Evaluation of a decision support system for initiation and control of oral anticoagulation in a randomised trial

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Abstract

Objectives: To determine whether a computerised decision support system for initiation and control of oral anticoagulant treatment improves quality of anticoagulant control achieved by trainee doctors.
Design: Randomised controlled trial.
Setting: District general hospital in North London.
Subjects: 148 inpatients requiring start of warfarin treatment.
Interventions: Management by trainee doctors (to achieve therapeutic range of international normalised ratio of 2 to 3) with indirect assistance from computerised decision support system (intervention group) or without such assistance (control group).
Main outcome measures: Median time to therapeutic range, stable dose, and first pseudoevent (excessive international normalised ratio after therapeutic range has been reached) and person time spent in the therapeutic range.
Results: 72 patients were randomised to the intervention group and 76 to control group. Median time to reach international normalised ratio of ≥ 2 was not significantly different in the two groups (3 days). Median time to achieve a stable dose was significantly lower in intervention group than in controls (7 days v 9 days, $P = 0.01$) without excessive overtreatment or undertreatment with anticoagulant. Patients in intervention group spent greater proportion of time in therapeutic range, both as inpatients (59% v 52%) and outpatients (64% v 51%).
Conclusion: The computerised decision support system was safe and effective and improved the quality of initiation and control of warfarin treatment by trainee doctors.

Introduction

The quality of antocoagulant control during the initiation and maintenance of warfarin treatment is generally poor.[1-5] This may be due to the complex pharmacology of warfarin, failure to follow guidelines, and the inexperience of trainee doctors, who are responsible for managing most inpatient and some outpatient warfarin treatment in Britain. Poor control of anticoagulant treatment may lead to increased morbidity and mortality, longer hospital stays, and therefore increased healthcare costs.

Several methods for predicting the initiation and maintenance doses of warfarin have been developed.[6] Regression methods are based on the dose-response relation at a given time after loading doses and do not require computerisation. A modified version of such a method allows "flexible" loading doses on the second and third days after starting treatment and then predicts the maintenance dose on day 4 based on the international normalised ratio.[7 8] However, the method is inflexible in that a loading dose of other than 10 mg on day 1 cannot be used, maintenance doses greater than 8 mg cannot be determined, it aims for a wide target range of international normalised ratio (2 to 4), and it gives no guidance on adjusting doses after day 4. A randomised controlled trial found no significant improvement in oral anticoagulation with this regression method.[9] Regression and mathematical methods have also been developed and evaluated for control of oral anticoagulation in outpatients.[10]

Computerised pharmacokinetic and pharmacodynamic models that describe the time course of warfarin dose-response relations have also been developed and evaluated.[6 11 12] These allow more flexible loading doses, with determination of a maintenance dose of any size and for any therapeutic range. They also allow for adjusting doses beyond day 4. However, these methods still require a doctor to determine the final dose and the optimal monitoring interval. The methods are complex, time consuming, and require expertise in pharmacokinetics and statistics, and they may therefore not be acceptable to all doctors. Furthermore, studies have not yet shown that such methods have any significant advantage over regression methods.

We felt the need for a simple method that could provide guidance on both initiation and maintenance of anticoagulation and which would be acceptable to all doctors. We report the findings of our randomised controlled trial of a simple dosing and monitoring method based on simple proportional-derivative control in engineering terminology.[13]

Patients and methods

Computerised decision support system
Using a computerised pharmacokinetic and pharmacodynamic model and computer simulation, we developed an initiation regimen aiming for a therapeutic range of international normalised ratio of 2 to 3.[14] We

developed a flexible regimen so that any loading dose between 5 mg and 10 mg could be used on day 1. The induction doses on the first three days were based on the daily international normalised ratio and the previous dose. Adjustments of the maintenance dose for outpatients were based on the error (target international normalised ratio minus actual international normalised ratio) and the previous dose (simple proportional controller), which is a modified version of a maintenance controller.[15] Proportional-derivative controllers (daily and weekly controllers) were necessary for adjusting the maintenance dose in the phase between induction and control of the maintenance dose for outpatients. The doses in these controllers were based on the error, the rate of change of error, and the previous dose.

For safety reasons, the decision support system would not recommend a dose when there was no measurement of the international normalised ratio (all controllers), when there was no previous ratio but a change of dose by a doctor (daily and weekly controllers), or when the ratio was very low (maintenance controller) or very high (weekly and maintenance controllers). The ratio was monitored daily on the first three days, and then monitoring intervals were based on the error and previous interval.

