

RESEARCH

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1187 RESEARCH NEWS All you need to read in the other general medical journals

THIS WEEK'S RESEARCH QUESTIONS

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Rapid or standard intravenous rehydration for dehydrated children?

Because of its potential benefits (quickly reducing a child's agitation and clinical signs of dehydration and improving alertness and appetite), rapid intravenous rehydration has become part of clinical practice, despite a lack of evidence of efficacy. So Stephen Freedman and colleagues (p 1189) conducted a pragmatic controlled trial in a paediatric emergency department in Toronto, Canada. They compared rapid (60 mL/kg) and standard (20 mL/kg) rehydration with saline over an hour in 226 children with dehydration from gastroenteritis who had not responded to oral rehydration and had been prescribed intravenous rehydration.

They found no difference between the groups in the proportions who were rehydrated at two hours or who required prolonged treatment, nor in the dehydration scores over the four hour study period. Indeed, the median time to discharge was longer in the rapid rehydration group. The authors unsurprisingly conclude that rapid intravenous rehydration had no clinical benefits in children with mild to moderate dehydration and that, given its potential side effects, it should not be used routinely.

Rapid responses to the full article on bmj.com and the linked editorial, by Alan Nager (p 1183), make several criticisms of the paper, largely relating to the pragmatic nature of the trial reflecting current clinical practice. In particular, they don't like the inclusion of mild to moderately dehydrated children rather than limiting the study to those with severe dehydration (which is uncommon in Western countries) and the suboptimal measurement of dehydration. However, none argue with the general conclusion that, in the absence of large rigorous clinical trials to establish its efficacy, rapid intravenous rehydration should not be adopted unquestioningly.

Comparative safety and efficacy of hip implants

It has become clear over the past year that the regulation and approval of new medical devices falls far short of that for new drugs, posing serious risks to patients (for a comprehensive primer on the topic see www.bmj.com/about-bmj/article-clusters) The "metal on metal" hip replacement has caused particular concern.

In these devices, both parts—the prosthetic head of femur and the cup—are made of hardened alloy. This seemed a good design, as it allowed the femoral head to be bigger and less likely to dislocate. But last year the UK Medicines and Healthcare Products Regulatory Agency (MHRA) issued an alert about severe cases of metallosis related to the release of ions from these implants, and recommended that patients should be followed up at least annually for five years postoperatively, and more frequently in the presence of symptoms. A few months later Johnson and Johnson recalled for safety reasons more than 93 000 metal on metal hip resurfacing devices.

The US Food and Drug Administration (FDA) has been monitoring reports of such failures and, in November 2009, it commissioned and funded a formal systematic review to

determine the comparative safety and effectiveness of different hip implants. Art Sedrakyan, from Cornell University, and colleagues from the FDA and from Harvard Medical School and School of Public Health now report the findings of that review (p 1188). They found reports of only 3139 patients and 3404 hips enrolled in 18 studies from 1995 to 2011, but also reviewed reports of more than 830 000 hip implant operations in national registries. Overall, metal on metal or ceramic on ceramic implants had no advantage over traditional polyethylene based bearings, and metal on metal bearings seemed associated with a substantially higher occurrence of revision surgery. The reporting of the comparative trials was often "less than adequate," and the authors highlight the difficulties of obtaining strong evidence in orthopaedics, saying that we need international collaborations to advance reporting and harmonise the methods of evaluating devices.

The FDA is on the case. On 2-3 December it hosted a public workshop where experts from the FDA (including Sedrakyan and colleagues), MHRA, academia, surgeons, patients, and journal editors (including from the *BMJ*)

discussed ways to improve the development, approval, and postmarketing surveillance of medical and surgical devices and procedures (<http://1.usa.gov/rB8kM1>). The workshop focused particularly on how the IDEAL framework for surgical innovation might be used to improve evidence generation and evaluation (<http://bit.ly/vzmHkc>). This is definitely a story to watch.



