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Issue 95 – June 2016

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- Chronic disease in people with severe mental illness: reducing excess mortality
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- Mechanical thrombectomy for large vessel occlusion stroke

**NICE** Evidence search  
Health and Social Care

busy professionals can keep up to date.

### Eyes on Evidence: end of service

The way in which NICE supports awareness of new evidence is changing. **From July 2016, NICE will no longer be providing the Eyes on Evidence awareness service.** This article explains the other routes by which

To search for selected and authoritative evidence in health, social care and public health, please go to [NICE Evidence search](#). Evidence search brings together high quality evidence from hundreds of trusted sources – including NICE, the Cochrane Library and Public Health England – and selected new systematic reviews from PubMed. The service does not require a login or subscription.

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- [Evidence summaries: new medicines](#)

Summaries of the best available evidence for selected new medicines, or for existing medicines with new indications, to inform local NHS planning and decision-making.

- [Medicines evidence commentaries](#)

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## Perioperative anticoagulation for people with atrial fibrillation

### Overview:

- A randomised controlled trial in the USA and Canada studied people with atrial fibrillation who stopped taking warfarin before elective surgery or an invasive procedure.
- People who did not receive 'bridging' heparin had a lower risk of bleeding and no higher risk of thromboembolism than those who did receive heparin.
- This study is applicable to people with atrial fibrillation in the UK, although the dose of bridging heparin used was around twice that used in the UK.



**Background:** People with atrial fibrillation are at increased risk of developing blood clots that can block blood flow to a tissue (thromboembolism) such as the brain ([Benjamin et al. 1998](#)). Many people with atrial fibrillation regularly take anticoagulation drugs, such as warfarin, to reduce this risk of blood clots and stroke.

Surgery and invasive procedures are associated with a risk of bleeding, which may be increased by anticoagulation therapy in people with atrial fibrillation ([Gallego et al. 2012](#)). Warfarin is typically stopped several days before a procedure in people with atrial fibrillation and resumed afterwards ([Baron et al. 2013](#)). However, stopping anticoagulation therapy may temporarily increase the risk of thromboembolism, although the size of the risk is not known.

During the interruption of warfarin treatment, 'bridging' anticoagulation therapy, such as with low-

molecular-weight heparin, can be used to minimise the time that people with atrial fibrillation do not have anticoagulation. However, the efficacy of this approach is unknown, and it may be associated with a higher risk of bleeding and adverse events ([Steinberg et al. 2015](#)).

**Current advice:** The NICE guideline on [atrial fibrillation](#) recommends assessing the risk of stroke using the CHA<sub>2</sub>DS<sub>2</sub>-VASc score in people with:

- symptomatic or asymptomatic paroxysmal, persistent or permanent atrial fibrillation
- atrial flutter
- a continuing risk of arrhythmia recurrence after cardioversion back to sinus rhythm.

Anticoagulation should be offered to men with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 1, and men or women with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 2 or more. The risk of bleeding should be taken into account.

The recommended options for anticoagulation are [apixaban](#), [dabigatran etexilate](#), [rivaroxaban](#) or a vitamin K antagonist. The options for anticoagulation should be discussed with the person, and the choice of drug based on their clinical features and preferences.

The NICE pathway on [atrial fibrillation](#) brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

**New evidence:** [Douketis et al. \(2015\)](#) investigated whether using bridging anticoagulation therapy was necessary in people with atrial fibrillation who were undergoing an operation or other invasive procedure.

This randomised controlled trial enrolled adults with atrial fibrillation or flutter from 108 sites in the USA and Canada. Participants had to have been receiving warfarin therapy for at least 3 months and be scheduled to undergo an elective operation or invasive procedure that merited stopping warfarin therapy.

A total of 1884 people were assigned to bridging anticoagulation therapy with low-molecular-weight heparin (dalteparin sodium; n=934), or a matching placebo (n=950). Participants stopped warfarin 5 days before their procedure. They then received the assigned study drug at 3 days before the procedure until approximately 24 hours before the procedure, and for 5–10 days after the procedure.

At 30 days, the incidence of arterial thromboembolism (such as stroke or transient ischaemic attack) was 0.4% (4/918 participants) in the no bridging group and 0.3% (3/895 participants) in the bridging group (mean between-group difference=0.1 percentage points, 95% confidence interval [CI] -0.6 to 0.8 percentage points). The event rates indicated that in terms of thromboembolism risk, not using bridging anticoagulation was not inferior to using bridging anticoagulation (p=0.01 for non-inferiority).

Major bleeding occurred in 1.3% (12 participants) of the no bridging group and 3.2% (29 participants) of the bridging group. The risk of major bleeding was significantly lower in the no bridging group than in the bridging group (relative risk=0.41, 95% CI 0.20 to 0.78, p=0.005).

Limitations of this study include that the majority of participants (73.4%) were men and most were at low risk of stroke (mean CHADS<sub>2</sub> score=2.3), so the findings may not be generalisable to women or higher risk populations. In addition, the sample size was smaller than planned because of lower than expected rates of thromboembolism.

