

## Preventing postextubation airway complications in adults

Corticosteroids should be given only to patients at high risk of reintubation



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To receive artificial ventilation for acute respiratory failure adult patients usually have an endotracheal tube placed through the mouth and larynx into the upper trachea. Although initially life saving, the endotracheal tube causes mechanical irritation of the larynx and trachea, which in turn may cause inflammation and oedema. Infected oral secretions pooling in the larynx above the cuff of the endotracheal tube will exacerbate the inflammation. While present the endotracheal tube acts as a stent, but when it is removed these processes may narrow the upper airway, leading to symptoms and signs of upper airway obstruction and at worst the need for reintubation. In the linked meta-analysis, Fan and colleagues assess whether steroids are effective in preventing postextubation laryngeal oedema and reducing the need for subsequent reintubation of the trachea in critically ill adults.<sup>1</sup>

The scale of the problem is difficult to assess, because estimates of the incidence of signs or symptoms of upper airway obstruction after extubation vary from 2.3% in unselected ventilated patients<sup>2</sup> to 22% in those ventilated for more than 36 hours,<sup>3</sup> and estimates of reintubation rates vary from 1% of all patients<sup>2</sup> to 19% of patients with evidence of laryngeal oedema before extubation.<sup>4</sup> However, even if the risk in the general population in intensive care is small, the problem remains clinically important, as reintubation distresses patients, stresses staff, and carries a risk of increased mortality independent of the patient's severity of illness.<sup>5</sup>

In an attempt to reduce the risk of reintubation, corticosteroids are sometimes prescribed to reduce upper airway oedema before extubation. The use of corticosteroids in this context is certainly plausible. Postmortem studies have found oedema, inflammatory changes, and neutrophil infiltrates caused by endotracheal intubation, and these effects have been shown to be reduced by corticosteroids in experimental studies.<sup>6</sup> In vivo corticosteroids also produce a time dependent and dose related reduction in airway oedema (as assessed by the size of the leak of ventilator gas around the endotracheal tube during inspiration when the sealing cuff is deflated<sup>4</sup>). However, whether reducing laryngeal oedema with corticosteroids causes an overall benefit to the patient remains contentious.

A recent systematic review based on five clinical trials and 1873 patients concluded that corticosteroids did not significantly alter reintubation rates in adults and so their use was not recommended.<sup>7</sup> Fan and colleagues' review includes an additional

80 patients from another study and comes to a very different conclusion, suggesting that corticosteroids markedly reduce reintubation rates (odds ratio 0.29, 95% confidence interval 0.15 to 0.58).<sup>1</sup> The difference in results comes from a combination of the new data, and a careful selection of the "most appropriate" data from the five other studies. Where possible, Fan and colleagues included only patients who needed reintubation for laryngeal oedema and excluded those who were reintubated for other reasons, who would not respond to corticosteroids and who would dilute any effect. This selection allowed them to use a less conservative (fixed effects) model than that used in the previous review.<sup>7</sup>

However, the authors note the possibility of publication bias and that most of the studies did not report an intention to treat analysis, both of which can lead to an overestimation of treatment effects. Because corticosteroids are potent drugs with a range of side effects, and even brief courses are harmful in critically unwell patients with head injuries (probably by mechanisms unrelated to the head injury),<sup>8</sup> a closer examination of the balance between risks and benefits is warranted before acting on their conclusion that multiple dose steroids reduce reintubation rates.

