Antenatal corticosteroids in late preterm infants

Limited evidence suggests no effect on respiratory disorders or other complications of late prematurity

PASCALBROZE/REPORTERS/SPL

RESEARCH, p 858

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Current practice in the United Kingdom is to give a single course of antenatal corticosteroids to the mother if birth between 26^{+0} and 34^{+6} weeks' gestation is a risk, with consideration given to its use between 23^{+0} and 25^{+6} weeks of pregnancy. The evidence for this comes largely from a systematic review and is supported by national guidelines.[1] This systematic review of 21 studies (3885 women and 4269 infants) showed that treatment of women at risk of preterm birth with a single course of antenatal corticosteroids reduced the risk of neonatal death by 31% (95% confidence interval 19% to 42%), respiratory distress syndrome by 44% (31% to 57%), and intraventricular haemorrhage by 46% (31% to 67%).[2] There is evidence that antenatal corticosteroids are used worldwide, although the gestations at which they are used varies with the availability of neonatal care.[3-5]

The evidence for whether corticosteroids are effective in late preterm pregnancies (between 34^{+0} and 36^{+0} weeks) is sparse. The fetal lung develops in five stages. From 28^{+0} to 35^{+0} weeks' gestation, the alveoli can be counted and with increasing age they become more mature. Lung volume increases fourfold between 29^{+0} weeks and term. The surfactant and pulmonary antioxidant systems develop in parallel from 24 weeks. Fetal lungs are assumed to have reached surfactant maturity by 34 weeks, so few studies have specifically looked at the efficacy of antenatal corticosteroids between 34^{+0} and 36^{+0} weeks of pregnancy.

The evidence for their use between 34 and 36+ weeks' gestation has rested largely on the results from two trials, one by the authors of the linked paper.[7 8] These showed a 47% (31% to 0.91%) reduction in respiratory distress syndrome in babies exposed to corticosteroids between 33^{+0} and 35^{+0} weeks (7/52 *v* 15/57,[8] 11/160 *v* 19/175[7]). No significant effect was shown with antenatal use of corticosteroids at 35-37 weeks or greater than 36 weeks.

To date, no study has specifically been designed to assess the effect of corticosteroids between 34 and 36 weeks of pregnancy, even though infants born at these gestations are at risk of respiratory morbidity, mainly transient tachypnoea of the newborn and respiratory distress syndrome.[9 10] In the linked study, Porto and colleagues assess the effectiveness of corticosteroids for reducing respiratory disorders in infants between 34 and 36 weeks' gestation.[6] This randomised controlled trial compared corticosteroids with placebo in 320 women at 34-36 weeks of pregnancy who were at risk of imminent premature delivery.[6] It found no significant effect of corticosteroids on respiratory disorders (a composite outcome of respiratory distress syndrome and transient tachypnoea of the newborn), although the overall incidence of respiratory distress syndrome in the population studied was small (corticosteroid group: 1.4%, placebo group: 0.84%; P=0.54). The main respiratory condition affecting these babies was transient tachypnoea of the newborn (23.8% *v* 22.3%; P=0.77), and corticosteroids did not reduce the incidence in either arm. Corticosteroids did not reduce the risk of respiratory morbidity even after adjustment for subgroups of gestational age (34 weeks, 35 weeks, and 36 weeks).

So what should clinicians do? The study has some limitations. Sixteen of 143 babies in the intervention arm and 11 of 130 in the control arm were delivered after 37^{+0} weeks, which could account for the low rates of respiratory distress syndrome. Furthermore, there was a 13.4% attrition rate because of discharge and delivery at other hospitals. The authors also concede that the study was not powered to assess differences in rates of respiratory distress syndrome alone, and overall rates of this syndrome were too small to detect the effect of antenatal corticosteroids.

