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Building up a computerized follow-up register and information system for cervical cytology

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Abstract

It is well known that cervical intraepithelial neoplasia (CIN) and human papilloma virus (HPV) infection are closely related to cervical cancer. The cervical cytology examination (pap-test), followed by a colposcopic examination and a biopsy are the common tools for the early detection and the establishment of diagnosis of the cervical precancerous lesions. The monitoring and surveillance of those precancerous lesions is essential for the prevention of cervical cancer and for effective patient management. Nowadays, the long-term care of patients with a chronic and/or serious disease is feasible with the use of computerized follow-up registers or through more complex information systems. Nevertheless, manual recording is still the predominant method of data collection in 'Alexandra' University Hospital and this is the case in most health services in Greece due to scarcity of resources. A 'circulating' outpatient card, where information on gynecologic cytology, colposcopy and biopsy examinations is recorded, was the basis for the development of a computerised follow-up register and information system for cervical cytology in the Department of Cytopathology.

Keywords: Uterine neoplasms — cervix neoplasms; Medical records systems, Computerized; Population surveillance; Registries — medical records

1. Introduction

It is well known that cervical intraepithelial neoplasia (CIN) and human papilloma virus (HPV) infection are closely related to cervical cancer. The gynecologic cytology examination, broadly known as pap-test, followed by a colposcopic examination and a biopsy are the common means for the early detection and the establishment of diagnosis of these cervical precancerous lesions. There is no doubt also that the monitoring and surveillance of the precancerous lesions

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help cervical cancer prevention efforts and better patient management [1].

A follow-up register is an essential mechanism for helping surveillance and for studying the distribution and pattern of a disease [2]. In recent years the introduction of computers in medicine has provided the tools for better patient care and health services management, as well as for better clinical, epidemiologic and other research. New systems are announced every day with many more features and much less costs. Hence, computerized disease follow-up registers are among the new developments in the fields of Medicine and of Cytopathology [3–9]. However, since many factors may influence the development and the spread of computer systems within a country (such as scarce financial or staff resources as well as differences in the natural language and in the organisational infrastructure) it is important to know about the success or failure of those systems as well as the quality of the stored data [10–11].

2. Old system procedures

2.1. Situation and patient management

In Greece, there is no GP referral system or an organized cervical mass screening programme and the cervical cytology examination (pap-test) is provided by the Hospitals or Health Centres (public or private) to those women who need prompt attention. Furthermore, there is no Health Services Personal Identification Number (PIN) code system for Greek citizens at this point in time.

Pap-smears taken by medical or paramedical staff at three different sources are sent to the Cytopathology Department (CPL) of 'Alexandra' University Hospital for further processing and interpretation. These three sources are: (i) the Outpatient Gynecology Clinic (OGC) of the Hospital; (ii) a number of collaborating Health Centres; and (iii) a pilot cervical screening programme in Chalkidiki (a rural area of Greece) which is financed by the EEC 'Europe Against Cancer' Programme. Approximately 67%, 25% and 8%, respectively is the contribution of these three sources to the CPL's yearly turnover of cervical smear examinations.

A week after the collection date, women may ask at the Registration office (ROF) to get their test result. If the test is normal they are informed of the importance to repeat the examination within 3 years. Patients presenting inflammations and other benign lesions are treated by gynecologists at the OGC whereas patients with abnormal tests are sent to the Colposcopy Clinic (COC) for colposcopy and biopsy. The appointment for colposcopy is arranged within a period of 2 months according to the severity of the lesion. A second smear is taken right before the colposcopic examination and the biopsy and thus it is possible to check a patient's compliance at the CPL. The biopsy specimens are sent to the Anatomic Pathology Department (APL) and women with proven dysplasia or carcinoma are sent for treatment.

2.2. Registration, patient records and data flow

Each of the sources mentioned above has a Registration Office (ROF) which is responsible for: (i) the registration of women; (ii) the routing, storage and maintenance of records; and (iii) the routing and guiding of women. Only the ROF in Chalkidiki uses a microcomputer. The sum of records kept by the above three sources is approximately 90 000.