**Commentary by Prof Beverley Hunt, Professor of Thrombosis & Haemostasis at Kings College London and Consultant at Guy's & St Thomas' NHS Foundation Trust:**

“Warfarin has been the mainstay of oral anticoagulation for people with atrial fibrillation at risk of ischaemic stroke for the last 60 years. Management is not easy, however, because of warfarin's slow onset and offset of action and unpredictable pharmacokinetics. Due to the long period of time

taken for the anticoagulation effect of warfarin to diminish, it is normal practice to stop warfarin 5 days before an operation in people with atrial fibrillation. To mitigate the perceived risk of the person having an arterial thromboembolic event while warfarin levels are falling, it has been normal practice to offer 'bridging' anticoagulation therapy with a short acting low-molecular-weight heparin such as dalteparin sodium, enoxaparin, or tinzaparin sodium.

"This study is the first to look at the utility of bridging anticoagulation therapy in people on long-term warfarin for atrial fibrillation. It found that there was no increased risk of arterial thromboembolism without heparin bridging, a very important finding with enormous practical implications. Moreover, from the safety perspective there was also a statistically lower rate of major and minor bleeding in those who did not receive heparin bridging.

"However, the doses of heparin used in this US-based study were based on weight and were considerably greater than those used in the UK, where bridging is usually a fixed dose. So for example, a 70 kg man in this study would have received 7,000 IU dalteparin twice daily. In the UK, he would have received 5,000 IU once daily. Therefore the dose would have been more than double the UK dose, so the increased bleeding rate seen in this study cannot be applied to UK-based practice.

"There is an international drive to improve the care of people on warfarin that has paradoxically coincided with the emergence of more efficacious and safer alternatives, such as the direct oral anticoagulants [apixaban](#), [dabigatran etexilate](#), [rivaroxaban](#) and [edoxaban](#). These drugs are being used increasingly in preference to warfarin for the prevention of stroke in atrial fibrillation. Managing bridging anticoagulation in people receiving direct oral anticoagulants is much easier, because of their short onset and offset of action. Therefore this study has no applicability to patients with atrial fibrillation on direct oral anticoagulants."

**Study sponsorship:** US National Heart, Lung, and Blood Institute.

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## Nurse-led titration of drug doses in chronic heart failure

### Overview:

- In people with heart failure, nurse-led titration of doses of beta-blockers, angiotensin-converting-enzyme inhibitors and angiotensin-II-receptor antagonists was associated with lower rates of hospital admission than titration by doctors.
- Nurse-led titration of these drugs was also associated with lower all-cause mortality.
- This Cochrane review highlights the value of nurse-led titration, but more robust studies are required to examine safety and cost effectiveness before this strategy can be recommended over usual care.

**Background:** Heart failure due to left ventricular systolic dysfunction (also known as heart failure with reduced ejection fraction) can be treated with beta-blockers or angiotensin-converting-enzyme (ACE) inhibitors, with angiotensin-II-receptor antagonists (ARBs) a second-line option ([NICE 2010](#)).



These drugs have a dose-dependent effect, so the dose a person receives should be titrated up to an optimal level. However, there can be some reluctance in primary care doctors to increase doses ([Philips et al. 2004](#)). An alternative approach is titration of doses by nurses, which has been shown to improve outcomes in people with heart failure ([Jain et al. 2005](#)).

**Current advice:** The NICE guideline on [chronic heart failure in adults](#) (currently [being updated](#)) recommends offering both ACE inhibitors and beta-blockers licensed for heart failure to all people with heart failure due to left ventricular systolic dysfunction. Clinical judgement should be used when deciding which drug to start first.

Therapy with ACE inhibitors should be started at a low dose and titrated upwards at short intervals (for example, every 2 weeks) until the optimal tolerated or target dose is achieved. Beta-blockers should be introduced in a 'start low, go slow' manner.

An ARB licensed for heart failure may be considered as an alternative to an ACE inhibitor for people who have intolerable side effects or who remain symptomatic despite optimal therapy with an ACE inhibitor and a beta-blocker.

The NICE pathway on [chronic heart failure](#) brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

**New evidence:** A Cochrane review by [Driscoll et al. \(2015\)](#) compared nurse-led titration of drug doses with titration by doctors in people with heart failure.

The review identified 7 randomised controlled trials on titration of beta-blockers, ACE inhibitors and ARBs in 1684 adults with chronic heart failure due to left ventricular systolic dysfunction. Nurse-led titration took place in an outpatient clinic in 4 studies; the remaining 3 studies considered nurse-led titration in primary care, via telephone follow-up and in a residential care facility. Follow-up ranged from 6 months to 18 months.

In a pooled meta-analysis of 4 studies (3 on beta-blockers and 1 on beta-blockers and ACE inhibitors, n=560), nurse-led titration was associated with a lower risk of hospital admission for any cause than titration by a doctor (risk ratio [RR]=0.80, 95% confidence interval [CI] 0.72 to 0.88, p=0.00022).