Meanwhile, what should doctors do when patients come with concerns or symptoms related to their metal on metal hip implants? Camdon Fary and colleagues advise on the assessment and management of any such patient who presents with potential joint failure (Practice, p 1218). The authors recommend referring for an expert ultrasound examination followed by magnetic resonance imaging if a lesion is detected, and warning the patient that another hip replacement is on the cards.

Research online: For these and other new research articles see www.bmj.com/research

Association between bisphosphonate use and implant survival after primary total arthroplasty of the knee or hip In a UK cohort study using data for over 40 000 patients undergoing primary hip or knee arthroplasty, bisphosphonate users had a lower rate of revision at five years and a longer time to revision than non-users, Daniel Prieto-Alhambra and colleagues report. The findings require confirmation in experimental studies (doi:10.1136/bmj.d7222).

Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence

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● PRACTICE, p 1218

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● Feature: Europeans are left to their own devices
(*BMJ* 2011;342:d2748)

● Feature: Out of joint: the story of the ASR
(*BMJ* 2011;342:d2905)

● News: Medical devices regulation needs to be overhauled, says cardiologist
(*BMJ* 2011;343:d6671)

STUDY QUESTION

Does the type of bearing used in hip replacements affect the short and long term outcomes reported by patients and the rates of revision surgery?

SUMMARY ANSWER

Functional outcomes and general quality of life measures were no different between patients with newer (metal on metal or ceramic on ceramic) compared with traditional polyethylene based hip implants. There was some evidence of higher rates of revision surgery associated with metal on metal implants compared with metal on polyethylene hips used in conventional hip replacement.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The UK regulator alerted the public about concerns related to metal on metal hip implants. This review found only limited evidence regarding comparative effectiveness of various hip implant bearings, and the results do not indicate any advantage for metal on metal or ceramic on ceramic implants compared with traditional polyethylene based bearings. Metal on metal bearings are likely to be associated with a substantially higher occurrence of revision surgery.

Selection criteria for studies

We searched summaries of safety and effectiveness of all hip implants that are publicly available and identified all relevant publications in Medline, Embase, and the Cochrane Controlled Trials Register from January 1995 to June 2011. We included any study reporting functional outcomes or occurrence of revision surgery, or both in conventional hip replacement.

Primary outcomes

We focused on outcomes relevant to patients, such as functioning/quality of life and requirement for hip revision surgery.

Main results and role of chance

There were 3139 patients and 3404 hips enrolled in

18 comparative studies and over 830 000 surgeries in national registries. The mean age ranged from 42 to 71, and 26-88% were women. Disease specific functional outcomes and general quality of life scores were no different or favoured patients receiving traditional metal on polyethylene rather than metal on metal implants in the trials. In a pooled analysis of four studies metal on metal bearing implants were associated with 2.4 points lower Harris hip scores at two year follow-up compared with metal on polyethylene bearings. While one clinical study reported fewer dislocations associated with metal on metal implants, there was evidence of a higher occurrence of implant revision associated with metal on metal compared with metal on polyethylene implants in the three largest national registries (Australia, New Zealand, England and Wales) that included over 720 000 patients.

One comparative trial reported fewer revisions with ceramic on ceramic implants compared with metal on polyethylene implants, but one of the national registries (New Zealand) reported the opposite, and the reports from other national registries did not indicate any difference between these bearings.

Ceramic on polyethylene was associated with a higher occurrence of revision than metal on polyethylene in one national registry (New Zealand) but a lower occurrence in another (England and Wales). Three other national registries did not report any difference between these bearings.

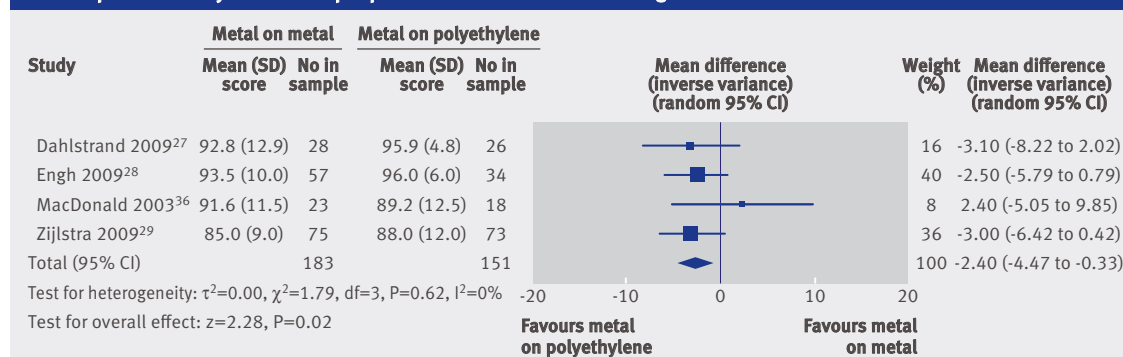
Bias, confounding, and other reasons for caution