Given these concerns and the difference in the results of the two meta-analyses, it may be prudent to give steroids only to patients at high risk of reintubation, a view reinforced by Fan and colleagues' analysis of this subgroup. Although factors identified as increasing the risk of reintubation include female sex,<sup>2,3</sup> short stature, admission after trauma,<sup>3</sup> and (in some studies) prolonged intubation,<sup>2</sup> arguably the most useful way to assess the risk of reintubation is to measure the leak around the deflated endotracheal tube cuff; a value of 18% or less of tidal volume or an absolute value of 110 ml per breath carry the best predictive power for the occurrence of laryngeal oedema.<sup>4</sup>

More sophisticated studies are needed to determine whether steroids usefully alter a patient's overall course after extubation. These should probably only enrol patients at high risk; use multiple dose regimens given sufficiently early before extubation to have an effect; and be analysed on an intention to treat basis using patient centred and institution centred outcomes, such as duration of artificial ventilation, length of stay in the intensive care unit or hospital, and mortality. These trials need to be large to produce a reliable estimate of effect and to detect infrequent but serious complications of steroids.

A major practical barrier exists to undertaking this research and to using corticosteroids clinically to reduce reintubation rates. To pretreat patients with corticosteroids assumes extubation is a predictable event,<sup>9</sup> or that the intensive care unit has sufficient capacity to delay extubation for 12-24 hours after a successful trial of spontaneous breathing while the corticosteroids take effect. Neither assumption may be the case for most intubated patients in intensive care.

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## Eating behaviour and obesity

Eating fast and until full trebles the risk



In the linked study, Maruyama and colleagues show a significant positive association between two eating behaviours (eating until full and eating quickly) and overweight in a large sample of Japanese adults.<sup>1</sup> The study builds on evidence that eating behaviours are important in promoting positive energy balance (taking in more energy than is expended) and may contribute to the current epidemic of obesity. The drive to overconsume energy when it is available is probably an evolutionary imperative; however, until the last decade or so most adults did not have the opportunity to take in enough energy to enable fat to be stored.

The ideal situation—whereby our eating behaviours are controlled by biological regulatory systems that tightly regulate appetite and consumption and keep our weight in check—is being challenged. We do not know what drives us to eat quickly or to eat until we are full. Have these drivers changed in parallel with the obesity epidemic and are they modifiable? It may be that the changing sociology of food consumption, with fewer families eating together, more people eating while distracted (for example, while watching television), and people eating “fast food” while on the go all promote eating quickly. Furthermore, the increased availability of relatively inexpensive food, which is more energy dense and served in substantially larger portions, may promote eating beyond satiety. Maruyama and colleagues show that the combination of these two factors—eating quickly and eating until full—are additive (odds ratio for being overweight and having both eating behaviours compared with having neither 3.13 (95% confidence interval 2.20 to 4.45) for men and 3.21 (2.41 to 4.29) for women).

Experimental studies show that humans are relatively ineffective at regulating energy intake.<sup>2</sup> For example we rely on visual cues (such as the amount of food that has been removed from a plate) more than the internal cues of fullness<sup>3</sup>; the volume of food eaten is not modified in

response to increased energy density; food consumption increases with variety offered; and the volume eaten is predicted by volume served.

The effect of the changing food environment on children in particular is likely to be challenging for the future health of the population. As with adults, there is little evidence of short term energy regulation in the face of changing environmental stimuli,<sup>4</sup> and the capacity for regulation seems to decrease as children age.<sup>5</sup> A study of preschool children found that the strongest correlate of the amount of food consumed at a meal was the amount served, and that the amount consumed was not influenced by energy consumed as snacks between meals.

Furthermore, a study in preschool children reported that 85% of parents encouraged children to eat more than they may have wanted, and that the same proportion then did, with 38% eating substantially more.<sup>6</sup> It seems likely that any early capacity for energy regulation may be over-ridden by parental pressure to eat more.<sup>7</sup>

Clinicians should recognise that behavioural counselling, using cognitive therapy, can help in the management of this aggressively “eat more” food environment. Evidence suggests that adults can successfully modify their speed of eating and in turn their energy intake.<sup>8,9</sup> Furthermore, adults are likely to be responsive to monitoring feedback regarding feelings of fullness. Helping patients to increase their daily physical activity will further reduce energy imbalance.

