

National Institute for Health and Clinical Excellence

Epilepsy (update): scope consultation

Scope Consultation Table

3 February 2009 – 2 March 2009

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
NICE	PIIP at NICE	1	General	The Patient and Public Involvement Programme at NICE welcomes this update to the Epilepsies clinical guideline. We note that it is only to focus on pharmacological treatments, and suggest that the final scope might clarify how the other parts of the existing guideline will be treated after this update has taken place.	Parts of the existing guidelines that are not updated will remain in force.
NICE	PIIP at NICE	2	General :Equalities	<p>We noted the discussion at the stakeholder meeting about people with learning disabilities, and suggest consideration of specific mention of this group of people in terms of this guideline. The link includes the text copied below, for information.</p> <p>http://www.scottish.parliament.uk/msp/crossPartyGroups/groups/epilepsy-docs/epilepsy_minute310108.pdf</p> <ul style="list-style-type: none"> - The prevalence of epilepsy in the general population is less than 1% (40,000 Scots) - In the learning disability (LD) population of an estimated 120,000 people, around 20% will have epilepsy – that's 24,000 people, over half of the epilepsy population - Glasgow community based study shows 38% of the learning disability population has epilepsy - Challenge for epilepsy management is communication and care support (health care by proxy) - People with epilepsy and LD are the highest users of emergency admissions 	Thank you for your comment. People with learning disabilities will be included in the updated guideline as a specific subgroup. As treatment will be directed at the epilepsy syndromes, any issues concerning side effects will be addressed within the guideline update.

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				- This is a high risk group for morbidity and mortality, particularly sudden and unexpected death	
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	2	General	It is essential that paediatric epilepsy has to be separately treated. This is because of the wide range of syndromes, both severe and damaging and mild and often benign which are confined to childhood. The cognitive and behavioural aspects require specific multidisciplinary care. The parental care and educational dimensions are crucial. The main interface problem is over transition services to adult life in which the need for continuing integrated medical, psychiatric, learning disability care and social support are both important and very difficult to find.	Thank you for your comment. It is recognised that there are differences between adult and paediatric groups, and this will be considered in this guideline update. Paediatric epilepsy was addressed separately in the previous guideline, and will again be separately addressed in the guideline update.
SH	Special Products Limited	3	General	The injection solution has been given <i>intranasally</i> to children. Severe irritation of the nasal mucosa may occur after using the Injection Solution (which contains Midazolam Hydrochloride solution at pH 3-3.5. However, this does not occur if Midazolam Maleate buccal liquid (pH 5.0-5.5) is administered. Ref. Lugo RA, <i>et al.</i> Complication of intranasal Midazolam. <i>Pediatrics</i> 1993; 92: 638	Thank you for your comment. This has been noted.
SH	Royal College of Paediatrics and Child Health	1	General	Q3 – Satisfactory.	Thank you for your comment. This has been noted.
SH	Royal College of Paediatrics and Child Health	2	General	The scope appears to be covering mainly drug therapeutics. This is obviously is a key area and very welcome considering the experience accrued on the newer drugs and more importantly indications and evidence on the newest drugs. The scope is not comprehensive. The frontiers in epilepsy now are in genetics and appropriate gene testing, role of metabolic screen in children, accrued evidence and experience on newer therapies such as vagal nerve stimulation etc. This is relevant for secondary care paediatricians.	Thank you for your comment. This is currently outside of the scope of this guideline update. Referral guidelines for referral to tertiary care were considered in the previous guideline. Our remit is to update the pharmacological section of the guideline. With regards to vagal nerve stimulation, please refer to the Health Technology

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					Assessment document. No new studies have been published since the HTA to change recommendations.
SH	Royal College of Paediatrics and Child Health	3	General	The subgroup of children with complex neurodisability who are frequently on polytherapy for their usually intractable epilepsy. Is there evidence and potential for guidance?	Thank you for your comment. The use of polypharmacy could also apply to a child without neurodisability, so will be covered in the guideline. We will address the evidence base in the guideline.
SH	Royal College of Paediatrics and Child Health	24	General	<p>"This guideline will also include side effects of generic prescribing, potential withdrawal from drugs, poly-therapy, drug interactions and side effects." This sentence is rather unclear:</p> <ol style="list-style-type: none"> 1) We are unsure why side effects are mentioned twice. Are the side effects of generic prescribing different from side effects in general? 2) My own clinical practice suggests that an important group of side effects of anti-epileptic drugs are effects on behaviour. These must be included in the scope of the guideline. To this end, could it be explicitly stated that behavioural side effects will be considered by the guideline development group? 3) Will side effects include an evaluation on the impact of the treatment on school performance? 4) Will young people with epilepsy be consulted on this guideline / be advisors to relevant sections? Young people (12-18) with chronic epilepsy have a very clear insight into it's impact on their lives, and the impact of the treatments offered, this should be considered. 	<p>Thank you for your comments.</p> <ol style="list-style-type: none"> 1) This was an error and has been changed. 2) Side effects relating to behavioural change will be addressed in the guideline. 3) Cognition will be covered as part of this guideline update. 4) We will endeavour to ensure that young people are consulted. 5) With the newer drugs we will be looking into drug interactions.

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				5) Will family planning advice for those on AEDs be part of this guidance?	
SH	Royal College of Paediatrics and Child Health	25	General	Children are different to adults and epilepsy in childhood is very different to that in adulthood with a different range of epilepsy syndromes.	Thank you for your comment. This has been noted.
SH	Royal College of Paediatrics and Child Health	26	General	The guideline and scope is welcome particularly with the demarcation of the age groups as suggested. However, if neonates are not included in this guidance, where will their needs be covered? It would seem prejudicial to leave them out in this instance.	Thank you for your comment. We consider this to be a separate group that would require separate guidance. Stakeholders are invited to submit topics for consideration.
SH	Epilepsy Bereaved	5	General	Epilepsy Bereaved welcome the NICE Update but we have concerns that the scope does not mention the need to reduce the unnecessary deaths from SUDEP and other epilepsy deaths or refer to the NICE National Clinical Audit of Epilepsy Related Deaths 2002	Thank you for your comment. Reduction of SUDEP or epilepsy deaths is outside the scope of this guideline update. This has however been covered in the previous guideline.
SH	Epilepsy Action	1	General	Epilepsy Action is submitting below a number of areas which we strongly believe should be considered for inclusion in the scope. Our opinion is that these issues have a direct and fundamental effect on the health of people with epilepsy and, in some cases, could result in a reduced life expectancy or unnecessary loss of lives. We are disappointed to see that the scope includes only a partial review and that the focus is solely on anti-epileptic drugs. We urge NICE to give our submission its due attention, and that the topics and references listed below are carefully considered.	Thank you for your comment. Please see the responses below.
SH	Epilepsy Action	4	General	Ketogenic diet and modified Atkins Epilepsy Action would like NICE to consider broadening the Scope to include the use of ketogenic diet and modified Atkins as forms of treatment of epileptic seizures in children and adults and list below several research papers in support of this:	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this guideline update

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				<p>1) Porta N, Vallee L, Boutry E, Fontaine M, Dessein AF, Joriot S, Cuisset JM, Cuvelier JC, Auvin S. Comparison of seizure reduction and serum fatty acids levels after receiving the ketogenic and modified Atkins diet. <i>Seizure</i>. 2009 Feb 2. [Epub ahead of print].</p> <p>2) Porta N, Vallee L, Boutry E, Auvin S. The ketogenic diet and its variants: State of the art. <i>Rev Neurol (Paris)</i>. 2008 Nov 20 [Epub ahead of print].</p> <p>3) Kossoff EH, Dorward JL. The modified Atkins diet. <i>Epilepsia</i>. 2008 Nov;49 Suppl 8:37-41.</p> <p>4) Kossoff EH, Turner Z, Blumi RM, Pyzik PL, Vining EP. A randomized crossover comparison of daily carbohydrate limits using the modified Atkins diet. <i>Epilepsy Behav</i>. 2007 May;10(3):432-6. Epub 2007 Feb 26.</p> <p>5) Weber S, Molgaard C, Karentaudorf, Uldall P. Modified Atkins diet to children and adolescents with medical intractable epilepsy. <i>Seizure</i>. 2008 Dec 1 [Epub ahead of print].</p> <p>6) Carrette E, Vonck K, de Herdt V, Dewaele I, Raedt R, Goossens L, Van Zandijcke M, Wadman W, Thadani V, Boon P. A pilot trial with modified Atkin's diet in adult patients with refractory epilepsy. <i>Clin Neurol Neurosurg</i>. 2008 Sep;110(8):797-803. Epub 2008 Jun 24.</p> <p>7) Kang HC, Lee HS, You SJ, Kang du C, Ko TS, Kim HD. Use of modified Atkins diet in intractable childhood epilepsy. <i>Epilepsia</i>. 2007 Jan;48(1):182-6.</p> <p>8) Neal EG, Chaffe H, Schwartz RH, Lawson MS, Edwards N, Fitzsimmons G, Whitney A, Cross JH. The Ketogenic diet for the treatment of childhood epilepsy: a randomised controlled trial. <i>Lancet Neurology</i>. 2008, 7(6):500-6 Jun.</p> <p>9) Neal EG, Chaffe H, Schwartz RH, Lawson MS, Edwards N, Fitzsimmons G, Whitney A, Cross JH. Growth of children in classical and medium-chain triglyceride ketogenic diet. <i>Pediatrics</i>, 2008, 122:e334-40.</p> <p>10) Kossoff EK, Hedderick E, Turner Z, Freeman JM. A case-control evaluation of the ketogenic diet versus ACTH for new onset infantile spasm. <i>Epilepsia</i>, 2008,49(9)1504-09.</p>	

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				11) Jung DE, Kang HC, Kim HD. Long-term outcome of the ketogenic diet for childhood intractable epilepsy due to focal malformation of cortical development. <i>Pediatrics</i> , 2008;122:330-3.	
SH	Epilepsy Action	5	General	<p>Ambulance services in cases of status epilepticus Epilepsy Action asks NICE to consider adding this topic to the Scope as we believe it to be of great importance in the care and treatment of people with epilepsy and provide the following evidence: In 2007 Epilepsy Action surveyed all ambulance trusts in England. This was in response to concerns from people with epilepsy following a fatality where a girl, having a seizure, died because the ambulance crew attending were unable to administer diazepam. The ambulance crew consisted only of technicians who are not authorised to carry controlled drugs such as diazepam. To our understanding guidelines prevent them from administering diazepam. The findings of the survey are available from Epilepsy Action but in essence there is no national guidance for how ambulance services should respond to emergency call outs in cases of status epilepticus. Consequently the lives of people with epilepsy could be put at risk unnecessarily. Epilepsy Action is aware of two separate cases within the last 2 ½ years where two young women died, seemingly unnecessarily, as the ambulance crews attending were both staffed by technicians only which meant that they could not administer diazepam at the scene. Epilepsy Action has pursued this with the Joint Royal Colleges Ambulance Liaison Committee who, although sympathetic to our cause, has been unable to take this matter any further. 1) Survey of Ambulance Trusts, Epilepsy Action, January 2008</p>	Thank you for your comment. Service delivery is outside the scope of this guideline update. However the most appropriate treatment for status epilepticus and when it is initiated will be determined by this guideline update.
SH	Epilepsy Action	14	General	<p>Menopause: 1) Hormone Replacement Therapy (HRT) and 2) metabolic bone disease Epilepsy Action would like NICE to consider extending the Scope to include guidance on two issues in relation to the menopause in women with epilepsy. The menopause and/or HRT use can have a significant impact on seizure control and side effects of anti-epileptic drugs. This, in turn, impacts on the health and quality of life in women with epilepsy. There is also evidence that, as bone mass thins after</p>	Hormone Replacement therapy will be covered as part of the drugs interactions section. Metabolic bone disease will be covered as part of the analysis of side effects.