The reporting of methods and results in the comparative studies was less than adequate in many instances. International collaborations are needed to advance the reporting and harmonise the methods of trials and registry based evaluations.

Study funding/potential competing interests

This study was partially funded by the US Food and Drug Administration.

Harris hip scores two years after hip replacement with different bearings



Rapid versus standard intravenous rehydration in paediatric gastroenteritis: pragmatic blinded randomised clinical trial

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EDITORIAL by Nager

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STUDY QUESTION

Does rapid rather than standard intravenous rehydration result in improved clinical outcomes in children with gastroenteritis requiring intravenous rehydration?

SUMMARY ANSWER

There are no relevant clinical benefits with rapid rather than standard intravenous rehydration to haemodynamically stable children requiring intravenous rehydration.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Limited evidence exists to guide the rate of intravenous rehydration in children with gastroenteritis. Our study found no clinical advantages with rapid rather than standard intravenous rehydration.

Design

We conducted a single centre two arm, parallel, randomised pragmatic controlled trial. A computer generated permuted block randomisation sequence stratified by severity of dehydration was used. Participants, caregivers, outcome assessors, investigators, and statisticians were blinded to the treatment assignment. Eligible children received rapid (60 mL/kg) or standard (20 mL/kg) rehydration with 0.9% saline over an hour; subsequent fluids were administered according to a protocol. Masking was achieved with opaque covers and soundproof boxes to conceal the infusion bags/tubing and intravenous pumps, respectively.

Participants and setting

Eligible children were recruited between December 2006 and April 2010 in the emergency department of The Hospital for Sick Children, Toronto. They were aged >90 days, had a diagnosis of dehydration secondary to gastroenteritis, had not responded to oral rehydration, and were prescribed intravenous rehydration. Excluded children weighed <5 kg or >33 kg, required fluid restriction, had a suspected surgical condition, had a history of a severe chronic systemic disease, abdominal surgery, or had bilious or bloody vomit. We also excluded children who had hypotension, hypoglycaemia, or hyperglycaemia.

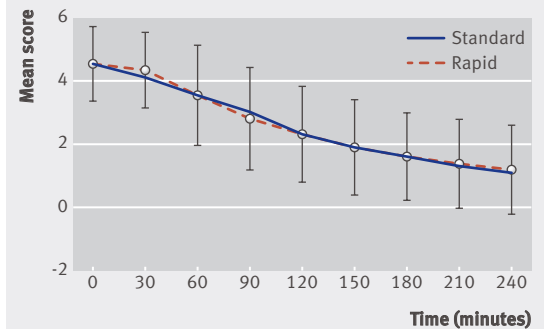
Primary outcome

The primary outcome was clinical rehydration two hours after the start of treatment.

Main results and the role of chance

114 children were randomised to rapid rehydration and 112 to standard. There was no evidence of a difference between the rapid and standard rehydration groups in the proportions of participants who were clinically rehydrated at two hours (41/114 (36%) v 33/112 (30%); difference

Clinical dehydration score over time in children with gastroenteritis treated with rapid or standard intravenous rehydration



6.5%, 95% confidence interval -5.7% to 18.7; $P=0.32$). The rates of prolonged treatment were similar (52% rapid v 43% standard; difference 8.9%, 21% to -5%; $P=0.19$). Although scores on the clinical dehydration scale were similar throughout the study period ($P=0.96$), the median time to discharge was longer in the children allocated to rapid rehydration (6.3 v 5.0 hours; $P=0.03$).