Nurse-led titration was also associated with a lower rate of hospital admission related to heart failure (RR=0.51, 95% CI 0.36 to 0.72, p=0.00012; 2 studies on beta-blockers and 2 on beta-blockers and ACE inhibitors, n=642).

Meta-analysis of 6 studies (n=902) showed that people who received nurse-led titration were less likely to die from any cause than those who had titration by a doctor (RR=0.66, 95% CI 0.48 to 0.92, p=0.015). The authors estimated that approximately 56 deaths could be avoided in every 1000 people if everyone with heart failure had nurse-led titration of their drug doses.

Limitations of this analysis include that all the studies could not blind participants and study personnel to group allocation. In addition, only 2 studies reported on adverse effects of titration (1 of which reported no adverse events and the other reported an adverse event in the nurse-led titration group but did not specify type or severity).

**Commentary by Dr Clare J Taylor, General Practitioner and NIHR Academic Clinical Lecturer, University of Oxford:**

“The benefits of ACE inhibitors, beta-blockers and ARBs in people who have heart failure with reduced ejection fraction have been known for many years. Guidelines globally advocate the use of these drugs, but the effect of the type of healthcare professional managing the up-titration has not been described.

“This Cochrane review assessed the effect of nurse-led titration, compared with titration by a doctor (usual care), on the outcome of people who had heart failure with reduced ejection fraction. The review found that all-cause mortality and hospitalisations were lower in the nurse-led titration group. However, data on the number of participants who achieved target dose and on the frequency of adverse events are lacking, or from low quality evidence. This is a major weakness of the review and limits the applicability of the findings.

“Randomised controlled trials assessing the effectiveness of ACE inhibitors, beta-blockers and ARBs have reported large positive effects on hospitalisation and survival rates. Yet in clinical practice, people with heart failure often receive substantially less than the target dose.

“Doctors may be reluctant to up-titrate for two reasons. Firstly, people with heart failure may have several chronic diseases, and doctors may choose not to initiate or up-titrate drugs that may exacerbate other conditions. For example, heart failure and chronic kidney disease often coexist. Initiating or increasing the dose of an ACE inhibitor in a person with these 2 conditions can, usually temporarily, worsen renal function. Secondly, the participants in the clinical trials supporting the use of these drugs were significantly younger than the real-world patient population and with few or no comorbidities. This disparity means some doctors feel the evidence from the trial populations may not be applicable to the people they manage.

“Nurse-led clinics are already an integral part of many heart failure services within the NHS. The clinics tend to focus solely on heart failure treatment and aim to achieve the target dose required to optimise benefit, according to a disease-specific protocol. Initiation and up-titration of several drugs is resource intensive, and nurse-led clinics have more capacity to see people frequently to optimise treatment.

“This Cochrane review highlights the value of nurse-led titration, but more robust studies are required to examine safety and cost effectiveness before this strategy can be recommended over usual care.”

**Study sponsorship:** National Health and Medical Research Council, Australia and Cochrane Heart Group.

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## Basic versus advanced life support for medical emergencies

### Overview:

- A US study found that in people taken to hospital for major trauma or stroke, basic life support from paramedics was associated with better short- and long-term survival than advanced life support.
- The effects of basic life support versus advanced life support were less clear for people with respiratory failure or acute myocardial infarction.



**Background:** Basic life support refers to providing initial airway, breathing and circulation support to a person experiencing out-of-hospital cardiac arrest ([Resuscitation Council \[UK\] 2015](#)). An automated external defibrillator (AED) may also be used, but no other equipment aside from a protective barrier device. This support can be provided by a bystander or a paramedic.

Advanced life support is emergency care that involves drugs or invasive procedures, such as tracheal intubation, after basic life support has started and when appropriate an AED has been used ([Resuscitation Council \[UK\] 2015](#)). This care is delivered by paramedics at the site of the emergency and on the way to hospital.

Whether advanced life support is associated with better outcomes than basic life support is unclear ([Jayaraman et al. 2014](#)). Evidence suggests that advanced life support improves survival in patients with myocardial infarction, and basic life support is more appropriate for people with trauma ([Ryynänen et al. 2010](#)).

**Current advice:** The Resuscitation Council (UK) has produced guidance on [adult basic life support and automated external defibrillation](#) and on [adult advanced life support \(NICE accredited\)](#).

The guidance on adult basic life support for people who experience out-of-hospital cardiac arrest emphasises calling for an ambulance immediately, starting cardiopulmonary resuscitation (CPR) and using an AED.

The guidance on adult advanced life support recommends defibrillation for people who have cardiac arrest and shockable rhythms (ventricular fibrillation or pulseless ventricular tachycardia). People with non-shockable rhythms (asystole or pulseless electrical activity) should receive CPR. The guidance also recommends a number of invasive and pharmaceutical interventions, such as tracheal intubation and administration of adrenaline.