We determined the error settings in the proportional-derivative controllers by using a combination of the computerised pharmacokinetic and pharmacodynamic model, 57 test cases, and the judgment of experienced clinicians. We determined the error settings for the outpatient controller empirically, mainly from the experience gained from using a similar system at the Whittington hospital over the past eight years.

Study design

We undertook this study at the Whittington Hospital, which has acute medical and surgical units. The study was approved by the local ethics committee, and we obtained verbal informed consent from the patients who entered the study.

Inpatients who required initiation of warfarin treatment were eligible for inclusion in the study. The exclusion criteria were patients who had recently taken more than two doses of warfarin, patients whose maintenance dose of warfarin was known, patients taking an oral anticoagulant other than warfarin, a patient's or treating doctor's refusal to participate in the trial, and therapeutic ranges of the international normalised ratio outside 2-3. We did not exclude patients with known hazards—such as other drugs and medical conditions—that affected the dose-response relation of warfarin or those that might predispose to haemorrhage.

Before any baseline hazards were recorded, we used simple randomisation with a table of random numbers[16] to assign the patients to management by doctors aided by the decision support system (intervention group) or to management by doctors alone (control group). The doctors were mainly trainee doctors (n = 42 for inpatients). For outpatient control, the intervention group was managed by a nurse practitioner and six trainee doctors aided by the decision support system, while the control group was managed by the same six trainee doctors without the assistance of the decision support system. The patients were unaware of which study group they belonged to.

Patients were followed up until they reached one of the predetermined study end points: warfarin stopped because duration of treatment was completed or the diagnosis had been revised; patient followed up elsewhere; any event such as death, major haemorrhage, or thromboembolism; warfarin stopped for longer than one week for major procedures; change of therapeutic range; or end of study period.

Study conduct

Patients' blood samples for measuring the international normalised ratio were usually taken between 9 am and 11 am, and warfarin doses were usually taken at about 5 pm. The international normalised ratio was determined with a Sysmex CA1000 optical density coagulometer used with a low opacity Manchester thromboplastin (international sensitivity index 1-1.2). The laboratory participates in the British external quality control scheme.[17]

We provided all the doctors with guidelines on anticoagulation from the *Drugs and Therapeutics Bulletin*.[8] For the doctors treating patients in the intervention group, we also provided the computerised decision support system's suggestion for the next warfarin dose and interval to the next measurement of the international normalised ratio. These doctors could reject the decision support system's recommendations if they thought they were inappropriate. All the doctors were free to seek advice from any expert.

For each patient, the daily warfarin dose, international normalised ratio measurement, any identifiable changes in hazards, and any major event such as death, major haemorrhage, or thromboembolism were recorded. All the patients were given the Department of Health's anticoagulant treatment booklet, which gives simple information on the problems of warfarin treatment.[18]

Outcome criteria

The main outcome criteria for the initiation of warfarin treatment were the time to reach an international normalised ratio of ≥ 2, the time to reach a stable dose (defined as the first dose that maintains the ratio between 2 and 3 for three consecutive days after starting treatment), and the time to first pseudoevent (ratio ≤ 1.5 or ≥ 5) after the therapeutic range is reached.

The main outcome criteria for controlling the maintenance dose was the quality of anticoagulant control in inpatients and outpatients, measured by the person time spent at a stable international normalised ratio, assuming the ratio changed linearly between two measurements,[19] and the frequency of measurements of the ratio. We did not include major haemorrhagic or thromboembolic events requiring hospital admission as major outcome measures because these tend to occur infrequently and would have required a much larger trial.

Statistical analysis

We analysed data from all the patients up to their study end point and analysed data from the patients in the intervention group regardless of whether the computerised decision support system's advice was accepted,

rejected, or not available (that is, on an "intention to advise" basis). All "time to event" data were analysed by Kaplan-Meier curves and the log rank test. We analysed the quality of anticoagulant control by methods suggested for measuring rates of recurrent events because individual patients would have had unequal follow up and events might have recurred in an individual.[20] [21] An event was taken as a day spent at a particular international normalised ratio. The interval between measurements of the international normalised ratio was analysed by the Mann-Whitney test. The tests were two sided, and a P value of 0.05 was used as the level of significance.

