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(Accepted 4 February 1998)

## Screening for human T cell leukaemia/lymphoma virus among blood donors in Sweden: cost effectiveness analysis

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### Abstract

**Objective:** To analyse the cost effectiveness of a national programme to screen blood donors for infection with the human T cell leukaemia/lymphoma virus.

**Design:** Three models for calculating the costs and benefits of screening were developed. The first model analysed the cost of continuously testing all donations; the second analysed the cost of initially testing new blood donors and then retesting them after five years; the third analysed the cost of testing donors only at the time of their first donation. Patients who had received blood components from donors confirmed to be infected with the virus were offered testing.

**Setting:** Sweden.

**Main outcome measures:** Prevalence of infection with the virus among blood donors, the risk of transmission of the virus, screening costs, and the outcome of infection.

**Results:** 648 497 donations were tested for the virus; 1625 samples tested positive by enzyme linked immunosorbent assay. 6 were confirmed positive by western blotting. The prevalence of infection with the virus was 2/100 000 donors. 35 patients who had received blood infected with the virus were tested; 3 were positive. The cost of testing every donation was calculated to be \$3.02m (£1.88m); this is 18 times higher than the cost of testing new donors only, and only 1 additional positive donor would be discovered in 7 years. Regardless of the model used, screening was estimated to prevent only 1 death every 200 years at a minimum cost of \$36m (£22.5m).

**Conclusion:** Based on these estimates the Swedish National Board of Health and Welfare decided that only new blood donors would be screened for infection with the virus.

### Introduction

Human T cell leukaemia/lymphoma viruses types I and II were identified in the early 1980s<sup>1,2</sup>; serological tests for these retroviruses became available in 1986.<sup>3</sup>

Infection with the virus is associated with tropical spastic paraparesis,<sup>4</sup> adult T cell leukaemia/lymphoma, and some inflammatory disorders.<sup>5,6</sup> The virus is primarily sexually transmitted,<sup>7</sup> but it may also be transmitted from mother to child either perinatally<sup>7</sup> or through breast feeding.<sup>8,9</sup> The virus may also be transmitted through blood transfusions.<sup>10</sup>

Japan began screening blood donors for infection with the virus in 1986.<sup>11</sup> Similar screening was introduced in the United States in 1988 and in France in 1991. Screening also occurs in Canada, Holland, Australia, Finland, Denmark, Portugal, Greece, and Luxemburg.

In Sweden, after a pilot screening of blood donors in 1993 the National Board for Health and Welfare decided to test all blood donations for one year starting in March 1994. We present an analysis of the cost effectiveness of this screening programme.

### Subjects and methods

**Blood donation**—National data on blood donors and donation practices were obtained from the Swedish Society for Transfusion Medicine and the National Board for Health and Welfare. Before registering for their first blood donation potential donors complete a written questionnaire and are interviewed to assess possible risk factors for infectious diseases. All blood donations are tested for HIV, and hepatitis B and C; only the first donation is tested for syphilis.

**Recipients of transfusions**—There are no detailed national data on the recipients of blood transfusions. A pilot study was done at the blood bank at South Hospital which serves several other hospitals in the region. Data on 255 randomly selected patients who had received blood components during February 1992 were collected; this data included the age of the patient, survival time after transfusion, and which blood components were received.

**National screening programme**—In March 1994, a national one year programme to screen every blood and plasma donation for the human T cell leukaemia/lymphoma virus was launched. Screening tests were performed at blood banks, local microbiological

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BMJ 1998;316:1417-22

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laboratories, or regional virological laboratories. Commercially available enzyme linked immunosorbent assays were used. The assays were performed according to the manufacturer's instructions. Positive tests were confirmed by western blotting, according to guidelines issued by the World Health Organisation and the HTLV European Research Network.<sup>12, 13</sup> Western blotting was performed in regional virological laboratories or at the Swedish Institute for Infectious Disease Control. All laboratories used Diagnostic Biotechnology HTLV-blot 2.3 (Diagnostic Biotechnology, Science Park, Singapore) for confirmation. For a test to be classed as positive by western blotting, two envelope bands and at least one core band had to be positive. Any other reactivity was classified as indeterminate. All except one of the samples that tested positive by western blotting and several of those classed as indeterminate were also tested by polymerase chain reaction at the Swedish Institute for Infectious Disease Control.<sup>14</sup> Blood from donors with two samples that tested positive by enzyme linked immunosorbent assay was not used even when the tests were not confirmed by western blotting. Donors whose samples were confirmed as positive were informed at the blood bank and referred to a specialist in infectious diseases. The total number of screening tests performed and the number of those with positive results were reported to the Swedish Institute for Infectious Disease Control.

