National Institute for Health and Care Excellence

8-year surveillance (2016) – Medicines adherence (2009) NICE guideline CG76

Appendix B: stakeholder consultation comments table

Consultation dates: 21 September 2016 to 4 October 2016

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Ferrer Internacional S.A.	No	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	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.

- guidelines on modifying their behavioural patterns towards a balanced and healthy lifestyle.
- [1] Basinlal S, Castellano JM, Fuster V. Global burden of CVD: focus on secondary prevention of cardiovascular disease. International Journal of Cardiology 2015; 201 Suppl 1:S1-S7.
- [2] Nichols M, Townsend N, Scarborough P, Rayner M. Cardiovascular disease in Europe: epidemiological update. European Heart Journal 2013;34:3028-3034.
- [3] Nichols M, et al. European Cardiovascular Disease Statistics. European Heart Network and European Society of Cardiology 2012.
- [4] Barrios V, Escobar C. Improving cardiovascular protection: focus on a cardiovascular polypill. Future Cardiology 2015;12(2):181-196.
- [5] Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C, Budaj A, et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. Eur Heart J 2013;34:2949-3003.
- [6] Zeymer U, Berkenboom G, Coufal Z, Belger M, Sartral M, Norrbacka K, et al. Predictors, cost, and outcomes of patients with acute coronary syndrome who receive optimal secondary prevention therapy: results from the antiplatelet treatment observational registries (APTOR). Int J Cardiol 2013;170(2):239-245.
- [7] Zhao M, Cooney M, Klipstein-Grobusch K, Vaartjes I, De Bacquer D, De Sutter J, et al. Simplifying the audit of risk factor recording and control: A report from an international study in 11 countries. Eur J Prev Cardiol 2016; [Epub ahead of print].
- [8] Kotseva K, Wood D, De Bacquer D, De Backer G, Rydén L, Jennings C, et al. EUROASPIRE IV: A European Society of Cardiology survey on the lifestyle, risk factor and therapeutic management of coronary patients from 24 European countries. Eur J Prev Cardiol. 2016 April; 23
- [9] Zeymer U, Jünger C, Zahn R, Bauer T, Bestehorn K, Senges J, et al. Effects of a secondary prevention combination therapy with an aspirin, an ACE inhibitor and a statin on 1-year mortality of patients

with acute myocardial infarction treated with a beta-blocker. Support for a polypill approach. Curr Med Res Opin 2011;27(8):1563-1570.

[10] Sleight P, Pouleur H, Zannad F. Benefits, challenges, and registerability of the polypill. European Heart Journal. 2006;27(14):1651-1656.

[11] Kotseva K, Wood D, De Bacquer D, De Backer G, Rydén L, Jennings C, et al. EUROASPIRE IV: A European Society of Cardiology survey on the lifestyle, risk factor and therapeutic management of coronary patients from 24 European countries. Eur J Prev Cardiol 2016 April;23.

[12] Castellano J, Sanz G, Peñalvo J, Bansilal S, Fernández-Ortiz A, Alvarez L, et al. A polypill strategy to improve adherence: results from the FOCUS project. J Am Coll Cardiol 2014;64(20):2071-2082.

[13] Thom S, Poulter N, Field J, Patel A, Prabhakaran D, A S, et al. Effects of a fixed-dose combination strategy on adherence and risk factors in patients with or at high risk of CVD: the UMPIRE randomized clinical trial. JAMA 2013;310(9):918-929.

[14] Selak V, Elley C, Bullen C, Crengle S, Wadham A, Rafter N, et al. Effect of fixed dose combination treatment on adherence and risk factor control among patients at high risk of cardiovascular disease: randomised controlled trial in primary care. BMJ 2014;348.

[15] Patel A, Cass A, Peiris D, Usherwood T, Brown A, Jan S, et al. A pragmatic randomized trial of a polypill-based strategy to improve use of indicated preventive treatments in people at high cardiovascular disease risk. European Journal of Preventive Cardiology 2014;22(7):920-930.

[16] Piepoli M, Hoes A, Agewall S, Albus C, Brotons C, Catapano A, et al. European Guidelines on cardiovascular disease prevention in clinical practice (version 2016). Atherosclerosis. 2016 September.

[17] Chrysant SG, Chrysant GS. Treatment of Modifiable Risk Factors Is Associated With Decrease in Coronary Heart Disease Incidence: Time to Use the Polypill. J Clin Hypertens 2016.

