Appendix B: stakeholder consultation comments table

Consultation dates: 21 September 2016 to 4 October 2016

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Overall response</th>
<th>Comments</th>
<th>NICE response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrer Internacional S.A.</td>
<td>No</td>
<td>As concerning cardiovascular disease (CVD), it is a major cause of disability and premature death worldwide (1). Despite European and UK guidelines advocating the use of medical therapies in CVD, many patients do still not achieve the guideline-recommended treatment. CVD is the leading contributor to mortality in the 53 countries of the World Health Organization (WHO) Europe Region, causing almost 4.1 million deaths each year, which means 46% of all deaths in Europe (2). Overall, CVD is estimated to cost the European economy almost EUR 196 billion a year (3). The combined use of aspirin, angiotensin-converting-enzyme (ACE) inhibitors and lipid-lowering therapies has been proven (4, 5) to be highly effective in lowering the risk of secondary CV events. One of the key risk factors to recurrent cardiovascular events is the lack of adherence to medication. Recent studies have demonstrated a suboptimal use of medicines targeted for the prevention of recurrent CV events, showing that only 43% of patients with acute coronary syndrome (ACS) are actually prescribed with optimal treatment for secondary prevention (6, 7). EUROASPIRE study (8) demonstrated that a large majority of coronary patients does not follow the recommendations set by</td>
<td>Thank you for your comments relating to medicines adherence in the area of cardiovascular disease. The cited studies have been considered for inclusion but were published prior to the surveillance search period, are not eligible publication types or are not directly relevant to the guideline review questions. The cost effectiveness study relating to the polypill is considered to be more relevant to the NICE guidelines Cardiovascular disease: risk assessment and reduction, including lipid modification, and Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease. The guideline is a general guideline and is not able to make specific recommendations about individual diseases. However, it does recommend (1,2,8) using interventions, including simplifying the dosing regimen, to overcome practical problems associated with non-adherence. Due to the inconclusive evidence to support these interventions, they should be targeted to specific needs that are identified. The cited studies and other evidence retrieved in the current and previous surveillance reviews is not conclusive and is unlikely to impact on the guideline recommendations. The related NICE guideline on medicines optimisation should also be referred to for the optimal use of medicines, including polypharmacy. NICE guideline CG76 and the NICE guideline on medicines optimisation are both integrated in the Medicines Optimisation pathway.</td>
</tr>
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Appendix B: stakeholder consultation comments table for 8-year surveillance of — Medicines adherence (2009) NICE guideline CG76

<table>
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<tr>
<th>Guidelines on modifying their behavioural patterns towards a balanced and healthy lifestyle.</th>
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<tr>
<th>Stakeholder</th>
<th>Recommendation</th>
<th>Comments</th>
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<tbody>
<tr>
<td>The Dispensing Doctors’ Association Ltd</td>
<td>Yes</td>
<td>No comment</td>
</tr>
<tr>
<td>London North West Healthcare NHS Trust &amp; NHS Specialist Pharmacy Service</td>
<td>Yes</td>
<td>I agree that this guideline is still useful in its current form and is likely to continue to be useful for the next 3-5 years. There is a minor suggestion for an amendment to the recommendations. Suggest replacing the term “patient beliefs”, which is open ended, with the more specific term “patient treatment necessity beliefs” This is because the Horne et al 2013 meta-analysis allows us to be more specific about the TYPES of beliefs that practitioners should consider i.e. patient’s treatment necessity beliefs and concerns not just general beliefs.</td>
</tr>
<tr>
<td>Guild of Healthcare Pharmacists</td>
<td>Yes</td>
<td>We could not identify a need to update the guideline</td>
</tr>
</tbody>
</table>
| European Society for Patient Adherence, COMpliance, and Persistence (ESPACOMP) | No | “Introduction
Adherence to medicines is defined as the extent to which the patient's action matches the agreed recommendations.”
This is a dated and somewhat unhelpful definition of medication adherence because it makes no distinction between the three phases of adherence: treatment initiation, implementation of dosing and persistence with treatment.
Linked to the above comment, much of the guideline is dedicated to the initiation phase. However, the distinction between the 3 phases of adherence is particularly important, given:
25% of patients do not initiate a new prescription | Thank you for your comments relating to the definition of medicines adherence. There is a degree of overlap between NICE guideline CG76 and the NICE guideline on medicines optimisation, both of which are integrated in the Medicines Optimisation pathway. The definition of medicines adherence is broad and aims to define what it is rather than the phases involved. It will be reconsidered at a future surveillance point in conjunction with the NICE guideline on medicines optimisation. In relation to the comments about phases of adherence, NICE guidelines are not designed to cover all aspects of care and local policies should be followed where necessary. The New Medicines Service in England is mentioned in the surveillance report with relevant evidence. However, the guideline is only applicable to the NHS in England, and therefore the Discharge Medicine Service in Wales is not included. |
Daily, 15% of patients do not implement as prescribed
During the first year, 40% of patients have discontinued treatment
This should form the basis for understanding patients’ lack of adherence, and provide a means to improve adherence, which will differ according to which phase is under consideration.