The NICE guideline on [major trauma](#) recommends drug-assisted rapid sequence induction of anaesthesia and intubation as the definitive method of securing the airway in patients with major trauma who cannot maintain their airway and/or ventilation. This should be performed as soon as possible and within 45 minutes of the initial call to the emergency services, preferably at the scene of the incident.

The NICE guideline also has recommendations on management of chest trauma, haemorrhage and pain in pre-hospital settings.

**New evidence:** A retrospective cohort study by [Sanghavi et al. \(2015\)](#) compared survival rates between people who received basic life support and those who received advanced life support.

The authors analysed data from a random sample of 20% of people in the US Medicare programme (a

health insurance scheme for people over 65 years and those with disabilities) who lived in non-rural areas.

The study cohort comprised people who had received basic or advanced life support from paramedics for trauma, acute myocardial infarction, stroke or respiratory failure. Mortality data were taken from Medicare records. Data were analysed using propensity score matching (to account for observed patient, hospital and geographic differences) and instrumental variable analyses (to account for variation in whether advanced life support was available).

In propensity score analyses, the proportion of people with trauma (n=79,687), stroke (n=119,989) or respiratory failure (n=82,530) who were still alive at hospital discharge, 30 days, 90 days, 1 year and 2 years was higher with basic life support than with advanced life support. For example, among people taken to hospital with trauma, 82.3% of people who had basic life support were still alive at 90 days after hospital discharge compared with 76.2% who had advanced life support (difference=6.1 percentage points, 95% confidence interval [CI] 5.4 to 6.8 percentage points)

The association between basic life support and higher survival persisted in instrumental variable analyses of people with trauma or stroke but not in those with respiratory failure, where advanced life support was associated with better survival at 1 and 2 years.

In people with acute myocardial infarction, advanced life support was associated with better survival rates than basic life support in propensity score analyses. This changed in instrumental variable analyses, where basic life support was associated with better survival rates.

Limitations of this study include that the data did not capture people who died before they reached hospital. The study groups may have differed in unobserved characteristics such as illness severity or the quality of hospital care, causing residual confounding. In addition, the results are specific to the US healthcare system, so may not be applicable to other countries (for example, those where advanced life support is provided by doctors rather than paramedics).

**Commentary by Dr Bob Winter, National Clinical Director for Critical Care and Emergency Preparedness, Resilience and Response, NHS England:**

“This study by Sanghavi et al. (2015) found that basic life support was associated with better survival than advanced life support for people with trauma or stroke. One possible explanation for the observed results could be the diagnoses where a difference was observed. Major trauma and stroke are 2 conditions where definitive care can be delivered only in a hospital setting. The fact that basic life support seemed superior in people with these 2 diagnoses raises the possibility that patients benefited from the more rapid transport to hospital by providers of basic life support.

“Pre-hospital advanced life support interventions may have added more value in people with respiratory failure or myocardial infarction. Although people with these conditions may not have experienced a clear cut survival advantage from advanced life support, they did not show a disadvantage. It is possible that those patients designated as being appropriate for advanced life support were more severely ill, although the authors attempted to control for this with propensity matching.

“The recently published NICE guideline on major trauma recommends drug-assisted rapid sequence induction of anaesthesia and intubation in people with major trauma. This approach initially appears to be inconsistent with the results of this study, which found that advanced life support, which often includes intubation, was associated with lower survival than basic life support in people with trauma. On the other hand, it is possible that drug-assisted intubation has different outcomes to advanced life support without the provision of anaesthesia. The results for cardiac arrest are consistent with other studies of advanced life support versus basic life support.

“This study has some limitations because it is a retrospective analysis based on insurance data

that may not accurately reflect physical diagnoses. Some patients who were in the advanced life support cohort may not have actually received advanced life support, but would have been designated as such if advanced life support was considered necessary at the point of ambulance dispatch.

"In addition, these data were from the Medicare insurance programme, which covers people over 65 years and those with disabilities, so the findings may not be generalisable to the whole population. The study was conducted in the USA, so the results may not be generalisable to other healthcare systems, where paramedics have different skill sets and in some cases do not offer advanced life support."

**Study sponsorship:** National Science Foundation, Agency for Healthcare Research and Quality, and National Institutes of Health.

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## Ultrasound during pregnancy to identify small-for-gestational-age infants

### Overview:

- A study of UK data found that ultrasound screening of all women was almost 3 times better at identifying small-for-gestational-age infants than screening only when clinically indicated.
- Among infants identified as small-for-gestational-age on screening, those who also had slow abdominal circumference growth velocity were at significantly higher risk of poor outcomes.

**Background:** Infants are classified as small for gestational age (SGA) if they have a birth weight less than the 10th percentile ([Royal College of Obstetricians and Gynaecologists 2013](#)). Many of these infants will simply be constitutionally small, but a subset will have fetal growth restriction. Fetal growth restriction is associated with a number of adverse outcomes, such as stillbirth ([Pilliod et al. 2012](#)) and cerebral palsy ([McIntyre et al. 2013](#)).