Results

Table 1 shows the patients' demographic and clinical characteristics. Of 170 consecutive inpatients who were considered, 148 were randomised to treatment while the other 22 were excluded because of failure to recruit them or because they satisfied one or more of the exclusion criteria. Of the 76 patients in the control group, 64 were followed up as outpatients, as were 53 of the 72 patients in the intervention group (P = 0.11). Duration of follow up of patients in the two groups was not significantly different (P = 0.69). Four patients died during the study—three from metastatic carcinoma and one from bowel obstruction. None was due to poor anticoagulant control. One thromboembolic event in each study group was due to undertreatment with anticoagulant (international normalised ratio 1.5 in control group and 1.9 in intervention group), while four haemorrhagic events were due to overtreatment with anticoagulant—three in the control group (ratios 3.5, 4, 10) and one in the intervention group (ratio 10).

Initiation of warfarin treatment

Figure 1 shows the Kaplan-Meier curve for the time to achieve an international normalised ratio of ≥2. One patient in the control group and three patients in the intervention group were censored. Eight patients in the control group and four patients in the intervention group were below the therapeutic range on discharge from hospital.

Figure 2 shows the Kaplan-Meier curves for the time to achieve a stable dose. Fourteen patients in the control group and 11 patients in the intervention group did not achieve dose stability before reaching a study end point.

Figure 3 shows the Kaplan-Meier curves for the time to the first pseudoevent. More pseudoevents occurred in the control group than the intervention group (41 *v* 25). Eighteen of the pseudoevents in the control group were due to overtreatment with anticoagulant compared with 12 in the intervention group. The median time to the first pseudoevent among inpatients (whose compliance and drug treatment were known) was 8.7 (SE 2.32) days in the intervention group and 7 (2.64) days in the control group (P = 0.03).

Control of maintenance dose of warfarin

To compare the quality of oral anticoagulant control, we examined the international normalised ratios after the therapeutic range had been attained. Table 2 shows the time spent at various ratios by the two patient

Table 1 Demographic and clinical characteristics of 148 hospital inpatients requiring oral anticoagulation by treatment group* (values are numbers of patients unless stated otherwise)

	Control group (n=76)	Intervention group (n=72)
Median (range) age (years)	65 (18-92)	67 (15-93)
Men:women	40:36	31:41
Diagnosis:		
Deep vein thrombosis	42	29
Pulmonary embolus	14	26
Atrial fibrillation	15	12
Valve disease	2	2
Mural thrombus	0	1
Systemic embolus	2	0
Prophylaxis	1	2
Baseline hazards present†	65	61
Heparin given during hospital stay:	67	66
Median (range) maintenance dose (mg)	5 (1-18)	5 (1-13)
Study end points:		
Stopped:		
Duration of treatment complete	25	22
Diagnosis reviewed	2	3
Operation	2	4
Event:		
Death	2	2
Haemorrhage	4	2
Thromboembolism	1	4
Patient moved away	11	8
End of study	27	26
Change of therapeutic range	2	0
Violation of protocol	0	1
Median (range) length of follow up (days)	88 (5-389)	93 (3-392)

*Intervention group was treated by doctors advised by computerised decision support system, while control group was treated by doctors alone.
†Anaemia (haemoglobin concentration <115 g/l); renal impairment (serum urea >10 mmol/l and creatinine >130 μmol/l); liver impairment (serum bilirubin >17 μmol/l and serum aspartate transaminase >40 IU/l, serum γ-glutamyl transferase >40 IU/l, or serum albumin <30 g/l); abnormal baseline clotting tests; excess alcohol intake (>42 units/week in men, >28 units/week in women). Some patients had more than one baseline hazard.

groups as inpatients and outpatients. The intervention group spent more time within the therapeutic range than the control group, both as inpatients (59 *v* 52 days) and outpatients (64 *v* 51 days).