Given the fundamental importance of preventing overweight, clinicians need to engage with parents. Evidence shows that parents can be supported to make effective changes to their children’s eating habits,<sup>10</sup> and that young children can be taught to recognise internal cues and alter consumption accordingly.<sup>11</sup> Clinicians should encourage parents to adopt a child led feeding strategy that acknowledges a child’s desire to stop eating that begins from birth. Reassure parents that well children don’t starve. Furthermore, because children find it

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difficult to regulate their energy intake, it is important to inform parents of the environmental stimuli that promote positive energy balance such as serving excessively large meals.

Discussion about replacing energy dense snack foods and drinks with core foods and water, appropriate serving sizes and body weight, what comprises a healthy diet, eating in non-distracting environments, eating together with an adult, and role modelling with slow and relaxed eating is likely to be useful.

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## Preventing diabetes in Bangladeshi people in Britain

Education is the key to empowerment and being able to resist cultural norms

In the linked qualitative study, Grace and colleagues assess lay beliefs and attitudes, religious teachings, and professional perceptions in relation to the primary prevention of diabetes in socioeconomically deprived British Bangladeshis.<sup>1</sup>

Lifestyle changes, in the form of regular exercise and dietary modifications, can prevent 58% of type 2 diabetes in people at high risk.<sup>2</sup> South Asians in Europe—people from Pakistan, India, Bangladesh, and Sri Lanka—have a four to six times greater risk of developing type 2 diabetes than white Europeans. They also get the disease about 10 years earlier and have higher rates of cardiovascular complications, renal complications, and death. People from Bangladesh are the worst affected,<sup>3</sup> so prevention in this group is a public health priority.

Several characteristics of the socioeconomically deprived migrant south Asian community in Europe have been reported, including being a hard group to reach<sup>4</sup>; being "fatalistic"; and often blaming their diabetes on migration, stresses, and factors other than diet.<sup>5,6</sup> They see a cure for their diabetes as possible if they went back to their own warm country<sup>7</sup> and being overweight as a marker of prosperity and good health.<sup>5,7</sup> Satisfaction with bigger body sizes has been associated with economic marginalisation and black ethnicity.<sup>8,9</sup>

Educationally underprivileged south Asians have expressed many barriers to exercising. They do not consider the western concept of exercise to be part of their tradition and do not recognise that physical activity can prevent ill health.<sup>10</sup> Women are uncomfortable about exercising in public and prioritise family and cultural obligations over exercise.<sup>10,11</sup> Men work long antisocial hours with little time left for exercise.<sup>11</sup> Prayers—"namaz" (a ritual recitation offered in sequential different standing and sitting positions usually for five to 20 minutes, five times a day) is erroneously viewed as physical activity. Poor language ability and sports facilities that were inappropriate in terms of sex and culture were other reported

barriers.<sup>10,11</sup> A need to receive culturally specific advice on activity from doctors was identified.<sup>10</sup> These barriers illustrate the need for systematic solutions targeted at the behaviours of daily living in this community.

The study by Grace and colleagues could make a substantial contribution to health equity and public health for several reasons.<sup>1</sup> The methodology is culturally and contextually adapted to enhance the depth of inquiry and validity. Barriers to a healthy lifestyle expressed as personal cultural inhibitions or apprehensions by lay participants were proposed to religious leaders (Imams) as "vignettes." The use of photographs of active and inactive figures and Bangladeshi and western meals provided precision in a community where exercise meant different things to different people and the type and quantity of ingredients in foods could vary by 50-200% between and even within households.

What are the key messages for health professionals, patients, and policy makers? Religious leaders saw fatalism as a misrepresentation of Islamic teachings. They emphasised the resonance between Islamic teachings and healthy lifestyles, and delineated that a healthy lifestyle—eating fruit and vegetables, controlling portion sizes, looking after your body, and taking physical activity—was crucial to health. The central role of personal lifestyle choices, including diet, excess body weight, and physical inactivity, in the development of diabetes was recognised by religious leaders and lay people. Contrary to taboos expressed by community members, jogging in public places was not disapproved of by religious leaders, who approved of conventional outdoor exercise including walking. Religious leaders were seen as trusted sources of information. They had access to large sections of the community and were keen to incorporate discussion of ways to prevent diabetes into their teaching. Their inclusion in public health interventions is vital.