“Key principles
Be aware that although adherence can be improved, no specific intervention can be recommended for all patients. Tailor any intervention to increase adherence to the specific difficulties with adherence the patient is experiencing.”

This broad statement makes no distinction between initiation, implementation and persistence. It is likely that certain types of intervention may be more effective for each specific type of (poor) adherence. There is no reference to the potential roles of the New Medicines Service in England, and the Discharge Medicine Service in Wales, for instance, in improving treatment initiation. See for instance: Value Health 2013;16:891-900. Interventions to promote better persistence, where discontinuation is predominantly a volitional action, compared with implementation, which has a significant unintentional component, require different approaches. For a review of the components of adherence enhancing interventions, see: JAMA 2013;310:2611-2.

“1.2 Assessing adherence
The purpose of assessing adherence is not to monitor patients but rather to find out whether patients need more information and support.”

There is mounting evidence that monitoring of some form or another is essential to accurately assess (measure) adherence and monitoring in itself can also provide a basis for effective intervention. See for instance: Drugs. 2013 May;73(6):545-62.

CG76 recommendation 1.2.5 states that no specific intervention can be recommended for all patients. Recommendation 1.2.8 states that because evidence supporting interventions to increase adherence is inconclusive, interventions should only be used to overcome practical problems associated with non-adherence if a specific need is identified. Interventions should be targeted to the need.

The new and previous evidence identified through the surveillance is also inconclusive and therefore consistent with this recommendation. Interventions which could potentially impact on CG76 with future high quality evidence are:

- caregiver interventions
- case management
- electronic monitoring drug dispensing device
- financial incentives
- practical social support
- improved prescription drug coverage
- educational and cognitive behaviour interventions
- devices with dose-memory and combined dose-memory and dose-reminder functions
- nurse-led and pharmacist-led interventions
- complex interventions with multiple components
- medicines self-monitoring and self-management programs
- shared decision making
- tailored Internet interventions
- wireless technology, including smartphone applications

The new evidence on directly observed therapy does not support its use in increasing adherence.

The new evidence is also relevant to the NICE guideline on medicines optimisation which includes a more detailed section on medicines review with specific reference to polypharmacy and older people (recommendation 1.4.1).
The areas highlighted by stakeholder and topic expert feedback will continue to be monitored for new evidence at the next surveillance review point.

The cited evidence on describing, defining and monitoring adherence, and the components of adherence enhancing interventions, precedes the search period for the current surveillance review, but new evidence in these areas will be considered at a future surveillance review.

<table>
<thead>
<tr>
<th>Action on Hearing Loss</th>
<th>No</th>
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| Action on Hearing Loss, formerly RNID, is the UK’s largest charity working for people with deafness, hearing loss and tinnitus. Our vision is of a world where deafness, hearing loss and tinnitus do not limit or label people and where people value and look after their hearing. We help people confronting deafness, tinnitus and hearing loss to live the life they choose, enabling them to take control of their lives and removing the barriers in their way. We give people support and care; develop technology and treatments and campaign for equality.

Throughout this response we use the terms ‘people with hearing loss’ to refer to people with all levels of hearing loss and ‘people who are deaf’ to refer to people who are profoundly deaf who use British Sign Language (BSL) as their first or preferred language. We are happy for the details of this response to be made public.