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				<p>menopause; women taking some anti-epileptic drugs have an increased risk of bone mass loss and consequent osteoporosis. We would like to draw NICE's attention to the following papers:</p> <ol style="list-style-type: none"> 1) Roste LS, Tauboll E, Svalheim S et al. Does Menopause effect the epilepsy? Seizure 2008;17:172-175 2) Harden CL. Hormone replacement therapy: will it effect seizure control and AED levels? Seizure 2008;17:176-180 3) Harden CL, Herzog AG, Nikolov BG et al. Hormone replacement therapy in women with epilepsy: A randomized, double-blind, placebo-controlled study. Epilepsia 2006;47(9):1447-1451 4) Harden CL. The current state of postmenopausal hormone therapy: Update for neurologist and epileptologist. Epilepsy Currents 2007;7(5):119-122 5) Pack A. Bone health in people with epilepsy: is it impaired and what are the risk factors? Seizure 2008;17:181-186 6) Sheth RD, Harden CL. Screening for bone health in epilepsy. Epilepsia 2007;48(9):39-41 7) Petty SJ, Paton LM, O'Brien et al. Effect of antiepileptic drugs on bone mineral measures, Neurology 2005;65:1358-1365 	
SH	Epilepsy Action	17	General	<p>Management of epilepsy in prisons</p> <p>Epilepsy Action believes the scoping document should be widened to include guidance on health care services for people with epilepsy in prisons.</p> <p>The original guideline does not mention the needs of people with epilepsy in prison. Since the original launch the healthcare of prison has become a responsibility of Primary Care Trusts.</p> <p>A recent audit of healthcare provision for UK prisoners with suspected epilepsy found there were significant differences between the healthcare services and access to information offered to prisoners and the recommendations in these guidelines.</p> <p>1) P. Tittensor, J. Collins, R.A. Grunewald and M. Reuber. Audit of healthcare provision for UK prisoners with suspected epilepsy, Seizure 2008, 17 (1); 69-75</p>	<p>Thank you for your comment. Treatment is not different for this group and will therefore be covered in line with all other adult populations.</p>

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SH	NHS Direct	1	General	NHS Direct have considered the content of the scope and have not comments but welcome the development of the new guideline.	Many thanks for your comment.
SH	National Hospital for Neurology and Neurosurgery	1	General	Whilst NICE seek to make this document a clinical guideline, it must be recognised that stakeholder organisations will use the “guidelines” as supporting evidence for their own purposes. Thus a narrow remit cannot be adopted – the reality of the impact of the guidelines has to be recognised, requiring a broadening and a deepening of its scope. The importance that NICE as an organisation gave to clinical expertise during the Scoping meeting requires explicit statement and emphasis in the revised guidelines: it must be made clear that the guidelines are not “rules” and that clinical experience and the individual patient’s circumstances and wishes must take precedence.	Thank you for your comment. The guideline update will only address areas where there has been a significant change. The guideline update will be integrated appropriately with the previous guideline.
SH	British Dietetic Association	1	General	Will this scope consider the evidence base that Ketogenic diet therapy, ‘is effective in the treatment of drug resistant epilepsy comparable to any new anti epileptic drug’? (E Neal et al 2008)	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this guideline update
SH	Royal College of Nursing	2	General	Bearing in mind that this guideline will only address pharmacological guidance and will deal with any variation in practice in that respect, we would expect that it would not provoke much debate. The drugs included seem reasonable and we note that buccal midazolam is included which is critical.	Thank you for your comment. This has been noted.
SH	National Collaborating Centre for Nursing and Supportive Care’s TLoC GDG	1	General	The transient loss of consciousness guideline development group (TLoC GDG) welcomes this opportunity to comment on the scope of the update of Clinical Guideline 20 (CG20). One of the key aims of the TLoC GDG is to provide guidance to the NHS that ensures that people who have experienced a transient loss of consciousness receive accurate and timely diagnosis of the underlying condition that has caused them to blackout. The main types of TLoC are syncope, epileptic seizures and psychogenic non-epileptic seizures. Differentiating between these can be complicated by the fact that both syncope and psychogenic	Thank you for your comment. Differential diagnosis is fully discussed in the previous guideline. It was covered in detail in Appendix A. Discussion of differential diagnosis in the guideline update would be outside of the remit of the guideline update.

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				<p>seizures can be associated with abnormal movements, which may be reported by witnesses and may be confused with convulsions seen in epilepsy. If the clinician suspects that the individual has experienced an epileptic seizure, then the further care of that individual is likely to follow the recommendations within CG20.</p> <p>However, it is estimated that 25% of people diagnosed with epilepsy have been misdiagnosed (CG20, p86 of the Full Guideline); many of whom have an underlying cardiac reason for their symptoms that has not been identified. One of the principal aims of the TLoC guideline is to increase the number of people receiving a correct initial diagnosis, thereby reducing inappropriate further investigations and inappropriate treatment. It is also crucial that the Epilepsy Guideline provides comprehensive guidance on differentiating epileptic seizures from TLoC from other causes so that the opportunity to correct any initial misdiagnosis is not lost.</p> <p>We would advise NICE to widen the scope of the update to include diagnostic reassessment to identify non-epileptic causes of seizures. Evidence based guidance in this area will prevent these people from continuing to receive inappropriate treatment for epilepsy, which has the potential to release substantial resources, and it will also improve their access to more appropriate treatments which will hopefully improve their health related quality of life.</p>	
SH	National Society for Epilepsy	7	General	<p>We feel that the guideline would benefit from a statement about the aims of treatment in order to contextualise pharmacological treatment (under the heading of ‘Pharmacological treatment’ preceding point 1.8.5). For example, setting out a clear objective for treatment helps to identify a way of measuring the success of, or failure of, treatment. Such a statement may include the complete control of all seizures with the minimum dose of the smallest number of anti-epileptic drugs and with the least side effects or impact on the individual’s quality of life. This is an important statement for an</p>	This has been noted. Thank you for your comment.

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				individual's understanding of their epilepsy treatment, particularly as some are unaware of the basics of what anti-epileptic drugs aim to achieve.	
SH	National Society for Epilepsy	8	General	We believe that the guideline should specify targets for how to engage with hard to reach communities (such as socially disadvantaged groups, black and minority ethnic communities and people with learning disabilities). Hard-to-reach communities may be poorer served by epilepsy services. Anecdotal evidence from people attending specialist and tertiary care services suggests that it is mostly those who know and can use the 'system' that push to get the treatment they need. For example, in order to access services such as referrals for treatment review, individuals often have to both be aware of the current NICE recommendations regarding referrals and also be empowered and enabled to request these services. This can often be overwhelming for any individual but harder still for those who may be disengaged from medical services.	Thank you for your comment. We will report on all these groups if they are included in the studies.
SH	National Society for Epilepsy	9	General	We believe that the Ketogenic Diets should be included within the pharmacological treatment of epilepsy, and be positioned as a form of treatment considered alongside drugs for early treatment for children with epilepsy. New evidence since 2004 supports the use and efficacy of the Ketogenic Diets for some children with epilepsy and as such, children may benefit from considering this form of treatment earlier rather than later in their epilepsy. The guidelines could indicate at what stage the diets should be considered for an individual rather than trialling several medications before being considered difficult-to-treat and meeting the criteria for other treatment options.	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this guideline update
SH	National Society for Epilepsy	10	General	We believe that the indications for blood test monitoring should be strengthened and expanded beyond the current recommendations (section 1.8.26) to include the use of therapeutic drug monitoring. The recent special report (Patsalos	Thank you for your suggestion. Therapeutic drug monitoring was included in the previous guideline. We carried out an update review

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				PN et al (2008) 'Antiepileptic drugs – best practice guidelines for therapeutic drug monitoring: A position paper by the subcommission on therapeutic drug monitoring, ILAE Commission on Therapeutic Strategies. <i>Epilepsia</i> 49 (7): 1239-1276) places a greater value on TDM as an essential tool in optimising appropriate and individualised treatment for some individuals with epilepsy.	to identify new research since the previous guideline was published. New evidence was found that could overturn current pharmacological recommendations, but we did not find new evidence for other areas that could change current recommendations. The paper suggested is a position paper, which we would not normally include to review for this guideline.
SH	National Society for Epilepsy	11	General	We believe that the indications for referral for epilepsy surgery should reflect the importance of early referral for individuals who are unlikely to gain seizure control through pharmacological treatment. The guidelines do not currently support this (section 1.8.37).	Thank you for your comment. The previous guideline addressed primary and secondary care, and has given guidance for tertiary care referral.
SH	National Society for Epilepsy	12	General	We believe that there should be an increased pressure or incentive on primary and secondary care physicians to follow and implement the guidelines as set out in the CG20. Research into the impact of the NHS, as well as a review of the implementation of the NICE guidelines on the care and management of individuals with epilepsy, demonstrate that services are not meeting the identified needs. As the guideline has been in existence for over 4 years yet significant progress has not happened, some incentive or compulsion may be required to implement the guidelines and thus improve services. References - 'wasted money, wasted lives: the human and economic cost of epilepsy in England' (2007) report by the All Party Parliamentary	Thank you for your comment, this has been noted. Implementation is outside of the remit of the development of the guideline update itself. Your comments will be forwarded to the NICE implementation team.

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				Group on Epilepsy, supported by the Joint Epilepsy Council. - 'Epilepsy in England: time for change' (2009) report by Epilepsy Action.	
SH	National Society for Epilepsy	13	General	We believe that CG20 should be reviewed in its entirety, and that sections outside of pharmacological treatment of epilepsy should be considered for early review. While the current scope considers only the pharmacological treatment of epilepsy, other sections of the guideline, significant in the diagnosis and overall management of epilepsy, and in the support of individuals with epilepsy and their families, are of equal importance. We understand the logistical arguments for a partial review, but believe that people with epilepsy deserve guidelines that cover the factors that most affect their treatment and life. An overall review of the guideline would allow for investigation into these factors and why the current guidelines are struggling to deliver for people with epilepsy.	Thank you for your comment.. We carried out an update review to identify new research since the previous guideline was published. New evidence was found that could overturn current pharmacological recommendations, but we did not find new evidence for other areas that could change current recommendations.
SH	National Society for Epilepsy	14	General	References for feedback on issues around medication which are important for individuals with epilepsy. The following websites include the views and experiences of individuals with epilepsy. - www.healthtalkonline.org is a charity website providing personal stories and patient experiences. It has a section on epilepsy. - www.youthhealthtalk.org is a charity website providing the personal stories and patient experiences of young people. It has a section on epilepsy. - www.epilepsysociety.org.uk/forum is an online community for people with epilepsy and their families, friends and carers hosted by the National Society for Epilepsy. - www.forum4e.com is an online community for people with epilepsy hosted by Epilepsy Action.	Thank you for your suggestion. These websites have been noted.
SH	National Society for Epilepsy	15	General	We propose that a third position as a patient/carer ('non-professional') member is added to the guideline development group (GDG). Many members of staff from voluntary organisations	Thank you for your comment. We have considered the addition of a third patient/carer member and

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				<p>for epilepsy would be interested in participating in the GDG. We believe that the voluntary organisations can make a meaningful contribution to representing the views of individuals with epilepsy, through their services such as membership, volunteering and through their helplines and support groups, and can represent a broad range of issues that are relevant to the successful use of new pharmacological treatments. This includes representing the issues important to the range of ages covered within the guideline (from 28 days upwards), of people at different stages of living with epilepsy from diagnosis to having come to terms living with a chronic condition, and from mild epilepsy to those with severe disabling epilepsy.</p> <p>It is felt that the successful use of new pharmacological treatments is not just a clinical issue, and that an experienced member of the voluntary sector in the field would contribute significantly to the developmental work. However, with the current GDG having only two parent/carer member positions, taking a position by the voluntary sector would be at the expense of an individual with epilepsy or their carer, which would seem inequitable.</p>	<p>feel that two is appropriate considering the scope for the guideline update. This could include somebody from a patient organisation as well as a patient/carer.</p>
SH	National Society for Epilepsy	16	General	<p>We propose that specialists in the field of learning disabilities and care of the elderly medicine are included as specific members within the GDG. Currently the GDG advertises for two Consultant Neurologists, a Consultant Paediatric Neurologist and a Consultant Paediatrician. Within this there is no position for neurologists or epilepsy specialists with specific expertise in learning disability or care of the elderly medicine. These two patient groups benefit from an individual and specialised approach to their epilepsy treatment which may not be fully represented by the GDG as it currently stands. With the substantial increase in the elderly population leading to many more people experiencing epilepsy through degenerative diseases and complex health conditions, it is felt that this group requires specific attention.</p>	<p>Thank you for your comment. As part of the recruitment process we look for members who will bring a range of expertise and experience of working with patients. The developers aim to recruit a learning disabilities advisor and consultant geriatrician as co-opted experts for this guideline update. A co-opted consultant in obstetrics and gynaecology has been recruited.</p>

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SH	Society of British Neurological Surgeons	4	General	The Society of British Neurological Surgeons, representing the professional views of Epilepsy Surgeons, therefore proposes that this update considers guidelines for the early and appropriate referral of patients with drug refractory epilepsy to a tertiary centre for surgical evaluation.	Thank you for your comment. The previous guideline addressed primary and secondary care, and gave guidance for tertiary care referral. This can be found on page 25 of the NICE guideline.
SH	Janssen Cilag Ltd	4	General	Patient adherence plays a very important role in efficacy outcomes and retention on AED therapy and should therefore be explicitly considered within the scope. Reasons for or factors contributing to poor compliance and strategies to address compliance problems should be actively considered in the scope of these guidelines	Thank you for your comment. Please refer to the Medicines Adherence guideline in related NICE guidance (to add link)
SH	Janssen Cilag Ltd	5	General	Seizure control is a primary aim of AED therapy; hence a clinical question should focus on how clinicians can best assess whether a patient's seizure control is optimised on their current AED therapy and when a new or adjunctive treatment should be introduced.	Thank you for your comment. This has been noted and will be covered.
SH	Janssen Cilag Ltd	6	General	A clinical question should be included to explore the best way of establishing if a patient is experiencing psychiatric/behavioural/cognitive side effects from their current AED therapy	Thank you for your comment. This is beyond the scope of this guideline update but could be suggested as a research question.
SH	Janssen Cilag Ltd	7	General	In light of the new medicines adherence guidelines, a clinical question should focus on the optimal method to discuss AED treatment choices with patients to encourage patient involvement in the decision making process	Thank you for your comment. Please refer to the Medicines Adherence guideline.
SH	Janssen Cilag Ltd	8	General	When recommending what information should be given to patients at diagnosis regarding drug treatment it would be useful to assess the need for details of realistic and achievable outcomes (in addition to seizure freedom and reduced seizure frequency) as well as potential side effects.	Thank you for your comment. This was covered in the previous guideline.
SH	Janssen Cilag Ltd	9	General	A clinical question should be included to explore the optimal way of	Thank you for your comment.