**Retrospective study**—A decision to trace patients who had received blood components from donors confirmed to be infected with the virus was taken by the National Board for Health and Welfare in 1994. Patients who had received such transfusions were contacted and offered testing. This retrospective study was possible because the blood banks keep records not only of all donors and recipients of blood components but also because we had access to the national census file on all living and recently deceased Swedish citizens.

**Cost effectiveness analysis**—Cost effectiveness analyses were used to estimate the costs of screening under three different models. The calculation of costs included actual laboratory costs for the screening and necessary confirmation procedures. Costs of the sociopsychological effects of the screening and for counselling donors who had positive or indeterminate test results were not quantified and are not included in the calculations. The calculation of the benefits of

screening (in terms of the morbidity and mortality that were prevented) were based on estimated risks of transmission, disease, and the survival rates of patients in our pilot study who had received transfusions. Transmission risks were estimated from published information<sup>15, 16</sup> and our own retrospective study. The risk of developing the disease and the risk of dying as a result of being infected with the virus were estimated from limited published information.<sup>15</sup>

## Results

### *Blood donations and transfusions*

About 235 000 people donated blood or plasma during 1994; this total included about 34 000 new donors. Blood donors provide an average of 1.88 donations each year for 10 years. During 1994 they donated 444 000 units of whole blood and 209 000 kg of plasma for fractionation; these donations accounted for 522 000 transfusions of erythrocyte concentrates, platelet concentrates, and plasma units. One donation was equivalent to 1.18 transfusions. The data from the pilot study in South Hospital were in accordance with the overall profile in Sweden (one donation was equivalent to 1.23 transfusions).

### *Recipients of transfusions*

The 255 patients who had received transfusions in the pilot study in the Stockholm area had a median age of 70 years; 34 (13%) were younger than 40. The patients received from 1 to 15 units (mean 2.5) during the month of the study. A total of 492 (78%) out of 635 units transfused were erythrocyte concentrates, 21 (3%) were platelets, and 122 (19%) were plasma. The survival rate of all patients who received transfusions was 67% (172/255) at 1 year and 49% (125/255) at 3 years. One out of 10 patients was both younger than 40 and survived for at least 3 years and we therefore assumed that they had a possible life expectancy of more than 30 years.

### *Screening programme*

A total of 648 497 donations were screened for the virus; 1625 (0.25%) samples tested positive by enzyme linked immunosorbent assay. Six donors were confirmed as positive by western blotting; all had the type I profile. Five of these donors were confirmed positive by polymerase chain reaction. About half of the samples that initially tested positive had indeterminate profiles when tested by western blotting. In a subset of 571 samples that repeatedly tested positive by enzyme linked immunosorbent assay 280 (49%) were classed as indeterminate when western blotting was used. All of the 272 indeterminate samples later tested by polymerase chain reaction were negative. No donor was infected with type II virus.

One donor who tested positive had been detected during the pilot study; thus, seven potential donors (two men and five women) tested positive for the virus. The prevalence of infection with the virus among blood donors in Sweden was therefore 2/100 000. Three of the infected donors were of Swedish origin and had no risk factors that would have led to their exclusion from blood donation before testing. The remaining four were originally from Denmark, the

**Table 1** Test results of patients who received transfusions from donors who tested positive for human T cell leukaemia/lymphoma virus in Sweden

Blood donor	Year registered as blood donor	Transfusion recipients identified (No)	Transfusion recipients alive (No)	Test result (No)		
				Positive	Negative	Not tested
1	1985	19	13	0	10	3
2	1991	10	5	1	2	2
3*	1966	21	1	0	1	0
4	1990	6	3	1	2	0
5	1993	5	3	0	3	0
6†	1994	0	0	0	0	NA
7‡	1970	34	16	1	14	1
Total		95	41	3	32	6

NA=not applicable.

\*Only recipients younger than 65 and transfused after 1988 were traced.

