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tion as an Internet linked central server, offering the users (TCs, CBBs and Manager) four distinct applications for different functions. Access to these applications is through the WWW, so the only tool needed by users is a Web navigator. In order to enter into the program, it its necessary to be recognized as a user, first of the program and then of the applications, with recognition being based on pairs of login & password codes. Basic features of the four applications are as follows.

Application "TC"

This application is used by TCs, to which it offers the support required for opening and updating records of their transplants. Data are organized in formats based on Eurocord forms. TCs may access data from their own patients either in the form of individual records or tabulated in formats which may be fed directly into common statistical programs. The use of this application requires recognition as a user of the program (first pair of login & password codes) and as a user of the TC application (second pair of login & password codes). Authorization to enter data is assigned to "Reporters" who are required to identify themselves by means of secure personal ID codes.

Application "BANK"

This application is used by CBBs to which it is the support required to open records of the units served to TCs, with the possibility of tracing the units sfinal destiny. Like TCs, user CBBs also have access to data of transplants done with their units, both in the form of individual records and tabulated in formats that may be transferred to usual statistical programs. Use of this application also needs recognition as a user of the program and of the application (two pairs of login & password codes). As for the TC application, authorization to enter data is assigned to Reporters who also need to identify themselves by means of secure ID codes.

Application "MANAGER"

This application is the one required to perform managerial functions. It is only accessible to persons authorized to perform these functions, using their own login & password codes for access.

Application "STAT"

This is the application that offers results of statistical analyses, performed by the Manager, on data from all patients in the Registry. This data must have been previously audited and validated. It is accessible to all users of the program through their login & password codes as program users (no additional specific codes for this application are required).

Program functionality

The program adapts to the data collection forms used in the Eurocord project, with the possibility of adding new fields in later versions. Basic operating features of the program are *confidentiality* of primary data, *inalterability* of validated data, and *identifiability* of data sources. Confidentiality and security are guaranteed by the requirements of login & password codes for access (these are activated by the Manager upon request from potential users) as well as by transmission of data in encrypted forms, and by maintenance of regularly updated backup copies.

Potential users of the program are TCs performing UCBT, CBBs providing units to the TCs and the Registry Manager. The use of the WWW service greatly simplifies the use of the program as there is no need for local installation or updating of the program to be performed by users. Operative usage is facilitated by the availability of an internal mail system that allows two-way communication between users as well as general broadcasts from the manager. Reception of new mail messages is automatically flagged to users on accessing the program.

Once recognized as users, TCs and CBBs have access to the program, but limited to the STAT application. For access to the TC and/or BANKS applica-

CBU that may have been previously opened by the CBB serving the unit.

TCs and CBBs may at any time recover data of their own cases, either as individual records or in tabulated HTML format, directly transferrable to usual statistical programs, so that they may perform any kind of analysis desired. To facilitate this, the program also provides the "filter" or "convertor" required to convert the provided tabulated data from HTML into ASCII format. Individual records are also accessible to the Manager to perform the functions of auditing and validation that are required prior to making patients' data usable for statistical analysis of the whole Registry. The Manager is also in charge of other administrative functions such as incorporation of new users or assignment or changes of codes, although users may also change their own. The manager's functions are facilitated by the availability of internal mail and by a built-in system for monitoring the use of the Registry.

Basic statistical analyses are automatically performed by the system on validated data of from patients included in the Registry, both comprehensive of all cases and restricted to subgroups of patients. The subgroups may be defined by combinations of two criteria: 1) diagnosis, type of transplant (related, unrelated) or protocol used; and 2) degree of HLA compatibility. Results from these analyses are made available, without restrictions, to all users through the STAT application, with reference to the date they were performed. They are limited to: number of patients included in each analysis; ranges and means of age, weight, number of cells of the transplants (total and per kg) and survival time; number of survivors; incidence of GvHD; and TCs having performed the largest number of transplants, listed by decreasing number of their cases, up to a maximum of five TCs. The results of more detailed analyses that may be performed, as decided by the Committee responsible for the Registry, will also be accessible to users. Results to be published, as decided by this Committee, may be publicly accessible through Internet Web pages.