All the information concerning a woman is recorded on a folded card. This card is identified by a serial number issued at the time of first registration by the relevant ROF. This serial number is stated also on the examination order form together with the patient's names and some other details. Although the procedures are the same in all ROFs, the serial numbers refer only to the ROF which issued the card. This means that the same serial number may appear for patients from different ROFs (hence they cannot be used as a main reference point in the Patient Master index file of the CPL).

This folded card is attached to every examination order and the medical doctors at the OGC, the CPL, the COC and the APL are responsible for recording on the card all the information concerning the woman's history and gynecologic examination, the cytology report, the colposcopy and the biopsy report on every occasion respec-

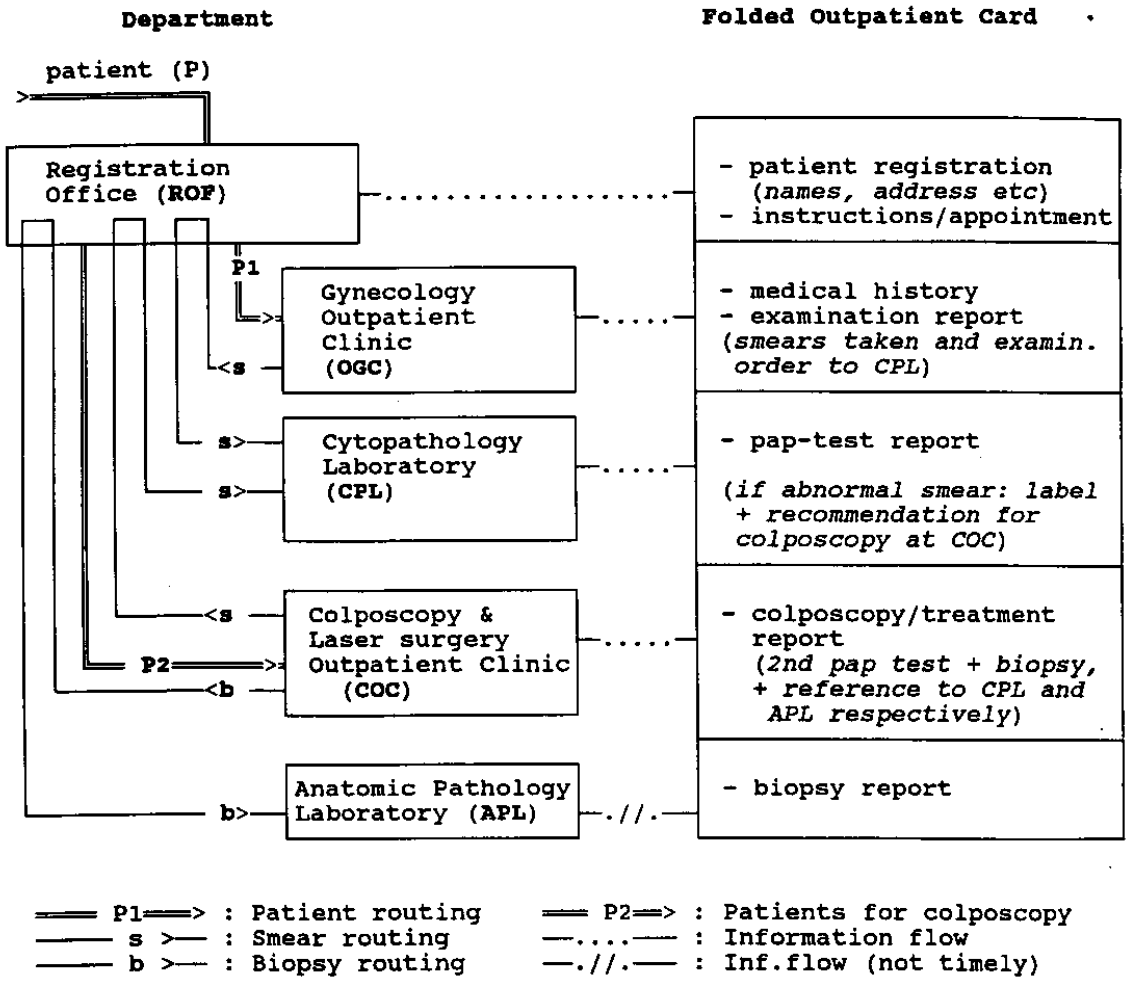

Fig. 1. Simplified representation of the actions taken and the information recorded on the outpatient card.