Harms

One child in each group developed an interstitial displacement of the intravenous catheter, and one child in each group developed a dysnatraemia. Four children in the standard group and two in the rapid group experienced oedema.

Bias, confounding, and other reasons for caution

Some children with mild dehydration could have been enrolled. Subgroup analysis, however, did not show a trend towards increased benefit among children with more severe dehydration.

Generalisability to other populations

This study included children typical of those administered intravenous rehydration in developed countries, thus supporting the generalisability of the findings. Given that we found no benefit with our intervention, which is more aggressive than most rapid intravenous rehydration strategies, our findings can be generalised to regimens using smaller fluid boluses. We did not, however, study children with compromised cardiovascular stability; hence the results cannot be generalised to such children.

Study funding/potential competing interests

This study was funded by the Physicians' Services Incorporated Foundation.

Trial registration

Clinical Trials NCT00392145.

The financial cost of doctors emigrating from sub-Saharan Africa: human capital analysis

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STUDY QUESTION

What is the lost investment of domestically educated doctors migrating from sub-Saharan African countries to Australia, Canada, the United Kingdom, and the United States?

SUMMARY ANSWER

The overall estimated loss of returns from investment for all doctors currently working in the destination countries was \$2.17bn (95% confidence interval 2.13bn to 2.21bn), with costs ranging from \$2.16m (1.55m to 2.78m) for Malawi to \$1.41bn (1.38bn to 1.44bn) for South Africa.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

A lack of adequately trained health workers contributes to weakened health systems. Currently the impact of doctors' emigration on investments in the health system of individual countries is unknown. Among the nine sub-Saharan African countries most affected by HIV/AIDS that were included in this study, more than \$2bn of investment was lost through the emigration of trained doctors.

Participants and setting

Nine sub-Saharan African countries (Ethiopia, Kenya, Malawi, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe) with an HIV prevalence of 5% or greater or with more than one million people with HIV/AIDS, at least one medical school, and data available on the number of doctors practising in destination countries.

Design

Human capital cost analysis using publicly accessible data.

Primary outcome(s)

The loss of investments owing to the financial cost of educating a doctor (through primary, secondary, and medical school) emigrating to developed countries using current country specific interest rates for savings; cost according to the number of source country doctors currently working in the destination countries; and savings to destination countries of receiving trained doctors.

Main results and the role of chance

In the nine source countries the estimated government subsidised cost of a doctor's education ranged from \$21 000 (£13 000; €15 000) in Uganda to \$58 700 in South Africa. The overall estimated loss of returns from investment for all doctors currently working in the destination countries was \$2.17bn. In sensitivity analyses, the best case estimate was \$1.41bn and worst case estimate was \$13.53bn. The ratio of the estimated compounded lost investment over gross domestic product showed that Zimbabwe and South Africa had the largest relative losses. Australia, Canada, the United Kingdom, and the United States benefit importantly from the recruitment and licensure of doctors educated elsewhere. The benefit was largest for the United Kingdom (\$2.7bn) and the United States (\$846m).

Bias, confounding, and other reasons for caution

We chose interest rates on the lower end of available data, did not quantify the number of doctors practising outside the destination countries or those that emigrated but never entered medical practice. These limitations may result in underestimates of the true loss to the source countries under study. However, we did not consider the number of doctors who return to their source countries nor examine the benefits of doctors sending financial resources back to families in the home countries. While these may mitigate losses, little is known about how widespread or systematic they may be.

Generalisability to other populations

Emigration of doctors from developing countries to developed ones is not restricted to these nine source countries. Our results show that important monetary losses were incurred by all countries included here and we believe this can be generalised to other sub-Saharan African countries with medical education facilities.

Study funding/potential competing interests

This study received no funding. We have no competing interests.

