Stroke rehabilitation in adults (update)

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1	AbbVie Ltd	Draft guideline	030	General	1.15.5 **In response to the question "*Would it be challenging to implement any of the draft recommendations?*"** Yes, we strongly disagree with the recommendation limiting treatment of spasticity to one botulinum neurotoxin A (BoNT-A) at one dose (i.e. Dysport® 500U) and in upper limb only. We believe this recommendation is neither appropriate nor possible to implement because it: 1. Does not align with other clinical guidelines nor UK clinical practice 2. Does not recognise that the toxins have unique clinical characteristics and indications and are not interchangeable (BOTOX® SmPC; Dysport® SmPC; Xeomin® SmPC) 3. Is inconsistent with the extensive evidence base for botulinum toxins in the management of stroke related spasticity 4. Is based on an economic analysis that fails to include the majority of evidence identified in the clinical review (Evidence Review P), does not reflect real life management of stroke spasticity, or acknowledge the	Thank you for your comment: The recommendation was based on the cost effectiveness results as well as the available published health economic evidence. The de novo health economic analysis did have limitations that were already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic evidence which suggested that botulinum toxin A was not cost effective. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made. A research recommendation is included in the guideline specifically designed to address this. Adjustments to the health economic model have been made following careful consideration of the points raised in the stakeholder consultation. These included:

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					differences in the marketing authorisations for available BoNT-As (BOTOX® SmPC; Dysport® SmPC; Xeomin® SmPC) 5. May have a detrimental effect on patient outcomes; particularly for patients with both upper and lower limb spasticity and those with lower limb spasticity only The recommendation is based on the flawed finding (draft guideline, page 59) that "*Only Dysport was found to be both cost effective and beneficial in terms of both reducing spasticity and improving activities of daily living"*. We believe that the draft recommendations should be amended to take into account the full body of evidence and the MHRA approvals on BoNT-A products to allow a broader range of treatment options to manage spasticity patients, including options for both upper and lower limb spasticity. This would provide guidance to the NHS which is consistent with UK and global guidelines as well as long standing established clinical practice and real world evidence, thereby ensuring no patient is left without treatment options.	- exploring a longer time horizon (5 years) - using nationally available discounted costs of Botulinum toxin where available and provided by manufacturers (only available for Xeomin) - use of Masakado 2020 instead of Elovic 2016 for Xeomin, the former MAS responder status data was provided during consultation and latter had been incorrectly labelled as MAS responder when in fact it was AS responder data - exploring a longer interval between repeats based on ULIS III (Turner Stokes 2021) observational data (25 week interval) and on an open label extension Xeomin RCT (Kanovsky 2011) (14 week interval) - exploring extrapolating the 12 weeks RCT MAS responder data, using the rate of discontinuation from Shaw 2010. - adjusting the QALYs and number of injections in the model to ensure a full year is captured, not 48 weeks. As a result of the edits made to the model the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin

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					References: SmPC BOTOX® (botulinum toxin type a). Summary of Product Characteristics. Last updated 25 Apr 2023. Accessed via https://www.medicines.org.uk/emc/product/859/smpc on 23 May 2023 SmPC Dysport® (botulinum toxin type a). Summary of Product Characteristics. Last updated 05 Apr 2023. Accessed via https://www.medicines.org.uk/emc/product/964/smpc#gref on 30 May 2023 SmPC Xeomin® (botulinum toxin type a). Summary of Product Characteristics. Last updated 28 Jul 2022. Accessed via https://www.medicines.org.uk/emc/product/2162/smpc#gref on 30 May 2023	(up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time.
2	AbbVie Ltd	Draft guideline	030	General	1.15.5 **The recommendation regarding stroke-related spasticity does not align with other clinical guidelines in the UK and internationally** • The Royal College of Physicians (RCP) guideline for the treatment of focal spasticity includes all three BoNT-A products, with no specification regarding dose, for treatment of	Thank you for your comment. NICE recommendations are based on clinical and cost effectiveness evidence. These other guidelines do not consider cost effectiveness when making their recommendations.

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					upper and lower limb spasticity. The guideline makes it clear that the toxins have unique indications and are not interchangeable (RCP 2018; Section 6.3 and 6.6, page 15-16). • The National Clinical Guideline for Stroke which applies across the UK and is accredited by NICE, recommends BoNT-A for persistent or progressive focal spasticity after stroke affecting one or two areas, but does not recommend a specific toxin and does not limit the location to upper limb (Stroke Association, 2023; Section 4.24 page 103). • Similarly, the American Academy of Neurology guidelines state that Dysport®, BOTOX® and Xeomin® are established as effective, have acceptable safety profiles and should be offered for upper limb spasticity (Level A), whilst Dysport® and BOTOX® are established as effective and should be offered for lower-limb spasticity (Level A) (Simpson, 2016; page 1822).	

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					References British Royal College of Physicians. Spasticity in adults: management using botulinum toxin (2018) http://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin Simpson, D. M. et al (2016). *Neurology*, *86*(19), 1818–1826. https://pubmed.ncbi.nlm.nih.gov/27164716/ Stroke Association. National Clinical Guideline for Stroke, UK and Ireland (2023) https://www.stroke.org.uk/professionals/resources-professionals/national-clinical-guideline-stroke	
3	AbbVie Ltd	Draft guideline	030	General	1.15.5 **The recommendation regarding stroke-related spasticity does not align with established clinical practice** • BoNT-A has been in clinical use for treating post-stroke spasticity for more than 30 years and is accepted as part of standard of care for adult focal post-stroke spasticity (Williams, 2020) • Clinical experts consulted by AbbVie regarding this draft guideline have advised that they are extremely concerned regarding	Thank you for your comment. The recommendations made are based on both the clinical and cost effectiveness. The published cost effectiveness studies identified overall suggest that botulinum toxin A is not cost effective except for one analysis by Doan 2013 which made selective use of downstream resource use and did not conduct a probabilistic sensitivity analysis. The de novo analysis only found Dysport in upper limb at the lower dose to be cost

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					restriction to use only one toxin at one dose (i.e. Dysport® 500U) and that the recommendation does not reflect their practise or the local pathway. They stated that: o This recommendation demonstrates a lack of understanding of spasticity and how it is managed o There was no scientific rationale for the restriction and access to all three toxins is needed in order to tailor treatment appropriately and across a range of muscles, not only upper limb o The dose recommendation did not make sense nor reflect evidence-based practice, where much higher doses are often used o Since the toxins are not interchangeable the recommendation could cause a huge burden for services o There is no rationale for confining the recommendation for BoNT-A to the	effective. This analysis had limitations, hence only a consider recommendation was made at the time to reflect the uncertainty in the evidence. Further adjustments have been made to the model (see response to AbbVie comment 1) and the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made.

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					upper limb and not including the lower • Multiple clinicians noted that the recommendation does not align to RCP spasticity guidelines (2018), and that these should be referred to. **References** British Royal College of Physicians. Spasticity in adults: management using botulinum toxin (2018) http://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin Williams, G. et al (2020). *Disability and rehabilitation*, 1-11.	
4	AbbVie Ltd	Draft guideline	030	General	1.15.5 **The recommendation does not recognise the unique characteristics of each botulinum toxin and the fact that they are not interchangeable: choice of a BoNT-A should always be made by the healthcare professional based on the established safety and efficacy of each product in the specific indication and the individual profile of each patient.** Each BoNT-A is unique and non-interchangeable:	Thank you for your comments. The recommendations are based on treatments that were found to be clinically and cost effective. Each drug was considered separately to account for the uniqueness of each. Further adjustments have been made to the model (see response to AbbVie comment 1)

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					• BoNT-As are different products that have a unique clinical profile characterised by differences in efficacy, impact on pain, duration of effect, safety, diffusion and immunogenicity properties, leading to a unique benefit/risk proposition for each product. • Each BoNT-A product has unique MHRA-approved indications, and clinicians therefore base their usage on the clinical properties and labelled indications of that product (Nelson, 2022; Brin, 2014; Slawek, 2018). • As clearly indicated in the SmPC of each product, BoNT-A units are non-interchangeable (BOTOX® SmPC; Dysport® SmPC; Xeomin® SmPC). In addition, many studies show that there is no single dose conversion ratio between products (Ferrari, 2018). • By assuming all BoNT-A products are perfectly interchangeable, the recommendation artificially restricts clinician and patient choice, resulting in an unfair distortion of free market competition.	and the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time. Other drugs and or indications were either found to be not cost effective or were not assessed for cost effectiveness due to a lack of clinical evidence available to enable adequate health economic modelling. A research recommendation has been included in the guideline specifically to explore the clinical and cost effectiveness of Botulinum toxin A. With regards to the concern around switching, please note the recommendations are intended for new cases and therefore switching is not being suggested.

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					The recommendation may lead to inappropriate and detrimental switching of patients to a non-equivalent product (forced non-medical switching). • Such switching may result in clinicians using Dysport® without dosing guidance in muscles for which it is not approved when other products such as BOTOX® are approved and indicated for those muscles (and have appropriate evidence based dosing guidance included in the SmPC). This could put patients at a safety risk. • Switching for non-medical reasons can result in negative impact on patient outcomes and can have a considerable impact in patients with chronic diseases who are already on stable medication regimens. • Alternatively, patients may be denied an approved treatment for their affected muscles altogether because they are not included in the Dysport® indication. The recommendations do not allow for treatment to be tailored to account for individual circumstances:	

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					• When considering BoNT-A administration, the exact dosage and number of injection sites must be tailored to the individual and the treatment goals based on the size, number and location of muscles involved, the severity of spasticity, the presence of local muscle weakness, and the patient response to previous treatment. Therefore, it is inappropriate to recommend only one dose of a specific toxin for use in upper limb spasticity. • Real-world evidence demonstrates that BOTOX® is used across a greater number and a different range of muscles and joints of the spastic upper limb compared with Dysport®, with more patients receiving BOTOX® injections in the forearm and hand muscles (Nelson, 2022) • Since the available approved BoNT-A products differ in terms of the muscles indicated in spasticity, patients with spasticity involving certain muscles would legally not have access to treatment. • Some patients may not be able to receive the BoNT-A product recommended in the	

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					draft consultation, including those who are allergic to excipients in the Dysport® preparation, such as lactose. • The recommendation also undermines the role of the individual patient in shared clinical decision making, which is a fundamental principle applicable across the NHS and enshrined in law. The differences between the products, both in product characteristics, labelled indications and clinical characteristics, together with the lack of a conversion ratio for the BONT-As makes it inappropriate to mandate the use of a single product. A choice of BoNT-As is needed so that clinicians can individualise and treat each patient appropriately. **References** Brin MF, *et al. Biologics*. 2014;8:227–241; Ferrari A, *et al. Funct Neurol.* 2018;33(1):7–18 Nelson M, *et al.* Poster presented at the 12th World Congress for Neurorehabilitation; 14–17 December 2022; Vienna, Austria;	

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					Sławek J, *et al. Neurol Neurochir Pol.* 2021;55(2):141–157. SmPC BOTOX® (botulinum toxin type a). Summary of Product Characteristics. Last updated 25 Apr 2023. Accessed via Ukmi website on 23 May 2023 SmPC Dysport® (botulinum toxin type a). Summary of Product Characteristics. Last updated 05 Apr 2023. Accessed via https://www.medicines.org.uk/emc/product/964/smpc#gref on 30 May 2023 SmPC Xeomin® (botulinum toxin type a). Summary of Product Characteristics. Last updated 28 Jul 2022. Accessed via https://www.medicines.org.uk/emc/product/2162/smpc#gref on 30 May 2023	
5	AbbVie Ltd	Draft guideline	General	General	**"*Would implementation of any of the draft recommendations have significant cost implications?*"** Yes, we believe that the draft recommendations may have significant cost implications as they may lead to sub-optimal management of spasticity.	Thank you for your comment. The recommendations made are based on both the clinical and cost effectiveness. The published cost effectiveness identified overall suggests that botulinum toxin A is not cost effective except for one analysis by Doan 2013 which made selective use of downstream

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					RCP guidelines (2018; Executive Summary, page vii) state that "If used according to the guidance, BoNT-A has the potential to reduce the overall costs of ongoing care in people with severe spasticity through the prevention of contracture and deformity, and improved ease of care and handling." The committee considered that a recommendation would result in increased use that could result in a significant resource impact. However, rather than increasing use of BoNT-As, the very restrictive recommendations could lead to decreased use, denying patients access to the treatments available today and the full range of benefits that they provide. **Reference** British Royal College of Physicians. Spasticity in adults: management using botulinum toxin (2018) http://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin	resource use and did not conduct a probabilistic sensitivity analysis. Further adjustments have been made to the de novo model (see response to AbbVie comment 1) and the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time. Other drugs and or indications were either found to be not cost effective or were not assessed for cost effectiveness due to a lack of clinical evidence available to enable adequate health economic modelling. Thus, restricting the committee's ability to make recommendations for them. A research recommendation has been included in the guideline specifically to explore the clinical and cost effectiveness of Botulinum toxin A.

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6	AbbVie Ltd	Evidence review P	006	036	**The economic model structure deviates from the NICE reference case by failing to showcase a lifetime horizon** The model employs a limited time horizon of only one year, with a scenario analysis extending to two years. The provided rationale for the short time horizon was solely based on the absence of survival impact associated with BoNT-A treatments. • However, this approach fails to account for the long-term costs and health benefits associated with BoNT-A treatment. • By focusing solely on a short-term perspective, the model overlooks the potential extended impacts on patient outcomes, including activities of daily living. • This deviation from a lifetime horizon results in an incomplete assessment and inconsistency with the NICE reference case.	Thank you for your comment. The lack of longitudinal data limited the time horizon for the outcomes listed in comment. The reference provided is an internet based survey relating to the self-reported impact of spasticity on patients and caregivers (multiple choice questions, Likert scale and free text answers). It is not specific to people who have had a stroke. This was published as a conference abstract with limited data reported. It does not provide any usable outcomes such as quality of life data. Following stakeholder consultations comments, a sensitivity analysis has been conducted to explore a 5 year time horizon. Extrapolation of the clinical data informing the model beyond 5 years was deemed too uncertain.

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					• Moreover, it is important to note that the NICE methods guide emphasises the need to capture all costs and benefits, without solely relying on the impact on survival. By using a 1-year horizon and 2 years as a scenario analysis, the cost-effectiveness results may be skewed against BoNT-A. It would have been possible to carry out a lifetime horizon basing estimates of longer-term effects on data from longer term follow-up studies. **Reference:** Patel et al. Burden of spasticity among patients and caregivers: results of a multinational survey. P3.55. Presented at TOXINS 2019 | Copenhagen, Denmark | 16–19 Jan 2019	
7	AbbVie Ltd	Evidence review P	007	026	**In the economic model, costs of BoNT-A are artificially overinflated by the incorrect assumption that people continue to receive treatment even when not responding** The economic model does not reflect clinical practice as it does not incorporate a treatment	Thank you for your comments. The discontinuation (proportion not receiving repeat injections) was based on 1 year UK data (Shaw 2010) which reported the proportion receiving repeat injections, where repeats were given based on assessment of need. This was

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					discontinuation rule based on MAS responder rates. This is an basic approach commonly applied in economic evaluations, taken in previous economic analyses in stroke (Ward et al 2005). This appears to stem from effectiveness and costs having been handled separately in the model. As a result patients who are non-responders are assumed to continue receiving treatment, driving up the cost per quality-adjusted life year (QALY). This contradicts guidelines from the Royal College of Physicians (2018): no prescriber or patient would wish to continue to receive a treatment that does not work, exposing the patient to potential side-effects. To reflect clinical practice, a treatment discontinuation rule based on MAS responder rates should be included in the economic model. Furthermore, the prices paid by the NHS for BOTOX® are confidential, so the costs included in the model are not reflective of actual NHS costs. **References:**	used as there was no longitudinal data on proportion of responders from RCT data identified in the clinical review. A sensitivity analysis has been added to explore extrapolating the 12 weeks RCT MAS responder data, using the rate of discontinuation from Shaw 2010. This does not change the conclusions of the model. Only flat nationally available discounted prices (such as Patient Access Schemes) can be incorporated into the analyses. All three manufacturers were contacted and these were only available for Xeomin. Note: Ward 2005 used 2002-2004 cost data and so was assessed as too dated for inclusion in the health economic evidence review for this question.

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8	AbbVie Ltd	Evidence review P	012 031	005-008 011-012	**Unadjusted patient population differences in the included studies led to biased conclusions; the placebo response in the Dysport® study was 40% lower than in the included BOTOX® and Xeomin® studies which the authors state may have occurred by chance** • MAS responder data were used to inform treatment effect in the economic analysis, by applying the mean difference in MAS responders for BoNT-A compared to placebo onto the placebo proportion of MAS responders. The proportion of MAS responders in the placebo arms of the trials were used for the usual care comparator in these analyses. • As noted by the authors of Gracies et al, 2015 (Dysport®), the treatment size effects were high because placebo effects were low with respect to results of previous randomised controlled trials of BoNT-A, and	Thank you for your comment. There are differences between the trials but it was not possible to quantitively address these other than ensuring the model uses mean differences in responders. Further discussion of the heterogeneity between trials has been added to the model write up. The committee acknowledged the de novo health economic analysis had limitations as already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic evidence which suggested that botulinum toxin A was not cost effective. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made. A

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					that the results of the placebo group may have occurred by chance. They state that "*if we had repeated this same trial a number of times, the current placebo effect might be lower than the average trial distribution of placebo effects*" • Without any adjustments the analysis artificially inflates the Dysport® incremental difference as there was a 40% lower response in Dysport® studies compared to the Xeomin® and BOTOX® studies • A conclusion should not be made based on such heterogenous trials.	research recommendation is included in the guideline specifically designed to address this.
9	AbbVie Ltd	Evidence Review P	015	041	**The recommendation largely ignores more than 30 years of clinical trial evidence and real-world clinical experience of the management of spasticity, relying solely on three studies that utilise a Modified Ashworth Scale (MAS) responder analysis** The economic model report states that "*Fifty RCTs reporting MAS mean data were available however only three RCTs reported responder data*".	Thank you for your comment. The limited evidence base used has been discussed as a limitation of this analysis already. Of note there was an error in the model report as the 50 RCTs were for the whole evidence review not just BoNT-A RCTs. This has been edited (now 18 RCTs). No alternative approach to modelling cost utility was identified or suggested in stakeholder

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					• The studies in the economic analysis were chosen as they included MAS responder data, however very little rationale is given for choosing this outcome on which the economic model and subsequent recommendation is based. • Responder analysis is not the typical endpoint used in clinical trials, and few studies report this outcome. Therefore, although a large number of studies investigating BoNT-As for treatment of focal spasticity were identified in the evidence review, only a fraction of these were used to inform efficacy estimates in the economic model. • The three selected studies represent a small proportion of patients treated in clinical trials (the BOTOX®, Dysport® and Xeomin® studies included 468, 243 and 259 patients, respectively) (Elovic, 2016; Gracies, 2015; Wein, 2018)	consultation that would make use of a wider body of evidence. As noted previously, the committee acknowledged the de novo health economic analysis had limitations as already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic evidence which suggested that botulinum toxin A was not cost effective. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made. A research recommendation is included in the guideline specifically designed to address this.

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					• It would have been possible to either structure the economic model on a different clinical endpoint or to have more than one model that would have allowed more than 6% of the clinical evidence to be used. It is not good practice to use clinical evidence so selectively.	
10	AbbVie Ltd	Evidence review P	016	General	**The fixed doses of BoNT-As used in the cost analysis may not reflect the most commonly used dose in clinical practice, and in many patients may not be effective, limiting the cost-effectiveness conclusions** • Dosing varied considerably across trials and populations studied, specifically in the upper and lower limb. A post-hoc analysis (Gracies et al., 2018) of the Dysport® trial revealed that 99.2% of patients in cycle 1 received 1,000 U Dysport® in the upper limb, with a trend towards even higher doses in subsequent cycles (19.7% at cycle 2 and 43.2% at cycle 4 receiving 1,500 U	Thank you for your comment. The doses included in the health economic model are based on the available clinical data (identified in the clinical review) reporting MAS responder data. Of note, as Gracies 2018 was a post hoc analysis it will not have met the clinical inclusion criteria and therefore not form part of the evidence base to inform the proportion of MAS responders. Further adjustments have been made to the de novo model (see response to AbbVie comment 1) and the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper

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					Dysport®). Response seemed to be maintained with these higher doses. In contrast, the BOTOX® trial (Wein et al., 2018) utilised doses between 300 U and 400 U, resulting in improved response for MAS, possibly due to targeted treatment of affected muscles as typically practiced. • AbbVie has engaged with a wide group of experts since the draft recommendation was published. They have advised that they routinely use doses of Dysport® higher than 500U and do not feel that 500U Dysport® is sufficient to achieve a clinically effective result for all relevant patients. • It is crucial to consider these dose variations and their impact on response rates in the 1-year and 2-year scenarios of the economic model, particularly when assessing the acquisition cost of the drugs. Considering these factors, it is reasonable to infer that utilitising the real-world dosing strategies could lead to improved cost-effectiveness outcomes for BoNT-A treatment.	limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time.

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					References: Francisco GE, et al. J Rehabil Med. 2021 Jan 1;53(1). Gracies, J. M. et al. Lancet Neurology. 2015; 14(10):992-1001 Simpson, D. M. et al. Neurology. 2016 May 10; 86(19): 1818–1826Wein, T. Pm & R. 2018; 10(7):693-703	
11	AbbVie Ltd	Evidence review P	017	017 - 019	**The utility values used in the economic analysis are not appropriate for assessing BOTOX®** There is uncertainty regarding the generalisability of the utility values used in the economic analysis to a UK population: • The utility values utilised in the model, as mentioned in section 2.3.5 of the evidence review P spasticity model write-up, were obtained from Makino et al, 2019, an Australian cost utility analysis. These values were originally derived from EQ-5D data collected by Kanovsky et al, 2009 through a non-randomized, repeated-treatment, open-label study conducted in the Czech Republic, Hungary, and Poland.	Thank you for your comment. The limitations of the utility value have already been captured in the model write up and committee discussion of the evidence. No alternative approach to modelling cost utility was identified or suggested in stakeholder consultation that would make use of a wider body of evidence. As noted previously, the committee acknowledged the de novo health economic analysis had limitations as already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic

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					• Markino et al, 2019 used the EQ-5D data obtained from Kanovsky et al, 2009 and applied Australian public preferences data set to obtain utility values. • There is no information on how the analysis was carried out, or on how much data were missing or how this was handled. • The timing of the EQ-5D data collection was not reported in Kanovsky et al, 2009, raising uncertainty about whether it fully captures the treatment effect. • This results in uncertainty regarding the applicability of these results to a UK setting. The utility values used in the model are derived from Kanovsky et al, 2009, a study that only assessed upper-limb spasticity: • The economic model applied the same utility values for both upper and lower limb spasticity, without considering treatment-specific utilities. • Upper-limb spasticity is distinct from the condition being considered for BOTOX®	evidence which suggested that botulinum toxin A was not cost effective. Regarding Hansen 2017, this conference abstract was highlighted in the model write up. Of note minimal methodological detail is reported in the abstract. It was agreed however based on its conclusion that mapping mean Modified Ashworth Scale scores to EQ-5D would not be undertaken. The approach taken in the de novo analysis was not mapping, but rather using the reported EQ5D values for MAS responders from a trial. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made. A research recommendation is included in the guideline specifically designed to address this.

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					treatment in the model, namely lower-limb spasticity • As a result, the utility values used in the analysis may not accurately reflect the health-related QoL experienced by the target patient population, particularly considering the distinct functional differences between lower limb and upper limb spasticity. • Lower limb spasticity is primarily associated with mobility limitations, while upper limb spasticity involves other functions and hygiene maintenance. Therefore, comparing these two conditions directly may not be appropriate due to their distinct nature. The MAS responder status may not be a reliable measure of quality of life in spasticity patients: • The utility values for "responder" and "non-responder" were based on Makino et al. However, there are concerns regarding the appropriateness of this data source and whether MAS responder status truly correlates with the QoL of spasticity patients.	

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					• Studies by Ansari et al, 2008 and Bohannon and Smith, 1987 have demonstrated the limitations and reliability issues of MAS as a measure of spasticity. • Additionally, Hansen et al, 2017 concluded that MAS cannot be mapped to EQ-5D, indicating that the predicted utility values based on MAS levels may not meaningfully differentiate QoL outcomes for spasticity patients. • Furthermore, the review by Pandyan et al, 1999 highlights the properties and limitations of MAS as measures of spasticity. Therefore, caution should be exercised when relying solely on MAS responder status as an indicator of QoL in spasticity patients. In summary, there is uncertainty regarding the utility values used in the economic model, and it would have been possible to use values based on a broader range of sources. **References:**	

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					Ansari, NN, et al. NeuroRehabilitation (2008). 23 (3): 231–7 Bohannon RW and Smith MB; Physical Therapy (1987), 67(2), 206–207 Hansen RN, et al. Value in Health. 2017; 32 20(9):A727T Kanovsky P, et al. Clinical 40 Neuropharmacology. 2009; 32(5):259-265 Makino, K et al. PharmacoEconomics Open. 2 2019; 3(1):93-102 Pandyan AD, et al. Clin Rehabil, 13 (1999), pp. 373-383	
12	AbbVie Ltd	Evidence review P	019	016	**Downstream healthcare resource utilisation costs are neglected in the model, which is a major limitation of the NICE economic model and has implications for cost-effectiveness of BoNT-A** • The economic model does not consider the potential benefits of treatment on downstream healthcare resource utilisation (HCRU) costs within the 1-year and 2-year timeframe.	Thank you for your comment. Due to challenges in accurately quantifying downstream costs, a threshold analysis was undertaken, to estimate the magnitude of downstream savings needed for BoNT-A to be cost-effective. Lundstrom 2009 does not provide direct evidence that BoNT-A reduces these costs. The RCP guideline statement is not based on quantitative evidence.

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					• There seems a clear link between degree of spasticity and future use of health care resources but this is ignored, to the detriment of all forms of BoNT-A. Lundström et al, 2009 analysis on a Swedish stroke registry found a four-fold increase in direct costs of stroke survivors with spasticity compared with stroke survivors without spasticity. • RCP guidelines state that "If used according to the guidance, BoNT-A has the potential to reduce the overall costs of ongoing care in people with severe spasticity through the prevention of contracture and deformity, and improved ease of care and handling". • A previous cost-effectiveness analysis (data from Ward et al, 2005) shows resource use varied by BoNT-A treatment, but this was not considered in the NICE economic model. • In addition, in the NICE economic model, Dysport® was found to be cost-effective only when a dose of 500 U was used for upper limb spasticity, and the usual care arm included twice-yearly neurology visits.	Ward 2005 was excluded from the health economic evidence as it uses 2002-2004 costs, which are dated. Furthermore, the resource use was based Delphi panels or expert opinion surveys/questionnaires in industry funded publications and conference abstracts and therefore were not considered to be robust sources of evidence.

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					However, this representation of HCRU costs for usual care is likely an underestimation. Allocating costs to the usual care arm would improve the cost-effectiveness of all toxin treatments. • It would have been possible to include these costs/savings using data from relevant studies of the costs of residual spasticity. **References:** British Royal College of Physicians. Spasticity in adults - British Royal College of Physicians Guidelines, 2018 Lundström et al, 2009. Stroke, 41, 319–324. Ward et al, J Rehabil Med 2005; 37: 252-257	
13	AbbVie Ltd	Evidence Review P	031	013	**The three selected studies used in the economic analysis are not comparable, leading to biased conclusions** • Two studies investigate on upper limb spasticity and one study investigates lower limb spasticity.	Thank you for your comment. The differences between trial populations has been included as a limitation of this analysis. No alternative approach to modelling cost utility was identified or suggested in stakeholder

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					• The time to treatment post stroke varies substantially across the studies, leading to an unmatched time parameter. • The study inclusion criteria was different for the BOTOX® and Dysport® studies, for MAS scores (MAS ≥3 compared to MAS ≥2 in the target muscle group, respectively). • Only the study by Wein et al reports on UK participants. • The age of participants is imbalanced, with Dysport® study patients being on average 4 years younger than BOTOX® study patients Without an indirect treatment comparison (ITC) that uses a common comparator arm to estimate the relative treatment effect between the comparators, conclusions based on naïve comparison may lead to bias, particularly considering the differences in placebo effect observed in the included studies. Using the naïve comparison approach, each trial individually compared the toxin to placebo and thus without the ITC adjustment may be influenced by the differences in patient characteristics.	consultation that would make use of a wider body of evidence. As noted previously, the committee acknowledged the de novo health economic analysis had limitations as already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic evidence which suggested that botulinum toxin A was not cost effective. Cost effectiveness evidence was not available for each dose and indication, thus limiting the recommendations that could be made. A research recommendation is included in the guideline specifically designed to address this.

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					BoNT-A trials are in general not comparable due to differences in patient characteristics, doses, primary efficacy endpoints including the MAS scores, and measuring scales/timepoints (Schnitzler 2020). While we acknowledge the challenges of identifying consistently reported data to inform the economic model, the severe limitations of the NICE economic model for treatment of spasticity should not be the basis of a recommendation, particularly where they contradict other UK guidelines (RCP and Stroke Association). **References:** Royal College of Physicians. Spasticity in adults: management using botulinum toxin (2018) http://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin Schnitzler, A. et al. (2020). Value in Health, Volume 23, S260 Stroke Association. National Clinical Guideline for Stroke, UK and Ireland (2023) https://www.stroke.org.uk/professionals/resources-professionals/national-clinical-guideline-stroke	

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14	AbbVie Ltd	Evidence Review P	031 - 019	022 - 029	**Excluding evidence on impact of contractures renders the scope too narrow and results in a recommendation that could be detrimental to patients' long-term recovery** Evidence review P states that: *"The RCTs included in this analysis do not include BoNT-A treatment in the sub-acute stroke stage and therefore, benefits on contractures are not incorporated."* and *that "Given that the RCT evidence informing this analysis is not reporting on early use of BoNT-A it was not considered appropriate to include savings associated with contractures into the analysis."* • Contracture development is one of the most harmful consequences of spasticity due to the combination of increased stiffness and loss of range of movement (Lindsay, 2021). • Once contractures are present, these are often very difficult to treat and can have long-lasting, major functional implications, including difficulties carrying out personal hygiene, dressing or even sitting (RCP, 2018).	Thank you for your comment. Unfortunately, the RCTs informing the model are not in an early intervention population and treatment would not have been aimed at the reduction of contractures therefore it was not possible to capture cost effectiveness of this. This is addressed in limitations of analysis already. On further examination of the studies included in the clinical review, the majority of studies where botulinum toxin was investigated excluded people who had contractures, and none reported contractures as an outcome. Therefore, including contractures in our protocol would not have led to a change in the results of the analysis. Lindsay 2023 (within trial cost effectiveness analysis of Lindsay 2021) was included as part of the published health economic evidence. This study was deemed to be partially applicable with potentially serious limitations, the main concerns were that QALYs were not

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					• Ignoring the contribution of contracture management to spasticity outcomes puts the patient's post-stroke recovery at risk, as delayed treatment of spasticity after stroke can lead to permanent muscle shortening and soft tissue contracture (Lindsay, 2021, Treister, 2017; Lieber, 2004). • Early BOTOX® treatment leads to reduction/prevention of contractures. In a National Institute for Health and Care Research (NIHR)-funded randomised controlled trial (Lindsay, 2021), a single early cycle of BOTOX® (18 days after stroke) reduced the rate of contracture formation without hindering recovery, and consequently reduced the need for concomitant treatment such as splinting (Lindsay, 2021). • Statistically significant mean contracture cost savings (£1,481 per patient) were reported in the BOTOX® group vs. placebo (Lindsay, 2023).	calculated as quality of life was not reported and that long-term costs for the management of contractures were taken from a 2001 US study.

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					The costs for long-term management of contractures can be high. In addition to the significant negative impact on patient outcomes. By excluding this evidence an opportunity for cost savings to the National healthcare system is missed. **References:** British Royal College of Physicians. (2018). Spasticity in adults – British Royal College of Physicians Guidelines 2018. Lieber, R. L. et al (2004). *Muscle & Nerve: Official Journal of the American Association of Electrodiagnostic Medicine*, *29*(5), 615-627. Lindsay, C. et al (2021). *Clinical rehabilitation*, *35*(3), 399-409. Lindsay, C. et al (2023). *Clinical rehabilitation*, *37*(3), 373–380. Treister, A. K. et al (2017). *PM&R, 9*(1), 63-75.	
15	AbbVie Ltd	Evidence review P	032	Section 4.4	**The results of the de novo economic analysis completed by the assessment group provides different results to the five published health economic studies identified in the literature review**	Thank you for your comment. The developers acknowledge there is heterogeneity in the HE evidence.

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					Given the heterogeneity between the previously published economic analyses and the de novo economic analysis, their contradictory results, and the significant methodological limitations of the de novo analysis, it is not possible to draw definitive conclusions around the cost effectiveness of the botulinum toxins. To do this gives undue weight to the current analysis within the context of all of the available evidence and it would not be scientifically justified.	As noted previously, the committee acknowledged the de novo health economic analysis had limitations as already outlined in the guideline. Despite these limitations, the committee were keen to use this analysis to make recommendations, as the alternative was to base it on the published health economic evidence which suggested that botulinum toxin A was not cost effective.
16	AbbVie Ltd	Evidence Review P	167	'Model methods'	**There seems to be a fundamental misunderstanding of spasticity and why from a modelling perspective, upper and lower limb spasticity should be modelled separately**. The outcome, dosing, and patient goals are different when considering patients with upper limb versus lower limb spasticity. A singular model ignores these key aspects and is therefore, inappropriate. Failure to model upper and lower limb spasticity separately, and consider the wider clinical evidence that could be used to inform the modelling has resulted in a scenario where only Dysport® and	Thank you for your comment. Each comparator was considered separately (hence the use of its own usual care comparator) and measured against the NICE £20,000 per QALY threshold. The upper and lower limb were modelled separately and had there been evidence to model each drug in each dose and indication this would have been done. Unfortunately, no evidence for MAS responder data was available for all drugs and indications.

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					Xeomin® have been assessed for cost-effectiveness in upper-limb spasticity, while only BOTOX® has been assessed for cost-effectiveness in lower-limb spasticity.	
17	AbbVie Ltd	Evidence Review P	167	'Model methods'	**The economic analysis is based purely on MAS responder data and ignores patient relevant outcomes e.g. the Disability Assessment Scale (DAS), therefore excluding BOTOX® from assessment in upper limb spasticity** Very little rationale is given for choosing the outcome used to define model health states beyond availability of data and it is unclear if MAS responder is the most relevant outcome to be modeled. • It is stated (Evidence Review P, page 167) that a ≥1 point reduction in MAS was considered in the studies to be 'statistically meaningful' however that is inappropriate for a guideline recommendation where clinical significance should be a key factor in determining endpoint selection.	Thank you for your comment. Disability Assessment Scale (DAS) was used in the published CUA by Doan 2013, whereby a utility was assigned to each 'disability state' in the model. Therefore, to replicate this model approach, data on the DAS domain distribution is required. Only two RCTs included in the clinical review reported this; Brashear 2002 which was the RCT that provided the clinical evidence for the existing CUA by Doan 2013, and the other is Gracies 2015 (Dysport). Given the limited new evidence, alternative outcome measures were considered to enable modelling of BoNT-A. There was more MAS responder data available in the clinical review and so the Committee chose the option with largest body of evidence.

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					• There is little evidence on the utility of MAS responder for treatment continuation decisions in clinical practice and/or linkage to quality of life and healthcare resource use and/or costs. • Evidence Review P (spasticity model write-up, page 015) discusses dichotomising the continuous MAS data so the mean data could be used for cost-effectiveness estimates but this was not considered feasible – conceptualising a modelling approach which is able to cope with means would allow the majority of the extensive clinical evidence to be incorporated. The exclusive focus on MAS responders as the only clinical endpoint that can be modelled means that BOTOX® cannot be recommended in the NICE clinical guideline in upper limb spasticity. Clinical evidence exists but has been excluded because it does not meet the rigid requirements of the cost-effectiveness model.	We have checked the references of 'key comparator studies' listed and only Brashear 2002 was included in the clinical review and had DAS data extracted. See detail below: - Gordon 2004 was an open label study and therefore outside protocol - Marciniak 2012 only discontinuation outcome extracted in clinical review. The DAS data was reported as F scores and P values. Therefore, cannot be reliably imputed into means and standard deviations for the purposes of this review and so used in the analysis. - Nam 2015 compares a new botulinum toxin type (NABOTA) which is not relevant to the protocol as it is not licensed for use in the UK - Do 2017 compares letibotulinum toxin A with onabotulinum toxin A - this is not relevant to the protocol as letibotulinum toxin A is not licensed for use in the UK - Simpson 2009 only MAS and discontinuation extracted in clinical review. Selective reporting for DAS so high risk of bias for the outcome reporting and selective choice of the principal therapeutic target introducing outcome selection bias.

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					The evidence review and economic analysis do not adequately incorporate the benefit of treatment on other clinically meaningful long term and functional benefits such as improving activities of daily living, caregiver impact, loss of productivity: • Patients with poorly treated spasticity suffer significant impairment and limitations in their daily activities e.g., difficulty with hygiene and limited mobility, compromising social and work participation and impairing quality of life (Bhimani, 2014). • Key comparator studies (Brashear, 2002; Gordon, 2004; Marciniak, 2012; Nam, 2015; Do, 2017; Simpson, 2009) using the DAS, confirmed that patients treated with BOTOX® compared to other BoNT-As demonstrated greater improvements in personal hygiene, dressing, pain, or limb position, allowing them to lead a more normal life, in addition to long-term benefits in quality of life. The DAS is a meaningful and established clinical method for evaluating functional disability in patients with spasticity of upper limb following stroke and	Doan 2013 was included as published health economic evidence. This cost utility found that BOTOX was cost effective in Scenario 1 where the cost of Botox, specialist office visits and day-hospital visits were included but not cost effective in Scenario 2 where day hospital visits were excluded. Scenario 1 justified inclusion of reduction in day hospitalisation rate with Botox based on it being the only significant difference in the BoTULS RCT economic analysis, however, the BoTULS study also reported statistically significant differences in the proportion of participants reporting contacts for practice nurse and social worker; overall its cost analysis also found an increase in other costs with botulinum toxin A. Therefore, the Committee considered the results of Doan 2013 to be uncertain. Of note, one of the limitations of Danchenko 2022 cost utility analysis was that the utility values used for upper limb, although taken from people with post-stroke spasticity, were not based on the same measure of response

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					may be a more appropriate measure than the MAS from which to derive utility values for economic modelling of upper limb spasticity: • The Danchenko et al (2022) article referenced by the evidence group as reference for the model used DAS scores to derive upper limb utility based on Doan et al (2012), which found that in patients with upper limb post-stroke spasticity, increasing disability in the hygiene, dressing, and pain domains of the DAS were associated with diminishing helath-related QoL. • In previously published cost-effectiveness analyses, utility values for upper limb spasticity are mostly based on DAS scores which assess function and ability to self-care whereas the lower-limb values are based on barefoot walking speed (Danchenko, 2022; Moore, 2021). **References:** Bhimani, *Rehabil Res Pract*. 2014; 2014: 279175. Brashear, A. et al (2002). *N Engl J Med*, 347(6), 395-400. Danchenko N, et al. *Journal of Medical Economics*. 2022; 25(1):919-19 929	used in this analysis: MAS and GAS, but rather based on EQ-5D data for different walking speeds and DAS, respectively.