†Discovered to be positive at time of first donation.

‡Discovered during pilot programme.

### Screening blood donors for human T cell leukaemia/lymphoma virus in Sweden

#### Donors

- Mean age: 35 years
- Number of new donors registering each year: 30 000
- Number of established donors: 270 000
- Mean number of donations by each donor each year: 1.9
- Mean period of donation: 10 years
- Mean number of transfusions from each donation: 1.2

#### Screening costs

- For enzyme linked immunosorbent assay: \$5.00 (£3.20)
- For confirmation by western blotting or polymerase chain reaction\*: \$300 (£188)

#### Infection with human T cell leukaemia/lymphoma virus

- Prevalence among new blood donors: 1.3/100 000
- Annual incidence†: 5 in 10 million
- Risk of transmission from infected blood: 15%
- Risk of developing adult T cell leukaemia/lymphoma after transfusion with infected blood: 2.5% after 30 years with 100% mortality
- Risk of developing tropical spastic paraparesis after transfusion with infected blood: 1% after 3 years, but 0% mortality

#### Recipients of transfusions

- Survival of all recipients after transfusion: 50% after 3 years, 14% after 30 years

\*Confirmation test required for 1 out of 400 positive enzyme linked immunosorbent assays

†Based on a prevalence of 1/100 000 among Swedish donors after a mean of 20 years of exposure before first donation

#### Cost effectiveness analysis

Three models were considered in the cost effectiveness analysis; they were assumed to have been implemented after all previously registered donors had been tested. The first model analysed the cost of continuously testing all donations; the second model analysed the cost of initially testing new blood donors and then retesting them after five years; and the third model analysed the cost of testing donors only at the time of their first donation.

The cost of testing every donation was 18 times higher than the cost of testing only new donors. The cost to prevent one transmission of the virus was 15 times higher when all donations were tested when compared to testing donors only at the time of their first donation. These estimates of the cost effectiveness of the three models are summarised in table 2.

Only one additional positive donor would be discovered every seven years when there is a change from the third model (only new donors tested) to the first model (testing all donations); this would cost an additional \$2.85m (£1.78m) each year. Testing all donations would prevent 0.24 (1.59–1.35) transmissions each year or one transmission every four years. Screening would prevent about one death in 200 years, irrespective of which model is used. Moving from the third model (only new donors tested) to the first model (testing all donations) would prevent one death every 13 years. The incremental costs would then be \$3.6bn (£2.25bn) for each death prevented. Moving from the third model (only new donors tested) to the second model (initial testing of new donors and then retesting them after five years) would incur additional incremental costs of about \$400m (£250m) for each death prevented.

United Kingdom, Iran, and Chile. The calculated prevalence for donors born in Europe was 1.3/100 000 and for donors born in Sweden 1/100 000.

#### Retrospective study

In total 95 patients were identified as having received blood components from the seven donors who tested positive. A total of 41 (43%) recipients were alive and 35 were available for testing. Three of them tested positive (table 1).

## Discussion

### Prevalence of infection

The prevalence found among blood donors in Sweden (2/100 000) was similar to that found in Denmark<sup>17</sup> and the Netherlands.<sup>18</sup> The slightly higher prevalence found in the United Kingdom (5/100 000<sup>19</sup>) and France (7/100 000<sup>20, 21</sup>) may reflect a higher proportion of donors who originally came from an endemic area, such as the Caribbean, or a greater likelihood of having

**Table 2** Estimated costs and benefits after the first year of three models of screening blood donors for human T cell leukaemia/lymphoma virus in Sweden. In the first model all donations were tested; in the second model only new donors were tested and then retested after 5 years; in the third model donors were only tested at the time of their first donation

	Model		
	Every donation tested	New donors tested and then retested after 5 years	Only new donors tested
Costs each year (\$ million)	3.02	0.32	0.17
Total costs (\$ million) for:			
Each positive donor identified	1.90	0.22	0.13
Each transmission prevented	5.59	0.70	0.44
Each case of disease prevented	222	25	15
Each death prevented	540	63	36
No of donors identified as positive each year*	0.54	0.46	0.39
No of events prevented each year:			
Transmission of the virus†	1.59	1.47	1.35
Cases of disease	0.0136	0.0126	0.0116
Deaths (incidence)	0.0056 (1/180 years)	0.0051 (1/195 years)	0.0047 (1/210 years)

\*Infected new donors (0.39) + newly infected old donors.