Clinicians should therefore not alter their current practice on the basis of this single underpowered randomised controlled trial but await incorporation of these results into the systematic review on antenatal corticosteroids, which is currently being updated. High risk pregnancies that require delivery at 34-36 weeks should not be delayed. Although clinicians should be aware of the risk of transient tachypnoea of the newborn in these neonates, other factors, such as the risk of infection to the long term morbidity of the infant, need to be taken into account in any decisions to delay delivery.

Although most of the studies reviewed in the systematic review were conducted in industrialised countries, corticosteroids should be equally effective in all settings.[3] There is evidence that corticosteroids are used globally. In middle income countries where mechanical ventilation is available, a 53% reduction in mortality (relative risk 0.47, 0.35 to 0.64) and 37% reduction in morbidity (0.63, 0.49 to 0.81) between 31 and 36 weeks' gestation have been reported with antenatal corticosteroid use.[4 5] It has been suggested that antenatal corticosteroids would be even more effective in low income countries, where many preterm babies currently receive little or no medical care.[5] Effective implementation in different global settings is a challenge, and research should be directed towards ways of achieving this.

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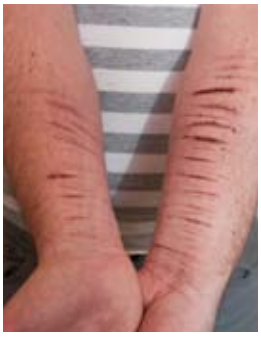
Prevention of self harm in adolescents

Interventions should be tailored to individual risk factors and the social context



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RESEARCH, p 860

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The linked randomised trial is the largest clinical trial so far to target self harm in adolescents, including non-suicidal self injury and suicide attempts.[1] Despite a promising pilot study and excellent trial management, when added to routine care the intervention of developmental group therapy did not significantly reduce the occurrence, frequency, or severity of self harm. Possible explanations for this lack of effect are that self harm is too heterogeneous for any one intervention to be effective, the effects of routine care overwhelmed those of the experimental treatment, or the treatment targeted individual rather than contextual factors.

Each group received nine or 10 sessions of routine care, much more than either condition received in the pilot study. As the authors note, the increased amount of treatment and possible improvement in routine treatment over the past decade may have overwhelmed the effect of developmental group therapy, which was essentially compared with minimal treatment in the original study.

ASSIST included adolescents who engaged in non-suicidal self injury and suicidal behaviour. Although non-suicidal self injury and suicide attempts often occur in the same individual and share some common risk factors, their motivations, reinforcers, and neurobiology are distinct. Non-suicidal self injury is most commonly used as a mood regulation strategy and is associated with higher pain thresholds, lower opioid activity, and supersensitivity to the μ opioid receptor.[2 3] Non-suicidal self injury, which is thought to relieve negative affect through the release of endogenous opioids, is highly reinforcing, and this raises the question of how useful opioid antagonists might be in preventing it. One treatment may therefore not be effective for both types of disorder. For example, dialectic behavioural therapy, one of the treatments on which developmental group therapy is based, decreased suicidal behaviour but not non-suicidal self injury when compared with expert community care.[4]

Developmental group therapy targets the full range of problems that adolescents with either form of self harm might have, including depression, substance use, conduct problems, abuse, and peer and parental conflict in an average of only 10 sessions.[1] It is possible that participants in ASSIST may not have received enough of a "dose" of any one intervention to result in change.

In adults who attempt suicide, dialectic behavioural therapy and cognitive behavioural therapy have been shown to reduce the rate of re-attempts.[4 5] These two very different interventions both have focused models of suicidal behaviour, which aim to improve regulation of emotion and combat negative thoughts that lead to suicidal behaviour, respectively. Both treatments use chain analysis, which details the sequence of events, thoughts, feelings, behaviours, and context that led up to an episode of self harm, in order to develop a safety plan and to choose and prioritise strategies to help patients resist their urges to self harm.