Sensitivity analysis of estimated lost investment using variations on time working in destination countries, interest rates, and cost of education

Source country	Estimated lost investment for source countries (\$, millions)		
	All doctors from source countries	Assuming later emigration and attendance at private schools	Compounding over full length of career and using deposit rate
Ethiopia	24.63	21.76	260.32
Kenya	16.75	11.89	59.02
Malawi	2.16	1.40	5.15
Nigeria	674.26	387.14	2297.82
South Africa	1412.70	960.88	9764.50
Tanzania	3.49	0.48	68.36
Uganda	13.61	8.33	103.97
Zambia	12.14	9.37	276.42
Zimbabwe	39.61	23.14	699.17

Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey

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EDITORIAL by Baskin and Gross

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STUDY QUESTION

What was the prevalence of inappropriate authorship (honorary and ghost authors) in articles published in six leading general medical journals in 2008?

SUMMARY ANSWER

21% of articles published in these journals in 2008 had evidence of an inappropriate author, including 7.9% with a ghost author and 17.6% with an honorary author.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Inappropriate authorship is prevalent in a range of biomedical journals and types of articles, with some reports as high as 39% for honorary authors. This study shows that inappropriate authorship remains a problem, but the more serious ghost authorship may be declining.

Participants and setting

An international sample of corresponding authors of 896 research articles, review articles, and editorial or opinion articles published in six general medical journals with high impact factors in 2008: *Annals of Internal Medicine*, *JAMA*, *Lancet*, *Nature Medicine*, *New England Journal of Medicine*, and *PLoS Medicine*.

Design

Cross sectional survey of journal authors using a web based questionnaire. Reported prevalence of inappropriate authorship was compared with that measured in a 1996 survey that used an identical questionnaire.

Primary outcomes

Self reported compliance with International Committee of Medical Journal Editors (ICMJE) criteria for authorship for all authors on the selected articles, and a comparison with results in 1996.

Main results and the role of chance

630 corresponding authors responded to the survey (70.3%). The prevalence of articles with honorary

authorship or ghost authorship, or both, was 21.0%. This represents a significant decline in prevalence from that reported in the 1996 study (29.2%). Of the 545 authors with useable data on honorary authorship, 17.6% met criteria for honorary authorship, which was not significantly different from that reported in 1996 (19.3%). The prevalence of honorary authors for research articles was significantly higher compared with 1996 (25.0% v 16.3%), whereas it was significantly lower for review articles (15.0% v 25.5%) and editorials (11.2% v 20.8%). Among the 622 authors with useable data on ghost authorship, 7.9% of the articles met criteria for ghost authorship, which was significantly lower than in 1996 (11.5%). The prevalence of ghost authors was not statistically significantly different by article type between 2008 and 1996.

Bias, confounding, and other reasons for caution

The analyses are based on self reported data from corresponding authors. Some under-reporting of honorary and ghost authors may be expected, based on social desirability bias, even though respondents were assured of the confidentiality of their survey responses. Corresponding authors may not have accurately recalled their or their co-authors' activities and contributions to a particular publication. Finally, we used ICMJE authorship criteria to define honorary and ghost authors. These criteria might not have been widely known or followed by the authors who participated in our study, although these criteria are used by more than 600 biomedical journals, including the journals in this study.

Generalisability to other populations

Because only six general biomedical journals with high impact factors were included, these results may not be generalisable to other medical journals.

Study funding/potential competing interests

At the time this research was conducted, all authors were employed as editors of *JAMA*, one of the journals included in this study. All costs of the study were met by *JAMA*.

Prevalence of honorary and ghost authors in articles published in six general medical journals in 2008, by article type

Article type	Honorary authors		Ghost authors	
	No of articles	% (95% CI) of articles	No of articles	% (95% CI) of articles
Research	55/220	25.0 (19.7 to 31.1)	27/226	11.9 (8.3 to 16.9)
Reviews	18/120	15.0 (9.6 to 22.6)	8/134	6.0 (2.9 to 11.5)
Editorials	23/205	11.2 (7.5 to 16.3)	14/262	5.3 (3.1 to 8.8)
Total	96/545	17.6 (14.6 to 21.0)	49/622	7.9 (6.0 to 10.3)

*Honorary author analyses based on 545 articles with usable data; ghost author analyses based on 622 articles with usable data.