Action on Hearing Loss disagrees with NICE’s proposal not to update the Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence clinical guideline. Given the growing prevalence and impact of deafness and hearing loss and the common barriers to communication faced by people who are deaf or have hearing loss when they visit the GP or other NHS services, we believe this clinical guideline should be updated to include references to NHS England’s Accessible Information Standard. The Standard, which became a legal requirement on 1st August 2016, provides clear guidance for providers of NHS care and publicly funded adult social care on

Thank you for your comments relating to hearing loss and the need to incorporate the Accessible Information Standard into the guideline. From 31 July 2016, all organisations that provide NHS care or adult social care are legally required to follow the Accessible Information Standard. However, NICE is not a provider of care and its clinical guideline recommendations are not subject to legal obligations, as stated in the NICE charter. It is outside the scope of the guideline to stipulate this legislation in its recommendations, but it is included in the list of standards users are expected to follow on the Making decisions using NICE guidelines page on the NICE website.

NICE is committed to the provision of quality information to the public. In December 2009 NICE was certified as a quality provider of health and social care information by The Information Standard - a certification scheme for health and social care information aimed at the public.

The cited evidence relates to hearing loss and is not directly relevant to medicines adherence.
making their services accessible for people with disabilities and sensory loss, including people who are deaf or have hearing loss.

Below, we provide some background information on the prevalence and impact of deafness and hearing loss and the common barriers to communication faced by people who are deaf or have hearing loss when accessing healthcare. We also set out our recommendations for updating this guideline.

1. Background

1.1 Prevalence and impact
There are 11 million people with hearing loss across the UK, about one in six of the population. Hearing loss can be caused by regular and prolonged exposure to loud sounds, ototoxic drugs, genetic predisposition or complications from injuries or other conditions. Age related damage to the cochlear is the single biggest cause of hearing loss. Over 70% of people over 70 years old have hearing loss and due to the ageing population, the number of people with hearing loss is set to grow in the years to come. By 2035, we estimate there will be approximately 15.6 million people with hearing loss. Around 40% of people with learning disabilities have hearing loss and evidence suggests that people with learning disabilities are more likely to develop hearing loss earlier compared to the general population.

There are also an estimated 900,000 people in the UK with severe or profound hearing loss. Some people with severe or profound hearing loss use British Sign Language (BSL) as their main language and may consider themselves part of the Deaf Community, with a shared history, language and culture. Based on the 2011 census, we estimate that there are at least 24,000 people across the UK who use BSL as their main language – although this is likely to be an underestimate.
A significant body of evidence shows that hearing loss is a serious condition that can have an adverse impact on a person’s health and quality of life. Studies have found that hearing loss is independently associated with increased use of health services, an increased burden of disease amongst adults and an increased risk of mortality. Hearing loss has also been associated with more frequent falls, diabetes, stroke, and sight loss. There is strong evidence of a link between hearing loss and dementia. Evidence suggests that people with learning disabilities are at greater risk of poor health due to their hearing loss.

Research shows that people with hearing loss may find it difficult to communicate with other people and this may lead to feelings of loneliness, emotional distress and withdrawal from social situations. People with hearing loss are more likely to develop paranoia, anxiety and other mental health issues – for example, evidence shows that hearing loss doubles the risk of developing depression. There is strong evidence of a link between hearing loss and dementia. There is evidence of an association between sensory loss and challenging and self-injurious behaviours. People who are born deaf may also be at greater risk of mood, anxiety, personality or developmental disorders.

Hearing aids are shown to improve quality of life and help people communicate, stay socially active and reduce the risk of loneliness and depression. New evidence suggests they may reduce the risk of dementia. However, many people are waiting too long to get their hearing tested. Research shows that people wait on average ten years before seeking help for their hearing loss and the average age for referral is in the mid-70s. Delays in treatment mean people with hearing loss are less likely to benefit from hearing aids. Evidence suggests that hearing aids are most effective when fitted early and people with severe hearing loss may find it more difficult to adapt to hearing aids. There are currently no national screening programmes for adults with hearing loss and more could be done to encourage people to seek help and check their hearing.
1.2 Access to health