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					Do, K. H. et al. (2017). *Clinical rehabilitation* 31(9): 1179-1188. Doan QV, Brashear A, Gillard PJ, et al. *R. Pm R*. 2012;4(1):4–10. Gordon, M. F. et al (2004). *Neurology*, 63(10), 1971-1973. Marciniak, C. M. et al. (2012). *American journal of physical medicine & rehabilitation* 91(12): 1007-1019. Moore P. *Value Health*. 2021;24:S160 Nam, H. S. et al. (2015). *J Neurol Sci* 357(1-2): 192-197. Simpson, D. M. et al (2009). *J Neurol Neurosurg Psychiatry*, 80(4), 380-385.	
18	AbbVie Ltd	Evidence Review P	General	General	**The clinical characteristics and benefits of BOTOX® compared to other toxins, supported by a comprehensive body of evidence, are not reflected in the recommendations** • The extensive evidence base of clinical trial and real-world evidence for BOTOX® in post-stroke spasticity has consistently demonstrated benefits on muscle tone reduction, pain alleviation, improvement in function, quality of life (QoL) and patient and clinician satisfaction, including improvements	Thank you for your comment. The references provided were not considered for this review question for the following reasons: • Kaji (2010a/b), Lindsay (2021), Patel (2020)) were included in the clinical review for this question but were not incorporated into the economic model as they did not report MAS responder data. • Francisco, 2020a, Francisco, 2020b, Esqenazi 2021 (all based on the

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					beyond the initial treatment cycles (Bulloch 2015; Kaji 2010a; Kaji 2010b; Francisco, 2020a; Francisco, 2020b; Esquenazi 2021; Rosales 2008). • A 2023 MHRA BOTOX® label expansion increased the number of muscles indicated in spasticity significantly and to also expand the indication to all causes of adult spasticity (not just post stroke) (BOTOX® SmPC). By not providing a recommendation for either upper or lower limb spasticity the guideline is effectively denying access to patients where detailed MHRA analysis only recently reaffirmed the efficacy and safety of usage and even removed the aetiological restriction. • The guideline does not take into account the benefits that may be realised with early BoNT-A treatment. Early treatment with BOTOX® improves muscle tone and reduces the rate of contracture formation compared with late treatment (Patel, 2020; Picelli, 2021; Lindsay, 2021). and may reduce the development of permanent disability with a consequent significant	observational ASPIRE study) also did not report MAS responder data.. • Bulloch 2015 was a literature survey of randomized, single- and double-blind clinical studies on branded botulinum neurotoxins. • Lindsay 2021 and 2023 applied 2001 cost data for contractures. Of note, the de novo model did not incorporate contractures as the RCTs upon which the model was based were not in an early post stroke population. • Picelli 2021 was excluded from the clinical review as it was a longitudinal, cohort study and not a randomised controlled trial. • Rosales 2008 was excluded from the clinical review as it was a systematic review which assessed the efficacy and safety of BoNT-A in post-stroke spasticity. • Woo 2021 was excluded from the clinical review as this was a retrospective chart

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					reduction in contracture costs (Lindsay 2023). In addition, higher doses may be used in patients receiving BoNT-A injections within 12 weeks after stroke, resulting in longer intervals between subsequent injections (Woo, 2021), that may also yield cost savings. • BOTOX® is the only BoNT-A with a marketing authorisation that acknowledges its impact on pain (no other toxin has this highlighted in their marketing authorization (BOTOX® SmPC; Dysport® SmPC; Xeomin® SmPC). • BOTOX® can be used for patients who may be allergic to lactose • BOTOX® is not interchangeable with other BoNT-As. **References:** Bulloch, S. et al (2015) Toxicon, 93(S1):S13. Esquenazi et al. (2021) PM R, 13:1079-1093. Francisco, G.E. et al (2020a) Toxicon, X 7:100040. Francisco, G.E. et al (2020b) PM R, 12:1120-1133. Kaji, R. et al (2010a) J Neurol, 257:1330-7. Kaji, R. et al (2010b) Curr Med Res Opin, 26:1983-92. Lindsay, C. et al. (2021). Clin rehabi, 35(3), 399-409.	review comparing early vs. late start BoNT-A injections. • The SmPC references do not address the cost-effectiveness of BoNT-A products required for a NICE recommendation.

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					Lindsay, C. et al (2023). *Clinical rehabilitation*, *37*(3), 373–380. Patel, A. T. et al. (2020). J of Neural Transm, 127(12), 1619-1629 Picelli, A. et al. (2021). Toxins, 13(6), 374 Rosales, R.L. et al (2008) J Neural Transm, 115(4):617-23. SmPC BOTOX® (botulinum toxin type a). Summary of Product Characteristics. Last updated 25 Apr 2023. Accessed via Ukmi website on 23 May 2023 SmPC Dysport® (botulinum toxin type a). Summary of Product Characteristics. Last updated 05 Apr 2023. Accessed via https://www.medicines.org.uk/emc/product/964/smpc#gref on 30 May 2023 Woo, J., et al. (2021). Journal of the Neurological Sciences, 425, 11744 SmPC Xeomin® (botulinum toxin type a). Summary of Product Characteristics. Last updated 28 Jul 2022. Accessed via https://www.medicines.org.uk/emc/product/2162/smpc#gref on 30 May 202	
19	AbbVie Ltd	Evidence review P	Sheet: Model	Cells: I11-J12,	**The model structure exhibits a critical error in the QALY calculations by miscalculating a timeframe of 48 weeks instead of the intended 52 weeks.**	Thank you for your comment. This error has now been addressed, the QALYs have been increased to ensure they

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			engine	129-J30, I48-J49	• The model utilises responder data from the initial 12 weeks of the clinical trial for each toxin and calculates QALYs for this 12-week period, subsequently multiplying the results by a factor of 3 to estimate the 1-year annual QALY. • However, the error arises from using a multiplier of 3 instead of the accurate value of 3.33 for the remaining first year, and a multiplier of 4 instead of 4.33 for the second year. • This miscalculation leads to an underestimation of the total QALYs and consequently affects the generated incremental cost-effectiveness ratio (ICER). The underestimation of QALYs and the subsequent impact on the ICER findings highlight the need to rectify this error for a more accurate assessment of cost-effectiveness in the evaluation of treatment interventions for spasticity patients.	capture 52 and not 48 weeks. The costs have also been adjusted to account for 4.3 injections a year. This error alone did not impact the conclusion of the results.

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20	Association of British Neurologists	Stroke Rehabilitation Guidelines	030-031	001	Spasticity – new guidelines are welcomed. The recommendations are appropriate when thinking about managing spasticity to avoid long term complications. However, when managing spasticity in order to allow patients to train more effectively (accessing underlying finger extension for example), spasticity management must be followed by intense physiotherapy, or else the goal of improved function will not be met, and the cost of the spasticity treatment will have been wasted. The addition of NMES is welcome.	Thank you for your comment. The committee agrees that spasticity management should be in conjunction with appropriate physiotherapy. Recommendations on intensity of physiotherapy are given in an earlier section of the guideline and should be applied when relevant to those with spasticity as well as those who are not experiencing spasticity.
21	Association of British Neurologists	Stroke Rehabilitation Guidelines	012-013	007	We agree with these additions.	Thank you for your comment
22	Association of British Neurologists	Stroke Rehabilitation Guidelines	019-020	013	Swallowing - we agree with these recommendations.	Thank you for your comment
23	Association of British	Stroke Rehabilitation	017-018	018	Vision - we agree with these recommendations.	Thank you for your comment

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	Neurologists	Guidelines				
24	Association of British Neurologists	Stroke Rehabilitation Guidelines	006-007	023	We support these changes which improve information provided to patients and carers about Early Supported Discharge (including psychological and emotional support). It is unclear why these recommendations apply only to 'before and during early supported discharge' and not the community rehabilitation phase, which is likely to be more long term.	Thank you for your comment. The relevant recommendation is based on a qualitative review of evidence on Early Supported Discharge which is why this is specified in the recommendation.
25	Association of British Neurologists	Stroke Rehabilitation Guidelines	006	012	We support the recommendation to provide rehabilitation for as long as it continues to help patients achieve their treatment goals, even after they have left hospital. The wording allows treatment at the level of impairment, activity and participation. The concept of a recovery plateau does not apply to activity and participation and so this implies life-long treatment to promote recovery should be available. This is what is implied by the wording of the recommendation, but could be made even more explicitly, particularly for the benefit of patients and carers so they know what they can ask for. It is important that this change in guidelines is made clear and explicit to patients and carers. There will be implications for staffing levels which	Thank you for your comment. The committee agrees that this is an important recommendation and are pleased that support has been expressed by a number of stakeholders. We believe the recommendation is sufficiently clear, and includes the possibility of life-long treatment to promote recovery.

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					will need to be met in community care settings to comply with this guideline, but we need to face up to this challenge. The first way to do this is to be clear about optimal treatment based on the evidence.	
26	Association of British Neurologists	Stroke Rehabilitation Guidelines	012	022	These recommendations are different to those in the National Clinical Guidelines (2023), which make recommendations specifically for motor recovery and state that 'People with motor recovery goals undergoing rehabilitation after a stroke should receive a minimum of 3 hours of multidisciplinary therapy a day (delivered or supervised by a therapist or rehabilitation assistant focused on exercise, motor retraining and/or functional practice)….'. This is based on evidence regarding the effects of greater amounts of therapy (dose) (Kwakkel et al, 1999; Kwakkel & Wagenaar, 2002; Bhogal et al, 2003a; Bhogal et al, 2003b; Kwakkel et al, 2004) and is reflected in other clinical guidelines around the world (Australia (Stroke Foundation, 2022), Canada (Teasell et al, 2020) and the Netherlands (Veerbeek et al, 2014a)). Please see also Daly JJ, McCabe JP, Holcomb J, Monkiewicz M, Gansen J, Pundik S. Long-Dose Intensive Therapy Is Necessary for Strong, Clinically	Thank you for your comment. The committee have considered comments from a variety of stakeholders in relation to this recommendation and have amended it. It is now in line with that in the National Guideline. The reason why these studies were excluded are: Kwakkel, et al. 1999 was excluded for having an inappropriate comparison (arm and leg rehabilitation compared to immobilisation rather than comparing different intensities of therapy). Kwakkel and Wagennar, 2002 was excluded for having an inappropriate comparison (comparing three groups receiving the same intensity of therapy). Bhogal, et al. 2003a was excluded for having an inappropriate comparison (reported hours per week rather than hours per day and therefore could not be included in the analysis.)

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					Significant, Upper Limb Functional Gains and Retained Gains in Severe/Moderate Chronic Stroke. Neurorehabil Neural Repair. 2019 Jul;33(7):523-537. This is essentially a replication of an RCT (McCabe et al Arch Phys Med Rehabil. 2015 Jun;96(6):981-90) that delivered 300 hours of upper limb rehab over 12 weeks (= 5 hrs/day) and showed large changes at the impairment level. Why have these studies not been considered by the committee? The NICE and NCG should be aligned. This could be achieved by amending the recommendations regarding physiotherapy to read '…. For at least 1 to 2 hours a day' in line with OT and SLT. They should also both be clear that this recommended time refers to 'time-on-task' not simply session length (Time on task is often approx. 50% of session length). In relation to speech and language therapy, 45 mins is unlikely to be enough. The NCG state 'Intensive speech and language therapy such as	Bhogal et al, 2003b was not identified in the search. However, on checking, this is a systematic review and does not fulfil our criteria. The citations were checked for relevant studies. Kwakkel, et al. 2004 was excluded as it was a systematic review that did not fulfil our criteria. However, citations were checked for relevant studies. Daly, et al. 2019 was excluded for having an inappropriate comparison (compared the same intensity of therapy being delivered to different parts of the upper limb rather than comparing intensity of therapy). McCabe, et al. 2015 is not relevant to this review due to having an inappropriate comparison (all participants received the same intensity of therapy). You are correct that the RELEASE meta-analysis was identified and evaluated by the committee. On comparing the different results in this analysis, no clinically important differences were found between the different

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					comprehensive aphasia programmes may be considered from 3 months after stroke for those who can tolerate high-intensity therapy.' ICAPS deliver 6-7 hours a day of therapy and should be acknowledged. The NCG states 'One way of delivering higher doses of therapy is through comprehensive aphasia programmes, with positive results seen in one non-randomised trial (Hoover et al, 2017) and one observational study (Leff et al, 2021). However, not all people with aphasia can manage the high-intensity treatment mandated by these programmes. These studies suffer from selection bias and their results cannot be generalised to all people with aphasia, and more high quality research is needed.' There is no comment on doses of SALT require for PWA. It is clear that PWA require a minimum of 50 hours of SALT contact in order to make functional gains in their communicative ability. The evidence for this has accrued over the last 20 years and includes the RELEASE meta-analysis that the committee have included in their document Evidence review E, but doesn't seem to have made it through to the recommendation stage: Bhogal's	intensities in this analysis in improving communication outcomes. A research recommendation has been included in the guideline for more intense multidisciplinary team-led therapy delivered for 7 days a week compared to 5 days a week which offers the opportunity for investigation of the complexity of how rehabilitation is delivered.

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					seminal meta-analysis suggested 100 hours (Bhogal et al., 2003), the latest Cochrane review between 60 and 208 hours (Brady et al., 2016) and the most recent evidence from the RELEASE project, 50+ hours (Brady et al., 2022). One further comment. Separating PT, OT, SLT (and neuropsychology) as separate and independent treatments does not reflect clinical practice. Almost all stroke deficits will require MDT input, PT/OT for upper limb, SLT/OT/neuropsychology for aphasia/cognitive communication deficit. Although the committee can only consider the studies provided, recommendations for future research might include examining MDT-based treatments that reflect the fact that neurorehabilitation is a complex intervention (unlike drugs or surgery).	
27	Association of British Neurologists	Stroke Rehabilitation Guidelines	013	009	Telerehabilitation – we agree with these recommendations.	Thank you for your comment.

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28	Association of British Neurologists	Stroke Rehabilitation Guidelines	017	011	Fatigue - we agree with these recommendations.	Thank you for your comment.
29	Association of British Neurologists	Stroke Rehabilitation Guidelines	018	003	Include links to free-to-use apps that have been shown to be effective in controlled trails e.g.: Read-Right (Woodhead et al., 2015), for people with hemianopic alexia and Eye-Search (Ong et al., 2015; Szalados et al., 2020), for people with reduces visual search due to hemianopia. Ong, Y. H., Jacquin-Courtois, S., Gorgoraptis, N., Bays, P. M., Husain, M., & Leff, A. P. (2015). Eye-Search: A web-based therapy that improves visual search in hemianopia. Ann Clin Transl Neurol, 2(1), 74-78. https://doi.org/10.1002/acn3.154 Szalados, R., Leff, A. P., & Doogan, C. E. (2020). The clinical effectiveness of Eye-Search therapy for patients with hemianopia, neglect or hemianopia and neglect. Neuropsychol Rehabil, 1-12. https://doi.org/10.1080/09602011.2020.1751662 Woodhead, Z. V. J., Ong, Y. H., & Leff, A. P. (2015). Web-based therapy for hemianopic alexia is	Thank you for your comment. The use of apps to manage hemianopia was not identified as an area for review in this version of the guideline at scoping and we are not able to make a recommendation about this at this time.

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					syndrome-specific. BMJ Innovations, 1(3), 88-95. https://doi.org/http://dx.doi.org/10.1136/bmjinnov-2015-000041	
30	Association of British Neurologists	Stroke Rehabilitation Guidelines	018	009	Hearing - we agree with these recommendations.	Thank you for your comments.
31	Association of British Neurologists	Stroke Rehabilitation Guidelines	018	018	Mirror therapy is still a little controversial because it is deployed in so many different ways. Please state that it should be used as an adjunct to a multidisciplinary (PT and OT) upper limb rehabilitation programme, not instead of. The current wording simply suggests it can be used as part of a rehabilitation programme, which would allow mirror therapy to be used as the only upper limb treatment. The NCG recommendations are clearer – 'People with stroke may be considered for mirror therapy to improve arm function following stroke as an adjunct to usual therapy.'	Thank you for your comment. The committee agrees with you and the wording of the recommendation has been amended.
32	Association of	Stroke Rehabi	019	001	Mouthcare - we agree with these recommendations.	Thank you for your comments.

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	British Neurologists	litation Guidelines				
33	Association of British Neurologists	Stroke Rehabilitation Guidelines	022	010	Should probably add in the word 'app' as not identical to computer based programme and apps are more common	Thank you for your comment. The wording has been amended.
34	Association of British Neurologists	Stroke Rehabilitation Guidelines	022	010	It is not clear to us why two apps for patients with aphasia that have been subjected to RCTs and published in peer-reviewed journals have been omitted from the NICE guideline process. They are in scope, in the correct time period and are not in the excluded studies section of the relevant [J] Evidence reviews for computer-based tools for speech and language therapy, Appendix J – Excluded studies. iReadMore is an app that was tested in a registered, randomised clinical trial in PWA who had central alexia. Participants completed two 4-week blocks of iReadMore training (34 hours each). iReadMore training resulted in an 8.7% improvement in reading accuracy for trained words (95% confidence interval	Thank you for your comment. The developers had not identified Fleming, et al. as being a relevant study for the review, and have now added it, thank you for this. This does not change the results of the review. Woodhead, et al. is a study where all people receive the iReadMore intervention while the crossover trial compares people receiving transcranial direct current stimulation to people receiving sham transcranial direct current stimulation while participating in the study. Therefore, this is not a relevant comparator for this review. This has been added to the excluded studies table.

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					6.0 to 11.4; Cohen's d = 1.38) (Woodhead et al., 2018). Similarly, Listen-In, an app for PWA with auditory comprehension impairment was tested in a registered, randomised clinical trial. Repeated measures analyses of variance compared change in spoken language comprehension on two co-primary outcomes over therapy versus standard care. The first study-specific co-primary outcome (Auditory Comprehension Test (ACT)) showed large and significant improvements for trained spoken words over therapy versus standard care (11%, Cohen's d=1.12). Gains were largely maintained at 12 and 24 weeks (Fleming et al., 2020). Fleming, V., Brownsett, S., Krason, A., Maegli, M. A., Coley-Fisher, H., Ong, Y.-H., Nardo, D., Leach, R., Howard, D., Robson, H., Warburton, E., Ashburner, J., Price, C. J., Crinion, J. T., & Leff, A. P. (2020). Efficacy of spoken word comprehension therapy in patients with chronic aphasia: a cross-over randomised controlled trial with structural imaging. Journal of Neurology, Neurosurgery &	

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					Psychiatry, jnnp-2020-324256. https://doi.org/10.1136/jnnp-2020-324256 Woodhead, Z. V. J., Kerry, S. J., Aguilar, O. M., Ong, Y. H., Hogan, J. S., Pappa, K., Leff, A. P., & Crinion, J. T. (2018). Randomized trial of iReadMore word reading training and brain stimulation in central alexia. Brain, 141(7), 2127-2141. https://doi.org/10.1093/brain/awy138	
35	Association of British Neurologists	Stroke Rehabilitation Guidelines	026	015	The recommendation on robot-assisted arm training is misguided. The committee acknowledge that robotic devices can have an effect, but certainly no greater than face to face physiotherapy. However, robotic devices are simply impairment treating devices. Robotic devices are not meant to improve functional goals or quality of life. Turning impairment reduction into functional goals requires specialist treatment from PT/OT – the so-called 'transfer package'. The situation is similar to constraint induced movement therapy which requires education in how to transfer impairment gains into functional goals – the transfer package.	Thank you for your comment. The committee took into account cost-effectiveness data that indicated that robot arm therapy was not cost effective. To note, some of the studies included robot devices that were combined with conventional therapy (including physiotherapy and occupational therapy) where they were not able to achieve clinically important benefits in functional goals and quality of life, indicating that the impairment benefits could not be changed into clinically important functional gains and improved quality of life in those studies. Based on this, the assessment of the evidence including the

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					We know that robotic devices are not designed to have an effect on functional goals and QoL (the trials confirm this), but they can impact impairment, which can then be turned into functional gains and improved QoL by a multidisciplinary rehabilitation team. Recommending not using robots because of evidence that there is no effect on something they were not designed to do makes little sense. Robotic devices might reduce staffing needs to offset cost, but it is unclear whether this has been examined yet We suggest altering the recommendation to 'Robot-assisted arm training is not superior to physiotherapy, but may be used as an adjunct to treat impairment as part of a multidisciplinary approach to upper limb rehabilitation if devices are available'.	absence of cost-effectiveness, we will not change this recommendation. However, we appreciate that this is evolving technology and more supportive evidence may emerge in the future.
36	Association of British	Stroke Rehabilitation	029	006	We strongly agree that post-stroke shoulder pain should be actively sought as it is a major unnecessary cause of upper limb impairment	Thank you for your comment.

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	Neurologists	Guidelines				
37	Association of British Neurologists	Stroke Rehabilitation Guidelines	029	011	Steroid and nerve block injections may reduce pain, but must be combined with appropriate physical management, or else the problem will recur. For example, frozen shoulder is common after stroke, but requires physiotherapy. Physiotherapy will not work unless the pain is first managed. Please indicate that physical therapy also needed or else recommendation does not make sense.	Thank you for your comment. The committee agrees that shoulder pain management should be in conjunction with appropriate physiotherapy. Recommendations on intensity of physiotherapy are given in an earlier section of the guideline and should be applied when relevant to those with shoulder pain as well as those who are not experiencing this.
38	Association of British Neurologists	Stroke Rehabilitation Guidelines	036	009	The recommendation to test whether 7 day rehabilitation is better than 5 day rehabilitation will not be particularly fruitful, especially if delivered at current low doses (an extra 2 days of not very much is still not very much). It is widely accepted that a higher 'dose' of rehabilitation is more effective. Research should now focus on how to practically achieve the highest tolerable dose possible using combinations of MDT and technologies.	Thank you for your comment. There is currently insufficient evidence to firmly recommend an increase in dose of rehabilitation from 5 to 7 days. Moreover, the cost-effectiveness of this increase is not well supported by current evidence. We also note the number of comments where people are disappointed that we are unable to recommend 7-day rehabilitation and the research recommendation therefore addresses a perceived need for further data.

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39	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	The strength of evidence behind each recommendation does not come through	Thank you for your comment. Recommendations were written in standard NICE style and reflect strength of evidence through wording (for example: use of offer or consider). Please also see the rationale and impact sections that provide some information about how much evidence is available, and for more detailed information please see the individual evidence reports for each section.
40	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	No mention of sexual health post stroke including the use of phosphodiesterase inhibitors	Thank you for your comment. This topic was not put forward for inclusion during the scoping process and therefore was not part of this update.
41	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	There is nothing on apathy (which probably affects about a quarter of people after stroke)	Thank you for your comment. This was not prioritised for inclusion during the scoping process and therefore was not part of this update.

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42	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	No mention at all of "sleep" or "insomnia"	Thank you for your comment. This was not prioritised for inclusion during the scoping process and therefore was not part of this update. .
43	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	No mention of obstructive sleep apnoea which is common after stroke and can cause fatigue and affect stroke rehab / driving	Thank you for your comment. This was not prioritised for inclusion during the scoping process and therefore was not part of this update (although there is a section on fatigue).
44	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Common issues that are encountered are memory decline, cognition and fatigue post-stroke and there isn't clear guidance on which specific standardised tools to use and when to assess and who should be assessing them and in what setting. (e.g. Cognition, memory-how do I assess this? When do we assess at 6/52 or 6/12 roughly and is this in F/U or MDT setting with other professionals?)	Thank you for your comment. Assessment of memory and cognition is outside of the scope for this update of the guideline and therefore we did not compare the available assessment tools. A review of the assessment of fatigue was included and is present in section 1.7, specifying the recommended tools and frequency of assessment. The committee did not specify who should be assessing them nor

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						where because they did not want to limit this to specific roles and settings.
45	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Suggest recommendations on hand oedema management, complex regional pain syndrome post stroke, secretion management, management of dysphonia.	Thank you for your comment. These topics were not put forward for inclusion during the scoping process and therefore were not part of this update.
46	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Suggest including recommendations on fragility fracture assessment and addressing bone health in rehab	Thank you for your comment. These were not put forward for inclusion during the scoping process and therefore were not part of this update. The developers note that you have suggested a number of potentially valuable topics for inclusion in this and your preceding comments and would recommend that you put these forward during the scoping phase if/when this guideline is next updated. The comments will be passed to NICE's surveillance team.

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47	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	No clear mention of comorbidities. It is unusual to see a patient with just one problem post-stroke and they often have other health problems which can influence how rehabilitation can be delivered. E.g. a person with shoulder pain often has mood disorders, poor sleep and impaired physical fitness. So considering interventions that focus only on the shoulder are unlikely to be effective on their own. The complex interaction between physical and psychological factors hasn't really be addressed sufficiently, nor is there really an acknowledgement that many patients will have comorbidities and also more than one post-stroke problem	Thank you for your comment. We agree that comorbidities are important, but this is the case in all long-term medical conditions, and it is impractical to go into detail about them in each and every guideline. We would recommend considering other guidance as appropriate for the relevant comorbidities. When considering shoulder pain, the committee recommended to assess people with shoulder pain to identify the cause, which includes assessing the complex interaction of factors that lead to it (including physical and psychological factors).
48	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Consider review of the term 'feeding'. Can be considered demeaning to patients (we might 'feed' animals but people eat and drink).	Thank you for your comment. The wording has been changed to eating and drinking.
49	British and Irish Association of	Draft Guideline	General	General	Has the AGREEE II tool been used to guide the development process? There is a substantial gap in relation to implementation in practice.	Thank you for your comment. The AGREE II tool has not been used to guide the development process. This guideline has been developed following the processes in

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	Stroke Physicians (BIASP)					Developing NICE guidelines: the manual, following systematic reviews of the evidence and the committee's assessment of that evidence. AGREE II is a specific tool used for assessing the quality of practice guidelines but that hasn't been done here as we haven't used other guidelines as evidence.
50	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Needs to be global efforts to collaborate with other guideline developers to explore how to reduce duplication of effort. I'm sure that NICE has spent a lot of time doing its own literature searches-as have multiple other guideline developers. We need to find a way to reduce waste in guideline production. e.g. A systematic review and synthesis of global stroke guidelines on behalf of the World Stroke Organization - Gillian E Mead, Luciano A Sposato, Gisele Sampaio Silva, Laetitia Yperzeele, Simiao Wu, Mansur Kutlubaev, Joshua Cheyne, Kolawole Wahab, Victor C Urrutia, Vijay K Sharma, PN Sylaja, Kelvin Hill, Thorsten Steiner, David S Liebeskind, Alejandro A Rabinstein, 2023 (sagepub.com)	Thank you for your comment. In many ways we agree with you, but would also point out that NICE is unique in producing guidance which takes both clinical and cost-effectiveness from a UK perspective into account. NICE try to collaborate where possible and will use others systematic review work to avoid duplication if relevant reviews are done to the same standard and meet the review protocol criteria

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51	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	General	General	Has it been considered if patients with intracerebral haemorrhage and ischaemic stroke have the same rehabilitation needs? patterns of post-stroke impairments might be different in the two groups- and if so, should treatments depend on pathological type of stroke?	Thank you for your comment. The pathological type of stroke was not specified for sub-group analysis as the committee felt that this would be linked to pattern and severity of post-stroke impairment and that these are more relevant to rehabilitation needs. Patterns of post-stroke impairment (for example: location of stroke, severity of stroke) were analysed as subgroup analyses when data was available, and heterogeneity was not resolved using this factor.
52	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	009	General	1.2.3 suggest mention premorbid **frailty** specifically	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.
53	British and Irish Association of Stroke	Draft Guideline	009	003	1.2.1 suggest using the term **delirium** specifically	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.

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	Physicians (BIASP)					
54	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	009	017	1.2.2 I see no mention of a close MDT working (e.g. in the form of a post stroke cognitive clinic) to address post-stroke cognitive dysfunction by medical, OT and neuropsychology clinicians. There is no mention that the treating clinician should consider an underlying neurodegenerative condition (e.g. Alzheimer's disease) and referred to memory clinic, if appropriate. There was mention of "assessing cognition using valid assessment tools" but no examples were given (e.g. OCS, ACE-III) and there was no guidance about the timing of these assessments (or whether to avoid assessing in a HASU setting). Is this intentional?	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.
55	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	012	General	Consider aligning to the recently published National Clinical Guideline for Stroke. https://www.strokeguideline.org/	Thank you for your comment. Although various stakeholders have commented on differences between the two guidelines, we note that in most respects there is agreement between them. One important reason for any differences is that NICE guidance takes both clinical and cost-effectiveness into account.

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56	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	012	General	Regarding intensity of stroke rehabilitation. Suggest referring to the increased workforce needed to deliver this increase in rehabilitation	Thank you for your comment. This is already included in the rationale for the intensity section.
57	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	012	General	It is generally felt that lay peoples understanding of physiotherapy is much greater than occupational therapy and it our opinion that the guidance should be around the rehabilitation activity rather than the discipline delivering it. This would align with the approach with the National clinical guidelines.	Thank you for your comment. In most of the guideline the recommendations do as you say, focussing on what should be done rather than who does it. In a small number of instances the evidence dealt with a specific discipline, but even here the recommendations are made in terms of the type of therapy rather than the therapist.
58	British and Irish Association of Stroke Physicia	Draft Guideline	017	010	Great to see the new topic of fatigue. I think the paradigm for assessing fatigue-could have been extended. For mood disorders, the paradigm is to make a diagnosis (using a case definition/diagnostic interview)-and then assess severity. The same paradigm is used for Chronic fatigue syndrome-and for trials in CFS, eligibility	Thank you for your comment. We agree that mood disorders are important Consideration of mood disorders is a part of the psychological functioning section of the guideline and would happen concurrently with fatigue assessment.

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	ns (BIASP)				criteria are based on case definition fulfilment. So, discarding the case definition for fatigue after stroke because it might take too much time (in fact it doesn't, it's quick) and hasn't been extensively tested yet is arguably not the best approach. Also, when assessing fatigue, it's crucial also to look for coexisting anxiety and depression which frequently are associated with fatigue.	
59	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	017	010	We would also welcome some guidance on management of fatigue.	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue, and serve as a baseline against which active interventions can be tested. However, we have not conducted a

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						review into interventions for fatigue in this update.
60	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	018	018	1.8 Vision. We would welcome guidance on management strategies.	Thank you for your comment. Management of visual problems was not identified as a priority for update during scope consultation.
61	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	019	General	Suggest mention risk feeding as per RCSLT guidelines. https://www.rcslt.org/members/clinical-guidance/eating-and-drinking-with-acknowledged-risks-risk-feeding/#section-2 and as per RCP guidelines https://www.rcplondon.ac.uk/projects/outputs/supporting-people-who-have-eating-and-drinking-difficulties	Thank you for your comment. The committee have discussed this and agree that the issue of risk feeding occurs reasonably frequently and should be mentioned within the updated section on swallowing. A consensus recommendation has been added.
62	British and Irish Association of	Draft Guideline	019	013	1.11 Swallowing. We recommend they consider mentioning transcutaneous neuromuscular electrical stimulation (NMES) for post stroke dysphagia, as per NICE IPG634 published in 2018 (1	Thank you for your comment. There was insufficient evidence to recommend neuromuscular electrical stimulation firmly for post stroke dysphagia. Therefore, a research

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	Stroke Physicians (BIASP)				Recommendations | Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults | Guidance | NICE)	recommendation was made. The guidance provided by NICE IPG634 applies as previously (that if people wish to use it then they should inform the clinical governance leads in their NHS trusts, ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these and provide them with clear written information to supported shared decision making, and audit and review clinical outcomes of all people having neuromuscular electrical stimulation for oropharyngeal dysphagia).
63	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	019	013	We could not see the use of validated screening tools (at bedside e.g.- GUSS, TOR-BSST, or further interventions such as VFSS, FEES)	Thank you for your comment. The assessment of dysphagia was not identified as an area for update in the scope for the guideline and the evidence for these tools has not been evaluated.
64	British and Irish Association of Stroke	Draft Guideline	024	018	Fitness training. Whilst the recommendation is consistent with the RCP guidance, it is disappointing that there is really no mention of involving fitness instructors in its implementation (or for that matter, to consider fitness instructors as part	Thank you for your comment. This topic was not put forward for inclusion during the scoping process and therefore was not part of this update.

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	Physicians (BIASP)				of the multidisciplinary team). There has been extensive work done about implementation of fitness training-there are Scottish Government funded recommendations-and also evidence from Australia and USA about how to put this into practice.	
65	British and Irish Association of Stroke Physicians (BIASP)	Draft Guideline	033	General	1.17.3 consider including driving assessment referral as a recommendation	Thank you for your suggestion. Medical fitness to drive is dealt with in DVLA documentation and was not in the scope for this guideline update.
66	British and Irish Orthoptic Society	Guideline	004	011	Audiology are not listed as a service for which access should be provided when needed despite there being a hearing section further into the guideline (section 1.9)	Thank you for your comment. Audiology has been added.
67	British and Irish Orthoptic Society	Guideline	005	008	Great to see orthoptists listed as a core member of the MDT	Thank you for your comment.

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68	British and Irish Orthoptic Society	Guideline	014	003	Visual impairment should be listed as an impairment which needs to be taken into account when providing information	Thank you for your comment. We agree that this is important. The recommendation states that the person's information needs and how to deliver this information should be identified. A holistic approach should be taken for this. The examples given (following the words 'such as') are intended as examples only, not a comprehensive list.
69	British and Irish Orthoptic Society	Guideline	015	011	Prism glasses are listed here but a recent Cochrane review (Longley et al., 2021) stated no high-quality evidence found for this intervention. Non-drug treatments for spatial neglect/inattention following stroke or adult brain injury | Cochrane	Thank you for your comment. This recommendation is from 2013 and the evidence was not formally reviewed as part of this update. The Cochrane review emphasises that, while high quality evidence is lacking in the authors' opinion, this does not mean that the treatment is ineffective.
70	British and Irish Orthoptic Society	Guideline	017	1.8.1	There is a repetition of "after stroke" in this sentence, needs one of them removing	Thank you for your comment. The recommendation has been amended.
71	British and Irish Orthopti	Guideline	017	1.8.3	This statement should be reworded as follows: "Offer scanning therapy to people who have persisting homonymous visual field loss (blindness	Thank you for your comment. The committee agrees and the wording of this recommendation has been amended.

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	c Society				in one side of the visual field of both eyes) after stroke and regardless of whether they are aware of it." This is because a high percentage of stroke survivors cannot or do not report symptoms of visual field loss (Hepworth et al., 2021) this shouldn't impact on the treatment offered. "Eye" Don't See: An Analysis of Visual Symptom Reporting by Stroke Survivors from a Large Epidemiology Study - ScienceDirect	
72	British and Irish Orthoptic Society	Guideline	018	019	There is no advice within this section on management of eye movement disorders or alleviation of symptoms such as diplopia.	Thank you for your comment. The management of eye movement disorders and symptoms was outside the scope for this update of the guideline.
73	British and Irish Orthoptic Society	Guideline	032	007	Visual demands of the job should also be identified, in addition to the others listed in the first bullet point	Thank you for your comment. This is a 2013 recommendation and was not reviewed as part of this update.
74	British and Irish Orthoptic Society	Guideline	048	1.8.1/1.8.2	Clarification needs to be made that no evidence was found in relation to the questions posed by the guideline. Currently the wording "No evidence was identified in the review" and "There was a lack of evidence for assessing vision problems after stroke"	Thank you for your comment. The first sentence has been amended.

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					it makes it sound as if there is no evidence relating to post-stroke visual impairment.	
75	British and Irish Orthoptic Society	Guideline	048	1.8.1/1.8.2	The guideline states "Many people experience problems with there eyesight" there are specific incidence and prevalence figures published (Rowe et al., 2019) High incidence and prevalence of visual problems after acute stroke: An epidemiology study with implications for service delivery | PLOS ONE	Thank you for your comment. This incidence and prevalence data is included in the more detailed committee discussion of the review (Evidence review C). The purpose of the rationale and impact section is to summarise this briefly.
76	British and Irish Orthoptic Society	Guideline	048	1.8.1/1.8.2	Add in falls to sentence about safety risks	Thank you for your comment. This has been added.
77	British and Irish Orthoptic Society	Guideline	063	General	Could vision be added in to the list of issues which exacerbate other problems and impede recovery	Thank you for your comment. Vision has been added.
78	British Association of Art Therapists;	Guideline	012	General	1.2.18 Regarding rec 1.2. 15 (specification of three therapies) and 1.2.18 "Ensure all rehabilitation sessions: • include activities linked to the person's goals; • are tailored to any ongoing medical needs, including post-stroke fatigue; • take into account any psychological factors (such as the person's mood or	Thank you for your comments. The therapies named in recommendation 1.2.15 are needed by a majority of people after stroke, and they were prioritised for inclusion in the intensity review at stakeholder consultation. In fact we found limited evidence for other

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	British Association of Music Therapists; Association for Dance Movement Psychotherapy UK; British Association of Dramatherapists				motivation on the day of the session). Base the timing, sequencing and content of the sessions on these goals, interests and needs, with the person's agreement." We are concerned that only occupational therapy, physiotherapy and speech and language therapy are specified. Many people experience depression, anxiety and sometimes severe emotional sequelae following stroke, and there is some evidence that arts therapies and arts participation can address mood and self-esteem post-stroke (Alwledat et al., 2023; Baumann et al., 2012; Beesley et al., 2011; Kongkasuwan et al., 2016; Rushing et al., 2022). Also, providing interventions tailored to potentially important "goals, interests and needs" goes beyond functionality alone, and may make the work of rehabilitation more motivating and meaningful; such as the universal human need for expression and creativity, and some people's particular need to re-claim lost abilities in arts-related or creative activities (e.g. Michaels, 2010; Pąchalska et al., 2021). Whilst ameliorating purely physical and speech comprehension and production difficulties is essential, people also have spiritual, vocational, creative and expressive needs. Arts therapies are	types of therapy when comparing different intensities of rehabilitation. Arts therapies (with the exception of music therapy) were not included in the scope for this guideline and so the evidence was not reviewed. Music therapy was reviewed in evidence review N but insufficient evidence was found to recommend it at this time. The committee acknowledge that various forms of art therapy may be of value to people recovering from stroke depending on their individual interests. Community participation interventions, which may include arts participation, are recommended (see recommendation 1.17.6).

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					routinely offered in some countries and contexts but their presence is patchy. Where they are available, they can not only help with low mood, but can distract from pain, and reconnect people with things that are meaningful to them in their lives, including religion and spirituality, which go beyond pure functioning (e.g. see review by Lo et al., 2018). Group arts therapies and arts-based activities are also cost-effective and provide opportunities for social connection (e.g. Gegor et al., 2021). We further suggest that the need for interventions and rehabilitation sessions to be culturally competent should be mentioned (e.g. see Ng'Uni, 2017). References: Alwledat, K, Ali AM, Abuzied Y, et al. (2023). Creative art therapy for improving depression, anxiety and stress in patients with stroke: a quasi-interventional study. SAGE Open Nursing, 9, 1-10. DOI: 10.1177/23779608231160473	

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					Baumann, M, Peck, S, Collins, C & Eades, G (2013) The meaning and value of taking part in a person-centred arts programme to hospital-based stroke patients: findings from a qualitative study, Disability and Rehabilitation, 35:3, 244-256. Beesley, K, White, JH, Alston, MK, Sweetaple AL, & Pollack, M. (2011) Art after stroke: the qualitative experience of community dwelling, Disability and Rehabilitation, 33(23-24):2346-55 Gregor, S, Vaughan-Graham, J, Wallace, A, Walsh, H, & Patterson, K,K (2021) Structuring community-based adapted dance programs for persons post-stroke: a qualitative study, *Disability and Rehabilitation*, 43:18, 2621-2631. Lo Temmy Lee Ting, Lee Janet Lok Chun, Ho Rainbow Tin Hun (2018). Creative Arts-Based Therapies for Stroke Survivors: A Qualitative Systematic Review. *Frontiers in Psychology, 9,* 1664-1078.	