tively. Thus, a medical communication flow is achieved (Fig. 1) although it is not always timely. Furthermore, a special color label at the front of the card indicates that the woman had at least one abnormal smear in her life and that she is under surveillance. These labelled cards are treated separately since they represent the population to follow-up. Replicate records of those cards (with more details according to specialty) are kept by each of the above departments for their own purposes. In order to have updated information, a member of the medical staff is responsible every week for the additional data collection from the other departments concerning those patients.

No formal mechanism exists to call non-attenders because of the procedural difficulties. It is obvious though that the old system relies on the patient's compliance with the instructions given. Furthermore, since all entries are done manually, data accuracy and reliability is not guaranteed and several problems may arise as described by other authors [12–16]. Using the data from a previous study [17], we estimated that the inaccuracies of patient records concerning telephone numbers and addresses, reached 11%.

2.3. The approach to computerisation

In 1988 the CPL acquired a microcomputer and all the information concerning the labelled cards

was entered thereafter in a small database file. In May 1991 it was estimated that approximately 25% of the patients records, in the database, were lost to follow-up.

The above figure and the fact that this small database was not adequate to meet all the contemporary needs led to the decision for a new computer system.

The market did not offer a suitable solution in the Greek language and the imported foreign language systems were too expensive for our limited budget. Thus, in October 1991 it was decided to set up a working team to deal with a new computer system project.

The purpose of the project was: (a) to develop a computer system to cope with the day to day activity of the cytopathology laboratory concerning only the gynecologic cytology examinations; and (b) to build a computerized follow-up register for the surveillance and study of the lesions of the cervix uterus.

The evolution of the project was very slow reflecting our limited resources. Nevertheless, this work represents the unlimited efforts of the staff for the improvement of the service our laboratory provides. A careful system's analysis was performed and all the working procedures were predefined. The software development started in March 1993 and lasted until November 1993. Finally, in the 1st January 1994 the new system was successfully implemented and has now completed the first 11 months of life.

3. The new system

3.1. Hardware

The system is situated at the CPL and runs at present on a single user 386 compatible microcomputer with 130 MB hard disk storage capacity and is linked to a dot matrix printer.

3.2. Software, Database structure and file relations

The front end of the system is a 'work' (WOF) file where all the examination orders are entered every day and held temporarily. Once the order is executed (ie. cytology report) and the work on a record is completed as appropriate, the data are then transferred to the relevant permanent files. The permanent files consist of a patient master index (PMI) file and five satellite files. The PMI holds patient's identification and personal data as well as the follow-up status. Also, it is related to all other files through the patient's unique serial number issued by the computer (Fig. 2). On the other hand, the satellite files hold information on the patient's medical history and on the following medical events: gynecologic cytology, colposcopy and biopsy examinations as well as therapies. A number of files are used also for the management and maintenance of the system (system activity files, index files, etc). Most of the files are dBASE compatible and the software is written in CLIPPER. Fourteen modules are built around a central module and it is very easy to enhance the old or add new modules. Two levels of passwords prevent unauthorised access. Also, to ensure protection, a small hidden file necessary for the program to run, is deleted after an unsuccessful log-in. A dedicated software program was developed to back-up the system's files to diskettes in a compressed format.

3.3. Functional configuration

The hardware and software configuration allows for a maximum of 180 thousand patients records to be held on the PMI. Respectively, follow-up details for 50 000 patients and data on 480 000 gynecologic cytology examinations can be handled by this system. A 6-year period is the maximum expected life span.

