

MSc Programme in International Health Epidemiology and Statistics

It's not just about the numbers
Lecture 1

Aims of the lecture

- To explain the need for critical appraisal of research information
- To describe the publication process and potential for bias
- To explain terms required to review example papers
 - mortality rates, age specific rates, person years at risk, hazard ratios, incidence and prevalence

Numbers in health

- “Almost 12,000 preventable deaths in hospitals every year due to errors in care”
- “Former-smokers gain up to 11lbs a year after they quit the habit”
- “Around 366 million people worldwide have diabetes mellitus”
- “Satisfying unmet need for contraception could prevent 104000 maternal deaths per year (29% reduction)”.
- “Limiting the time we spend sitting to just three hours a day could add an extra two years to our life expectancy”

Exercise

- Is the information based on evidence or opinion?
- Is it interesting?
- Is the information trustworthy?

From The Times
October 14, 2009

Half of cot deaths linked to sleeping with parents

Sam Lister, Health Editor

More than half of cot deaths occur when a baby is sleeping with a parent, with drinking or drug-taking by the adult a likely contributory factor, a study suggests.

An analysis of all unexpected infant deaths, from birth to two years old, in a four-year period in the South West showed that the majority occurred when a parent was with the child, often asleep on the sofa.

The number of cot deaths has dropped dramatically since the early 1990s, with the help of better health awareness programmes. But experts said that more work was needed to reach different social and cultural groups with advice to avoid dangerous sleeping arrangements.

The team of researchers at the universities of Bristol and Warwick studied a possible link between cot death and socio-economic deprivation by comparing the unexpected infant deaths with a control group at 'high risk' — young, socially deprived mothers who smoked — as well as another randomly selected control group.

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BBC NEWS
LIVE BBC NEWS CHANNEL

Last Updated: Monday, 18 June 2007, 09:36 GMT 10:36 UK
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Pureed baby food is 'unnatural'

Spoon-feeding babies pureed food is unnatural and unnecessary, a childcare expert has warned.

Gill Rapley, deputy director of Unicef's UK Baby Friendly Initiative said feeding babies in this way could cause health problems later in life.

Rapley says there is no need to feed babies pureed foods.

She said children should be fed only with breast or formula milk for six months, then weaned onto solids to improve control over how much they ate.

This could prevent babies becoming picky about food.

Mrs Rapley has spent 25 years as a health visitor, and she said: 'I found so many parents were coming to me with the same problems - 'my child is constipated, my child is really

“ There is no longer any window of a baby's development in which they need something more than milk and less than solids ”

Gill Rapley

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RESEARCH

pico **Hazardous cosleeping environments and risk factors amenable to change: case-control study of SIDS in south west England**

Peter S Blair,¹ Peter Sidebotham,² Carol Evason-Coombe,¹ Margaret Edmonds,¹ Ellen MA Heckstall-Smith,¹ Peter Fleming¹

EDITORIAL by Mitchell

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STUDY QUESTION What are the circumstances in which sudden infant death syndrome (SIDS) occurs?
SUMMARY ANSWER Many of the SIDS infants had coslept in a hazardous environment. The major risk factors, regardless of markers for socioeconomic deprivation, are amenable to change: particularly never cosleeping on a sofa, and avoiding alcohol or drugs before cosleeping in a bed.
WHAT IS KNOWN AND WHAT THIS PAPER ADDS A higher proportion of the residual deaths from SIDS now occur among more deprived families and those who cosleep with their infant. Many of the deaths while cosleeping occurred in potentially hazardous environments, including on a sofa or shared surface with an adult who had consumed alcohol or drugs.