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					Michaels, D. (2010). A space for linking: Art therapy and stroke rehabilitation. *International Journal of Art Therapy,* 15, 65-74. Ng'Uni, A (2017). The effect of therapeutic art therapy on cognitive function in post stroke older adults at the university teaching hospital. MSc dissertation, University of Zambia. Kongkasuwan R, Voraakhom K, Pisolayabutra P, Maneechai P, Boonin J, Kuptniratsaikul V. (2016) Creative art therapy to enhance rehabilitation for stroke patients: a randomized controlled trial. Clin Rehabil. Oct;30(10):1016-1023. doi: 10.1177/0269215515607072. Pąchalska, M., Góral-Półrola, J., & Chojnowska-Ćwiąkała, I. (2021). Effects of individually-tailored TDCS and symbolic art therapy for chronic associative prosopagnosia after infection by SARS-COV-2, neuro-COVID-19, and ischemic stroke. *Acta Neuropsychologica,* 19(3), 2021, 329-345. Rushing, J, Capilouto G, Dressler EV, et al. (2022). Active music therapy following acute stroke: a	

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					single-arm repeated measures study. *Journal of Music Therapy,* 59(1), 36-61	
79	British Association of Art Therapists; British Association of Music Therapists; Association for Dance Movement Psychotherapy UK; British Association of	Guideline rationale and impact section	054-055	Walking therapies & group circuit training	Walking therapies and group circuit training are recommended on the basis of small studies with uncertain numbers of staff and risk of bias. It is stated that they were "supported by the personal experience of some committee members" and can be offered by band 4 and 5 physiotherapists and assistants and so are not expensive. Studies on group arts therapies and arts activities (not among the recommended therapies), have similar quality issues but some promising indications. We support the recommended therapies, but we are concerned that there are disparities in which therapies become 'recommended by NICE' based on what appears to be an insufficiently rigorous processes of decision-making. Given that patient choice is helpful to eventual outcomes, this may need to be addressed. Perhaps where high-quality evidence is lacking, there is a need to improve representation in relation to who is on the committee or whose experience feeds into it, based on therapies that are currently offered in a significant number of places, or to devise a way of ensuring and demonstrating that	Thank you for your comment. Specific recommendations on walking therapy and group circuit training were made because this topic was prioritised for evidence review after stakeholder consultation on the scope of the guideline update, not because of the people on the committee. Group art therapies and art activities (with the exception of music therapy, see Evidence review N) were not included in the scope because they were not put forward at the time of scoping. With regards to music therapy, a different outcome was reached. However, the difference came in a) the amount of clinical evidence and the larger sample sizes of some trials included in that evidence, and b) while the economic evidence suggested that circuit class training was not cost-effective (Dean, et al 2018; Harrington, et al 2010), both analyses were based on a single trial respectively, and showed better outcomes for the control group. This is in contrast to the wider evidence base,

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	Dramatherapists				the same evidence standards are applied to all therapies.	which reported clinical benefits and no harms compared to usual care. Circuit training was also not considered to incur large additional costs either, as classes can be delivered by band 4 or 5 physiotherapists, as well as physiotherapy assistants. While there was evidence of cost-effectiveness for one intervention for music therapy (Tarrant, et al. 2021), there were limitations to this that effected the applicability of the results and made it so that it was difficult to apply to the NHS, c) the potential cost savings that a group based approach could take compared to individual therapy. Committee members had positive experiences of both interventions, as communicated in the committee discussions of both evidence reports. Taking into account all of these factors, the committee recommended circuit training rather than music therapy. All the recommendations are quality assured by an independent team at NICE to make sure that the processes, methods and decisions behind the recommendations are rigorous and

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						justified. Stakeholder consultation adds a further layer of scrutiny.
80	British Dietetic Association (BDA) Neurosciences Specialist Group	Guideline	004	019	Good nutrition and hydration are essential to health and recovery. Both malnutrition and dehydration are common in hospital inpatients with stroke and are associated with poor outcomes. Adequate workforce provision of both clinician and catering dietetic roles are key to ensuring the importance of food, nutrition and hydration is understood and integrated into a patient's nutritional goals, contributing to a positive rehabilitation environment. It is therefore disappointing to see dietetics included in "provide access to other services" rather than included in the core MDT for an inpatient stroke unit. This also conflicts with recommended staffing from the 2023 National Clinical Guideline for Stroke, section 2.5	Thank you for your comment. Dietitians have been added to the list in the core MDT.
81	British Dietetic Association (BDA)	Guideline	013	015	Section 1.3.2: Consider adding in: "access to a therapist for support" (as is called out in National Clinical Guideline 2023 Aphasia section 4.43, recommendation C)	Thank you for your comment. Recommendation 1.3.2 is not equivalent to the recommendation I in section 4.43 of the National Guideline. That section is about aphasia whereas our 1.3.2 applies to other

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	Neurosciences Specialist Group					forms of telerehabilitation as well, and indeed is probably most relevant to physiotherapy at present. It will usually consist of a remote link to a session conducted by a therapist, and the person after stroke automatically has access to the therapist. In the communication section of the NICE guideline computer-based programmes are recommended but only in the limited context of word finding, and as an adjunct to face to face speech therapy rather than a substitute. .
82	British Dietetic Association (BDA) Neurosciences Specialist Group	Guideline	019	001 - 011	Section 1.10: Would recommend adding the importance of communicating any care plan across care settings	Thank you for your comment. Please see recommendation 1.1.14 which discusses communicating information on transfer.
83	British Dietetic Associat	Guideline	019	020 - 021	Recommendation 1.11.3: Recommend amending to "Give families and carers information about dysphagia (difficulty in swallowing) and advice on	Thank you for your comment. We think that you are suggesting combining 1.11.3 with recommendation 1.11.2. These are

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	ion (BDA) Neurosciences Specialist Group				what to do if someone is coughing or choking while eating and drinking."	2 separate actions and it is preferred to keep them in separate recommendations.
84	British Dietetic Association (BDA) Neurosciences Specialist Group	Guideline	020	014 - 019	Recommendation 1.11.6: Re: Would it be challenging to implement any of the draft recommendations? - Would argue it will be difficult for staff to implement a free water protocol, particularly in acute/other care settings. Currently there are incidents where provision of food/fluids has not been inline with SLT recommendations, posing risk to patient safety. Allowing an individual different textures of fluids introduces an opportunity for error. Are there trialled resources/bundles/protocols to support successful implementation of such a protocol that can be shared to minimise risk?	Thank you for your comment. This recommendation has been removed following comments from a number of stakeholders.
85	British Dietetic Association (BDA)	Guideline	020	005 - 006	Suggest adding in reference to IDDSI (International Dysphagia Diet Standardisation Initiative) for fluid and diet modification descriptors, as an internationally recognised set of descriptors (IDDSI - Home).	Thank you for your comment. We believe that this level of detail is not required for what is a single bullet point within a recommendation.

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	Neurosciences Specialist Group					
86	British Dietetic Association (BDA) Neurosciences Specialist Group	Guideline	020	006	Recommendation 1.11.4, bullet point #3: The recommendation suggests one example of modification of diet is through changing the texture of the diet. This suggests there are other ways of modifying diet that should be considered eg portion size, temperature, flavour etc. The question therefore is: is there evidence to support diet modification strategies, beyond texture modification? The current wording suggests there are but does not specify these.	Thank you for your comment. The evidence was limited in this area. In one study diet modification included consistency based on the results of an MBS evaluation (DePippo, et al. 1994). In another the study did not provide a clear explanation as to what was meant, but stated 'appropriate dietary modification' (Carnaby, et al. 2006). The committee did not want to prevent healthcare professionals from using approaches that were appropriate based on their expertise but provided an example identified from the studies.
87	British Dietetic Association (BDA) Neurosciences	Guideline	066	Table 2	Table 2: Recommend adding in dietitian to core MDT (dietitians are part of recommended staffing for hyperacute, acute and rehab units in the National Clinical Guideline for Stroke 2023). The purpose is for patients after a stroke, who are unable to maintain adequate nutrition and hydration orally, to have access to a dietitian for specialist dietetic assessment, advice and monitoring. This can	Thank you for your comment. Dietitians have been added to the core MDT membership.

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	Specialist Group				inform MDT shared decisions regarding nasogastric tube and or gastrostomy feeding (Overview | Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition | Guidance | NICE)	
88	British Psychological Society	Draft Guideline	General	General	We have noted that there is a lack of explicit mention within the guidance of post-stroke emotionalism. It is our view that, given the known prevalence of post-stroke emotionalism; its impact on rehabilitation and recovery; its probable association with anxiety; and the now-available TEARS-Q screening tool, post-stroke emotionalism must be addressed within the final guidance. **Comments 3-6 outline our specific suggestions on where to include this.**	Thank you for your comment. This topic was not put forward for inclusion during the scoping process and therefore was not part of this update. We would suggest that you raise it when the guideline is next updated. It will be passed on to the NICE surveillance team.
89	British Psychological Society	Draft Guideline	General	General	This comment provides references to evidence informing our suggestions on post-stroke emotionalism (PSE). Please see: **PSE prevalence** https://doi.org/10.1136/jnnp-2022-329042	Thank you for the references.

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					https://doi.org/10.1016/j.jstrokecerebrovasdis.2015.11.038 **TEARS-Q screening** https://doi.org/10.1177/0269215520981727 https://doi.org/10.1177/02692155211024801 **PSE lived experience** https://doi.org/10.1080/09638288.2021.2002439 **Interventions** https://doi.org/10.1080/10749357.2019.1654241	
90	British Psychological Society	Draft Guideline	014 - 016	General	We are concerned that under Section 1.5: Cognitive Functioning, there is no mention of executive functioning. **We suggest adding the following sub-section under Section 1.5:**	Thank you for your comment. This was not prioritised for inclusion during the scoping process and therefore was not part of this update.

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					[Executive Functioning **1.5.10: Assess for executive functioning, including: the ability to plan, organise and execute goal-orientated activity; the ability to initiate and inhibit behavioural and emotional responses; any impacts on insight as well as social awareness and interaction.** **1.5.11: Assessment of executive functioning is to include the consideration of impaired executive functioning on the mental capacity to make fully-informed decisions, in the context of the Mental Capacity Act and 'frontal lobe paradox'.]**	
91	British Psychological Society	Draft Guideline	016-017	General	Under Section 1.6: Psychological Functioning, we **suggest adding the following guideline:** **[1.6.6: Ensure that mood screening uses validated tools that are adapted for people with communication difficulties.]**	Thank you for your comment. Section 1.6 has not been updated and the evidence on screening tools was not evaluated. If you feel that substantial changes are justified the developers suggest that you put these forward at the scoping stage of any future updates. The topic will be passed on to the NICE surveillance team.

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92	British Psychological Society	Draft Guideline	009	026 - 030	We suggest adding a line under section 1.2.3 *(after line 24 –* '*changes to, or impairment of, psychological and neuropsychological 24 functioning relating to:')* **[add subheading '– post stroke emotionalism (uncontrollable crying or laughter after stroke)']**	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.
93	British Psychological Society	Draft Guideline	012	018	We suggest line 18 be reworded to: **[take into account any psychological factors (such as the person's mood, motivation or emotionalism on the day of the session).]**	Thank you for your comment. Emotionalism affects a significant number of people after a stroke, but it is not a condition which is present one day and not the next. The point of this recommendation is to adapt rehabilitation activity in accordance with the person's mood or motivation each day.
94	British Psychological Society	Draft Guideline	016	018	We suggest adding the following to line 18: **[their emotional functioning, including post-stroke emotionalism]**	Thank you for your comment. Although a change was made to this recommendation as a safety consideration, the topic was not reviewed for this update and we cannot make more extensive changes.
95	British Psychol	Draft Guideline	017	003 - 005	We suggest the following rewording of section 1.6.4: **[When new or persisting mood and emotional difficulties including emotionalism are identified**	Thank you for your comment. Section 1.6 has not been updated and the evidence on mood and emotional difficulties

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	ogical Society				**at the persons 6-month or annual stroke review, refer them to appropriate services for detailed assessment and treatment]**	including emotionalism was not evaluated. If you feel that substantial changes are justified, we suggest that you put these forward at the scoping stage of any future updates. The topic will be passed on to the NICE surveillance team.
96	British Society of Physical and Rehabilitation Medicine	Draft guideline	004	005-010	1.1.1 Stroke Units A proportion of patients with stroke will experience significant disabilities which will need input from a specialist neuro rehabilitation team. This is like the needs of the people recovering from major trauma. The stroke patients identified as having complex needs should be referred for a review by a specialist in rehabilitation medicine and if required and transferred to Level 1 or 2 specialist inpatient rehabilitation unit. **Rehabilitation Prescription:** In other areas (e.g., trauma) a patient held rehabilitation prescription (RP) is recommended to identify ongoing rehabilitation needs and a clear plan for how these will be met – especially if the needs are complex. Proof of principle for the RP was provided in the national clinical audit for specialist rehabilitation following major injury (nhs-audit-report-v9-rgb.pdf	Thank you for your comment. The committee agrees that a significant minority of people will need care in a specialist rehabilitation unit and recommendation 1.1.1 has been amended accordingly. Evidence supporting rehabilitation prescriptions was not looked for because this was not in the scope of the guideline.

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					(kcl.ac.uk). If this principle works for trauma surely it would make sense to apply it for stroke patients with complex rehabilitation needs. BSPRM request NICE to review this evidence and include RP for all stroke patients as a part of the guidance.	
97	British Society of Physical and Rehabilitation Medicine	Draft guideline	005	007-018	1.1.3 A core multidisciplinary stroke rehabilitation team should comprise the following professionals with expertise in stroke rehabilitation Specialists in Rehabilitation Medicine: Please include specialists in rehabilitation medicine as a part of the multidisciplinary team for stroke rehabilitation. In following circumstances, the referral to rehabilitation medicine should be considered. Hemicraniectomy Stroke causing Tetraplegia. Spinal cord stroke Locked in state. Prolonged Disorders of consciousness after stroke Oral secretion management Persistent Shoulder pain Spasticity affecting hand muscles. Lower limb spasticity Contractures	Thank you for your comment. The committee agree that there should be access to rehabilitation units and specialists and have amended the relevant recommendations.

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					Unable to mobilise after 4 weeks of stroke. Persistent disability after 20 weeks after stroke Needs for vocational rehabilitation. Complex rehabilitation needs (Category A or B) requiring a Level 1 or 2 rehabilitation service.	
98	British Society of Physical and Rehabilitation Medicine	Draft guideline	012	001-006	1.2.15.Offer people after stroke the following therapies, if needed, for at least 5 days a week: The two-day weekend break could potentially lead to loosing of some rehab gains. BSPRM would recommend providing minimum of 1 hour of therapy on weekends. The type of therapy could be determined by the treating MDT.	Thank you for your comment. This appears to make sense, but we found very limited evidence examining intense rehabilitation delivered for 7 days a week. However, based on the committee's expertise and qualitative evidence, the committee recommended that therapy should be for **at least** 5 days a week. Emphasis was given in the recommendations that therapy timing, sequencing and content should be based on the person's goals with the person's agreement and this should include consideration of 7 days of therapy.
99	British Society of Physical and	Draft guideline	013	009-020	1.3 Telerehabilitation. BSPRM agree that telerehabilitation is the way forward. Currently the organisation and delivery of such services are not robust. It will be useful to add a recommendation for regular once in 4 weeks face	Thank you for your comment. The committee acknowledges that service development will be required for implementation of telerehabilitation services in a manner which works well for everyone. The

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	Rehabilitation Medicine				to face review of the patient by an MDT team member in the community to hospital.	studies did not discuss once in 4 weeks face to face review between the person after stroke and an MDT member, so we would not be able to support this based on the evidence. Recommendation 1.3.1 states that telerehabilitation could be considered instead of, or as well as, face-to-face therapy. Therefore, if this is a concern for either party then they could agree to regular follow up on a time frame that best suits them. From the examples of when a combination of telerehabilitation and face-to-face therapy was provided we are not able to provide an ideal time frame for this due to the heterogeneity in the studies included in the analysis.
100	British Society of Physical and Rehabilitation Medicine	Draft guideline	017	010-017	1.7 Fatigue: We are supportive of the move to include fatigue. The draft guideline lacks guidance on interventions for fatigue. We world recommend including following interventions if the screening shows fatigue. If fatigue is present, then to look for causes such as pain, sleep disturbances including sleep disordered breathing,	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made

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					nutritional, endocrine, depression, iatrogenic- use of anti-seizure medications like levetiracetam and anti-spasticity medications like Gabapentin and Pregabalin, opioids for pain. 2. The draft guideline recommends only the assessment of fatigue and makes no mention of its management. Reference could be made to NICE guidance on other fatiguing conditions like Post COVID Syndrome. There is a particular indication to consider High Intensity Interval Walking Training in long term stroke survivors (Boyne P et al Optimal intensity and duration of walking rehabilitation in patients with chronic stroke: A randomised clinical trial. JAMA Neurol 2023. https://doi.org/10.1001/jamaneurol.2023.0033 In patients with fatigue there is need to tailor the rehabilitation activities to the fatigue levels- shorter sessions, and time tabled rest times. 3. Advice on how to manage fatigue. Occupational therapy to advice on energy conservation techniques.	recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue and serve as a baseline against which active interventions can be tested. However, we have not conducted a review into interventions for fatigue in this update.

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101	British Society of Physical and Rehabilitation Medicine	Draft guideline	019	013	1.11 Swallowing Please include oral secretion management under this session. Oral secretions can cause drooling, social isolation and aspiration. The management strategies include. Oral exercise by SLT Medications such as Hyoscine patch, glycopyrrolate and botulinum toxin injections. The botulinum toxin injections need to be done in consultation with a rehabilitation medicine consultant.	Thank you for your comment. Exercises and pharmacological treatments for troublesome oral secretions were not put forward for inclusion in the update during scoping, and the evidence for them was not considered by the committee.
102	British Society of Physical and Rehabilitation Medicine	Draft guideline	021	012	1.12 Communication Please consider screening people with communication difficulties for depression using a validated tool	Thank you for your comment. This section was not updated as a part of the current update.
103	British Society of Physical and Rehabilit	Draft guideline	030	014-020	1.15 .5 Spasticity BSPRM has significant concerns about this part of the draft guideline. The draft guidelines have not considered that National clinical guidelines for management of spasticity adults(http://www.rcplondon.ac.uk/guidelines-	Thank you for your comments. The committee is aware of the National clinical guidelines for the management of spasticity in adults and other key national and international guidelines. However, they have considered the evidence base by conducting a systematic review of the

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	ation Medicine				policy/spasticity-adults-management-using-botulinum-toxin) and other key national and international guidelines. 1. The guidelines recommend a specific brand of botulinum toxin (Dysport). There are 3 licenced products We would recommend removing the brand names from the guidelines and use generic name – botulinum toxin. 2. The dosage will depend on the severity and distribution of spasticity and the goals for treatment. Instead of mentioning a specific dose (which will be insufficient in a substantial proportion of cases and for which there is no evidence base) the guideline should refer to the national clinical guidelines for management of spasticity adults published by the royal college of physicians (Spasticity in adults: management using botulinum toxin RCP London). Botulinum toxin should only be administered in the context of an appropriate multidisciplinary rehabilitation programme targeted towards the goals for treatment. 3. The guidelines recommend Botulinum toxin only for focal spasticity of the upper limb. The mechanism of spasticity is same for both upper and lower limbs. We do not understand the rationale	evidence for interventions for spasticity, and investigating the clinical and cost-effectiveness of these. This evidence showed that each brand of botulinum toxin produced clinically important benefits in improving spasticity outcome measures, but only Dysport showed clinically important benefits in reducing pain, while only BOTOX showed clinically important benefits in improving activities of daily living scores (all when compared to placebo). The only scenario offering a cost effective strategy for using botulinum toxin A was when Dysport up to a dose of 1000 units per treatment or up to 400U of Xeomin, spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time. Other types of botulinum toxin were not found to be cost effective. There was only evidence available for health economic modelling (MAS responder data) for BOTOX in lower limb, and it was not found to be cost effective. Therefore, the committee did not make a recommendation in

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					behind this recommendation. The toxin is widely used for focal spasticity of the lower limb. BSPRM would recommend including botulinum toxin injections for management of spasticity in lower limb.	this case but made a research recommendation instead. The committee did not make a 'do not' recommendation in this scenario, but in the absence of evidence of benefit and cost-effectiveness they are unable to recommend treatment with botulinum toxin A for the lower limb or with brands of botulinum toxin apart from Dysport (up to 1000U) and Xeomin (up to 400U).
104	British Society of Physical and Rehabilitation Medicine	Draft guideline	033	004	1.17: Long term health and social support We welcome the decision to include this in the guidelines. The Specialists in rehabilitation medicine consultants have expertise and experience in managing people with the long-term permanent disabilities and vocational rehabilitation. We would suggest referring the patients with persistent disabilities 6 months after the stroke to Rehabilitation medicine specialist for ongoing management and long term follow up. The specialist in rehabilitation medicine should review these patients annually and provide following inputs: Monitoring for and prevention of complications due to immobility such as contractures, pressure ulcers Liaison with community rehabilitation teams	Thank you for your comment.

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					Management of spasticity Management of incontinence Management of post stroke depression and other mood disorders Vocational rehabilitation Monitoring of mobility aids Seating and wheelchair	
105	British Society of Physical and Rehabilitation Medicine	General	General	General	British Society of Physical and Rehabilitation Medicine (BSPRM) is the leading professional body for doctors who are specialists in Rehabilitation medicine and other healthcare professionals involved in the field of rehabilitation medicine in the UK. The Society is dedicated to advancing the knowledge and practice of rehabilitation medicine in the UK, and to promoting excellence in patient care. We represent physicians, surgeons, nurses and healthcare professionals, who are passionate about improving the lives of patients with disabilities. BSPRM is thankful to NICE for providing us with an opportunity to review draft of new NICE guidelines on rehabilitation following stroke. The rehabilitation medicine has a separate training programme with a set of competencies and curriculum. The specific roles of a rehabilitation medicine doctor relate to the process of	Thank you for your comment. The developers note this is a 2013 recommendation. However, the committee have discussed your suggestion and agree that rehabilitation specialists should be included.

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					rehabilitation, and management of specific issues related to impairments such as spasticity, weakness, cognitive problems, communication and behavioural issues. No other profession has this kind of specific, focussed training on rehabilitation. We note with concern that the speciality of rehabilitation medicine is excluded from the recommendations for members of the multidisciplinary team for stroke rehabilitation. This will deprive opportunities for patients, especially for those with more complex needs, from gaining from inputs from doctors trained specifically to address their complex needs. These stroke survivors require review, assessments, interventions and ongoing oversight by a consultant in rehabilitation medicine. BSPRM urge NICE to review and rectify this glaring omission which is detrimental to the long-term management of people with complex needs after a stroke.	
106	Communication Matters	Draft guideline	General	General	It is focused on the communication section (1.12) on page 21. ***Augmentative and Alternative Communication (AAC) refers to any strategies, equipment or technology used by individuals who have***	Thank you for your comment. Please note that most of section 1.12 was not identified as needing an update following consultation on the scope with stakeholders. The only exception is recommendation 1.12.8 which concerns computer-based aids to

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					difficulty speaking to enhance the effectiveness of their participation in communicative interactions. Examples range from computer-based voice output systems, specialist software and apps on mainstream tablets to paper-based communication books and partner supported written choice. People with both motor speech difficulty and/or language impairment following stroke may benefit from AAC. Need for AAC following stroke may be lifelong or transient. ***Within the guideline we would like to see a clearer distinction between the important computer-based tools used to support the delivery of therapy and those tools/technologies (AAC) that support participation in conversation/interaction.***	speech and language therapy and specifically recommends those which aid word finding. The committee recognise that this is a developing area and that evidence supporting a broader range of communication therapies may become available. The topic will be passed on to the NICE surveillance team.
107	Intercollegiate Stroke Working Party	Draft Guideline	General	General	**General**. The Working Party was significantly concerned by the inconsistencies in the appraisal of the available evidence by the committee. On the one hand the committee considered an extensive appraisal of the evidence regarding rehabilitation intensity in attempting to draw a narrow distinction between the cost-effectiveness, for example, of 5-	Thank you for your comment. The same standards of evidence assessment were applied to every question addressed by this update in that a thorough search for all relevant clinical and cost-effectiveness evidence was made. The disparity in length of the sections reflects the disparity in the amount

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					day therapy compared to 7-day therapy, and on the other it would appear that 'personal experience of some committee members' was sufficient to make significant generalisations regarding, for example, universal hearing assessments. This suggests that a different evidentiary standard was being applied by the committee to different areas of clinical practice, something that undermines confidence in the rigour of the overall evidence appraisal process, and could suggest that some voices on the committee were taking an unjustified predominance over other, more evidence-based voices. This cannot be a good impression to be leaving the reader with when there are such significant resource implications for many of the guideline recommendations – the hard graft of implementing these recommendations must be properly supported by evidence or at the very least, a broad and transparent expert consensus.	of evidence available to analyse. Taking account of personal experience of the GC membership is in accordance with NICE methods and process where evidence is lacking. In addition, there is independent quality assurance (QA) by a NICE QA team (separate from those who develop the guidance) and the process of stakeholder consultation to review the work done and include a wider expert input than just the committee. This is all to make sure the decision-making is rigorous, transparent and of a high standard. The committee have reconsidered the recommendation to assess hearing in the light of stakeholder comments and agree that the wording should be softened.
108	Intercollegiate Stroke Working Party	Draft Guideline	006	012	**Section 1.1.8.** The Working Party supports the recommendation to provide rehabilitation for as long as it continues to help patients achieve their treatment goals, even after they have left hospital. The wording allows treatment at the level of	Thank you for your comment. The committee agree that full implementation will be challenging but making the recommendation is an important first step.

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					impairment, activity and participation. The concept of a recovery plateau does not apply to activity and participation and so this implies life-long treatment to promote recovery should be available. It is important that this change in guidelines is made clear and explicit to patients and carers. There will be implications for staffing levels which will need to be met in community care settings to comply with this guideline.	
109	Intercollegiate Stroke Working Party	Draft Guideline	006	023	**Section 1.1.11.** These recommendations should relate to all patients receiving community rehabilitation according to the new English national stroke service model, not just those receiving Early Supported Discharge.	Thank you for your comment. These recommendations followed a review of the evidence for the Early Supported Discharge review and so was recommended for this area. We did not review the evidence around other discharge models, but the committee agree that there is no obvious reason why this should not apply to other parts of rehabilitation as well.
110	Intercollegiate Stroke Working Party	Draft Guideline	012	001	**Section 1.2.15.** The Working Party was concerned by the imbalance in the evidence standard applied to this section compared to some others within the draft guideline. Over 2,000 pages of exhaustive evidence analysis was produced to weigh the evidence behind dose and intensity of rehabilitation, including recommending remedial therapy for 5	Thank you for your comment. The question of optimal intensity of rehabilitation was identified by the committee as having potentially major cost implications not addressed by existing health economic literature. In keeping with standard NICE process the committee developed its own

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					rather than 7 days a week, and this extensive analysis contrasts sharply with Recommendations elsewhere, such as that all patients with stroke should receive a specialist orthoptist assessment when no evidence was identified for the review at all. This inconsistency in approach to the evidence undermines the overall credibility of the guideline.	health economic analysis. The extensive appraisal is the result of there being a large number of papers on intensity plus the obligation to properly describe the health economic analysis. With this evidence, the committee was able to make strong recommendations. Please also note that therapy is recommended for **at least** 5 days per week, and so may include 7 days a week if required by the person. This is consistent with the Working Party guideline. This evidence was not available for the topic of orthoptist assessment based on the protocol agreed with the committee. However, in this area, the committee agreed that there was a large safety concern and so NICE had a duty to make a strong recommendation in this area. Therefore, in this case, taking into account the committee's expert opinion, knowledge of the epidemiology of vision problems that is well documented in literature and the concern for safety for the stroke survivor and others, a strong recommendation was made. These two processes are compatible and complementary

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						processes used to make recommendations in NICE guidelines, and do not reflect an inconsistency in how the guideline was constructed.
111	Intercollegiate Stroke Working Party	Draft Guideline	012	001	**Section 1.2.15.** These recommendations are different to those in the National Clinical Guideline for the UK and Ireland (2023; 'NCG23' available at www.strokeguideline.org), which makes recommendations specifically for motor recovery and states that 'People with motor recovery goals undergoing rehabilitation after a stroke should receive a minimum of 3 hours of multidisciplinary therapy a day (delivered or supervised by a therapist or rehabilitation assistant focused on exercise, motor retraining and/or functional practice)….'. This is based on evidence regarding the effects of greater amounts of therapy (dose) (Kwakkel et al, 1999; Kwakkel & Wagenaar, 2002; Bhogal et al, 2003a; Bhogal et al, 2003b; Kwakkel et al, 2004) and is reflected in other clinical guidelines around the world (Australia (Stroke	Thank you for your comment. Stakeholders have made some very reasonable points about the available evidence and the committee have reflected on this. The recommendation has been amended. Our recommendations were made using systematic reviewing methodology where evidence was searched for using methods as outlined in Developing NICE guidelines: the manual. The studies listed were excluded from our review (please see the excluded studies table in the evidence report for more information). We agree that the time spent should be time-on-task. This is highlighted in the qualitative evidence review in the area (please see the evidence review).

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					Foundation, 2022), Canada (Teasell et al, 2020) and the Netherlands (Veerbeek et al, 2014a)). The NICE and NCG23 should be aligned, as any discrepancy is likely to cause confusion and hamper uptake – a point particularly emphasized by the patient and public voice members of the Working Party. Alignment could be achieved by amending the recommendation regarding physiotherapy to read '…. For at least 1 to 2 hours a day' in the same way that 'at least' is used for OT and SLT. They should also both be clear that this recommended time refers to 'time-on-task' not simply session length (given that time on task is often approx. 50% of session length). However, the distinction between the disciplines delivering rehabilitation made here is artificial and does not reflect the realities of clinical practice. Occupational therapists are involved in a lot of motor recovery activity, especially upper limb work, as well as functional translation of motor gains. There is therefore no justification for singling out one discipline for greater input. Separating the three therapies in this way shows a lack of understanding of the overlapping nature of MDT work in stroke rehabilitation, and the	The RELEASE meta-analysis was identified and evaluated by the committee. On comparing the different results in this analysis, no clinically important differences were found between the different intensities in this analysis in improving communication outcomes. Therefore, the committee could not recommend a change to the current recommendation based on these results.

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					absence of any mention of the role of nurses, psychologists, orthoptists etc in the complex MDT delivery of neurorehabilitation is an unwelcome oversimplification and potentially misleading. On the same issue of rehabilitation therapy intensity, was the RELEASE collaboration (2022) reviewed regarding intensive SLT for aphasia around 3-6 months? This extensive, international evidence synthesis was the basis for the recommended increase in SLT input for aphasia in the NCG23 which goes beyond the previously recommended levels of 45 minutes/day. The NCG23 states that 'Intensive speech and language therapy such as comprehensive aphasia programmes may be considered from 3 months after stroke for those who can tolerate high-intensity therapy.' Comprehensive aphasia programmes deliver 6-7 hours a day of therapy and should be considered by the committee, particularly as they exceed the evidentiary standard that appears to have been applied to other Recommendations with the draft guideline.	

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					RELEASE Collaborators; Brady MC, Ali M, VandenBerg K, et al. Precision rehabilitation for aphasia by patient age, sex, aphasia severity, and time since stroke? A prespecified, systematic review-based, individual participant data, network, subgroup meta-analysis. Int J Stroke. 2022 Dec;17(10):1067-1077. doi: 10.1177/17474930221097477.	
112	Intercollegiate Stroke Working Party	Draft Guideline	012	011	**Section 1.2.17.** The Recommendation that intensive therapy should be started as soon as possible after a stroke is not supported by the evidence from the definitive clinical trial in this area. The AVERT trial provided strong evidence that intensive motor rehabilitation provided immediately after major stroke was probably associated with worse outcomes and tangible harm. Langhorne P, Collier JM, Bate PJ, Thuy MN, Bernhardt J. Very early versus delayed mobilisation after stroke. Cochrane Database Syst Rev. 2018 Oct 16;10(10):CD006187. doi: 10.1002/14651858).	Thank you for your comment. The AVERT trial was not part of our evidence review because the protocol excluded trials including people during the first 24 hours after a stroke (as this would fall under our Acute Stroke guidance). However, the AVERT trial was considered in NG128 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management. The committee agrees that it is relevant to recommendation 1.2.17 in this Stroke Rehabilitation update and have added a cross reference, and amended the recommendation to state that rehabilitation should only commence when safe to do so.

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113	Intercollegiate Stroke Working Party	Draft Guideline	013	003	**Section 1.2.21.** This reads as though there is an assumption that rehabilitation is not being delivered in the patient's own home. We suggest that it is rephrased.	Thank you for your comment. The wording has been amended.
114	Intercollegiate Stroke Working Party	Draft Guideline	013	014	**Section 1.3.1 – Telerehabilitation.** The wording '..instead of, or as well as…' is a recipe for ambiguity. The evidence will point to one or the other – as a replacement for face-to-face therapy, or as a supplement to it. To avoid ambiguity in implementation, the committee should recommend one or the other, but not both. Some recognition of the assessment of the patient as suitable for telerehabilitation is required here, as not all patients are appropriate e.g. those with significant cognitive deficits.	Thank you for your comment. Based on the evidence review, we disagree. The evidence did not clearly show that telerehabilitation services alone or a combination of telerehabilitation and face-to-face services were superior. Therefore, we recommended that there should be a choice. This allows for the option to be available dependent on the needs and preferences of the person, the healthcare professional and the service. Regarding suitability for telerehabilitation, we are not aware of a generally accepted way of **assessing this**. There are some situations where telerehabilitation may be self-evidently unsuitable, for example people with significant cognitive impairment, but it is not clear how to make this judgement in less obvious cases

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115	Intercollegiate Stroke Working Party	Draft Guideline	017	010	**Section 1.7 Fatigue.** The Working Party were struck by the illogicality of recommending assessment for fatigue without also considering the evidence and recommendations for interventions to alleviate or help to manage it. To do one without the other is simply to set up patients and their families for frustration and disappointment. At the very least, the committee should recommend an explanation of the nature of fatigue, and its likely impact on rehabilitation, supported by written information e.g. from the third sector such as the Stroke Association. In Section 1.7.1 the word 'written' appears superfluous, as if excluding an assessment made verbally or on a tablet.	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue, and serve as a baseline against which active interventions can be tested. However, we have not conducted a review into interventions for fatigue in this update.
116	Intercollegiate Stroke Working Party	Draft Guideline	017	022	**Section 1.8 Vision.** The Working Party was not convinced by the recommendation that all people with stroke should receive a specialist orthoptist assessment, especially when the committee itself confirmed that no evidence to support this recommendation was identified for the review. Cross-sectional surveys of acute stroke admissions	Thank you for your comment. Vision problems may not be apparent to non-specialist members of the rehabilitation team during the screening, while stroke survivors may also be unaware of a problem which can result in accidents related to driving and falls (RNIB 2021, BIOS 2016, Goodwin 2014).

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					provide evidence that about half of all people with stroke have visual problems identified by early screening – about the same proportion of patients that have communication disabilities identified. Yet no-one is suggesting that patients in whom screening assessment by any trained healthcare professional confirms the absence of communication disability should then go on to receive a comprehensive speech therapy assessment – the resource costs could not be justified. More logically, screening for visual disorders should be performed by any appropriately trained healthcare professional, with full specialist assessment reserved for those with identified problems. That represents a much more responsible use of available resources. There is no mention in this section of the interventions that should be considered following assessment other than eye movement therapy for hemianopia in the 2013 legacy section 1.8.3, although the 2013 legacy sections 1.5.3 and 4 mention interventions for visual inattention. This creates the erroneous impression that these are the only NICE-recommended interventions that might	Given these factors, it was agreed to be important to make a recommendation despite the lack of evidence. Communication difficulties are commonly identified earlier and hence do not require a comprehensive speech therapy assessment. Furthermore, a full orthoptic assessment on the stroke ward is considered to take either the same time (in more complex cases) or less (for mild/normal cases) as screening by non-specialists, which saves time overall as it negates the need for the initial non-specialist screening prior to a selective referral. The updated recommendations on therapy for visual disorders are limited to orthoptist assessment. This is because stakeholders did not identify treatment of visual disorders as a topic requiring update during scope consultation. It will be passed on to the NICE surveillance team.

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					be delivered by orthoptists, which we are sure is not the desired effect. Overall, this leaves Section 1.8 looking inconsistent and incomplete, with universal urgent specialist assessment recommended despite an explicit recognition that no evidence to support it has been identified, and with limited interventions for visual disabilities recommended as part of Stroke Rehabilitation. A rethink of Section 1.8 is required.	
117	Intercollegiate Stroke Working Party	Draft Guideline	018	012	**Section 1.9 Hearing.** The Working Party were struck by the non-evidence-based nature of the recommendation that all patients should receive a hearing assessment within 6 weeks, and indeed the committee acknowledge this themselves in simultaneously making a Research Recommendation as the prevalence of hearing disorders resulting from stroke is at present unknown. A recommendation for universal assessment is unjustifiable when the basic prevalence is unknown. There may well be grounds for the committee to recommend hearing screening as good practice (as indeed it may be in many predominantly older disease populations) with	Thank you for your comment. On reflection the committee agree with you that the evidence is insufficient for the strength of the recommendation, and the wording has been changed.

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					further referral for those identified with problems, but the present arbitrary and universal recommendation cannot be justified by the evidence as it stands.	
118	Intercollegiate Stroke Working Party	Draft Guideline	019	009	**Section 1.10 Mouth care.** The Working Party recommend adding the importance of communicating any care plan across care settings. If a national protocol for mouth care exists, is there any value in developing a local one?	Thank you for your comment. The provision of information across care settings is discussed in section 1.1.14. Mouthcare matters is a national protocol for mouth care used in many settings, but it has not been compared to other tools and some providers may prefer to use local protocols.
119	Intercollegiate Stroke Working Party	Draft Guideline	019	021	**Section 1.11.2 and 3 Swallowing.** Recommend combining to "Give families and carers information about dysphagia (difficulty in swallowing) and advice on what to do if someone is coughing or choking while eating and drinking."	Thank you for your comment. On balance the committee prefer that the recommendations should remain separate since they refer to different pieces of information
120	Intercollegiate Stroke Working Party	Draft Guideline	020	014	**Section 1.11.6 Swallowing**. The evidentiary basis for the recommendation regarding the use of a free water protocol is flimsy at best, and to assert an absence of harm on the strength of two small studies of 34 mobile people is not justifiable and takes no account of the virtual certainty of a type 2	Thank you for your comment. The committee has discussed this again and agrees. The recommendation has been removed and a research recommendation made instead.

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					statistical error (failing to detect an effect [harm] when one may be present). In truth, the committee should not make any kind of recommendation for an intervention on such an unscientific basis, instead opting for a recommendation for more research. If the recommendation is not to be entirely withdrawn, the Working Party would alert the committee to the challenges for staff to implement a free water protocol, particularly in acute and other care settings. Currently there are a high level of incidents where provision of food/fluids has not been in line with SLT recommendations. Allowing an individual different textures of fluids introduces a further opportunity for error. Are there resources/bundles/protocols to support implementation of such a protocol that have been successfully tested in clinical settings?	
121	Intercollegiate Stroke Working Party	Draft Guideline	022	010	**Section 1.12.8.** It is not clear why two apps for patients with aphasia that have been tested in RCTs and published in peer-reviewed journals have been omitted from the NICE guideline process. They are in scope, in the correct time period and are not in the excluded studies section of the relevant	Thank you for your comment. The developers had not identified Fleming, et al. as being a relevant study for the review, and have now added it, thank you for this. This does not change the results of the review.

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					evidence reviews for computer-based tools for speech and language therapy, Appendix J – Excluded studies. iReadMore is an app that was tested in a registered RCT in people with aphasia who had central alexia. Participants completed two 4-week blocks of iReadMore training (34 hours each). iReadMore training resulted in an 8.7% improvement in reading accuracy for trained words (95% confidence interval 6.0 to 11.4; Cohen's d = 1.38) (Woodhead et al., 2018). Similarly, Listen-In, an app for people with aphasia with auditory comprehension impairment was tested in a registered RCT. Repeated measures analyses of variance compared change in spoken language comprehension on two co-primary outcomes between therapy and standard care. The first study-specific co-primary outcome (Auditory Comprehension Test (ACT)) showed large and significant improvements for trained spoken words (11%, Cohen's d=1.12). Gains were largely maintained at 12 and 24 weeks (Fleming et al., 2020).	Woodhead, et al. is a study where all people receive the iReadMore intervention while the crossover trial compares people receiving transcranial direct current stimulation to people receiving sham transcranial direct current stimulation while participating in the study. Therefore, this is not a relevant comparator for this review. This has been added to the excluded studies table.