3.4. Terminology encoded

The terminology used for smear results is based on the revision of the Bethesda System [18–19] which is adapted to the language characteristics and the working methods in Greece. Thus, the CIN classification is maintained to help the communication with the clinicians. An encoded version of this cytology reporting system is comprised in the software program. We have also encoded the colposcopy and the histology reports according to the terminology systems which are used by the COC and the APL, respectively. A number of key-phrases can be selected through pull-down or function-key menus in order to generate a report. No special knowledge is required

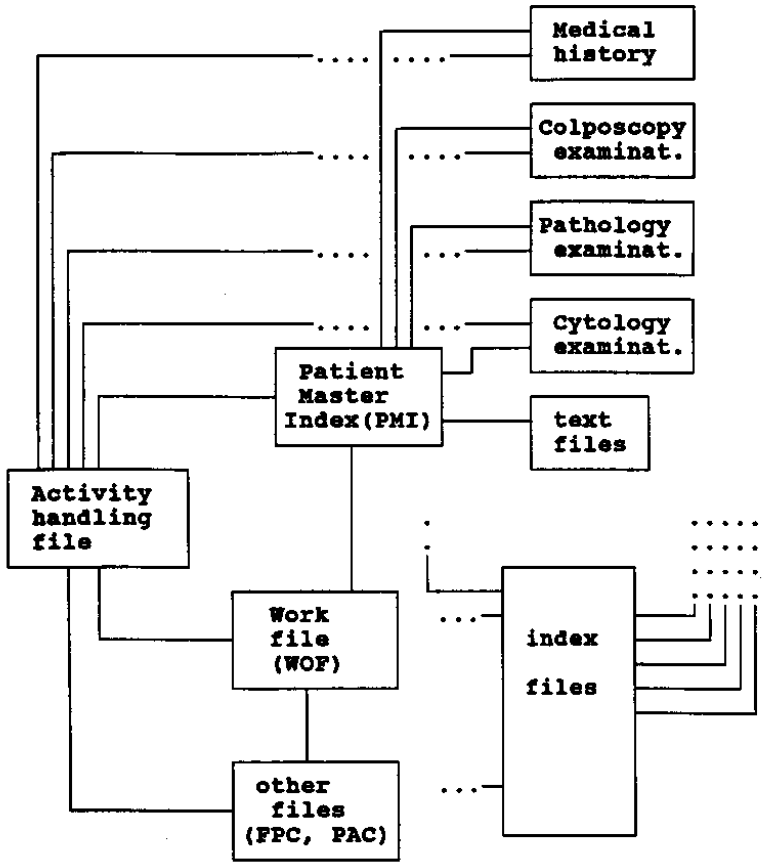

Fig. 2. Simplified representation of file relations.

since what the user selects on the screen is compatible with the key-phrases stated on the handwritten report. When required, four lines of text comments can be added to the report through a dedicated function.

3.5. Data entry

The secretary of the CPL is devoted for the data entry and is assisted by other members of the staff when required. The day to day work comprises three main tasks: (a) the log-in of the new examination orders and of the previous day's examination results; (b) capture of follow-up data; and (c) system control and maintenance. Data-entry error traps are used in all entry forms to avoid data inconsistencies and data incompleteness as much as possible [20]. For example: (i) the date of the last menstruation is invalid if it is later than the date when the smear was taken; and (ii) a number of variables (such as the year of birth) should not be empty, etc. Also, an internal procedure prevents duplication of an examination order.

3.6. Capture of follow-up data and register update

After the completion of all entries of a day's examination orders, a computer procedure compares the ROF numbers and the patient names with those on the PMI to identify old clients. An interactive procedure then asks whether these old clients are correctly identified and whether other clients should be included or not. At this step, the secretary checks whether all the color labelled

cards (concerning patients under surveillance) are included and acts as appropriate. After this step the computer generates a unique serial number for every new client. All the identified old clients bearing a follow-up status are sent to the Follow-up Capture (FPC) file. All the new clients with abnormal test results are also sent to the same file:

When an abnormal test result is entered, the record is then automatically labelled. A scale of three categories is used to indicate the follow-up status according to severity of the lesion (1 = low grade lesions, 2 = high grade lesions, 3 = cancer). The worst label is always predominant in subsequent smears.

Thus, the FPC file contains all the patients to be followed up. The secretary is prompted by the program to seek modified or additional information on those patients by comparing the computer record and the color labelled patient's card. When this 'capture of follow-up data' procedure is completed the name of a patient is deleted from the FPC file. When required, additional information is sought to the appropriate department by the responsible doctor.