Support of healthy behaviours by religious leaders is extremely important in a community with strong



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religious and family values. Such support is crucial for changes in daily living behaviours to occur, especially in women. In conjunction with health education and English literacy this could act as an important driver for social and health change.

The participants did not lack knowledge, but a complex value hierarchy existed wherein religious, social, and cultural norms and familial obligations were chosen over exercise and healthy eating.

Advice on physical activity could include information about jogging or exercising at home, with or without videos. In my experience (with health promotion activities in India), most Asian women like classical or folk dance and they could be encouraged to take up this activity at home using tape recorded music or at local women's dance groups. The possibility of selected swimming pools or gyms providing one to two hour slots dedicated to women and children could be explored. Loose fitting cotton salwars could be permitted instead of gym wear.

The study also found that all lay participants viewed education as a powerful force of change and route to independence for women. There was recognition that education could lead to liberal interpretation of religious teachings and ability to resist cultural norms.<sup>1</sup> This powerful message on the community's keenness to become empowered through education is a compelling call to policy makers and public health

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## Enabling women to breast feed

Is a challenge for the health professions



Breast feeding improves infant and maternal health and cognitive development in both developed and developing countries, and it is the single most important preventive approach for saving children's lives.<sup>1,2</sup> Yet most infants in developed countries are formula fed within the first three months of birth, either exclusively or partially,<sup>3</sup> and in many developing countries exclusive breast feeding (no additional fluids, cereal, or other foods) is rare. The hazards of formula feeding have been highlighted by recent reports of deliberate chemical contamination of formula in China, which has resulted in thousands of seriously ill infants as well as infant deaths ([www.bmj.com/cgi/content/full/337/oct01\\_1/a1890](http://www.bmj.com/cgi/content/full/337/oct01_1/a1890)); but in the Western world there have been many more episodes of bacterial contamination, for example with *Salmonella* species. In the United Kingdom, the women most likely to formula feed are young, white, and from low socioeconomic backgrounds. This poses a major public health and inequalities challenge.

Despite national and international policy initiatives, neither the duration of breast feeding nor the exclusivity of breast feeding up to six months of age have improved in the UK; 40% of women who start to breast feed discontinue by the time their baby is 6 weeks old, and only 20% of infants are exclusively breast fed at six weeks. The reasons women give for discontinuation are consistent over time and internationally; they think that they do not have enough milk, breast feeding is painful, and they

have problems getting the baby to feed.<sup>4</sup> These distressing problems could mostly be prevented.

Comparative international data show that rates of breast feeding are related to sociocultural factors and support rather than to clinical problems. In Norway, where the incidence of breast feeding fell in the early 20th century—as it did in many developed countries—mother to mother support and policy interventions resulted in it returning to over 90% within 25 years.<sup>5</sup> Other countries, including Canada and Australia, have introduced changes in policy and practice with positive results in recent years.

These problems were the subject of a symposium at the annual conference of the Royal College of Paediatrics and Child Health (RCPCH). A compelling account of one woman's struggle to breast feed, which was only resolved when she finally met a midwife who understood positioning and attachment, provoked several paediatricians in the audience to admit that they did not know the basic skill of helping mothers to position the baby so that feeding was effective and pain free. This supported recent evidence that health professionals, especially doctors, are not adequately trained in breast feeding and that changes are needed in professional education.<sup>6</sup> Evidence also exists for the fundamental role of support for women, the need to avoid harmful interventions such as restricting the frequency and duration of feeding, and the important role of the United

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Nations (International) Children's (Emergency) Fund (Unicef) baby friendly initiative.<sup>7-9</sup>

