Issue 75 – August 2015

This month in Eyes on Evidence

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A study of cross-sectional and longitudinal European data found that young people with mild or moderate cerebral palsy mostly had similar quality of life to young people in the general population, but had less social support from friends and peers.

Fractional flow reserve to guide percutaneous coronary intervention in people with stable coronary artery disease
An international multicentre randomised controlled trial reported that people with stable coronary artery disease who had significant stenosis according to fractional flow reserve values had better outcomes with percutaneous coronary intervention plus medical therapy than with medical therapy alone.

Latanoprost for newly diagnosed open-angle glaucoma
A randomised controlled trial found that, in people with newly diagnosed open-angle glaucoma, latanoprost eye drops significantly increased the time to visual field deterioration within 24 months compared with placebo eye drops.

Childhood factors and inactivity in adulthood
A British cohort study found that a number of physical, social and behavioural factors in childhood – such as height, social status and conduct problems – were associated with low physical activity in adulthood.

‘Positive’ and ‘negative’ emotive content in tobacco control TV adverts
A UK study reported that ‘positive’ televised tobacco control adverts increased the rate of calls per month to the NHS Stop Smoking quitline in line with how often the adverts were aired, whereas ‘negative’ campaigns increased the rate of calls only once exposure exceeded a certain threshold.

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Quality of life in young people with cerebral palsy

Overview: Cerebral palsy encompasses a number of life-long neurological conditions that affect movement and coordination (NHS Choices 2014). The main symptoms of cerebral palsy are: muscle stiffness or floppiness; muscle weakness; random and uncontrolled body movements; and difficulties with balance and coordination.

Previous evidence suggests that children with cerebral palsy report similar quality of life (QoL) to children in the general population (Bjornson et al. 2008). However, the evidence on QoL among young people with cerebral palsy is inconsistent.

Current advice: The NICE guideline on spasticity in children and young people with non-progressive brain disorders recommends that the child or young person and their parents or carers should be offered contact details of patient organisations that can provide support, befriending, counselling, information and advocacy.

NICE is currently preparing a guideline on diagnosis and management of cerebral palsy (anticipated publication date October 2016).

The NICE pathway on spasticity in children and young people brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

New evidence: Colver et al. (2015) used data from the SPARCLE study to assess QoL in young people with cerebral palsy. The SPARCLE study recruited 818 children with cerebral palsy from population-based registers in 7 European countries, including the UK. Participants were interviewed at home aged 8–12 years (SPARCLE1) and aged 13–17 years (SPARCLE2). Participants self-reported their QoL, using the 10-domain KIDSCREEN questionnaire (scale 0–100 for each domain), and how frequently they experienced pain each week.

This analysis used cross-sectional data from 431 young people who were able to self-report their QoL at 13–17 years. Most participants had no or moderate motor limitations. A total of 355 of these young people

reported QoL at both 8–12 years and 13–17 years and were included in longitudinal analyses. Young people with cerebral palsy were compared with matched young people in the general population.

The cross-sectional analysis found that young people with cerebral palsy had no worse QoL than young people in the general population on 9 of the 10 domains assessed. QoL was worse among young people with cerebral palsy in terms of social support available from friends and peers (mean difference compared with the general population=–2.7, 95% confidence interval –4.3 to –1.4).

Pain was the main factor that affected QoL among young people with cerebral palsy. Impairment type and severity also had an impact on QoL; for example, seizures in the previous year were associated with reduced QoL for moods and emotions and impaired walking ability was associated with reduced autonomy.

In the longitudinal analyses, QoL decreased between childhood and adolescence for 5 of the 10 domains assessed, but the changes in mean score on each domain were small at less than 3 points. QoL in young people was affected by high parenting stress in childhood and childhood psychological difficulties.

Limitations of this analysis include that children and young people with severe learning difficulties who could not self-report were excluded. In addition, children with cerebral palsy and the general population controls were recruited differently, and around a third of children with cerebral palsy targeted for inclusion in the study did not take part.

