LETTERS TO THE EDITOR

Assessment of the SF-36 version 2 in the United Kingdom

EDITOR,—I read with interest the recent article detailing changes to the format of the SF-36.¹ The authors present data regarding the psychometric properties and epidemiological characteristics of the SF-36 version 2. The authors present the results from a large data sample of people aged 18-64. The analysis reveals that the questionnaire has good internal consistency and construct validity. The layout of the new questionnaire is certainly improved and in this respect I think that participants will find it easier to complete. However, I believe that many of the problems that were inherent in the original version have not been resolved. The validity and reliability of the questionnaire relies in part upon users completing it accurately. Any change in the questionnaire's format should be designed to improve the accuracy of users responses, which will in turn improve the psychometric qualities of the questionnaire. The authors concede that the present data are only based upon people of working age and so it remains unclear how suitable this measure is for older age groups. They suggest that further research is needed to determine how applicable the SF-36 is for this age group.

In my personal experience I would suggest that the SF-36 is not a suitable measure to use with older age groups. The main shortcoming with the questionnaire is not the layout but rather the language of the questions. I would be grateful for an opportunity to draw your attention to my experience of using this tool as an outcome measure with a large group of surgical patients. I have used the SF-36 with approximately 200 patients who were recruited to examine the effects of different vascular surgery procedures on quality of life and cognitive function. Patients were assessed before their operation and six months later. Quality of life was assessed using the SF-36 and the Hospital Anxiety and Depression Scale (HAD). The HAD scale is widely referred to in the psychiatric literature (reported sensitivity = 72-88% and specificity = 68-94%).²⁻⁴ The patients in the first study were undergoing carotid endarterectomy (CEA), which is a prophylactic procedure carried out to reduce the risk of stroke. The second study examined the effects abdominal aortic aneurysm repair (AAA) on quality of life. The average age of patients in the two studies was 69 and 73 respectively.

It became evident very quickly that some patients failed to understand the questionnaire and completed it incorrectly. Patients were supervised when they completed the form. If I believed that a patient had misinterpreted a question then I would stop them and re-read the question to them and also read out each response option (for example, all of the time, most of the time, etc). If the patient then said that they under-

stood the question they would be left to complete the rest of it. I noted down any occasion when a patient changed their mind regarding their response after I had re-read the question.

Problems were most commonly encountered with the following questions.

Question 3 The following questions are about activities that you might do during a typical day. Does your health limit you in these activities? If so, how much?

Yes, limited a lot Yes, limited a little
No, not limited at all

Some patients misunderstood the concept of health limiting their physical activity. This may be because they misread the question or simply didn't understand it. Commonly, relatively elderly patients would read "3a Vigorous activities such as running ..." and would tick "No, not limited at all". When I re-read the question to the patient they would typically respond "No, no I can't do that sort of thing". In this example 23% of patients went on to change their mind when the question was re-read. If left unchecked I suspect that many of these patients would have gone on to complete all 10 parts of question 3 incorrectly.

Question 5 During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

After answering 14 consecutive questions regarding physical activity, many patients appeared to find it difficult to switch to thinking about emotional problems in question 5. Commonly patients reported that they thought questions 4 and 5 were the same and so they responded with the same answers. When the question was re-read, 19% of patients felt that their first response to the question was incorrect. Clearly it is difficult to judge given the nature of the question whether people were completing it correctly. Therefore the scores from this question were compared with patients' scores from the HAD scale. The scores from question 5 form the basis of the role functioning-emotional scale (RE). Patients' scores from this scale had a low correlation with the measures of anxiety and depression from the HAD scale (anxiety $r = -0.27$, depression $r = -0.26$). A strong association between scores on the RE scale and the mental health scale (MH) ($r = 0.60$) has been reported.⁵ In the total sample reported here ($n=208$) this correlation was much lower ($r=0.35$).

Question 9 The following questions are about how you feel and about how things have been with you during the past month

Some patients also had difficulties interpreting question 9 and in particular they appeared to find the Likert scale hard to use. (I note that Likert scales are used more frequently in the revised version). Some patients appeared to re-code the scale as "bad" to "good" rather than "All of the time" to "None of the time". For example a patient may respond "None of the time" to questions 9b and c regarding feelings of anxiety and depression. Further down the questionnaire they would respond "None of the time" again to 9h "Have you been a happy person?" while saying "Yes I am a happy person". When the question was re-read, many patients changed their original response and felt that they had made a mistake.