For inpatients, the median interval between tests was 2 (range 1-22) days in the intervention group and 2 (1-30) days in the control group (P = 0.07). For outpatients, the median interval between tests was
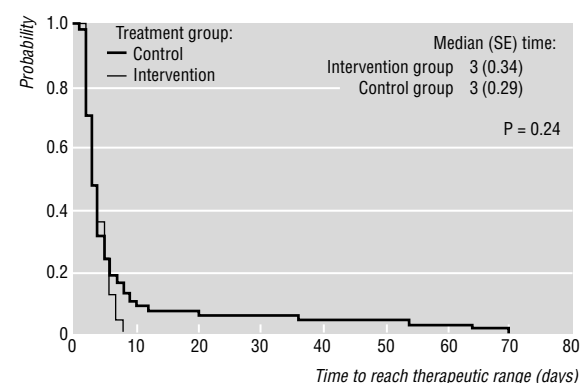
Fig 1 Kaplan-Meier curve for time for patients requiring anticoagulation to reach therapeutic range (international normalised ratio ≥2) after start of warfarin treatment (intervention group was treated by doctors advised by decision support system, while control group was treated by doctors alone)
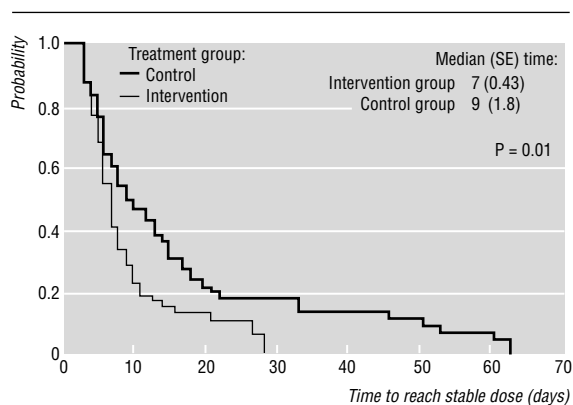
Fig 2 Kaplan-Meier curve for time for patients requiring anticoagulation to achieve a stable dose after start of warfarin treatment (intervention group was treated by doctors advised by decision support system, while control group was treated by doctors alone)
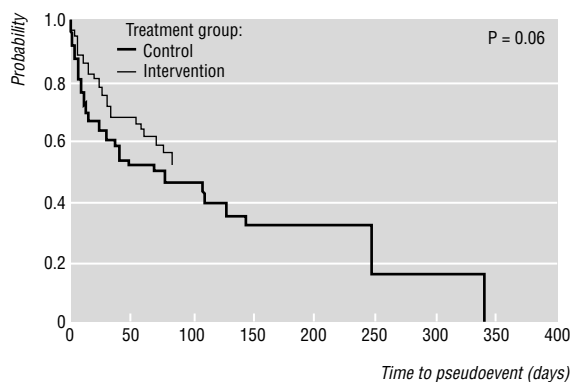
Fig 3 Kaplan-Meier curve for time to first pseudoevent (international normalised ratio ≤1.5 or ≥5) after therapeutic range is reached among patients requiring anticoagulation (intervention group was treated by doctors advised by decision support system, while control group was treated by doctors alone)

14 (2-63) days in the intervention group and 14 (1-91) days in the control group (P = 0.2). There was no difference between the study groups in the attendance rate at outpatient clinics.

Discussion

Initiating warfarin treatment

The therapeutic range was attained more quickly in the patients in the intervention group. A higher proportion of patients in the control group were not in the therapeutic range as outpatients, when they would not have been receiving heparin and would therefore have been at high risk of recurrent thromboembolism. A stable dose was determined more quickly in the intervention group without excessive undertreatment or overtreatment with anticoagulant, as shown by the time to the first pseudoevent. Theoretically, this should allow earlier discharge from hospital with less frequent monitoring.

Our results of the initiation of anticoagulation are similar to those in other randomised controlled trials comparing computer assisted control with control by doctors only.[11 22 23] White et al found that the mean time to attaining the therapeutic range and a stable dose was 3.2 days and 5.7 days respectively in the computer assisted group compared with 4.5 days and 9.4 days respectively in the control group.[11] They used a different definition of a maintenance dose.

Control of maintenance dose of warfarin

The intervention group spent more time within the therapeutic range as inpatients and outpatients. Although there was a tendency to undertreat patients in the control group, there was no increase in the number of thromboembolic events. However, a much larger study would be required to show any difference. Also we did not investigate the longer term effects of undertreatment such as chronic venous insufficiency and leg ulcers.

Other randomised studies comparing computer assisted dosing with treatment by doctors or nurse practitioners alone have not reported any difference in the quality of anticoagulant control.[10 12] Poller et al found no difference between computer assisted groups and their control group in the proportion of measured international normalised ratios being within the therapeutic range (51.5-59.7%, P = 0.62).[10] In contrast, we found that, for outpatients, the percentage of ratios within the therapeutic range was 44% in the control group and 58% in the intervention group.

