CANNOT BE BADGERED: a sorry tale from MASCOT

Clinical trials in children are few and far between so funding from NIHR for MASCOT, a large clinical trial comparing treatment options at in children whose asthma is uncontrolled on low dose inhaled corticosteroids, was welcome. However, what followed was a litany of frustrating delays due to an astonishing burden of bureaucracy, communication problems, governance issues and difficulties with recruitment (See page 457). As a result, the trial was not completed and over £1 million of public money was wasted. While this fiasco was rumbling on, the BADGER trial, starting about the same time, was successfully completed in the USA. What can be learnt from this disaster? It strikes us that there are three areas where immediate reform should be possible. First, a reliable and quick supply of placebo inhalers and tablets should be available for studies of this sort. Second, research staff should have direct access to patient lists in primary and secondary care and should be able to communicate directly with patients, unless individuals have opted out. Third, the Multicentre Research Ethics Committee decision and local Governance processes must be speeded up. Ros Smyth (See page 459) is optimistic that progress will be made in some of these areas if the recommendations of the new Health Research Agency are acted upon. We hope she’s right. However, this is just one illustration of our national obsession with process (wearisomely correct in all too common in NICU survivors will this interact with smoking, which is an issue the respiratory community is far from meaning that their problems have been successfully salvaged in NICU matters in the short term, but what is the long-term fate of these babies with likely fixed chronic airflow limitation? Will they be the new phenotype, pauci-inflammatory COPD cohort in years to come? How will this interact with smoking, which is all too common in NICU survivors? This is an issue the respiratory community needs to address. Just because these babies have been successfully salvaged in NICU is far from meaning that their problems are over. See page 468.

Animal models have demonstrated the importance of optimising Vitamin D status in the developing fetal lung. So it is therefore obvious that optimising Vitamin D status during pregnancy and early childhood is a good thing, and only a matter of time before one of the many ongoing birth cohort studies demonstrated this, right? No, wrong: the KOALA study (more than 400 children, followed from birth to age 6–7) were unable to show any effect of either childhood Vitamin D levels, childhood Vitamin D intake, or recommended use of Vitamin D ≥10 µg/day during pregnancy, on childhood spirometry. A salutary lesson: sometimes research into the blindingly obvious does not give the obvious answers. See page 474.

Nervous about your lungs?

This 72-year-old woman presented with neurological problems, and was found to have lung and spinal cord nodules. See page 546 for this month’s pulmonary puzzle, where things are not quite as they seem.

Highlights from this issue

doi:10.1136/thoraxjnl-2011-200427

Andrew Bush and Ian Pavord, Editors

Airwaves

Andrew Bush and Ian Pavord, Editors

CANNOT BE BADGERED: a sorry tale from MASCOT

Clinical trials in children are few and far between so funding from NIHR for MASCOT, a large clinical trial comparing treatment options at in children whose asthma is uncontrolled on low dose inhaled corticosteroids, was welcome. However, what followed was a litany of frustrating delays due to an astonishing burden of bureaucracy, communication problems, governance issues and difficulties with recruitment (See page 457). As a result, the trial was not completed and over £1 million of public money was wasted. While this fiasco was rumbling on, the BADGER trial, starting about the same time, was successfully completed in the USA. What can be learnt from this disaster? It strikes us that there are three areas where immediate reform should be possible. First, a reliable and quick supply of placebo inhalers and tablets should be available for studies of this sort. Second, research staff should have direct access to patient lists in primary and secondary care and should be able to communicate directly with patients, unless individuals have opted out. Third, the Multicentre Research Ethics Committee decision and local Governance processes must be speeded up. Ros Smyth (See page 459) is optimistic that progress will be made in some of these areas if the recommendations of the new Health Research Agency are acted upon. We hope she’s right. However, this is just one illustration of our national obsession with process (wearisomely correct in all too common in NICU survivors will this interact with smoking, which is an issue the respiratory community is far from meaning that their problems have been successfully salvaged in NICU matters in the short term, but what is the long-term fate of these babies with likely fixed chronic airflow limitation? Will they be the new phenotype, pauci-inflammatory COPD cohort in years to come? How will this interact with smoking, which is all too common in NICU survivors? This is an issue the respiratory community needs to address. Just because these babies have been successfully salvaged in NICU is far from meaning that their problems are over. See page 468.