3.7. Patient attendance control functions

When a test result is abnormal and a colposcopic examination is recommended, the patient's data are sent to the patient attendance control file (PAC). According to the COC protocol, the cytology examination is repeated before any intervention. Hence, the patient is expected to appear again in the 'work' (WOF) file after a period of time. A dedicated function identifies the patients who complied with the instructions by comparing the PAC file and the WOF. Their names are then deleted from the PAC file and the rest represent patients to call for an appointment.

Patients under follow-up who did not attend for a long time can also be identified and called for an appointment. This function will be evaluated in the future because the system is still very new.

3.8. Other system functions

(a) Patient identification:

— an individual patient record can be identified by: (i) her names; (ii) the source ROF number; (iii) the computer's serial number; and (iv) the smear slide number.
— patient groups can be identified according to diagnostic category, follow-up status and referring source and a suitable print-out list can be generated. More complicated requests require external programming at the moment.

(b) Laboratory activity reports can be generated to help the department's management and the workload planning.
(c) Temporary files can be generated for epidemiologic and other research purposes and can be worked with most statistical packages. A number of predefined functions is available and more complicated requests need external programming.

3.9. Costs

We estimated that the aggregate time which was spent for the development of the system (analysis, design and programming) was approximately 1.3 man years or $20 000. The capital cost for a microcomputer with a 486 microprocessor and 250 MB hard disk and for a small laser printer is $3400. On the other hand, the estimated running costs are $13 000/year. In this figure, we included the salary of one secretary assuming that the department's workload will not exceed a maximum of 30 000 pap-tests per year. The estimated costs of manual recording, are $10 000/year but comparing with the effectiveness and potential of the computerised system we deem that the difference is worthwhile.

3.10. The system up to date

Data on 3984 labelled patients of the period 1988–93 (old database) were transferred to the new system's files before the start of operation [1-1-94]. During the 11 months of operation, 21 434 examinations were recorded and 20 587 new clients were added to the PMI. Also, 310 new clients presented abnormal smears and were included in the population to follow-up (Hospital's incidence). The patients' compliance with the recommendation for colposcopy examination was 63% during the first 6 months.

On the other hand, 847 patients (21.3%) from the old database came for regular follow-up. However, this low figure does not mean that the 78.7% are lost to follow-up since a large number of those patients had several consecutive normal smear results after treatment and are under a less intense follow-up scheme.

4. Discussion and conclusions

We shall tackle three subjects: (a) the circumstances and prerequisites for the building of the register; (b) our choices and the problems we have faced; and (c) the targets and future considerations for the new system.

4.1. Circumstances and prerequisites

The persistent large deficits of the national budget during the last years have led the Greek government to postpone the funding and implementation of HIS in all hospitals belonging to the National Health System. Our hospital could not be excluded from these measures. Nevertheless, despite these disappointing circumstances, we have decided to proceed with our own resources. The appropriate skills and knowledge were essential not only for the development of our register, but also for its proper use. Certainly, for the success of the various health services information systems adequate training of personnel is necessary and should be seriously considered by the health services manpower planners [21–22]. For that purpose, several training schemes exist in Europe [22–25].

Three facts were also essential for the capturing of information and the building of the computerised register: (i) the registration of all women prompting for cytology examination on a unique manual outpatient record (labelled for patients with cervical lesions); (ii) the 'circulation' of this record between departments (attached to the pap-examination order); and (iii) the repetition of the cytology examination right before the colposcopy and the biopsy at the COC. This third fact allows the measurement of patients' compliance with the recommendation for colposcopy. As a consequence, the CPL medical staff knows which patients (and when) to seek at the APL for the biopsy results.

The measured compliance figure (63%) is low and is under investigation. However, it may reflect to some extend the (Greek) peoples' attitude to shift to the private sector when a health problem occurs.

4.2. Choices and problems

The choice of the operating system and the programming language was primarily based on our existing skills, knowledge and the available hardware. Certainly, small systems based on MS-DOS can be easily build because it is relatively easier to find skilled programmers and technical support when required and at a reasonable cost (especially in countries where the language characteristics do not help with the learning process and where the spread of computers is slow). Among the disadvantages on the other hand are: (i) the compatibility problems in the linking with a central system or with the network of a modular Hospital Information System; and (ii) the protection of the system.