Recent studies on the extent and range of weight loss in the first 10 days of life illuminate the contribution of weighing to avoiding potentially serious dehydration and confirm that this can be achieved without increasing maternal anxiety.<sup>10</sup> The growth trajectory of healthy breastfed babies differs from that of formula fed infants, and this sometimes worries mothers if not explained. Charts based on the growth of healthy breastfed infants have now been developed, although training will be needed for them to be used effectively. Staff also need to be well informed about topics and controversies that, if not sensibly managed, can lead to anxiety and even discontinuation of breast feeding; for example, the role of ankyloglossia (tongue tie) as a cause of breastfeeding problems,<sup>11</sup> and the management of the infant suspected of having breast milk associated jaundice.<sup>12</sup>

For breast feeding to become the norm in developed countries, real and sustained changes are needed in policy, practice, and education. Implementation of the baby friendly initiative in hospital and community settings has been recommended by the National Institute for Health and Clinical Excellence.<sup>9</sup> Accreditation in this initiative covers the core problems of training staff, supporting mothers, removing inappropriate interventions, defining strategy, coordinating change, and mainstreaming improved practice. These measures increase the rates of initiating breast feeding, the rates of exclusive breast feeding up to six months, and the duration of breast feeding, even in women in low income groups. However, the proportion of NHS trusts with such accreditation in England is much lower than in other UK countries, which poses a challenge for the relevant health professionals and managers.

Changes in the provision of health services are unlikely to succeed without changes in society that would enable women to breast feed in public, to have their employment protected when breast feeding, and to be protected from misleading advertising regarding formula

milk. Children also need to be taught that breast feeding is the norm. A national strategy to tackle the large scale changes is needed. Such changes are advocated by the national breastfeeding manifesto, which is supported by the relevant royal colleges and voluntary groups.

Doctors, midwives, and health visitors should support such changes but need not wait until they are in place. Women and infants need their doctors to advocate breast feeding, to learn the basic skills, to revise protocols for weight monitoring to ensure that breast feeding is protected, and to support their colleagues who are working to promote and protect breast feeding. Helping women to breast feed will avoid discontinuation and distress and encourage other women to breast feed. It's not rocket science, but the effect on health outcomes will be profound and long lasting.

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## Fresh thinking about the Declaration of Helsinki

A comprehensive approach to ethical research

The Declaration of Helsinki is the cornerstone of research ethics.<sup>1</sup> Its periodic revision provides an opportunity for debate about its purpose and effectiveness.<sup>2</sup> The sixth revision, being considered by the World Medical Association (WMA; [www.wma.net/e/ethicsunit/helsinki.htm](http://www.wma.net/e/ethicsunit/helsinki.htm)) this autumn, follows extensive consultation.<sup>1,2</sup> However, debate about the operational details often loses sight of the objectives and principles.<sup>2</sup> Much has changed in the nature of research and bioethical thinking since the declaration was conceived.<sup>1-3</sup> Public confidence in research is at an all time low, and the current model and traditional ethical tools seem to be failing to meet their objectives. It is time for fresh thinking.

The declaration's objectives were framed, in response

to past abuses, to protect human subjects in research.<sup>2</sup> However, the framework put in place to protect subjects has been criticised as paternalistic and for failing to address the full scope of ethically responsible research.<sup>1</sup>

We propose an alternative comprehensive framework in which basic ethical principles collectively inform, support, and direct all aspects of research—from the design of the research agenda and research questions, through the process of evaluation and execution, to the dissemination of results and distribution of benefits. This would broaden the scope of ethical research beyond that of the behaviour of the individual investigator to include the full range of stakeholders.