[18] Becerra V, Gracia A, Desai K, Abogunrin S, Brand S, Chapman R, et al. Cost-effectiveness and public health benefit of secondary

		cardiovascular disease prevention from improved adherence using a polypill in the UK. BMJ Open 2015;5.	
The Dispensing Doctors' Association Ltd	Yes	No comment	Thank you
London North West Healthcare NHS Trust & NHS Specialist Pharmacy Service	Yes	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.	Thank you for your comments. The suggested change to the term "patient beliefs" will be considered for the relevant recommendations when the guideline is next updated.
Guild of Healthcare Pharmacists	Yes	We could not identify a need to update the guideline	Thank you
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. Vrijens B. et al. A new taxonomy for describing and defining adherence to medications. Br J Clin Pharmacol. 2012 May;73(5):691-705. 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 dosereminder 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 <u>medicines</u> <u>optimisation</u> 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.
Action on Hearing Loss	No	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 guarter 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.

www.england.nhs.uk/accessibleinfo

- ² Action on Hearing Loss (2015) Hearing matters. Available at: www.actiononhearingloss.org.uk/hearingmatters.
- ³ Davis (1995) Hearing in adults. London: Whurr.
- 4 Foundation for people with learning disabilities, 2015. Hearing Loss. Available from:

Advances in psychiatric treatment. 16, 228-235.

Annals of Internal Medicine, 113 (3), 188-194.

http://www.learningdisabilities.org.uk/help-information/learning-disability-a-z/h/hearing-loss/; Kiani R and Miller H (2010) Sensory impairment and intellectual disability

⁵ Chisholm et al (2007) A systematic review of health-related quality of life and hearing aids: Final report of the American Academy of Audiology task force on the health-related quality of life benefits of amplification in adults. *Journal of American Academy of Audiology*, 18, 151-183; Ciorba et al (2012) The impact of hearing loss on quality of life of elderly adults. *Clinical interventions in aging*, 7, 159-63; Dalton et al (2003) the impact of hearing loss on quality of life in older adults. *The Gerontologist*, 43 (5), 661-68; Mulrow et al (1990)

Quality-of-life changes and hearing impairment, a randomized trial.

⁶ Appollonio et al (1996) Effects of sensory aids on the quality of life and mortality of elderly people: A multivariate analysis. *Age and Ageing*, 25, 89-96; Genther et al (2013) Association of hearing loss with hospitalization and burden of disease in older adults. *Journal of the American Medical Association*, 309 (22), 2322; Karpa et al (2010) Associations between hearing impairment and mortality risk in older persons: the Blue Mountains Hearing Study. *Annals of Epidemiology*, 20 (6), 452-9.

⁷ Lin and Ferrucci (2012) Hearing loss and falls among older adults in the United States. *Archives of internal medicine*, 172 4, 369-371.

⁸ Kakarlapudi et al (2003) The effect of diabetes on sensorineural hearing loss. *Otology and Neurotology*, 24 (3), 382-386; Mitchell et al (2009) Relationship of Type 2 diabetes to the prevalence, incidence and progression of age-related hearing loss. *Diabetic Medicine*, 26 (5), 483-8; Chasens et al (2010) Reducing a barrier to

diabetes education: identifying hearing loss in patients with diabetes. *Diabetes Education*, 36 (6), 956-64.

⁹ Formby et al (1987) Hearing loss among stroke patients. *Ear and Hearing*, 8 (6), 326-32; Gopinath et al (2009) Association between age-related hearing loss and stroke in an older population. *Stroke*, 40 (4), 1496–1498.

10 Chia et al (2006) Association between vision and hearing impairments and their combined effects on quality of life. *Archives of Ophthalmology*, 124 (10), 1465-70.

11 Lin FR et al. (2011) 'Hearing loss and incident dementia'. Archives of Neurology, 68 (2), 214-220; Gurgel et al (2014) Relationship of Hearing Loss and Dementia: A Prospective, Population-Based Study. Otology & Neurotology. 35 (5), 775-781; Albers et al (2015) At the interface of sensory and motor dysfunctions and Alzheimer's disease. Alzheimers and Dementia Journal, 11 (1), 70–98.

¹² Kiani R and Miller H (2010) Sensory impairment and intellectual disability Advances in psychiatric treatment. 16, 228–235;

¹³ Hétu et al (1993) The impact of acquired hearing loss on intimate relationships: implications for rehabilitation. *Audiology*, 32 (3), 363-81; Arlinger (2003) 'Negative consequences of uncorrected hearing loss – a review'. *International Journal of Audiology*, 42 (2), 17-20; Monzani et al (2008) 'Psychological profile and social behaviour of working adults with mild or moderate hearing loss'. *Acta Otorhinolaryngologica Italica*, 28 (2), 61-6.