†No of donations prevented (including future donations) × transfusion/donation ratio × donors identified as positive × transmission risk.

a sexual partner from an endemic area. The prevalence rates among Europeans without obvious risk factors appear to be uniform at about 1 to 2/100 000. No donor of Swedish origin tested positive for infection with type II virus. In Europe, few donors have tested positive for infection with type II virus despite the relatively high prevalence of infection with type II among injecting drug users.<sup>13</sup> This is in contrast to a study in the United States where almost half of the donors who tested positive for human T cell leukaemia/lymphoma virus were infected with type II.<sup>22</sup>

#### Laboratory testing

We assumed that no donor infected with the virus escaped detection since enzyme linked immunosorbent assays have high sensitivity.<sup>23</sup> In our study, samples that were positive when tested by enzyme linked immunosorbent assay were tested by western blotting for confirmation. Samples that were positive by western blotting also tested positive by polymerase chain reaction. However, no samples that were classed as indeterminate by western blotting were positive when tested by polymerase chain reaction. This is consistent with previous studies that found that samples classed as indeterminate only occasionally tested positive by polymerase chain reaction.<sup>18 24 25</sup> False positive results with the enzyme linked immunosorbent assay were found in 1 out of 400 donors, giving an overall specificity of 99.8%. This is similar to findings in Holland.<sup>18</sup>

We believe that the chance that our study failed to detect a donor positive for type II virus is low; the screening assays mainly were based on type I whole viral lysates and thus relied on cross reactivity for detection of type II virus. Our own evaluation of the type I derived assays has shown 85% to 100% sensitivity for type II virus (S Andersson, unpublished data).

Half of the samples that were positive on initial screening were classed as indeterminate by western blotting. We believe that these findings represent technical artefacts, although they could represent reactivities to other infectious agents that are as yet unrecognised or seroconversion of samples from people who had recently become infected. The large number of samples that tested positive at the initial screening and were classed as indeterminate by western blotting was a result of the large total number of donors screened. All donors who repeatedly tested positive by enzyme linked immunosorbent assay were excluded from making donations. Every year about 80 newly recruited blood donors are expected to be banned from further blood donation. The costs of screening include the psychological stress caused to donors because of learning potentially worrying information and the costs to the laboratories and blood banks in additional work. Improvements in screening tests may minimise these problems.

#### Transmission

Thirty five patients who received blood components from donors who tested positive for the virus were tested. Three were positive; none of the three had any risk factors for infection other than the blood transfusion. This indicates that they became infected at the time of transfusion. Almost half of the patients who had received blood components from donors who

tested positive for the virus had already died, since most of them had been transfused several years before the study. We have no reason to believe that infection would result in an increase in early mortality and an underestimation of transmission.

We found an overall risk of transmission of 9%. Recent studies have found risks of transmission from whole blood to be 13%<sup>15</sup> and 27%,<sup>16</sup> and older studies have found up to a 63% risk of transmission.<sup>10</sup> The lower current risk probably reflects improved separation methods and increasingly efficient removal of white blood cells, where the virus is normally found.<sup>26</sup>

Infectiousness also depends on the length of time the blood is stored; there is little transmission of the virus after 10 days in storage.<sup>16</sup> The amount of time blood components are stored varies between blood banks and at different times of the year. Platelets must be transfused within five days of collection and are likely to pose a relatively high risk of transmission. Theoretically the risk of transmission should decrease if blood components are transfused only after being stored for 10 days. However, waiting 10 days before using blood components could lead to problems such as an increased risk of haemolysis, increased storage costs, shortened half life of transfused red blood cells, and reduced access to donated blood.

One transfused patient who received plasma tested positive for the virus. This was unexpected since plasma normally contains only a few white blood cells and is often stored for a longer time than other blood components.

#### Cost effectiveness

An analysis of the cost effectiveness of screening should take several variables into account, such as the prevalence and incidence of infection in the population, the risks of transmission, the mortality and morbidity of those infected with the virus, and the expected survival rate of patients receiving blood components from donors infected with the virus.