The observations reported here are little more than anecdotal. My method of record-

ing errors was arbitrary. Indeed my method of re-reading questions to patients when I considered that they had made a mistake could be criticised for biasing patients' responses. However, when I started using the SF-36 I quickly became convinced that many patients were failing to understand the questions. I believe that version 2 has not resolved the shortcomings that were inherent in the original version. As it stands I believe that the SF-36 should not be used as an assessment of quality of life in older patients. Investigators should also be cautious about using the tool with any patients who have evidence of head injuries, cognitive impairments or communication problems.

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Reply

We have some sympathy with the views expressed by Dr Lloyd, and have indeed written regularly on the issues of questionnaire selection.^{1,2} Measures should be selected for inclusion in studies because evidence is available to support their use, or because the study is designed to assess a given measure with a specific population. We would agree that caution is required when using any version of the SF-36 in older age groups because of the fact that an, albeit fairly limited, body of evidence has emerged that suggests the measure may be inappropriate. However, while caution should be the watch word when it comes to selection and interpretation of measures, we would also advise readers not to readily dismiss the SF-36 for older adults. Dr Lloyd's letter raises the issue in a rather speculative and, as he himself remarks, a rather anecdotal fashion. Two criticisms could be raised against his concerns, one related to the manner in which his research was conducted and another concerning the properties of scales, rather than items.

Firstly, Dr Lloyd remarks that he has used the SF-36 in studies in which he has re-read parts of the form to elderly patients because he believed they had misunderstood or misinterpreted questions. As he himself points out such treatment of patients could influence their responses, (for example they may change their answers because they thought they had got the question wrong in some way). He remarks that while some people may criticise him for biasing patient responses he only did so because he quickly became aware that many questions were misunderstood by patients. Such a view should be supported by evidence. Many people have

offered such criticisms of the SF-36 but have produced scarce scientific proof to support their claims. Claims that the measure is inappropriate for the elderly are more often than not based upon little more than anecdotes, rather than rigorously conducted qualitative studies.

Secondly, Dr Lloyd suggests that there will be errors in the answers provided by older respondents to the questions on the SF36. This is not particularly surprising and is to be expected with all age groups. All questionnaire items consist of true measurement plus an error term. The trick is to reduce the error term as much as is possible. This is why health status measurement has for the most part adopted multi-item scales. If we take more than one item to measure the same underlying attribute then the summed score of all the items will be more reliable than a single question. This is because all true measurement from each item will be summed, while error terms on all the items will be random and, effectively, non-additive (the logic here is that for every person who scores a little high on a given item there will be someone who scores a little low, and so on). This, of course, assumes that items have been selected carefully and are neither unrelated or too closely related; an assumption that is implicitly built into the SF-36.

Recent data report on the successful use of the SF-36 in older patients in a large scale survey. Normative data are available.³ This evidence would seem to suggest the SF-36 is useful in this patient group, but specific research must investigate this issue. In a world that now embraces evidence based medicine it might be wise to adopt a similarly rigorous approach to questionnaire selection and application.

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Mortality in poorer areas

EDITOR,—Law and Morris state that “about 85% of the overall excess mortality with deprivation was attributable to heavier smoking” in their study of deaths in England and Wales in 1992.¹ They correctly state that strengths of their study include allowing for the generally higher tar yield and number of cigarettes smoked by lower socioeconomic smokers, and the generally younger age of starting smoking for lower socioeconomic people. They also offer the plausible argument that cohort studies may be biased against finding a substantial role for smoking as an intermediary between lower socioeconomic status and mortality, because people recorded as non-smokers in a cohort study may actually have recently stopped smoking because of the early symp-

toms of smoking related disease. An ecological study will avoid this latter bias in part.