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				ensuring that AED therapy is maintained according to the specialist's recommendations when a patient's care is moving from secondary to primary care	Individual care plans were included in the previous guideline.
SH	Janssen Cilag Ltd	10	General	A patient's clinical care is often overseen by both primary and secondary health care professionals. A clinical question should explore how primary and secondary care should communicate when a change to a patient's AED medication occurs.	Thank you for your comment. This clinical question is outside the remit of the guideline update.
SH	Janssen Cilag Ltd	11	General	A clinical question should be included to explore how best to determine a patient's co-morbidities and cognitive impairment when a patient's medication is being initiated, switched or altered. This could be conducted using defined patient interview or screeners.	Thank you for your comment. This is a research question. Please refer to the Medicines Adherence guideline.
SH	The National Centre for Young People with Epilepsy	1	General	<p>The National Centre for Young People with Epilepsy (NCYPE) welcomed the 2004 Clinical Guideline as providing clear guidance for medical practitioners. However, Epilepsy Action's 2008 survey of Primary Care Trusts and Acute Trusts shows that aspects of the Clinical Guidelines are simply not being implemented, e.g. that <i>'all children with a recent-onset suspected seizure should be seen urgently by a specialist'</i>.</p> <p>Whilst the NCYPE supports the review of the Clinical Guideline, it is time to consider whether a Technology Appraisal for treatments relevant for those with epilepsy to ensure that children and young people with epilepsy receive the medical service they need and which NICE has already defined. For example, the Technology Appraisal might provide recommendations on diagnostic techniques to tackle the current level of misdiagnosis, surgical procedures as surgery is the only known cure for the epilepsies, and health promotion activities to increase the number of children and young people with epilepsy who are seizure-free and the number who can get the most from their education and wider lives.</p> <p>The NCYPE therefore recommends a national audit takes place into service provision for children and young people with epilepsy, identifying in more detail how the NICE Clinical Guidelines are being</p>	Thank you for your comment. This will be passed onto the NICE implementation team.

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				applied; this would be an appropriate first step towards the eventual adoption of a Technology Appraisal.	
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	1	General	<p>The JEC welcomed the 2004 Clinical Guideline as providing clear guidance for medical practitioners. However, the All-party Parliamentary Group on Epilepsy's Report in 2007 "<i>Wasted Money Wasted Lives</i>" and Epilepsy Action's survey of PCTs and ATs launched in January 2009 in the document "<i>Time for Change</i>" show that aspects of the Clinical Guidelines are simply not being adopted.</p> <p>Whilst the JEC supports the review of the Clinical Guideline, we are disappointed that the scope includes only a partial review and that the focus is solely on anti-epileptic drugs and call upon NICE to broaden the scope of the review beyond pharmacological management.</p>	Thank you for your comment. Your comment will be passed onto NICE implementation. Updates to guidelines are carried out when new evidence is published that may overturn a recommendation within a guideline . Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence changed previous recommendations.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	7	General	<p>Ketogenic diet and modified Atkins</p> <p>The JEC would like NICE to consider broadening the Scope to include the use of ketogenic diet and modified Atkins as forms of treatment of epileptic seizures in children and adults. New evidence since 2004 supports the use and efficacy of the Ketogenic Diets for some children with epilepsy and as such, children may benefit from considering this form of treatment earlier rather than later in their epilepsy. The guidelines could indicate at what stage the diets should be considered for an individual rather than trialling several medications before being considered difficult-to-treat and meeting the criteria for other treatment options.</p>	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this updated guideline.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	12	General	<p>References for feedback on issues around medication which are important for individuals with epilepsy. The following websites include the views and experiences of individuals with epilepsy.</p>	These websites have been noted with thanks.

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				<ul style="list-style-type: none"> • www.healthtalkonline.org is a charity website providing personal stories and patient experiences. It has a section on epilepsy. • www.youthhealthtalk.org is a charity website providing the personal stories and patient experiences of young people. It has a section on epilepsy. • www.epilepsysociety.org.uk/forum is an online community for people with epilepsy and their families, friends and carers hosted by the National Society for Epilepsy. • www.forum4e.com is an online community for people with epilepsy hosted by Epilepsy Action. 	
SH	Association of Child Psychotherapists	1	General	The ACP welcomes the guidelines' focus on the clinical needs of children and young people with epilepsy. As child and adolescent psychotherapists working in paediatric settings, we fully acknowledge the centrality of medical treatment. However, we are disappointed that the draft scope of the review, in solely considering pharmacology, excludes psychosocial issues.	Thank you for your comment. Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence significantly changes previous recommendations.
SH	Association of Child Psychotherapists	2	General	The current guidelines (October 2004) indicate that access to "counselling" should be available. We consider that this aspect of care, particularly in relation to children and young people, requires greater emphasis and detail. With regard to children, Kim (1991), quoted by Otero and Hodes (2000) (see references below) found that childhood epilepsy involves increased risk of psychiatric disorder and school and family problems. We would suggest that this indicates a need for psychotherapeutic intervention with children and their families at an emotional level with the intention of mitigating the psychological sequelae.	Thank you for your comment. Please see comment above.
SH	Association of Child Psychotherapists	3	General	From clinical experience, we would argue that epilepsy in children often leads to considerable anxieties in parents faced with dilemmas	Thank you for your comment. This issue is outside the remit of

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				regarding the wish to protect the child from risk as against allowing the child to lead a normal life – an issue faced by the parents of disabled children more generally. These complex difficulties may be compounded in the parents by feelings of shame and guilt. Without sensitive, clinically-informed support and treatment, these natural emotions can set in train cumulative distortions of family relationships with deleterious effects for marital and sibling relationships.	this guideline.
SH	Association of Child Psychotherapists	4	General	Otero and Hodes (2000), in a study of 21 families with a child who had epilepsy, found that “good treatment compliance was found to be associated with less maternal hostility and criticism”. They note that “significantly more of the group who had a good level of compliance had recovered from epilepsy at follow-up”.	Thank you for your comment. This has been noted.
SH	Association of Child Psychotherapists	5	General	The review of research for the 2004 guidelines cites Wilde (1996) (see references below), in a study of the effects of epilepsy on adolescence, in which the issue of stigma was a significant factor. Whilst the majority of these patients had adjusted to their medical circumstances, a minority did not seem to have done so. It is such patients who are most in need of psychological treatments and support.	Thank you for your comment. This has been noted.
SH	Association of Child Psychotherapists	6	General	A clinical case provides an example of the difficulties which can arise and the role of psychological services in addressing them. A sixteen-year-old young man, without siblings, in a single parent family, was seen in a mental health paediatric liaison service because his nocturnal epileptic symptoms had caused such anxiety to his mother and himself that it had necessitated him sleeping in his mother's bed. This arrangement had led to emotional difficulties. A brief intervention by two child and adolescent psychotherapists in the paediatric liaison service allowed the young man and his mother to share their concerns about his auditory hallucinations and their joint sense of the fragility of his mental and physical health. The intervention resulted in a referral to their local Child and Adolescent Mental Health Service (CAMHS) for individual therapy for the son and parenting support for the mother.	Thank you for your comment. This has been noted.
SH	Association of Child	7	General	Conclusions	Thank you for your comment.

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	Psychotherapists			A range of psychological interventions is required for children with epilepsy and their families. Some interventions are needed at a cognitive level (such as Cognitive Behavioural Therapy, or CBT) but others employing psychodynamic psychotherapeutic techniques, carried out by suitably trained and qualified clinicians, are essential to address the effects of the deep seated anxieties of children and young people with epilepsy and their parents and families.	These interventions are covered in the previous guideline.
SH	Association of Child Psychotherapists	8	General	<p>References</p> <p>Kim WJ (1991) Psychiatric aspects of epileptic children and adolescents. <i>Journal of the American Academy of Child and Adolescent Psychiatry</i> 30: 874-86</p> <p>Otero S. and Hodes M. (2000) Maternal expressed emotion and treatment compliance of children with epilepsy. <i>Developmental Medicine and Child Neurology</i>, 42: 604-608</p> <p>Wilde M, Haslam C,(1996) Living with epilepsy: a qualitative study investigating the experience of young people attending out-patients clinics in Leicester. <i>Seizure</i> 5:63-72.</p>	Thank you for your comment.
SH	EpilepSy Nurses Association	1	General	ESNA (EpilepSy Nurses Association) welcome the opportunity to comment on the scope of the planned update of Clinical Guideline 20 – The Epilepsies: The Diagnosis and Management of the Epilepsies in Adult and Children in Primary and Secondary Care (G20). One of the key aims of ESNA is to promote an ‘ordinary life’ philosophy of care for people with epilepsy. Following the publication of SANAD we accept the need to review the guidelines for pharmacological management but are disappointed that there is no scope within the guidelines to review the management of people	<p>Thank you for your comment, this has been noted.</p> <p>Management of non-epileptic attack disorder is outside the scope of this guideline update.</p> <p>Buccal midazolam will be part of the management of status epilepticus.</p>

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				<p>with non epileptic attack disorder, which is a common condition and presents many management problems.</p> <p>We would urge the update to consider reviewing the use of Buccal Midazolam, as rescue medication for prolonged seizures within this scope.</p>	
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	1	General i.e. 1	<p>Confining the scope to pharmacological management of the epilepsies is ignoring the major deficiency of childhood epilepsy management which involve the behavioural/psychiatric problems and cognitive impairments that are present in 50% of those with active epilepsy.</p> <p>We would strongly recommend that either:</p> <ol style="list-style-type: none"> 1) Ideally the scope of the guideline is reviewed to include the non-pharmacological management of childhood epilepsies or 2) that the pharmacological management is reviewed but there is an acknowledgement in it that there is an urgent need for review of the non-pharmacological management and that NICE has commissioned this to be done within 2 years of the current review. <p>In our own experience behavioural/psychiatric problems and cognitive impairments are commonly overlooked and child psychiatric services do not usually provide a service. There are major interactions between seizure activity, anti-epilepsy drugs and cognition and behaviour. Attention deficit/hyperactivity, autism spectrum disorder, obsessional and oppositional behaviour. Because of the need for integrated medical and behavioural care paediatricians have to provide such services. We therefore urge that behavioural and cognitive disorders are identified early and managed.</p> <p>There are now easily administered screening tools and assessments</p>	<p>Thank you for your comment. Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence significantly changed the previous recommendations.</p> <p>Service implementation is outside the scope of this guideline. The previous guideline recommends referral to tertiary care.</p>

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				<p>that can be used. Management including psychological, educational and pharmacological management can make an initial difference to a child's future and much of this work is medical. In collaboration with the All Party Parliamentary Group for Epilepsy we have developed guidelines for school age children which are attached and enclosed in their publication 'Wasted Money, Wasted Lives'. The proposal therefore is to widen the guidelines to include behavioural/psychiatric problems, particularly to satisfy your section 2c.</p>	
SH	Epilepsy Action	6	General but also see Current guidance 4.11 and 4.11.32	<p>Maternal death in epilepsy Epilepsy Action believes it is imperative that the scope includes reference to the increased risk of maternal death for women with epilepsy. We believe the guidance should include recommendations made to challenge the 7 – 10 per cent increased risk of maternal death for women with epilepsy.^{1,2} For example; joint medical and obstetrics clinics, referral for specialist opinion in early pregnancy and effective treatment of status epilepticus in pregnant women³. 1) Adab N, Chadwick DW. Review Management of women with epilepsy during pregnancy. The Obstetrician and Gynaecologist 2006;8:20-25 2) Meador KJ, Baker GA, Finnell RH et al. In utero antiepileptic drug exposure fetal death and malformation. Neurology 2006;67:407-412 3) Lewis G et al. Saving Mothers Lives 2003-5. Confidential Enquiry into Maternal and Child Health 2007;131- 137 & 194-222</p>	Thank you for your comment. The use of AEDs in pregnancy will be covered in the guideline update.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	8	General but also see Current guidance 4.11 and	<p>Maternal death in epilepsy We believe it is imperative that the scope includes reference to the increased risk of maternal death for women with epilepsy. We believe the guidance should include recommendations made to challenge the 7 – 10 per cent increased risk of maternal death for women with epilepsy.^{1,2} For example; joint medical and obstetrics clinics, referral for specialist opinion in early</p>	Thank you for your comment. The use of AEDs in pregnancy will be covered in the guideline update.