Developmental group therapy recognises that many of these adolescents encounter social adversity, which it attempts to buffer through building their problem solving and emotion regulating skills. Sometimes these skills may not be enough to counteract a toxic social environment. For example, parental depression, family discord, and a history of abuse have been shown to wipe out the effectiveness of cognitive behavioural therapy for the treatment of adolescent depression.[6 7] Therefore, sometimes direct intervention with the parent, family, or social system may be more effective than an exclusive focus on building skills. However, a randomised controlled trial of home based family treatment for adolescents who attempted suicide also showed no significant effects, so perhaps an exclusive emphasis on either individual or contextual factors will not meet the needs of many suicidal adolescents.[8]

Treatment studies of self harm and depression in adolescents have almost entirely focused on the remediation of emotional and cognitive weaknesses, rather than on the enhancement of personal and family resources that promote emotional health. Risky health behaviours, including self harm, are less likely to occur in the presence of a strong parent-child bond, consistent parental supervision and discipline, and a positive connection between the adolescent and the school.[9] Interventions that augment family and individual resilience by improving the parent-child relationship can protect against mental health disorders and dysfunction up to six years after the intervention is delivered.[10]

We have not yet figured out how to protect adolescents from self harm. Treatments that have the best chance of success may be those that are based on a simple sharply focused model of suicidal behaviour that differentiates

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between non-suicidal self injury and suicide attempts, that personalise interventions on the basis of a chain analysis, and that focus on building protective factors within the person's social context. Given the emerging biology of non-suicidal self injury, future intervention studies should target the opioid system with opioid antagonists.

If psychotherapy is "the art of wooing nature," then self harm behaviour in adolescents is a condition that has spurned all suitors.[11 12] Auden described this art as the ability to facilitate healing despite human variability; "all humans have prejudices of their own that can't be foreseen."[12] If these unforeseen "prejudices," that predispose to self harm, such as low tolerance of distress or hopelessness, could be identified they could be used to personalise treatment.

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Migration of doctors and the "fitness to practise" process

Diversity in the workforce brings benefits but also challenges

RESEARCH, p 859

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One of the more controversial aspects of the migration of doctors is whether international medical graduates offer the same quality of care as doctors who train and practise in destination countries. This debate is fuelled by the increasing dependence on doctors who were trained abroad—a quarter of practising doctors in the United States attended medical school in another country, and recent policy changes in the United Kingdom have led to a greater reliance on doctors who were trained abroad in the NHS. Across countries, the "fitness to practise" process or its equivalent, which investigates and adjudicates on concerns about the fitness of individual doctors to practise medicine, is widely held as the great quality arbiter, protecting patients from unfit doctors. In the linked study, Humphrey and colleagues assess whether country of medical qualification is associated with high impact decisions (the most severe forms of censure) at different stages of this process after allowing for other characteristics of doctors and inquiries.[1]

The process of licensure for doctors migrating to developed countries is rigorous. For instance, in the US the Educational Commission for Foreign Medical Graduates (ECFMG) certifies international medical graduates through verification of educational credentials in the source country and pass rates on the first two steps of the US Medical Licensing Examination. All international medical graduates must then graduate from a residency programme in the US to be eligible for full licensure. The UK General Medical Council (GMC) similarly oversees a process of registration and licensure for migrating doctors, although eligibility criteria vary by the country of training. Despite the best efforts of licensing bodies, unfit physicians—trained domestically and abroad—enter the workforce. The question remains whether the review and adjudication process is fair and equitable in the context of an increasingly diverse workforce.

Humphrey and colleagues found that medical qualification outside the UK was associated with high impact decisions at each stage of the fitness to practise process, even when controlling for inquiry related variables and other doctor related demographic characteristics.[1] This is an important contribution to the literature, given the observed inconsistencies in relevant research to date. One single state study in the US also found that international medical graduates, when compared with US medical school graduates, were more likely to experience licence revocation, practice suspension, probation, and public reprimand,[2] all equivalent to the

ALAMY

Medical students attending a lecture

high impact adjudications described by Humphrey and colleagues.[1] However, another single state study in the US found no such association.[3] Additional research on the association between other doctor related characteristics, such as ethnicity, and the fitness to practise process is needed.