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					Fleming, V., Brownsett, S., Krason, A., Maegli, M. A., Coley-Fisher, H., Ong, Y.-H., Nardo, D., Leach, R., Howard, D., Robson, H., Warburton, E., Ashburner, J., Price, C. J., Crinion, J. T., & Leff, A. P. (2020). Efficacy of spoken word comprehension therapy in patients with chronic aphasia: a cross-over randomised controlled trial with structural imaging. Journal of Neurology, Neurosurgery & Psychiatry, jnnp-2020-324256. https://doi.org/10.1136/jnnp-2020-324256 Woodhead, Z. V. J., Kerry, S. J., Aguilar, O. M., Ong, Y. H., Hogan, J. S., Pappa, K., Leff, A. P., & Crinion, J. T. (2018). Randomized trial of iReadMore word reading training and brain stimulation in central alexia. Brain, 141(7), 2127-2141. https://doi.org/10.1093/brain/awy138	
122	Intercollegiate Stroke Working Party	Draft Guideline	028	013	**Section 1.13.30-31.** Mirror therapy is still controversial because it is deployed in so many different ways. The Working Party recommend explicitly stating that it should be used as an adjunct to a multidisciplinary (PT and OT) upper limb rehabilitation programme, not instead of. The current wording simply suggests it can be used as	Thank you for your comment. The committee agree with you and the wording of the recommendation has been amended.

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					part of a rehabilitation programme, which would allow mirror therapy to be used as the only upper limb treatment. The NCG23 recommendations are clearer – 'People with stroke may be considered for mirror therapy to improve arm function following stroke as an adjunct to usual therapy.'	
123	Intercollegiate Stroke Working Party	Draft Guideline	029	013	**Section 1.14.4 Shoulder pain.** Steroid and nerve block injections may reduce pain, but must be combined with appropriate physical management, or else the problem will recur. For example, frozen shoulder is common after stroke, but requires physiotherapy. Physiotherapy will not work unless the pain is first managed. Please indicate that adjunctive physical therapy should also be part of the treatment.	Thank you for your comment. The recommendations in this section should not be taken in isolation from one another. The committee agree that more than one form of therapy may be required in any particular case. Please note recommendation 1.14.2 which states that the cause of shoulder pain should be sought and management geared to cause(s) when found. In your example, if a frozen shoulder is diagnosed physiotherapy should be offered.
124	Intercollegiate Stroke Working Party	Draft Guideline	030	009	**Section 1.15.** Recommendations 1.15.4 and 1.15.6 are most surprising, as the evidence shows that stretching, splinting and electrical stimulation (NMES or FES) do not improve spasticity. They should either be corrected or removed. It is also surprising that TENS is recommended as the	Thank you for your comments. The developers acknowledge that there is uncertainty around the benefits of these interventions and have amended the wording to state that they might be considered. In

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					evidence is very unlikely to have exceeded the evidentiary standard. It is much less strong than that for other recommendations (or that which shows electrical stimulation to be ineffective), so it appears inconsistent to include it here. The recommendations contradict those in the new 2023 National Clinical Guideline for Stroke, and expert guidelines from other countries such as Australia, Canada and the US.	relation to stretching and splinting, this makes recommendation 1.15.4 compatible with the 2023 National Guideline. With regards to NMES, FES and TENS, the evidence review found some evidence of clinically important benefits for each of these in improving spasticity outcome measures and improving activity of daily living scales. The evidence was limited. Therefore, recommendation 1.15.6 is expressed in the more cautious "Consider" form and has not been changed. We also note that the guidelines from Australia and the USA suggest there may be a role for NMES.
125	Intercollegiate Stroke Working Party	Draft Guideline	030	014	**Section 1.15.5.** The dose of botulinum toxin should be appropriate to the issue and the muscle/s being treated. Having the total stated here could be dangerous and lead people to always inject a total of 500 units, which in some instances may be excessive. The recommendation should state 'a maximum of 500 units across all sites'. Botulinum toxin treatment should always be associated with a stretching regime or splinting - this	Thank you for your comment. The committee acknowledge your point. It was not the intention to imply that 500 units must be given, and the wording has been amended.

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					is one of the only indications for splinting and would be recommended within 7-10 days of injection.	
126	Intercollegiate Stroke Working Party	Draft Guideline	032	025 - 026	**Section 1.16.5.** The Working Party considers that referral for vocational rehabilitation should be offered, rather than merely considered. To 'offer' puts the decision in the patient's hands rather than the clinician making what may be an arbitrary judgement. Although the evidence for vocational rehabilitation is not compelling, expert consensus in the 2023 National Clinical Guideline for Stroke for the UK and Ireland judged it sufficient to make a recommendation (stronger that the evidence for universal vision and hearing assessments, for example). This recommendation should apply not just to people who were in paid employment, but also to people who may have been volunteering, or in education.	Thank you for your comment. The word "offer" is generally used in NICE guidance when evidence behind a recommendation is strong and in this instance the committee judged that the evidence was not sufficient.
127	Intercollegiate Stroke Working Party	Draft Guideline	034	007	**Section 1.17.6.** The nature of a 'community participation programme' should be specified, as these will differ widely.	Thank you for your comment. This has been outlined in the "Terms used in this Guideline" section.

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128	Intercollegiate Stroke Working Party	Recommendations for Research	040 - 041	005 - 003	The recommendations for research into acupuncture (over and above research into any other intervention) appear somewhat arbitrary.	Thank you for your comment. The committee was aware that there is a significant amount of evidence for acupuncture that we were unable to include because it is not available in English. There were also positive results seen in small studies that were available. Given this, the committee wanted to have further research in this area including cost-effectiveness evidence in a UK setting so that they could have a full understanding of the clinical and cost effectiveness of acupuncture for reducing spasticity and shoulder pain after stroke.
129	Intercollegiate Stroke Working Party	Recommendations for Research	036	009	The recommendation to test whether 7-day rehabilitation is better than 5-day rehabilitation will not be particularly fruitful, especially if delivered at current low doses (an extra 2 days of not very much is still not very much). It is widely accepted that a higher 'dose' of rehabilitation is more effective, so research effort should now focus on how to practically achieve the highest tolerable dose possible using combinations of multidisciplinary therapy and technologies.	Thank you for your comment. There is currently insufficient evidence to firmly recommend an increase in dose of rehabilitation from 5 to 7 days. Moreover, the cost-effectiveness of this increase is not well supported by current evidence. We also note the number of comments where people are disappointed that we are unable to recommend 7-day rehabilitation and the research recommendation therefore addresses a perceived need for further data.

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130	Intercollegiate Stroke Working Party	Recommen-dations for Research	037	021	Tools for fatigue: The Working Party were struck by the contradiction between these tools being recommended for use, along with a recommendation that their clinical and cost effectiveness should be investigated. If the latter is as yet unproved, then the former cannot apply.	Thank you for your comment. The two statements are not contradictory. The review conducted was a tool validity and reliability review which established which tools were likely to be the most valid and reliable to use in the context of the NHS in the United Kingdom. However, a search was conducted to investigate whether any tools for fatigue showed clinical or cost-effectiveness to improve outcomes for people after stroke and no studies were identified. Therefore, to establish if these tools are effective in improving outcomes, evidence is required. The recommendation to use these tools is made as a more cautious "consider" recommendation to reflect the lack of unequivocal evidence of benefit, but the committee would argue that there are already good reasons for using them as laid out in the rationale and the evidence review.
131	Intercollegiate Stroke	Recommen-dations for	041	018	The recommendation that the clinical effectiveness of electrical stimulation methods in spasticity is investigated appears to be at odds with the recommendation that their use is considered in	Thank you for your comment. We understand why it appears that these two statements are odds. However, the recommendations for electrical stimulation recommendations is a

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	Working Party	Research			Section 1.15.6. If that former is as yet unproved, then that latter cannot apply.	weaker consider recommendation to reflect the relative weakness in the evidence (rather than a stronger offer recommendation where it would be inappropriate to also make a research recommendation). In other word, the committee believe that there is evidence suggesting this may be a beneficial treatment for some people, but that further research would be useful to fully prove this and perhaps to refine our understanding of the optimal circumstances for using it.
132	Ipsen Ltd.	Draft Guideline	General	General	The guideline appears disconnected. The ordering of management interventions is not logical, or evidence based. Management of factors triggering spasticity should be considered before other interventions (pharmacological or physical). See national guidance previously published. The recommendations seem to recommend that physical interventions should be tried before pharmacological intervention, rather than appropriate 'patient' selection based on clinical presentation – the need for an individualised patient	Thank you for your comments. On the order of interventions, the order of bullet points in 1.15.4 is not intended to imply that the interventions are provided in that order. Interventions, and the timing of their application, should be considered using a person-centred approach. Furthermore, the recommendations note that as a part of this approach options for managing spasticity should be discussed within a multidisciplinary team. The discussion at the

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					centred approach appears to have been lost in the draft guidance that has been produced. Ipsen are therefore concerned that this guideline will not support optimal care for stroke rehabilitation of adults and in fact could potentially lead to inconsistent management and confusion among healthcare professionals, affecting patient care and patient outcomes. Some recommendations are the opposite of what is recommended in other guidelines. For instance, this guideline makes no recommendations for the use of botulinum toxin for lower limb spasticity where botulinum toxin in combination with physical intervention (in selected cases) may make marked functional (activity level) differences to individuals. The guideline does recommend botulinum toxin for upper limb; however it recommends only Dysport but at a dose that does not allow for goal orientated dosing according to patient need. The NICE draft recommendations (see example below) contradict the recently updated National clinical guideline for stroke for the UK and Ireland.	multidisciplinary team should involve the person after stroke and anyone important to their care and decide what treatments are most appropriate for them at that time. The committee did not make any recommendation as the cost effectiveness was uncertain for lower limb. One published health economic study only included lower limb (Danchenko 2022), but this did not provide a comparison versus usual care. The de novo model only explored BOTOX in the lower limb due to the lack of availability of MAS responder data for the other two drugs, and it was not cost effective. The difference between recommendation 1.15.5 and the equivalent recommendation in 2023 national guideline to which you refer is that NICE guidance formally evaluates both clinical and cost-effectiveness evidence and in this case, it is the cost-effectiveness evidence which imposes limits on what NICE can recommend.

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					The 2023 edition is a partial update of the 2016 edition and was developed in collaboration with the Scottish Intercollegiate Guidelines Network (SIGN) and the National Clinical Programme for Stroke, Ireland. **The 2023 edition is endorsed for use in clinical practice by the Royal College of Physicians (RCP) of London, SIGN and the Royal College of Physicians of Ireland**. National clinical guideline for stroke for the UK and Ireland, 2023 Edition, 04 April 2023 (Page 103) *"People with persistent or progressive focal spasticity after stroke affecting one or two areas for whom a therapeutic goal can be identified (e.g., ease of care, pain) should be offered intramuscular botulinum toxin. This should be within a specialist multidisciplinary team and be accompanied by rehabilitation therapy and/or splinting or casting for up to 12 weeks after the injections. Goal attainment should be assessed 3-4 months after the injections and further treatment planned according to response."*	The 2018 RCP document does not highlight an unequivocal benefit of early use. It says *if used appropriately in early phases of rehabilitation, it **may prevent** soft tissue shortening* (bold type is ours*)*. Moreover, our guidance does not say it should not be given early on.

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					This guideline has also been accredited by NICE, so we are unclear how this disconnect could occur between this guideline and the one NICE has created. The RCP guideline (2018) – *Spasticity in adults: management using botulinum toxin*, also recommend BoNT-A and highlight the benefits of early intervention in addition for those patients with severe and long-standing spasticity, the need for longer term treatment repeated where BoNT-A treatments may be required over several years. The NICE draft guideline does not appear to take into account that early intervention with botulinum toxins may be critical to effective management in some individuals and inappropriate in others – again illustrating the lack of a patient centred approach.	
133	Ipsen Ltd.	Draft Guideline	30	014-020	The guideline states: *For people who have focal spasticity of the upper limb after stroke, consider botulinum toxin A (Dysport) at a total dose of 500 units per treatment, spread across injections in different sections of the affected limb. Ensure that:*	Thank you for your comment. Dysport treatment for the lower limb was not included in the recommendation as the cost effectiveness is unknown. It was not included in the health economic model as there was no RCT data reporting Modified Ashworth Scale

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					- *people do not receive more than 1 treatment every 3 months and* - *response to the treatment is monitored and it is stopped if it is not effective. [2023]* This recommendation is based on the health economic analysis conducted and reported in Evidence review P - Spasticity and Evidence review P - Spasticity model write up. As per Dysport's dosing this should be based on patient need and a 500 unit dose may not be sufficient for patients with upper limb spasticity. In addition, there is no recommendation for the use of Dysport in lower limb for which it is licensed. Ipsen believes the health economic analysis fails to consider the use of Dysport in the long term and where patients who benefit from treatment will receive repeat injections over potentially many years. It can be seen from the health economic analysis that longer time horizons make the use the of Dysport in 500 and 1000 unit doses cost-effective in upper limb spasticity. See also comments below regarding the Evidence review P - Spasticity and	responder data, which was required for incorporation into the model. Of the published health economic evidence, only one study reported Dysport in lower limb, but this was not assessing the cost effectiveness of Dysport to usual care but rather to another botulinum toxin A. A research recommendation has been included to explore the clinical and cost effectiveness of all three formulations of botulinum toxin A in both upper and lower limb. Following stakeholder comments, further sensitivity analyses have been conducted in the model, including extending to a 5-year time horizon. The committee have reconsidered the evidence and amended the recommendation accordingly.

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					Evidence review P - Spasticity model write up sections.	
134	Ipsen Ltd.	Evidence review P	1066	Appendix J – excluded studies	The clinical review is incorrect in stating that the study by Gracies et al. (2017) is a *"Secondary publication of an included study that does not provide any additional relevant Information".* This study is a pivotal registration study that supported the licensing application of abobotulinumtoxinA (Dysport) in the treatment of spastic lower limb in adults. The clinical effectiveness review should include the study by Gracies et al. (2017) because it provides important evidence about the efficacy and safety of abobotulinumtoxinA in the treatment of lower limb spasticity. The paper states that the double-blind phase of this study provides Class I evidence that for adults with chronic spastic hemiparesis, a single abobotulinumtoxinA injection reduces lower extremity muscle tone. Therefore, this study should have been included in the health economic analysis for lower limb spasticity.	Thank you for your comment. Thank you for identifying that we had not included Gracies et al. 2017. We have now included this in the analysis. This did not change the results examining the clinical effectiveness of abobotulinum toxin A. Unfortunately, this study does not include MAS responder data and therefore cannot be included in the health economic analysis. No differences in quality of life were observed in the RCT phase and values were not reported in paper. EQ-5D (VAS only) and SF-36 were reported for the open label extension, but this is no longer randomised and is not provided by responder status and therefore cannot be used within the health economic model.

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135	Ipsen Ltd.	Evidence review P - Spasticity (Evidence reviews for interventions for spasticity) Evidence review P - Spasticity model	171-72	014 - 031	Whilst the recommendations for botulinum toxin do acknowledge limitations in the health economic analysis it has not done enough to address them. These limitations are of great importance as they can significantly alter the cost-effectiveness analysis of botulinum toxin. With regard to the stated limitations in the analysis, namely: - *"lack of clarity as to what current practice is in terms of follow up attendances for people with spasticity but not receiving BoNT-A. If they have no regular follow up attendances then BoNT-A is unlikely to be cost effective"*. o One would have thought the purpose of a guideline would be to encourage consistency and help ensure there is regular follow-up attendances. The RCP guideline (2018) emphasises BoNT-A treatment should be within a specialist multidisciplinary team and goal attainment should be assessed 3-4 months after the injections and further treatment planned according to response. o Initiatives such as patient initiated follow-up (PIFU) is an example	Thank you for your comment. Please see below a response to each point raised. - The lack of clarity of current practice in terms of follow up attendances related to whether those people with spasticity who didn't have BoNT-A injections had regular follow ups or not. Thus, highlighting uncertainty as to the true incremental cost of BoNT-A. - Gracies 2017: This study has now been added to the clinical evidence however as it does not include MAS responder data, nor any useable QoL data, it has not been incorporated into the economic model. - A sensitivity analysis has now been conducted to explore longer injection intervals based on the ULIS III (Turner Stokes 2021) observational trial and Kanovsky 2011 (25 and 14 weeks respectively).

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		write up			where effective and appropriate follow-up can be achieved taking into account the challenges the NHS has in terms of resource and capacity. What is more important is ensuring there is follow-up of patients who receive BoNT-A such they are able to achieve the mutually agreed treatment goals with their healthcare professional. - *"Analysis is based on single RCTs (no meta-analysis possible) and not all indications reported here (upper and lower limb for each drug). Many other BoNT-A RCTS were identified in the clinical review, however only these three RCTs reported the same outcome used in the economic model (MAS). It is not clear if they are representative of the full body of clinical evidence."* o As noted in Point 2 above this guideline has incorrectly classified a pivotal study by Gracies et al. (2017) as a secondary study and excluded it as evidence to inform this NICE	

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					guideline. This is registration study that supported for the licensing of abobotulinumtoxinA (Dysport) in the treatment of lower limb spasticity in adults which included the Modified Ashworth Scale (MAS) as an endpoint and its omission should be considered as an oversight at the very least. - *"The analysis has not accounted for the longer time between injections reported in an observation trial (ULIS-III). Increasing the duration between injections could result in either fewer injections for the same QALY gain or same number of injections but a longer QALY benefit. Therefore, the current model may underestimate the cost effectiveness of BoNT-A compared to an approach which allows longer intervals between injections (lowering costs and/or raising QALYs)."* o It would have been informative if analyses had been undertaken to consider the impact on the level of cost-effectiveness if an increased	

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					duration between injections had been evaluated. The use of longer dosing intervals would also have the additional benefit of increasing capacity to enable follow-up of more patients so they are not lost in the system	
136	Ipsen Ltd.	Evidence review P - Spasticity model write up	006	036 - 043	Time horizon. The health economic model looked at a 12 week, 1- and 2-year time horizon. The rationale provided in the health economic analysis for not including a lifetime horizon was that there is no evidence to suggest spasticity treatments would impact mortality and that the literature suggested that most people received up to 4 injection cycles, approximately every 12 weeks and the number of patients requiring additional cycles progressively decreases. The BoTULS (Shaw et al, 2010) and ULIS III (Turner-Stokes et al, 2021) studies are the references cited to justify that a 1-year time horizon was deemed sufficient to capture the impact of repeat injections of BoNT-A.	Thank you for your comment. A 5 year time horizon has been added as a sensitivity analysis and the committee have revisited the recommendations in light of this. Unfortunately, the RCTs informing the model are not in an early intervention population and therefore it is not possible to capture the cost effectiveness of early intervention. This is addressed in the discussion of limitations.

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					In the BoTULS study proportions of patients who received repeat BoNT-A injections at 3, 6 and 9 months were 67.7%, 61.0% and 51.4% respectively. However, participants recruited after 2 July 2007 into the BoTULS study were followed for 3 months only. This was described as a pragmatic decision taken because the trial was behind schedule as a result of initial low recruitment rates. Curtailing 12-month follow-up allowed the trial to be completed within the initial study timetable. At the end of the study period (3 or 12 months) participants in whom research therapists felt would benefit from botulinum toxin treatment were referred to local spasticity services. Following the last outcome assessment 51.2% in the intervention group were referred to a spasticity service for botulinum toxin. This implies patients needed to continue treatment in the longer term. Limiting the time horizon to such a relatively short period when people who experience spasticity following stroke for many years is inappropriate. Some people with post stroke spasticity may need treatment for several years and repeat treatments may be required to enable patients to achieve and	

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					maintain their treatment goals. Therefore, much longer time horizons beyond two years should be used. It can be seen in the sensitivity analysis that increasing the time horizon to 2 years increases the cost-effectiveness of toxins and for Dysport it becomes cost-effective at the 1000 unit dose which as described in point 3 above enable dosing to be based on patient need and response. The economic analysis also fails to consider the potential benefit of early intervention. In the BoTULS study the median time from stroke to randomisation into the study was 329 days with 46.7% of patients being randomised 1 year after their stroke.	
137	Ipsen Ltd.	Evidence review P - Spasticity model write up	017	004 - 024	<u>Utilities</u> It is recognised that the EQ-5D is not a sensitive instrument for spasticity and therefore a flawed analysis. The health economic analysis for BoNT-A uses utilities from Makino et al. (2019), which is noted in the guideline, may have flaws because the EQ-5D questionnaire collection times were not reported, and therefore it is not clear if these were done when the effects of treatment are expected to	Thank you for your comment. The limitations associated with Makino 2019 EQ5D source have already been outlined in the model write up and committee discussion of the evidence. Using MAS responder to estimate QALYs was deemed the only viable approach to capture the largest number of RCTs identified in the clinical evidence.

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					peak (approximately 4 weeks) or if they were done once the effects had started to diminish over time. It was also recognised in the cost utility analysis that the EQ-5D data used was for upper-limb spasticity and therefore the EQ-5D data may be less applicable to lower limb spasticity benefits or to other BoNT-A types or doses from which this utility data is taken from. There should therefore be some recognition that the benefits of BoNT-A on quality of life may be underestimated in the cost-utility analysis and better accounted for in the recommendations.	Had the de novo health economic analysis not been performed the committee would have not been able to make any recommendations for botulinum toxin A as the published health economic evidence suggested that botulinum toxin A was not cost effective.
138	Managing Adult Malnutrition in the Community	Draft Guideline	General	General	The guideline provides considerable detail on physical rehabilitation and speech and language therapy. Whilst reference is made to NICE guideline CG32 there are a range of issues both physical and cognitive, specific to stroke, that can affect the ability to eat and drink and that are not confined to dysphagia / swallowing issues. Given the guideline provides sections on the physical issues experienced e.g., movement, vision etc, it could be of value to make the link between how these issues adversely affect the ability to eat and drink more explicitly. In addition, nutrition, and in particular	Thank you for your comment. As you point out, recommendation 1.2.1 advises that nutritional status is assessed and signposts to CG32 for further advice if needed. The management of nutrition was not identified as a priority during stakeholder consultation on the scope of the update and as no evidence review has been carried out it is not possible to add in further detail.

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					adequate protein to prevent loss of muscle mass, is essential to optimise the effectiveness of physical rehabilitation. With considerable emphasis in the updated guideline on the role of therapists such as physical therapy, nutrition surely deserves a mention alongside to ensure that the physical therapy goals are not compromised by inadequate / sub-optimal nutrition. A simple statement such as 'ensure nutritional requirements, including protein, are met to optimise the effect of physical therapy' would be helpful. Whilst we acknowledge the guideline includes a link to CG32 which provides advice on nutritional support, a simple table or section summarising nutritional considerations that are common post-stroke (see list below), would be of help to readers. In addition, nutrition requires attention throughout the pathway of care from acute through the rehabilitation phase. A statement to encourage 'nutrition screening and assessment, managing and monitoring to prevent malnutrition, sarcopenia, pressure injuries and dysphagia to optimise recovery' should be an integral component of the	

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					guideline if the intention is to optimise recovery. This might help avoid situations seen in clinical practice whereby nutrition is overlooked and the connection between nutrition and recovery is not recognised nor acknowledged. If it is not possible nor feasible to include a separate table, then nutritional factors could be mentioned in other sections. e.g., consider that unintentional weight loss, loss of muscle secondary to poor nutritional intake may impede rehabilitation therapy. Potential table To facilitate rehabilitation and optimise recovery, nutritional status and the ability to eat and drink should be monitored weekly, checking the following and taking action, including referral to the dietitian for individualised assessment and advice. Key factors to monitor post-stroke from a nutrition perspective include. - unintentional weight loss - nutritional and fluid intake	

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					- eating assessment, dependence, and assistance requirements - biochemical measures that necessitate dietary modification (e.g., impaired glucose metabolism) - functional ability including muscle strength measures (e.g., hand grip strength) - evaluation of muscle mass and strength including unaffected extremities that might impact on the ability to eat and drink. It would be useful to include a section on nutrition rather than a link to nutrition guidelines CG32 to emphasise the importance of good nutritional care for patients who have had a stroke. Nutrition may also influence the likelihood of stroke recurrence. For further information we would refer you to Holdoway et al. (2022) Nutrition Management across the Stroke Continuum of Care to Optimize Outcome and Recovery. The Journal of the International Society of Physical and Rehabilitation Medicine; 5(4):121-128 https://jisprm.org/temp/IntJPhysRehabilMed54121-4320372_120003.pdf	

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139	Managing Adult Malnutrition in the Community	Draft Guideline	005	007-018	We are concerned that dietitians aren't mentioned as core members of the stroke multidisciplinary team on page 5. Whilst the guideline appropriately refers to dysphagia, eating and drinking difficulties after stroke are not confined to dysphagia and are wide ranging. On this basis we would argue that dietitians, alongside other allied healthcare professionals in this team, are crucial to ensure that the multidisciplinary team comprises members that can advise on all aspects of care, whether for an individual or by guiding local actions, policy and principles in both the acute setting and beyond into rehabilitation. Other guidelines such as those from the Stroke Association Guidelines; https://www.strokeguideline.org/app/uploads/2023/04/National-Clinical-Guideline-for-Stroke-2023.pdf which are accredited by NICE and developed in collaboration with SIGN do include dietitians as core members of the stroke team. Given the complexity of nutritional problems we feel that not including a dietitian in the core team represents unfair exclusion of a valued healthcare professional that can assess the adequacy of	Thank you for your comment. Dietitians have been added to the list.

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					nutritional intake and advise on suitable dietary adjustments to optimise nutritional intake that influences recovery and rehabilitation. Excluding the dietitian from the core multidisciplinary team seems out of step with other updates for example the guideline recommends a routine orthoptist assessment for all people after stroke and so this necessitates their inclusion in the multidisciplinary team. The committee acknowledged 'clinical neuropsychologists could also be included in the multidisciplinary team' and we see no reason nor rationale why a similar statement for dietitians should not be included, to ensure that those whose ability to eat and drink, not confined to dysphagia or swallowing issues, have equitable access to the healthcare professionals who can best assess and support them.	
140	Merz Pharma UK Ltd	Evidence review P	General	General	**Executive summary** Merz have reviewed the NICE draft guidelines for Stroke Rehabilitation in Adults [GID-NG10175],	Thank you for your comment. The three drugs were kept separate in the protocol and thus not meta-analysed. The ratio of equivalence is not clearly established in

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					alongside the Evidence Review for Interventions for Spasticity [P] and the Economic Analysis Report. Merz are disappointed in the conclusions drawn by NICE regarding the recommendations of botulinum toxin type A preparations, particularly that Xeomin (incobotulinumtoxinA) was found to not be cost-effective when used to treat focal post-stroke spasticity of the upper limb. In the following comments, Merz have highlighted a number of areas of uncertainty and limitations associated with the conducted analysis. The analysis incorporates a number of assumptions that are not aligned with the NICE reference case, are not aligned with UK clinical practice and are associated with considerable uncertainty. As such, the economic analysis conducted to assess the cost-effectiveness of Xeomin versus usual care is inadequate for decision-making. Primarily, the results of the economic analyses lack face validity as the three preparations of botulinum	literature, with recent evidence (Brin (2014), Ferrari A (2018), Sławek J (2021)) arguing against the formation of universal conversion ratios. With regards to the concerns raised with face validity of results, the results are driven by the available clinical data. As outlined in the model write up, the use of Modified Ashworth Scale (MAS) responder data was the only available option to model botulinum toxin A whilst making use of the widest evidence base. The limited data available to allow for modelling is one of the reasons for the research recommendation for the clinical and cost effectiveness of botulinum toxin A included in the guideline. With regards to other points please see responses below: - Masakado 2020 (J-PURE) has now replaced PURE to ensure the use of RCT data reporting MAS responder data rather than AS responder data.

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					toxin type A are considered to be clinically equivalent, when used at 'equi-equivalent' doses.[1, 2] All three botulinum toxin type A preparations operate via the same mechanism of action and they all contain the same active ingredient (*Clostridium botulinum*).[3-5] Furthermore, Xeomin has previously been demonstrated to be clinically comparable to Dysport when used to treat dystonia[6] and there is no evidence to suggest Dysport would be superior to Xeomin in the treatment of spasticity. However, the conducted economic analysis concludes that Dysport (at a dose of 500U [units]) is approximately 1.5 times more effective than Xeomin (at a dose of 400U). Considering the high degree of similarity between the botulinum toxin preparations and the previously demonstrated clinical equivalence, and the fact that the 'equi' equivalent dose of Dysport is typically considered to be approximately four times higher than Xeomin,[2, 6-8] the comparative efficacy evidence on which the	- The dosing used in the economic analysis was based on the dosing reported in the available studies with MAS responder data. - A new sensitivity analysis has been added exploring a longer time horizon of 5 years. - The utility values used in the analysis are poorly reported, and this has been noted as a limitation in the guideline, however no valid alternative has been identified or proposed. - A longer interval between repeat injections has been explored (25 and 14 weeks) in a new sensitivity analysis following stakeholder consultation comments. - The confidential patient access scheme price for Xeomin has now been included in the model. As a result of the edits made to the model the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the

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					economic analysis is founded, and the associated results, lack face validity. Beyond the face validity of the results, Merz note a number of key issues with the clinical and economic analyses, including: • The selection of the PURE trial as the only source of efficacy evidence for Xeomin • The use of Modified Ashworth Scale and Ashworth Scale, which are not equivalent • The dosing used in the economic analysis • The use of shortened time horizons • Uncertainty regarding the original source for the utility values for responder and non-responder patients • The assumptions informing treatment frequency and discontinuation Each of these points are considered in detail in the following sections.	treatment is stopped if it is not effective at this time. The references provided for this comment have been addressed in previous comments (see a fuller response regarding on Turner-Stokes 2013, Pandyan 1999 and Wissel 2017 in your subsequent comments) or are currently incorporated into the economic evidence and/or cost-utility model (Kaňovský 2009/2011, Makino 2019, Shaw 2010, Masakado 2020**).** Fletcher 2017 could not be found as the study was a conference submission. **References:** Brin MF, et al. Biologics. 2014;8:227–241; Ferrari A, et al. Funct Neurol. 2018;33(1):7–18 Sławek J, et al. Neurol Neurochir Pol. 2021;55(2):141–157.

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					Finally, Merz note that the analysis does not incorporate the confidential list price for Xeomin, as detailed in comment 9. Considering these points, Merz request that the following comments are considered and the analysis, and corresponding recommendations, are updated accordingly. **References (CS added – DELETE once reviewed):** 1. Pharmaceutical Benefits Advisory Committee (PBAC). Public Summary Document - Incobotulinumtoxin A. Available from: https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2019-11/files/incobotulinumtoxin-a-psd-november-2019.pdf [Accessed: 26 May 2023]. 2. Scaglione F. Conversion Ratio between Botox®, Dysport®, and Xeomin® in Clinical Practice. Toxins (Basel) 2016;8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810210/pdf/toxins-08-00065.pdf 3. Medicines and Healthcare products Regulatory Agency (MHRA). Botox Summary of Product Characteristics. Available at:	

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					https://mhraproducts4853.blob.core.windows.net/docs/adcde7e679274a9f83066eb9a9a6cb6b14df0d06 [Accessed: 25 May 2023]. 4. Medicines and Healthcare products Regulatory Agency (MHRA). Dysport Summary of Product Characteristics. Available at: https://mhraproducts4853.blob.core.windows.net/docs/a1a218c9644f1951052878716e8f52f3d4eeed80 [Accessed: 25 May 2023]. 5. Medicines and Healthcare products Regulatory Agency (MHRA). Xeomin Summary of Product Characteristics. Available at: https://mhraproducts4853.blob.core.windows.net/docs/d10f2f136a6338ccdcfedaca52025eef50a5cecf [Accessed: 25 May 2023]. 6. Grosset DG, Tyrrell EG, Grosset KA. Switch from abobotulinumtoxinA (Dysport®) to incobotulinumtoxinA (Xeomin®) botulinum toxin formulation: a review of 257 cases. J Rehabil Med 2015;47:183-6. 7. Cossar M, Cozens A. Botulinum toxin treatment for spasticity: clinical experience with changing from abobotulinumtoxinA (Dysport®) to incobotulinumtoxinA (Xeomin®), In 9th World Congree on Controversies in Neurology (CONy), Budapest, Hungary, 26-28th March, 2015.	

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					8. Fletcher NA, Crummie N. Efficacy of a 4:1 dose ratio in patients switching botulinum toxin formulation from abobotulinumtoxinA to incobotulinumtoxinA, In Toxins 2017, Madrid, Spain, 18-21 January 2017, 2017. 9. Elovic EP, Munin MC, Kaňovský P, et al. Randomized, placebo-controlled trial of incobotulinumtoxina for upper-limb post-stroke spasticity. Muscle & Nerve 2016;53:415-421. 10. Masakado Y, Abo M, Kondo K, et al. Efficacy and safety of incobotulinumtoxinA in post-stroke upper-limb spasticity in Japanese subjects: results from a randomized, double-blind, placebo-controlled study (J-PURE). Journal of neurology 2020;267:2029-2041. 11. Pandyan AD, Johnson GR, Price CI, et al. A review of the properties and limitations of the Ashworth and modified Ashworth Scales as measures of spasticity. Clin Rehabil 1999;13:373-83. 12. Wissel J, Bensmail D, Ferreira JJ, et al. Safety and efficacy of incobotulinumtoxinA doses up to 800 U in limb spasticity: The TOWER study. Neurology 2017;88:1321-1328. 13. Royal College of Physicians. Spasticity in adults: management using botulinum toxin. National guidelines. 2018:68-78.	

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					14. National Institute for Health and Care Excellence. NICE health technology evaluations: the manual. Process and methods [PMG36]. 15. Turner-Stokes L, Fheodoroff K, Jacinto J, et al. Results from the Upper Limb International Spasticity Study-II (ULISII):a large, international, prospective cohort study investigating practice and goal attainment following treatment with botulinum toxin A in real-life clinical management. BMJ Open 2013;3. 16. Shaw L, Rodgers H, Price C, et al. BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. Health Technol Assess 2010;14:1-113, iii-iv. 17. Makino K, Tilden D, Guarnieri C, et al. Cost Effectiveness of Long-Term Incobotulinumtoxin-A Treatment in the Management of Post-stroke Spasticity of the Upper Limb from the Australian Payer Perspective. Pharmacoecon Open 2019;3:93-102. 18. Kanovský P, Slawek J, Denes Z, et al. Efficacy and safety of botulinum neurotoxin NT 201 in poststroke upper limb spasticity. Clin Neuropharmacol 2009;32:259-65.	

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					19. Kaňovský P, Slawek J, Denes Z, et al. Efficacy and safety of treatment with incobotulinum toxin A (botulinum neurotoxin type A free from complexing proteins; NT 201) in post-stroke upper limb spasticity. J Rehabil Med 2011;43:486-92.	
141	Merz Pharma UK Ltd	Evidence review P	General	General	**Differences in mean MAS responders in the placebo arm of each clinical trial** As highlighted in response to comment 2, the trials included in the analysis for Xeomin and Botox are not comparable. The economic analysis presents the proportion of MAS responders in the placebo arm of the clinical trials included for each botulinum toxin type A preparation (Table 5). This demonstrates that there are substantial differences in the proportion of responders in the placebo arm of each trial; after 4 weeks, the proportion of responders in the placebo arms of the Xeomin, Dysport and Botox trials were 37.5%, 15% and 39%. The proportion of placebo responders in the	Thank you for your comment. There are differences between the trials, however it was not possible to quantitively address these other than ensuring the model uses mean differences in responders. Further discussion of the heterogeneity between trials has been added to the model write up and to the limitations of this analysis.

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					Xeomin and Botox trials are highly similar, whilst it is substantially lower in the Dysport trial. If it is assumed that the treatment received by patients in the placebo arm of each trial is equivalent, then it is likely that the difference in proportion of responders in the placebo arm is due to differences in the trial methodology and/or the patient populations included in the trials. Considering that a much lower proportion of patients in the placebo arm of the Dysport trial were responders, the Dysport trial may have included a less fit population of patients when compared to the Xeomin and Botox trials. Considering the baseline characteristics of patients included in the placebo arms of the trial for Dysport versus the trial for Xeomin, the mean age of patients was 52.7 years versus 57.1 years, respectively. Furthermore, the median time since last stroke was 58.8 months versus 27.8 months for the placebo arm of the Dysport trial versus the Xeomin trial, respectively.	

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					Although this baseline difference is accounted for when calculating the mean difference in responders, the baseline level may still impact the observed data in the trial.	
142	Merz Pharma UK Ltd	Evidence review P	General	General	**Xeomin, Botox and Dysport should be considered to be clinically equivalent** Xeomin, Botox and Dysport are three different formulations of botulinum toxin type A; Xeomin is incobotulinumtoxinA, Dysport is abotulinumtoxinA and Botox is onabotulinumtoxinA. IncobotulinumtoxinA (Xeomin) is a purified form of botulinum toxin type A which does not contain accessory proteins. All three botulinum toxin type A preparations operate via the same mechanism of action, by blocking cholinergic transmission at the neuromuscular junction by inhibiting the release of acetylcholine, and they all contain the same active ingredient (*Clostridium botulinum*).[3-5] Given the high degree of similarity in terms of their mechanism of action and composition, it is	Thank you for your comment. The committee agreed at the start of development of this guideline to keep all three drugs separate in the protocol for this review and therefore not meta-analysed in the clinical review. This was based on the lack of established potency equivalence or established conversion ratio between formulations. The ratio of equivalence is not clearly established in literature, with recent evidence (Brin (2014), Ferrari A (2018), Sławek J (2021)) arguing against the formation of universal conversion ratios. The source of Modified Ashwoth Scale responder data for Xeomin has now been changed from Elovic 2016 to to Masakado 2020, following the error you have correctly identified.

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					reasonable to assume that the clinical efficacy of each botulinum toxin type A preparation is highly similar, or clinically equivalent. Furthermore, incobotulinumtoxinA has been demonstrated to be clinically equivalent to onabotulinumtoxinA in the treatment of other neurological indications.[9] In the economic analysis, Xeomin, Botox and Dysport are all individually compared to usual care (placebo), and different conclusions are made on the relative efficacy of the botulinum toxin type A preparations. For example, after four weeks, the mean difference in responders for patients receiving the relevant botulinum toxin versus patients receiving placebo is 32%, 51% and 13% for Xeomin, Dysport (500U) and Botox, respectively (Economic analysis report, Page 16, Table 5). Based on these efficacy data, the economic analysis is considering Dysport to be over 1.5 times more effective than Xeomin (and nearly 4 times more effective than Botox) at the four-week timepoint. At later time points, such as 12 weeks,	The limited data available to allow for modelling has been noted in the guideline and is one of the reasons for the research recommendation for the clinical and cost effectiveness of botulinum toxin A was made. See your other comments for responses to references.

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					the economic analysis is considering Dysport to be twice as effective as Xeomin. Furthermore, considering the results of the analysis conducted over a 2-year time horizon, the quality-adjusted life years (QALYs) associated with Dysport are 0.76 compared with 0.45 for Xeomin; again, this analysis assumes that Dysport is over 1.5 times more effective than Xeomin. However, an independent comparison of the relative efficacy of Xeomin versus Dysport as a treatment for post-stroke upper limb focal spasticity was previously conducted by the Pharmaceutical Benefits Advisory Committee (PBAC) of Australia.[1] In this analysis, PBAC conclude that Xeomin is non-inferior to Dysport in terms of comparative effectiveness.[1] This was based on an indirect comparison of the available data for both Xeomin and Dysport. Moreover, it was concluded that 1U of Xeomin is clinically equivalent to approximately 4.3U of Dysport, which is supported by further evidence from the published literature.[2] A number of	

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					UK-specific studies have published data showing that Dysport and Xeomin are typically dosed at a 4:1 ratio, for both post-stroke spasticity and other indications, such as dystonia,[6-8] which is further supported by the recommended doses published in the National Royal College of Physicians Guidelines for spasticity in adults (appendix 2).[13] Based on a 1:4 ratio, the clinically equivalent dose to 400U of Xeomin would be approximately 1,600U of Dysport. Considering the high degree of similarity between the botulinum toxin preparations and the previously demonstrated clinical equivalence, the comparative efficacy evidence on which the economic analysis is founded, and the associated results, lack face validity. In particular, the assumption that a 400U dose of Xeomin is modelled to be substantially less effective than a 500U dose of Dysport, which is far lower than the commonly cited clinically equivalent dose, appears to be fundamentally flawed.	