However, there are problems with the ecological study of Law and Morris that suggest the figure of 85% is likely to be a substantial overestimate. Firstly, the median local authority district size of 102 000 is large for a study that is attempting to “ecologically infer” the relation of deprivation and smoking with mortality. Greenland and colleagues have shown that the larger the size of the study unit in ecological studies, the more likely that cross level bias (the “ecological fallacy”) will cause error in the inferred relations at the individual level.²⁻⁵ The direction and magnitude of the cross level bias is impossible to predict from the ecological data alone, but is often biased away from the null. Secondly, and a component of the previous reason, both the predicted and observed relative risks used by Morris and Law will be confounded by other lifestyle factors, resulting in an overestimate of the contribution of smoking. Thirdly, the external source of the relative risk data for smoking,⁶ while a highly reputable study, was based on a cohort of male doctors and may not be generalisable to the total population of England and Wales. This lack of generalisability would arise if, as would be expected, non-smoking doctors had a lower mortality rate than non-smoking members of the population generally because of a favourable profile of other risk factors. This in turn could result in higher relative risks of smoking being observed among doctors than non-doctors.

Yes, smoking is undoubtedly an intermediate variable between deprivation and mortality. But I doubt that if, in the counterfactual, none of the population alive in England and Wales at 1992 had ever smoked (or even just that there was no variation by deprivation in smoking) that as much as 85% of the inequality in mortality by deprivation would have been removed.

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- 1 Law M, Morris J. Why is mortality higher in poorer areas and in more northern areas of England and Wales? *J Epidemiol Community Health* 1998;52:344–52.
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Reply

We concluded in our paper that all cause mortality was 15% higher in the most deprived compared with the least deprived districts, and that heavier smoking accounted for most (about 85%) of this excess mortality.¹ We disagree with Blakely that the figure of 85% is likely to be a substantial overestimate. Statistical calculations are not necessary to see that smoking accounts for most of the excess mortality in the more deprived districts. One need only consider the specific causes of death that are more common in deprived districts (table 2 in our

paper¹); almost all of them are smoking related. Three diseases that are strongly smoking related (lung cancer, chronic bronchitis and emphysema, and ischaemic heart disease) accounted for two thirds of the excess mortality, and other smoking related cancers and circulatory diseases accounted for a further sixth of the excess. Diseases reflecting other behavioural differences (cirrhosis of the liver, AIDS), or differences in medical care, accounted for little of the total excess mortality, while two important aetiological factors in circulatory diseases, serum cholesterol and blood pressure, show little difference between deprived and affluent districts (see references 37–39 in our paper¹).

Blakely has three concerns about our smoking analysis. We do not think the “ecological fallacy” of Greenland and colleagues (which may produce a bias in either direction) is a material problem in this context, particularly as we are not inferring relations at the individual level. Exaggeration of relations between smoking and diseases through confounding is unlikely. Asbestos and other occupational exposures that cause lung cancer may be more common in smokers, but these exposures cause relatively few lung cancer cases in relatively few districts. Associations between smoking and other heart disease risk factors tend to be weak, and as stated above, blood pressure and serum cholesterol show little variation between affluent and deprived districts. Blakely suggests that relative risk estimates from the British Doctors Study are not generalisable. The results of the British Doctors Study in relation to smoking have in general been supported quantitatively by other large cohort studies, and we confirmed this for ischaemic heart disease.² Moreover one would expect estimates of relative risk to be generalisable: the proportionate increase in risk in smokers should be the same in populations where smoking is relatively common or uncommon or where, for reasons other than smoking, the disease is relatively common or uncommon.

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Bayesian analysis

EDITOR,—We are delighted to see your journal publish an excellent paper showing by example how a statistical analysis that has run into difficulties can be converted into a Bayesian analysis and thus rescued.¹

Burton *et al*¹ state that a 95% confidence interval can be interpreted as a 95% Bayesian credible interval (also known as a posterior probability interval), thus allowing the interpretation that the true hypothesis is 95% certain to lie within the interval, provided that the design admits “a uniform prior distribution for the main outcome measure”. Lindley² is cited as the theoretical justification for this assertion.

We would like to add some caveats, without which the assertion is not strictly correct. These caveats are uncontroversial in Bayesian theory and are supported by Lindley and, presumably, Burton *et al.* We hope that it will be helpful if we make them explicit.