Why might the high impact decisions be more common in foreign trained graduates? With regard to the question of quality, recent research in the US and Canada found that doctors who trained abroad had similar or better clinical outcomes than those who trained domestically.[4 5] Yet research in Australia showed that patients assess foreign born doctors as less competent and trustworthy than native born doctors or those trained in a developed nation (regardless of country of origin) when all other characteristics are constant.[6] Consistent with these findings, non-native doctors have reported racial and ethnic discrimination at work in the US.[7] This interpersonal bias towards foreign doctors may manifest as a lower threshold for complaints by patients and others. A workplace climate that is hostile and discriminatory towards foreign doctors could also influence their performance and evaluation.[8] Certainly, the potential effects of discrimination should be included in our discussions as we explore options to expand our healthcare workforce globally.

Although discrimination may contribute to the differences seen by Humphrey and colleagues,[1] we should consider other potential causes. Firstly, a history of unprofessional behaviour in medical school has been associated with high impact decisions among native-born doctors in the US and the UK.[9 10] Perhaps the system identifies a higher proportion of students with these poor prognostic characteristics and dismisses them earlier in the domestic training process compared with students with similar characteristics who train abroad. Secondly, international medical graduates are more likely to work as generalists and often practise in designated healthcare shortage areas and rural locations.[11] Practice patterns may be an important consideration when assessing outcomes of fitness to practise proceedings at the GMC and elsewhere. We should also think about how the sociocultural differences between patients or peers in destination countries and foreign doctors might affect the disciplinary process.

Humphrey and colleagues present compelling evidence that should stimulate action within the profession. The GMC can be a model for other oversight bodies in the area of data collection, transparency, and public accountability. We should encourage a self auditing process within the GMC and similar bodies, including review of practices and procedures. We also need to evaluate diversity, or lack thereof, within the leadership and membership of oversight boards.

Furthermore, the system may be broken on a larger scale. How do oversight boards measure and benchmark disciplinary performance? The discipline process has always been a reactive one, and this may have partly resulted in the observed inequities. The system relies heavily on external reporting, which does not prevent initial patient harm and is subject to a host of introduced biases. As our geographical borders become more porous and diversity increases within the workforce, oversight bodies will play a pivotal role in securing high quality care and professional equity.

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Multidisciplinary palliative care in unborn and newborn babies

Coordinated clinical care and psychological, spiritual, and social support must be provided throughout the process

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In September 2010 the *BMJ* published an article about palliative care and achieving a good death in the 21st century.[1] However, the article did not comment on palliative care in the fetus and the newborn. Perinatal palliative care is the holistic provision of supportive care and end of life care. The eligibility of the fetus or neonate for such care should first be established using a multidisciplinary model that is centred on the family.[2]

Spontaneous and induced pregnancy losses are common. Evidence shows that parents undergo a grief reaction and require support and counselling in the long term.[3] The management of such situations has an enduring effect on the psychological and emotional wellbeing of parents and the wider family. Family centred care has become a crucial part of care of neonates.[4]

If the overall prognosis for the baby is in doubt, palliative care is considered and discussed with parents in the prenatal or early neonatal period. Examples include neonates who are born at the limits of viability or with a serious and potentially lethal congenital malformation,

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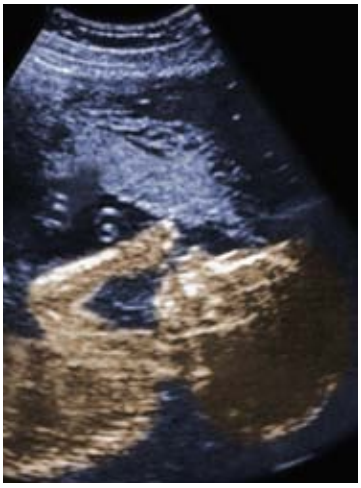
neonates who do not respond to aggressive medical management, and those in whom such management would prolong suffering or merely postpone death.[5] Also, babies with aneuploidy or genetic syndromes that are not immediately lethal require palliative care. Five situations in which it may be appropriate to withhold or withdraw life sustaining treatment have been described in babies.[6] Most commonly these fall into the "no chance of survival," "no purpose," or "unbearable" categories, and the outcome very much depends on discussions between all members of the healthcare team and the parents.