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					As such, it must be considered whether the modelled differences in efficacy are arising from uncertainties associated with the data and assumptions used in the economic analysis, such as the differences in trial populations and endpoints (MAS versus AS) used, rather than actual differences in efficacy in UK clinical practice.	
143	Merz Pharma UK Ltd	Evidence review P	General	General	**Limitations associated with the treatment frequency and discontinuation assumptions used in the economic analysis** Discontinuation of botulinum toxin treatment was based on a UK real-world evidence study,[16] in which most patients received Dysport. Merz agree that it is reasonable to assume that discontinuation rates would be similar for Xeomin and Dysport, but would highlight that discontinuation does not appear to have been linked to efficacy/responder values in this analysis. In practice, treatment continuation would be dependent on a patients' response to treatment and therefore the accuracy of these inputs is limited.	Thank you for your comment. The discontinuation (proportion not receiving repeat injections) was based on 1 year UK data (Shaw 2010) which reported the proportion receiving repeat injections, where repeats were given based on assessment of need. This was used as there was no longitudinal data on proportion of responders from RCT data identified in the clinical review. A sensitivity analysis has been added to explore extrapolating the 12 weeks RCT MAS responder data, using the rate of discontinuation from Shaw 2010. This does not change the conclusions of the model. A sensitivity analysis has been conducted exploring a 25 week injection interval based on

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					There are also limitations associated with the 12-week treatment frequency used in the analysis. The 12-week interval is the minimum treatment interval recommended in the SmPC but is not necessarily reflective of clinical practice – indeed, it is unrealistic to assume that all patients would receive all future repeat injections at exactly 12-week intervals. In the OLEX phase of the Kanovsky et al. (2011) trial,[19] the median treatment interval for patients with upper limb spasticity treated with Xeomin was 99 days (14.1 weeks [95% CI: 95.7,108.7]). As highlighted in the economic analysis report, use of a shorter treatment interval results in increased treatment costs, in turn reducing cost effectiveness. Merz would therefore highlight that the dosage costs used in the analysis are likely an overestimate of the costs accrued in clinical practice.	Turner-Stokes 2021 ULISIII observational evidence. In this sensitivity analysis it was assumed the costs were reduced but the QALY benefit remained the same compared to a 12-week interval. This analysis reduced the ICERs for all comparators and suggested that the only additional comparator that may be cost effective was 400U of Xeomin over 2 and 5 years. The committee however had concerns that there was insufficient evidence to suggest the treatment effect would be maintained over such a long treatment interval time and so did not base a recommendation on this sensitivity analysis. A sensitivity analyses was also added for a 14 week injection interval. This does not change the conclusions of the model however the ICER for Xeomin 400U wrist (with PAS cost applied) was just over the £20,000 per QALY threshold. Based on this analysis the committee agreed to include up to 400U Xeomin for upper limb in the recommendation as maintenance of effect over 14 weeks was considered more plausible.

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144	Merz Pharma UK Ltd	Evidence review P	006	036	**Use of shortened time horizons** The economic analysis explored 12-week, 1-year and 2-year time horizons, which, based on the evidence in the published literature, are not sufficient to capture all costs and outcomes associated with botulinum toxin treatment. The NICE reference case states that a time horizon long enough to reflect all important differences in costs or outcomes between the technologies being compared should be used for economic analyses.[14] In practice, there is evidence that patients can remain on treatment well beyond the time horizons used in this analysis and would therefore accrue relevant costs and outcomes associated with treatment beyond this time horizon. The ULIS-II study was a large international real-world cohort study which included 456 adults with poststroke upper limb spasticity in whom a decision	Thank you for your comment. A sensitivity analysis has been conducted exploring a 5 year time horizon. As a result of the edits made to the model the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time.

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					had been made to inject botulinum toxin.[15] In this patient population, two thirds of participants had received botulinum toxin treatment for over 1-year, and the maximum number of injections previously received was 45 (interquartile range [IQR]: 1–8, range: 1–45). The median time since treatment initiation was 24 months and maximum treatment duration recorded was 168 months (range: 3–168).[15] It should also be noted that all of the patients in this study were still being treated with botulinum toxin injections. Similarly, Shaw et *al*. (2010)[16] found that 51.4% of patients were still receiving repeat injections at the end of their first year of treatment. Based on the preferred extrapolation used in the cost-effectiveness analysis (Figure 2, Page 15), ~38% of patients are on treatment at 2 years. As such, there is no reason to suggest that this 38% of patients would immediately discontinue their treatment at the end of Year 2.	

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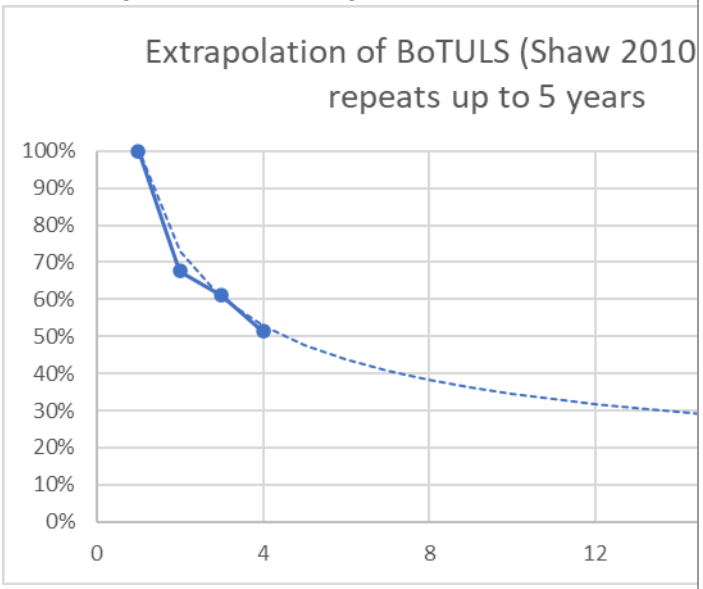
					Further extrapolation of these data from Shaw et al. (2010), using the same methods the economic analysis report, shows that a substantial proportion of patients would remain on treatment at 5 years (approximately 25%; Figure 1). This extrapolation, while uncertain, appears to be aligned with the data from the ULIS-II study,[15] in which 25% of patients received 8 or more previous injections, with a maximum number of 45 previous injections.	

					Figure 1: Extrapolation of BoTULS data on repeat injections up to 5 years  These data demonstrate that the short 12-week, 1-year and 2-year time horizons are inappropriate for this population, and undoubtedly omit some of the costs and benefits associated with longer-term treatment based on the extremely uncertain	

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					assumption that all patients would discontinue treatment after a short period of time. It is also worth highlighting that the use of these shortened time horizons in the modelling approach excludes the potential long-term benefits of botulinum toxin treatment for patients who will remain on treatment the longest, and therefore, are likely obtaining the most benefit from treatment. The use of shortened time horizons could be seen to inherently bias the results against Xeomin (and the other botulinum toxins treatments), compared to longer-term time horizons which would fully capture the costs and benefits (in line with the NICE reference case). This is observed in the decrease in the ICERs observed in the two-year time horizons scenarios; it is only reasonable to assume that the cost-effectiveness of Xeomin would increase further with the consideration of extended time horizons that more appropriately reflect clinical practice.	

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					Merz recommend that time horizons up to at least 5 years be explored, to fully evaluate the costs and benefits associated with botulinum treatment. Clinical validation of the typical treatment duration should be obtained to gain a greater understanding of the number of repeat injections that patients would receive in UK clinical practice and therefore ensure the analysis is correctly reflecting this.	
145	Merz Pharma UK Ltd	Evidence review P	015	General	**Selection of Modified Ashworth Scale responder data as the only efficacy endpoint** It is unclear from the economic analysis report why MAS responder data is selected as the only efficacy endpoint to inform the economic analysis, apart from the fact that it was previously used in a cost-utility analysis of botulinum toxin type A preparations, considering that the selected trial for Xeomin reports AS responder data (see comment 2 for further details). Merz agree that MAS responder data represents an appropriate measure of efficacy to include in the economic analysis, but if doing so, a trial reporting MAS responder data for Xeomin,	Thank you for your comment. Incorporating Modified Ashworth Scale responder data as an approach to modelling was considered the only available way of incorporating HRQoL and thus estimating QALYs. No other approach was identified that would allow for more incorporation of clinical evidence. This is detailed in the health economic model write up. Thank you for identifying the mis-categorisation of Elovic 2016 RCT as Modified Ashworth Scale when indeed it was Ashworth Scale. JPURE (Masakado 2020) has now been added into analysis and Elovic2016 removed. As a result of the post stakeholder consultation edits

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					such as J-PURE, reported by Masakado *et al. (*2020), should be included. **Modified Ashworth Scale responder data and Ashworth Scale responder data are not equivalent** As highlighted in comment 2, the PURE trial reports AS responder data, whilst the trials for Botox and Dysport report MAS responder data. Merz wish to highlight that AS and MAS are not equivalent endpoints, and a 1-point change in AS and MAS are therefore not comparable. The AS was developed as a simple tool to test the efficacy of anti-spastic drugs, and it includes a scale from 0 to 4, with 4 representing the maximum level of spasticity. The MAS was subsequently developed by including an additional category of 1+, which falls between 1 and 2. This converted the 5-point AS to a 6-point scale, with the aim of increasing the sensitivity of the measure to changes in spasticity.[11]	made to the model, including this new data, the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time.

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<tr><td></td><td></td><td></td><td></td><td></td><td>An overview of the points included in the AS and MAS, and associated interpretation, are presented in Table 1.

Table 1: AS and MAS
<table>
<tr><th>Score</th><th>AS (5-point scale)</th><th></th></tr>
<tr><td>0</td><td>No increase in tone</td><td>No increas</td></tr>
<tr><td>1</td><td>Slight increase in tone, giving a catch when the limb was moved in flexion or extension</td><td>Slight incre and releas ROM whe extension</td></tr>
<tr><td>1+</td><td>NA – category not included in AS</td><td>Slight incre followed b remainder</td></tr>
<tr><td>2</td><td>More marked increase in tone but limb easily moved</td><td>More mark the ROM,</td></tr>
<tr><td>3</td><td>Considerable increase in tone, passive movement difficult</td><td>Considera movement</td></tr>
<tr><td>4</td><td>Limb rigid in flexion or extension</td><td>Affected p</td></tr>
</table></td><td></td></tr>
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					Abbreviations: AS: Ashworth Scale; MAS: Modified Ashworth Scale; ROM: range of motion. **Source**: Adapted from Pandyan *et al.*, 1999.[11] Considering the differences in the MAS and AS, it is apparent that the scales are not comparable; importantly for the economic analysis conducted, a ≥1-point change in the MAS and AS does not demonstrate an equivalent treatment effect. As the MAS is more sensitive, a 1-point change in MAS can be achieved by a relatively smaller improvement in spasticity when compared to the AS; one patient may be classified as a responder based on MAS, but a non-responder based on AS. As such, comparing the efficacy of the Xeomin, based on AS, with the efficacy of Botox and Dysport, based on MAS, is not a fair comparison. As outlined in comment 2, if MAS is to be the sole outcome informing the economic analysis, alternative trials for Xeomin must be considered.	

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					Furthermore, the economic analysis uses health state utility values that are derived from responder and non-responder patients based on MAS. The appropriateness of the utility values is discussed further in comment 8, but it is not appropriate to apply utility values derived from MAS responder data to AS responder data. Based on the decreased sensitivity of AS versus MAS, it is reasonable to assume that a responder based on a ≥1-point change in AS has an increased health-related quality of life (HRQoL) than a responder based on a ≥1-point change in MAS.	
146	Merz Pharma UK Ltd	Evidence review P	017	004	**Uncertainty regarding the original source for the utility values for responder and non-responder patients** The utility values for responder and non-responder patients were obtained from Makino *et al.* (2019),[17] which references Kanovsky *et al.* (2009)[18] as the original source. However, upon further investigation it is highly unclear from where these values were sourced. Merz can confirm that EQ-5D data was not collected during the clinical trial reported by Kanovsky *et al.* (NCT00432666) and is not	Thank you for your comment. During development we had tried contacting both authors and received no response. AbbVie have found more information according to their comments. Overall, the developers agree there is poor reporting. This is a limitation that was already captured in the write up. No alternative data source was identified that reported quality of life by MAS responder status following botulinum toxin A. Furthermore, no alternative

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					mentioned or reported in either the Kanovsky *et al*. (2009) or Kanovsky *et al*. (2011) publications.[18, 19] As such, it is unclear where the utility values reported in Makino *et al.* (2019)[17] have been derived from, adding a substantial source of uncertainty into the presented cost-effectiveness analyses. Due to the small incremental QALYs associated with botulinum toxin treatment, the reported ICER is highly sensitive to changes in QALYs, and any uncertainty associated with the utility values is likely to have a significant impact on the final cost-effectiveness results. It is therefore unreasonable to conclude that Xeomin is not cost-effective compared with usual care based on the results of an analysis which are underpinned by utility values, which have been incorrectly referenced, and for which the original source cannot be located, meaning that no methodological details on the collection of these EQ-5D data is available. As such, the validity of the	approach to modelling using another clinical outcome was identified that would allow for the incorporation of more RCTs into the analysis. The committee were keen to conduct modelling despite these limitations, to support positive recommendations for botulinum toxin A. Without the de novo analysis no recommendations would have been possible as the existing health economic evidence was not supportive of botulinum toxins. Following direct communication with Merz after the submission of this comment requesting detail on the evidence available from the TOWER trial, it was established that EQ-5D data was not available by Modified Ashworth Scale responder status but only by Ashworth Scale, therefore this study was not a suitable alternative.

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					overall cost-effectiveness analyses presented in the draft guideline must be considered highly uncertain. It should be noted that the TOWER trial, reported by Fheodoroff *et al.* (2020), did report EQ-5D data for patients with upper and lower limb spasticity, and could potentially be used as an alternative source for utility data to inform a revised economic analysis. Merz can provide EQ-5D data from this study upon request.	
147	Merz Pharma UK Ltd	Evidence review P	017	027	**Use of list prices in the economic analysis** Drug costs for all three treatments were calculated using the list price from the BNF and did not consider the confidential PAS prices to which they are supplied to the NHS. Xeomin is available at a confidential discount price of [redacted] per 100U vial, representing a discount of [redacted]% on the published list price. As a result, the drug costs reported in the economic analysis are an overestimate of those that would be borne by the NHS in practice. As a result the incremental costs compared with usual care are also an overestimate,	Thank you for your comment: The Patient Access Scheme (PAS) price for Xeomin has now been included in the analysis.

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					therefore directly impacting the cost-effectiveness of botulinum toxins compared with usual care. The PAS prices for each Botulinum toxin should be used in the analysis to provide a more accurate estimate of the incremental costs accrued compared with usual care. (Confidential information redacted)	
148	Merz Pharma UK Ltd	Evidence review P	017	032	**Limitations associated with the dosage included in the economic analysis** As highlighted in comment 2, only one possible dose for Xeomin has been considered (400U), whilst multiple doses for Dysport (500 U and 1000U) have been considered in the economic analysis. As highlighted previously, the J-PURE trial is an additional trial providing efficacy data for Xeomin as a treatment for upper limb post-stroke spasticity.[10] In this trial, the efficacy of Xeomin is investigated when given at two different doses: 250U or 400U. Given that efficacy data are available for Xeomin at a lower dose, the cost-effectiveness of Xeomin at	Thank you for your comment. Masakado 2020 (JPURE) has now been added and Elovic 2016 (PURE) has been removed to ensure the inclusion of MAS responder data only. As a result, both doses of Xeomin (250U and 400U) are now included interventions.

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					250U should be explored to ensure a fair assessment of all botulinum toxin type A preparations is being conducted – data to inform this analysis are provided from the J-PURE trial as part of Table 4 in Comment 2. Furthermore, in the economic analysis conducted, the full dose of Xeomin is included for costing purposes (400U). However, the AS responder data used to inform the efficacy of Xeomin are based on improvements in AS for the primary target clinical pattern only, rather than all clinical patterns being treated with the full dose. If the economic analysis is only considering efficacy data for one target clinical pattern, then the dose and associated cost should correspond appropriately. For the majority of clinical patterns, the maximum dose permitted to treat the muscles for a single clinical pattern is lower than the 400U included in the economic analysis. As such, in the majority of cases, the costs associated with treating one clinical pattern with Xeomin are likely to	

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					be lower than the costs included in the economic analysis. Furthermore, the TOWER study investigated the efficacy of Xeomin when treating multiple clinical patterns (using a maximum dose of 800U).[12] This trial demonstrated that treating a greater number of clinical patterns was associated with increased efficacy, in terms of improved muscle tone (measured by the Resistance to Passive Movement Scale, based on AS) and goal attainment.[12] If the maximum dose of Xeomin is to be used in the analysis, the potential for additional efficacy gains beyond those observed for the primary treatment clinical pattern that would not be currently captured in the AS responder data from the PURE trial should also be accounted for.	
149	Merz Pharma UK Ltd	Evidence review P	015 – 016	General	**Limitations associated with the selection of the PURE trial as the only source of efficacy evidence for Xeomin (incobotulinumtoxinA)** The economic analysis report outlines that one clinical trial reporting evidence for Xeomin, the	Thank you for your comment. Masakado 2020 (JPURE) has now been added and Elovic 2016 (PURE) removed to ensure the inclusion of MAS responder data only. As a result, both doses of Xeomin (250U and 400U) are now included interventions.

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					PURE trial (published by Elovic *et al.* [2016]), was selected as the primary efficacy evidence for inclusion in the economic analysis.[9] The report states that the PURE trial was selected to inform the efficacy of Xeomin in the economic analysis on the basis that it reports Modified Ashworth Scale (MAS) responder data. However, Merz wish to highlight that Elovic *et al.* (2016) reports Ashworth Scale (AS) responder data, rather than MAS responder data.[9] This is not highlighted in the report and a number of associated comments in the report which state that Elovic *et al.* (2016) reports MAS data are incorrect. In addition, the differences between AS and MAS have important implications on the interpretation of responder data, and this has not been acknowledged throughout the economic analysis report. See comment 3 for further information on this. The economic analysis report states that "only three RCTs with MAS responder data are usable for modelling", with the three randomised controlled	

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					trials (RCTs) being Elovic *et al.* (2016), Gracies *et al.* (2015) and Wein *et al.* (2018). As Elovic *et al.* (2016) reports AS, rather than MAS, responder data, this statement is incorrect. Furthermore, in addition to Elovic *et al.* (2016), a number of additional and potentially relevant trials for Xeomin as a treatment for post-stroke spasticity of the upper limb exist. These include Wissel *et al.* (2017), Kanovsky *et al.* (2009), Kanovsky *et al.* (2011), Kanovsky *et al*. (2016) and Barnes *et al.* (2010), all of which report AS responder data. Given this, the draft guidance does not provide a clear rationale for the exclusion of this clinical trial data in favour of the sole consideration of Elovic *et al.* (2016). Most notably, in addition to these trials, Xeomin was also investigated in the J-PURE trial which uses the MAS, which is directly aligned with the endpoints used to inform the cost-effectiveness analysis for the other botulinum toxin Type A preparations,	

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					which also used the MAS. The J-PURE trial, reported by Masakado *et al.* (2020), is an additional trial investigating the efficacy and safety of Xeomin as a treatment for upper limb post-stroke spasticity, which reports MAS responder data for both 400U and 250U doses of Xeomin.[10] An overview of the MAS responder data based on a dose of 400U or 250U of Xeomin reported in Masakado *et al.* (2020) is presented in Table 2.[10] **Table 2: MAS responder data reported in Masakado *et al.* (2020)[10]** **(Table removed)** **Abbreviations**: MAS: Modified Ashworth Scale. **Source**: Adapted from Masakado *et al.* (2020)[10] The J-PURE study did not collect details on the treatment of the 'primary target clinical pattern', and so it is not possible to directly compare the proportion of responders for the primary target	

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					clinical pattern according to the AS in the PURE study, compared to the MAS in the J-PURE study. However, it is possible to compare the proportion of patients experiencing a response with respect to individual clinical patterns at Week 4 between the PURE and J-PURE studies, as detailed in Table 3 below, based on Merz data on file for the J-PURE study. In the Elovic *et al.* (2016) study, the primary target clinical pattern consisted of either the flexed elbow, flexed wrist or clenched fist – therefore, results are presented for these individual clinical patterns for both studies. A response was defined a ≥1 point improvement according to the AS in the PURE study, and a ≥1 point improvement according to the MAS in the J-PURE study. As shown in Table 3, the relative difference between 400U Xeomin versus placebo [redacted] in the J-PURE study for all but one of the endpoints considered, compared to the PURE study. One of the contributing factors is likely to be	

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					the reduced sensitivity of the AS compared to the MAS, as discussed further in response to Comment 3. **Table 3: Comparison of Xeomin versus placebo in the PURE and J-PURE studies** (Table removed) However, these differences highlight the importance of considering all of the potentially relevant evidence for Xeomin, rather than solely using the PURE trial, which may underestimate the relative difference between Xeomin versus placebo when compared to other clinical trials. It is unclear from the economic report what exact criteria have been used to select the PURE trial as the sole source of efficacy evidence for Xeomin, and why the J-PURE trial in particular has not been considered for inclusion in the economic analysis. Additional clinical results from the J-PURE study are provided in Table 4, in order to allow the incorporation of the results from the J-PURE study	

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					into the economic model, based on Merz data on file. **Table 4: Relative difference in the proportion of patients responding to Xeomin versus placebo in the J-PURE study** (Table removed) Given the existence of numerous trials reporting on the efficacy of Xeomin, and the other botulinum toxin type A preparations, it is unclear why the totality of evidence available for Xeomin has not been considered when assessing the relative efficacy of Xeomin versus usual care and the associated cost-effectiveness. Furthermore, Merz wish to highlight that the trials included for the three botulinum toxins are not comparable. In particular, the trial included for Dysport (abotulinumtoxinA) explores multiple possible doses (500U and 1000U), whilst the Xeomin trial (and Botox [onabotulinumtoxinA] trial) includes a fixed dose of 400U. If the possibility of using lower doses is being explored for Dysport, the	

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					same should be applied for the other botulinum toxins. See comment 4 for further information.	
150	National Hospital for Neurology & Neurosurgery	Draft Guideline	012-013	007 - 003	We agree with these additions.	Thank you for your comment.
151	National Hospital for Neurology & Neurosurgery	Draft Guideline	006-007	023	We support these changes which improve information provided to patients and carers about Early Supported Discharge (including psychological and emotional support). It is unclear why these recommendations apply only to 'before and during early supported discharge' and not the community rehabilitation phase, which is likely to be more long term.	Thank you for your comment. These recommendations followed a review of the evidence for the Early Supported Discharge review and so was recommended for this area. We did not review the evidence around other discharge models, but the committee agree that there is no obvious reason why this should not apply to other parts of rehabilitation as well.
152	National Hospital for Neurology & Neurosurgery	Draft Guideline	006	012	We support the recommendation to provide rehabilitation for as long as it continues to help patients achieve their treatment goals, even after they have left hospital. The wording allows treatment at the level of impairment, activity and participation. The concept of a recovery plateau does not apply to activity and participation and so this implies life-long treatment to promote recovery	Thank you for your comment. The committee agrees that this is an important recommendation and are pleased that support has been expressed by a number of stakeholders. We believe the recommendation is sufficiently clear and includes the possibility of life-long treatment to promote recovery.

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					should be available. It is important that this change in guidelines is made clear and explicit to patients and carers. There will be implications for staffing levels which will need to be met in community care settings to comply with this guideline.	
153	National Hospital for Neurology & Neurosurgery	Draft Guideline	012	002	These recommendations are different to those in the National Clinical Guidelines (2023), which make recommendations specifically for motor recovery and state that 'People with motor recovery goals undergoing rehabilitation after a stroke should receive a minimum of 3 hours of multidisciplinary therapy a day (delivered or supervised by a therapist or rehabilitation assistant focused on exercise, motor retraining and/or functional practice)….'. This is based on evidence regarding the effects of greater amounts of therapy (dose) (Kwakkel et al, 1999; Kwakkel & Wagenaar, 2002; Bhogal et al, 2003a; Bhogal et al, 2003b; Kwakkel et al, 2004) and is reflected in other clinical guidelines around the world (Australia (Stroke Foundation, 2022), Canada (Teasell et al, 2020) and the Netherlands (Veerbeek et al, 2014a)). Please see also Daly JJ, McCabe JP, Holcomb J, Monkiewicz M, Gansen J, Pundik S. Long-Dose Intensive Therapy Is Necessary for Strong, Clinically	Thank you for your comment. Stakeholders have made some very reasonable points about the available evidence and the committee have reflected on this. The recommendation has been amended. Our recommendations were made using systematic reviewing methodology where evidence was searched for using methods as outlined in Developing NICE guidelines: the manual. The studies listed were excluded from our review (please see the excluded studies table in the evidence report for more information). We agree that the time spent should be time-on-task. This is highlighted in the qualitative evidence review in the area (please see the evidence review).

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					Significant, Upper Limb Functional Gains and Retained Gains in Severe/Moderate Chronic Stroke. Neurorehabil Neural Repair. 2019 Jul;33(7):523-537. This is essentially a replication of an RCT (McCabe et al Arch Phys Med Rehabil. 2015 Jun;96(6):981-90) that delivered 300 hours of upper limb rehab over 12 weeks (= 5 hrs/day) and showed large changes at the impairment level. Why have these studies not been considered by the committee? The NICE and NCG should be aligned. This could be achieved by amending the recommendations regarding physiotherapy to read '…. For at least 1 to 2 hours a day' in line with OT and SLT. They should also both be clear that this recommended time refers to 'time-on-task' not simply session length (Time on task is often approx. 50% of session length). In relation to speech and language therapy, 45 mins is unlikely to be enough. The NCG state 'Intensive speech and language therapy such as	The RELEASE meta-analysis was identified and evaluated by the committee. On comparing the different results in this analysis, no clinically important differences were found between the different intensities in this analysis in improving communication outcomes. Therefore, the committee could not recommend a change to the current recommendation based on these results.

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					comprehensive aphasia programmes may be considered from 3 months after stroke for those who can tolerate high-intensity therapy.' ICAPS deliver 6-7 hours a day of therapy and should be acknowledged. The NCG states 'One way of delivering higher doses of therapy is through comprehensive aphasia programmes, with positive results seen in one non-randomised trial (Hoover et al, 2017) and one observational study (Leff et al, 2021). However, not all people with aphasia can manage the high-intensity treatment mandated by these programmes. These studies suffer from selection bias and their results cannot be generalised to all people with aphasia, and more high quality research is needed.' There is no comment on doses of SALT require for PWA. It is clear that PWA require a minimum of 50 hours of SALT contact in order to make functional gains in their communicative ability. The evidence for this has accrued over the last 20 years and includes the RELEASE meta-analysis that the committee have included in their document Evidence review E, but doesn't seem to have made it through to the recommendation stage: Bhogal's	

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					seminal meta-analysis suggested 100 hours (Bhogal et al., 2003), the latest Cochrane review between 60 and 208 hours (Brady et al., 2016) and the most recent evidence from the RELEASE project, 50+ hours (Brady et al., 2022). One further comment. Separating PT, OT, SLT (and neuropsychology) as separate and independent treatments does not reflect clinical practice. Almost all stroke deficits will require MDT input, PT/OT for upper limb, SLT/OT/neuropsychology for aphasia/cognitive communication deficit. Although the committee can only consider the studies provided, recommendations for future research might include examining MDT-based treatments that reflect the fact that neurorehabilitation is a complex intervention (unlike drugs or surgery).	
154	National Hospital for Neurology &	Draft Guideline	013	010-018	Telerehabilitation – we agree with these recommendations.	Thank you for your comment.

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155	National Hospital for Neurology & Neurosurgery	Draft Guideline	017	010	Fatigue - we agree with these recommendations.	Thank you for your comments.
156	National Hospital for Neurology & Neurosurgery	Draft Guideline	017	018	Vision - we agree with these recommendations. But should point toward resources for eye-movement therapies that have been shown to be effective in controlled trials (see Computer-Based Tool section below)	Thank you for your comment. Consideration of computer-based tools for vision therapy was not within the scope for this update of the guideline. It will be passed on to the NICE surveillance team.
157	National Hospital for Neurology & Neurosurgery	Draft Guideline	018	003	Include links to free-to-use apps that have been shown to be effective in controlled trails e.g.: Read-Right (Woodhead et al., 2015), for people with hemianopic alexia and Eye-Search (Ong et al., 2015; Szalados et al., 2020), for people with reduces visual search due to hemianopia.	Thank you for your comment. The use of apps to manage hemianopia was not identified as an area for review in this version of the guideline at scoping and we are not able to make a recommendation about this at this time.

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					Ong, Y. H., Jacquin-Courtois, S., Gorgoraptis, N., Bays, P. M., Husain, M., & Leff, A. P. (2015). Eye-Search: A web-based therapy that improves visual search in hemianopia. Ann Clin Transl Neurol, 2(1), 74-78. https://doi.org/10.1002/acn3.154 Szalados, R., Leff, A. P., & Doogan, C. E. (2020). The clinical effectiveness of Eye-Search therapy for patients with hemianopia, neglect or hemianopia and neglect. Neuropsychol Rehabil, 1-12. https://doi.org/10.1080/09602011.2020.1751662 Woodhead, Z. V. J., Ong, Y. H., & Leff, A. P. (2015). Web-based therapy for hemianopic alexia is syndrome-specific. BMJ Innovations, 1(3), 88-95. https://doi.org/http://dx.doi.org/10.1136/bmjinnov-2015-000041	
158	National Hospital for Neurology & Neurosurgery	Draft Guideline	018	009	Hearing - we agree with these recommendations.	Thank you for your comment.

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159	National Hospital for Neurology & Neurosurgery	Draft Guideline	019	001	Mouthcare - we agree with these recommendations.	Thank you for your comment.
160	National Hospital for Neurology & Neurosurgery	Draft Guideline	019	013	Swallowing - we agree with these recommendations.	Thank you for your comment.
161	National Hospital for Neurology & Neurosurgery	Draft Guideline	022	010	Should probably add in the word 'app' as not identical to computer based programme and apps are more common	Thank you for your comment. The word "app" has been added.
162	National Hospital for Neurolo	Draft Guideline	022	010	It is not clear to us why two apps for patients with aphasia that have been subjected to RCTs and published in peer-reviewed journals have been omitted from the NICE guideline process. They are	Thank you for your comment. The developers had not identified Fleming, et al. as being a relevant study for the review, and

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	gy & Neurosurgery				in scope, in the correct time period and are not in the excluded studies section of the relevant [J] Evidence reviews for computer-based tools for speech and language therapy, Appendix J – Excluded studies. iReadMore is an app that was tested in a registered, randomised clinical trial in PWA who had central alexia. Participants completed two 4-week blocks of iReadMore training (34 hours each). iReadMore training resulted in an 8.7% improvement in reading accuracy for trained words (95% confidence interval 6.0 to 11.4; Cohen's d = 1.38) (Woodhead et al., 2018). Similarly, Listen-In, an app for PWA with auditory comprehension impairment was tested in a registered, randomised clinical trial. Repeated measures analyses of variance compared change in spoken language comprehension on two co-primary outcomes over therapy versus standard care. The first study-specific co-primary outcome (Auditory Comprehension Test (ACT)) showed large and significant improvements for trained spoken words over therapy versus standard care (11%, Cohen's	have now added it, thank you for this. This does not change the results of the review. Woodhead, et al. is a study where all people receive the iReadMore intervention while the crossover trial compares people receiving transcranial direct current stimulation to people receiving sham transcranial direct current stimulation while participating in the study. Therefore, this is not a relevant comparator for this review. This has been added to the excluded studies table.

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					d=1.12). Gains were largely maintained at 12 and 24 weeks (Fleming et al., 2020). Fleming, V., Brownsett, S., Krason, A., Maegli, M. A., Coley-Fisher, H., Ong, Y.-H., Nardo, D., Leach, R., Howard, D., Robson, H., Warburton, E., Ashburner, J., Price, C. J., Crinion, J. T., & Leff, A. P. (2020). Efficacy of spoken word comprehension therapy in patients with chronic aphasia: a cross-over randomised controlled trial with structural imaging. Journal of Neurology, Neurosurgery & Psychiatry, jnnp-2020-324256. https://doi.org/10.1136/jnnp-2020-324256 Woodhead, Z. V. J., Kerry, S. J., Aguilar, O. M., Ong, Y. H., Hogan, J. S., Pappa, K., Leff, A. P., & Crinion, J. T. (2018). Randomized trial of iReadMore word reading training and brain stimulation in central alexia. Brain, 141(7), 2127-2141. https://doi.org/10.1093/brain/awy138	
163	National Hospital for	Draft Guideline	026	015	The recommendation on robot-assisted arm training is misguided. The committee acknowledge that robotic devices can have an effect, but certainly no	Thank you for your comment. . The committee took into account cost-effectiveness data that indicated that robot arm

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	Neurology & Neurosurgery				greater than face to face physiotherapy. However, robotic devices are simply impairment treating devices. Robotic devices are not meant to improve functional goals or quality of life. Turning impairment reduction into functional goals requires specialist treatment from PT/OT – the so-called 'transfer package'. The situation is similar to constraint induced movement therapy which requires education in how to transfer impairment gains into functional goals – the transfer package. We know that robotic devices are not designed to have an effect on functional goals and QoL (the trials confirm this), but they can impact impairment, which can then be turned into functional gains and improved QoL by a multidisciplinary rehabilitation team. Recommending not using robots because of evidence that there is no effect on something they were not designed to do makes little sense. Robotic devices might reduce staffing needs to offset cost, but it is unclear whether this has been examined yet	therapy was not cost effective. To note, some of the studies included robot devices that were combined with conventional therapy (including physiotherapy and occupational therapy) where they were not able to achieve clinically important benefits in functional goals and quality of life, indicating that the impairment benefits could not be changed into clinically important functional gains and improved quality of life in those studies. Based on this, the assessment of the evidence including the absence of cost-effectiveness, we will not change this recommendation. However, the developers appreciate that this is evolving technology and more supportive evidence may emerge in the future.

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					We suggest altering the recommendation to 'Robot-assisted arm training is not superior to physiotherapy, but may be used as an adjunct to treat impairment as part of a multidisciplinary approach to upper limb rehabilitation if devices are available'.	
164	National Hospital for Neurology & Neurosurgery	Draft Guideline	28	017	Mirror therapy is still a little controversial because it is deployed in so many different ways. Please state that it should be used as an adjunct to a multidisciplinary (PT and OT) upper limb rehabilitation programme, not instead of. The current wording simply suggests it can be used as part of a rehabilitation programme, which would allow mirror therapy to be used as the only upper limb treatment. The NCG recommendations are clearer – 'People with stroke may be considered for mirror therapy to improve arm function following stroke as an adjunct to usual therapy.'	Thank you for your comment. The committee agree with you and the wording of the recommendation has been amended.
165	National Hospital for Neurolo	Draft Guideline	029	006	We strongly agree that post-stroke shoulder pain should be actively sought as it is a major unnecessary cause of upper limb impairment	Thank you for your comment.

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	gy & Neurosurgery					
166	National Hospital for Neurology & Neurosurgery	Draft Guideline	029	011	Steroid and nerve block injections may reduce pain, but must be combined with appropriate physical management, or else the problem will recur. For example, frozen shoulder is common after stroke, but requires physiotherapy. Physiotherapy will not work unless the pain is first managed. Please indicate that physical therapy also needed or else recommendation does not make sense.	Thank you for your comment. The recommendations in this section should not be taken in isolation from one another. The committee agree that more than one form of therapy may be required in any particular case. Please note recommendation 1.14.2 which states that the cause of shoulder pain should be sought and management geared to cause(s) when found. In your example, if a frozen shoulder is diagnosed physiotherapy should be offered.
167	National Hospital for Neurology & Neurosurgery	Draft Guideline	030	001	Spasticity – new guidelines are welcomed. The recommendations are appropriate when thinking about managing spasticity to avoid long term complications. However, when managing spasticity in order to allow patients to train more effectively (accessing underlying finger extension for example), spasticity management must be followed by intense physiotherapy, or else the goal of improved function will not be met, and the cost of the spasticity treatment will have been wasted.	Thank you for your comment. The committee agree. The guideline does not imply that treatment of spasticity takes place without any of the therapies covered in other sections, including intense physiotherapy.

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					The addition of NMES is welcome.	
168	National Hospital for Neurology & Neurosurgery	Draft Guideline	036	009	The recommendation to test whether 7 day rehabilitation is better than 5 day rehabilitation will not be particularly fruitful, especially if delivered at current low doses (an extra 2 days of not very much is still not very much). It is widely accepted that a higher 'dose' of rehabilitation is more effective. Research should now focus on how to practically achieve the highest tolerable dose possible using combinations of MDT and technologies.	Thank you for your comment. There is insufficient evidence to make a recommendation to increase intensity from 5 to 7 days and uncertainty in how tolerable this is, as highlighted in the qualitative evidence from this review. Moreover, the cost-effectiveness of this increase is not well supported by current evidence.
169	Neater Solutions Limited	Evidence review M	General	General	There have been inconsistent outcomes reported in studies using devices to aid with upper limb rehabilitation. However, if the intervention is properly supported by physio and occupational therapists (PT/OT), then it can be very successful (see review and meta-analysis reference below). Neuroplasticity is an acknowledged rehabilitation phenomenon. For a patient to benefit, they need to perform multiple repetitions of exercises for extensive periods of time. This is a challenge to health services both in terms of staff cost and simply in terms of staff availability. If affordable equipment were available that successfully encouraged patients to perform multiple repetitions of beneficial exercises (as assessed by PT/OT) this could be	Thank you for your comment. The RATULS RCT was included as directly applicable economic evidence for this review as it was a large, recent NIHR funded, UK-based study. This study concluded that robot-assisted arm training was not cost-effective when compared to both usual care and enhanced-upper limb training as it incurred higher costs and lower quality of life.

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					beneficial to patient outcome at relatively low cost ie: good cost-utility (QALYs). Good outcomes require patient engagement and other factors affecting patient suitability. Studies involving unsuitable patients negatively affect overall results. "Robotic arm use for upper limb rehabilitation after stroke: A systematic review and meta-analysis" Bih-O Lee, Ita Daryanti Saragih, Sakti Oktaria Batubara First published: 31 March 2023 Kaohsiung Journal of Medical Sciences, Volume 39, Issue 5 Pages 435-445 https://doi.org/10.1002/kjm2.12679 "CONCLUSION: Robotic arm interventions significantly improved upper limb function and hand function in patients with stroke. Upper limb function significantly improved when the robotic arm intervention duration was 30–60 min per session. Despite heterogeneity across the studies, a robotic arm could help patients with stroke have better health outcomes."	
170	Neater Solutions Limited	Evidence review M	084 - 085	017-035 001-003	The example given in GID-NG10175 tables 5 & 6 does not make sense to us. (Two project managers and two engineers have looked at this with us.) We do not understand why and how the discount factor	Thank you for your comment. A comment will be added to the evidence review noting the uncertainty around the discounted capital costs reported. However, sufficient evidence for other

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					has been applied with the (lowest) final annual cost from table 5 then used in table 6. The equipment used in the example has a far higher cost than is necessary to achieve useful therapy. (Confidential information removed). We are happy to discuss this in more detail.	Robot-training interventions, in the form of clinical trials and/or economic evaluations must be published before it can be incorporated into the evidence review.
171	NHS England	Guideline	General	General	We strongly suggest reference to and greater mention of how to ensure services are accessible to disabled people, people from BAME communities and other under-represented groups. We note there is very limited mention of health inequalities and the impact this might have in accessing services, rehabilitation and self-management going forward.	Thank you for your comment. The NICE guideline on patient experience in adult NHS services provides guidance on ensuring services are accessible. Extra mentions have been added to the guideline to emphasise this. We have also amended the recommendation on community participation programmes to recommend that these services are accessible.
172	NHS England	Guideline	General	General	With respect to disabled adults, including autistic people and those with a learning disability or both, we strongly suggest that it is essential that particular attention is made to ensure families and carers are involved in the screening and assessment processes, as they will be able to support in more accurately assessing the degree of difference in cognition, movement and strength as a	Thank you for your comment. The sections of the guideline on assessment were not part of this update. A reference to the NICE guideline on care and support of people growing older with learning disabilities has been made in the section on assessing care and support needs to support healthcare professionals to find information in this area.