Limitations of study

The two patient groups in our study were similar in size, clinical characteristics, and duration of follow up. Other factors, however, such as change in hazards over time and outpatient compliance with treatment were not determined satisfactorily and were assumed to be similar in both groups.

Table 2 Quality of anticoagulant control among patients given warfarin as inpatients and outpatients by treatment group* (values are days per 100 patient days of treatment)

	Inpatients				Outpatients			
INR†	Control group (n=62)	Intervention group (n=60)	Relative rate (95% CI)‡	Excess days (95% CI)§	Control group (n=64)	Intervention group (n=53)	Relative rate (95% CI)‡	Excess days (95% CI)§
<1.5	5.6	1.3	4.2 (2.2 to 7.9)	4.3 (0 to 1.2)	4.2	1.3	3.3 (1.3 to 8.7)	2.9 (0.3 to 5.5)
<2.0	21.4	18.3	1.2 (0.8 to 1.7)	3.1 (−4.2 to 10.4)	31.8	21.1	1.5 (1.1 to 2.1)	10.7 (2.1 to 19.2)
2-3	52.2	59.4	0.9 (0.7 to 1.0)	−7.2 (−16.3 to 1.9)	51.0	63.7	0.8 (0.7 to 0.9)	−12.7 (−21.6 to −3.8)
>3.0	26.4	22.3	1.2 (0.8 to 1.7)	4.1 (−4.3 to 12.6)	17.2	15.1	1.1 (0.7 to 1.8)	2.1 (−5.6 to 9.7)
>5.0	2.8	1.2	2.4 (0.6 to 9.8)	1.6 (−0.8 to 4.1)	1.1	0.8	1.5 (0.2 to 14.3)	0.3 (−1.5 to 2.2)

*Intervention group was treated by doctors advised by computerised decision support system, while control group was treated by doctors alone.
†International normalised ratio.
‡Comparing rate in control group with rate in intervention group.
§No of days per 100 patient days of treatment spent at given range of international normalised ratios in the control group in excess of that in the intervention group.
Total follow up times for inpatients of control and intervention groups were 571 and 596 days respectively, and for outpatients of control and intervention groups were 6331 and 6032 days respectively.

Because of logistical problems, it was difficult to shield the doctors treating the control group from the computerised decision support system's suggestions, especially for outpatient control. Hence, there may have been some learning effect and therefore a carry over effect in the treatment of the control group. The doctors could have been randomised to the different groups, but this would have been difficult as there was a high turnover during the study and the study groups might have differed in size and hazards. We did, however, control for factors such as illicit use of the aid by doctors treating the control group, the problems of unfamiliar technology, and feedback from the decision support system about previous performance.

Conclusion

Our study shows that our computerised decision support system was safe and effective in the initiation and control of warfarin treatment. It is difficult to predict whether the same use and acceptance of the system would occur if it were made available directly to trainee doctors. A fuller evaluation of the system—including its direct usability, clinical effectiveness, and cost effectiveness—is necessary. However, it has the potential to improve the quality of anticoagulant control by trainee doctors as well as allowing dosing and monitoring in primary care.[24]

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Any questions
Is eczema more common in vegetarians?

The simple answer is no. Eczema is a very complex field and eczemas can be classified as endogenous or exogenous.

The most common endogenous eczema—atopic eczema—may be related to dietary intolerance, specifically to dairy produce and nuts.[1] It is possible, therefore, that a vegetarian with atopic eczema who ate a lot of nuts could run into trouble with nut allergies which could exacerbate his or her eczema.

The actual role that diet plays in atopic eczema is still controversial and the majority of patients with atopic eczema do not benefit from any dietary exclusion.

Exogenous eczemas are generally caused by contact with either irritants or allergens and this would not be affected by dietary intake. There is certainly no evidence that vegetarians have a higher incidence of eczema.

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Netlines

The year 2000—are you ready?

● Recent news reports have highlighted the problem of the year 2000. In case you missed them, the problem is that many computer systems will fail to work properly after 1 January 2000 because they store years in two digit format (such as 97, 98, 99) and will think that they are suddenly in the year 1900. The worst case scenario includes empty supermarket shelves, planes grounded, traffic system malfunctions, and power cuts accompanied by a stock market crash and economic depression as business failures cascade through the economy and faith in financial and banking systems plummets (**ftp://www.year2000.com/pub/year2000/y2kfaq.txt**).

