the numerator.
262	UK Clinical Pharmacy Association	6	Question 3: Statement 6 **their** HCP feels like its narrowing it down a bit, thinking of all the teams that provide help and support to patients in the community should it be **a** HCP.
263	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	6	Question 1: It does not mention the actual use of medication use review in the standard, just that a discussion should take place about having one, it is mentioned later in the descriptions but believe this should be reflected in the standard itself as just having a discussion about having a MUR does not in itself improve outcomes
264	British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)	6	Question 3: Ensure that it is clear in the systems/processes who will perform the MUR to avoid duplication with pharmacist, GP and clinic all doing the same job
265	North West Commissioning	6	Q2 – linked provider, GP and Community Pharmacy systems - integrated patient record to avoid duplication and gaps.

ID	Stakeholder	Statement number	Comments
	Support unit (On behalf of Greater Manchester Medicines Management Group)		
266	Bath and North East Somerset CCG	6	Question 1: why is this only intended to be done in Primary Care? This should be in all settings of care
267	Bath and North East Somerset CCG	6	Question 2: needs to be recorded and measured through QoF
268	Bath and North East Somerset CCG	6	Question 3: need to be a QoF indicator, more information needs to be provided to define what a structured medicines review is, it should include a statement that where NICE patients decision aid are available they should be used
269	Royal College of Physicians	6	Our experts disagreed that this draft quality statement accurately reflected the key areas for quality improvement and noted that it should simply state that 'People taking multiple medicines or taking medicines for long-term conditions have a structured medication review (from time to time).'
270	Tees, Esk and Wear Valleys NHS Foundation Trust	6	Q1. No – does not refer to completing a medication review, needs to stress the need to perform the review. Q2/Q3. The biggest challenge here is who performs the review (in terms of organisation), who the review is with (in terms of professional), whether it's holistic. Who gets to find out who has done it and how is this managed between organisations. How will this cover community pharmacy input etc. Patient satisfaction outcomes would be a good measure for this? Measure of waste reduction? Not sure how this could easily be measured. Q2. The quality standard refers to discussing the need for a medication review rather than completing a medication review - the latter is more relevant for improving quality. It would also be useful to clarify definition of who is responsible e.g. often considered a GP role to complete the holistic medication review, however, in long-stay services the responsibility should fall to these services. In Forensic services, staff are caring for patients with long-term mental health and physical health conditions – to bring both strands together for a holistic review would be possible but a challenge with current arrangements and staff levels. Frequency of medication review would also be a helpful addition to support this quality statement. Q3. Access to a central patient record would help immensely for patients who move around many in-patient settings as information about long-term physical conditions and management plans can be lost to the team currently managing their mental and physical health.
271	East Lancashire Hospitals NHS Trust	7	Outpatient attendances should be overtly included in this standard. Features of a safe transfer of care should be included, such as what medicines are started, stopped, changed and why. Recommendations for ongoing care. Inclusion of real-time documentation of changes to prescribing should be mandated for care