Uses of the program

In Spain, the program is operative and immediately and freely available to all TCs interested in including their cases in the RETSCU for use of the TC application. To initiate its use, TCs are required only to contact the Manager* with whom they must agree the login & password codes to be registered for access both to the program and to the application, as well as the name and secure ID code of the person(s) authorized to act as Reporter(s), that is, authorized to create and to update records. At the time of writ-

This function is at present being performed by the first author of this paper (see address for correspondence).

ing this the program already contains the data from four Spanish TCs. For use of the BANK application, the program is also available, along similar terms, to Spanish CBBs and to CBB of any other country providing units to be transplanted in Spanish TCs. Figure 1 shows a diagram of the system's organization and use. Figures 3 and 4 show example printouts of real demographic statistics of the transplants performed by one TC and of the screen showing the compatibility data of an individual record.

The program may be provided for use in the management of other national or regional Registries. There is also the possibility of several Registries using the same program, or another program of compatible design, being linked and integrated into a multinational Registry (Figure 2). To be used in this way, the program would require some adaptations,
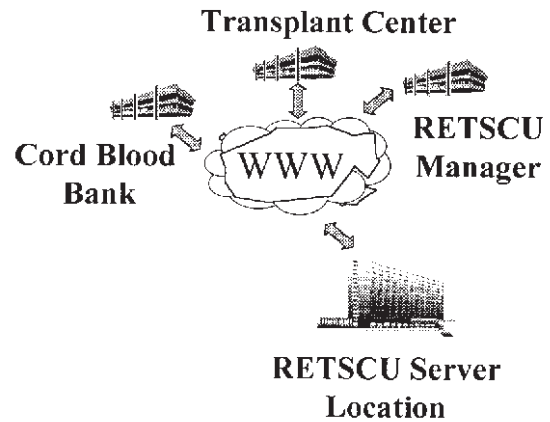
Figure 1. Diagram of the system's organization and use at national/regional level.

RM	= Regional Manager
EM	= European Manager
RRH	= Regional Registry Host
ERH	= European Registry Host
CBB	= Cord Blood Bank
TC	= Transplantation Center
←→	= WWW service (http protocols)
←·→	= Other Internet Services

Figure 2. Diagram of the system's organization for multinational use.

Figure 3. Example of real statistics on transplants performed by one TC automatically calculated by the system.

Figure 4. Example of the screen of a case record showing compatibility data.

although these are not difficult to do. The program could also be used to support a single multinational Registry, although it may be anticipated that managerial functions would become rather cumbersome as the Registry grows.

Conclusions

Clinical trials and technological development in the field of CBT may be facilitated by the development of Registries for accrual of uniformly formatted data derived from patients transplanted according to common protocols.[6] The WWW supported program we have developed may allow more efficient functioning of Registries, guaranteeing confidentiality, data protection, automated controls of coherence and congruence and offering descriptive statistics capabilities. The use of WWW support facilitates the maintenance of Registries since no local installations or updates are required, and data entry is much simplified. Direct

access by users to the records of their own cases and to their data properly tabulated allow them to perform their own statistical analyses as desired, with their primary data not being accessible to other users. Basic statistical analyses of all cases in the Registry are performed automatically by the system on data previously audited and validated by the Manager, as a guarantee of quality control. More elaborate analyses can also be performed easily by the Manager as frequently as decided by the Committe in charge. The easy access of users to this information may be of interest for continued improvements of their patient's care. The use of WWW pages allows rapid publication of results of general interest.

ful for detecting and correcting a few problems othat would have been therwise difficult to discover.

Disclosures

Conflict of interest: none.

Redundant publications: no substantial overlapping with previous papers.

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