Ultrasound scanning can be used in late pregnancy to estimate the weight of the fetus and whether it is growing as expected. A recent Cochrane review concluded that routine late-pregnancy ultrasound in low-risk or unselected populations does not benefit mother or baby ([Bricker et al. 2015](#)).

**Current advice:** The NICE guideline on [antenatal care for uncomplicated pregnancies](#) recommends that fetal growth should be determined using symphysis–fundal height measured and recorded at each



antenatal appointment from 24 weeks. It advises that the evidence does not support the routine use of ultrasound scanning after 24 weeks of gestation, and therefore ultrasound should not be offered. Routine doppler ultrasound should not be used in low-risk pregnancies.

The NICE guideline on [diabetes in pregnancy](#) recommends offering pregnant women with diabetes ultrasound monitoring of fetal growth every 4 weeks from 28 to 36 weeks.

The NICE guideline on [hypertension in pregnancy](#) recommends that women with chronic hypertension and women at high risk of pre-eclampsia should undergo ultrasound assessment of fetal growth, and umbilical artery doppler velocimetry, between 28 and 30 weeks and between 32 and 34 weeks.

The NICE pathway on [antenatal care](#) brings together all related NICE guidance and associated products on the area in a set of interactive topic-based diagrams.

**New evidence:** A prospective cohort study by [Sovio et al. \(2015\)](#) compared the effectiveness of universal versus selected ultrasound screening during the third trimester of pregnancy for identifying SGA infants. The study also evaluated whether ultrasound indicators could be used to determine SGA infants at risk of adverse outcomes.

This study recruited 4512 (56%) pregnant women from 8028 nulliparous women with singleton pregnancies who attended a single hospital in Cambridge for their dating ultrasound scan.

All women underwent research ultrasound scans at 20 weeks, 28 weeks and 36 weeks (universal ultrasound). The scans had both routine elements (review of fetal anatomy and biometric measurements) and research elements (uterine and umbilical artery doppler flow velocimetry).

A subset of women (n=1666, 42%) were selected for additional clinically indicated ultrasound scans during their third trimester (selective ultrasound), as per routine clinical care.

Estimated fetal weight was calculated using universal and selective ultrasound scans. Infants were identified as at risk of being SGA if their estimated fetal weight was less than the 10th percentile. Infants were subsequently classified SGA at delivery if their birthweight was less than the 10th percentile for gestational age.

A total of 352 (9%) infants were classified as at risk of SGA on ultrasound and were SGA at delivery. Universal ultrasound identified 57% of SGA infants (sensitivity), whereas selective ultrasound correctly identified 20% of SGA infants (relative sensitivity=2.9, 95% confidence interval [CI] 2.4 to 3.5). Infants who were identified as at risk of SGA by ultrasound scan were at higher risk of neonatal morbidity than infants of normal size (relative risk=1.6, 95% CI 1.2 to 2.1, p=0.001).

Several indicators of fetal growth restriction were evaluated to assess whether universal ultrasound screening could predict poor outcomes in infants identified as at risk of SGA during pregnancy.

Of the 5 indicators, only abdominal circumference growth velocity was associated with neonatal morbidity in SGA infants. Infants who were classified as SGA on ultrasound screening and who fell in the lowest decile of abdominal circumference growth velocity were significantly more likely to experience neonatal morbidity (relative risk=17.6, 95% CI 9.2 to 34.0, p<0.0001) and severe adverse perinatal outcomes (39.8, 95% CI 3.6 to 436.6, p=0.007) than infants who were normal weight on screening.

**Commentary by Dr Marie Anne Ledingham, Consultant in Maternal and Fetal Medicine, The Queen Elizabeth Hospital Glasgow:**

“Current evidence on the use of routine ultrasound scanning in pregnancy to detect fetal growth restriction is controversial, with the [most recent Cochrane review](#) suggesting no benefit.

“However, the results of this new study by Sovio et al. (2015) suggest that universal ultrasound scanning at 20, 28 and 36 weeks’ gestation in nulliparous women performs better than clinically indicated ultrasound scanning in the detection of SGA infants (relative sensitivity=2.9, 95% CI 2.4 to 3.5). Universal ultrasound scanning may therefore improve the detection rate of SGA babies who are at risk of neonatal morbidity (such as metabolic acidosis or neonatal admission) and reduce the risk of these adverse outcomes.

“In infants identified by universal ultrasound as being SGA, those with the slowest abdominal circumference growth velocity had an almost 18 times increased risk of adverse outcomes and about a 40 times increased risk of severe morbidity. However, those infants in whom the growth velocity was normal had no increased risk. This finding may be extremely relevant in clinical practice because it may help clinicians determine which SGA infants are pathologically rather than constitutionally small and reduce intervention in the small but normal group.