ID	Stakeholder	Statement number	Comments
			systems i.e. ePrescribing systems should force capture of this information and paper charts should include the feature
272	North Bristol NHS Trust	7	This is very similar to statement 5
273	Great Western Hospitals NHS Foundation Trust	7	Any difference from statement 5?
274	British Thoracic Society	7	**Health and social care providers adopt a multidisciplinary approach to communicating complete and accurate information about the use of a person's medicines when people move between care settings.** This again is an excellent idea but cross community IT systems need to be in place to facilitate this.
275	Northumbria Healthcare NHS Foundation Trust	7	This could be sensibly incorporated into one of the other sections in the quality standard.
276	NHS England	7	Outcome does not seem directly related to the statement and should be around evidence that multidisciplinary working is actually occurring.
277	Epilepsy Action	7	A multidisciplinary approach to communicating complete and accurate information about the use of a person's medicine when moving between care settings is essential. A complete and up-to-date care plan, written in conjunction with an epilepsy specialist, should aid this process. Patients should also have access to their own healthcare plan, outlining any changes to treatment for any of their long-term conditions, together with a copy of any discharge notes, to make sure there is no conflict between treatments for different conditions and that all healthcare professionals are kept up-to-date.
278	Guild of Healthcare Pharmacists	7	Should there be evidence that the process has actually been implemented rather than the process being in place?
279	Thames Valley and Wessex Chief Pharmacists Network	7	The current barriers to this are often IT infrastructure and misapplied information governance rules. These should be tackled at a national level.
280	Pharmicus	7	All such data needs to be comprehensive, up to date and clear. A standardised layout to use would again be beneficial.
281	Gloucestershire Hospitals NHS Foundation Trust	7	Should there be evidence that the process has actually been implemented rather than the process being in place?
282	Janssen	7	How will this be tracked or measured to ensure it happens? Should the QS be identifying who should be involved and who leads this process?
283	Janssen	7	Janssen fully support he principle of communicating complete and accurate information between care sectors and that there needs to be a multi-disciplinary approach to doing so. Nevertheless it would be helpful to support health and social care providers in understanding how this can be implemented. Who should take on the responsibility for leading this process and how will different providers come together to discuss patients' needs?
284	Royal Pharmaceutical Society	7	We whole-heartedly support this quality standard and this was the main objective in our guidance published in 2012 'Keeping patients safe when they transfer between care providers: Getting the medicines right'.

ID	Stakeholder	Statement number	Comments
			Information could be more easily shared if all those health professionals involved in a patient's care had read and write access to the patient's record.
285	Luton & Dunstable Hospital NHS Foundation Trust	7	The statements in this standard are too woolly and need to be refined. The statement and measures references social care but the rationale only talks about healthcare professionals. It is not clear what information is to be transferred – is another statement about medicines reconciliation or is this broader including barriers to adherence, support to help medicines taking, monitoring clinical parameters to inform medication etc. Local data collection of what? Evidence of protocols are evidence something actually happening? Again this is measuring paperwork is in place not that outcomes are being delivered. Again medicines related patient safety incidents are multi-factorial – the outcome has no specificity to the standard.
286	North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)	7	Q2 linked systems required – IG issues, cultural changes required Q3 – persons and place centred approach required. Define the population served intended to gain benefit.
287	Gloucestershire Hospitals NHS Foundation Trust	7	Question 3: One of the real barriers to the effective transfer of information is the number of different IT systems that are in use within the NHS and the lack of any ability for the different systems to communicate with each other. There is very little information that comes into hospital when a patient is admitted and this can compromise care. The Summary Care Record is a useful piece of information but it must be understood that this may not always be up to date and is only part of the information when undertaking medicines reconciliation
288	Bath and North East Somerset CCG	7	Question 1: the specification of this needs to be clearer, data needs to be shared to prescribers, regular community pharmacies and others e.g. defined carers in Care Home settings and Care providers in Domiciliary settings where appropriate - a time frame should be defined as in Statement 4
289	Bath and North East Somerset CCG	7	Question 2: I am very unclear what the Statement is suggesting is the right route of sharing, is it Summary Care Record? (this would make sense as it should be accessible to most. It should be the "current care providers" responsibility to identify appropriate "receivers" of information – this should then be recorded in a measurable way from NHS Providers and this should be set out in the NHS Standard contract
290	Royal College of Physicians	7	Question 1: Our experts feel that this statement should be amended. Currently its intention is unclear.
291	Royal College of Physicians	7	No. Our experts do not think it would be possible to collect the data for this particular measure. Question 2: Written protocols do not ensure that health and social care providers adopt a multidisciplinary approach. A reduction of medicines-related patient safety incidents when the person moves between care settings cannot be attributed to this intervention.
292	Tees, Esk and Wear Valleys NHS Foundation Trust	7	Q1. Yes, but far reaching and may need to be more focussed