CHUCK SWARTZELL, VISUALS UNLIMITED/SPL

26 week old fetus

The EpiCure study indicates that one in five babies born before 26 weeks' gestation has severe neurological and developmental morbidity when assessed at 6 years of age.[2 7] This cohort includes babies born alive at less than 22 weeks who are at the limits of viability, and babies born with severe and multiple morbidities in whom parents and healthcare professionals may consider supportive care only. In pregnancies terminated at less than 22 weeks' gestation, 4% of neonates show signs of life at birth,[8] a situation that may require palliation, if survival is prolonged.[2]

About 5% of pregnancies are complicated by congenital structural malformations, 15% of which are potentially lethal. Access to termination of pregnancy and the gestational limit at which this may be applied are the subject of professional, political, legal, and public debate. Currently, late termination of pregnancy is legal at any gestation until birth if the child has a substantial risk of severe mental or physical disability.[9] The Royal College of Obstetricians and Gynaecologists' guideline recommends that after 22 weeks' gestation, termination of pregnancy should involve an offer of fetocide.[10] Many parents decide to continue with such a pregnancy, which requires planning for perinatal palliative care.[11] Qualitative evidence suggests that this choice may lessen the potential emotional and psychological effects associated with abortion.

A recent working party report of the British Association of Perinatal Medicine focused on palliative care.[12] This document indicates that holistic palliative care planning must begin with the identification and clear definition of pathology, followed by agreement within the multidisciplinary healthcare team about diagnosis and prognosis,[4 12] which should be shared and discussed with the family. Family centred care, including psychological, spiritual, and social support must be applied throughout the process.[4] Qualitative studies indicate that communication among hospital staff is paramount and can avoid potential insensitivities. Prenatal maternal assessment should continue but be provided in a focused and sensitive way. Formal written care plans should be communicated to all involved with the pregnancy, with agreed management of the intrapartum period. In many cases this will involve awaiting spontaneous onset of labour and avoiding unnecessary intervention. However, caesarean section is occasionally warranted for maternal indications or to increase the chance of the baby being live born, even if this is for a relatively short time. The family should be given the opportunity to visit the delivery suite and meet key staff.[4 6 12]

The staff that will be present at delivery and any planned resuscitation and postnatal care should be agreed prospectively. The plan should be continuously and prospectively reviewed, so that the baby can be monitored and supportive care can be delivered. If a palliative care pathway is agreed, parents should be made aware of what might happen; in particular, that a baby may show signs of life for some time. The role of appropriate sedation and analgesia should be discussed. The advantages of postmortem examination in confirming specific pathology should be explained and the risks of recurrence in subsequent pregnancies fully discussed. Some parents may wish to take their dying baby home, and after discussion this could be arranged and appropriate support provided. Perinatal bereavement services should be used, with ongoing psychological and emotional support offered to family members, as well as practical help with certification and registration of death and support and information on burial or cremation. Staff should ensure that the mother's local primary care team is informed by telephone and in writing about ongoing care and support. Parents should be offered a follow-up appointment to review results of investigations, such as the postmortem examination.

In this way "achieving a good death for all" can include the care of unborn and newborn babies.[1]

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King's Fund report on quality of care in general practice

Commissioning consortiums need to use professional leadership to improve care

LIFE IN VIEW/SPL

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International comparative studies show that strong primary care can be the foundation for efficient healthcare systems.[1] In England, almost all the population is registered with general practitioners who work with multidisciplinary primary healthcare teams that provide a wide range of services. Care is largely free, and general practitioners act as gatekeepers into most specialist care. The system is therefore often seen as an exemplar of how primary care can enable good health outcomes to be achieved at reasonable cost.