Many people who are deaf or have hearing loss struggle to access the GP and other NHS services when they need to due to poor deaf awareness or the lack of communication support. Our Access All Areas report shows after attending an appointment with their GP, more than a quarter of survey respondents (28%) had been unclear about their diagnosis and approximately a fifth (19%) had been unclear about their medication. When asked why they felt unclear after their appointment, more than half (64%) said the GP did not face them and more than half (57%) said the GP did not always speak clearly – suggesting that if health professionals followed simple communication tips, this could improve understanding and make treatment more effective. People with hearing aids may also benefit from hearing loop systems, yet over a third (35%) said these weren’t available. The situation is even worse for people who are deaf. Research by the Our Health in Your Hands campaign shows more than two thirds (68%) of survey respondents who asked for a sign language interpreter for their GP appointment didn’t get one and more than two fifths (41%) felt unclear about their diagnosis because they couldn’t understand the sign language interpreter.

Without a qualified BSL interpreter or other communication support, people who are deaf may be at risk of worse care and poor health. Research by the charity SignHealth shows that over a third (34%) of people who are deaf were unaware they had high or very high blood pressure and more than half (55%) of those who said they had cardiovascular disease were not receiving appropriate treatment. This suggests that people who are deaf may not be getting the care they need due to problems with communication and understanding. Additional research suggests that people who are deaf may be unable to access preventive services and are at greater risk of cardiovascular disease due to the lack of information available in sign language.

2. Recommendation
Given the growing prevalence and impact of hearing loss and the relationship between hearing loss and other conditions, ensuring people with hearing loss get the support they need to communicate well when they visit the GP or other NHS services is crucial for effective care. People who are deaf may need a qualified BSL interpreter or other qualified communication support to discuss their treatment options and may need health information in BSL. Without appropriate support, people who are deaf or have hearing loss may find it difficult to participate fully in discussions with health professionals, which could lead to confusion over diagnosis and medication and ineffective treatment.

NHS England’s Accessible Information Standard, which became a legal requirement on 1st August 2016, provides clear guidance for providers of NHS care and publicly funded adult social care on making their services accessible for people with disabilities and sensory loss, including people who are deaf or have hearing loss. The Standard sets out a clear process to make sure people with disabilities and sensory loss get the support they need to communicate well and understand information they’re given – including the communication and/or information needs of parents, guardians and carers.

The Standard provides detailed guidance for providers on how to meet their legal duties under the Equality Act 2010 and is highly relevant for the Communication and Providing information sections of Recommendation 1.1: Patient involvement in decisions about medicines. We believe the Accessible Information Standard is a key policy document relevant to the successful implementation of this clinical guideline and to the effective communication between many patients and professionals, as well as patients’ ability to comply with treatment and medication, and to manage their health conditions. As a result, the guideline should be updated to include references to the Standard in the sections of Recommendation 1.1 identified above.

1 www.england.nhs.uk/accessibleinfo
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22 Ringham (2012) Access All Areas. Available at: www.actiononhearingloss.org.uk/accessallareas


26 www.england.nhs.uk/accessibleinfo

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**Do you agree with the proposal to put the guideline on the static list?**

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<tbody>
<tr>
<td>Ferrer Internacional S.A.</td>
<td>No</td>
<td>Adherence to medication has been widely identified as a risk factor to the recurrence of CVD. Good adherence is associated with</td>
<td>Thank you for your comments relating to medicines adherence in the area of cardiovascular disease. The cited studies have been considered for inclusion but were published prior to the surveillance</td>
</tr>
</tbody>
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positive health outcomes and poor adherence to treatment actually increases the likelihood of suffering a recurrent CV event (9, 10). In order to reduce low adherence rates, many experts have studied the link between compliance with medication and pill burden as a potential key to modifying treatment outcomes through adapting patient's behavioural patterns.

Optimization of treatment regimens and increased compliance can help to prevent the recurrence of CV events (11). The polypill approach has been advocated to help overcome some of these barriers to CVD prevention (8) and trials showed that the polypill significantly increases adherence to treatment when compared to administering either the individual drugs separately (12) or when compared to usual care (13,14, 15).