Animal models have demonstrated the importance of optimising Vitamin D status in the developing fetal lung. So it is therefore obvious that optimising Vitamin D status during pregnancy and early childhood is a good thing, and only a matter of time before one of the many ongoing birth cohort studies demonstrated this, right? No, wrong: the KOALA study (more than 400 children, followed from birth to age 6–7) were unable to show any effect of either childhood Vitamin D levels, childhood Vitamin D intake, or recommended use of Vitamin D ≥10 µg/day during pregnancy, on childhood spirometry. A salutary lesson: sometimes research into the blindingly obvious does not give the obvious answers. See page 474.

Nervous about your lungs?

This 72-year-old woman presented with neurological problems, and was found to have lung and spinal cord nodules. See page 546 for this month’s pulmonary puzzle, where things are not quite as they seem.

CANNOT BE BADGERED: a sorry tale from MASCOT

Clinical trials in children are few and far between so funding from NIHR for MASCOT, a large clinical trial comparing treatment options at in children whose asthma is uncontrolled on low dose inhaled corticosteroids, was welcome. However, what followed was a litany of frustrating delays due to an astonishing burden of bureaucracy, communication problems, governance issues and difficulties with recruitment (See page 457). As a result, the trial was not completed and over £1 million of public money was wasted. While this fiasco was rumbling on, the BADGER trial, starting about the same time, was successfully completed in the USA. What can be learnt from this disaster? It strikes us that there are three areas where immediate reform should be possible. First, a reliable and quick supply of placebo inhalers and tablets should be available for studies of this sort. Second, research staff should have direct access to patient lists in primary and secondary care and should be able to communicate directly with patients, unless individuals have opted out. Third, the Multicentre Research Ethics Committee decision and local Governance processes must be speeded up. Ros Smyth (See page 459) is optimistic that progress will be made in some of these areas if the recommendations of the new Health Research Agency are acted upon. We hope she’s right. However, this is just one illustration of our national obsession with process (wearisomely correct in all too common in NICU survivors will this interact with smoking, which is an issue the respiratory community is far from meaning that their problems have been successfully salvaged in NICU matters in the short term, but what is the long-term fate of these babies with likely fixed chronic airflow limitation? Will they be the new phenotype, pauci-inflammatory COPD cohort in years to come? How will this interact with smoking, which is all too common in NICU survivors? This is an issue the respiratory community needs to address. Just because these babies have been successfully salvaged in NICU is far from meaning that their problems are over. See page 468.

Animal models have demonstrated the importance of optimising Vitamin D status in the developing fetal lung. So it is therefore obvious that optimising Vitamin D status during pregnancy and early childhood is a good thing, and only a matter of time before one of the many ongoing birth cohort studies demonstrated this, right? No, wrong: the KOALA study (more than 400 children, followed from birth to age 6–7) were unable to show any effect of either childhood Vitamin D levels, childhood Vitamin D intake, or recommended use of Vitamin D ≥10 µg/day during pregnancy, on childhood spirometry. A salutary lesson: sometimes research into the blindingly obvious does not give the obvious answers. See page 474.

Nervous about your lungs?

This 72-year-old woman presented with neurological problems, and was found to have lung and spinal cord nodules. See page 546 for this month’s pulmonary puzzle, where things are not quite as they seem.
Highlights from this issue

Andrew Bush and Ian Pavord

*Thorax* 2011 66: i
doi: 10.1136/thoraxjnl-2011-200427

Updated information and services can be found at:
http://thorax.bmj.com/content/66/6/i

These include:

**Email alerting service**
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/