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			4.11.32	pregnancy and effective treatment of status epilepticus in pregnant women ³ . 1) Adab N, Chadwick DW. Review Management of women with epilepsy during pregnancy. The Obstetrician and Gynaecologist 2006;8:20-25 2) Meador KJ, Baker GA, Finnell RH et al. In utero antiepileptic drug exposure fetal death and malformation. Neurology 2006;67:407-412 3) Lewis G et al. Saving Mothers Lives 2003-5. Confidential Enquiry into Maternal and Child Health 2007;131- 137 & 194-222	
SH	Royal College of Paediatrics and Child Health	5	1.1.1	Title: The pharmacological management of the epilepsies in children and young adults (partial update of clinical guideline 20)	Thank you for your comment. This has been noted.
SH	The National Centre for Young People with Epilepsy	5	2 c	The term 'healthcare professionals' here needs to include those in the voluntary sector who work with individuals with epilepsy. These people provide services for the NHS and are subject to the same regulatory legislation.	Thank you for your comment. The guidelines are directed towards staff in the NHS
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	6	2 c	The term "healthcare professionals" here needs to include those in the voluntary sector who work with individuals with epilepsy. These people provide services for the NHS and are subject to the same regulatory legislation.	Please see the comment above.
SH	Association of British Neurologists	1	3 a	The incidence of epilepsy should read 50/100,000 per year	Thank you for your comment. This has been corrected
SH	Epilepsy Bereaved	1	3 a	Include the incidence of epilepsy related deaths i.e. 1000 per year in the UK of which 42% may be avoidable	Thank you for your comment. This has been noted.
SH	Beacon Pharmaceuticals Ltd	1	3 b	We believe that the previous guideline did not give sufficient emphasis to optimal management and we welcome further input on this issue. We believe that no medicine can be effective unless the patient takes it and there are several recent studies that demonstrate that patients with epilepsy do not adhere to their treatment despite being aware of	Thank you for your comment. Please refer to the Medicines Adherence guideline.

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				<p>the serious consequences.</p> <p>The answer may lie in a more concordant approach in terms of helping the patient to achieve their treatment goals by gaining a greater understanding of the issues that they face in adherence. One key point relates to the number of doses per day and there is good evidence that the fewer the doses the better the compliance. We believe that the ideal for most patients with epilepsy is a simple once daily regimen.</p> <p>There are many patients with epilepsy who are young, elderly or who have mental disability and these patients may suffer varying degrees of dysphagia. This can be a serious issue that can influence concordance. In these patients there is a need to find a presentation that the patient is able to swallow to ensure concordance.</p> <p>In order to achieve this one option is to use syrup presentations, but many of these prove to be unpalatable or may be required in too large a quantity for adults. These are further factors that can complicate concordance.</p> <p>Some multiple unit controlled release presentations may help in terms of providing a more palatable option with fewer daily doses.</p> <p>When one AED does not control epilepsy the guideline is to change to another AED. However, if the real issue is poor adherence this change may not be the ideal route to control of the epilepsy. Perhaps the answer is to seek options to improve adherence as outlined above.</p>	
SH	Royal College of Paediatrics and Child Health	6	3 b	Ketogenic diet and Vagal nerve stimulation are other treatment modalities that should be referred to in this list.	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this updated guideline.

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					With regards to vagal nerve stimulation, please refer to the Health Technology Assessment document. No new studies have been published since the HTA to change recommendations.
SH	Epilepsy Bereaved	2	3 b	Up to 85% of individuals with epilepsy can achieve seizure control with optimal and individualised anti-epileptic drug treatment	Thank you for your comment. This has been noted.
SH	Society of British Neurological Surgeons	1	3 b	Surgery is a clinically indicated in a subset of patients that fail to respond to AEDs. There is clear Class 1 evidence for this (Weibe N Engl J Med. 2001 Aug 2;345(5):311-8). The direct care costs of patients with drug refractory epilepsy are very high (Jacoby et al Epilepsia. 1998 Jul;39(7):776-86.) and the savings accrued by early appropriate surgery are substantial, with a break-even point of 5 years post surgery	Thank you for your comment. Surgery was addressed in the previous guideline (through guidelines for referral to tertiary care).
SH	Epilepsy Bereaved	3	3 b	Optimal management leading to control of all symptoms of seizures can also reduce the risks of SUDEP and other epilepsy related deaths	Thank you for your comment. This has been noted.
SH	Beacon Pharmaceuticals Ltd	2	3 c	We agree that newer AEDs may increase healthcare costs. An economic answer may be in increasing the optimal management of epilepsies with established AEDs such as sodium valproate. Some possible strategies are outlined above and some newer controlled release versions can be relatively inexpensive options.	Thank you for your comment. This has been noted.
SH	Epilepsy Bereaved	4	3 c	Include the cost of avoidable deaths in England and Wales each year. <i>The latest published figure is in the National Clinical Audit of Epilepsy Related Deaths 2002 but we are currently working with Health economists in Kings College Hospital (London) to update the figure and we would be pleased to share that figure when available</i>	Thank you for your comment. This has been noted.
SH	Beacon Pharmaceuticals Ltd	3	3 d	The SANAD study confirmed a clear role for sodium valproate.	Thank you for your comment. This has been noted.
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	7	3 d	The SANAD trial despite its merits in design gives little information about childhood epilepsies apart from the idiopathic generalised epilepsies.	Thank you for your comment. This has been noted.

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SH	Royal College of Paediatrics and Child Health	7	3 d	The SANAD trial conclusions and implications are different for adults compared to children. This is not reflected in the statement for this section but I think will naturally transpire if the age groups are considered separately as proposed.	Thank you for your comment. This has been noted.
SH	Royal College of Paediatrics and Child Health	8	3 d	The SANAD trial included only small numbers of children and it requires careful evaluation before it influences paediatric practice	Thank you for your comment. This has been noted.
SH	Sanofi-Aventis	1	3 d	This section of the draft scope mentioned the importance of reviewing new evidence regarding anti-epileptic drugs. The SANAD trial was mentioned as a recent large multi-centre trial and we would like to highlight the following two points: <ol style="list-style-type: none"> 1. The SANAD data is inappropriately presented; Valproate was seen to be better tolerated than Topiramate, more efficacious than Lamotrigine and was said to remain the drug of choice for generalised and unclassified epilepsies (SANAD Arm B). 2. It should be noted that Valproate was not chosen by the researchers as a drug of choice in arm A of the SANAD study for treatment of patients with partial epilepsy. 	Thank you for your comment. This has been noted, and revised accordingly.
SH	National Hospital for Neurology and Neurosurgery	3	4.1.1	We would also recommend that people with learning disabilities are recognised explicitly as a special group.	Thank you for your comment. People with learning disabilities will be included as a specific subgroup in the updated guideline. As treatment will be directed at the epilepsy syndromes, any issues concerning side effects will be addressed within the guideline update.
SH	National Society for Epilepsy	1	4.1.1	We welcome the inclusion of age groups from 28 days upwards and of the identified subgroups of women (of child-bearing age) and older people. However, we recommend that children and	Thank you for your comment. People with learning disabilities will be included in the updated

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				<p>individuals with learning disabilities should also be identified as unique groups with specific relevant treatment issues which cannot be addressed within one 'homogenous' population of people with epilepsy.</p> <p>The needs of people with learning disabilities and epilepsy will only be met if considered within the context of their complex condition/s, specific service provision and treatment options. For those people with severe learning disability that have epilepsy, its treatment - or lack of treatment - can be a defining aspect of their survival and quality of life.</p>	guideline as a specific subgroup.
SH	Janssen Cilag Ltd	3	4.1.1	<p>AED therapy recommendations for the following specific subgroups may differ from the general recommendations in the guidelines and therefore these specific subgroups should be included in the scope of the guideline update:</p> <ul style="list-style-type: none"> - Patients with a history of or current mood disorders - Patients with a history of or current cognitive impairment due to AEDs - Patients with a history of or current behavioural disorders - Obese Patients - Patients with a history of or current migraine - Patients with learning disabilities 	Thank you for your comment. These groups will be covered in this guideline update. We will consider all side-effects.
SH	The National Centre for Young People with Epilepsy	2	4.1.1 a	<p>The draft scope rightly identifies children and young people with epilepsy as distinct groups within the population. Paediatric epilepsy has crucial differences to that of adults and any review of the NICE Guideline must recognise the specific needs of children. 'Young adults' with epilepsy, defined as those aged twelve to eighteen in the draft scope, also have particular needs and it is right to treat them as a distinct grouping – although most young adults defined in this way are under the care of paediatricians.</p> <p>The case for separate consideration of paediatric epilepsy includes the following:</p>	Thank you for your comment. This has been noted.

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				<ul style="list-style-type: none"> • There are many syndromes both benign and malignant that are confined to childhood or have their active phase in childhood; • 60% of epilepsy starts in childhood; • The vast majority of pathologies that lead to surgical treatment arise in childhood; • The problems presented by childhood epilepsy are dominated by the additional impairments of cognition and behaviour. Parents' major concerns at medical consultations are to do with problems relating to behaviour and educational progress. 	
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	3	4.1.1 a	<p>The designation of 12-18 year olds as 'young adults' is misleading. All 12-16 year olds and some 17-18 year olds are the responsibility of paediatricians and if they require investigation and admission it is to a paediatric unit. Many of those with active epilepsy in their teens have learning impairments. All of their family and educational issues are the ones that are the normal activities of paediatrics. Maturity varies in the teens and this is something that we are suited to assessing and managing.</p>	<p>Thank you for your comment. Pharmacological issues will still remain the same for these subgroups. Service provision is outside of the remit of this guideline update.</p>
SH	Sanofi-Aventis	2	4.1.1 a	<p>This section of the draft scope stated that women who are pregnant or of child-bearing age will be included in the guidance. We are pleased that this group of patients is being considered.</p> <p>It is widely accepted that prenatal exposure to antiepileptic drugs may increase the risk of major congenital malformations. The challenge is to identify the most appropriate antiepileptic drug for the individual patient, with respect to seizure control as well as developmental toxicity, and to use that drug in a way that controls seizures with minimised risks to the mother as well as the foetus. The European Pregnancy Registry (EURAP) still identifies sodium valproate as the best drug at preventing seizures during pregnancy, and this needs to be taken into account when specialists discuss treatment options with their patient.</p>	<p>Thank you for your comment. This has been noted.</p> <p>This has been noted. Drug interactions will be covered in this guideline update.</p>

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				The importance of using effective contraception in all women of child bearing age with epilepsy; sodium valproate remains efficacious in all types of epilepsy and unlike the majority of the newer anti-epileptic drugs, it is a non hepatic enzyme inducing drug which does not alter the effectiveness of the oral contraceptive drug.	
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	4	4.1.1 a	Although the omission of neonates from this revision is understandable it is very important that NICE addresses this issue, perhaps indicating its intention to review this subject.	Thank you for your comment. We consider this to be a separate group that would require separate guidance. Stakeholders are invited to submit topics for consideration.
SH	Royal College of Paediatrics and Child Health	9	4.1.1 a	The term 'young adults' needs to be considered carefully. The public would consider this to apply to those aged 16-18 years old, but not to those aged 12-16 year old. The term 'teenagers' should be used. It is not considered prejudicial by most people and it is accurate.	Thank you for your comment. Pharmacological issues will still remain the same for these subgroups.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	2	4.1.1 a	<p>The draft scope correctly identifies children and young people with epilepsy as distinct groups within the population. Paediatric epilepsy has crucial differences to that of adults and any review of the NICE Guideline must recognise the specific needs of children.</p> <p>Evidence for separate consideration of paediatric epilepsy includes:</p> <ul style="list-style-type: none"> • There are many syndromes that are confined to childhood or have their active phase in childhood • 60% of epilepsy starts in childhood • The vast majority of pathologies that lead to surgical treatment arise in childhood • The problems presented by childhood epilepsy are dominated by the additional impairments of cognition and behaviour. Parents' major concerns at medical consultations centre around problems relating to behaviour and educational progress. 	Thank you for your comment. Children and adults will be addressed separately in this updated guideline. People with learning disabilities will also be included in the updated guideline as a specific subgroup.