European guidelines have openly and strongly advocated for the use of medical therapies in the prevention of secondary CV events and in particular for the use of poly pills to increase adherence (16). To date, some poly pills have been investigated for CVD prevention, for which one a marketing authorisation has been granted in the Europe Union, in other European countries and in Latin-America so far (17).

Indeed, a recently published study demonstrated that the use of a polypill appeared to be a cost-effective strategy to prevent fatal and non-fatal CV events in the UK (18).

Most than probably in less than three years a polypill to increase adherence to prevent secondary events in patients with CVD could be granted in UK.

A guideline on Medicines adherence to involve patients in decisions about prescribed medicines and supporting adherence should consider in advance the polypill approach in patients with CVD.

search period, are not eligible publication types or are not directly relevant to the guideline review questions.

The guideline is a general guideline and is not able to make specific recommendations about individual diseases.

However, it does recommend (1.2.8) using interventions, including simplifying the dosing regimen, to overcome practical problems associated with non-adherence. Due to the inconclusive evidence to support these interventions, they should be targeted to specific needs that are identified. The cited studies and other evidence retrieved in the current and previous surveillance reviews is not conclusive and is unlikely to impact on the guideline recommendations.

The related guideline on medicines optimisation should also be referred to for the optimal use of medicines, including polypharmacy. NICE guideline CG76 and the NICE guideline on medicines optimisation are both integrated in the Medicines Optimisation pathway.

We consider that the recommendations are still current and the evidence base is unlikely to change in the foreseeable future.

Consideration to transfer a clinical guideline back to the active surveillance list may occur in the following circumstances:

- The high level review at 5 years yields new evidence which may impact on the guidance
- Stakeholders notify NICE of relevant new evidence which may impact on guidance at any time point, for example safety data.
- A quality standard is commissioned that relates to a guideline on the static list

<p>| The Dispensing Doctors’ Association Ltd | Yes | No comment | Thank you. |
| London North West Healthcare NHS Trust &amp; NHS Specialist Pharmacy Service | Yes | No comment | Thank you. |</p>
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<tr>
<th>Guild of Healthcare Pharmacists</th>
<th>Yes</th>
<th>As there is no need to update the guideline it seems appropriate to place it on the static list</th>
<th>Thank you for your comment.</th>
</tr>
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</table>
| European Society for Patient Adherence, COMpliance, and Persistence (ESPACOMP) | No  | Medication adherence research is a rapidly evolving field, requiring the guideline to be updated regularly to reflect changes in the evidence base. New studies, which consider such interventions as financial incentives (BMJ Open 2016;6:e011673) or mHealth (PLoS Med. 2013;10(1):e1001362) are set to influence how adherence is managed in the near future. | Thank you for your comments. We did not identify any published or ongoing research in the current or previous surveillance reviews to indicate an impact on the guideline recommendations. The cited studies covering financial incentives and mHealth were published outside the current surveillance period. We consider that the recommendations are still current and the evidence base is unlikely to change in the foreseeable future. Consideration to transfer a clinical guideline back to the active surveillance list may occur in the following circumstances:  
  - The high level review at 5 years yields new evidence which may impact on the guidance  
  - Stakeholders notify NICE of relevant new evidence which may impact on guidance at any time point, for example safety data.  
  - A quality standard is commissioned that relates to a guideline on the static list |
| Action on Hearing Loss | No  | As stated in our answer to question 1, this guideline should not be placed on the static list as it needs to be updated to include references to NHS England’s Accessible Information Standard. | Thank you for your comments relating to hearing loss and the need to incorporate the Accessible Information Standard into the guideline. From 31 July 2016, all organisations that provide NHS care or adult social care are legally required to follow the Accessible Information Standard. However, NICE is not a provider of care and its clinical guideline recommendations are not subject to legal obligations, as stated in the NICE charter. It is outside the scope of the guideline to stipulate this legislation in its recommendations, but it is included in the list of standards users are expected to follow on the Making decisions using NICE guidelines page on the NICE website. NICE is committed to the provision of quality information to the public. In December 2009 NICE was certified as a quality provider of health and social care information by The Information Standard - a certification scheme for health and social care information aimed at the public. |
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- A quality standard is commissioned that relates to a guideline on the static list.

No comments

DoH had no comments for this consultation

Royal College of Nursing had no comments for this consultation