“The limitations of this study include the fact that it was conducted in nulliparous women, therefore the findings cannot be extrapolated to determine the effectiveness in a multiparous group. The study also showed that universal screening was associated with a lower specificity (90%) than clinically indicated screening (98%) and a higher false positive rate (10% versus 2%). In clinical practice this would mean an increase in the number of women identified as having SGA infants who may then be potentially at increased risk of intervention. Approximately 30% of stillborn babies are SGA, and the use of universal screening would potentially identify more of these babies at risk of this complication in pregnancy. However, this study was underpowered to detect any benefit in terms of reduction in the number of stillbirths due to universal ultrasound screening.

“Routine universal screening by ultrasound scan at 20, 28 and 36 weeks may therefore improve detection rates of SGA infants. Use of abdominal circumference growth velocity may help identify a subgroup of infants who are at increased risk of adverse outcomes and allow targeted intervention directed only at those infants who are pathologically growth restricted.”

**Study sponsorship:** National Institute for Health Research, Medical Research Council, Sands and GE Healthcare.

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## Balance training to prevent injuries from falls in older people

### Overview:

- A 2-year group and individual training programme to improve balance (the Ossébo balance training programme) reduced the risk of falls that resulted in injury among women aged 75–85 years who lived in the community.
- More research is needed to establish if this specific training programme is of clinical benefit and cost effective.



**Background:** People aged 65 and older are at high risk of falling, with 30% of people older than 65 and 50% of people older than 80 falling at least once a year ([NICE 2013](#)). Falls are estimated to cost the NHS more than £2.3 billion per year.

Exercise programmes that emphasise balance training are effective at reducing falls among older people who live in the community ([Gillespie et al. 2012](#)). A meta-analysis suggested that such programmes also seem to prevent falls that result in injuries, including severe ones such as fractures ([El-Khoury et al. 2013](#)), but the quality of the evidence was not robust.

**Current advice:** The NICE guideline on [falls in older people](#) recommends that all older people who have fallen several times or are at increased risk of falling should be considered for an individualised multifactorial intervention.

A muscle-strengthening and balance programme should be offered as a specific component of the multifactorial intervention. This programme should be individually prescribed and monitored by an appropriately trained professional. Those most likely to benefit are older people living in the community with a history of recurrent falls and/or balance and gait deficit.

The NICE pathway on [falls in older people](#) brings together all related NICE guidance and associated products on the area in a set of interactive topic-based diagrams.

**New evidence:** [El-Khoury et al. \(2015\)](#) conducted a randomised controlled trial to assess whether a 2-year balance retraining programme reduced injurious falls among older women living in the community.

Voter registration lists were used to recruit women aged 75–85 who lived in the community in 16 cities in France. These women were invited by letter to attend a free balance and health examination. Women were eligible to participate in the study if they were assessed as having poor balance or gait.

A total of 4221 women attended the baseline balance and health examination (11% of those invited). Of these women, 1138 were eligible to participate in the study and 706 agreed to be randomised to the intervention group (n=352) or the control group (n=354).

The intervention comprised 2 years of free weekly supervised exercise sessions in small groups, supplemented by individually prescribed home exercises (the Ossébo balance training programme). The exercises were designed to improve muscle strength, muscle extensibility, postural stability, joint flexibility, balance, reaction time, coordination and spatial awareness. The intervention was delivered by a network of community-based instructors with moderate levels of training and expertise.

The primary outcome was the rate of injurious falls: both severe (such as those that caused fractures) and moderate (for example those that resulted in bruising or sprains).

Over the 2-year study, 397 injurious falls were reported in the control group (in 189 [53.4%] women), and 305 falls in the intervention group (in 170 [48.3%] women). The rate of injurious falls was 19% lower in the intervention group than in the control group (hazard ratio=0.81, 95% confidence interval 0.67 to 0.99, p=0.04).

Women in the intervention group were significantly better than those in the control group in a range of measures of balance and gait, such as time to walk 6 metres (p=0.005 at 2 years). When questioned about health-related quality of life, women in the intervention group reported significantly better physical function throughout the study (p=0.01 at 1 year and p=0.03 at 2 years) and better general health (p=0.04) and vitality at 1 year (p=0.01).

Limitations of this study include the low recruitment rate (11%) and the high dropout rates (16% in the

intervention group and 14% in the control group). In addition, participation in the intervention programme was rarely consistent, with most participants missing some sessions throughout the intervention.

**Commentary by Dr Alison Shepherd, Speciality Trainee in Geriatric Medicine and Dr Damien Reid, Consultant in Medicine for the Elderly, Hairmyres Hospital, NHS Lanarkshire:**

“This large multicentre study assessed the efficacy of a defined strength and balance training programme in reducing injurious falls in a subgroup of people aged 75–85 years in France. Participants were female, living at home, and assessed as being at moderate risk of injurious falls, ‘neither too fit nor too frail’. In the previous year, 42% of this 75–85 year old cohort had reported at least one fall, comparable to a figure of about 30% in the total population of over 65s living in the community ([Gillespie et al. 2012](#)). The authors specifically recruited women with low-to-moderate risk of falling to test the effects of their intervention on the general population of older people, rather than on people identified as at high risk of falls by their contact with medical services ([El-Khoury et al. 2015](#)).