The calculation of the expected seroprevalence of human T cell leukaemia/lymphoma virus types I and II in new blood donors was based on the prevalence in donors who did not come from endemic countries.<sup>16</sup> A more strict assessment of donors has been introduced in Sweden and potential donors from areas endemic for infection with HIV, human T cell leukaemia/lymphoma virus, or hepatitis B are excluded from donating blood. However, an increasing number of Swedish citizens are born to immigrants from endemic areas.

The incidence of infection among already established blood donors was estimated from the prevalence in Swedes and was based on the assumption that the risk of acquiring infection mainly occurs after age 15. With an assumed mean age of blood donors of 35 years, the cumulative incidence of 1/100 000 reflects 20 years of exposure to sexual transmission for each donor. This provides a risk of seroconversion among regular donors of about one in 4 million donations; this is similar to the risk found in France.<sup>21</sup>

In the cost effectiveness analysis the risk of transmission from a positive donor to a recipient was assumed to be 15% for each transfusion. This was based on findings both in the retrospective study and

in other published data as discussed above.<sup>10 15 16</sup> A risk of 30% would obviously reduce the costs by half.

We assumed that adult T cell leukaemia/lymphoma is always fatal. The incubation time from infection to the development of clinical disease and death is normally more than 30 years. Only 10% of those patients who received transfusions in our pilot study in 1992 were likely to have lived for more than 30 years after transfusion. In our analysis, the risk of developing adult T cell leukaemia/lymphoma as a result of transfusion was therefore low and even this low risk may represent an overestimate, since it is possible that the development of adult T cell leukaemia/lymphoma may be associated only with infection in childhood or infancy.<sup>10</sup>

Complications occurring secondary to tropical spastic paraparesis may cause premature death but no data are available to quantify this risk and we have therefore not included mortality from tropical spastic paraparesis in our analysis.

It is not feasible to selectively screen only blood donations intended for specific groups of patients, such as pregnant women and children, although this might eliminate most of the deaths caused by transmission by transfusion. It might be more practical to improve filtration so that more leucocytes were removed from all blood components intended for use in pregnant women or children; this might further decrease the risk of transmission.

In our analysis the costs of preventing one transmission when only new donors were screened was \$440 000 (£275 000). According to the findings of another study the costs in the United Kingdom would be about one tenth the costs in the United States (\$47 000; £29 375),<sup>27</sup> while in France the costs were estimated to vary from 1.3m French francs (\$200 000; £125 000) in the first year of screening to 5.7m French francs (\$900 000; £563 000) in the third year of screening.<sup>20</sup> The differences in costs between our study and the others<sup>19 27</sup> reflect several differences in calculations. The two studies did not account for the benefits of excluding donors who test positive from donating in the future. The findings from the United Kingdom are based on only the first year of screening and the French study is based on screening all donations. The studies also do not report on the survival rates of patients who received transfusions from donors who tested positive so they do not include comparable information on the prevention of morbidity and mortality.

### Healthcare policy

Decisions on healthcare policy, as with many other decisions in society, are often taken in part as a result of an analysis of the cost effectiveness of different activities. In most healthcare systems there has been a reluctance to consider life and health in purely economic terms. Generally, however, insurance companies and traffic planning authorities are already dependent on such evaluations. In Sweden, the mean cost to society for a person killed in a traffic accident has been estimated to be about \$1.4m (£875 000)<sup>28</sup> The mean cost in seven other countries in western Europe was found to be similar at about \$1.5m (£937 500).<sup>28</sup> These estimates may form the basis for decisions on allocations of resources, for example the costs of the prevention of fatal car accidents. In Sweden

### Key messages

- The human T cell leukaemia/lymphoma virus is primarily sexually transmitted; it may also be transmitted through blood transfusions
- Infection with the virus may cause adult T cell leukaemia/lymphoma or tropical spastic paraparesis
- Many countries, including Sweden, have begun screening blood donors for the virus; however, a low prevalence of infection in non-endemic areas, a low risk of developing adult T cell leukaemia/lymphoma in people infected with the virus, a long incubation period, and the older age of most transfusion recipients make screening costly
- Three models of screening were compared: testing every donation, testing new donors and then retesting them after five years, and testing new donors only
- Regardless of the model used screening in Sweden would only prevent one death every 200 years at a minimum cost of \$36m (£22.5m)

the cost of saving one life if only new blood donors are screened for the human T cell leukaemia/lymphoma virus is 35 times higher than the value of the life of a person killed in a traffic accident.