Commentary by Mr Mathew David Sewell, Consultant Spine Deformity Surgeon, The James Cook University Hospital, South Tees Hospitals NHS Foundation Trust, Middlesbrough:

“QoL is defined by the World Health Organization (WHO) as ‘the individual’s perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns’. The WHO considers QoL and participation, the latter defined as involvement in life situations, as key outcome measures to assess following intervention for children with impairments.

“Data obtained through the SPARCLE studies suggest that participation is more affected in children with cerebral palsy than QoL. SPARCLE1 reported that children with cerebral palsy aged between 8–12 years had lower participation than children in the general population (Fauconnier et al. 2009). Those with more severe impairments had lower participation across most domains. The picture is quite different for QoL, which was less influenced by impairments and was broadly similar between children with cerebral palsy and the general population (Dickinson et al. 2007).

“The current study provides further evidence to suggest that young people with cerebral palsy have at least equivalent QoL to those in the general population, and that frequency of pain is the most significant factor associated with lower QoL. Child psychological difficulties and parenting stress were identified as modifiable risk factors associated with lower QoL. The only domain in which adolescents with cerebral palsy had lower QoL than the general population was in the domain of social support and peer relationships.

“The large sample size provides a compelling argument that these results are valid. However, the high non-response rate and exclusion of children not able to self-report (mostly the more severely affected children) represents a selection bias that limits the study’s validity and generalisability.

“As practising clinicians, we should ask young people with cerebral palsy about pain, psychological stressors and parenting stresses, as targeted intervention in these areas could improve QoL. Young people with cerebral palsy may need particular help developing and maintaining peer relationships. This could be through facilitating greater participation (for example, helping the young person attend school and therefore make friends). It should be remembered that all children and young people with cerebral palsy are different, and each requires individualised management plans that seek to maximise QoL and participation across all domains.”

Study sponsorship: SPARCLE1 was funded by the European Union Research Framework 5 Program, the German Ministry of Health, and the German Foundation for the Disabled Child. SPARCLE2 was funded by the Wellcome Trust (UK and Ireland); the Medical Faculty of the University of Lübeck (Germany); CNSA, INSERM, MiRe–DREES, and IRESP (France); Ludvig and Sara Elsass Foundation, The Spastics Society and Vanforefonden (Denmark); Cooperativa Sociale 'Gli Anni in Tasca' and Fondazione Carivit, Viterbo (Italy); Göteborg University—Riksforbundet for Rorelsehindrade Barn och Ungdomar and the Folke Bernadotte Foundation (Sweden).

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Fractional flow reserve to guide percutaneous coronary intervention in people with stable coronary artery disease

Overview: Coronary artery disease is caused by narrowing (stenosis) of the arteries that supply the heart muscle (NICE 2003). Stable coronary artery disease typically manifests as stable angina, which is characterised by chest pain occurring at predictable levels of exertion, emotion, or another stressor.

Science Source/ Science Photo Library

One possible treatment for coronary artery disease is percutaneous coronary intervention (PCI). In PCI, a small balloon is inflated in the affected artery to widen it (angioplasty), and a metal mesh tube called a stent may be put in place to hold the artery open (NHS Choices 2013). Whether PCI is beneficial in people with stable coronary artery disease is controversial, with some evidence suggesting that PCI is no better than medical therapy in these individuals (Pursnani et al. 2012).

Fractional flow reserve (FFR) is a physiological parameter that can be used to determine the extent to which stenosis narrows a coronary artery (NICE 2014). The FFR within the affected vessel is measured with a coronary pressure wire during angiography or PCI. An FFR value of 0.80 or less indicates that the stenosis has caused a drop in maximal blood flow of 20% or more and has the potential to cause myocardial ischaemia (that is, the stenosis is functionally significant).

PCI does not appear to be beneficial in people who have non-significant stenosis on the basis of FFR values (Pijls et al. 2007), but may improve outcomes in people with functionally significant stenosis (De Bruyne et al. 2012).