A robust approach to ethical research requires a

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rethinking of the concepts of autonomy, justice, vulnerability, and benefit. The conflicting values and duties inherent in research—for example, the duties to the individual versus society in the distribution of potential risks and benefits—also need to be dealt with.<sup>4</sup>

Historically, ethics dealt with how we treat other individuals and prioritised respect for autonomy (people's right to make their own decisions about their lives)<sup>5</sup> in a way that has not served us well.<sup>3</sup> Autonomy is intimately linked to health outcomes and is best understood in relation to factors in society that shape identity and moral agency (the capacity to make choices).<sup>3,4</sup>

Injustice derives from inequalities in power structures, resources, and knowledge, which are particularly acute in resource poor countries. Moving to a model in which the subjects of research are seen as partners would reduce these inequalities. Such a model would do more to increase autonomy<sup>1,3,6,7</sup> and justice than an approach based merely on protection. Similar considerations apply to population groups, where inequalities can be reduced by engaging and empowering their members<sup>1,6,7</sup> in participatory research, as shown in social science and community health research.<sup>4</sup>

Vulnerability should be considered as a state—resulting from these inequalities—and should not simply be identified with special groups such as prisoners, pregnant women, or children.<sup>8,9</sup> The overprotection and subsequent exclusion of such groups offend justice, limit generalisability, and perpetuate inequality.<sup>1</sup>

Although research is primarily directed towards individuals it has much wider implications for society. A system based solely on preventing harm (“negative” ethical obligations)<sup>2</sup>—in the context of exploiters and victims, and researchers versus ethics committees—is ill equipped to deal with the broader (“positive”) obligation to benefit society.<sup>3,6</sup>

The declaration must be reinterpreted in the social, cultural, political, and economic contexts in which research occurs.<sup>1,2</sup> Considered “dead,”<sup>10,11</sup> the declaration's life was further threatened when the United States Food and Drug Administration removed the requirement for trials conducted outside of the USA to comply with it. Because the declaration sets international standards for research ethics it must reflect differences in local capacity for ethical oversight,<sup>1</sup> and cultural values attached to the meaning of research, uncertainty, and the individual.

With this background, can we expect dramatic advances in the objectives and philosophical considerations of the declaration after the consultation? The WMA has started to tackle several of these themes. Justice is addressed by strengthening the definition of vulnerability,<sup>9</sup> by emphasising equity in access based on inclusion rather than exclusion, and by tackling barriers to access.

Transparency is addressed by requiring clinical trials to be registered and stipulating that people have the right to information about the research they are involved in.<sup>2</sup> The vision and scope of the declaration has expanded to include methodologies such as observational studies; however, the underlying principles should cover the whole reach of research on humans. To do less violates

justice. It is now recognised that ethical obligations extend to communities and populations who may be either the direct object of research or affected by it.

To create a culture of ethical responsibility, the declaration needs to speak to all stakeholders, not just researchers. Although WMA represents doctors, dental and nursing organisations participated in the consultation, and other researchers are now “invited” to adopt the document. The declaration must be a moral compass for the whole research agenda and be binding on all people. It should have the capacity to shape research at all levels.

Despite progress, controversies continue. The two related controversial articles (29 and 30)<sup>2</sup> are likely to remain, even if they are restructured. Article 29 recognises that researchers have a responsibility that extends beyond the duration of a study, including individuals' and communities' rights to access any benefits. Arguments about whose responsibility this is and the availability of resources do not diminish its importance. Article 30 is more controversial because it is perpetually misframed in terms of arguments about the ethical and scientific correctness of placebos rather than the principle that individuals should not knowingly be deprived of beneficial interventions.

Regulations are not an appropriate primary response to problems that are social in origin.<sup>4,12</sup> Rather than being based on moral reasoning, ethical codes have largely been devised to shape policy.<sup>7,10</sup> However, they are also only instruments and cannot achieve their objectives in isolation from an ethical social culture.

These broader perspectives pose new challenges to those charged with ethical review and oversight, too often within narrow conceptual frameworks.<sup>1</sup> The proposed changes to the declaration are improvements, but to remain the centrepiece for ethically responsible research it will need to show that it meets several criteria. It must be proactive,<sup>3</sup> dynamic,<sup>2</sup> universal, transparent, responsive, and consultative.<sup>2</sup> Most importantly, it should inspire us all to approach research in an ethically responsible manner.

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