The result of a standard analysis cannot be interpreted as a Bayesian result if the analysis has incorporated any of the following elements:

- Bonferroni corrections or other adjustments to error levels
- analyses that are mathematically multivariate even though there is a univariate main outcome measure—for example, standard methods for analysing clinical trials with interim analyses
- analyses that ignore sources of variance—for example, common methods of evaluating survey data that take into account sampling variation but not measurement error
- conditional designs that violate the likelihood principle³ by adjusting the result of any part of an analysis on the grounds that another analysis was either planned or carried out—for example, clinical trials again
- test statistics chosen for their frequentist properties—for example, unbiased statistics used in preference to more natural or more powerful biased statistics

It can be seen from this list that the design of Bayesian studies can be markedly different from the more common frequentist designs. A major benefit of Bayesian theory to the practising epidemiologist is the fact that Bayesian designs can be vastly more flexible. For example, in a Bayesian design conservatism in combining multiple results is built in to the model and does not have to be adjusted according to the number of analyses.^{4–6}

In summary, there are many cases in which Bayesian theory can be used to provide a fruitful alternative interpretation to a standard calculation, as Burton *et al.* suggest; but there are other cases in which a Bayesian analysis yields not only a different interpretation but also a different design and different numbers.

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Reply

We thank Dr Grossman and Dr Parmar for their positive comments. Their letter provides

a valuable addendum to our original paper¹ and, as they assumed, we concur completely with what they have written.

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Bracken fern consumption and human bladder cancer

EDITOR,—In a recently published paper, Wilson *et al*¹ reviewed four studies that explored the relation between bracken and human health: a case-control study of gastric cancer in North Wales; a cohort study of oesophageal cancer in Japan; an ecological study in North Wales that compared standardised mortality and incidence rates for gastric and oesophageal cancer in 34 districts with survey maps of bracken areas; and an ecological study in Costa Rica that compared age specific incidence rates for gastric, oesophageal, and cervical cancer among people born in bracken free compared with bracken infested areas. Although some weak associations were noted in these studies, Wilson *et al* felt that statistical analyses were limited and that little evidence exists for a carcinogenic hazard from bracken.

We would like to call attention to the results of our case-control study that assessed the risk of bladder cancer from bracken fern consumption.² Bracken has been shown to be carcinogenic in experimental and observational animal studies, producing bladder tumours in guinea pigs and cattle.^{3–5} Our study was conducted in northern New England to determine reasons for the high bladder cancer mortality rates in this area.

The study included all white residents of Vermont and New Hampshire who died during 1975–79 from bladder cancer. Two randomly selected controls per case, matched on state, gender, race, age (± 2 years) and year of death, were randomly selected from all other resident deaths (excluding suicides). A questionnaire sought information on demographic characteristics, lifetime occupational and residential histories, history of tobacco and beverage use, medical history including bladder infection, and consumption of selected dietary items including bracken fern (fiddlehead greens). Interviews were conducted with the next of kin of 325 cases and 673 controls. Odds ratios (OR) were calculated using both conditional and unconditional logistic regression. As both methods yielded similar results, the unconditional results were presented. A total of 24 cases (7.4%) and 71 controls (10.6%) were reported to have ever eaten bracken fern (OR=0.6, 95% confidence intervals (CI)=0.4, 1.0). Regular consumption of bracken fern was reported for 15 cases (4.6%) and 38 controls (5.6%), OR=0.8 (CI=0.4, 1.4). Our negative findings are consistent with a Canadian population-based case-control study of 480 male and 152 female case-control pairs that showed no excess bladder cancer risk associated with consumption of fiddlehead greens.⁶ These studies provide further support for the conclusions of Wilson *et al*¹ that bracken

poses no serious health threat to exposed populations.

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Reply

We thank Brown *et al* for their helpful letter in response to our paper about the possible effects of bracken upon human health.¹

Although we were aware of, and commented upon bracken consumption by people in Japan and South America, we were not aware that bracken, in the form of “fiddlehead greens” was eaten by some of the population of New England. Most studies of possible associations between cancers in humans and bracken have looked only at the risk of stomach and oesophageal cancers.^{2–5} Therefore, the case-control study by Brown *et al* is particularly valuable and does indeed strengthen the evidence that consumption of bracken may not pose a serious threat to human health.

However, within the United Kingdom, the commonest human exposure to bracken is via possible inhalation and ingestion of spores, not through consumption of the plant as a foodstuff. We were unable to find any studies attempting to explore the relation between this exposure and human health effects. Such studies in populations who repeatedly work among bracken during the sporing season would be especially pertinent.

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Human rights—a public health issue?