Current advice: The NICE guidance on management of stable angina recommends PCI for people with stable angina and suitable coronary anatomy whose symptoms are not satisfactorily controlled with optimal medical treatment and in whom coronary artery bypass graft surgery is not appropriate.

NICE has technology appraisal guidance on coronary artery stents for people with either stable or unstable angina or with acute myocardial infarction, and on drug-eluting stents for the treatment of coronary artery disease.

The NICE pathway on acute coronary syndromes brings together all related NICE guidance and associated products on the conditions in a set of interactive topic-based diagrams.

New evidence: De Bruyne et al. (2014) did an open-label randomised controlled trial of PCI plus medical therapy versus medical therapy alone in people with stable coronary artery disease and functionally

significant stenoses, as determined by FFR (the Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 [FAME 2] trial).

People with stable coronary artery disease who were suitable for PCI were recruited from 28 sites in Europe and North America. People who had at least 1 stenosis in a major coronary artery with an FFR of 0.80 or less were randomly assigned to PCI plus medical therapy or to medical therapy alone.

People in the PCI group received second-generation drug-eluting stents in all stenoses that had an FFR of 0.80 or less. All participants received daily aspirin, a beta-blocker (alone or in combination with a calcium-channel blocker, a long-acting nitrate or both), an angiotensin-converting-enzyme inhibitor or angiotensin-receptor blocker, and atorvastatin alone or in combination with ezetimibe (not licenced for coronary artery disease in the UK).

Between May 2010 and January 2012, 1220 people were enrolled to the study. A total of 888 had at least 1 stenosis with an FFR of 0.80 or less and were randomly assigned to undergo PCI plus medical therapy (n=447) or to receive medical therapy alone (n=441). The primary end point was a composite of death from any cause, non-fatal myocardial infarction, or urgent revascularisation within 2 years.

At 2 years, significantly fewer people in the PCI group than in the medical therapy group experienced at least 1 primary outcome event (8.1% versus 19.5%; hazard ratio=0.39, 95% confidence interval [CI] 0.26 to 0.57, p<0.001). The difference between the groups was largely because fewer people needed urgent revascularisation in the PCI group compared with the medical therapy group (4.0% versus 16.3%; hazard ratio=0.23, 95% CI 0.14 to 0.38, p<0.001). The groups did not differ significantly in their rates of death or myocardial infarction.

The authors concluded that PCI plus medical therapy is more effective than medical therapy alone in people with stable coronary artery disease who FFR has identified as having functional ischaemia. Limitations of this study include that recruitment was stopped early because of a highly significant between-group difference in the primary outcome. In addition, the participants had stenoses in large coronary arteries with a mean FFR of 0.64, indicating profound and extensive ischaemia. The findings may not therefore be generalisable to people with lesser stenosis.

Commentary by Dr Darlington Obi Okonko, Consultant Cardiologist, King's College Hospital NHS Foundation Trust, London:

“Current US and European cardiac society guidelines support the use of FFR measurements to guide revascularisation decisions in people with stable coronary artery disease. This approach is particularly important when the degree of stenosis is intermediate, when evidence of ischaemia is lacking, and when symptoms or stenosis severity on angiography are not in line with previous ischaemia testing. PCI confers risks to treated people, costs time and money, and does not improve survival compared with optimal medical therapy, so objective metrics such as FFR are welcomed as means of preventing unnecessary procedures.

“To this end, the FAME investigators have conducted 2 trials assessing the impact of FFR-guided PCI on outcomes. In the current report of FAME-2 by De Bruyne et al. (2014), use of FFR to guide PCI reduced the primary composite end point by 77% relative to medical therapy, with the results driven by reductions in urgent revascularisation.

“Although these results might improve the current uptake of FFR in the UK, enthusiasm should be tempered by a methodological flaw in the trial. FAME-2 was an open-label study, and the lack of appropriate blinding, preferably with a sham intervention group, minimises its clinical value.