Main results and the role of chance
The median age at death (66 days) was more than three weeks less than in a study in the same region a decade earlier. Of the SIDS infants, 54% died while cosleeping compared with 20% among both control groups. Much of this excess is explained by a significant multivariable interaction between cosleeping and recent parental use of alcohol or drugs (31% \pm 7% random controls) and the increased proportion of SIDS infants who had coslept on a sofa (17% \pm 1%). More SIDS infants than random controls used a pillow for the last sleep (21% \pm 3%), were swaddled (24% \pm 0%), were found prone (29% \pm 10%), were preterm (26% \pm 5%) or were in fair or poor health for the last sleep (28% \pm 6%). More mothers

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Risk factors for SIDS
We already know enough; the challenge is how to change behaviour

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In the linked study, Blair and colleagues report on a four year case-control study of sudden infant death syndrome (SIDS) in south west England.¹ The number of cases in the study is small, as a result of two factors. Firstly, the recommendation to avoid the prone sleeping position in the "Back to Sleep"² campaign resulted in a dramatic reduction in mortality from SIDS in the early 1990s.³ Secondly, the change from the side to the back sleeping position led to the subsequent slower decline in mortality from SIDS.⁴ However, this study did come up with several important findings.

The study used two control groups—a random control group and a high risk group. The risk factors were similar whichever group the SIDS cases were compared with. This is important because it indicates that risk factors for SIDS apply to all sections of the community and are not just a consequence of social deprivation, because SIDS now occurs predominantly in disadvantaged communities. The prevalence of the exposure—for

between advantaged and disadvantaged sections of the population. This is consistent with findings from New Zealand, where mortality from SIDS in Maori people is substantially higher than in non-Maori people, who are predominantly of European descent. This difference is accounted for by the higher exposure to maternal smoking and bed sharing in Maori people.⁵

Blair and colleagues' study highlights co-sleeping as a risk factor for SIDS.^{6,7} More than half of deaths from SIDS occurred while the infant was sleeping with a parent. This is in accordance with other recent studies.⁸⁻¹⁰ Most authorities—for example, the American Academy of Pediatrics and the Ministry of Health in New Zealand—advise parents to avoid sharing a bed with their infant if they have been drinking or taking drugs.^{11,12} Presumably, alcohol and drugs impair the arousal of the adult co-sleeper. However, the dangers of this combination of behaviours are, for the first time, convincingly shown in this study. The box lists what we already know

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Probiotics for the prevention of pediatric antibiotic-associated diarrhea

This record should be cited as:
Johnston BC, Supina AL, Ospina M, Vohra S. Probiotics for the prevention of pediatric antibiotic-associated diarrhea. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD004827. DOI: 10.1002/14651858.CD004827.pub2.

Authors' conclusions
Probiotics show promise for the prevention of pediatric AAD. While per protocol analysis yields treatment effect estimates that are both statistically and clinically significant, as does analysis of high quality studies, the estimate from

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Good quality information

- Trustworthy source
- Free from conflict of interest
- Subject to transparent review process
- Conclusions supported by evidence
- Relevant

Type of articles in journals

- Research reports
 - original studies
 - systematic reviews
- Letters of support or criticism
- Education articles
- Review articles
 - EBM summaries, POEMs
- Editorials
- News reports

Why researchers write papers

- So that other people can learn from the research findings
- Publicizes research in a way that can be critically assessed and cited
- For researchers CV and career prospects
- For research institutions prestige and funding (RAE 2001, 2008)

Why journals publish papers

- To further their discipline
- Many journals linked with professional bodies
 - BMA and BMJ, RCGP and BJGP
- For their subscribers, what they want to read
- Needs to be interesting

Peer review

- Review by experts in the field
- Possibly review by methodology expert such as statistician
- Report back to editor
- May be open review or closed

What now?



- Most authors will try again with a different journal
- Change the focus e.g. from general to specialist journal
- Try less competitive journal



Richard Smith
Former editor BMJ

“You can get any old rubbish published if you go far enough down the food chain”

BBC Radio 4 File on Four

Can we trust what is in medical research papers?

- Not necessarily
- Written by fallible human beings and reviewed by fallible human beings
- Most papers have flaws but these may be minor not affecting conclusions or major leading to serious error
- Need to read critically

The screenshot shows a BBC News Health article. The headline is "India malaria deaths hugely underestimated, says report" by Ania Lichtarowicz. A highlighted text box contains the sentence: "The authors conclude that more than 200,000 deaths per year are caused by malaria." Below this, a sub-headline reads: "The data, published in the Lancet, suggests there are 13 times more malaria deaths in India than the World Health Organization (WHO) estimates." A small image shows a person in a white coat attending to a patient in a hospital bed.