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				<p>Additionally, "young adults" with epilepsy, defined as those aged 12-18 in the draft scope, also have particular needs and it is correct to treat them as a distinct group, even though most young adults are under the care of paediatricians.</p> <p>We also recommend that people with learning disabilities should be identified as a unique group with specific relevant treatment issues considered within the context of their complex condition(s).</p>	
SH	Royal College of Paediatrics and Child Health	10	4.1.1 b	The guideline should include management of febrile seizures. It is a very common clinical problem and some severe epilepsies present in this way. The SIGN guideline on epilepsy includes such guidance	Thank you for your comment. Management of febrile seizures is outside of the scope of the guideline update.
SH	Royal College of Paediatrics and Child Health	11	4.1.2 a	It is illogical to exclude neonates. Epileptic seizures are most common on day 1 of life. Important epilepsies present in this age group. Clinicians need guidance on their management	Thank you for your comment. We consider this to be a separate group that would require separate guidance. Stakeholders are invited to submit topics for consideration.
SH	Royal College of Paediatrics and Child Health	12	4.2	How will the guideline link with the NHS Clinical Knowledge Summaries paper on epilepsy?	The NICE update guideline will specifically focus on the pharmacological management of the Epilepsies. As part of the scoping process we consider current existing guidelines such as CKS and the recommendations made. CKS is a useful tool for information and practical 'know how', however it has a different remit than that of the guideline.
SH	National Hospital for Neurology	4	4.2	CG20 recognised the importance of referral to tertiary centres.	Many thanks for your comments.

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	and Neurosurgery			However, experience makes clear that many patients needing tertiary care are still not being referred, or are referred late, despite CG20 recommendations, which remain valuable reference points for non-specialists. Audit and research have made it clear that tertiary centre evaluations alter patient management (eg Von Oertzen J et al J Neurol Neurosurg Psychiatry. 2002 Dec;73(6):643-7; Yogarajah M et al., J Neurol Neurosurg Psychiatry. 2009 Mar;80(3):305-10). Non-tertiary centres will not have the equipment, facilities or expertise to achieve the required depth of evaluation: recommendations for referral for therapeutic management, including surgical treatment, must therefore be bolstered. Capacity within tertiary centres should be strengthened.	We will forward your comment to the Implementation team at NICE.
SH	National Society for Epilepsy	2	4.2	<p>We believe that specific guidance around the treatment of status epilepticus (and frequent seizures and seizure clusters) within accident and emergency care should be identified and included.</p> <p>This relates in particular to the evidence supporting the use of buccal midazolam and fosphenytoin. The care management of people with epilepsy in A&E departments is also an issue, and there are too many cases of people injured by falling off trolleys, for example, in A&E while having seizures. While the latter issue is outside the proposed scope of the current update, any leverage on this issue that NICE could provide would be welcomed.</p>	Thank you for your comment. Treatment of status epilepticus will be covered in the guideline update.
SH	National Society for Epilepsy	3	4.2	<p>We believe that the status of referral to tertiary care (currently a good practice point) should be strengthened. We welcome the inclusion of tertiary services within the scope of the partial update and suggest that the indications for referral to tertiary care should be strengthened beyond just 'good practice' to reflect the important and unique contribution of tertiary services for individuals with hard to treat epilepsy or treatment complications.</p> <p>Fundamental to epilepsy management is appropriate pharmacological treatment and, for some individuals with hard to treat epilepsy, this can only be achieved through the expertise within</p>	Thank you for your comment. We will cover this as appropriate according to the available evidence in the guideline update.

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				<p>tertiary centres. We believe that the good practice of referral to tertiary services is not being implemented, resulting in many individuals who would benefit from this service continuing to be inadequately serviced in primary or secondary care.</p> <p>While there are currently sufficient tertiary centres for epilepsy, we believe their capacity should be increased to support the new pharmacological treatments, with related increases in expertise and equipment, to service the volume of appropriate referrals for tertiary services. We suggest that evidence to support this statement should be compiled, that barriers to referral from primary to secondary care, and from secondary to tertiary care be articulated, and that indications for referrals to be given further emphasis.</p>	
SH	Joint Royal Colleges Ambulance Liaison Committee, Guidelines Development Group	1	4.2 and 4.3	<p>Ambulance service staff are commonly the first healthcare professionals to attend a patient who is suffering a seizure and most of these patients are already known to suffer from epilepsy. Current statute precludes paramedics from possessing midazolam to treat these patients, although they are allowed to administer the patient's own medication. Currently, the only benzodiazepine available for possession by paramedics is diazepam.</p> <p>When drafting the new guideline it would be greatly appreciated if consideration would be given to the emergency treatment options for seizures, bearing in mind the limitations in statute. It may, of course, be that the updated guideline may be used to influence a future amendment of statute relating to the possession of drugs by paramedics.</p>	Thank you for your comment. Treatment of status epilepticus will be covered in the guideline update.
SH	Society of British Neurological Surgeons	2	4.2 b	<p>The scope of this document includes tertiary care. Therefore the issue of when to stop additional trials of new or add-on AEDs and refer appropriate patients for surgery lies within the remit of this update. Please note that an evaluation of epilepsy surgery is not being proposed here, simply guidelines for the early and appropriate referral to a tertiary centre for surgical evaluation after adequate trials of AEDs</p>	Thank you for your comment. This was dealt with in the previous guideline. Further evidence will be reviewed as appropriate.

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SH	The National Centre for Young People with Epilepsy	6	4.2 b	The reference to the tertiary sector here is welcome as experts in the field of epilepsy have a vital role to play in treating more intractable or complex forms of epilepsy. Research shows that only 28% of children and young people are seizure free, and many of those with continuing seizures would benefit significantly from access to tertiary care, including assessment and treatment available from third sector organisations. NICE's review of the guidelines should continue to highlight the value of early, and perhaps repeated, referral to tertiary sector experts.	Thank you for your comment. The previous guideline addressed management in primary and secondary care, and has given guidance for tertiary care referral.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	10	4.2 b	Tertiary care and surgery The JEC welcomes the inclusion of tertiary care in the scoping document. We believe that the indications for referral for epilepsy surgery should reflect the importance of early referral for individuals who are unlikely to gain seizure control through pharmacological treatment.	Thank you for your comment. This is covered in the previous guideline. Further evidence will be reviewed as appropriate.
SH	Epilepsy Action	16	4.2. b	Tertiary care and surgery Epilepsy Action welcomes the inclusion of tertiary care in the scoping document and would like to highlight two papers on epilepsy surgery as follows: 1) Solomon J K, McEvoy A, Lhatoo SD, Kitchen ND, Shorvon SD, Journal of Neur, Neurosurg and Psych, Jan 2002 2) MC Walker, DR Fish, Epilepsy 2007: From Cell to Community, ILAE and NSE, chapter 48	These references are noted with thanks.
SH	Faculty of Occupational Medicine, Royal College of Physicians, London	1	4.2 c	You state that the guidelines will also be relevant to the work but will not cover the practice of those working in Occupational Health Services. This I think is unlikely as the work of the occupational health physician and the practice of the occupational physician are not easily divisible and occupational health services frequently need to advise upon fitness to work in people with epilepsy, especially those newly diagnosed, or those on changing medication. A full understanding of the expected less common side affects of anti epileptic drugs (AED's) is essential for advising the employee and employer on safe work practice. I therefore feel that 4.2C should state	Thank you for your comment. This is outside the remit of this guidance.

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				that the guidelines will be relevant to the work and practice of occupational health services and perhaps relevant to the work of the other services described.	
NICE	PIIP at NICE	4	4.3	We think it is important to add a sub-section about specific information and advice for people about their medication, particularly noting the different age groups involved.	Thank you for your comment. Please refer to the Medicines Adherence guideline. This was also covered in the previous guideline.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	2	4.3	<p>The draft scope of this update is focused solely on pharmacological management. Whilst we agree that this area of the existing guideline needs to be updated to reflect the new evidence that has become available, we are disappointed that no consideration has been given to the need for update within the rest of the existing guideline.</p> <p>The methods section of the Full Guideline (p33) states that a full literature search and critical appraisal could not be undertaken for all of the key clinical questions due to the time and resource limitations within the guideline development process. Although this is understandable, we would expect that the update of the guideline would now assess whether the best possible evidence has been used to inform the existing recommendations, even if there hasn't been a substantial change to the evidence base.</p> <p>The TLoC GDG is concerned about the following recommendations in the existing guideline that fall into this category:</p> <ol style="list-style-type: none"> 1) care for individuals with psychogenic non-epileptic seizures – recommendation 1.5.6 (see point 3 below) 2) referral to tertiary services either when seizures are not controlled as or there is diagnostic uncertainty – recommendation 1.8.38 (see point 4) 3) referral to a cardiologist if there is diagnostic uncertainty – recommendation 1.6.28 (see point 5) 	<p>Thank you for your comment. It is NICE policy to only update guidelines where new evidence may change current recommendations. In addition to searches conducted the expert knowledge of the GDG is used to ensure key papers have not been missed. Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence significantly changed previous recommendations.</p> <p>Management of non epileptic seizures is outside the scope of this guideline update. The previous guideline addressed management of epilepsy in primary and secondary care, and has given guidance for tertiary</p>

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					care referral which includes diagnostic uncertainty.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	3	4.3	<p>The TLoC GDG is particularly concerned that the current guideline does not provide a clear pathway of care for individuals with psychogenic non-epileptic seizures, many of whom will be wrongly given a diagnosis of epilepsy. Recommendation 1.5.6 of CG20 advises that suitable referral should be made when non-epileptic attack disorder is suspected. This recommendation is based on expert consensus rather than evidence and it does not provide any guidance on what would lead the clinician to suspect that an attack does not have an epileptic origin.</p> <p>Section 8.4 of the Full Guideline reports that the clinical question on this topic was not subject to a full evidence review due to the time and resource limitations within the guideline development process. The GDG recommends a full evidence review is included in the update.</p> <p>In addition, no mention is made of the role of psychotherapy in the treatment of non epileptic psychogenic seizures.</p>	Thank you for your comment. Management of non epileptic seizures is outside the scope of this guideline update.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	4	4.3	In recommendation 1.8.38, psychological or psychiatric comorbidity is given as a possible criterion for referral to tertiary services when either seizures are not controlled or there is diagnostic uncertainty. It is not clear what services should be provided within tertiary care and how these may benefit a patient who has psychogenic-non epileptic seizures and who has been misdiagnosed and received inappropriate treatment. Again this clinical question was not subject to a full evidence review and the only evidence statement provided relates to surgical management in temporal lobe epilepsy. The GDG recommends a full evidence review is included in the update.	Thank you for your comment. This is outside of the remit of this guidance.
SH	National Collaborating Centre	5	4.3	Some patients with underlying cardiac conditions present with	Thank you for your comment.

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	for Nursing and Supportive Care's TLOC GDG			<p>apparent seizures. Many of these people may be misdiagnosed as having epilepsy and it is essential that they are identified and referred for appropriate investigations and treatment.</p> <p>There are recommendations in the existing guidance but these are often not based on a full evidence review as these topics were not prioritised when the original guideline was developed. For example, recommendation 1.6.28, which is based on expert consensus, advises that referral to a cardiologist should be considered if there is diagnostic uncertainty but it provides no guidance on what would lead the clinician to suspect that the cause may be cardiological rather than neurological.</p>	This is outside the remit of this guideline update.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	6	4.3	The TLoC GDG considers that there is an important area of omission in CG20 - the re-assessment of the diagnosis if a patient is unresponsive to medication - and recommends that a question on this is added to the update.	Thank you for your comment. Re-assessment of diagnosis is covered in the previous guideline.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	7	4.3	In CG20, 12-lead ECG is mentioned under 'other tests' (recommendation 1.6.27), but there is nothing under 'First seizure 1.4' or 'Diagnosis 1.5', raising the whole question of differential diagnosis (cardiac) and misdiagnosis. Furthermore, the recommendation regarding 12-lead ECG should also indicate who should read the ECG results (e.g. a cardiologist) as this will influence the diagnosis. The TLoC GDG advises that this area should be addressed in the update.	Thank you for your comment. The use and interpretation of ECG is outside the remit of this update guideline.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	8	4.3	Recommendation 1.6.15 in CG20 is not strong enough and needs updating - since video EEG telemetry is often required to clarify diagnosis, it should be made universally available.	Thank you for your comment. There is no evidence to suggest a change to the previous guidance. Implications for service are outside the scope of this guideline
SH	National Collaborating Centre for Nursing and Supportive	9	4.3	People who present with seizures triggered by alcohol or substance misuse are not covered by CG20 and the update should provide	Thank you for your comment. This is outside of the guideline