"Given that they were aware of their study arm allocation, people in the medical therapy alone arm of FAME-2 might have been more anxious and therefore more likely to present with angina, triggering urgent revascularisation. Additionally, doctors might have been more likely to diagnose unstable angina in people who they knew had significant coronary stenoses.

“Urgent revascularisation and, to a lesser extent, myocardial infarction are ‘soft’ end points that are

suboptimal for testing a procedure that can add risk, time and cost to routine catheter lab work. Sham-controlled FFR trials are needed to fully justify widespread use of this exciting measure."

Study sponsorship: St Jude Medical.

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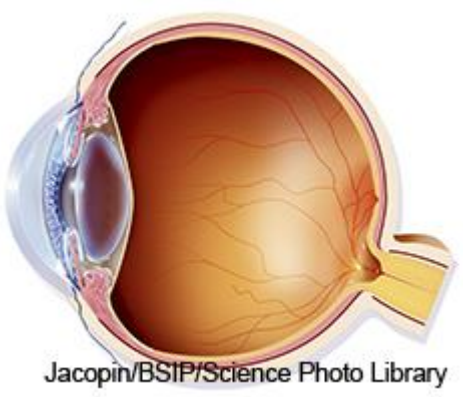
Latanoprost for newly diagnosed open-angle glaucoma



Overview: Chronic open-angle glaucoma (COAG) is a common and potentially blinding condition (NHS Choices 2013). Many people will be unaware there is a problem with their eyes until severe visual damage has occurred.

Approximately 6% of registrations for blindness in England and Wales are attributed to glaucoma (Liew et al. 2014). An estimated 1.2% of people aged 40 years or older have COAG, rising to 4.3% in white Europeans aged 80 years or older (Tuck and Crick 1998). The prevalence may be higher in people of African and Caribbean family origin or who have a family history of glaucoma.

Ocular hypertension is a major risk factor for COAG, although the disease can occur with or without raised eye pressure. Until recently there have been no placebo-controlled trials looking at preserving vision with drugs that reduce intraocular pressure.

Current advice: The NICE guideline on diagnosis and management of chronic open angle glaucoma recommends that a prostaglandin analogue is offered to people newly diagnosed with early or moderate COAG and who are at risk of significant visual loss in their lifetime.

If intraocular pressure has not been reduced sufficiently to prevent the risk of progression to sight loss despite pharmacological treatment, and if adherence and eye drop instillation technique are satisfactory, the NICE guidance recommends offering another prostaglandin analogue, a beta-blocker, a carbonic anhydrase inhibitor or a sympathomimetic (more than 1 agent may be needed).

Other options in this case include laser trabeculoplasty or surgery with pharmacological augmentation (with mitomycin C or 5-fluorouracil) as indicated, which should also be considered after trying 2 alternative pharmacological treatments. If intolerance to a medication occurs, an alternative pharmacological treatment or a preservative-free preparation (if there is evidence that the person is allergic to the preservative) should be considered.

The NICE pathway on glaucoma brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

New evidence: Garway-Heath et al. (2015) report the findings of the United Kingdom Glaucoma Treatment Study (UKGTS), a randomised controlled trial of whether latanoprost, a prostaglandin analogue, preserved the visual field in people with newly diagnosed, previously untreated COAG.

The study randomised 516 people from 10 centres in the UK to either latanoprost 0.005% eye drops or latanoprost vehicle eye drops (placebo) once daily into both eyes. Treatment allocation was concealed. People were excluded if they had advanced glaucoma, mean baseline intraocular pressure of 30 mmHg

or higher, or impaired vision (Snellen visual acuity worse than 6/12), or if their retina could not be imaged clearly.

The primary outcome was time to visual field deterioration within 24 months (time from baseline to the fourth test of visual field that confirmed deterioration). The primary outcome was initially proportion of participants with visual field deterioration, but this was changed after an interim analysis to time to deterioration and the trial was stopped early.