“Given that reduction in injurious falls was the primary outcome measure in this study, it is surprising that neither the total number of previous falls, nor the number of injurious falls, was recorded before the intervention, even if this would have necessitated additional data collection. Randomisation was stratified for weight (<59kg and ≥59kg) and study centre, although not for history of falls. As a result, the control and intervention group weighed the same but had a different proportion of fallers: 45% and 39% respectively. This difference comprised 15.4% more people with a history of falls in the control group. The 19% difference in injurious falls between the two groups during the intervention period should be interpreted in this context.

“There was no economic assessment of this intervention, and in the absence of follow up data it is not possible to comment on any lasting benefit.

“Despite these caveats, this is a significant study proving the feasibility of delivering a long-term, progressive strength and balance programme requiring weekly attendance by participants and using normal facilities. It has greatly added to our knowledge of the practical challenges and barriers to providing a large scale, population-level, single intervention to reduce falls in a moderately at-risk older population. Healthcare professionals should continue to follow NICE advice to offer individualised muscle-strengthening and balance interventions to people at risk of falling.”

**Study sponsorship:** Assistance Publique-Hôpitaux de Paris, the French Ministry of Health, the French National Research Agency, the National Institute of Health Prevention and Education, and the Council of the Ile-de-France region.

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## Ongoing effects of child contact arrangements in cases of domestic abuse

### Overview:

- A qualitative study in Scotland found that children of women who had experienced domestic abuse were exposed to further parental domestic abuse and conflict through contact arrangements with their fathers after their parents had separated.
- The possibility of ongoing domestic abuse and its effects on children should be considered in assessments of child contact arrangements.

**Background:** Domestic violence and abuse is defined as any incident or pattern of incidents of controlling, coercive or threatening behaviour, violence or abuse between people aged 16 or over who are, or have been, intimate partners or family members regardless of gender or sexuality ([Home Office 2015](#)). This includes psychological, physical, sexual, financial and emotional abuse.

Children and young people who are exposed to domestic violence are at increased risk of experiencing emotional, physical and sexual abuse and of developing emotional and behavioural problems ([Holt et al. 2008](#)).

Parents who divorce or separate may need a court order (a 'child arrangements order') to agree where their children will live, when they will spend time with each parent and who will pay child maintenance ([Children and Families Act 2014](#)).

In cases where adults or children have experienced, or are at risk of experiencing, domestic abuse or violence, family courts must ensure that child arrangements orders protect the safety and wellbeing of the child and the parent with whom the child is living, and do not expose them to the risk of further harm ([Lord Chief Justice 2014](#)). In particular, the court must be satisfied that any contact ordered with a parent who has perpetrated violence or abuse is safe and in the best interests of the child.

**Current advice:** NICE guidance on [domestic violence and abuse](#) recommends that health and social care staff should be trained to recognise the indicators of domestic violence and abuse, and understand how it affects children and young people. Staff should also be trained and confident to discuss domestic violence and abuse with children and young people who are affected by or experiencing it directly.

Specialist domestic violence and abuse services for children and young people should address the emotional, psychological and physical harms arising from a child or young person being affected by domestic violence and abuse, as well as their safety.

The NICE pathway on [domestic violence and abuse](#) brings together all related NICE guidance and associated products on the area in a set of interactive topic-based diagrams.

**New evidence:** A qualitative study by [Morrison \(2015\)](#) interviewed women who had experienced domestic abuse and their children to assess the effects of child contact arrangements with their non-resident fathers after the relationship had ended.

Mothers who had experienced domestic abuse and their children were recruited from statutory and voluntary domestic abuse support services in Scotland. In-depth interviews were conducted with 16



mothers and 18 children (ages 8–14 years). At the time of interview, 13 of the 16 families had court-ordered child contact arrangements. The remaining 3 had contact that was arranged out of court.

Some mothers continued to experience physical violence when fathers picked up or returned children from contact visits. Other mothers reported emotional abuse and harassment linked to contact visits, such as the father shouting and swearing at them at contact handovers. These episodes of physical and mental abuse were routinely witnessed by the children, who described them negatively.

In terms of the contact visits themselves, both mothers and children described how fathers spoke negatively about and denigrated the mothers during contact visits. This experience was described as distressing by children.

Children were often exposed to ongoing conflicts during visits as a result of being used as messengers between parents. Messages from fathers to mothers included information about changes to future contact visits, information related to ongoing parental disputes (such as over finances) and threats.

Two mothers suspected that their children had been sexually abused by their fathers during contact visits. Three children described being physically abused during visits and the majority described emotional abuse.

Limitations of this study include that the study recruited only mothers who used domestic abuse services and who had spoken openly about their abuse. In addition, all the interviews were conducted and analysed by a single researcher.