¹⁴ Saito et al (2010) Hearing handicap predicts the development of depressive symptoms after three years in older community-dwelling Japanese. *Journal of the American Geriatrics Society*, 58 (1), 93-7; Monzani et al (2008) Psychological profile and social behaviour of working adults with mild or moderate hearing loss. Acta Otorhinolaryngologica Italica, 28 (2), 61–66; Eastwood et al (1985) Acquired hearing loss and psychiatric illness: an estimate of prevalence and co-morbidity in a geriatric setting. *British Journal of Psychiatry*, 147, 552–556.

¹⁵ Lin FR et al. (2011) 'Hearing loss and incident dementia'. *Archives of Neurology*, 68 (2), 214-220; Gurgel et al (2014) Relationship of Hearing Loss and Dementia: A Prospective, Population-Based Study. *Otology & Neurotology*. 35 (5), 775-781; Albers et al (2015) At the interface of sensory and motor dysfunctions and Alzheimer's disease. *Alzheimers and Dementia Journal*, 11 (1), 70–98.

¹⁶ Carvill S and Marston G (2002) People with intellectual disability, sensory impairments and behaviour disorder: a case series. *Journal of Intellectual Disability Research*, 46 (3), pp.264-272.

¹⁷ Black and Glickman (2002) Demographics, psychiatric diagnoses, and other characteristics of North American Deaf and hard of hearing inpatients. *J Deaf Stud Deaf Educ* 2006, 11 (3), 303-321.

¹⁸ Chisholm et al (2007) A systematic review of health-related quality of life and hearing aids: Final report of the American Academy of Audiology task force on the health-related quality of life benefits of amplification in adults. *Journal of American Academy of Audiology*, 18, 151-183; Mulrow et al (1992) Sustained benefits of hearing aids. *Journal of Speech and Hearing Research*, 35 (6), 1402-5; National Council on the Aging (2000) The consequences of untreated hearing loss in older persons. *Head and Neck Nursing*, 18 (1), 12-16; Yueh et al (2001) Randomized trial of amplification strategies. *Archives of Otolaryngology - Head & Neck Surgery*, 127 (10), 1197-204.

¹⁹ Acar et al (2011) Effects of hearing aids on cognitive functions and depressive signs in elderly people. *Archives of Gerontology and Geriatrics*, 52 (3): 250-2;

Pronk et al (2011) Prospective effects of hearing status on loneliness and depression in older persons: identification of subgroups. *International Journal of Audiology*, 50 (12), 887-96; Dawes et al (2015) Hearing Loss and Cognition: The Role of Hearing Aids, Social Isolation and Depression. *PLoS ONE*, 10 (3): e0119616; National Council on the Aging (2000) The consequences of untreated hearing loss in older persons. *Head and Neck Nursing*, 18 (1), 12-16.

²⁰ Amieva et al (2015) Self-Reported Hearing Loss, Hearing Aids, and Cognitive Decline in Elderly Adults: A 25-Year Study. *Journal of the American Geriatrics Society*, 63 (10), 2099-2104; Dawes et al

(2015) Hearing Loss and Cognition: The Role of Hearing Aids, Social Isolation and Depression. <i>PLoS ONE</i> , 10 (3): e0119616; Deal et al (2015) Hearing impairment and cognitive decline: A pilot study conducted within the atherosclerosis risk in communities neurocognitive study. <i>American Journal of Epidemiology</i> , 181(9), 680-90.
²¹ Davis et al (2007) Acceptability, benefit and costs of early screening for hearing disability: A study of potential screening tests and models. <i>Health Technology Assessment</i> , 11, 1–294.
²² Ringham (2012) Access All Areas. Available at: www.actiononhearingloss.org.uk/accessallareas
23 Our Health in Your Hands (2012) Survey of BSL users about access to communication support in healthcare. Available at:

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

Stakeholder	Overall response	Comments	NICE response
Ferrer Internacional S.A.	No	Adherence to medication has been widely identified as a risk factor to the recurrence of CVD. Good adherence is associated with	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

The Dispensing Doctors'		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 polypills to increase adherence (16) To date, some polypills 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
The Dispensing Doctors' Association Ltd	Yes	No comment	Thank you.
London North West Healthcare NHS Trust & NHS Specialist Pharmacy Service	Yes	No comment	Thank you.

Guild of Healthcare Pharmacists	Yes	As there is no need to update the guideline it seems appropriate to place it on the static list	Thank you for your comment.
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.

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.

No comments

DoH had no comments for this consultation

Royal College of Nursing had no comments for this consultation