The mean age of participants was around 65 years; 47% were female and 53% male. At baseline, the 2 groups were mostly similar. However, arteriosclerosis (stroke, angina and claudication) was twice as common in the latanoprost group (10%) than the placebo group (5%), and mean intraocular pressure was slightly higher in the placebo group (20.1 mmHg) than the latanoprost group (19.6 mmHg). Baseline mean central corneal thickness was 541 mm, and mean visual field measurement, in terms of standard automated perimetry mean deviation, was –1.5 dB.

Primary outcome data were available for 461 people, and 94 (20%) of these had visual field deterioration that was considered to be consistent with progression of glaucoma (15.2%, 95% confidence interval [CI] 10.8 to 20.4% of the latanoprost group compared with 25.6%, 95% CI 20.1 to 31.8% of the placebo group, p=0.006). Time to first visual field deterioration during 24 months (the primary end point) was significantly longer in the latanoprost group than the placebo group (adjusted hazard ratio [HR]=0.44, 95% CI 0.28 to 0.69, p=0.003). Significant differences in time to deterioration were also seen at both 12 months and 18 months. The mean reduction in intraocular pressure was 3.8 mmHg in the latanoprost group and 0.9 mmHg in the placebo group. Equal numbers of serious adverse reactions were reported (9 in each group).

A strength of this study is that participants had not received previous glaucoma treatments, which might influence the results. A limitation is that around half of participants had incomplete follow-up for various reasons. In addition, participants in UKGTS were predominantly white (about 90%) and people with advanced COAG were excluded, which might reduce generalisability of the findings.

The authors concluded that this was the first placebo-controlled trial to show preservation of the visual field with an intraocular-pressure lowering drug in people with COAG.

Commentary by Professor John Sparrow, Consultant Ophthalmologist and Honorary Professor of Ophthalmic Health Services Research and Applied Epidemiology, University of Bristol:

“This UKGTS report in the *Lancet* finally provides good evidence in support of prostaglandin analogue monotherapy for COAG. Latanoprost is widely prescribed internationally for the treatment of open-angle glaucoma. However, the efficacy of this drug, and others in its class, has to date been based on comparative studies focusing mostly on proxy outcomes, such as a reduction in intraocular pressure and assessment of optic disc damage.

“This study confirms the widely held assumption that lowering eye pressure with latanoprost translates into reduced damage to the visual field, as measured by standard automated perimetry. Publication of this direct evidence is reassuring in view of the NICE recommendation to use a prostaglandin analogue drug as first-line treatment for COAG.

“In addition to delivering a clinically important result, Garway-Heath and colleagues have shown that new therapies for visual field protection in glaucoma can be tested on time scales much shorter than previously considered feasible. Their multicentre large sample approach, combined with clustering of visual field testing and meticulous field and statistical analysis, shows that visual field differences are detectable within a period as short as a year. Such methodological refinements have the potential to redirect glaucoma research from assessment of proxy measures to direct measurement of what matters to patients: their ability to see. Longer term studies will, however, still be needed to confirm whether these benefits persist beyond 2 years.”

Study sponsorship: This study was funded by Pfizer, with supplementary funding from the National Institute for Health Research and the University College London Institute of Ophthalmology.

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Childhood factors and inactivity in adulthood

Overview: In Europe, 35% of people are not physically active, with 63% of men and women in the UK classed as inactive (Hallal et al. 2012). Various factors in early life, such as family income and maternal education, can affect whether a child is subsequently inactive as a young person (Hallal et al. 2006). Childhood factors may also influence whether a person is physically inactive in adulthood.

Current advice: Guidance from the Chief Medical Office recommends that children and young people (5–18 years) should engage in moderate to vigorous intensity physical activity for at least 60 minutes and up to several hours every day. The guidance adds that adults should do at least 150 minutes (2.5 hours) of moderate intensity activity in bouts of 10 minutes or more – for example, 30 minutes of activity on at least 5 days a week.