ID	Stakeholder	Statement number	Comments
			Q2. The discharge CPA process helps with this but unclear whether a reduction in medicines-related incidents will be a meaningful measure of improved quality. Although note restricted to medicines - another area of attention is the referral process, where referrals into long-stay services could have MDT approach to identify needs of patients (physical as well as mental health conditions) so these can be considered before transfer to the new care setting. Q3. IT systems etc. – everything mentioned above. Willingness for organisations to work together. Standardisation of expectations of organisations and what information they can and will provide. Perhaps standardised electronic documentation – transferable between different clinical systems.
293	North Bristol NHS Trust	Suggested statement	**There should be a quality standard for <u>Medicines reconciliation at discharge</u> from hospital** In hospital this should involve discussion with the patient on the ward, where the patient's notes are available. The updating and completeness of records and safe transfer of information is critical, especially with increasing use of repeat dispensing, remote dispensing and electronic transfer of information. The ability to contribute to SCR would assist this. **Reconciliation at discharge** should involve working with the CCGs/ LPC and the use of "PharmOutcomes" or "Refer to Pharmacy" for Community Pharmacy referrals; liaising more over communicating on discharge as per: NHS/PSA/W/2014/014: "Risks arising from breakdown and failure to act on communication during handover at the time of discharge from secondary care" and establishing baseline data for the discharges that are not seen by Pharmacy. There should also be standards of % of discharges involving Pharmacy. also STOPP START Toolkit, and there is a Welsh Discharge Medication Record (DMR) project. STOPP/START is a toolkit for reviewing medication in frail/elderly patients. Medication review for patients with polypharmacy should occur in the acute hospital setting but changes to medicines for longterm conditions may not be appropriate at that time when patients are acutely unwell. Medicines can be identified for review for the GP to follow up when more appropriate and can come under medicines reconciliation at discharge. Polypharmacy reviews should be conducted in primary care using a format such as STOPP/START, with multidisciplinary input (e.g. GP and pharmacist).
294	British HIV Association (BHIVA) and HIV	Suggested statement	Yes, it does; however there needs to be a statement about GPs sending an updated list of medications to the specialist clinics at least twice a year to prevent incidents of drug interaction prescribing errors, double treatment etc.

ID	Stakeholder	Statement number	Comments
	Pharmacy Association (HIVPA)		
295	Northumbria Healthcare NHS Foundation Trust	Suggested statement	Primary care should receive an accurate list of medicines that a patient needs to continue on discharge. Accuracy should not be assumed. The list should also indicate things such as which medicines have been discontinued and for what reason, what has been started and for what indication, any follow up monitoring to be undertaken etc. There should be an additional quality standard to this effect. It forms an important conclusion to the hospital stay and ensures that QS 5 is truly meaningful (otherwise what is any primary care reconciliation sensibly undertaken against).
296	NHS England	Suggested statement	While its clearly important to report meds patient safety incidents I think there is a missed opportunity here to promote the use of electronic prescribing systems to support prescribing clinicians. These can significantly reduce meds errors and improve optimisation. I would like to see a Quality Statement recommending the use of e-prescribing support systems
297	College of Mental Health Pharmacy	Suggested statement	The first statement doesn't address the real starting point prior to prescribing new medicines, especially for chronic diseases like schizophrenia and asthma. We would really like to see an additional statement that comes first, something along the lines of: "Healthcare professionals explore people's experiences of medicines and their beliefs about medicines to identify barriers to adherence, before initiating medication, especially for long-term conditions." The quality statement 1, "People have the opportunity to be involved in making decisions about their medicines." Could be worded better as "People are encouraged to take a leading role in making decisions about their medicines."
298	College of Mental Health Pharmacy	Suggested statement	An additional statement to encourage more reporting, especially near-misses.
299	College of Mental Health Pharmacy	Suggested statement	Why is there not a quality statement saying that patients should be told the indication for their medicine and information about its side effects? There is no point in Quality Statement 3 "how to report" if you haven't been told what might be a side effect. And if that is the intention of the current wording "how to identify" then we don't think that's very clear.
300	Tees, Esk and Wear Valleys NHS Foundation Trust	Suggested statement	A quality standard around discharge information and acceptable timescales might be helpful to support statement 5.
301	National Osteoporosis Society	No comment	We have no substantive feedback about the draft but welcome the quality standard and would be interested in formally supporting it.
302	British Association of Dermatologists	No comment	The British Association of Dermatologists has no comments on the draft medicines optimisation quality standard.
303	Royal College of Nursing	No comment	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above quality standards consultation at this time. Thank you for the opportunity to participate.