**Commentary by Professor Jo Aldridge, Professor of Social Policy and Criminology, Department of Social Sciences, Loughborough University:**

“This is an important qualitative study that contributes new evidence and knowledge to current understanding about domestic violence and its impact on women and their children.

“A key message from the study is that current practices relating to contact arrangements between children and their fathers after parental separation often prioritise the need for contact over appropriate considerations of risks to children (and their mothers) of ongoing contact with abusive fathers. Evidence from the research points clearly to the fact that domestic abuse often continues after parental separation and may even escalate at the point of child contact with fathers.

“The author makes a number of important recommendations based on evidence from the study (some of which are also supported in findings from other research studies on domestic violence and child contact). One is that abusive fathers should be ‘held accountable’ for their abusive behaviour before contact arrangements are put in place. The author argues that consideration must also be given to the space and time needed for mothers and their children to recover from past abuse from former partners before decisions about child contact arrangements are made.

“Although this study makes an important contribution to the field of domestic violence and child contact arrangements, more research is needed on this important topic that includes larger samples of parents and children. However, in order to fully protect children from harm, or further harm, as a consequence of domestic violence, questions need to be asked about current practices in child contact arrangements and also decisions that are made about ‘the best interests of the child’.”

**Study sponsorship:** Economic Social Research Council and Scottish Women’s Aid.

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## Evidence summaries from NICE's Medicines and Prescribing Programme

**Medicines evidence commentaries** form part of NICE's [Medicines Awareness Service](#) and help contextualise important new evidence, highlighting areas that could signal a change in clinical practice. They do not constitute formal NICE guidance. These commentaries are published in NICE's [Medicines Awareness Weekly](#) service and are available online in [NICE Evidence search](#).

NICE has recently published the following Medicines evidence commentaries:

- [Chronic disease in people with severe mental illness: reducing excess mortality](#)

A meta-review of 16 systematic reviews looked at interventions to improve health and reduce mortality caused by chronic disease in people with severe mental illness.

- [Meniere's disease: betahistine not shown to be superior to placebo](#)

A randomised controlled trial compared the effects of low dose betahistine (24 mg twice daily), high dose betahistine (48 mg three times daily [an off-label dosage]) and placebo on vertigo in people with Meniere's disease.

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## Case study from the Quality and Productivity collection: Mechanical thrombectomy for large vessel occlusion stroke

Stroke is a serious and life-threatening medical condition that occurs when the blood supply to part of the brain is cut off.

Stroke is the second single most common cause of death in the world, causing 6.7 million deaths each year ([World Health Organization 2014](#)). Stroke affects 152,000 people annually in the UK; 1 person experiences a stroke every 3 minutes 27 seconds ([Townsend et al. 2012](#)). The burden of disease (disability, illness and premature deaths) caused by stroke is set to double worldwide by 2030 ([Feigin et al. 2014](#)).

A thrombotic stroke occurs when diseased or damaged cerebral arteries become blocked by the formation of a blood clot within the brain.

Mechanical thrombectomy is a specialised technique where a clot within a blood vessel in the brain is removed using a mechanical clot-retrieval device delivered via a catheter inserted through an artery in the person's groin. A thrombolytic agent may also be delivered to the site of the clot.

Mechanical thrombectomy is widely used in Europe and the USA, but is relatively new to the UK.

Mechanical thrombectomy is a better treatment for large vessel occlusion strokes in terms of safety and efficacy than intravenous thrombolytic drugs ([Dippel et al. 2014](#)).

In 2010, the University Hospitals of North Midlands NHS Trust set out to improve patient clinical outcomes by treating large vessel occlusive stroke with mechanical thrombectomy. By using this procedure, the trust

has significantly reduced mortality rates for this type of severe stroke.

Dr Sanjeev Nayak, Consultant Neuroradiologist at Royal Stoke University Hospital, said: “The University Hospitals of North Midlands NHS Trust has the largest patient population treated by mechanical thrombectomy in the UK. The trust now has one of the lowest mortality rates in the UK for severe strokes, reducing the mortality risk from 50% to 17%.

“There have also been significant cost-saving benefits to the NHS and social care providers from reduced hospital bed stay and reduced disability. There is no additional burden to the NHS because the majority of patients are admitted directly to the stroke unit after the procedure without the need for support in an intensive treatment unit.”

The procedure is paid for by commissioners. The trust has demonstrated the following annual savings:

- £0.8 million savings from a reduction in the length of stay in hospital
- £1.6 million savings from a reduction in social care costs

This case study complements new NICE interventional procedure guidance on [mechanical clot retrieval for treating acute ischaemic stroke](#) (February 2016).

The NICE Quality and Productivity collection provides users with practical case studies that address the quality and productivity challenge in health and social care. All examples submitted are evaluated by NICE to assess the degree to which the initiative meets the Quality and Productivity criteria: savings; quality; evidence; and implementability.

Visit the NICE website for more details of this case study on [mechanical thrombectomy for large vessel occlusion stroke](#) and other [Quality and Productivity case studies](#).

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