The design and updated results of Intersalt may still fail to convince sceptics of a causal relation between salt intake and blood pressure, and some of the difficulties in demonstrating an association should therefore be emphasised. These include the measurement of salt intake, which is notoriously inaccurate for individuals, and the range of variation, which may be too narrow within a population compared with the large variation between individuals. The Intersalt study does not have the perfect design to overcome these difficulties, and on its own it cannot answer the question as to whether high salt intake causes high blood pressure. But until someone sets up a 30 year longitudinal study to monitor sodium chloride intake and blood pressure prospectively in a sufficiently large population, this hybrid cross sectional, within population and cross population, ecological study is likely to be the only feasible epidemiological design.

The updated version of Intersalt provides robust results that are in concert with other studies, including experiments on animals and clinical trials.[7] A recent study on chimpanzees showed that adding 100 mmol of sodium a day to their food increased their systolic blood pressure by 12 mm Hg. Blood pressure rose further with further increases in sodium intake and fell when sodium supplementation was stopped.[8] The Intersalt results must be viewed in the context of such existing evidence suggesting a causal relation between salt intake and blood pressure. Whether the evidence is strong enough to warrant the reductions in salt recommended by the authors is, as always, a question of judgment. But useful clinical and public health actions have been undertaken on much weaker evidence.

DAG S THELLE
Professor

Centre for Epidemiologic Research,
Institute of Community Medicine,
University of Oslo,
Oslo N-0318, Norway

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Whose data are they anyway?

See pp 1249, 1253, 1254, 1255

Raw data from research on patients should be available, anonymised, to whoever wants them

> "I like taking part in studies because it's for the greater good, like giving blood."[1]

As reports of medical research show, there are almost no limits to what patients will put up with if they believe that their actions may benefit others. Seemingly, no questionnaire is too probing, no programme of clinic visits and tests too gruelling, and no drug too vile to stop patients volunteering for research.

Yet much of their goodwill is wasted. Many more research projects are begun than are completed, many more projects are completed than are written up, and many more papers are written up than are published. Of those that are published many are of poor quality,[2] and few provide their raw data in a form that readers could use to check the authors' claims. Patients could justifiably argue that they are being sold short, given the inconvenience and risk that research often entails.

Access to raw data, and their interpretation, lie at the heart of the latest skirmish in the salt wars, which dominate this week's *BMJ*. The president of the Salt Institute argues that "the entire Intersalt database... must be made available in its entirety to independent third parties for a thorough re-evaluation."[3] Intersalt's researchers respond that they have done the further analyses suggested by the Salt Institute only to see the results either misused or ignored.[4]

Intersalt has hardly been sparing with its data: an appendix accompanying the original paper gave 27 columns of data for each of the 52 population samples. Subsequently, an issue of the *Journal of Hypertension* devoted to the study carried 38 appendix tables, with 20 columns of data each. Further data have been published in peer reviewed journals. In addition, Intersalt researchers have said they are willing to do any scientifically sound and practically feasible further analyses proposed by the Salt Institute.

But what they will not do is hand over the raw Intersalt data. "As is customary in scientific investigation, raw data on individuals remain the confidential property of local investigators, in this case the 52 investigators in 32 countries."[4] Their justification is "the need to preserve the independence of scientific investigation, the integrity of the data, and the confidentiality of information on individuals."[5]

It is time for the customs to change if these are the strongest arguments that can be mustered in their support. Firstly, truly independent scientific investigation does not exist. The best we can hope for is for authors to be explicit about their methods and candid about any other relevant interests—thus alerting us to possible biases. Secondly, data have no intrinsic integrity of their own, such that sharing them with someone else might lead to their corruption. Undoubtedly, misuse of data is one of the downsides of sharing, but it is a price worth paying. And as long as avenues exist for criticising subsequent analyses that are seriously flawed then no lasting harm need result.

Researchers should share

The need to maintain the confidentiality of individuals seems the strongest justification, but there's a way round that too. When patients are recruited into studies their consent should be obtained for the sharing of their data with other researchers. Researchers should go one step further—and guarantee to participants that they will make available anonymised data to anyone who asks for it, after they have published their main results. Patients should demand this guarantee as a condition of their participation.