Registered stakeholders who submitted comments at consultation

- Bath and North East Somerset CCG
- British Association of Dermatologists
- British HIV Association (BHIVA) and HIV Pharmacy Association (HIVPA)
- British Medical Association
- British Thoracic Society
- College of Mental Health Pharmacy
- Department of Health
- Dispensing Doctors' Association
- East Lancashire Hospitals NHS Trust
- Epilepsy Action
- GlaxoSmithKline
- Gloucestershire Hospitals NHS Foundation Trust
- Great Western Hospitals NHS Foundation Trust
- Guild of Healthcare Pharmacists
- Janssen
- Luton & Dunstable Hospital NHS Foundation Trust
- Medicines Use and Safety Team NHS Specialist Pharmacy Services
- Merck Sharp & Dohme
- National Osteoporosis Society
- NHS England

- NHS Dorset Clinical Commissioning Group
- NHS Sheffield
- North Bristol NHS Trust
- North West Commissioning Support unit (On behalf of Greater Manchester Medicines Management Group)
- Northumbria Healthcare NHS Foundation Trust
- Pharmicus
- Royal Bournemouth and Christchurch NHS Foundation Trust
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- Royal College of Speech and Language Therapists (RCSLT)
- Royal Pharmaceutical Society
- Swansea University
- Tees, Esk and Wear Valleys NHS Foundation Trust
- Thames Valley and Wessex Chief Pharmacists Network
- The Royal College of General Practitioners
- UK Clinical Pharmacy Association
- Walgreens Boots Alliance

Appendix 2: Quality standard consultation comments table – non-registered stakeholders

ID	Stakeholder	Statement number	Comments
1	Westgate Practice	Quality Statement 1	Statement 'People and carers should have the opportunity to be involved in making decisions about their medicines'. Despite carers being mentioned in the rationale I feel they now play a considerable active role in decision making around medicines. The use of the word 'have' seems concrete in its terminology as some people do not want to take an active role.
2	Westgate Practice	Quality Statement 1	Definitions of terms – 'involved in making decisions'. An open question to elicit people's ideas concerns and expectations is the educational terminology used but an open question enables the gathering of information. It is this which leads to the development of a partnership between patients, carers and their health care professionals - sharing beliefs, experiences and understanding. Therefore everyone in the partnership is full informed to reach an agreement – concordance. This gives people and carers autonomy and from this responsibility for the medications taken. The partnership and concordance is key and should be mentioned.
3	Westgate Practice	Quality Statement 1	Measures Because this document moves away from medicines management (where structure and process can be measured) to outcome - focusing on helping patients understand their medicines and use them, concrete quality measures are going to be difficult to define concerning this statement There is now potential to add into patient satisfaction surveys at all levels of service providers– 'have you been offered the opportunity to be involved in decisions about your medicines'
4	Westgate Practice	Quality Statement 2	Rationale There is nothing in this rationale mentioning 'openness', 'no blame' or 'fair blame culture'. Risk decreases when there is potential in an organisation to increase reporting. The numbers of serious (red) patient safety incidents are few and are/should be dealt with accordingly under the policy for the organisation. This has to be done with honesty and integrity. There are many more green - no risk or amber -mild/ moderate incidents which need to be reported and learnt from.