The NICE guideline on promoting physical activity for children and young people recommends providing local indoor and outdoor opportunities for physical activity where children and young people feel safe. Physical activity facilities should be suitable for children and young people with different needs and their families, particularly those from lower socioeconomic groups, those from minority ethnic groups with specific cultural requirements, and those who have a disability.

The NICE pathway on physical activity brings together all related NICE guidance and associated products on the area in a set of interactive topic-based diagrams.

New evidence: A cohort study by Pinto Pereira et al. (2014) investigated whether childhood factors influenced physical inactivity in adults. The study used data from the 1958 Birth Cohort Study, an ongoing British longitudinal study that recruited 17,638 people born in a single week in 1958.

This analysis comprised 12,776 cohort members who had at least 1 measurement of physical inactivity at ages 33, 42 or 50 years. Inactivity was defined as taking part in physical activity less than once a week. Childhood factors were measured prospectively at birth and at 7, 11 and 16 years. These early-life factors were split into 3 domains: physical (such as birth weight); social (such as household amenities); and behavioural (such as sports aptitude).

Approximately a third of adults were inactive at each time point. In analyses adjusted for all childhood factors and a number of adulthood factors (such as education and BMI), 3 of the 12 physical childhood factors studied were associated with inactivity at 1 or more age in adulthood. Height at 7 years was negatively associated with inactivity at 42 years (odds ratio [OR]=0.94, 95% confidence interval [CI] 0.90 to 0.99) and 50 years (OR=0.94, 95% CI 0.89 to 0.99). Coordination and hand control problems were associated with inactivity at 50 years (OR=1.09, 95% CI 1.01 to 1.18). Cognitive ability at 16 years was negatively associated with inactivity at 42 years (OR=0.94, 95% CI 0.88 to 0.99).

Of the 8 social factors considered, low parental social status at birth (OR=1.07, 95% CI 1.01 to 1.13), parental divorce (OR=1.19, 95% CI 1.04 to 1.35) and institutional care (OR=1.30, 95% CI 1.07 to 1.59) were associated with inactivity at 50 years.

Among the 9 behavioural factors assessed, low physical activity at 16 years was associated with inactivity at all 3 adult time points (33 years: OR=1.15, 95% CI 1.09 to 1.21; 42 years: OR=1.16, 95% CI 1.11 to 1.21; and 50 years: OR=1.09, 95% CI 1.04 to 1.14). A number of behavioural factors measured at 16 years were associated with inactivity at 33 years, 42 years or both: average or below average sports aptitude; smoking; externalising behaviour, such as conduct problems; and poor social ability.

Limitations of this analysis include that physical activity in adulthood was self-reported and did not include occupational activity, only leisure activity. Childhood factors were measured using a mix of approaches, such as parental reports and self-report, so could be subject to bias. The study was observational, so other factors not accounted for in the adjusted analyses could have affected the results.

Commentary by Dr Andy Pringle, Reader in Physical Activity, Exercise and Health, Institute of Sport, Physical Activity and Leisure, Leeds Beckett University:

“Pinto Pereira and colleagues identify a number of early life factors that are associated with physical inactivity at different stages of adulthood. Their findings endorse the importance of efforts to reduce physical inactivity in children, but also highlight that factors other than childhood inactivity, such as parental divorce, need to be considered.

“For instance, the NICE guideline on behaviour change recommends assessing and understanding the needs of individuals when planning interventions and programmes to change health-related behaviour. The key factors identified by Pinto Pereira could be used alongside other determinants of physical activity to contribute to a comprehensive needs assessment in children. This is not only important in shaping the design of interventions, but also in making the case for a physical activity intervention.

“The aspiration of promoting a physically active lifestyle with children and young people is to have ‘one eye to the future’. Considering the factors that could impact on inactivity (and morbidity) in adulthood could be valuable in supporting these processes. Pinto Pereira and colleagues make the case that their research adds support for investment in ‘early life’ interventions. Their findings also suggest the existence of groups for whom action may be required, so that the risk of leisure time physical inactivity in adulthood is reduced.