Most of the operational problems we have faced occurred during the first 2 months of operation, but they have all been solved without the interruption of the system. A main problem was the synchronisation of the staff and of certain laboratory procedures with the computer usage. However, a continuous evaluation of the program functions contributes to the improvement of the system. Minor problems occur occasionally when the woman's or their husband's surname is used interchangeably on the examination order form and on the outpatient folded card. However, the ROF identification number prevents duplication of records and the computer program prompts for corrections.

4.3. Targets and future considerations

The quality assurance of the test results is one of the most important subjects nowadays [26–30]. This task has been performed yearly since 1989 by the CPL and in a previous study we have concluded that the manual comparison of the cytology test results with the related biopsy results is a very laborious and expensive work [31]. The new computer system can facilitate this procedure but, at the moment, only in retrospect. A computer

system in the APL and the development of an appropriate communication program is necessary for a reliable quality assurance. This is one of the main targets of the two laboratories and an application is already made for the support of a joint project.

Another aim is to achieve a computer communication link with the ROF of the pilot cervical cancer screening programme in Chalkidiki with which the information exchange of patient data, at the moment, is achieved via diskettes. This will provide a better control of the screening programme.

In conclusion, it is clear that the new system is a computerised version of a part of the preexisting mechanism. Our aim was not to substitute but rather to complement this mechanism with more effective features. Thus, better organised data are available and several functions are now possible with respect to better patient care. For example, it is more convenient now to produce the appropriate lists and to call patients who did not attend or did not comply with the instructions. Also, our follow-up register is still experimental and further research is in progress to evaluate its functionality and effectiveness as well as the data completeness and accuracy. We believe that our work will contribute in the promotion of the concepts related to disease follow-up registers and Medical Informatics in our country. We trust also that the invaluable information which will be gathered up to the implementation of an integrated information system in the Hospital will be extremely useful.

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References

[1] Hakama M, Chamberlain J, Day NE, Miller AB and Prorok PC: Evaluation of screening programmes for gynaecological cancer, *Br J Cancer*, 52 (1985) 669–673.

[2] Goldberg J, Gelfand HM and Levy PS: Registry evaluation methods: a review and case study, *Epidemiol Rev*, 2 (1980) 210–220.

[3] Jones RB, Hedley AJ, Peacock I and Alisson SP: Tattersall: A computer assisted register and information system for diabetes, *Methods Inf Med*, 22 (1983) 4–14.

[4] Subbuswamy SG, McCormick A and Peters EE: Computerization of histopathology/cytology records: Use of a commercial data storage system, *J Clin Pathol*, 37 (1984) 157–162.

[5] Wastell DG, Acheson EJ and Tindall S: Development of a computerized clinical system, *Curr Perspect Health Comput*, (1986) 94–100.

[6] The OCCURS Group: Computerisation of screening for cervical cancer, *Health Bull (Edinb)*, 46 (1988) 146–152.

[7] Jimenez Ayala M, Rubio FS, Bullon R, Rodriguez Ardanaz C and Velasco Rodriguez A: Computerized recording and reporting system for cytology and colposcopy, *Acta Cytol*, 32 (1988) 593–598.

[8] Aller RD, French R, Mitchell S and Gondos B: Computerized reporting and follow-up of gynecologic cytology, *Acta Cytol*, 35 (1991) 15–24.

[9] Meisels A and Morin C: Computerized reporting of vaginal/ectocervical/endocervical cytology using the Bethesda system. In *Cytopathology of the Uterine Cervix*, Vol 1, ASCP Press, Chicago, 1991, pp. 227–235.

[10] Jones RB, Nutt RA and Hedley AJ: Improving the quality of data in a computerised patient master index: implications for costs and patient care, *Effective Health Care*, 2 (1984) 97–103.

[11] Vickers N and Pollock A: Incompleteness and retrieval of case notes in a case note audit of colorectal cancer, *Qual Health Care*, 2 (1993) 170–174.