ID	Stakeholder	Statement number	Comments
			Organisations need to have robust policies and procedures which are known and if not, people should know where to locate them. These policies can have forms to cover all these eventualities. Therefore more potential minor problems in systems can be discussed and acted upon to ensure a more serious incident does not occur. It is a requirement of all health care professionals to reflect on their practice and through appraisals, learn.
5	Westgate Practice	Quality Statement 2	Measures All organisations should be able to show policies and procedures when asked to do so – easily measured. Minutes of meeting of critical incidents with learning outcomes and changes in policies or patterns of working should be documented clearly. CQC request to see these documents and evidence of the changes that have occurred. Reporting to NRLS (can be done anonymously) and therefore to NPSA gives numbers of patient related safety errors. It is important to note that many health care providers do not use the NRLS for reporting of incidents.
6	Westgate Practice	Quality Statement 3	Statement – 'People who take medicines *and their carers should* receive information on how to indentify and report medicines – related patient safety incidents'. Carers should be included in the statement and again use of the word 'should'
7	Westgate Practice	Quality Statement 3	Rationale Needs to include carers. Several medicines related patient safety incidents are identified through carers.
8	Westgate Practice	Quality Statement 3	Measures The quality measures surrounding this statement rely on a good partnership and openness between patient/carer and health care professional and therefore are difficult to define. Local level :- Evidence of patients being given information on where to report errors to – leaflets, websites. Once errors are reported there needs to be evidence of feedback, changes and the learning that has occurred. National:- NRLS (evidence that people are made aware of this resource – not well known)
9	Westgate Practice	Quality Statement 4	Rationale

ID	Stakeholder	Statement number	Comments
			This means that people and carers should both have a list of the up to date repeat medication which therefore can be taken with them into the acute setting.
10	Westgate Practice	Quality Statement 5	Statement This is a gold standard statement and all have been striving to achieve it for years but still it does not happen. The rationale is clear but I feel somewhere in this quality statement there has to be something mentioned about the barriers surrounding it or there will still be problems. People should be issued with an adequate supply of medication - 14 days supply of medication to allow for the potential 1 week delay. There appears to be no direct communication between hospital pharmacists and the individual/carer before discharge which would be invaluable. Drugs appeared to have been stopped in hospital with no explanation. Sometimes assumptions are made that they have continued with their routine drugs and this is not included on the discharge letter. There are now formularies developed within the primary and acute settings and where several formularies overlap there can be restrictions on prescribing and changes have to be made at primary care level. Some hospitals fax over the discharge letter to pharmacists try and achieve this goal which can further cause problems.
11	Westgate Practice	Quality Statement 5	Measures Structure – All sectors across the health service should be able to show that there is a policy in place for medicine reconciliation in the GP list. This needs to be agreed amongst the various trusts and commissioning bodies - communication Process – Feedback concerning poor and late discharge summaries direct or through commissioning bodies should occur.
12	Westgate Practice	Quality Statement 6	Statement ‘People taking multiple medicines or taking medicines for long- term conditions *should be offered* a structured medication review’ with a health care professional. This statement says that a discussion needs to take place about the need for and purpose of a structured medication review. In the quality statement it then states when the need and purpose is identified it will take place. When health care professionals in primary care prescribe a medication there is a discussion then about the need for review. All patients on any drugs have a medication review date on their records. If a drug requires monitoring it remains the responsibility of the clinician to ensure it is done and the patient has to be reviewed. If the patient continues to collect a repeat prescription over their review date there are processes in place to ensure that the patient has an appointment for review or if they decline review,

ID	Stakeholder	Statement number	Comments
			surgeries have their own policies. Though I do understand what is trying to be achieved here most of the people on repeat medication have to be reviewed due to the nature of the medication they have been prescribed. People and carers need also to be made aware that the health care professional will not necessarily be a doctor. There are now some excellent reviews being done in primary care by face to face consultations or telephone consultations with in house pharmacists.
13	Westgate Practice	Quality Statement 6	Measures By changing the wording of the statement there is the potential to look at measuring medicine wastage and engagement in medication reviews.
14	Westgate Practice	Quality Statement 7	Most of this is in the NICE quality standard 85 – Managing medicines in care homes. One specific person within the care setting is involved in ensuring that accurate information is transferred across. The measures both structure and outcomes are easy to record.