Another way to estimate the value of a life is to determine how much the public is willing to pay to avoid a certain risk. In Britain the cost to society of a person killed in a car accident was found to be less than the cost to society of a person killed in a train accident.<sup>29</sup> This discrepancy occurred because people were assumed to have less personal control when travelling by train as opposed to travelling by car. In the case of a transfusion then the recipient may be assumed to have an almost total lack of control. Thus, a relatively high cost for saving each life may therefore be reasonable.

The HIV epidemic has increased society's awareness of bloodborne infections and raised concern over their prevention. Swedish society seems prepared to allocate considerable resources to decrease risks and increase benefits. However there are limits to a society's resources and ultimately a political decision will be made; this decision should be based on sound calculations. In our analysis the older age of most transfusion recipients, the long incubation time of adult T cell leukaemia/lymphoma, and the low risk of developing clinical disease from infection with the virus strongly affected the benefits of screening. Thus, although the incremental costs for testing all blood donations were considered to be too high, not testing at all was considered unethical.

Most countries have not started screening blood donors for the human T cell leukaemia/lymphoma virus. Those countries that do screen generally test every unit. In May 1995, as a result of the cost effectiveness analysis presented here, the Swedish National Board for Health and Welfare decided that only new blood donors and donors who had not been tested earlier would be screened for the human T cell leukaemia/lymphoma virus.

We thank Patrik Olin, Swedish Institute for Infectious Disease Control, for his contributions. We also thank those colleagues who participated in the screening programme, the general policy discussions, and specific investigations related to this publication: Jan Albert, Gunnel Biberfeldt, Ove Berglund, Bo Bresky, Hans Fredlund, Johan Giesecke, Lena Grillner, Åke Gustavsson, Mona Hild, Olle Järnmark, Björn Lager, Ami Lexmark, Anders Lindberg, Annika Lindholm, Lisbeth Messeter, Rut Norda, Olof Ramgren, Gunnar Sundström, Madeleine von Sydow, Jan Säfwenber, Tommy Söderström, Carl Olof Welin, Bengt Wadman, Barbro Wiechel, Olof Åkerblom, and the Swedish Society for Transfusion Medicine.

Contributors: ET coordinated and performed most of the study, especially the final compilation and analysis of data. AB acted as a consultant to the national screening programme, assisted in the analysis of data, initiated the development of the cost effectiveness models, and is guarantor for the paper. SA was responsible for the polymerase chain reaction analysis and developing the guidelines, evaluation and analysis of the laboratory screening. MA coordinated the compilation of all data on blood screening. KR coordinated the tracing of transfusion recipients who had received infected blood. EL was instrumental in developing the structure of the national screening programme. JB conducted the pilot study. HBH directed the pilot study and was responsible for tracing the recipients of infected blood. AK assisted in compiling clinical data on donors infected with the virus. MN assisted with the pilot study. AS contributed to the discussion on the principles of blood transfusion. The paper was written by ET, SA, and AB.

Funding: None.

Conflict of interest: None.

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(Accepted 4 February 1998)

### One hundred years ago British practitioners in Italy

Sir,—In connection with the contemplated change in the sanitary law of Italy in its bearing on foreign practitioners, I was this week requested to present my titles to practise in other countries at the Office of Hygiene in Florence. The following were the first impressions they made on my friend Signor Boncinelli, medical officer of health. I first handed him my London University MD certificate. This, he said, states that you are a Doctor in Medicine, but it does not state that it entitles you to practise, the same remark applied to the MRCP diploma; the diploma of the Royal College of Surgeons only states that you are thereby entitled to practise surgery; the diploma of the Society of Apothecaries

grants you permission to practise medicine, surgery, and midwifery, but as it is granted by a pharmaceutical society, how can it be a licence to practise as a medical man? Finally the diploma of the Swiss Federation met the case, and gave entire satisfaction. This may serve as a hint to our various licensing bodies to revise the wording of their certificates so that they may be comprehensible *urbi et orbi*. It is also to be hoped that the Italian authorities will acquaint themselves with the relative values of the various British and Irish diplomas.—I am, etc

Stuart Tidey, MD Lond, MRCPLond, Florence, February 19th. (*BMJ* 1898;i:592)