The year 1998 was important as it helped us to make a clear connection between two key global issues—human rights and public health. The two anniversaries, the 150th anniversary of the enactment in the UK of the first ever national Public Health Act in 1848, and the 50th anniversary of the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948, add further momentum to the implicit connection. An added bonus was the UK government’s decision to incorporate the European Convention of Human Rights into the UK law, thereby increasing the utility of the Convention for UK citizens. In the United Kingdom the Medical Foundation, whose patrons include Sir Richard Doll, has given the connection between human rights and public health a new vigour through its advocacy and pastoral work in the field.

The chains linking public health and human rights are the Covenant on Civil and Political Rights and the Covenant on Economic, Social and Cultural Rights. These covenants lay the main foundations of the Universal Declaration.

The first covenant details the basic civil and political rights of individuals and nations. This covenant provides for the following rights for nations:

- the right to self determination
- the right to own, trade and dispose of their property freely and not deprived of their means of subsistence.

The same covenant also attaches a number of rights to individuals:

- freedom of opinion and expression
- freedom of thought, conscience and religion
- freedom of assembly and association
- the right to privacy and right to protection of that privacy by law
- the right to liberty and freedom of movement
- the right to legal recourse when their rights have been violated, even if the violator was acting in an official capacity
- the right to presumption of innocence until proven guilty
- the right to appeal a conviction

The covenant forbids torture and inhuman and degrading treatment, slavery or involuntary servitude, arbitrary arrest and detention. It further forbids propaganda, advocating either war or hatred based on race, religion, national origin or language.

The covenant also provides for the right of people to choose freely whom they will marry and with whom they will found a family, and requires that duties and obligations of marriage and family be equally shared between partners. It also guarantees the rights of children and prohibits discrimination based on race, sex, colour, national origin or language.

As well as restricting the death penalty to the most serious of crimes, the covenant also guarantees condemned people the right to appeal for commutation to a lesser penalty and forbids the death penalty entirely for people under 18 years of age.

The covenant permits governments to temporarily suspend some of these rights in cases of civil emergency only, but also lists those rights that cannot be suspended for any reason.

The second covenant describes the basic economic, social and cultural rights of individuals and nations, including the right to:

- self determination
- wages sufficient to support a minimum standard of living
- equal pay for equal work
- form trade unions
- strike
- paid or otherwise compensated maternity leave
- free primary education and accessible education at all levels
- copyright, patent and trademark protection for intellectual property.

In addition, this convention forbids exploitation of children and requires all nations to cooperate to end world hunger. Each nation that has ratified this convention is required to submit annual reports on its progress in providing these rights to the Secretary General of the United Nations, who is to transmit them to the Economic and Social Council of the United Nations.

The two covenants implicitly recognise and reinforce the World Health Organisation’s Charter on health. Human health at a global level can only be effectively sustained if individuals within nations have certain enshrined rights that enable them to shape the outcomes of the key decisions that affect resource use and allocation within and between nation states.

The Universal Declaration of Human Rights needs champions within nations, both to keep the Declaration in the public eye and to assist individuals whose rights as defined by the Declaration have been breached or violated. There are many such organisations based in a number of countries. The Medical Foundation is one such body, and is prominent in the UK. The main focus of the Foundation’s work is campaigning on behalf of victims of torture. The Foundation also meets the immediate care needs of victims of torture.

The Foundation’s work is likely to acquire an added significance now that there is widespread support for the setting up of an International Criminal Court. It is proposed that the Court be a permanent tribunal with universal jurisdiction over individuals responsible for systematic violations of human rights. It is argued with force that the creation of a judicial institution is crucial to the struggle against the culture of impunity that is prevalent throughout the world. By designating massive and systematic violations of human rights as crimes and effectively prosecuting the violators, the international community would show its resolve to uphold justice and the rule of law as the foundation of peace and security. So far 74 states have signed the Rome Statute Signature and Ratification Chart, however it needs 60 states to ratify the Statute for the Court to be set. So far only one state, Senegal, has ratified the Statute. It is vital that internationally the public health movement persuades more nations to ratify the statute to enable the Court to become operational.

Public health practitioners have a vested interest in supporting the work of bodies such as the Medical Foundation, as they help to remind us that the twin goals of health and human rights for all are attainable, the obstacle being us collectively. The human rights agenda is vital for public health practitioners. It is too important for us to ignore it.