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	Care's TLOC GDG			recommendations on how these individuals should be identified and managed.	update scope. Please refer to the relevant guidelines for substance abuse: http://www.nice.org.uk/Guidance/PH4 . Alcohol use disorders guideline (http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11832) is currently in development, stakeholder comments will be sought for this.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	10	4.3	No mention is made of the role of psychotherapy in treatment of the psychological morbidity commonly associated with epilepsy.	Thank you for your comment. Psychotherapy is covered in the previous guideline.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	11	4.3	The advice on the oral contraceptive pill (OCP) in CG20 suggests that a minimum initial dose of 50 micrograms of oestrogen is recommended in those taking enzyme-inducing AEDs. Since no formulation of OCP with 50 micrograms of oestrogen is available, this recommendation needs reconsideration. The issue should be considered in the light of recent information about the interaction of Lamotrigine with the OCP too.	Thank you for your comment. This will be dealt with in the update guideline as part of the drug interactions.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	12	4.3	Rectal diazepam (1.9.2) is mentioned as first line treatment for prolonged seizures in the community, though nowadays buccal midazolam has taken its place.	Thank you for your comment. We will include buccal midazolam in the update guideline.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	13	4.3	Section 1.4 of CG20 'Following a first seizure' makes no reference to driving or the advice that should be given to patients, which is usually the first concern of the patient with a driving licence. The TLoC GDG recommends that this is added.	Thank you for your comment. This is covered in the previous guideline.
SH	National Collaborating Centre for Nursing and Supportive	14	4.3	CG20 suggests that GPs have an important role, however this is described in the briefest of detail. What should GPs be targeting in	Thank you for your comment. We will review this information for

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	Care's TLOC GDG			<p>the long term management of epilepsy?</p> <p>Also highlighted is the need to develop services and effective structured care for people with epilepsy in Primary Care. Since the original guideline in 2004, Intermediate care for epilepsy has become established and now has guidelines for the competencies required set in place by the RCGP and will be adopted by the DH in April 09. http://www.rcgp.org.uk/pdf/CIRC_PwSI%20Epilepsy%202.pdf</p> <p>It is not clear whether this is a useful addition and indeed where these new services should be used. Whilst evidence is scarce, best practice information is now available to draw from in reaching a recommendation.</p>	possible inclusion in this guideline update.
SH	National Collaborating Centre for Nursing and Supportive Care's TLOC GDG	15	4.3	<p>CG20 provides a disproportionate emphasis on Sudden Death in Epilepsy compared with that provided to consider the key role of the nurse specialist. The latter needs to be considered in more detail – and the GDG does not believe it is possible to provide a safe epilepsy service without nurse specialists, as they are essential to manage the risk to patients and prescribers. What is necessary to manage the risks should be explicit, e.g. copying correspondence to patients, documenting that the risk of the AED in pregnancy has been discussed. Prescribing roles should be considered in more detail, especially the interface between primary and secondary care where there is a delicate balance between safety and continuity of care. The TLoC GDG recommends that this aspect is reconsidered in the update.</p>	Thank you for your comment. The role of the prescriber will be covered in this guideline update.
SH	National Society for Epilepsy	4	4.3	<p>We welcome the inclusion of side effects of generic prescribing, potential withdrawal from drugs, poly-therapy, drug interactions and side effects within the update. Feedback on our Epilepsy Helpline suggests that these are issues of great importance and concern to individuals with epilepsy. There is great uncertainty of the facts around generic prescribing, interactions and side effects</p>	Thank you for your comment. This has been noted.

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				<p>amongst people with epilepsy. Common issues that arise for individuals with epilepsy include the following.</p> <ul style="list-style-type: none"> - A lack of understanding about the issues around generic prescribing and consistency of supply, and uncertainty around an individuals' 'rights' to request alternative forms of their dispensed medication. - Insufficient information and support around the process of joint decision making around drug withdrawal and the potential risks associated with unplanned or unstructured withdrawal. - Lack of information around poly-therapy and drug interactions including awareness of what to look out for, and what to do, if interactions are suspected. - Little information, support or understanding around the side effects of medication, including a lack of understanding of the terms that show how common side effects are (leading to the assumption that an individual will experience all the listed side effects as a guarantee). There is also commonly a misunderstanding that side effects have to be accepted as part of treatment, and a lack of understanding around alternative medications if side effects happen. 	
SH	Association of British Neurologists	2	4.3	Given that vagal nerve stimulation is similar in efficacy to new drugs in refractory epilepsy, and that some PCTs consistently refuse to fund it, it would be reasonable in my opinion to consider including VNS in the guidelines.	<p>Thank you for your comment. Vagal nerve stimulation is covered in the previous guideline.</p> <p>We will forward this comment to the implementation team.</p>
SH	National Society for Epilepsy	5	4.3	<p>We believe that comment and guidance on evidence about the risk of anti-epileptic drugs causing suicide or suicidal behaviour should be included within the update. There has been much publicity around warnings being added to AED packaging in the US, although there is no suggestion of this in the UK at present. However, this issue is gaining increased publicity and causing distress and concern for many individuals with epilepsy and their families and friends.</p>	Thank you for your comment. Risk of suicide will be considered when reviewing the evidence on side-effects.

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SH	National Society for Epilepsy	6	4.3	<p>We believe that sections 1.8.21 - 25 of the current guideline should be strengthened, and that providing appropriate support and information for individuals when starting, changing or stopping medication should be included as a specific recommendation. Individuals often feel that they have very little support when starting, changing or withdrawing from medication. Also, some individuals will benefit from an overall understanding of the long-term treatment strategy, individualised to them, including the indications for treatment changes.</p> <p>Common concerns around medication for individuals with epilepsy include the following. Although the current guidelines include statements on the following topics, considerable anecdotal feedback from our Epilepsy Helpline indicates that this part of the guideline is not being implemented.</p> <ul style="list-style-type: none"> - Although section 1.8.6 of the guideline states that treatment should be individualised to the person's 'lifestyle' and 'preferences' this is not always reflected in patient experience. Giving examples of individual patient factors that may be important would give weight to the significance of taking this into account within the treatment strategy. For example, the person's age, whether they are in education or employment and any significant factors within this, whether they drive or are the sole driver within a family, and how medication can impact on their quality of life. - Some individuals feel that they are either not involved in joint decision making around medication, or – at the other end of the spectrum - that they are given information and are expected to make a choice around medication without having the support to discuss their choices and concerns. - Some individuals are not given adequate support or easy access back to their specialist or specialist nurse during medication initiation, change or withdrawal. Many also find that their GP lacks the necessary experience and expertise to support them with any concerns that arise. 	Thank you for your comment. This will be covered in the guideline update. Please also refer to the Medicines Adherence guideline.

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				- A lack of understanding around the need for medication, the possibility of alternative drugs if current therapy is not working or causing unacceptable side effects, and the issues around sudden withdrawal of medication, can all lead to an individual stopping their medication. Suddenly stopping medication has risks of increased or prolonged seizures and, ultimately, a risk of death.	
SH	Faculty of Occupational Medicine, Royal College of Physicians, London	2	4.3 a	You state that the clinical guideline update will focus solely on the pharmacological management of epilepsies. The guideline will also include side affects of generic prescribing potential withdrawal from drugs polytherapy, drug interaction and side effects. I think it also essential that a section on the effect of antiepileptic drugs on work performance be included and an example of suitable text can be found on page 179 of "Fitness to Work, the medical aspects", 4th Edition, edited by Palmer, Cox and Brown, Oxford University Press 2007, ISBN 978-0-19-921565-2" where the specific effect of AED's most commonly used is briefly explained in relation to seizure control and work performance. Also the impact on cognitive function in healthy volunteers and patients with newly diagnosed epilepsy is described. A high proportion of the population with epilepsy remain at work with good seizure control and a revision of treatment with drugs with less side affects and a reduction in polypharmacy to monotherapy is becoming an important treatment aim. This is especially with drugs such as Lamotrigine and Oxcarbazepine which have far less impact on cognitive function. Hopefully this might be expanded in an additional section on "Antiepileptic drugs and work performance".	Thank you for your comment. This guideline is directed towards the NHS.
SH	Royal College of Pathologists	1	4.3 a	Include guidance on the monitoring of drug therapy for the drugs listed, including the indications for drug concentration monitoring (where appropriate) and monitoring for the development of side-effects (e.g. osteomalacia)."	Thank you for your comment. To be covered in the update guideline.
SH	Epilepsy Action	3	4.3 a	Generic prescribing/consistency of supply Epilepsy Action is pleased to see that the Scope will include side	Thank you for providing the references. These have been

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				<p>effects of generic prescribing and submit the following evidence:</p> <p>1) Haskins LS, Tomaszewski KJ, Crawford P. Patient and physician reactions to generic antiepileptic substitution in the treatment of epilepsy. <i>Epilepsy Behav.</i> 2005 Aug;7(1):98-105.</p> <p>2) Crawford P, Feely M, Guberman A, Kramer G. Are there potential problems with generic substitution of antiepileptic drugs? A review of issues. <i>Seizure</i> 2006 Apr;15(3):165-76. Epub 2006 Feb 28.</p> <p>3) Heaney DC, Sander JW. Antiepileptic drugs: generic versus branded treatments. <i>Lancet Neurol.</i> 2007 May;6(5):465-8.</p> <p>4) Gonzalez de Dios J, Ochoa-Sangrador C, Sempere AP. Generic drugs in the treatment of epilepsy. <i>Rev Neurol.</i> 2005 Dec 1-15;41(11):676-83.</p> <p>5) Radio 4 broadcast 3 February 2009 (included case study).</p> <p>6) If required Epilepsy Action is able to provide case studies where the issue of an alternative brand or parallel import has caused changes in seizure pattern or changes to side effects.</p> <p>7) Epilepsy Action is currently carrying out a large survey into consistency of supply issues among people with epilepsy. We expect to have the results of that study in the autumn 2009.</p>	noted.
SH	Sanofi-Aventis	3	4.3 a	<p>We are pleased that the guidance will include a review of generic prescribing (side effects).</p> <p>Although it is understood that generic drugs need to meet the necessary bioequivalence specifications, with epilepsy and the narrow therapeutic window of antiepileptic drugs such as sodium valproate, there is concern that permitted differences in bioavailability may be sufficient to allow loss of seizure control or toxicity in susceptible patients, with detrimental consequences.</p>	Thank you for your comment. This is noted with thanks.
SH	Society of British Neurological Surgeons	3	4.3 a	The average duration of drug resistant epilepsy in patients coming to surgery in the UK is 17 years. Refractory epilepsy can be diagnosed in the majority of patients within 2-3 years of seizure onset. Since 60-70% of patients become seizure free after surgery, there is a substantial waste of NHS resources on this patient population, as well	Thank you for your comment. This has been covered in the previous guideline. The previous guideline notes that referral for tertiary care is if people do not

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				as a significantly poorer quality of life outcome in those who have surgery late (especially in childhood and adolescence after which normal developmental, psychosocial and socioeconomic trajectories cannot be regained).	respond within 2 years. This will be forwarded to the implementation team.
SH	Janssen Cilag Ltd	1	4.3 a	With respect to the clinical question on the side effects of generic prescribing, we assume this to refer to all clinical consequences such as breakthrough seizures, hospitalisation and injury, not simply adverse drug reactions, however we would recommend clarification of this.	Thank you for your comment. Adverse events as much as is possible will be covered in the guideline update.
SH	Janssen Cilag Ltd	2	4.3 a	In the clinical management section, retention on AED therapy should be explicitly explored as a clinically meaningful endpoint alongside potential withdrawal from drugs	Thank you for your comment. Please refer to the medicines adherence guideline.
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	5	4.3 a	Pharmacological management should include the ketogenic diet. It is in effect a pharmacological treatment and has been used as such for 50 years. The recent publication of an RCT showing efficacy in children is important in this context.	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this guideline update.
SH	Royal College of Paediatrics and Child Health	13	4.3 a	Might it be appropriate to include ketogenic diet and vagal nerve stimulation?	Please see above.
SH	Royal College of Paediatrics and Child Health	14	4.3 a	The guideline has very narrow scope. Pharmacological management is only one aspect of management of epilepsy. Why is the scope so narrow. This will severely limit its usefulness. It is of crucial importance that drug side-effects are reviewed in detail in the guideline review. There is good evidence that (within certain limits) the major difference between the newer antiepileptics is their incidence of side effects and much less so their anticonvulsant effectiveness. The draft scope for consultation document does not emphasise this – and this is important because this may well have an effect on the gathering and analysis of evidence for the guideline. This is very important in children with neurodisabilities particularly learning disability (including autism). These children often have the most severe and difficult to treat epilepsies, they are the children who are most likely to be receiving drug combinations and the least likely	Thank you for your comment. This is a partial update, and we will be looking into drug side-effects.