Yet the English health system is embarking on major and controversial reorganisation, with general practice at the centre of the changes.[2] The general practitioner commissioning groups now being established as part of the reforms will have a duty to help the NHS Commissioning Board in continuously improving the quality of general practice. With enviable prescience, two years ago the King's Fund commissioned an inquiry to review the quality of general practice in England and make recommendations on how general practice can be supported to improve quality.[3] The report is published this week, and it should be studied carefully by all those leading commissioning consortiums.

Chaired initially by Niall Dickson and subsequently by Ian Kennedy, the inquiry assessed evidence relating to 14 aspects of general practice; subjected the findings to debate in seminars attended by professionals, managers, and the public; and brought their conclusions together in a report that includes key messages on how quality can be improved. The inquiry concluded that most of the care provided by general practice is good. They also found variation in performance as well as some gaps in quality, however, suggesting considerable scope for improvement.

Among the areas highlighted as in need of improvement are the clinical tasks of making an early diagnosis—for example, of cancer or acute conditions—and management of people with multiple long term conditions and associated preventive activities that reduce the risk of unscheduled admission. The timeliness of referrals and content of referral letters could be improved, and steps could be taken to tackle drug errors and patient adherence to drugs. Practices could make better use of technology to involve patients, and they could improve relationship continuity, management continuity, and access for those who need care but are not currently receiving it. They also need to give attention to population health as well as the care of individuals, and in partnership with consortiums, make real progress in reducing health inequalities. The report notes that the distribution of general practitioners varies between primary care trusts from 50 to more than 80 per 100 000 population.

The inquiry's analysis of the strengths and weaknesses of general practice led it to conclude that general practice now needs to make the transition from cottage industry to post-industrial care.[4] Today's general practice does not merit being described as a cottage industry; enormous advances have been made since the Collings report, which found overwhelming evidence to justify such an accusation.[5] In the quality and outcomes framework it even has some features of post-industrial care, such as measuring performance and transparent reporting, but there is some way to go in eliminating unwarranted variation and reducing waste and errors.

The enduring weakness of general practice is the problem of ensuring uniformly high quality care from large numbers of small, relatively isolated, and autonomous practices. Many general practitioners would argue that diversity is also its enduring strength, because it enables practices to tailor their care to individuals and, potentially, to local populations. The challenge of retaining this strength while dealing with the weakness is now being handed from primary care trusts to commissioning consortiums.

The inquiry sees the emergence of federations of practices such as commissioning consortiums as facilitating the transition to post-industrial care. Although most of the debate on the merits or otherwise of commissioning consortiums has focused on the commissioning process itself, much of the success of such consortiums will rest on the extent to which they can engage member practices in improvement activities. To reduce inappropriate use of hospital services and transfer care from high cost specialist settings to lower cost community settings, practices will need consistently to apply shared policies. One way or another, practices that are performing poorly will have to be improved.

Suggestions in the report on ways that commissioning consortiums can achieve the necessary quality improvements include effective leadership, peer review, publication of performance data, improved clinical audit, additional support for some practices in deprived areas, incentive schemes, and making the consequences of poor performance clear. Although these all have a part to play, they do not explain how consortiums can consistently engage all their member practices. Consortiums will be required to identify poor performance and work with the NHS Commissioning Board and the Care Quality Commission or the General Medical Council to understand the cause of poor performance and support remedial action.[6] The advantage of consortiums lies in their local knowledge and the relations they could establish with fellow general practitioners. Will the combination of professional leadership provided by the consortiums and the external leverage of the Commissioning Board and regulators succeed in driving the transformation to post-industrial care? If it does, it would be a remarkable triumph for professionalism. Health systems around the world should study the progress of consortiums in the next few years; it is just possible they may show how the power of professionalism can be harnessed to improve care.

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