“The strengths of this research include the large overall sample, long-term follow-up, use of repeat and identical measurements, and organisation of lifestyle factors into theoretically underpinned domains. These strengths should be set alongside the study’s limitations, such as the use of self-reported physical activity and the combination of methods and measures used to assess early life factors. Further research is needed to investigate the programming of adult health behaviours during childhood.”

Study sponsorship: Department of Health Policy Research Programme.

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'Positive' and 'negative' emotive content in tobacco control TV adverts

Overview: Telephone-based smoking cessation services, or quitlines, provide encouragement and support over the telephone to smokers who want to quit, or who have recently quit. The free NHS Smokefree National Helpline, for example, provides trained, expert advice to people in England who wish to stop smoking.

Tobacco control TV adverts have been shown to increase calls to smoking cessation quitlines (Farrelly et al. 2013). The emotive content of televised campaigns – whether 'positive' (eliciting happiness, satisfaction or hope), 'negative' (eliciting fear, guilt or disgust) or 'neutral' – may also affect whether people call a quitline. Both 'positive' campaigns, such as adverts that deal practically with how to quit (Mosebaek et al. 2007), and 'negative' adverts, such as those with graphic images (Nonnemaker et al. 2013), appear to increase quitline calls.

Current advice: The NICE guideline on smoking cessation services recommends both telephone counselling and mass-media campaigns, such as TV advertising, as effective interventions to help people stop smoking.

Local, regional and national communications campaigns should, among other things, use 'why to' and 'how to' quit messages that are non-judgemental, empathetic and respectful. For example, testimonials from people who smoke or used to smoke can work well.

The NICE pathway on smoking prevention and cessation brings together all related NICE guidance and associated products on the area in a set of interactive topic-based diagrams.

New evidence: Richardson et al. (2014) investigated how the emotive content of tobacco control TV adverts affected number of calls to the English NHS Stop Smoking quitline.

Government-funded tobacco control adverts that aired on TV in England between April 2005 and April 2010 were divided into 3 mutually exclusive categories: 'positive'; 'negative'; or 'neutral'. Exposure to the adverts per head of population was quantified in gross ratings points (GRPs), an advertising industry measure of campaign reach. Data on number of calls to the NHS Stop Smoking quitline were obtained from the UK Department of Health.

Of the total 18,618.9 GRPs reported over the whole study period, 8238.8 GRPs (44.2%) were designed to elicit 'negative' emotions, 9589.9 (51.5%) were designed to elicit 'positive' emotions, and 790.2 GRPs (4.2%) were 'neutral'. The NHS Stop Smoking quitline received a total of 1,227,189 calls during the 5-year study period, with a monthly average of 20,118 calls (range 8,034 to 66,091 calls).

The rate of calls per month increased by 58% when exposure to 'positive' adverts increased from 0 to 400 GRPs (rate ratio [RR]=1.58, 95% confidence interval [CI] 1.25 to 2.01). The rate of calls more than quadrupled when exposure to 'positive' adverts increased from 0 to 600 GRPs (RR=4.57, 95% CI 3.47 to 6.02). The authors suggest that these results indicate a dose-response relationship for 'positive' adverts, whereby monthly call rates increased considerably more at higher levels of exposure.

'Negative' adverts had no significant effect on monthly call rates up to an exposure of 400 GRPs (RR=1.03, 95% CI 0.94 to 1.14). An increase from 0 to 600 GRPs was associated with a 60.4% increase in the rate of calls to the quitline (RR=1.60, 95% CI 1.37 to 1.88).

This study was limited by the fact that full recordings were not available for around half of adverts, so the authors could not measure the detailed content of the adverts or how many adverts featured the quitline number. In addition, data were not available on time and channel of broadcast of the adverts, or on the content of calls to the quitline. The study could not account for individuals' actual exposure to adverts, which would have varied according to the person's frequency, channel and time of TV viewing.