Compelling arguments exist for sharing data; George Davey Smith listed several in a recent BMJ editorial (see box).[6] To facilitate the process grant giving bodies could make funding conditional on willingness to share data. Clearing houses for shared data could be set up, thereby reducing the burden on primary researchers. Searchable registers of active and completed projects would help. Ethics committees could insist that protocols allow for data sharing, meaning that unpalatable findings could still see the light of day even if the original

Arguments for sharing data[6]

- Using existing data to answer questions not directly addressed by the primary researchers is an efficient use of resources
- Replicating findings from one study within other datasets increases their robustness
- In planning a study data from earlier studies can help to formulate the research question, refine measurement instruments, and calculate sample sizes
- New datasets can be created through linkage of different sets of records on the same people
- It facilitates meta-analyses that combine data on individual patients
- Other researchers can check whether conclusions are justified
- Access to the original data from published studies makes fraud more difficult

researchers do not submit them for formal publication. The problems of publication bias would recede.

Medical journals also have a role. Some, such as the *American Journal of Public Health*, stipulate that data should be available to the editors and interested researchers. But the infinite capacity of the Internet allows us to go much further. Constraints on space no longer exist, and electronic files containing a study's raw data can be linked to the electronic version of the paper, guaranteeing its availability to subsequent researchers, whatever their aims. The *BMJ* welcomes the inclusion of such files with submissions (providing subjects have given their consent). We would also welcome researchers' views on how this facility might develop and whether inclusion of such files should become obligatory. Prudent researchers will start obtaining their patients' consent for data sharing now.

Many different interests are at stake in clinical research: a recently published book on the topic, *A Decent Proposal*, lists future patients, present patients, clinicians, research subjects, purchasers of health care, sponsors of research, health research institutions, and individual researchers.[7] Given the authors' claim that "conflicts of interest are not merely possible but pretty well inevitable," whose interests should we be most concerned to protect in medical research? The authors come down unequivocally on the side of the research subject. "This view is so widely accepted in modern Western medical practice, so well grounded in modern Western liberal thought, and moreover so firmly established at the heart of the whole institution of ethical review of clinical research, that we shall state it here without further justification."

If we give priority to the interests of the research subject then answering the question of how widely their data should be shared is easy. Patients volunteer for research because they want to benefit others. It is in their interests for the usefulness of their contribution to be maximised. Data sharing, rather than data hoarding, achieves this goal.

TONY DELAMOTHE
Deputy editor, *BMJ*

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Melatonin

See pp 1263

Claims made in the popular media are mostly nonsense

Melatonin, the hormone of the pineal gland, is currently the subject of much ill informed publicity and speculation in the entertainment media worldwide. Several books on the subject have made grossly exaggerated claims for its value, portraying it as a panacea and as an "anti-aging" treatment.[1 2] These claims are distortions of current knowledge of the physiological functions of melatonin and of its therapeutic potential.

What is known can be summarised briefly. Melatonin is normally made at night and may be considered to act as a signal of darkness to the body. In all life forms so far studied it seems to act as a time signal for the organisation of daily (circadian; sleep-wake) or seasonal rhythms, or both.[3] Melatonin seems to play an important part in setting the correct timing of sleep-wake cycles in mammals in the perinatal period and of subsequent pubertal development. When given to humans it has rapid, transient, mild, sleep inducing effects,[4] and it lowers alertness, body temperature and performance during the three or four hours after low doses have been given.[5 6] Correctly timed, it is able to shift the internal "body clock" both to later and earlier times,[3 7] and so melatonin has a potential value as a treatment for problems with sleep and other body functions that have been disordered by time effects.

The common ways in which time rhythms are upset include long distance air travel, shift work, and certain types of insomnia. Some blind people cannot maintain a 24 hour rhythm of sleep and waking.[3 8] Even normal healthy people may show a tendency for the internal clock to delay, telling them to sleep later than is socially and professionally desirable. Some authors have described a "melatonin deficiency" syndrome related to poor sleep in old age, but whether this is specific or simply related to declining circadian function is debatable.[9] Serum concentrations of melatonin can (albeit rarely) be very low in young, healthy, adults.[3] The timing of treatment with melatonin can be predicted when body clock time is known, and to some extent this may be judged by the habitual time of going to sleep and the duration of sleep. Optimal timing is not so simple after travel across time zones and in shift workers—and mistiming the dose might be expected to lead to major problems of alertness. Nevertheless, there is substantial published evidence showing that a carefully timed dose of melatonin can improve both the subjective and objective symptoms of jet lag.[10] The only serious side effect reported has been sleepiness after the dose. An improvement in daytime sleep and night time alertness was shown in simulated night shift work and in two small field studies.[10] Much more research is required, especially on work related performance.

No objective measures of success

Melatonin has also proved quite useful in disturbed sleep-wake cycles in visually impaired people, in the delayed sleep phase syndrome, in multiply disabled children,[3] and apparently in insomnia of the elderly.[11] It may improve the sleep quality of some normal healthy adults. For none of these conditions or indications have large trials been reported, and polysomnography has given inconsistent results, so that there