● Medical computer systems may also be vulnerable, so make sure your computer support services department is taking the problem seriously now. For more information, visit the Year 2000 Information Center on **http://www.year2000.com** or the UK Central Computer and Telecommunications Agency's Millennium Bomb Home Page (**http://www.open.gov.uk/ccta/mill/mbhome.htm**).

Coming soon to a medical school near you

● Hot on the heels of the recent research assessment exercise (**http://back.niss.ac.uk/education/hefc/rae96/c1_96.html**) comes a similar exercise aimed at assessing the quality of medical education in England and Northern Ireland, which will take place between 1998 and 2000. In case you haven't received the copious warnings and guidance in dead tree format, you can get a glimpse of what is to come on **http://www.niss.ac.uk/education/hefce/pub97/c3_97.html**.

British general practice on line

● British general practitioners are moving on line—see **http://www.ncl.ac.uk/~nphcare/GPUK/a_herd/practice.htm** for a list of practice web pages. There are now several British web sites devoted to general practice, including UK Primary Care (**http://www.ukpc.org/pub/about.htm**), the West Midlands General Practice Home Page (**http://medweb.bham.ac.uk/bc/RAGP.html**), and the Royal College of General Practitioners web site (**http://www.rcgp.org.uk/**). The electronic journal *General Practice On-Line* is on **http://www.priory.co.uk/journals/gp.htm**, and British general practitioners have their own mailing list, GP-UK (**http://www.ncl.ac.uk:80/~nphcare/GPUK/gpukhome.html**). A link on the GP-UK site takes you to the UKMedW3 web pages (**http://www.ncl.ac.uk/~nphcare/GPUK/a_herd/topmenu.htm**), which form an excellent starting point for exploring medicine on the web.

Cloned sheep in cyberspace?

● If you are worried or excited about the ramifications of cloning sheep take a look at the press release at the Roslin Institute (**http://www.ri.bbsrc.ac.uk/library/research/cloned.html**) or try the special report on the newly revamped *New Scientist* web site on **http://www.newscientist.com/nsplus/insight/clone/clone.html**. If, instead, you want to get inside the mind of Dolly, the sheep, try dissecting her brain using the Sheep Brain Dissection Guide on **http://academic.uofs.edu/department/psych/sheep/**. And if you want more puns like the one above, try PUN NET on **http://www.grfn.org/%7Ematt/pun-net.html**.

Self help on the net

● Many people turn to the Internet for emotional support to help them cope with chronic diseases, psychological disorders, and even simple loneliness. Often they receive help and accurate advice; sometimes they are misled or made worse by their experiences on line. The stronger the medical presence on line, the more likely it is for good advice and information to prevail. To sample the emotional support facilities available on the net see **http://www.lib.ox.ac.uk/internet/news/faq/archive/support.emotional.resources-list.html**. You may even wish to recommend some of the resources to your patients.

Mental Health Net

● Mental Health Net (**http://www.cmhc.com/**) claims to be the largest, most comprehensive guide to mental health on line, featuring over 6000 individual resources. The award winning site carries information on disorders such as depression, anxiety, panic attacks, chronic fatigue syndrome, and substance misuse. In addition, there are professional resources in psychology, psychiatry, and social work, together with journals and self help magazines.

Web authoring made simple

● If you want to start putting your own material on to the web, you will need to master HTML, the language used to create web pages—web page creation programs exist but don't give you as much control over the product. The NCSA Beginner's Guide to HTML (**http://www.ncsa.uiuc.edu/General/Internet/WWW/HTMLPrimer.html**) and the Yale Style guide (**http://info.med.yale.edu/caim/manual/**) will help get you started. If they are not enough then several dozen more HTML guides and tutorials are listed on the UK Yahoo site on **http://www.yahoo.co.uk/Computers_and_Internet/Information_and_Documentation/Data_Formats/HTML/Guides_and_Tutorials/**.

● Once you have polished off HTML, you may want to try creating CGI scripts to bring interactivity to your web pages. Try the Guide to HTML and CGI scripts by Mike Smith at Brighton University on **http://snowwhite.it.brighton.ac.uk/~mas/mas/courses/html/html.html**.

MSc in medical informatics

● The University of Teeside is advertising an MSc in medical informatics to start in September 1997. The course is designed for people working in the health service and consists of a collection of one week short courses (many also available as stand alone courses) and a major project. For more information, see **http://www-scm.tees.ac.uk/courses/masters/**.

Compiled by Mark Pallen
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web page **http://www.qmw.ac.uk/~rhbm001/mpallen.html**