Commentary by Louise Ross, Stop Smoking Service Manager, Leicester City Council:

"The issue of 'positive' versus 'negative' smoking cessation campaigns is often debated among practitioners. This exploration of the different effects of 'positive' and 'negative' campaigns opens up a number of key lines of enquiry, and will stimulate further debate. Both approaches are likely to resonate, but potentially with different groups, and it is possible that psychology of smokers has changed over time.

"In terms of 'negative' approaches, one single 'negative' campaign that is referred to repeatedly by members of the public is the Fatty Artery advertisement run by the British Heart Foundation. It is astonishing to think that, having captured the imaginations of so many back in 2004, this advert is still recalled more than 10 years later. Conversely, other 'negative' images were found to be both repellent and lacking in credibility.

"One area that Richardson et al. (2014) could not provide information on is what happened after the initial call to the quitline. What percentage of contacts resulted in actual attendance at a clinic, and a successful quit? 'Spur of the moment' calls to the service can result in 'did not attend' outcomes, so discovering the elements of campaigns that result in sustained attendance for treatment would be valuable.

"It is disappointing that Richardson et al. (2014) could not provide any analysis of the specific content of the adverts. For example, the inclusion of personal stories in smoking cessation materials can be very valuable. Credible, 'people like us', truthful stories have, in our experience, helped inspire and motivate others to take that first step – picking up the phone and getting good quality support to stop smoking."

Study sponsorship: Medical Research Council's National Prevention Research Initiative and ASH UK.

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Evidence summaries from NICE's Medicines and Prescribing Programme

NICE has recently published the following Evidence summaries: new medicines:

Type 2 diabetes: insulin degludec/liraglutide (Xultophy)
Insulin degludec/liraglutide (Xultophy) is the first fixed-ratio combination basal insulin and glucagon-like peptide-1 (GLP-1) receptor agonist preparation to be licensed in the UK. This evidence summary outlines 2 phase III studies that compared insulin degludec/liraglutide with insulin degludec alone or liraglutide alone in adults with type 2 diabetes.

Type 2 diabetes: dulaglutide
Dulaglutide (Trulicity, Eli Lilly and Company) is a GLP-1 receptor agonist. This evidence summary discusses 3 phase III randomised controlled trials of dulaglutide compared with placebo, exenatide, sitagliptin or liraglutide in people with type 2 diabetes.

Ulcerative colitis: budesonide multimatrix (Cortiment)
Budesonide multimatrix (MMX, Cortiment) is a corticosteroid that is taken orally but exerts its action topically in the colon. This evidence summary reviews 2 randomised, placebo and active-controlled phase III trials that compared budesonide MMX with placebo in adults with mild-to-moderate ulcerative colitis.

Evidence summaries: new medicines form part of NICE's service to provide high quality medicines and prescribing information to the NHS and patients in England. The summaries are aimed at commissioners, budget holders and groups such as Area Prescribing Committees to help them make informed decisions and aid local planning on the introduction of key new medicines. Evidence summaries: new medicines do

not constitute formal NICE guidance but are designed to support the managed introduction of selected new medicines or new indications for existing medicines not covered by NICE's Technology Appraisal programme.

NICE has also recently published the following Medicines evidence commentaries:

Acute coronary syndrome: ezetimibe added to simvastatin (IMPROVE-IT study)
This evidence commentary discusses a large, multicentre randomised controlled trial that evaluated the effects of ezetimibe plus simvastatin versus simvastatin alone on cardiovascular events in people with acute coronary syndrome.

Gastrointestinal bleeding: differences among anticoagulants
This evidence commentary reviews two American observational studies that assessed the risk of gastrointestinal bleeding in people prescribed the anticoagulants dabigatran, rivaroxaban or warfarin.

Cardiovascular disease: risk of diabetes and statin treatment
This evidence commentary outlines a Finnish observational study that examined whether there was a link between use of statins and new-onset diabetes.

Risk of suicide, attempted suicide or self-harm with antidepressants This evidence commentary reviews a UK cohort study that assessed the associations between different antidepressants and the rates of suicide and attempted suicide or self-harm in people with depression.

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