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					consequence of any CVA or TIA. Changes in functionality around communication/movement etc., may not be easily determined by clinicians particularly for those individuals who may have pre-existing impairments if they are disabled and so involving families is really important. This will be particularly critical for people who previously had very limited mobility, and/or cognition and for those people who may have limited speech or whom are non-verbal. Similarly, if a person does not have English as a first language or uses BSL then interpreters and family members will need to support in any assessment.	
173	NHS England	Guideline	General	General	We strongly suggest that given the important role primary care has in supporting individuals and families/carers after suffering a stroke and with longer term effects that the document articulates the support from GPs and the wider primary care team that is available to people and that this may be needed particularly where community participation services may not be accessible for people with a learning disability or autistic people. Social prescribers may be able to help in the support of more bespoke programmes.	Thank you for your comment. It is not clear to us which recommendations you are discussing here. Primary care is indeed important, but the guideline is about what should be done rather than who does it. The role of social prescription was not suggested for inclusion during scoping and therefore was not included as part of this update.

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174	NHS England	Guideline	General	General	We strongly suggest consideration for existing multidisciplinary input into the care of the person. Consideration should also be given to the role of an organisation's learning disability team or liaison nurse on issues of communication, reasonable adjustments, pain assessment etc. Their presence may be particularly useful in the early supported discharge planning meeting. (P06 Line 23).	Thank you for your comment. Getting appropriate input of other agencies such as the learning disability team applies to any medical admission. A link to the NICE guideline on care and support of people growing older with learning disabilities has been added, rather than making a specific recommendation.
175	NHS England	Guideline	General	General	We strongly suggest the document refers to and provides awareness of healthcare passports. Some people with a learning disability and some autistic people may have a healthcare passport giving information about the person and their health needs, preferred method of communication and other preferences. Ask the person or their accompanying carer if they have one of these. Their use would be particularly useful as part of any assessment or rehab but more so communication styles, improvement in communication is a key aspect of rehab after a stroke and a clear understanding of the baseline for a person with a learning disability will be really important in measuring progress.	Thank you for your comment. The advisability of asking about and acting on information in a healthcare passport applies to any medical admission. Therefore, a link to the NICE guideline on care and support of people growing older with learning disabilities has been added, rather than making a specific recommendation.

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176	NHS England	Guideline	General	General	We strongly suggest the document makes reference to the need to make reasonable adjustments throughout the rehabilitation process and across pathways and MDT. Particularly physio, SaLT and OT programmes, including adjusted equipment and liaison with specialist learning disability teams physios, SaLT and OTs for support	Thank you for your comment. We agree with this and have a number of recommendations that state the importance of adjusting rehabilitation in keeping with the person's particular need and goals (for example: 1.1.5, 1.1.14, 1.2.3, 1.2.7, 1.2.9, 1.2.20, and others). We also added a link to the NICE guideline on care and support of people growing older with learning disabilities to further support this.
177	NHS England	Guideline	General	General	Given the clear evidence around the association between stroke and depression, we strongly suggest neuropsychological assessment particularly around depression would need to be adapted for people with a learning disability in order to accurately identify and treat depression. Standard assessment tools would not be appropriate.	Thank you for your comment. The committee agree with you and believe this is covered in the guideline, particularly by recommendation 1.2.3. The guideline does not recommend a standard assessment tool for depression.
178	NHS England	Guideline	General	General	We strongly suggest the document makes reference to and raises awareness of the possibility and existence of diagnostic overshadowing. This occurs when the symptoms of physical ill health are mistakenly either attributed to a mental health or behavioural problem or considered inherent to the person's learning disability or autism diagnosis.	Thank you for your comment. A link to the NICE guideline on care and support of people growing older with learning disabilities has been added, rather than making a specific recommendation. The requirement to abide by the Mental Capacity Act applies to decision making in all medical conditions.

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					People with a learning disability or autism have the same illnesses as everyone else, but the way they respond to or communicate their symptoms may be different and not obvious. Their presentation following a stroke may be different from that for people without a learning disability or autism. It is critical ensure health professionals understand existing issues with mental capacity and 'cognitive state' arising from a learning disability and how this differs from confusion, mental state and cognitive state associated with a stroke. We strongly suggest the need to follow the Mental Capacity Act guidance around decision making and treatment decisions.	
179	NHS England	Guideline	General	General	Where appropriate, we strongly suggest providing link to the Royal College of Paediatrics documents, for example guidance to support diagnosis management and rehabilitation for stroke in childhood may be relevant: Stroke guideline 08.04.19 updated 2021.pdf (rcpch.ac.uk) – full guidance A5 booklet ENGLISH 08.04.19.pdf (rcpch.ac.uk) – parent/carer version	Thank you for your comment. Stroke in childhood is not part of the scope of this update.

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180	NHS England	Guideline	006	General	Important addition with regards to giving patient, family, and carers a named contact after early supported discharge	Thank you for your comment.
181	NHS England	Guideline	006	024	In line with the Accessible Information Standard 5-step principles, it is recommended patients and carers' language and communication needs should be recorded. Suggested that information regarding discharge or services transfer should be tailed to patients and carers' communication needs as well as digital literacy	Thank you for your comment. This is discussed in NICE's guideline on Patient Experience in adult NHS services, which has been cross-referred to in the guideline in this section and will provide guidance in this area.
182	NHS England	Guideline	007	General	Relevant training needs to be given to family and carers pre-discharge and **not** directed to see their GP for it post discharge.	Thank you for your comment. The committee does not agree that all training needs to be pre-discharge; some of it may be better done in the person's home particularly in people benefiting from Early Supported Discharge. However, this still allows training to be given by the Stroke Team rather than the GP. The recommendation does not imply that training is the GP's responsibility.
183	NHS England	Guideline	007	006	We strongly suggest that reference is made to monitoring of any presenting psychological needs and support and ensuring the accurate assessment of an individuals mental health post stroke and during rehabilitation is essential. No mention has	Thank you for your comment. The guideline states that rehabilitation should take pre-existing conditions into account. It does not go into detail about assessing and treating particular groups since this was not

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					been included around the need for particular consideration and adjustment that would be needed for particular groups has been included. What additional guidance is available to support clinicians in assessing and treating autistic adults and those with a learning disability, or both who may have additional mental health needs as a consequence of having a stroke.	suggested by stakeholders at scoping to be an area needing to be covered in this guidance.
184	NHS England	Guideline	013	General	Agree that planning or delivery of rehabilitation needs to be taken into account any travel needs or issues. It would be beneficial to add that this needs to be done by the provider of the rehabilitation	Thank you for your comment. All of the recommendations in the guideline are directed at providers of stroke rehabilitation.
185	NHS England	Guideline	017	015	Suggest increasing emphasis and strengthen by expanding 'anyone, including carers and/or family'	Thank you for your comment. Unfortunately, the line you wish us to expand on is not clear to us.
186	NHS England	Guideline	019	General	It would be beneficial to clarify whether electric/battery powered toothbrushes, mouthwash and oral gels should be prescribed if needed and if so by whom in the community.	Thank you for your comment. The recommendation does not state that electric toothbrushes should be prescribed because this may not be necessary in all circumstances. For example, a ward might have a supply of toothbrushes but change the heads between patients.

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						NICE guidance focuses on what should be done rather than specifying who should carry out an action.
187	NHS England	Guideline	022	010	Where there is reference to "circumstances in relation to word finding", we strongly suggest that that all information and technologies are available in accessible format. This may include but is not limited to easy read and plain English versions of written information. We strongly suggest reference to making reasonable adjustments: This is a legal requirement as stated in the Equality Act 2010 and is important to help you make the right diagnostic and treatment decisions for an individual. You can ask the person and their carer or family member what reasonable adjustments should be made. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a person to receive the assessment and treatment they need.	Thank you for your comment. NICE does not produce the computer programmes referred to in this recommendation and cannot control their format. All guidance recommendations are meant to be interpreted alongside the Equality Act and the NICE guideline on patient experience which covers issues such as accessibility of information. It is hoped that companies developing the programmes will do so in line with the NHS accessible information standard.
188	NHS England	Stakeholders and Committee	General	General	We have noted that there are a lot of AHP professional bodies who are in the stakeholders list as well as the committee member lists. However, it is noticed by the office that one of the key AHP professional groups, Royal College of Occupational	Thank you for your comment. We encourage all relevant organisations to register as stakeholders and comment on our guidelines. Ultimately it is the choice of those

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		member lists			Therapists could not be sighted in the stakeholders lists. Given their scope of practice and work within, it is important to include their views and comments in relation to the stroke rehabilitation.	organisations whether and when they comment.
189	NHS England - Stroke Programme	Draft guideline	General	General	General. NHSE Stroke programme, following discussion with multiple stakeholders and specialists within the stroke rehabilitation clinical practice was significantly concerned by the inconsistencies in the appraisal of the available evidence by the committee. On one hand the committee considered an extensive appraisal of the evidence regarding rehabilitation intensity in attempting to draw a narrow distinction between the cost-effectiveness, for example, of 5-day therapy compared to 7-day therapy, and on the other it would appear that 'personal experience of some committee members' was sufficient to make significant generalisations regarding, for example, universal hearing assessments. It would appear that a different evidentiary standard was being applied by the committee to different areas of clinical practice, something that undermines confidence in the rigour of the overall	Thank you for your comment. The same standards of evidence assessment were applied to every question addressed by this update in that a thorough search for all relevant clinical and cost-effectiveness evidence was made. The disparity in length of the sections reflects the disparity in the amount of evidence available to analyse. Taking account of personal experience of the GC membership is in accordance with NICE methods and process where evidence is lacking. In addition, there is independent Quality assurance (QA) by a NICE QA team (separate from those who develop the guidance) and the process of stakeholder consultation to review the work done and include a wider expert input than just the committee. This is all to make sure the

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					evidence appraisal process, and could suggest that some voices on the committee were taking an unjustified predominance over other, more evidence-based voices. When there are such significant resource implications for many of the guideline recommendations – the hard work of implementing these recommendations must be properly supported by evidence or at the very least, a broad and transparent expert consensus.	decision-making is rigorous, transparent and of a high standard. The committee have reconsidered the recommendation to assess hearing in the light of stakeholder comments and agree that the wording should be softened.
190	NHS England - Stroke Programme	Draft guideline	006	012	Section 1.1.8. NHSE Stroke Programme supports the recommendation to provide rehabilitation for as long as it continues to help patients achieve their treatment goals, even after they have left hospital. The wording allows treatment at the level of impairment, activity and participation. The concept of a recovery plateau does not apply to activity and participation and so this implies life-long treatment to promote recovery should be available. It is important that this change in guidelines is made clear and explicit to patients and carers. There will be implications for staffing levels which will need to be met in community care settings to comply with this guideline.	Thank you for your comment. The committee agree that full implementation will be challenging but making the recommendation is an important first step.

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191	NHS England - Stroke Programme	Draft guideline	006	023	Section 1.1.11. These recommendations should relate to all patients receiving community rehabilitation according to NHS England policy document - National Stroke Service Model, not just those receiving Early Supported Discharge.	Thank you for your comment. These recommendations followed a review of the evidence for the Early Supported Discharge review and so was recommended for this area. We did not review the evidence around other discharge models, but the committee agree that there is no obvious reason why this should not apply to other parts of rehabilitation as well.
192	NHS England - Stroke Programme	Draft guideline	012	001	Section 1.2.15. NHSE Stroke Programme was concerned by the imbalance in the evidence standard applied to this section compared to some others within the draft guideline. 538 pages of exhaustive evidence analysis was produced to weigh the evidence behind dose and intensity of rehabilitation, including recommending remedial therapy for 5 rather than 7 days a week, and this extensive analysis contrasts sharply with Recommendations elsewhere, such as that all patients with stroke should receive a specialist orthoptist assessment when no evidence was identified for the review at all. This inconsistency in approach to the evidence undermines the overall credibility of the guideline.	Thank you for your comment. The question of optimal intensity of rehabilitation was identified by the committee as having potentially major cost implications not addressed by existing health economic literature. In keeping with standard NICE process the committee developed its own health economic analysis. The extensive appraisal is the result of there being a large number of papers on intensity plus the obligation to properly describe the health economic analysis. With this evidence, the committee was able to make strong recommendations. Please also note that therapy is recommended for **at least** 5 days per week, and so may include 7 days a week if required by the person.

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						This evidence was not available for the topic of orthoptist assessment based on the protocol agreed with the committee. However, in this area, the committee agreed that there was a large safety concern and so NICE had a duty to make a strong recommendation in this area. Therefore, in this case, taking into account the committee's expert opinion, knowledge of the epidemiology of vision problems that is well documented in literature and the concern for safety for the stroke survivor and others, a strong recommendation was made. These two processes are compatible and complementary processes used to make recommendations in NICE guidelines, and do not reflect an inconsistency in how the guideline was constructed.
193	NHS England - Stroke Programme	Draft guideline	012	001	Section 1.2.15. These recommendations are different to those in the National Clinical Guideline for the UK and Ireland (2023; 'NCG23' available at www.strokeguideline.org), which makes recommendations specifically for motor recovery and states that 'People with motor recovery goals	Thank you for your comment. Stakeholders have made some very reasonable points about the available evidence

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					undergoing rehabilitation after a stroke should receive a minimum of 3 hours of multidisciplinary therapy a day (delivered or supervised by a therapist or rehabilitation assistant focused on exercise, motor retraining and/or functional practice)….'. This is based on evidence regarding the effects of greater amounts of therapy (dose) (Kwakkel et al, 1999; Kwakkel & Wagenaar, 2002; Bhogal et al, 2003a; Bhogal et al, 2003b; Kwakkel et al, 2004) and is reflected in other clinical guidelines around the world (Australia (Stroke Foundation, 2022), Canada (Teasell et al, 2020) and the Netherlands (Veerbeek et al, 2014a)). The NICE and NCG23 should be aligned – any discrepancy is likely to cause confusion and hamper uptake. Alignment could be achieved by amending the recommendation regarding physiotherapy to read '…. For at least 1 to 2 hours a day' in the same way that 'at least' is used for OT and SLT. They should also both be clear that this recommended time refers to 'time-on-task' not simply session length (given that time on task is often approx. 50% of session length). However, the distinction between the disciplines delivering rehabilitation	and the committee have reflected on this, the recommendation has been amended. Our recommendations were made using systematic reviewing methodology where evidence was searched for using methods as outlined in Developing NICE guidelines: the manual. The studies listed were excluded from our review (please see the excluded studies table in the evidence report for more information). We agree that the time spent should be time-on-task. This is highlighted in the qualitative evidence review in the area (please see the evidence review). The RELEASE meta-analysis was identified and evaluated by the committee. On comparing the different results in this analysis, no clinically important differences were found between the different intensities in this analysis in improving communication outcomes. Therefore, the committee could not recommend a change to the current recommendation based on these results.

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					made here is artificial and does not reflect the realities of clinical practice. Occupational therapists are involved in a lot of motor recovery activity, especially upper limb work, as well as functional translation of motor gains. There is therefore no justification for singling out one discipline for greater input. This shows a lack of understanding of the overlapping nature of MDT work in stroke rehabilitation. Separating the three therapies in this way, with no mention of the role of nurses, psychologists, orthoptists etc in the complex MDT delivery of neurorehabilitation is an unwelcome oversimplification and potentially misleading. By the same token, was the RELEASE collaboration (2022) reviewed regarding intensive SLT for aphasia around 3-6 months? This extensive, international evidence synthesis was the basis for the recommended increase in SLT input for aphasia in the NCG23 which goes beyond the previously recommended levels of 45 minutes/day. The NCG23 states that 'Intensive speech and language therapy such as comprehensive aphasia programmes may be considered from 3 months after stroke for those who can tolerate high-intensity	

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					therapy.' Comprehensive aphasia programmes deliver 6-7 hours a day of therapy and should be considered by the committee, particularly as they exceed the evidentiary standard that appears to have been applied to other Recommendations with the draft guideline. RELEASE Collaborators; Brady MC, Ali M, VandenBerg K, et al. Precision rehabilitation for aphasia by patient age, sex, aphasia severity, and time since stroke? A prespecified, systematic review-based, individual participant data, network, subgroup meta-analysis. Int J Stroke. 2022 Dec;17(10):1067-1077. doi: 10.1177/17474930221097477.	
194	NHS England - Stroke Programme	Draft guideline	012	011	Section 1.2.17. The Recommendation that intensive therapy should be started as soon as possible after a stroke is not supported by the evidence from the definitive clinical trial in this area. The AVERT trial provided strong evidence that intensive motor rehabilitation provided immediately after major stroke was probably associated with worse outcomes and tangible harm.	Thank you for your comment. The AVERT trial was not part of our evidence review because the protocol excluded trials including people during the first 24 hours after a stroke (as this would fall under our Acute Stroke guidance). However, the AVERT trial was considered in NG128 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management. The committee agrees that it is relevant to

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					Langhorne P, Collier JM, Bate PJ, Thuy MN, Bernhardt J. Very early versus delayed mobilisation after stroke. Cochrane Database Syst Rev. 2018 Oct 16;10(10):CD006187. doi: 10.1002/14651858).	recommendation 1.2.17 in this Stroke Rehabilitation update and have added a cross reference, and amended the recommendation to state that rehabilitation should only commence when safe to do so.
195	NHS England - Stroke Programme	Draft guideline	013	003	Section 1.2.21. This reads as though there is an assumption that rehabilitation is not being delivered in the patient's own home. Suggest that it is rephrased.	Thank you for your comment. The wording has been amended.
196	NHS England - Stroke Programme	Draft guideline	013	014	Section 1.3.1 – Telerehabilitation. The wording '..instead of, or as well as…' is a recipe for ambiguity. The evidence will point to one or the other – as a replacement for face-to-face therapy, or as a supplement to it. To avoid ambiguity in implementation, the committee should recommend one or the other, but not both. Some recognition of the assessment of the patient as suitable for telerehabilitation is required here, as not all patients are appropriate e.g. those with significant cognitive deficits.	Thank you for your comment. Based on the evidence review, we disagree. The evidence did not clearly show that telerehabilitation services alone or a combination of telerehabilitation and face-to-face services were superior. Therefore, the committee recommended that there should be a choice. This allows for the option to be available dependent on the needs and preferences of the person, the healthcare professional and the service. Regarding suitability for telerehabilitation, we are not aware of a generally accepted way of

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						assessing this. There are some situations where telerehabilitation may be self-evidently unsuitable, for example people with significant cognitive impairment, but it is not clear how to make this judgement in less obvious cases.
197	NHS England - Stroke Programme	Draft guideline	017	010	Section 1.7 Fatigue. NHS England Stroke Programme did not understand the logic in recommending assessment for fatigue without also considering the evidence and recommendations for interventions to alleviate or help to manage it. To do one without the other is simply to set up patients and their families for frustration and disappointment. At the very least, the committee should recommend an explanation of the nature of fatigue, and its likely impact on rehabilitation, supported by written information e.g. from the third sector such as the Stroke Association. In Section 1.7.1 the word 'written' appears superfluous, as if excluding an assessment made verbally or on a tablet.	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue, and serve as a baseline against which active interventions can be tested. However, we have not conducted a review into interventions for fatigue in this update. The word 'written' has been removed from the recommendation.

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198	NHS England - Stroke Programme	Draft guideline	017	022	Section 1.8 Vision. NHS England Stroke Programme was not convinced by the recommendation that all people with stroke should receive a specialist orthoptist assessment, especially when the committee itself confirmed that no evidence to support this recommendation was identified for the review. Cross-sectional surveys of acute stroke admissions provide evidence that about half of all people with stroke have visual problems identified by early screening – about the same proportion of patients that have communication disabilities identified. Yet no-one is suggesting that patients in whom screening assessment by any trained healthcare professional confirms the absence of communication disability should then go on to receive a comprehensive speech therapy assessment – the resource costs could not be justified. More logically, screening for visual disorders should be performed by any appropriately trained healthcare professional, with full specialist assessment reserved for those with identified problems. That represents a much more responsible use of available resources.	Thank you for your comment. Vision problems may not be apparent to non-specialist members of the rehabilitation team during the screening, while stroke survivors may also be unaware of a problem which can result in accidents related to driving and falls (RNIB 2021, BIOS 2016, Goodwin 2014). Given these factors, it was agreed to be important to make a recommendation despite the lack of evidence. Communication difficulties are commonly identified earlier and hence do not require a comprehensive speech therapy assessment. Furthermore, a full orthoptic assessment on the stroke ward is considered to take either the same time (in more complex cases) or less (for mild/normal cases) as screening by non-specialists, which saves time overall as it negates the need for the initial non-specialist screening prior to a selective referral. The updated recommendations on therapy for visual disorders are limited to orthoptist assessment. This is because stakeholders did

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					There is no mention in this section of the interventions that should be considered following assessment other than eye movement therapy for hemianopia in the 2013 legacy section 1.8.3, although the 2013 legacy sections 1.5.3 and 4 mention interventions for visual inattention. This creates the erroneous impression that these are the only NICE-recommended interventions that might be delivered by orthoptists, which we are sure is not the desired effect. Overall, this leaves Section 1.8 looking inconsistent and incomplete, with universal urgent specialist assessment recommended despite an explicit recognition that no evidence to support it has been identified, and with limited interventions for visual disabilities recommended as part of Stroke Rehabilitation. A rethink of Section 1.8 is required.	not identify treatment of visual problems as a topic requiring update during scope consultation. It will be passed on to the NICE surveillance team.
199	NHS England - Stroke Programme	Draft guideline	018	012	Section 1.9 Hearing. NHS England Stroke Programme were concerned as to the lack of evidence for this recommendation " all patients should receive a hearing assessment within 6 weeks", and indeed the committee acknowledge this themselves in simultaneously making a	Thank you for your comment. On reflection the committee agree with you that the evidence is insufficient for the strength of the recommendation, and the wording has been changed.

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					Research Recommendation as the prevalence of hearing disorders resulting from stroke is at present unknown. A recommendation for universal assessment is unjustifiable when the basic prevalence is unknown. There may well be grounds for the committee to recommend hearing screening as good practice (as indeed it may be in many predominantly older disease populations) with further referral for those identified with problems, but the present arbitrary and universal recommendation cannot be justified by the evidence as it stands.	
200	NHS England - Stroke Programme	Draft guideline	019	009	Section 1.10 Mouth care. NHS England Stroke Programme recommend adding the importance of communicating any care plan across care settings. If a national protocol for mouth care exists, is there any value in developing a local one?	Thank you for your comment. The provision of information across care settings is discussed in section 1.1.14. Mouthcare matters is a national protocol for mouth care used in many settings, but it has not been compared to other tools and some providers may prefer to use local protocols.
201	NHS England - Stroke	Draft guideline	019	021	Section 1.11.2 and 3 Swallowing. Recommend combining to "Give families and carers information about dysphagia (difficulty in swallowing) and	Thank you for your comment. On balance the committee prefer that the recommendations should remain separate

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	Programme				advice on what to do if someone is coughing or choking while eating and drinking."	since they refer to different pieces of information.
202	NHS England - Stroke Programme	Draft guideline	020	014	Section 1.11.6 Swallowing. The evidentiary basis for the recommendation regarding the use of a free water protocol is limited, and to assert an absence of harm on the strength of two small studies of 34 mobile people is not justifiable and takes no account of the virtual certainty of a type 2 statistical error (failing to detect an effect [harm] when one may be present). In truth, the committee should not make any kind of recommendation for an intervention on such an unscientific basis, instead opting for a recommendation for more research. NHS England Stroke Programme would alert the committee to the challenges for staff to implement a free water protocol, particularly in acute and other care settings. Currently there are a high level of incidents where provision of food/fluids has not been in line with SLT recommendations. Allowing an individual different textures of fluids introduces a further opportunity for error. Are there resources/bundles/protocols to support	Thank you for your comment. The committee has discussed this again and agrees. The recommendation has been removed and a research recommendation made instead.

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					implementation of such a protocol that have been successfully tested in clinical settings?	
203	NHS England - Stroke Programme	Draft guideline	022	010	Section 1.12.8. It is not clear why two apps for patients with aphasia that have been tested in RCTs and published in peer-reviewed journals have been omitted from the NICE guideline process. They are in scope, in the correct time period and are not in the excluded studies section of the relevant evidence reviews for computer-based tools for speech and language therapy, Appendix J – Excluded studies. iReadMore is an app that was tested in a registered RCT in people with aphasia who had central alexia. Participants completed two 4-week blocks of iReadMore training (34 hours each). iReadMore training resulted in an 8.7% improvement in reading accuracy for trained words (95% confidence interval 6.0 to 11.4; Cohen's d = 1.38) (Woodhead et al., 2018). Similarly, Listen-In, an app for people with aphasia with auditory comprehension impairment was tested in a registered RCT. Repeated measures analyses of variance compared change in spoken language comprehension on two co-primary outcomes	Thank you for your comment. The developers had not identified Fleming, et al. as being a relevant study for the review, and have now added it, thank you for this. This does not change the results of the review. Woodhead, et al. is a study where all people receive the iReadMore intervention while the crossover trial compares people receiving transcranial direct current stimulation to people receiving sham transcranial direct current stimulation while participating in the study. Therefore, this is not a relevant comparator for this review. This has been added to the excluded studies table.

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					between therapy and standard care. The first study-specific co-primary outcome (Auditory Comprehension Test (ACT)) showed large and significant improvements for trained spoken words (11%, Cohen's d=1.12). Gains were largely maintained at 12 and 24 weeks (Fleming et al., 2020). Fleming, V., Brownsett, S., Krason, A., Maegli, M. A., Coley-Fisher, H., Ong, Y.-H., Nardo, D., Leach, R., Howard, D., Robson, H., Warburton, E., Ashburner, J., Price, C. J., Crinion, J. T., & Leff, A. P. (2020). Efficacy of spoken word comprehension therapy in patients with chronic aphasia: a cross-over randomised controlled trial with structural imaging. Journal of Neurology, Neurosurgery & Psychiatry, jnnp-2020-324256. https://doi.org/10.1136/jnnp-2020-324256 Woodhead, Z. V. J., Kerry, S. J., Aguilar, O. M., Ong, Y. H., Hogan, J. S., Pappa, K., Leff, A. P., & Crinion, J. T. (2018). Randomized trial of iReadMore word reading training and brain stimulation in central alexia. Brain, 141(7), 2127-2141. https://doi.org/10.1093/brain/awy138	

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204	NHS England - Stroke Programme	Draft guideline	028	013	Section 1.13.30-31. Mirror therapy is still controversial because it is deployed in so many different ways. NHS England Stroke Programme recommend explicitly stating that it should be used as an adjunct to a multidisciplinary (PT and OT) upper limb rehabilitation programme, not instead of. The current wording simply suggests it can be used as part of a rehabilitation programme, which would allow mirror therapy to be used as the only upper limb treatment. The NCG23 recommendations are clearer – 'People with stroke may be considered for mirror therapy to improve arm function following stroke as an adjunct to usual therapy.'	Thank you for your comment. The committee agree with you and the wording of the recommendation has been amended.
205	NHS England - Stroke Programme	Draft guideline	029	013	Section 1.14.4 Shoulder pain. Steroid and nerve block injections may reduce pain, but must be combined with appropriate physical management, or else the problem will recur. For example, frozen shoulder is common after stroke, but requires physiotherapy. Physiotherapy will not work unless the pain is first managed. Please indicate that adjunctive physical therapy should also be part of the treatment.	Thank you for your comment. The recommendations in this section should not be taken in isolation from one another. The committee agree that more than one form of therapy may be required in any particular case. Please note recommendation 1.14.2 which states that the cause of shoulder pain should be sought and management geared to cause(s) when found. In your example, if a

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						frozen shoulder is diagnosed physiotherapy should be offered.
206	NHS England - Stroke Programme	Draft guideline	030	009	Section 1.15. Recommendations 1.15.4 and 1.15.6 surprising, as the evidence shows that stretching, splinting and electrical stimulation (NMES or FES) do not improve spasticity. They should either be corrected or removed. It is also surprising that TENS is recommended as the evidence is very unlikely to have exceeded the evidentiary standard. It is much less strong than that for other recommendations (or that which shows electrical stimulation to be ineffective), so it appears inconsistent to include it here. The recommendations contradict those in the new 2023 National Clinical Guideline for Stroke, and expert guidelines from other countries such as Australia, Canada and the US.	Thank you for your comments. The developers acknowledge that there is uncertainty around the benefits of these interventions and have amended the wording to state that they might be considered. In relation to stretching and splinting, this makes recommendation 1.15.4 compatible with the 2023 National Guideline. With regards to NMES, FES and TENS, the evidence review found some evidence of clinically important benefits for each of these in improving spasticity outcome measures and improving activity of daily living scales. The evidence was limited. Therefore, recommendation 1.15.6 is expressed in the more cautious "Consider" form and has not been changed. We also note that the guidelines from Australia and the USA suggest there may be a role for NMES.

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207	NHS England - Stroke Programme	Draft guideline	030	014	Section 1.15.5. The dose of botulinum toxin should be appropriate to the issue and the muscle/s being treated. Having the total stated here could be dangerous and lead people to always inject a total of 500 units, which in some instances may be excessive. The recommendation should state 'a maximum of 500 units across all sites'. Botulinum toxin treatment should always be associated with a stretching regime or splinting - this is one of the only indications for splinting and would be recommended within 7-10 days of injection.	Thank you for your comment. The committee acknowledge your point. It was not the intention to imply that 500 units must be given, and the wording has been amended.
208	NHS England - Stroke Programme	Draft guideline	032	025 - 026	Section 1.16.5. NHS England Stroke Programme strongly recommends that referral for vocational rehabilitation should be offered, rather than merely considered. To 'offer' puts the decision in the patient's hands rather than the clinician making what may be an arbitrary judgement. Although the evidence for vocational rehabilitation is not compelling, expert consensus in the 2023 National Clinical Guideline for Stroke for the UK and Ireland judged it sufficient to make a recommendation (stronger that the evidence for universal vision and hearing assessments, for example). NHS England	Thank you for your comment. The word "offer" is generally used in NICE guidance when evidence behind a recommendation is strong and in this instance the committee judged that the evidence was not sufficient.

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					have also just launched a Vocational Rehabilitation e-resource and toolkit to support return to work for stroke survivors. This recommendation should apply not just to people who were in paid employment, but also to people who may have been volunteering, or in education.	
209	NHS England - Stroke Programme	Draft guideline	034	007	Section 1.17.6. The nature of a 'community participation programme' should be specified, as these will differ widely.	Thank you for your comment. This has been outlined in the "Terms used in this Guideline" section.
210	NHS England - Stroke Programme	Recommen-dations for Research	040 - 041	005 - 003	The recommendations for research into acupuncture (over and above research into any other intervention) appear somewhat arbitrary.	Thank you for your comment. The committee was aware that there is a significant amount of evidence for acupuncture that we were unable to include because it is not available in English. There were also positive results seen in small studies that were available. Given this, the committee wanted to have further research in this area including cost-effectiveness evidence in a UK setting so that they could have a full understanding of the clinical and cost effectiveness of acupuncture for reducing spasticity and shoulder pain after stroke.

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211	NHS England - Stroke Programme	Recommendations for Research	036	009	The recommendation to test whether 7-day rehabilitation is better than 5-day rehabilitation will not be particularly fruitful, especially if delivered at current low doses (an extra 2 days of not very much is still not very much). It is widely accepted that a higher 'dose' of rehabilitation is more effective, so research effort should now focus on how to practically achieve the highest tolerable dose possible using combinations of multidisciplinary therapy and technologies.	Thank you for your comment. There is currently insufficient evidence to firmly recommend an increase in dose of rehabilitation from 5 to 7 days. Moreover, the cost-effectiveness of this increase is not well supported by current evidence. We also note the number of comments where people are disappointed that we are unable to recommend 7-day rehabilitation and the research recommendation therefore addresses a perceived need for further data.
212	NHS England - Stroke Programme	Recommendations for Research	037	021	Tools for fatigue: Contradiction exists between these tools being recommended for use, along with a recommendation that their clinical and cost effectiveness should be investigated. If the latter is as yet unproved, then the former cannot apply.	Thank you for your comment. The two statements are not contradictory. The review conducted was a tool validity and reliability review which established which tools were likely to be the most valid and reliable to use in the context of the NHS in the United Kingdom. However, a search was conducted to investigate whether any tools for fatigue showed clinical or cost-effectiveness to improve outcomes for people after stroke and no studies were identified. Therefore, to establish if these tools are effective in improving outcomes, evidence is required. The recommendation to use these tools is made as

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						a more cautious "consider" recommendation to reflect the lack of unequivocal evidence of benefit, but the committee would argue that there are already good reasons for using them as laid out in the rationale and the evidence review.
213	NHS England - Stroke Programme	Recommen-dations for Research	041	018	The recommendation that the clinical effectiveness of electrical stimulation methods in spasticity is investigated appears to be at odds with the recommendation that their use is considered in Section 1.15.6. If that former is as yet unproved, then that latter cannot apply.	Thank you for your comment. We understand why it appears that these two statements are odds. However, the recommendations for electrical stimulation recommendations is a weaker consider recommendation to reflect the relative weakness in the evidence (rather than a stronger offer recommendation where it would be inappropriate to also make a research recommendation). In other word, the committee believe that there is evidence suggesting this may be a beneficial treatment for some people, but that further research would be useful to fully prove this and perhaps to refine our understanding of the optimal circumstances for using it.
214	NIMAST	Guideline	005	General	1.13 There is no mention of dieticians or pharmacists or health care support workers in the	Thank you for your comment.

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					core stroke rehabilitation team. They are essential to the delivery of stroke rehabilitation.	Dietitians have been added to recommendation 1.1.3. The committee stressed that no profession should be restricted from involvement based on this list, but that the list recognises the core specialties that should be involved in the team. Involvement of other professionals should be made on a case-by-case basis dependent on the needs of the person.
215	NIMAST	Guideline	012	General	1.2.15 Impact on practice: The delivery of 1-2 hours of physiotherapy will have significant resource implications regarding workforce and cost. However, we recognise the importance of this regard patient outcome. We would welcome the same recommendation for Occupational Therapy and Speech and Language therapy with regards to intensity of therapy.	Thank you for your comment. This recommendation has now been amended. The form it took in the draft guideline was based on the separate evidence available, hence the distinction between the types of therapy. The committee have considered all the comments about this and have agreed that it should be changed for the final published guideline. In its final form the recommendation does not distinguish between types of therapy.
216	NIMAST	Guideline	018	General	1.9 & following Does the evidence identify the number of patients who have new hearing deficits post stroke and is it appropriate to test all patients? This has significant workforce implications	Thank you for your comment. The protocol for the evidence review was not designed to identify this. However, we

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						attempted to look for evidence to quantify this and did not find any. Therefore, the committee agreed a research recommendation in this area. We realise our wording was unclear in this area. The intention of the committee was that all people should have a hearing screening (discussion about their hearing, which involves other people in their life, and could involve completing a questionnaire). People with suspected hearing problems after this should then be referred for a comprehensive audiology assessment. As the previous stroke rehabilitation guideline recommended that everyone should have a full medical assessment including hearing, we do not believe that this is as large a change in current practice, and we hope that this reinforces the need to focus on hearing given the impact this can have on a person's rehabilitation.
217	NIMAST	Guideline	030	General	1.15.5 The lack of robust clinical trial evidence should not prevent patients receiving treatment which benefits them especially when no other efficacious treatment is available.	Thank you for your comment. The recommendations have been based on which botulinum toxin A was cost effective.

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					As injectors of Botulinum toxin we know from experience that limiting treatment to 500 units of Dysport in the upper limb will leave most patients undertreated. NICE guidelines should take into account the experience of experts in the field especially in areas where high quality studies are absent. Since three brands of Botulinum toxin all contain the same active substance, it should be individual clinicians / hospitals who decide which brand they can acquire at the best price and therefore which brand they are going to use. [redacted] (Confidential comment removed).	Following stakeholder consultation comments, further adjustments have been made to the de novo model and the committee have edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time.
218	Northern Ireland Stroke Network	Guideline	006	012	Agree this should happen – resources to allow this?	Thank you for your comment. This may require extra resources, and this may be problematic and take time. However, recommending it is an important first step.
219	Northern Ireland Stroke Network	Guideline	006	012	Agree this should happen – resources to allow this? Rec 1.1.8 We agree that providing ongoing rehabilitation for as long as goals are being met is ideal however we recognise that this will be	Thank you for your comment. It is beyond NICE's remit to instruct exactly how a recommendation will be actioned since this can legitimately vary depending on local

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					challenging with current level of local resources. Perhaps ensuring strong links and consistent use of voluntary sector alongside services provided by local councils will assist in achieving this. Does it need to be statutory services or can longer term goals be met with other services?	circumstances. The recommendation does not rule out input from the voluntary sector.
220	Northern Ireland Stroke Network	Guideline	006	026	Rec 1.1.11 Having a named linked contact would be beneficial however further detail on what the remit of this "role" would be would be helpful ie what sort of problems, what level of access to this person etc. Staff are currently working at capacity and therefore concerns regarding added responsibility.	Thank you for your comment. It is beyond the NICE's remit to dictate the role's specification. As you say, the general principle of having such a contact should bring benefits, and is supported by our review of the qualitative literature.
221	Northern Ireland Stroke Network	Guideline	012	002	1.2.15 "Physiotherapy as needed for at least 1-2 hrs/day 5 days/week" –WHSCT Community Stroke Physiotherapy cannot guarantee 5 days of face-to-face physiotherapy/week nor more than 1 hour/day to applicable patients at present due to staffing levels and large geographical area to cover.	Thank you for your comment. The committee are aware that current resources are limited and that this recommendation may not be immediately deliverable. However, our detailed analysis shows that it is cost-effective for the NHS. Note that the wording of 1.2.15 has been amended in response to comments from several Stakeholders.

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222	Northern Ireland Stroke Network	Guideline	012	004	Resource implications – see intensity of treatment comments and staffing above. No indication of how long this intensity should continue for? 1 week, 6 weeks, 2 months, entire length of stay?? Link to page 6 line 12 recommendation. This is also different dosage to what is in new RCP guidelines Good to see recommendations for increased physiotherapy, would welcome more clarity on how this is to be provided and if it's in all stages of rehab-e.g.acute/ community. Will need significant investment	Thank you for your comment. You raise an interesting question. How long therapies should continue at the stated intensity is not clear from the literature reviewed for this update. Other recommendations state the guiding principles of continuation which are that progress towards treatment goals should be reviewed at intervals, and rehabilitation continued for as long as the person after stroke is benefiting from it.
223	Northern Ireland Stroke Network	Guideline	012	027	Welcome the acknowledgement on the need and benefit of joint sessions	Thank you for your comment.
224	Northern Ireland Stroke Network	Guideline	017	010	Great that specific recommendations for fatigue assessment are included but it would be helpful if this was supported by guidance on fatigue management strategies	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made

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						recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue, and serve as a baseline against which active interventions can be tested. However, we have not conducted a review into interventions for fatigue in this update.
225	Northern Ireland Stroke Network	Guideline	017	019	Great that specific recommendations for fatigue assessment are included but it would be helpful if this was supported by guidance on fatigue management strategies	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. At present data on fatigue is not collected systematically and the committee has therefore made recommendations about collecting data with standardised questionnaires. It is hoped that this will allow future assessment of the effectiveness of adjustments to rehabilitation in response to fatigue, and serve as a baseline

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						against which active interventions can be tested. However, we have not conducted a review into interventions for fatigue in this update.
226	Northern Ireland Stroke Network	Guideline	018	010	ALL patients to be offered hearing assessment – do they all NEED it? What if it's a pre-existing issue?	Thank you for your comment. The intention of the committee was that all people should have a hearing screening (discussion about their hearing, which involves other people in their life, and could involve completing a questionnaire). People with suspected hearing problems after this should then be referred for a comprehensive audiology assessment, as per NICE's guideline on hearing loss in adults. Whether or not any hearing problem pre-dates their stroke, this may be a barrier to successful rehabilitation and identifying and managing this optimally will be helpful in ensuring that reasonable adjustments to their rehabilitation are made.
227	Northern Ireland Stroke Network	Guideline	019	001	Great that mouth care is included but there are inconsistencies with the recommendations from RCP stroke guidance	Thank you for your comment. The committee are happy that their recommendations reflect the evidence.