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				to be able to report side effects. They are also the children in whom diagnosis and recognition of side effects is the most difficult.	
SH	Royal College of Paediatrics and Child Health	15	4.3 a	Why are the ketogenic diet and vagal nerve stimulation interventions not being considered alongside pharmacological interventions? Both are important alternatives/additions to pharmacological treatment and it is important to evaluate and consider them side by side. The ketogenic diet has an evolving evidence base for certain childhood epilepsies. There have been important publications since previous NICE guidance and TAs. Services to enable ketogenic diet 'prescription' are variable throughout the UK and decisions appear to be made on the basis of what can be resourced rather than what is clinically appropriate. The cost effectiveness and evidence base for this should be considered alongside emerging pharmacological options.	Thank you for your suggestion. Ketogenic diet as an intervention for children will be included in this guideline update. . With regards to vagal nerve stimulation, please refer to the Health Technology Assessment document. Vagal nerve stimulation was covered in the previous guideline. No new studies have been published since the HTA to change recommendations.
SH	The National Centre for Young People with Epilepsy	3	4.3 a & 2 a	<p>The NCYPE believes it is inappropriate for the review to focus 'solely on pharmacological management of the epilepsies'. The review should consider the role of other treatment choices such as the Ketogenic diet and the role of surgery.</p> <p>The review should also have a broader remit as healthcare providers have an important role to play in tackling cognitive and behavioural problems for the following reasons:</p> <ul style="list-style-type: none"> • At least 50% of children and young people with active epilepsy have cognitive, behavioural and/or psychiatric problems which form the most difficult part of their management; • The cognitive problems may be selective or global; • The psychiatric problems include Attention Deficit Hyper-activity Disorder, Autistic Spectrum Disorder, obsessional behaviour, confrontational behaviour, depression, anxiety and motor coordination problems; • Behavioural management in children requires a cognitive 	<p>Thank you for your comment. Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence significantly changed previous recommendations.</p> <p>Ketogenic diet as an intervention for children will be included in this guideline update</p>

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				<p>assessment to ensure that their educational provision is appropriate and to put behaviour in a developmental context;</p> <ul style="list-style-type: none"> • Anti-epileptic drugs and seizure activity are important in understanding behaviour in this group and management programmes have to coordinate all aspects; • The management of psychiatric illness in this group requires similar techniques to those commonly used including behavioural programmes, support and in a significant proportion the use of medication. <p>Currently Children and Adolescent Mental Health Services do not deal with the majority of these children or their problems and it is left to paediatricians to identify and manage them. The reason for this gap in professional services is a separate issue, but one that needs to be addressed.</p> <p>Our case is that these patients deserve to have all of their problems diagnosed and managed in a way which is integrated with their epilepsy management.</p> <p>The NCYPE has proposed guidelines to identify children with epilepsy in schools, to screen them for problems, and to provide integrated care. This has the support of the All Party Parliamentary Group for Epilepsy, as set out in their publication 'Wasted Money, Wasted Lives'. The NCYPE therefore calls upon NICE to broaden the scope of the review beyond pharmacological management.</p>	
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	3	4.3 a & 2 a	<p>The JEC welcomes the inclusion of side effects of generic prescribing, potential withdrawal from drugs, poly-therapy, drug interactions and side effects within the update; however, we believe it is inappropriate for the review to focus "solely on pharmacological management of the epilepsies". There is great uncertainty of the facts around generic prescribing, interactions and side effects amongst people with epilepsy. Common issues that arise for</p>	<p>Side-effects will be included in the guideline update.</p> <p>Please refer to Medicines Adherence guideline.</p>

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				<p>individuals with epilepsy include the following:</p> <ul style="list-style-type: none"> • A lack of understanding about the issues around generic prescribing and consistency of supply, and uncertainty around an individuals' 'rights' to request alternative forms of their dispensed medication. • Insufficient information and support around the process of joint decision making around drug withdrawal and the potential risks associated with unplanned or unstructured withdrawal. • Lack of information around poly-therapy and drug interactions including awareness of what to look out for, and what to do, if interactions are suspected. • Little information, support or understanding around the side effects of medication, including a lack of understanding of the terms that show how common side effects are (leading to the assumption that an individual will experience all the listed side effects as a guarantee). There is also commonly a misunderstanding that side effects have to be accepted as part of treatment, and a lack of understanding around alternative medications if side effects happen. <p>We believe the review should have a broader remit as healthcare providers have an important role to play as follows:</p> <ul style="list-style-type: none"> • At least 50% of children and young people with active epilepsy have cognitive, behavioural and/or psychiatric problems which form the most difficult part of their management; • The cognitive problems may be selective or global; • The psychiatric problems include ADHD, ASH, obsessional behaviour, confrontational behaviour, depression, anxiety and motor co-ordination problems; • Behavioural management in children requires a cognitive 	<p>Thank you for your comment. Evidence published since the previous guideline was found that could overturn pharmacological recommendations. We did not find any other areas where evidence significantly changed the previous recommendations.</p>

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				<p>assessment to ensure that their educational provision is appropriate and to put behaviour in a developmental context;</p> <ul style="list-style-type: none"> • AEDs and seizure activity are important in understanding behaviour in this group and management programmes have to coordinate all aspects; • The management of psychiatric illness in this group requires similar techniques to those commonly used including behavioural programmes, support and in a significant proportion the use of medication. <p>Currently CAMHS services do not deal with the majority of these children or their problems and it is left to paediatricians to identify and manage them. The reason for this gap in professional services is a separate issue, but one that needs to be addressed.</p> <p>We believe that these patients deserve to have all of their problems diagnosed and managed in a way which is integrated with their epilepsy management.</p> <p>The National Centre for Young People with Epilepsy (NCYPE) has proposed guidelines to identify children with epilepsy in schools, to screen them for problems, and to provide integrated care. This has the support of the APG on Epilepsy, as set out in their "<i>Wasted Money, Wasted Lives</i>" report.</p>	
NICE	PPIP at NICE	3	4.3 b	Given that this guideline covers children and adults, would it be helpful to clarify here the extent to which it might be expected that licensed indications include children.	Thank you for your comment. License indications for children will be made explicit in the guideline update.
SH	The National Centre for Young People with Epilepsy	7	4.3 b	There is a need for community rescue therapy to be included within protocols for the treatment of prolonged seizures.	Thank you for your comment. This has been noted.
SH	Royal College of Paediatrics and Child Health	16	4.3 b	Not infrequently in refractory epilepsies in childhood some of the drugs are used outside their licensed indications (eg in a younger age	This will be covered in the guideline update. All evidence will

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				group etc) for which there will be little or no 'clear support by evidence'. How will the working party address such issues?	be used
SH	Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health London	6	4.3 c	The omission of corticosteroids which are regularly used for infantile spasms, Landau-Kleffner syndrome and non-convulsive status epilepticus is surprising. Rufinamide in Lennox-Gastaut Syndrome is omitted but it is licensed for use. The use of stiripentol in Dravet's syndrome is licensed by EMEA on orphan status.	Thank you for your comments. Rufinamide and Stiripentol have now been included.
SH	Royal College of Paediatrics and Child Health	17	4.3 c	Drugs included in proposed and previous guideline – these are all AED's in the strict sense. Should steroids (used in many tertiary centres for refractory seizures even when infantile spasms are not the diagnosis) also be included? Similarly Pyridoxine?	This will be covered in the guideline update.
SH	Royal College of Paediatrics and Child Health	18	4.3 c	Further anti-epileptic drugs to be included – ACTH, ketogenic diet	Please see above.
SH	Royal College of Paediatrics and Child Health	19	4.3 c	In the list of drugs covered, Nitrazepam is not mentioned at all, which is an anticonvulsant that can be useful in young children with very abnormal brains with very difficult epilepsies. Paraldehyde and lorazepam are not mentioned either, which are important emergency treatments. In my opinion these should be included in the list being considered.	Thank you for your comment. Nitrazepam, paraldehyde and lorazepam will be added to the list of drugs.
SH	Royal College of Paediatrics and Child Health	20	4.3 c	Included should definitely be steroids (for example a guideline covering management of West syndrome would be a nonsense if steroids were not considered). There is also a strong case for including guidance on the use of immunoglobulins and the ketogenic diet. Both are 'medical treatments' used in treating childhood epilepsy. There is also a case for including vagal nerve stimulation	Thank you for your comment. Steroids will be covered in the update guideline. Guidance from the Department of Health (June 2008) on Intravenous immunoglobulins lists specific guidance for the use including epilepsy Ketogenic diet as an

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					intervention for children will be included in this guideline update With regards to vagal nerve stimulation, please refer to the Health Technology Assessment document. No new studies have been published since the HTA to change recommendations. Vagal nerve stimulation was covered in the previous guideline.
SH	Royal College of Paediatrics and Child Health	21	4.3 c	It is very good all the new drugs are included Diazepam and paraldehyde have been omitted but midazolam left in – will the guideline cover treatment of prolonged seizures/status? – in which case they should be included.	Thank you for your comment. Diazepam and paraldehyde will be included in the guideline update.
SH	Royal College of Paediatrics and Child Health	22	4.3 c	It seems strange to include buccal midazolam in this list. Is the scope including the community and hospital management of prolonged seizures? If so, then paraldehyde, diazepam and lorazepam should be included and the scope changed to include prolonged seizures. If not then the inclusion needs to be justified within the scope proposed.	Please see above.
SH	Royal College of Paediatrics and Child Health	23	4.3 c	Prednisolone/steroids should be included for completeness. This forms an important part of treatment for children with infantile spasms. The evidence base for steroids for other epilepsies needs review.	Thank you for your comment. Prednisolone/steroids will be included in the guideline update.
SH	Epilepsy Action	2	4.3 c	Buccal Midazolam Epilepsy Action welcomes the inclusion of Buccal Midazolam in the Scope and would like to draw NICE's attention to the following papers: 1) Baysun S, Aydin OF, Atmaca E, Gurer YK. A comparison of buccal midazolam and rectal diazepam for the acute treatment of seizures. Clin Pediatr (Phila). 2005 Nov-Dec;44(9):771-6. 2) McIntyre J, Robertson S, Norris E, Appleton R, Whitehouse WP, Phillips B, Martland T, Berry K, Collier J, Smith S, Choonara I. Safety and efficacy of buccal midazolam versus rectal diazepam for	Thank you for your comment. The references mentioned have been noted.

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				<p>emergency treatment of seizure in children: a randomised controlled trial. Lancet. 2005 Jul 16-22;366(9481):205-10.</p> <p>3) Appleton R, Macleod S, Martland T. Drug management for acute tonic-clonic convulsions including convulsive status epilepticus in children. Cochrane Database Syst Rev. 2008 Jul 16;(3):CD001905.</p>	
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	4	4.3 c	<p>The JEC welcomes the inclusion of Buccal Midazolam in the Scope and would like to draw NICE's attention to the following papers:</p> <p>1) Baysun S, Aydin OF, Atmaca E, Gurer YK. A comparison of buccal midazolam and rectal diazepam for the acute treatment of seizures. Clin Pediatr (Phila). 2005 Nov-Dec;44(9):771-6.</p> <p>2) McIntyre J, Robertson S, Norris E, Appleton R, Whitehouse WP, Phillips B, Martland T, Berry K, Collier J, Smith S, Choonara I. Safety and efficacy of buccal midazolam versus rectal diazepam for emergency treatment of seizure in children: a randomised controlled trial. Lancet. 2005 Jul 16-22;366(9481):205-10.</p> <p>3) Appleton R, Macleod S, Martland T. Drug management for acute tonic-clonic convulsions including convulsive status epilepticus in children. Cochrane Database Syst Rev. 2008 Jul 16;(3):CD001905.</p>	Thank you for your comment. The references mentioned have been noted.
SH	Beacon Pharmaceuticals Ltd	4	4.3 e	We believe that there is good potential to improving optimal use as outlined above.	Thank you for your comment.
SH	The National Centre for Young People with Epilepsy	4	4.3 e	<p>The NCYPE believes that it is right for the Guideline Development Group to make recommendations on the best approach to care.</p> <p>The existing Clinical Guideline states that '<i>All children with a recent-onset suspected seizure should be seen urgently by a specialist</i>', defining 'urgently' as within two weeks, and 'specialist' as a paediatrician with training and expertise in the epilepsies. Epilepsy Action's 2008 survey shows that this is not being achieved, and also shows that Primary Care Trusts do not know how many children and young people in their area have epilepsy.</p> <p>The Epilepsy Action survey demonstrates a lack of urgency in treating children and young people, and the NCYPE believes that it is</p>	Thank you for your comment. This will be forwarded to the implementation team.

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				<p>vital for the Guideline Development Group to highlight the need for shorter waiting times. It is vital that children and young people have rapid access to high quality diagnosis given the harrowing nature of seizures and the potentially major implications for children and young people, and their families and friends.</p> <p>Knowing how many children have epilepsy is an essential precursor to planning good services for them and, as a second detailed recommendation from the NCYPE in this area, the Group should also highlight the need for improvements in the collection of prevalence information.</p> <p>The NCYPE's third recommendation on the best approach to care would be for NICE to develop or encourage a guideline on multi-agency management of the comorbidities of epilepsy.</p>	
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	5	4.3 e	<p>The JEC believes that it is right for the Guideline Development Group to make recommendations on the best approach to care.</p> <p>The existing Clinical Guideline states that all children and young people with a recent onset suspected seizure should be seen within two weeks by a paediatrician with training and expertise in epilepsy. Epilepsy Action's 2009 "<i>Time for Change</i>" report shows that this is not being achieved, and also shows that Primary Care Trusts do not know how many children and young people in their area have epilepsy. We would strongly recommend the need for shorter waiting times to see paediatricians with training and expertise in epilepsy.</p>	<p>Thank you for your comment. Waiting times are outside the remit of this guideline.</p> <p>We will forward your comment to the implementation team.</p>
SH	Beacon Pharmaceuticals Ltd	5	5	We note the new guidance due on medicines adherence and see a good rationale for integrating with this review.	Thank you for your comment. This has been noted.
SH	Epilepsy Action	13	Current Guidance 4.11.23	<p>Routine monitoring in pregnancy Epilepsy Action would like to recommend that this section of the guidance is reworded. The phrase stating that 'routine monitoring is not recommended' should be changed to routine monitoring is</p>	Thank you for your comment. Routine monitoring in pregnancy will be considered in the guideline update.