The problem

- What is the burden of disease due to malaria?
- How do we measure it?
- Cases/deaths
- Deaths are recorded but cause of death unreliable without medical attention
- Most malaria deaths in malaria-endemic countries occur without medical attention



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The problem

- What is the burden of disease due to malaria?
- If we can't measure it we can't assess the impact of policies to reduce it.



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Closer look at the numbers

Number of deaths

- 75342 deaths in study period in study area
- 2681 death due to malaria

Will depend on

- size of population
- Time period (2 years)



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Person years at risk

For each person calculate the time studied

- Time from birth to death
- Time from birth to end of study
- Time from beginning of study to death
- Time living in study area if moving in/out

Add then up to get person years at risk

Approximately = Population size x study length

Mortality rate

Mortality rate per 100,000

$$= \frac{\text{Number of deaths}}{\text{person years at risk}} \times 100,000$$

For malaria example (table 1)
Malaria deaths (0 to 69 years) = 18 per 100,000

Age specific death rates

Probability of dying in next year depends on age

Overall death rate depends on number of old and young in the population

Age specific death rates

Estimate the death rate within different age bands

Malaria age specific death rates

Age band	Deaths per 100,000
1 – 59 months	44
5-14 years	12
15 to 29 years	8
30-44 years	10
45-59 years	27
60-69 years	75

Table 1
Dingra 2010

Malaria burden of disease

Number of deaths due to malaria in India

Could use

- age specific death rates
- number of people in each age band

Estimated 205,000 per year in whole country

(Dingra uses number of deaths in each age group and proportion likely to be due to malaria from study which give slightly different results for under 5s)

Extrapolation

What data has comes from study ?

What data has come from other sources ?

What assumptions are being made ?

Closer look at 'risk'

<http://www.guardian.co.uk/science/2012/mar/12/red-meat-death-heart-cancer>

Eating red meat raises 'substantially' risk of cancer or heart disease death

- Press Association
- guardian.co.uk, Monday 12 March 2012 20:00 GMT
- [Article history](#)



Photograph: David Sillitoe for the Guardian

Closer look at 'risk'

Incidence= number of new cases per population in a given time period

Incidence rate = cases per 1,000 population per year

Incidence rates

Incidence ratio=number of cases/number of person years at risk

All cause mortality=23926/2960000
=8083 per million
=808 per 100,000

Only presented as fractions in paper

Hazard ratio

Those eating little meat

Incidence rate = $1713/151212 \times 100,000$
= 1133 per 100,000

Those eating most meat

Incidence rate = $2130/151315 \times 100,000$
= 1408 per 100,000

Ratio of rates = $1408/1133 = 1.25$

Hazard ratio

Hazard is probability of event at set time point

Hazard ratios can be interpreted as ratio of incidence rates.

Probability of dying is 1.24 times higher in those eating most meat compared with those eating least.

Hazard ratio (HR)

Comes from Cox proportional hazards model

Pan figure in table 2 is 1.45 adjusted for age

Headline rates 1.13 for unprocessed meat and 1.20 for processed meat per serving

Prevalence

Prevalence=
Number with disease per 100,000
population

- One point in time
- Much higher than incidence for chronic conditions

Critical Appraisal Resources

- Fowkes – general checklist applicable to any study
- CASP checklists specific to study types
- Greenhalgh T How to read a paper. The basics of evidence based medicine. (2010)

Assignment

Choose from one of the following topics

- Factors associated with health inequality
- Important risk factors for morbidity and mortality of populations
- New interventions for treatment and prevention of diseases which play a major part in the burden of disease worldwide
- Organisation of primary care
- A different topic if discussed and agreed with the module leader

For the topic find an article in the media relating to a research paper (the research paper should contain at least one table or graph). Write an appraisal in 2000 words. Further details later.