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228	Northern Ireland Stroke Network	Guideline	020	020 - 023	Input at least 5 days a week – see resource and staffing comments re community teams as before. Also for how long?	Thank you for your comments. To respond to how long – as with other stroke rehabilitation therapies, therapy would be provided for as long as the person requires it to achieve goals. The studies included in the review found that on average these interventions were offered for 2-4 weeks.
229	Northern Ireland Stroke Network	Guideline	027	013	Great to see that this has been included in the new guidelines	Thank you for your comment
230	Northern Ireland Stroke Network	Guideline	028	020 - 024	Intensity of treatment – same comments as above re staffing resources in community. Also – for how long should this continue – see above comments.	Thank you for your comment. We acknowledge that this recommendation may be challenging, but our analysis shows that this level of intensity is cost-effective. As regards how long, as with other stroke rehabilitation therapies therapy would be provided for as long as the person requires it to achieve goals. The studies included in the review found that on average these interventions were offered for 2-4 weeks.
231	Northern Ireland	Guideline	029		?should include spasticity management if spasticity is contributing to pain.	Thank you for your comment. Recommendation 1.14.2 states that the cause of shoulder pain should be identified and the

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	Stroke Network					results of this assessment should be used to decide how to manage the pain. If this shows that spasticity is the cause of the pain then we would agree and would recommend that people refer to spasticity guidance. We recommend that where specific causes are identified that relevant guidance is followed as specific to that cause.
232	Northern Ireland Stroke Network	Guideline	029	006	Welcome that assessment for the exact cause of shoulder pain informs the treatment options	Thank you for your comment.
233	Northern Ireland Stroke Network	Guideline	029	011	Good to see more detail management strategies for shoulder pain included in the guidance	Thank you for your comment.
234	Northern Ireland Stroke Network	Guideline	030	001	Whilst it is brilliant that spasticity management now has its own section; would welcome more specifics re non pharmacological management strategies. Again significant funding / investment necessary to meet these recommendations	Thank you for your comment. The evidence base for most non-pharmacological treatments is too limited to go into fine detail and the committee believe this is best left to the practitioners in discussion with patients and their carers.

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235	Northern Ireland Stroke Network	Guideline	030	015	Why only DYSPORT mentioned – there are other manufacturers of BonTA. Doseage will be dependent on manufacturer and licences	Thank you for your comment. Dysport was the only type of botulinum toxin A mentioned as this was the only one shown to be cost effective in the draft economic model, and only if the maximum dose was limited. However, following amendment to the model Xeomin is also cost-effective in certain circumstances and has been added to the recommendation.
236	Northern Ireland Stroke Network	Guideline	030	026	Rec 1.15 Spasticity services requires further development in local area and therefore it will be challenging to meet these recommendations fully.	Thank you for your comment. The developers understand that there is current variation in access and hope that the recommendation will be a stimulus for improvement.
237	Nottinghamshire Healthcare NHS Foundation Trust	Draft guideline	005	000	Rec 1.1.3 – the core multi disciplinary team for stroke rehabilitation does not include access to dietetics. In Guideline NG123 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management, section 1.6 clearly documents that patients should be referred for dietary advice for patient requiring dietary modification or tube feeding as a result of swallowing issues. Poor nutritional intake, weight loss, and feeding and swallowing problems can persist for many months post-stroke	Thank you for your comment. Dietitians have been added to the list.

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					impairments can affect nutrition – for example, dysphagia and texture modified diet and fluids, confusion, limb weakness preventing self-feeding and food preparation, visual problems, depression, and cognitive impairment affecting memory and concentration. The National Clinical Guideline for Stroke recommends that stroke survivors with ongoing problems meeting their nutritional needs should have their dietary intake and nutritional status monitored regularly. Dietetic input is also necessary for weight management and secondary prevention advice regarding diet, References 1. Gomes F, Emery, PW, Weekes, CE. Risk of malnutrition is an independent predictor of mortality, length of hospital stay, and hospitalization costs in stroke patients. Journal of Stroke and Cerebrovascular Diseases. 2016;25(4): 799-806. 2. Finestone HM, Woodbury MG, Foley NC, Teasell RW, Greene-Finestone LS. Tracking clinical improvement of swallowing disorders after stroke. Journal of Stroke & Cerebrovascular Diseases. 2002;(11): 23-7.	

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					3. Jonsson AC, Lindgren I, Norrving B, Lindgren A. Weight loss after stroke: a population-based study from the Lund Stroke Register. Stroke. 2008;(39): 918-23. 4. Perry L. Eating and dietary intake in communication-impaired stroke survivors: a cohort study from acute-stage hospital admission to 6 months post-stroke. Clinical Nutrition. 2004;(23): 1333-43. 5. Royal College of Physicians (RCP), National clinical guideline for stroke. 5th Edition. Intercollegiate Stroke Working Party. 2016. Available from: https://www.strokeaudit.org/SupportFiles/Documents/Guidelines/2016-National-Clinical-Guideline-for-Stroke-5t-(1).aspx. The Association of UK Dietitians (BDA). Dietetics with a Community Stroke Rehabilitation Team. Available from: Dietetics with a Community Stroke Rehabilitation Team | British Dietetic Association (BDA)	
238	Nottinghamshire Healthcare NHS	Draft guideline	009	014	1.2.1 Without access to dietetics who would review a patient deemed at risk on a nutritional screen	Thank you for your comment. This recommendation covers screening on admission and cross refers to CG32 which specifies that nutrition screening should be

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	Foundation Trust					done by a health care professional with appropriate skills and training.
239	Nottinghamshire Healthcare NHS Foundation Trust	Draft guideline	021	009	1.11.11 Without access to dietetics who would provide nutrition support?	Thank you for your comment. Dietitians have been added to the list of those in the core multidisciplinary team (recommendation 1.1.3).
240	PTSD UK	Draft Guideline	004	011	Evidence suggests that up to 25% of stroke survivors go on to develop PTSD. As such, we'd suggest that perhaps this element 'provide access to other services that may be needed, for example:' should also include a mental health professional, or at the very least a screening or information service for PTSD in the months following a stroke.	Thank you for your comment. The list already includes liaison psychiatry.
241	PTSD UK	Draft Guideline	005	008	As above, we'd suggest that the core multidisciplinary stroke rehabilitation team should also comprise of a mental health practitioner to support in the overall rehabilitation – given that 25% of stroke survivors experience PTSD, which could hinder their recovery if undiagnosed and untreated.	Thank you for your comment. The recommendations already identify a clinical psychologist as a member of the core multidisciplinary team and state that access to liaison psychiatry should be available.

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242	PTSD UK	Draft Guideline	005	023	We'd suggest adding the element in bold here 'identify any ongoing needs of the person, and their family and carers, for example, access to benefits, care needs **(INCLUDING MENTAL HEALTH SUPPORT),** housing, participation in everyday and community activities, return to work, transport and access to voluntary services'	Thank you for your comment. This recommendation is specifically about social care needs rather than physical or psychological needs.
243	PTSD UK	Draft Guideline	006	004	We'd suggest adding the element in bold here 'Offer training in care (for example, in how to move people, to help them with dressing, **AND THE SYMPTOMS OF POST TRAUMATIC STRESS DISORDER TO BE AWARE OF**) to family members and carers who are willing and able to be involved in supporting the person after stroke.'	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.
244	PTSD UK	Draft Guideline	009	021	We'd suggest adding the element in bold here 'mental health, including signs indicating an increased risk of suicide (suicidality) such as suicidal thoughts, plans, actions and attempts, **and/or the symptoms of Post Traumatic Stress Disorder**'	Thank you for your comment. This recommendation is from 2013 and is not part of the current update.
245	PTSD UK	Draft Guideline	016	017	We'd suggest adding the element in bold here 'their mental health including the development of any signs that could indicate an increased risk of suicide (suicidality) such as suicidal thoughts, plans, actions	Thank you for your comment. Although a change was made to this recommendation as a safety consideration, the topic was not reviewed for this update and we cannot make more extensive changes.

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					and attempts, **and/or the symptoms of Post Traumatic Stress Disorder**'	
246	Royal College of Nursing	Draft Guideline	012 - 013	001 - 028 001 - 007	1.2.15 to 1.2.21 – Regarding Intensity of Stroke Rehabilitation there is mention of the therapies offered, what appears to us very good. However, we would like to highlight that there is no mention of the Nursing Role an Interventions on Stroke rehabilitation on the planning of Stroke Rehabilitation, what seams to us a great miss as Nursing Rehabilitation interventions are crucial and very important in multiple areas of STROKE REHABILITATION and HOLISTIC CARE. Examples are Management of Medication, Bowel and Bladder care, Skin care, monitoring of pressure areas, spasticity (including prevention of complications), Pressure relief, Bed and mattress, eating and drinking, mouth care, person and family support as part of the multidisciplinary Team, and on the periodic health and physical review (including linking with other professionals, GP, and Stroke Team). We believe that Nursing rehabilitation should be added on this chapter as Nurses have a crucial role on Stroke Rehabilitation.	Thank you for your comment. We acknowledge the enormously important role of nurses in stroke rehabilitation. However, the input of nurses (and doctors) is not delivered in discrete sessions as is the work of the therapists identified in the intensity recommendations, and therefore there is no need to specify the duration of nursing input.

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					Rehabilitation Nursing cannot be forgotten as part of the Hospital and Community Stroke Rehabilitation Multidisciplinary Team.	
247	Royal College of Nursing	Draft Guideline	006	12	1.1.8 – This is an important recommendation and we feel very strongly about the importance of continue rehabilitation as long as it helps the person to achieve their goals.	Thank you for your comment.
248	Royal College of Nursing	Draft Guideline	006	24	1.1.11 – Extremely important on our view that communication and share decision is crucial on early supported discharge and through all the rehabilitation process.	Thank you for your comment.
249	Royal College of Nursing	Draft Guideline	007	1	We believe that have a key person coordinating care and point of contact, will improve communication and outcomes, as well as reducing confusion, frustration and strain both on the person and family and/or friends.	Thank you for your comment.
250	Royal College of Nursing	Draft Guideline	013	010	1.3.1 – We believe that this recommendation should include: - The person has been assessed and deemed suitable for telerehabilitation.	Thank you for your comment. This raises the question of how to assess suitability, and we are not aware of a generally accepted way of doing so. There are some situations where telerehabilitation may be self-evidently unsuitable, for example people with significant cognitive impairment, but it is not clear how to make this judgement in less

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						obvious cases. Given this, the committee agreed that a discussion with the person and agreement with them was the best way to approach this.
251	Royal College of Nursing	Draft Guideline	019	001 - 011	1.10 – This is a very important aspects and we are glad that have been included. Nursing will have an important role on Mouth care and education. We believe that Nursing staff should be mentioned on this recommendation.	Thank you for your comment. NICE guidance will, as far as possible, focus on what should be done rather than who does it.
252	Royal College of Nursing	Draft Guideline	19 and 20	013 - 021 001 - 023	1.11 – Swallowing – It seams important to us to document on this section the professional that can be involved, including Nurses, SALT and dietician.	Thank you for your comment. NICE policy is, where possible, to focus on what should be done rather than who does it.
253	Royal College of Physicians (RCP)	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Speciality Committee for Rehabilitation and would like to comment as follows.	Thank you for your comments.
254	Royal College	General	General	General	We welcome these guidelines for rehabilitation following stroke. In the general the principles are	Thank you for your comment. References included in the D02 NHSE Service specification

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	of Physicians (RCP)				supported, but there is a disconnect between this and some of the other national clinical guidance and standards in the field of rehabilitation. For example: 1. There is no mention of specialist rehabilitation for stroke patients with more complex rehabilitation needs. • NHSE recognises that patient with highly complex needs require rehabilitation in a specialist Level 1 or 2 rehabilitation service as set in the D02 NHSE Service specification . • Approximately 60% of the patients treated under that specification have had a stroke, but this is a selected group of people with more complex (Category A or B) needs which include profound complex disability (ie physical cognitive and communicative difficulties) requiring the specialised skills and facilities of a tertiary centre – eg those with locked in syndrome, tetraplegia,	incorporate either outdated costs (published before 2007) or resource use estimates (e.g., Oddy, 2013 used 2001 data) which limits their applicability to reflect a current UK NHS context and so were excluded from this guideline update. However, your point about the need for access to specialist rehabilitation for a proportion of people after stroke is acknowledged and recommendation 1.1.2 has been amended accordingly. The point about rehabilitation prescriptions is interesting. At present however, these are of unproven value in stroke rehabilitation. The topic will be passed on to the NICE surveillance team. Regarding botulinum toxins, the recommendation for a specific dose of a particular product was made because this was the only option meeting the NICE threshold for cost-effectiveness. This analysis has been re-done following detailed comment from several stakeholders and the range of doses and forms of botulinum toxin in the recommendation has

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					severe spasticity, prolonged disorders of consciousness etc which are beyond the scope of stroke units ad community stroke teams • There is a strong evidence base that specialised rehabilitation for these highly complex and dependent patients is not only effective but highly cost-efficient. • Similarly, patients who suffer spinal cord strokes should be referred to specialist SCI units as their needs will be very different from cerebral circulation strokes. 2. These patients with more complex needs require review and ongoing oversight by a consultant in rehabilitation medicine (RM), who have specialist training and skills in management of complex and long-term disability beyond those found in a stroke physician. This is an important omission which should be rectified.	been extended. However, it still remains the case that not all of the available products meet NICE's cost-effectiveness threshold.

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					3. In other areas (e.g., trauma) a patient held rehabilitation prescription (RP) is recommended to identify ongoing rehabilitation needs and a clear plan for how these will be met – especially if the needs are complex. The RP can be used to direct patients towards the appropriate services to meet their needs as they progress down the care pathway. Proof of principle for the RP was provided in the national clinical audit for specialist rehabilitation following major injury. If this principle works for trauma, it equally makes sense to apply it for stroke patients with complex rehabilitation needs. 4. Our experts note that in some places isolated interventions appear to have been selected from the literature in a manner that makes no clinical sense. • For example, the recommendation for one specific dose of one particular Botulinum Toxin agent (500 units Dysport) for upper limb spasticity without reference to the national clinical guidelines that provide a	

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					comprehensive evidence-based person-centred approach to the management of spasticity (in both upper and lower limbs) • We submit that this recommendation would be poor practice, being ineffective in many patients and positively dangerous/damaging in others (please see below).	
255	Royal College of Physicians (RCP)	General	004	005	**People who need rehabilitation after stroke should receive it from a specialist stroke service either:** • **in a stroke unit and subsequently from a specialist stroke team in the community or** • **if they have left hospital through early supported discharge, directly from a specialist stroke team in the community. [2013]**	Thank you for your comment. These recommendations were from 2013 and not part of this update but the importance of the comment is noted and the wording has been amended.

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					As written, this recommendation allows only that patients are treated in a stroke unit or in the community. There should be a recommendation that: • Patients with more complex rehabilitation needs following stroke should be reviewed by a consultant in rehabilitation medicine. • Those identified as having category A or B needs for further specialist inpatient rehabilitation should be transferred to Level 1 or 2 rehabilitation unit.	
256	Royal College of Physicians (RCP)	General	005	008	**A core multidisciplinary stroke rehabilitation team should comprise the following professionals with expertise in stroke rehabilitation:** • **consultant physicians** • **nurses** • **physiotherapists** • **occupational therapists** • **speech and language therapists**	Thank you for your comment. Dietitians are generally part of the core MDT and have been added to the list. Orthotics is already in the list of services to which access should be available (see recommendation 1.1.2).

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					• **clinical psychologists or clinical neuropsychologists** • **orthoptists** • **rehabilitation assistants** • **social workers. [2013, amended 2023]** As many patients with stroke have dysphagia and are unable to meet their nutritional needs through an oral diet, our experts believe the core MD team should include a dietitian. Many patients following stroke will also benefit from orthotics, some of which will need to be bespoke. Orthotists should also be part of the core team.	
257	Royal College of Physicians (RCP)	General	005	023	**Health and social care professionals should collaborate to ensure a social care assessment is carried out promptly, where needed, before the person who has had a stroke is transferred from hospital to the community. The assessment should:** • **identify any ongoing needs of the person, and their family and carers, for example, access to benefits, care needs, housing,**	Thank you for your comment. This section of the guideline was not part of the current update.

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					participation in everyday and community activities, return to work, transport and access to voluntary services Our experts note that there is only mention of a social care assessment. A proportion of patients will have ongoing health needs and will meet the criteria for 100% NHS-funded Continuing Care. They will require the appropriate assessment for ongoing health care (eg using the NHS Decision Support Tool)	
258	Royal College of Physicians (RCP)	General	008	001	**On transfer of care from hospital to the community, provide information to all relevant health and social care professionals and the person after stroke. This should include a summary of the person's rehabilitation progress and current goals and details of their:** • **diagnosis and health status** • **functional abilities (including communication needs)** • **care needs, including washing, dressing, help with going to the toilet and eating**	Thank you for your comment. This recommendation is a reminder of what to cover in the transfer information. It does not mean that none of these things happen until the point of discharge. We believe this self-evident – everything on the list will have been assessed at appropriate times during the admission. As you point out the Mental Capacity Act applies throughout admission to stroke patients as to every other group of medical admissions, and it should not need a separate recommendation within every NICE guideline

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					• **psychological (cognitive and emotional) needs** • **medication needs (including the person's ability to manage their prescribed medications and any support they need to do so)** • **social circumstances, including carers' needs** • **mental capacity regarding the transfer decision** • **management of risk, including the needs of vulnerable adults** • **plans for follow-up, rehabilitation and access to health and social care and voluntary sector services. [2013]** Our experts note that it takes until the point of discharge for these guidelines to mention mental capacity assessment – and then only for ongoing placement. A significant proportion of patients with stroke will lack capacity to make decisions about their care and treatment.	

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					• It is a legal requirement of the Mental Capacity Act that every treatment given to a patient who lacks capacity is given in the patient's best interests and in line with their likely wishes. • It follows that capacity should be assessed from day 1 and best interests decision-making documented for each treatment decision (although in practice this rarely happens) • Some patients with have an advance decision to refuse treatment or will have appointed a Last Power of Attorney for Health and Welfare. If so, this should be identified at the outset and decision-making conducted accordingly. Despite this being a statutory requirement, this is an area of healthcare that is very poorly managed. This is therefore a significant omission that needs to be corrected.	
259	Royal College of	General	012	002	**Offer people after stroke the following therapies, if needed, for at least 5 days a week:**	Thank you for your comment. This recommendation is not to be taken in isolation. The preceding few recommendations,

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	Physicians (RCP)				• **physiotherapy for 1 to 2 hours a day** • **occupational therapy for at least 45 minutes a day** • **speech and language therapy for at least 45 minutes a day. [2023]** Intensity of rehabilitation should be tailored to the needs of the individual. The intensity specified here will not be appropriate for all patients: • Some will require much more than this (and so require the services of a specialist rehabilitation service that is able to deliver rehabilitation for 5-6 hours per day. • Others will not be able to tolerate even the intensity specified, for example if they have other comorbidities that impact on their tolerance of rehabilitation. • Some may require different proportions of input – for example, significantly more SLT, but less physiotherapy if they are mobile but have severe aphasia/dysphagia.	and the ones that follow, emphasise tailoring rehabilitation to the individual. The recommendation has been amended following a number of comments from several stakeholders. However, the principles in the recommendation, that therapy is given for at least this much time but only if needed (so people who need more therapy can receive more, and people who do not need it can receive less) are still included.

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					• A significant proportion of patients will require extensive psychology input. • Group therapies enable patients to mix with peers who are experiencing similar problems and form an important component of any coordinated MD rehab programme.	
260	Royal College of Physicians (RCP)	General	017	010	Our experts note that assessment of fatigue is mentioned but management has been omitted. Patients who have significant fatigue should have their rehabilitation programme adjusted to support management within the limits if their fatigue (ie should have interventions little and often), and a MDT fatigue rehabilitation programme should form part of their management https://www.ahajournals.org/doi/full/10h.1161/STROKEAHA.119.023552	Thank you for your comment. It is clear that fatigue is a significant problem for many people after stroke, and during scoping we looked for interventions that might be worth reviewing. However, advice from stakeholders was that there is little evidence of effective treatment. The guideline specifies that the intensity of rehabilitation should be adjusted in relation to fatigue (please see recommendation 1.2.18).
261	Royal College of Physicians (RCP)	General	029	011	**Consider the following options for managing shoulder pain:** • **taping** • **neuromuscular electrical stimulation (NMES)**	Thank you for your comment. The section 1.14 Managing shoulder pain states that you should 'Assess people with shoulder pain after stroke to identify the cause and use the results of the assessment to decide how to manage the pain'. This recommendation means that if you

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					• **intra-articular corticosteroid injection** • **nerve block (local anaesthetic). [2023]** Options for managing shoulder pain should be targeted to the cause of the shoulder pain. The options should include: • botulinum toxin injection of the relevant shoulder muscles if the shoulder pain is due to spasticity, as it will be in a proportion of patients. • Hydro-dilatation for adhesive capsulitis which has established evidence and now forms part of routine treatment for this cause of shoulder pain in rehabilitation programmes.	identify a cause for the shoulder pain that is treatable (such as spasticity or adhesive capsulitis) then this should be treated as is appropriate for the cause. The management strategies provided are more general management strategies for managing shoulder pain after stroke. More specific strategies to manage specific causes are either considered in other areas (such as botulinum toxin injections which are considered in the spasticity section) or were not considered in this guideline (such as hydro-dilatation for adhesive capsulitis) because it was not suggested during the scoping of the guideline. This guideline is for the management of stroke, rather than for the management of each cause of shoulder pain, and so these are not discussed in detail. However, we agree that the relevant treatment for individual conditions should be used as appropriate following the guidelines for those conditions.
262	Royal College of	General	030	014	**For people who have focal spasticity of the upper limb after stroke, consider botulinum toxin A (Dysport) at a total dose of 500 units per**	Thank you for your comment.

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	Physicians (RCP)				**treatment, spread across injections in different sections of the affected limb. Ensure that:** • **people do not receive more than 1 treatment every 3 months and** • **response to the treatment is monitored and it is stopped if it is not effective. [2023]** Our experts are concerned at the choice of 500 units of Dysport for spasticity. This blanket approach goes against the recent literature and international guidance on management of post stoke spasticity and needs to be corrected. • There are 3 licenced products of Botulinum Toxin A (BoNT-A) and there is no strong evidence for recommending one over another. • Importantly, the dosage will depend on the severity and distribution of spasticity and the goals for treatment. 500 units will be too much for some patients and not enough for others. The recommendation will be	Dysport 500U for upper limb had been recommended over others in the draft guideline as it was the only one that was cost effective. The dosage was based on clinical evidence available to inform the health economic model. Further sensitivity analyses have been conducted following stakeholder comments such as exploring a 5 year time horizon and a longer interval between injections. In addition, the clinical evidence informing Xeomin has been updated. Elovic 2016 has been removed and Masakado 2020 added. The former was AS responder data and therefore not appropriate and the latter MAS responder data has been provided thus allowing its inclusion. Finally, a Patient Access Scheme discounted price has been included for Xeomin. Following the changes to the model the committee edited the recommendation to consider Dysport (up to 1000U) and Xeomin (up to 400U) for upper limb spread across injections in different sections of the affected upper limb was given and that it was ensured

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					ineffective for many and dangerous for some. • Instead of mentioning a specific dose (which will be insufficient in a substantial proportion of cases and for which there is no evidence base) the guideline should refer to the national clinical guidelines for management of spasticity adults published by the Royal College of Physicians. • Botulinum toxin should only be administered in the context of an appropriate multidisciplinary rehabilitation programme targeted towards the goals for treatment. The guidelines also recommend Botulinum toxin only for focal spasticity of the upper limb. The mechanism of spasticity is same for both upper and lower limbs and BoNt-A is widely used for focal spasticity of the lower limb. There is no reason to recommend it for the upper limb and not the lower. The current recommendation also states that patients should not receive more than one treatment every 3 months. This may be valid for BoNT-A in other conditions (eg cervical dystonia or	that people do not receive more than 1 treatment every 3 months and that the treatment is stopped if it is not effective at this time. Cost-effectiveness of more frequent treatment or higher doses was not demonstrated.

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					bleopharospam), or possibly in long term treatment for spasticity - but many patients will benefit from serial injection at closer intervals in the early stages post stroke to prevent spasticity from become established and then will not require it again – please see the national clinical guidelines for further information. Even in established spasticity, the mean injection interval is usually significantly longer than 3 months – usually 4-6 months. Our experts believe that this section of the guidance has been formulated by isolated reading of an unusual subsection of the literature, and that the recommendations have not been formulated by people who have significant experience of management of spasticity using Botulinum toxin. Our experts are highly concerned about this section and advise it to be revised.	
263	Royal College of Physicia	General	030	026	**Refer people after stroke to a specialist spasticity service if they have:** • **ongoing spasticity that has not responded to treatment**	Thank you for your comment.

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	ns (RCP)				• **not been able to tolerate other treatments** • **complex needs in relation to spasticity (for example, people who need injection into small muscles or who need spasticity-related pain management). [2023]** Our experts agree that patients should be referred to a specialist spasticity service – but warn that the guidance as stands will make it very difficult for those specialist services to treat them effectively.	
264	Royal College of Speech and Language Therapists	Draft Guideline	General	General	The RCSLT is surprised that screening for delirium is not mentioned and wondered why it has been omitted.	Thank you for your comment. Please see recommendation 1.2.1 which covers looking for disorientation, a key early manifestation of delirium, and 1.2.2 which covers assessment of cognition.

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265	Royal College of Speech and Language Therapists	Draft Guideline	General	General	The RCSLT is surprised that the ICSS national model is not referenced in the Guideline, and wondered if NICE might add this.	Thank you for your comment. NICE documents generally avoid referencing documents produced elsewhere as their content may change during the life of the guideline. Furthermore, the ICSS model covers a number of different topics, and we are not sure which particular recommendations in this guideline update you feel would be enhanced by referencing it.
266	Royal College of Speech and Language Therapists	Draft Guideline	019 - 021	General	The RCSLT is concerned that the guideline does not mention people with dysphagia after stroke who are given the option to eat and drink orally despite the acknowledged risks. We recommend that this is added. References: • Royal College of Speech and Language Therapists. (2021). Eating and drinking with acknowledged risks: Multidisciplinary team guidance for the shared decision-making process (adults) https://www.rcslt.org/members/clinical-guidance/eating-and-drinking-with-acknowledgedrisks-risk-feeding/#section-2	Thank you for your comment. The committee have discussed this and agree that this situation occurs reasonably frequently and should be mentioned within the updated section on swallowing. A consensus recommendation has been added.

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					Royal College of Physicians. (2021). Supporting people who have eating and drinking difficulties. https://www.rcplondon.ac.uk/projects/outputs/supporting-people-who-have-eating-anddrinking-difficulties	
267	Royal College of Speech and Language Therapists	Draft Guideline	006	012 - 014	The RCSLT welcomes the statement that people will continue to receive rehabilitation after their stroke for as long as it continues to help them achieve their treatment goals. This is important as it highlights people being able to receive speech and language therapy in the community post-stroke over the longer-term. This is an area that has historically lacked investment and attention.	Thank you for your comment.
268	Royal College of Speech and Language Therapists	Draft Guideline	012	004 - 006	The RCSLT is concerned that the NICE recommendation on intensity for therapies is different to the recently published National Clinical Guideline for Stroke. Where major guidelines are not aligned, this can cause confusion to clinicians working in this clinical area. Will NICE address this difference and advise on how clinicians should implement these different pieces of guidance?	Thank you for your comment. Stakeholders have made some very reasonable points about the available evidence and the committee have reflected on this. The recommendation has been amended.

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269	Royal College of Speech and Language Therapists	Draft Guideline	012	006	The target of 45 minutes a day for speech and language therapy has not been fully implemented and there is geographic variation in uptake. As this guideline is implemented this area needs to be closely monitored to ensure continued access to vital speech and language therapy to people post stroke. Will NICE commit to action in this area to monitor speech and language therapy implementation and uptake?	Thank you for your comment. The committee agree that speech and language therapy is not available consistently and would like to see improvements. However, monitoring of service provision is outside NICE's remit.
270	Royal College of Speech and Language Therapists	Draft Guideline	012	027	The RCSLT welcomes the addition of this new section on holding joint speech and language therapy sessions with other therapies for people with communication needs. People with communication needs will struggle to access other therapies, and speech and language therapy gives people a means of communicating.	Thank you for your comment.
271	Royal College of Speech	Draft Guideline	013	009	In section 1.3 on telerehabilitation, the RCSLT is surprised to not see hybrid models of delivery mentioned. For example, the NROL (Neuro Rehab	Thank you for your comment. The search for this review did not include any studies that included this intervention. No references were provided in this comment that we could check

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	and Language Therapists				On-Line). We also could not see this in the evidence review paper. Could NICE advise if this was considered or ruled out and the reasons for this please?	for. On checking online, a letter discussing the intervention was found (https://jnnp.bmj.com/content/92/12/1354). This is a letter rather than a study and reported a non-comparative assessment and therefore would not meet the protocol inclusion criteria.
272	Royal College of Speech and Language Therapists	Draft Guideline	013	015	There is no direct mention of equipment provision. Whilst section 1.3.2 alludes to this, this section could be made clearer.	Thank you for your comment. The recommendation has been amended to make this clearer.
273	Royal College of Speech and Language Therapists	Draft Guideline	013	020	Whilst the telerehabilitation section states monitoring people taking part in telerehabilitation for symptoms or signs of depression, there is no crossover with the communication section. Communication difficulties can lead to mood disorders and depression, and this should be actively monitored. The RCSLT recommend that this is added.	Thank you for your comment. Whilst the committee agrees that communication difficulties can lead to mood disorders, that section of the guideline is not part of the current update.

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274	Royal College of Speech and Language Therapists	Draft Guideline	019	017 - 021	The RCSLT welcomes providing information to clients/carers on dysphagia and the associated risks. However, RCSLT would want to see the inclusion on information on informed decision making on eating and drinking with acknowledged risks. Could this be added? References: • Royal College of Speech and Language Therapists. (2021). Eating and drinking with acknowledged risks: Multidisciplinary team guidance for the shared decision-making process (adults) https://www.rcslt.org/members/clinical-guidance/eating-and-drinking-with-acknowledgedrisks-risk-feeding/#section-2 • Royal College of Physicians. (2021). Supporting people who have eating and drinking difficulties. https://www.rcplondon.ac.uk/projects/outputs/supporting-people-who-have-eating-anddrinking-difficulties	Thank you for your comment. The committee have discussed this and agree that the issue of risk feeding occurs reasonably frequently and should be mentioned within the updated section on swallowing. A consensus recommendation has been added.

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275	Royal College of Speech and Language Therapists	Draft Guideline	019	004	RCSLT welcomes the section on mouth care but recommends that it is clearly emphasised that these recommendations apply to both inpatient and community settings. An issue frequently found in community settings is poor dentition and a lack of access to any dental care. Mouth care for those with dysphagia living in their own home in the community seems to be more of an issue than those in the acute setting because they are not receiving regular mouth care by trained staff.	Thank you for your comment. All the recommendations within the guideline apply to healthcare practitioners in any NHS setting.
276	Royal College of Speech and Language Therapists	Draft Guideline	020	020 - 023	The RCSLT welcomes the recommendations to offer behavioural exercises and physical stimulation but recommends that clarification is needed regarding the amount of therapy offered. Dosage of oro-pharyngeal dysphagia rehabilitation therapy should be in line with the time and frequency indicated in the literature (as well as the needs of the patient), which will vary for different programmes.	Thank you for your comment. As you state, the dosage of therapy will vary for different programmes, therefore we did not find it possible to state a specific time to cover all. Intensity of rehabilitation was studied as a part of a separate review and recommendation 1.2.15 is relevant for all therapy areas. In terms of the evidence, the rationale and impact section of the guideline states that the average provided in the trials was 30 minutes a day, 5 days a week for 2 to 4 weeks. Therefore, we believe that this would be an appropriate amount of time, but since different timings have

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						not been compared to one another it is not appropriate to state this in the recommendation.
277	Royal College of Speech and Language Therapists	Draft Guideline	020	003	The RCSLT is very concerned that there is a lack of mention of the role of speech and language therapy in relation to swallowing, yet other sections do name occupational therapy and physiotherapy. While it is understood that specialist dysphagia management may involve a few professional groups, the RCSLT recommends adding "dysphagia-trained healthcare professional such as a Speech and Language Therapist". This would place this section on par with other sections which do highlight the key professionals involved in the delivery of care.	Thank you for your comment. NICE policy is, as far as possible, to focus on what should be done rather than who does it. In fact, only two of the new recommendations in this update mention physiotherapy and both of those mention speech and language therapy as well.
278	Royal College of Speech and Language	Draft Guideline	020	005	The RCSLT is concerned with the inclusion of section 1.11.4 on 'offering thickened fluids'. This needs to reflect the conversation/scrutiny in the speech and language therapy profession re: thickening drinks practice. The RCSLT recommends changing "offering thickened fluids" to "offering modified fluids (for example, small sips)".	Thank you for your comment. The committee agree and the wording has been changed.

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	Therapists				Supporting references: • *RCSLT Position statement on the use of thickened fluids in the management of people with swallowing difficulties* (March 2023) https://www.rcslt.org/wp-content/uploads/2023/03/Position-statement-thickened-fluids-1.pdf • Hansen, T., Beck, A.M., Kjaesrgaard, A. and Poulsen, I. (2022) 'Second update of a systematic review and evidence-based recommendations on texture modified foods and thickened liquids for adults (above 17 years) with oropharyngeal dysphagia', Clinical nutrition ESPEN, 49, pp. 551-555. https://doi.org/10.1016/j.clnesp.2022.03.039 • McCurtin, A., Boland, P., Kavanagh, M., Lisiecka, D., Roche, C. & Galvin, R.R. (2020) 'Do stroke clinical practice guideline recommendations for the intervention of thickened liquids for aspiration support evidence-based decision making? A systematic review and narrative synthesis', Journal of Evaluation in Clinical Practice, 26(6), pp. 1744.	

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					• O'Keefe, S.T. (2018) 'Use of modified diets to prevent aspiration in oropharyngeal dysphagia: is current practice justified?', BMC geriatrics, 18(1), pp. 167. • Steele, C.M., Alsanei, W.A., Ayanikalath, S., Barbon, C.E.A., Chen, J., Cichero, J.A.Y., Coutts, K., Dantas, R.O., Duivestein, J., Giosa, L., Hanson, B., Lam, P., Lecko, C., Leigh, C., Nagy, A., Namasivayam, A.M., Nascimento, W.V., Odendaal, I., Smith, C.H. & Wang, H. (2015) 'The influence of food texture and liquid consistency modification on swallowing physiology and function: A systematic review', Dysphagia, 30(1), pp. 2-26	
279	Royal College of Speech and Language Therapists	Draft Guideline	020	014	The RCSLT is surprised that there is no mention of instrumental assessment including FEES/VFES. Could this be added?	Thank you for your comment. This topic was not put forward for inclusion during the scoping process and therefore was not part of this update.

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280	Royal College of Speech and Language Therapists	Draft Guideline	020	015	The RCSLT recommend that this section is strengthened by saying a "dysphagia-trained healthcare professional such as a speech and language therapist". While it is understood that specialist dysphagia management may involve a few professional groups, the RCSLT recommends adding "dysphagia-trained healthcare professional such as a Speech and Language Therapist". This would place this section on par with other sections which do highlight the key professionals involved in the delivery of care.	Thank you for your comment. NICE policy is, as far as possible, to focus on what should be done rather than who does it.
281	Royal College of Speech and Language Therapists	Draft Guideline	021	012	In section 1.12 on communication, the RCSLT recommend strengthening this to say "to treat people with communication difficulties until they can make meaningful gains". Other sections of the NICE guideline reference ongoing therapy, and we would welcome this in the communication section for parity.	Thank you for your comment. This section was not updated as a part of this update (with the exception of computer-based therapy). Recommendation 1.1.8 recommends that people continue their care and rehabilitation for as long as it continues to help them achieve their treatment goals. The committee believes this should apply to all aspects of stroke rehabilitation including communication problems.

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282	Royal College of Speech and Language Therapists	Draft Guideline	022	010	In section 1.12.8, the RCSLT recommend that the word 'consider' is replaced with 'offer' to make this more active and to ensure that people can access computer-based programmes.	Thank you for your comment. In NICE guidance the word "offer" is only used when there is strong supportive evidence of clinical and cost-effectiveness. In this instance the committee did not feel the evidence was strong enough to use the word offer so used the term consider instead.
283	Royal College of Speech and Language Therapists	Draft Guideline	022	010	Computer based learning can benefit all people with speech, language and communication difficulties. It is broader than just "word finding" and beneficial across all language-based activities. Evidence is emerging, for example, for dysarthria and apraxia of speech post stroke. We recommend that "in relation to word finding" is removed. This will ensure that people after stroke can access appropriate practice-based digital therapies. References: Varley, R., Cowell., P. E., Dyson, L., Inglis, L., Roper, A., & Whiteside, S. P. (2016) Self-Administered Computer Therapy for Apraxia of	Thank you for your comment. The committee did not identify any evidence for benefits in areas other than word finding. Therefore, the committee was not able to recommend computer-based tools for speech and language therapy in any other area at this time. However, they recommended further high quality research to be conducted in other areas and recognise that there is potential for computer-based tools to be more broadly effective for delivering speech and language therapy.

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					Speech: Two-Period Randomized Control Trial With Crossover. Stroke. 2016;47:822–828, https://doi.org/10.1161/STROKEAHA.115.011939	
284	Royal College of Speech and Language Therapists	Draft Guideline	030	General	This section on spasticity should reflect that some individuals following stroke will have spastic dysarthria and that certain procedures (including pharmaceuticals) can have a positive impact on speech. The RCSLT recommend that this is added to this section. Findings that the majority of patients following a stroke have spastic or ataxic dysarthria: • De Cock, E., Oostra, K., Bliki, L., Volkaerts, A.-S., Hemelsoet, D., De Herdt, V. and Batens, K. (2021), Dysarthria following acute ischemic stroke: Prospective evaluation of characteristics, type and severity. International Journal of Language & Communication Disorders, 56: 549-557. https://doi.org/10.1111/1460-6984.12607 This Cochrane review concluded that intervention at an early stage improves impairment. • Mitchell C, Bowen A, Tyson S, Butterfint Z, Conroy P. Interventions for dysarthria due to	Thank you for your comment. Spastic dysarthria and its treatment was not put forward for inclusion during the scoping process and therefore was not part of this update.