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				<p>recommended in some anti-epileptic drugs. Information on specific monitoring of lamotrigine, oxcarbazepine and levetiracetam levels in pregnancy and post partum is recommended in the following papers:</p> <ol style="list-style-type: none"> 1) Tomson T et al EURAP study group. Seizure control and treatment in pregnancy. <i>Neurology</i> 2006;66:354-360 2) Pennell P, Peng L, Newport DJ et al. Lamotrigine in pregnancy. Clearance, therapeutic drug monitoring, and seizure frequency. <i>Neurology</i> online November 28, 2007, doi:10.1212/01.wnl.0000289511.20864.2a 3) Westin AA, Reimers A, Helde G et al. Serum concentration/dose ratio of levetiracetam before, during and after pregnancy: <i>Seizure</i> 2008;17:192-198 4) Brodtkorb E, Reimers A. Seizure control and pharmacokinetics of antiepileptic drugs in pregnant women with epilepsy. <i>Seizure</i> 2008;17:160-165 5) Tomson T, Hiilesmaa V. Epilepsy in pregnancy. <i>BMJ</i> 2007;335:769-773 6) Tomson T, Palm R, Kallen K et al. Pharmacokinetics of levetiracetam during pregnancy, delivery, in the neonatal period, and lactation. <i>Epilepsia</i> 2007;48(6):1111-1116 	
SH	Epilepsy Action	9	Current guidance 4.11.4 A 4.11.4 C	<p>Sodium valproate and teratogenic risks Epilepsy Action believes that this section of the guidance should be phrased more strongly and the wording to be changed from 'caution' to 'not used'. Recent research indicate that sodium valproate poses a significant to the health of a foetus, and where possible should not be used as a first line treatment in women of childbearing age. We refer you to the following papers:</p> <ol style="list-style-type: none"> 1) Morrow JI, Russell A, Guthrie E et al. Malformation risks of anti-epileptic drugs in pregnancy: A prospective study from the UK Epilepsy and Pregnancy Register. <i>J Neurol. Neurosurg. Psychiatry</i> online 2005; 2) Eriksson K, Viinikainen K, Monkkonen A et al. Children exposed to valproate in utero- Population based evaluation of risks and confounding factors for long term neurocognitive developments. 	Thank you for your comment. This will be dealt with. Please see above.

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				<p>Epilepsy Research 2005;65:189-200 3) Ardinger et al. Verification of the fetal valproate syndrome phenotype. Am J Med Genet 1998;29:171-85 4) Vinten J, Adab N, Kini U et al. Neuropsychological effects of exposure to anticonvulsant medication in utero. Neurology 2005;64:949-54 5) Fairgrieve SD Jackson M Jonas P. Population based prospective study of the care of women with epilepsy in pregnancy. BMJ 2000;321:674-5.</p>	
SH	Epilepsy Action	7	Current guidance 4.13.5	<p>Young people with epilepsy/transition services Epilepsy Action would like to suggest that transition services for young people are included in the Scope and highlighted more clearly in the guidance. There is evidence that currently multidisciplinary transitional services are allocated inadequate resources. This is despite adolescence being a critical period for creating positive health behaviours that would be carried into adulthood and influence long-term health. Self-management is a key area of government policy, yet transitional care clinics for people with epilepsy are scarce. In Epilepsy Action's survey of acute trusts and primary care trusts in 2008 found that only 36 per cent of acute trusts and 33 per cent of primary care trusts had transition services in place. We would like to draw your attention to the following papers: 1) Scal P. Transition for Youth With Chronic Conditions: Primary Care Physicians' Approaches. Pediatrics 2002;110:1315-1321 2) Scal P, Ireland M. Addressing transition to adult health care for adolescents with special health care needs. Pediatrics 2005;115(6):1607-1612 3) Hauser and Dorn. Transitioning adolescents with sickle cell disease to adult-centred care. Pediatric Nursing 1999;25:479-489 4) Viner RM and Barker M. Young people's health: the need for action. BMJ 2005;330:901-903 5) Viner RM. National survey of use of hospital beds by adolescents aged 12 to 19 in the United Kingdom. BMJ 2001;322:957-958 4) Sue Ryder Care on behalf of Epilepsy Action: Survey of epilepsy</p>	<p>Thank you for your comment. Transitional services for young people was covered in the previous guideline</p> <p>This will be forwarded to the implementation team.</p>

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				<p>services in acute trusts and primary care trusts in England 2009. http://www.epilepsy.org.uk/sites/epilepsy/files/images/campaigns/Epilepsy_in_England_-_Time_for_change_report.pdf</p>	
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	9	Current guidance 4.13.5	<p>Young people with epilepsy/transition services The JEC would like to suggest that transition services for young people are included in the Scope and highlighted more clearly in the guidance. There is evidence that currently multidisciplinary transitional services are allocated inadequate resources. This is despite adolescence being a critical period for creating positive health behaviours that would be carried into adulthood and influence long-term health. Self-management is a key area of government policy, yet transitional care clinics for people with epilepsy are scarce. In Epilepsy Action's survey of acute trusts and primary care trusts "<i>Time for Change</i>" it was found that only 36 per cent of acute trusts and 33 per cent of primary care trusts had transition services in place. We would like to draw your attention to the following papers: 1) Scal P. Transition for Youth With Chronic Conditions: Primary Care Physicians' Approaches. <i>Pediatrics</i> 2002;110:1315-1321 2) Scal P, Ireland M. Addressing transition to adult health care for adolescents with special health care needs. <i>Pediatrics</i> 2005;115(6):1607-1612 3) Hauser and Dorn. Transitioning adolescents with sickle cell disease to adult-centred care. <i>Pediatric Nursing</i> 1999;25:479-489 4) Viner RM and Barker M. Young people's health: the need for action. <i>BMJ</i> 2005;330:901-903 5) Viner RM. National survey of use of hospital beds by adolescents aged 12 to 19 in the United Kingdom. <i>BMJ</i> 2001;322:957-958</p>	Please see above.

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				4) Sue Ryder Care on behalf of Epilepsy Action: Survey of epilepsy services in acute trusts and primary care trusts in England 2009. http://www.epilepsy.org.uk/sites/epilepsy/files/images/campaigns/Epilepsy_in_England_-_Time_for_change_report.pdf	
SH	Epilepsy Action	10	Current Guidance 4.11.9	<p>Combined oral contraceptive pill Epilepsy Action believes that the current guidance on the combined oral contraceptive pill in epilepsy is flawed and needs to be updated. This should include information about progestin content, long-cycle use of oral contraceptives, and reduced lamotrigine levels as evidenced in the following papers:</p> <p>1) Schwenkhagen AM & Stodieck SRG. Which contraception for women with epilepsy? <i>Seizure</i> 2008;17;145-150. 2) Ohman I, Luef G, Tomson T. Effects of pregnancy and contraception on lamotrigine disposition: New insights through analysis of lamotrigine metabolites. <i>Seizure</i> 2008;17;199-202. 3) Thorneycroft I, Klein P, Simon J. The impact of antiepileptic drug therapy on steroidal contraceptive efficacy. <i>Epilepsy & Behavior</i> 2006;9;31-39. 4) Christensen J, Petrenaite V, Atterman J et al. Oral contraceptives induce lamotrigine metabolism: Evidence from a double-blind placebo controlled trial. <i>Epilepsia</i> 2007;88(3);484-489</p>	Thank you for your comment. This will be covered as part of the drug interaction in the update guideline.
SH	Epilepsy Action	15	Current Guidance 4.8.3	<p>Epilepsy specialist nurses and case loads Epilepsy Action would like to highlight to NICE the importance of strengthening of the epilepsy specialist nurse role, in particular to provide guidance on suitable case load. Epilepsy Action is currently conducting a piece of research into the cost effectiveness of the role of the epilepsy specialist nurse. We anticipate that this study will become available in May 2009.</p>	Noted. Thank you for your comment. Delivery of services and how this is managed locally is not within the remit of the guideline.
SH	Joint Epilepsy Council of the UK and Ireland (JEC)	11	Current guidance 4.8.3	<p>Epilepsy specialist nurses and case loads The JEC would like to highlight to NICE the importance of strengthening of the epilepsy specialist nurse role, in particular to provide guidance on suitable case load. Epilepsy Action is currently conducting a piece of research into the cost effectiveness of the role of the epilepsy specialist nurse and it is anticipated that this study will</p>	Noted. Thank you for your comment. Delivery of services and how this is managed locally is not within the remit of the guideline.

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				become available in May 2009.	
SH	Epilepsy Action	8	Current guidance 4.11.2 A – 4.11.4 and 4.11.2 C – 4.11.4 C	<p>Preconception counselling</p> <p>Epilepsy Action is of the view that the Scope should include a review of pre-conception counselling and that this section in the guidance should be worded more strongly. Women and adolescents need early and on-going access to pre conception counselling before planned or unplanned pregnancy occurs. We would like to draw NICE's attention to the following papers:</p> <p>1) Fairgrieve SD Jackson M Jonas P. Population based prospective study of the care of women with epilepsy in pregnancy. <i>BMJ</i> 2000;321:674-5.</p> <p>2) Kampman MT et al. Management of women with epilepsy: are guidelines being followed? Results from case-note reviews and a patient questionnaire. <i>Epilepsia</i> 2005;46(8):1286-1292</p> <p>3) Crawford P. Epilepsy and pregnancy. <i>Seizure</i> 2001;10:212-219</p> <p>4) Hart Y. Modern management of epilepsy in pregnancy. <i>Trends in Urology, Gynaecology & Sexual Health</i> 2006:18-211.</p> <p>5) Lewis G et al. Saving Mothers Lives 2003-5. Confidential Enquiry into Maternal and Child Health 2007.</p>	Thank you for your comment. This will be covered in the guideline update.
SH	Special Products Limited	4	Current Guidance Appendix C	Only provides doses for adults. Please refer to BNFC for buccal Midazolam doses for children	Thank you for your comment. This has been noted.
SH	Special Products Limited	1	Current Guidance reference 1.9.2	A recent study found that buccal midazolam was more effective than rectal diazepam for the treatment of children with seizures in the hospital setting. Buccal Midazolam did not appear to increase the risk of respiratory depression. Ref. McIntyre J, <i>et al.</i> Safety and efficacy of buccal midazolam versus rectal diazepam for emergency treatment of seizures in children: a randomised controlled trial. <i>Lancet</i> 2005; 366: 205–10.	Thank you for your comment. This has been noted.
SH	National Hospital for Neurology and Neurosurgery	2	Current guidance 1.8.37	The indications for, and timing of, referral for epilepsy surgery should be made more clear: this is a central aspect of treatment of epilepsy in some individuals. Earlier referral is necessary, as surgery has been	Thank you for your comment. The previous guideline has given guidance for tertiary care which

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				shown by RCT to be effective in carefully-selected individuals (Langfitt JT, Wiebe S. Curr Opin Neurol. 2008 Apr;21(2):179-83)	therefore includes surgery referral.
SH	Special Products Limited	2	Current Guidance reference 1.9.3	Please also add the following child-specific comment: The buccal route may be more acceptable in children. Ref: BNFC 2008, p280	Thank you for your comment. This will be covered in the guideline update.
SH	Epilepsy Action	11	Current Guidance 4.11.11	Contraceptive injections Epilepsy Action's view is that this guideline is no longer necessary and should be removed. The reason for this view is that research indicates that a shorter repeat interval is no longer recommended for depot injections of progesterone. This is evidenced in the following papers: 1) Thorneycroft I, Klein P, Simon J. The impact of antiepileptic drug therapy on steroidal contraceptive efficacy. Epilepsy & Behavior 2006;9:31-39. 2) Pfizer Ltd. Depo-Provera, summary of product characteristics. 2004. 9. 3) Gupta C, Osterman J, Santen R, et al. In vivo metabolism of progestins. J Clin Endocrinol Metab 1979;48:816-20	Thank you for your comment. This has been noted.
SH	Epilepsy Action	12	Current Guidance 4.11.18	Pre-conception counselling or drug management in pregnancy? Epilepsy Action is of the opinion that the wording in this section of the guidance is unclear in that it could refer to drug changes before pregnancy <u>or</u> to counteract breakthrough seizures during pregnancy. We would like to see this section reworded. If the information is in relation to pre-conception counselling the information would need to be moved to the appropriate section.	Please see above.

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