[12] Hannay DR: Accuracy of health-centre records, *Lancet*, 19 Aug. (1972) 371–373.

[13] Patel AR, Gray G, Lang GD, Baillie FGH, Fleming L and Wilson GM: Scottish hospital morbidity data: 1) Errors in diagnostic returns, *Health Bull (Edinb)*, 34 (1977) 215–220.

[14] Parkin DM, Clarke JA and Heasman MA: Routine Statistical Data for the Clinician: Review and Case Study, *Health Bull (Edinb)*, 34 (1977) 277–284.

[15] O'Gorman J: Data accuracy and reliability. In *Hospital Statistics in Europe* (Eds: PM Lambert and FH Roger), North-Holland Publishing Co., Amsterdam/New York, 1982, pp. 113–117.

[16] Roger FH: Medical record summaries: past, present and future in European hospitals, *Methods Inf Med*, 24 (1985) 117–119.

[17] Efstratiadou M, Terpos AA, Mentzelopoulou P, Tsiveleka A, Paisi M, Linos A: Epidemiologic studies on CIN lesions, Abstr. 21st Europ. Congr. on Cytology, *Acta Cytol*, 37 (1993) 587.

[18] National Cancer institute Workshop: The 1988 Bethesda System for Reporting Cervical/vaginal Cytological Diagnoses, *J Am Med Assoc*, 262 (1989) 931–934.

[19] National Cancer institute Workshop: The Bethesda System for reporting cervical/vaginal cytologic diagnoses, *Acta Cytol*, 37(2) (1993) 115–124.

[20] Norton LS, Buchanan AV, Rossman DL, Chakraborty R and Weiss KM: Data entry errors in an on-line operation, *Comput Biomed Res*, 14 (1981) 179–198.

[21] Gremy F: Why teach information sciences in medicine? Will they contribute to a solution in the present crisis of medicine? *Methods Inf Med*, 22(3) (1983) 121–123.

[22] Shortliffe EH and Perreault LE: The need for a course in medical computer applications, and the need for specialists in medical informatics. In *Medical Informatics: Computer Applications in Health Care*, Addison-Wesley Publishing Company, Palo Alto, CA, 1990, Preface xii–xv.

[23] Mohr JR, Leven FJ and Rothemund M: Formal Education in Medical informatics Review of ten years' experience with a specialized university curriculum (from the Institute of Medical Documentation, Statistics and Data Processing, University of Heidelberg), *Methods Inf Med*, 21(4) (1982) 169–180.

[24] Mantas J: ERASMUS programme in health information sciences, *Proceedings of the Conference on Training Strategies for Health information Systems*, Council of Europe, Strasburg, 29–31 October, 1991, pp. 34–39.

[25] Hasman A and Sosa M: Education and training of health informatics in Europe, *Technol. Health Care*, 2 (1994) 61–70.

[26] Bibbo M, Alenghat E, Bahr GF, Bartels PH, Dytch HE, Herbst AL, Keebler CM, Pishotta FT and Wied GL: A quality control procedure on cervical lesions for the comparison of cytology and histology, *J Rep. Med*, 28 (1983) 811–822.

[27] Collins DN and Patacsil DP: Proficiency testing in cytology in New York. Analysis a 14-year state programme, *Acta Cytolog*, 30 (1986) 633–642.

[28] BSCC Working Party: Recommended code of practice for laboratories providing a cytopathology service, *Br Soc Clin Cytol*, (1986) 8–9.

[29] Lundberg DG: Council on scientific affairs: quality assurance in cervical cytology the Papanicolaou smear, *J Am Med Assoc*, 262(12) (1989) 1672–1679.

[30] EEC: European guidelines for quality assurance in cervical cancer screening: quality assurance in the cytology laboratory, CEC DG V E.1.: *Europe against Cancer Programme*, March 1993, pp. 52–54.

[31] Terpos AA, Tsiveleka A, Mentzelopoulou P, Galani-Fotiou V, Efstratiadou M, Kyriopoulos JE: Estimating the cost effectiveness of the internal quality assurance procedure with or without the use of a computer system in the department of cytology, *Soc Econ Health* (Grk), 1(3) (1992) 23–34.