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					stroke and other adult-acquired, non-progressive brain injury. Cochrane Database Syst Rev. 2017 Jan 25;1(1):CD002088. doi: 10.1002/14651858.CD002088.pub3. PMID: 28121021; PMCID: PMC6464736. Use of technology (AAC) is also increasingly being reported in literature as helpful to those with stroke induced spastic dysarthria.	
285	Royal College of Speech and Language Therapists	Draft Guideline	034	012 - 016	In the section on 'terms used in this guidance', it suggests that apraxia is the disorder impacting on speech, this is not the case. People can have apraxia of the limbs affecting coordination and physical independence. The RCSLT recommend that this could be clarified.	Thank you for your comment. The wording has been amended.
286	Royal College of Speech and Languag	Draft Guideline	034	008	In section 1.17.6, the RCSLT recommend replacing the word 'consider' with 'offer' to make this a more active consideration. The majority of stroke survivors should be able to access such community programmes / activities to make improvements.	Thank you for your comment. The word "offer" is generally used in NICE guidance when evidence behind a recommendation is strong, and the committee did not feel that the evidence was sufficient in

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	e Therapists					this case. There was also an absence of cost-effectiveness evidence to support this.
287	Royal College of Speech and Language Therapists	Question	General	General	Q1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. Yes, complications will occur where the recommendations differ between this guideline and the National Clinical Guideline for Stroke. This will affect clinicians, such as speech and language therapists, delivering a stroke service. It will also impact on those who commission the service. It will cause confusion interpreting this guideline and delivering this in practice. As a result, this will make the guideline challenging to implement.	Thank you for your comment. We understand that this causes difficulty. NICE guidelines are not based only on clinical evidence but also assess whether management options are cost-effective for the NHS and this will lead to differences when compared to guidelines which do not consider cost-effectivenes. We note that in most respects the two guidelines are mutually compatible. After edits from the consultation process there should be more alignment.

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288	Royal College of Speech and Language Therapists	Question	General	General	Q1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. The SSNAP audits continuously reveal that speech and language therapy services struggle to meet the national targets on intensity and seven-day services. To change this will take work. To tackle this, it would be helpful if NICE would work with the RCSLT to develop national advice and support to support speech and language therapists to help implement these guidelines into practice.	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.
289	Royal College of Speech and Language	Question	General	General	Q2. Would implementation of any of the draft recommendations have significant cost implications? The majority of stroke units across the UK have a speech and language therapy workforce below the	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.

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	Therapists				recommended staffing level. This significant variation in speech and language therapy provision needs to be tackled. The consequence is that the ability of speech and language therapists to meet NICE targets is, and will continue to be, seriously impacted. To deliver against the communication and swallowing recommendations, the speech and language therapy team across inpatient stroke (section 1.1.2) and stroke rehabilitation (1.1.3) will need to be invested in. Speech and language therapy needs to be invested in and commissioned at a level which will enable people with communication and swallowing needs to have their needs identified, treated and met in line with the NICE recommendations.	
290	Royal Pharmaceutical Society	Guideline	General	General	We are concerned that medicines are not mentioned in this document. A person who has had a stroke may already have long term conditions that they are taking medicines for and / or may be initiated on medicines following their stroke. The	Thank you for your comment. A medicines review should happen whenever a person is admitted to hospital, including when the reason for admission is stroke. This is discussed in NICE's guideline on Medicines

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					ability of the person to take their medicines, and support they may require to do this, needs to be considered as part of the rehabilitation process. This would be particularly important for someone who has dysphagia.	optimisation: the safe and effective use of medicines to enable the best possible outcomes (NG5). In addition, 1.1.14 reminds people to check medicines when person is transferred, and 1.11.5 recommends reviewing in those with dysphagia.
291	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	005	018	Rec 1.1.3 – We are concerned that the wording 'social workers' is too general. We would like to make the following suggestion – 'integrated access to social care assessors'	Thank you for your comment. The committee believe that Social Care Assessors is a vaguer term than Social Workers, and less widely understood.
292	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	006	012	Rec 1.1.8 – We are concerned that this recommendation may imply that all patients need continuous input following stroke rather than being empowered to self-manage. This is at odds with the ICCS model. Suggestion: could it read 'stroke specific long term goals'?	Thank you for your comment. The committee do not agree that the recommendation promotes continuous input for all patients and therefore agree to keep the wording as it is. Several other stakeholders have expressed agreement for the recommendation as it is.
293	Sheffield Teaching	Guideline	012	004	REC 1.2.15 - We are concerned that the physiotherapy recommendation has increased from 45 minutes a day to 1 to 2 hours a day. Question 1:	Thank you for your comment. The committee are aware that current resources are limited and that this

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	Hospitals NHS Foundation Trust				Has the staffing ratio been adjusted accordingly to facilitate this extended time frame of physiotherapy input? It would be helpful if the NICE and new RCP guidelines matched in terms of recs on this and staffing levels were made in parallel.	recommendation may not be immediately deliverable. However, our detailed analysis shows that it is cost-effective for the NHS. Note that the wording of 1.2.15 has been amended in response to comments from several Stakeholders.
294	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	012	012	Rec 1.2.17 – We are concerned that this recommendation may imply that all patients will be receiving intensive therapy and that interpretation of the word 'intensive' may be subjective, as not all patients require intensive therapy. We would like to recommend the following: 'the benefits of having a patient centred therapy program that starts as soon as possible after stroke'. This would also align more with the National ICSS model in regard to self-managing.	Thank you for your comment. The wording of this recommendation has been amended
295	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	012	027	1.2.20 Excellent to have this guidance added. Would it also make sense to include the need for these patients to receive any and all information in an appropriate aphasia friendly format.	Thank you for your comment. The committee recognise the importance of aphasia friendly information but do not think this fits into the specific context of 1.2.20. It is covered by recommendations 1.2.9 and 1.4.1.

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296	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	017	019	Rec 1.8.1 comment 1: – We are concerned that this recommendation may imply that all patients require an official orthoptic assessment when this is not always necessary if no vision impairments have been reported. A more appropriate word would be screened rather than assessed for visual impairments. Rec 1.8.1 comment 2: - This is too specific to just visual field issues. Patients may suffer with a variety of visual issues following stroke such as double vision, nystagmus, inattention and field loss. We need to include these and not be too specific as it implies only patients with visual field loss need to be seen. We also would avoid saying "offer eye movement therapy". Suggestion: Could this say something more along the lines of "need screening by an appropriately trained member of the therapy team, and anyone whom they have concerns regarding vision should have an assessment by an orthoptist"	Thank you for your comment. The recommendation is that all people should have an assessment after a stroke for the reasons given in the rationale and in the evidence review. We think your comment 2 refers to 1.8.3 (recommendation 1.8.2 in the current version) rather than 1.8.1. This is a recommendation from the 2013 guideline and the evidence has not been reviewed for this update.
297	Sheffield Teaching Hospitals NHS	Guideline	018	010	Rec 1.9.1 – We are concerned that this recommendation may imply that all patients require an official hearing assessment when this is not always necessary. We would like to recommend the following: 'screen' rather than 'assessment'.	Thank you for your comment. This recommendation has been amended to state that all people after stroke should be screened. People with suspected hearing problems after this should then be referred for

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	Foundation Trust					a comprehensive audiology assessment, as per NICE's guideline on hearing loss in adults.
298	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	019	005	Question 2: Would the Trust be required to provide an electric or battery powered toothbrush to patients that do not have access?	Thank you for your comment. The committee believe this would be appropriate when these are needed for effective mouthcare, as stated in the recommendation. The rationale indicates that this is important because it reduces mortality. A ward might have a supply of toothbrushes and change the heads between patients.
299	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	019	013	1.11 Swallowing. Generally positive to have this enhanced guidance and note further research into cost effectiveness of neuromuscular electrical stimulation although not directly added to the guidance this time. Note that for the Free Water Protocol the evidence base is still small but this is a welcome the addition to the guidelines as an option for consideration for the patients who fit the specific criteria from these studies. Note no specific reference to palliative feeding approaches and risk feeding approaches have been made as are listed and helpful in the national guidelines.	Thank you for your comment. The committee have reconsidered both of these. Several Stakeholders have suggested that the possibility of risk feeding should be covered in the guideline and the committee have now added a consensus recommendation. Conversely several stakeholders have suggested that the evidence base for the Free Water Protocol is not sufficient for it to be recommended given that the small numbers in the studies do not allow potential harm to be adequately assessed. The committee have decided that it would be better to recommend additional research including

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						larger numbers of subjects, and the recommendation has been removed.
300	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	026	015	Question 3: We suggest the following phrasing: 'Do not routinely offer robot-assisted arm training as part of an upper limb rehabilitation program'	Thank you for your comment. We do not agree with this change in phrasing as the evidence indicated that robot-assisted arm training is not cost-effective and is not any more clinically effective then physiotherapy.
301	Sheffield Teaching Hospitals NHS Foundation Trust	Guideline	030	015	Question 3: Why was Dysport chosen as an example specifically?	Thank you for your comment. Dysport was the only type of botulinum toxin A that was shown to be cost effective in the draft economic model. It was not stated as an example, it is identified because other agents did not show cost effectiveness in the economic modelling conducted for the guideline (please see the report for more details). However, following amendment to the model Xeomin is also cost-effective in certain circumstances and has been added to the recommendation.
302	Sheffield Teaching	Guidelines	017	14	Rec 1.7.2 – none of the fatigue assessments listed are suitable for people with aphasia. This is listed as a future development and perhaps some	Thank you for your comment. The committee agree that a tool suitable for people with aphasia is needed. However, it is

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	Hospitals NHS Foundation Trust				comment to this end to acknowledge in the guideline that fatigue should be discussed and rated using tools suitable for the level of language a patient can access.	difficult to add the comment you suggest because it would inevitably lead to requests for a recommendation about an appropriate tool, and this would not currently be possible.
303	Sheffield Teaching Hospitals NHS Foundation Trust	Guidelines	021	12	1.12 Communication. No reference to the consideration of Conversation Partner Training for people living with aphasia and their loved ones. Presuming this, but couldn't see reference to review of evidence / cost effectiveness for this?	Thank you for your comment. This section of the guideline was not part of the current update (apart from recommendation 1.12.8) and Conversation Partner Training was therefore not reviewed. The topic will be passed on to the NICE surveillance team.
304	Stroke Association	Draft Guideline	General	General	The Stroke Association welcomes this opportunity to comment on the draft NICE stroke rehabilitation in adults guidance. Post-stroke rehabilitation is a vital and sometimes overlooked part of the stroke pathway. With around two-thirds of stroke survivors leaving hospital with some form of disability, those who have had a stroke often face immediate physical, psychological, cognitive, and practical challenges.[1] We want all stroke survivors to be able to access the rehabilitation they need, for as long as	Thank you for your comment. We are pleased that you find the guideline generally supportive of your aims.

[1] https://www.strokejournal.org/article/S1052-3057(04)00070-9/abstract

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					they need, and hope that this guideline update can help achieve this goal. Post-stroke rehabilitation services in the UK face significant challenges. The Stroke Association's Lived Experience of Stroke report found that half of stroke survivors felt they needed support for longer or more frequently.[2] In addition, 40% of survivors said they needed longer or more frequent support from physiotherapy services than was provided, and a third needed more speech and language or occupational therapy. This shows how the long-term under-resourcing of stroke rehabilitation services is translating into measurably poorer outcomes and experiences for stroke survivors. These challenges exist in both hospital and community settings. Despite stroke service models outlining ambitions for rehabilitation to be both 'needs-based' and available 7 days a week, resource constraints make a 5-day service common practice in community-based teams, placing	

[2] https://www.stroke.org.uk/lived-experience-of-stroke-report

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					restrictions on the accessibility of services.[3] Over a third of community rehabilitation teams have a waiting time of more than 2 weeks to start therapy.[4] 58% of post-hospital rehabilitation services had a time limit on their provision of rehabilitation in the most recent audit year.[5] Since the existing NICE stroke rehabilitation in adults guidance was developed there have been significant changes in how rehabilitation services are structured, as well as a number of system-wide initiatives to improve the provision of stroke services, including: • The NHS Long Term Plan; • The National Stroke Service Model (NSSM); • The Integrated Community Stroke Service (ICSS) model; • The Integrated Life After Stroke Service (ILASS) model.	

[3] https://www.england.nhs.uk/wp-content/uploads/2022/02/stroke-integrated-community-service-february-2022.pdf
[4] https://www.strokeaudit.org/Documents/National/PostAcuteOrg/2021/2021-PAOrgPublicReport.aspx
[5] https://www.strokeaudit.org/results/PostAcute2021/National.aspx

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					The NHS Long Term Plan, published by NHS England and Improvement in January 2019, includes the following ambition for stroke rehabilitation: • 'Implementation and further development of higher intensity care models for stroke rehabilitation are expected to show significant savings that can be reinvested in improved patient care. This includes reductions in hospital admissions and ongoing healthcare provision. Out of hospital, more integrated and higher intensity rehabilitation for people recovering from stroke, delivered in partnership with voluntary organisations including the Stroke Association, will support improved outcomes to six months and beyond'.[6] The NSSM was published in May 2021, laying out the role of the Integrated Stroke Delivery Networks (ISDNs) as the key vehicles for quality improvement in stroke care across England, and providing an initial outline of rehabilitation and life after stroke	

[6] https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf

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					service specifications, that have now been detailed in greater depth through the ICSS model and the ILASS model. On inpatient rehabilitation, the NSSM states that: • 'Patients must have a rapid initial multidisciplinary assessment to begin building a personalised rehabilitation plan, which must then be started as soon as clinically appropriate.' • 'High quality therapy should be offered seven days a week to all patients and by all required core clinical disciplines, at an appropriate intensity to meet each individual's rehabilitation goals.' On integrated community stroke service rehabilitation, the NSSM states that: • 'Early Supported Discharge (ESD) must be available in all areas' • 'All stroke survivors who need community rehabilitation should be offered it by their ICSS.' • 'All survivors (and carers where appropriate) should regularly review their rehabilitation	

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					goals with their ICSS (every four to six weeks). • 'The course of rehabilitation should last as long as the patient is willing and capable of participating, and showing measurable benefit from treatment.' • 'An ICSS should operate seven days a week.' • 'Psychological and neuropsychological rehabilitation must be routinely available as part of the core service provision throughout the patient journey.'[7] Expanding on the specification for community rehabilitation services, we have also seen the publication of the ICSS model, which outlines the need for community rehabilitation to be 'needs-based', integrated into one seamless service, and available 7 days a week. This model states specifically that: • 'The ICSS should offer adults who have had a stroke responsive and intensive rehabilitation.'	

[7] https://www.england.nhs.uk/wp-content/uploads/2021/05/stroke-service-model-may-2021.pdf

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					• 'ICSS should be provided for up to six months with the option for re-referral after discharge if rehabilitation needs and goals are defined, and with access to support services on discharge.' • ICSS should be a 'seven days a week service' up to 6 months. • Every ICSS should have core stroke rehabilitation services, including occupational therapy, physiotherapy, speech and language therapy, and clinical psychological input, as well as appropriate access to services such as vocational rehabilitation, life after stroke and voluntary services, and additional psychological support services.[8] Finally, we have also recently seen the publication of the ILASS model, which outlines what life after stroke services all stroke survivors in England should expect to receive, including access to a Stroke Key Worker, a 6 month review and a review annually thereafter, personalised care and support	

[8] https://www.england.nhs.uk/wp-content/uploads/2022/02/stroke-integrated-community-service-february-2022.pdf

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					planning, emotional support, and vocational rehabilitation. The key features of the ILASS model are that it is: • 'Integrated in the stroke care pathway and should be pro-actively provided in parallel to rehabilitation and other care; • Provided on a needs-based rather than time-limited basis; • Has a range of overarching outcomes which should be informed by the individual being supported and based on what matters most to them; • Should be delivered through dedicated support from a Stroke Key Worker for people affected by stroke, as well as other professionals'.[9] We welcome this update to the NICE stroke rehabilitation in adults guidance and hope that it can help us all drive towards the national policy ambitions that we have laid out above, ultimately improving rehabilitation services for stroke survivors.	

[9] https://future.nhs.uk/strokecommunity/view?objectId=166985189

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305	Stroke Association	Draft Guideline	General	General	Having laid out the policy context within which this guideline update is taking place above, we now want to outline general comments on the structure and nature of this guideline draft, before moving on to specific comments on recommendations below. We are grateful to NICE for the significant work that has been done to evaluate the large amount of new evidence in stroke rehabilitation that has emerged in recent years. The Evidence Reviews are documents of immense depth and detail that will be of use to clinicians and policymakers for many years to come. We are thank the NICE guideline development committee for their integration of qualitative insight into their evidence evaluation process; we strongly believe that the stroke survivor perspective should be given as much credence as the conclusions and analysis of randomised control trials, observational trials, and quantitative insight. We are, however, concerned that the rehabilitation guidance laid out in this draft does not align with the aspirations or service specifications laid out in the NHS Long Term Plan, NSSM, ICSS, and ILASS.	Thank you for your comment. On the general issue of aligning with national policy documents and service specifications, the committee also understand the benefits of this. However, as you rightly point out, the remits underpinning the production of these documents differ, and specifically NICE is obliged to consider clinical and cost-effectiveness in its guidance. This is relevant to the question of intensity of therapy. While conducting the evidence reviews, we found limited evidence that specifically investigated rehabilitation delivered 7 days a week compared to this being delivered 5 days a week. These studies did not show clinically important improvements of 7 days therapy compared to comparable therapy provided for 5 days a week, and therefore it is difficult to mandate 7 days across the board. Nonetheless, the committee agree that the ability to provide rehabilitation after stroke for 7 days a week may be important for continuing rehabilitation progress. In the recommendations they emphasised that the

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					The Stroke Association accepts and understands that the guideline's primary aim is to evaluate evidence and come to objective recommendations. To that extent, we acknowledge that differences of perspective may arise due to differing end objectives: the NICE guideline analyses the validity and implications of research and evidence, within a set scope of questions, while the Stroke Association aims to improve stroke services across the stroke pathway, driving towards the aspirations laid out in national service specifications. Nevertheless, we would posit that a situation in which national service specifications and clinical guidance diverge on what should be provided to stroke survivors is not in the best interest of stroke patients and stroke survivors themselves, as it creates unnecessary confusion and ambiguity about what level of service should be received or delivered. In turn, these misalignments have the potential to confuse clinicians and other healthcare professionals working under extreme pressure to design and deliver services with limited resources. We would therefore strongly suggest that the updated guidelines must explicitly reflect these	minimum time that rehabilitation should be offered for is 5 days a week and emphasised that the timing and sequencing could be adapted based on the person's goals, interests and needs to allow for therapy 7 days a week where this aligns with the person's goals. They also agreed a research recommendation for further research into intense rehabilitation 7 days a week compared to 5 days a week so that this could be better understood in the future. This would apply to both post-acute and ESD/community settings if required. There are currently no plans to merge the Acute and Rehabilitation Guidelines. Regarding section 1.17, the scoping process did not identify substantial new research evidence and so most of this was not included in the guideline update, but we did add a question on community participation projects so that longer term rehabilitation issues formed part of this update.

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					documents, which are central to national stroke care delivery. In turn, the guideline must be part of a wider joined-up integrated pathway to ensure every stroke survivor has an integrated recovery journey and people do not fall through the gaps. While the guideline, of course, has a necessarily limited scope which has been clearly defined in a set number of questions to be explored, we believe that a level of alignment between clinical guidance and national plans is a key vehicle to driving towards an integrated care pathway. As we reflect on in greater depth below, the recommended intensity for rehabilitation in this draft guidance does not align with the aspirations in national plans for a 7-day rehabilitation service, both in the post-acute inpatient and ESD/community settings. We also remain concerned that there are two separate guidelines for acute and rehabilitation stroke services, which suggests a lack of integration across the pathway. Stroke survivors across England should have equal access to personalised needs-based rehabilitation and life after stroke support, including regular reviews (including at six months). These services should be fully integrated	We also agree with the ICSWP's comment on the need for clarification on what constitutes a 'community participation programme'. We have clarified this in the 'terms used in this guideline' section.

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					across the stroke pathway, prioritised and invested in. We know, however, that services in the post-acute section of the pathway are deprioritised compared to the acute; a separation of clinical guidance into these two binary groupings has the potential to solidify this state of misaligned prioritisation. The Stroke Association is disappointed that we are not being invited to comment on section 1.17 Long-term health and social support, which is out of scope for the review of the guideline, aside from recommendation 1.17.6 on community participation programmes. This section as a whole is misaligned with the national ILASS model, and does not represent the expansion of high quality life after stroke services and interventions in the intervening years between the last guidance update in 2013 and the present day. In addition, this section does not represent the integral role of the third sector in supporting the long-term wellbeing of stroke survivors. This is in contrast with the National Clinical Guideline for Stroke (2023), which highlights, for instance, the	

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					importance of 'community-based support groups provided by voluntary or statutory services' in its section on further rehabilitation in the community setting (5.27 Further rehabilitation, recommendation C).[10] The National Stroke Service Model also recognises the importance of the third sector in delivering rehabilitation ambitions. The model notes that stroke services should 'Ensure effective patient flows and care pathways across the ISDN with clinical collaboration and co-ordination between all stakeholders including the voluntary sector'.[11] Voluntary sector organisations, including the Stroke Association, can help to provide the space and support necessary – through peer support groups, exercise classes and one-to-one engagement – to ensure that stroke survivors are able to access the support they need to continue their recoveries. We also have services that are based in hospital or alongside outpatient services, which we know clinicians value as our services pick up the often significant social, practical and emotional issues	

[10] https://www.strokeguideline.org/chapter/long-term-management-and-secondary-prevention/?id=571#571
[11] https://www.england.nhs.uk/wp-content/uploads/2021/05/stroke-service-model-may-2021.pdf

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					faced by stroke survivors and their families, freeing up clinical teams to focus on clinical issues. This means their time is used effectively and efficiently which will help ensure better provision of clinical support in and outside of hospital. Finally, as a member of the Intercollegiate Stroke Working Party (ICSWP), we support its consultation response to this guideline draft, including its emphasis on the importance of general alignment between the NICE stroke rehabilitation in adults guidance and the recently updated National Clinical Guideline for Stroke. We also concur with the ICSWP's comment on the need for clarification on what constitutes a 'community participation programme' as we have detailed below.	
306	Stroke Association	Draft Guideline	006 - 007	General	We welcome the introduction of the recommendation 1.1.11. In the Stroke Association's Lived Experience of Stroke Report from 2018, our survey found that 22% of stroke survivors did not feel they were involved in making choices about their recovery and support. There is a clear need, therefore, for shared decision making to be underlined in national guidance.	Thank you for your comment. The committee has discussed this and agrees that it is reasonable to include a stroke key worker within 1.1.11.

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					We would strongly suggest, however, that explicit reference to the Stroke Key Worker is made here. As outlined in the NSSM ('The discharging inpatient stroke team should refer their patient to a stroke key worker to ensure they can access appropriate personalised support', page 31) and the ILASS model ('The Stroke Key Worker should make contact with the person affected by stroke (or their family/carer) within 3-5 days of discharge', page 13), the Stroke Key Worker is an integral part of the stroke multidisciplinary team and their support should be made available to every stroke survivor during the transition from hospital to the community. We would also recommend that reference is made to informational documents (e.g. Personal Stroke Record) that can be provided to stroke survivors on transfer from hospital to the community, to enable individualised care and self-management. Suggested edit: '1.1.11 Before and during early supported discharge:	

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					• provide the person after stroke, and their family and carers, with information about early supported discharge and accessible and personalised information about their stroke (e.g. Personal Stroke Record), including details of who to contact if problems arise (e.g. a Stroke Key Worker), to support shared decision making about their care • assign a clinical member of the early supported discharge team or the stroke rehabilitation service to the person to act as a Stroke Key Worker and to coordinate their care.'	
307	Stroke Association	Draft Guideline	033 - 034	General	As we have noted above, the Stroke Association is disappointed that we are not being offered the opportunity to comment on recommendations 1.17.1 to 1.17.5 of section 1.17 Long-term health and social support, which were out of scope in this review but which we nevertheless believe are insufficient to represent both the need for long term and life after stroke support, as well as the range of	Thank you for your comment. The scoping process did not identify substantial new research evidence which might affect the recommendations in section 1.17 and so most of this was not included in the guideline update, but we did add a question on community participation projects so that longer term rehabilitation issues were considered. It will be

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					interventions and support services that are available to stroke survivors after their stroke. As referenced above, the ILASS model outlines which life after stroke interventions and support should be made available to stroke survivors after their stroke, including: personalised care and support planning; personalised information provision; holistic six month post-stroke review; emotional support; secondary prevention information and support; communication support; return to work support; peer support; and access to support for unpaid carers of people who have had a stroke. Recommendation 1.17.1 within this section fails to capture the need for stroke survivors to have access to a Stroke Key Worker, who can help to facilitate and coordinate their longer term care, as well as conduct 6 month reviews, which can enable stroke survivors to be re-referred into a relevant service and access further help and support. Recommendation 1.17.3, which 'encourage[s] people to focus on life after stroke' and provides examples of community participation activities ('sports and leisure pursuits', 'stroke support groups'), as well as social roles in work and	passed on to the NICE surveillance team as an area for future interest.

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					education, does not reference the significant role of the third sector and organisations such as the Stroke Association in providing life after stroke services. Finally, recommendation 1.17.5 does not reference who should be providing a 6 month review (e.g. a Stroke Key Worker).	
308	Stroke Association	Draft Guideline	012	General	There is significant misalignment between recommendation 1.2.15 and the recently updated National Clinical Guideline for Stroke. The National Clinical Guideline for Stroke outlines the following recommended rehabilitation intensities: • Stroke patients with motor recovery goals undergoing rehabilitation after a stroke should receive a minimum of 3 hours of therapy a day, at least 5 days out of 7. This 3 hour target replaces the 45 minutes of physiotherapy per day previously recommended. • People undergoing rehabilitation after a stroke should be supported to remain active for up to 6 hours a day (including therapist-delivered therapy). This 6 hour target for activity encompasses occupational therapy,	Thank you for your comment. You have made some very reasonable points about the available evidence and the committee have reflected on this. Therefore, the recommendation has been amended. Our guidance does not cover a target for remaining active, and so there is no conflict with the National Guideline in that respect. The committee also note that neither guideline is able to unequivocally recommend full 7 day working. Regarding the cost-effectiveness analysis, limited evidence for 7-day working prevented its inclusion into the model. A research recommendation was made to address this

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					thereby replacing the 45 minutes of occupational therapy per day previously recommended. • No specific speech and language intensity recommendation, but an emphasis on therapy provision for 'as frequently and for as long as they continue to make meaningful gains'.[12] The Stroke Association expresses concern that this misalignment may result in clinician, patient, and family uncertainty around the intensity of rehabilitation that should be delivered or received. We also note that this recommendation is misaligned with the National Stroke Service Model and Integrated Community Stroke Service's aspirations for a 7 day inpatient rehabilitation and ICSS rehabilitation service. The Stroke Association recognises and understands the reasons for this difference in recommendation. Specifically, we understand that each respective guideline has adopted a different standard and form	bearing in mind concerns of a potentially high resource impact. Considering that the EQ-5D captures activities of daily living (work, study, housework, family, or leisure activities) and mobility, it should sufficiently capture changes resulting from increased physiotherapy. Concerns regarding the EQ-5D's sensitivity, in particular towards cognition, communication and psychological issues (beyond anxiety and depression) are relevant when analysing any specific health outcomes but its use is necessary for NICE to apply a consistent approach for comparing treatment effectiveness across different disease areas.

[12] https://www.strokeguideline.org/

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					of research evidence evaluation in arriving at their recommendations, as well as having a different process for coming to a recommendation. We also understand that each guideline places contrasting emphases and weighting on cost effectiveness and health economics analysis in their recommendations. We have addressed these two primary differences – research evidence evaluation and the integration of cost effectiveness analysis – below. <u>Rehabilitation clinical research</u> The Stroke Association recognises the variability in quality of evidence in stroke rehabilitation, with evidence relating to communication and cognition being significantly more limited and weaker than evidence for physical function and motor recovery, for example. We also welcome the integration of qualitative insight into the evidence evaluation for these recommendations; stroke survivor, family/carer, and clinical insight is vital to the development of clinical guidance, particularly in areas such as stroke rehabilitation, where	

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					quantitative evidence is typically weaker than for interventions in the acute setting, for instance. We recognise, in this same light, that outcomes in some areas of rehabilitation and long term support (e.g. psychological support) are, by their very nature, harder to quantify in meaningful ways, and measure against appropriate control groups, within the context of a randomised control trial compared to other areas of rehabilitation (e.g. upper limb rehabilitation), in which the factors that contribute to someone's recovery of a specific function, for instance, can more easily be measured. The guideline development committee of course recognises these complexities: 'the committee agreed that conducting trials to investigate intensity are difficult within a randomised controlled trial setting' (Evidence Review E, Intensity of rehabilitation B, page 80, lines 14-15). <u>Quantitative cost effectiveness analysis</u> In making assessments of cost effectiveness, the Stroke Association would like to emphasise a number of factors that are central to quantitative	

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					judgements about rehabilitation. Firstly, we believe that it is inherently difficult to capture stroke survivor holistic wellbeing through economic modelling in the form of broad quality of life metrics; such modelling often negates individual experience in its attempt to quantify that which cannot be quantified. Indeed, the committee quite rightly recognises this difficulty in capturing the long term effects of good rehabilitation in the 'Evidence Review E: Intensity of Rehabilitation B': 'The committee's view was that some of the benefit of higher intensity is likely to be maintained after rehabilitation has ended and that there are likely to be some savings in care costs in the longer term, although both effects are difficult to quantify' (page 93, lines 12-14). We strongly agree with this perspective. Secondly, rehabilitation services in the acute and community settings have historically been under-resourced compared to medical services. While economic analysis quite rightly assesses the added marginal benefit of increased rehabilitation intensity as relatively low compared to the resources needed to achieve incremental improvements in outcomes, across all therapies, it is worth re-emphasising that	

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					rehabilitation services start from a much lower baseline than acute treatments. We therefore want to avoid a situation in which economic analysis justifies or legitimises the current low levels of resource allocation to rehabilitation, by asserting that the marginal added value of investment is low. This is not a comment on the guideline's economic modelling itself, but rather is a reflection on and an emphasis of the possible consequences of this guideline publication. Taking into account the varied and legitimate reasons for the difference between the National Clinical Guideline for Stroke rehabilitation recommendation and the recommendation laid out in this guideline, we strongly suggest that the underlying principles of best practice rehabilitation provision (needs-based and person-centred provision, accessible 7-days-a-week), as laid out in the National Clinical Guideline for Stroke and national service specifications, should be re-emphasised in this section, beyond their current emphasis. We note that in 'Evidence Review E: Intensity of Rehabilitation B', page 80, lines 34-37, it is stated that the guideline development commit:	

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					'acknowledged that, to achieve this [recommended intensity of therapy provision], therapy may require to be split and delivered in smaller chunks, which could include delivering the total time over a 7 day per week service. The committee agreed that a person-centred approach should be taken and that a 'needs-based' approach should be taken for rehabilitation and that this amount of time should be a guideline with people receiving as much therapy as they require.' The Stroke Association strongly agrees with this conceptual framing of rehabilitation intensity, and we would urge the committee to translate this framing into the language of recommendation 1.2.15, as suggested below. We believe that this slight edit to the framing of the recommendation 1.2.15 captures the uncertainty inherent in rehabilitation intensity recommendations, due to the limited and low quality of clinical research as outlined above, while still recommending an intensity that it commensurate with national service specifications and still drives towards an overall increase in the dose of rehabilitation that each stroke survivor has access to.	

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					Suggested edit: '1.2.15 Offer people after stroke the following therapies, if needed, for 5 to 7 days a week, taking into account individualised need for higher or lower intensities of rehabilitation above or below these recommendations: • physiotherapy for 1 to 2 hours a day • occupational therapy for at least 45 minutes a day • speech and language therapy for at least 45 minutes a day. [2023]'	
309	Stroke Association	Draft Guideline	012	General	Recommendation 1.2.17, on the 'benefits of having intensive therapy that starts as soon as possible after a stroke', is not supported by the AVERT trial, where this is associated with worse outcomes. Did the guideline development committee take this trial's conclusions into account when producing this recommendation?	Thank you for your comment. The AVERT trial was not part of our evidence review because the protocol excluded trials including people during the first 24 hours after a stroke (as this would fall under our Acute Stroke guidance). However, the AVERT trial was considered in NG128 Stroke and transient ischaemic attack in over 16s: diagnosis and initial management. The committee agrees that it is relevant to recommendation 1.2.17 in this Stroke Rehabilitation update and have added a cross

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						reference, and amended the recommendation to state that rehabilitation should only commence when safe to do so.
310	Stroke Association	Draft Guideline	013	General	We welcome these recommendations within 1.3 Telerehabilitation. They align with the perspectives of stroke survivors, as expressed in our Stroke Recoveries at Risk survey from 2020, which indicated a high level of satisfaction with telehealth methods of delivering post-stroke support.	Thank you for your comment.
311	Stroke Association	Draft Guideline	017	General	We welcome recommendations within 1.7 Fatigue. Many people describe fatigue as the most difficult and upsetting problem they have to cope with after a stroke, yet fatigue has not, until recently, been extensively covered in national clinical guidance.	Thank you for your comment.
312	Stroke Association	Draft Guideline	030	General	In relation to recommendations 1.15.4 and 1.15.6, the current evidence does not show stretching, splinting, or electrical stimulation improves spasticity, and this recommendation is misaligned with the updated National Clinical Guideline for Stroke (4.24 Spasticity and contractures).	Thank you for your comment. It is true that this advice and that in the National Clinical Guideline for Stroke are not aligned. The evidence for these 3 treatments is not strong, but showed some evidence of clinical effectiveness for a manageable cost. The committee took the view that they could be useful in some people and that the option

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						should be available so that if other treatments have not worked that they can consider them. The recommendation on stretching and splinting has now been weakened to a consider recommendation.
313	Stroke Association	Draft Guideline	032	General	We welcome this inclusion of the additional recommendation 1.16.5 within this section on return to work support, particularly as a quarter of all strokes happen to people of working age (i.e. under the age of 65) and around a third of stroke survivors in this age group have to give up their job following their stroke, while a further 15% have to reduce their working hours.[13] We would strongly suggest, however, that the guideline reflect the fact that the Stroke Key Worker can provide level three vocational rehabilitation, as outlined in the Integrated Life After Stroke Service (ILASS) model, thereby ensuring alignment with national-level service guidance.[14] We would also suggest that the language in this recommendation should be	Thank you for your comment. Whilst it is true that a Stroke Key Worker could provide vocational rehabilitation, there are other ways of providing this. NICE policy is, where possible, to focus on what should be done rather than who does it. The word "offer" is generally used in NICE guidance when evidence behind a recommendation is strong, and in this instance the committee judged t that the evidence was not sufficient.

[13] https://www.stroke.org.uk/sites/default/files/jn_1920.276a_-_pps_-_work_after_stroke.pdf; https://www.stroke.org.uk/sites/default/files/report_chapter_2_final.pdf
[14] https://future.nhs.uk/strokecommunity/view?objectId=166985189

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					changed to 'offer' vocational rehabilitation, rather than 'consider'. Suggested edit: 1.16.5 Offer a referral to a return-to-work programme for people who were working before their stroke, as well as ensuring access to a Stroke Key Worker, who can provide level three vocational rehabilitation [2023].	
314	Stroke Association	Draft Guideline	034	General	The Stroke Association welcomes the inclusion of a recommendation on social and community programmes, which we called for in our response to the draft scope; we appreciate NICE taking on our perspective. However, we believe recommendation 1.17.6 is insufficient to capture the range of programmes and support services present in the community that stroke survivors can benefit from. The threshold for accepting evidence for guidelines, such as this one, needs to be considered, especially as many of the services currently provided for stroke rehabilitation are not reliant on traditional forms of accepted evidence. And, there needs to be a balance between patient reported outcomes with	Thank you for your comment. Recommendation 1.17.6 has been altered in the light of other Stakeholder comments, and in order to keep it to a reasonable size a more extensive list of the types of activity which might be included in Community participation programmes have been added to the definition in the Term Used in the Guideline section.

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					clinically reported outcomes. The forthcoming national Patient Reported Experience Measures survey pilot will, in this light, act as a key source of evidence for the role of community programmes, support services and holistic life after stroke interventions in general. The types of services the third sector deliver, for example, are important to stroke survivors' recoveries and a hugely valuable part of their rehabilitation. We know services such as those providing emotional support deliver vital support for stroke survivors once they have left hospital. Currently, there is lack of direct RCT evidence for the value of community-based interventions such as stroke choirs, art groups, volunteering and community exercise groups. These interventions are greatly valued by participants and their carers and yet RCT evidence is lacking. While there are some RCTs ongoing that address issues such as music therapy and choirs, the nature of the RCT means that they look at very narrow interventions or outcomes. As we have referenced above, the nature of some aspects of rehabilitation and long term support means that the necessarily strict	

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					requirements of an RCT prevent the quantitative testing of outcomes: it is difficult, for instance, to objectively measure the benefit of a stroke survivor joining a stroke choir, without flattening down the reality of human experience to a quantitative metric that does not reflect the reality of any likely benefit. We greatly value, in this light, the fact that NICE has inserted this new recommendation on community participation programmes and appreciate that in this instance, limited RCT evidence has not been a barrier to inclusion of this recommendation, as shown by the published rationale for inclusion. Our suggestion below aims to slightly expand the language used to describe these programmes, to capture their range. Suggested edit: 1.17.6 Consider a referral for people after stroke, and their families and carers (if appropriate), to community participation programmes that are suited to the person's rehabilitation goals. Appropriate community participation programmes could include, but are not limited to:	

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					• Third sector participation programmes • Peer support groups • Music therapy groups • Art therapy groups. • Sport groups [2023]	
315	Sue Ryder	Guideline	006	012	1.1.8 Agreed, however, this will probably require additional resources and the treatment goals will need to be under constant review by a specialist therapist throughout the pathway to ensure that they continue to be realistic. Patient reported outcome measures should be in place from initial assessment and throughout the pathway to discharge. Also a functional measure that is more involved than Barthel, such as FIMFAM, should be in place throughout and uploaded onto UK ROC (UK rehabilitation outcomes collaborative).	Thank you for your comment. The committee agree with the need for review, although suggest that regular review is appropriate rather than constant. The committee did not compare the different functional measures which are available and are not in a position to change what is uploaded to UK-ROC.
316	Sue Ryder	Guideline	012	002	1.2.15 This would be ideal. The guideline doesn't state whether this input needs to be carried out by specialist therapists or trained assistants, or a mixture. This increase in daily intensity will be very	Thank you for your comment. The clinical review included a subgroup analysis to investigate the effect of different professionals providing the care. This analysis did not

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					difficult to provide without additional resources. If a non-specialist therapist is providing the treatment then the person with stroke (PwStroke) should be regularly reviewed by a specialist to enable progression and prevent complications arising.	resolve heterogeneity when present. Therefore, we are unable to comment as to whether this influences care or not. The economic modelling incorporated a 3:1 ratio of Band 6 physiotherapists to Band 3 rehabilitation assistants.
317	Sue Ryder	Guideline	029	011	1.14.4 also consider using an orthotic such as Omo Neurexa plus by Ottobock in a managing post stroke shoulder pain with a flaccid upper limb.	Thank you for your comment. We did not identify evidence for these orthotics during the review in this area so are not able to recommend them.
318	Sue Ryder	Guideline	032	025	1.16.5 Suitable Return to Work programmes vary from region to region and may not be available.	Thank you for your comment. We understand that there is current variation in access and hope that the recommendation will be a stimulus for improvement.
319	Sue Ryder	Guideline	036	009	1. This research needs to also consider the level of expertise of the member of staff carrying out the treatment (i.e specialist therapist, therapist or assistant) between a 5 day and 7 day service.	Thank you for your comment. The research suggestion includes measurement of cost-effectiveness and will therefore take account of different staff grades.
320	Sue Ryder	Guideline	042	014	I agree with this, however, this will require large additional resources.	Thank you for your comment.

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321	Sue Ryder	Guideline	044	004	The guideline discusses hospital rehabilitation in a stroke unit, early supported discharge and community rehabilitation. It does not discuss levels of inpatient rehabilitation such as Level 1 and Level 2 rehab. It would be useful to discuss criteria for admission to these units (and also staffing levels) as we currently rely on BSRM guidelines. For example, should the PwStroke be able to tolerate the recommendation of 1 to 2 hours of physio and 45 minutes each of OT and SALT for 5 days per week prior to admission to a Level 1 or 2 unit?	Thank you for your comment. Criteria for admission to Level 1 or 2 rehabilitation Units was not part of the scope for this update and detailed recommendations cannot be made. However, the committee have noted that access should be available in recommendations 1.1.1 and 1.1.2

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*