work then texts such as that by Stansfeld or Jaffe are probably preferable. They are more clear-cut and cover a wider field including Hodgkin's disease and reactive lymphadenopathy. If one is more interested in the background to the diagnostic arguments about non-Hodgkin lymphoma and to have an understanding of lymphoma classification then this book is required reading.

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News

QUALITY CONTROL

EVALUATION OF quality in health care has received enormous attention over the past few years and traditional quality control (QC) has concentrated on physicians performance. Recently, however, the study of procedures and outcomes has also become subject to QC and improvement [1, 2]. The application of industrial quality management science has been advocated, using the principles of recognition, analysis and elimination of variation [3].

The EORTC Genitourinary (GU) Group began working on QC in 1987 and because multicentre clinical trials involve many different procedures, the first priority was to obtain baseline information about the centres and their infrastructure, individual members and their co-workers, trial procedures and the attitude and education of the participating clinicians.

In 1987 the EORTC GU Group established a committee for QC to evaluate the quality of the work of the group and its members as well as to formulate instructions on maintainance and improvement of QC.

It was decided that an attempt should be made to site-visit the majority of institutions in which members of the group were practising. Checklists were drawn up for the visitors as a reminder of their task. After a test-visit to one institution, the procedures and the checklists were finalised (Appendix). At every site-visit the urologist (member of the GU Group) was interviewed (checklist 1), the institution was inspected and other specialists (pathologist, radiologist, pharmacist, oncologist, the medical superintendent etc.) were also interviewed (checklist 2). Finally, examples of trial patient files were examined (checklist 3). At the end of each site-visit a final interview with the GU Group member was held in which shortcomings and interpretation errors, if any, were discussed and advice for improvement given. The final evaluation by the QC committee (QCC) was provided subsequently.

A total of 35 institutions were visited which represents 70% of the institutions that currently participate in the GU Group trials. Unfortunately, in five instances the checklists were incomplete, so that only figures for 30 institutions are available. The complete tables are part of the final report produced by the QCC for the GU Group (1991).

The size of urological departments varied from 10 to 120 beds indicating that some members of the group are working in isolation, with partners or in large (university) clinics with a staff of consultants and residents. Accordingly, the time involved with EORTC matters ranged from 5 to 100%. It was clear that solo workers have to do most of the administration themselves while in larger clinics (14 out of 30) data managers are generally available.

Twenty-five institutions had ethical committees, although these were not always consulted about EORTC trials. Two-thirds of the institutions have an oncology department. In 25 centres residents in urology were involved in EORTC trials. 378 patient files were examined and the contents compared with the data forms from the EORTC Data Centre. A total of 163 transcription errors and 78 interpretation errors were encountered.

The following definition of quality was adopted: 'Quality is the degree of excellence with which the group is able to perform clinical trials concerning significant and scientifically relevant problems in urological oncology and to present their results in a reasonably short period of time'.

To comply with these criteria the group must have:

1. Well-designed protocols.
2. Reliable data from members and their institutions.
3. Excellent data management and follow-up.
4. Control and analysis by the Data Centre and its statisticians.
5. Publications in top class journals and presentations in high level meetings throughout the world.

The QCC came to the conclusion that the quality of the GU Group in general could be considered as good although a number of features needed improving and reevaluation at certain intervals would be necessary. The group has worked with a range of good protocols and in particular the standardised phase II protocols are satisfactory. However, phase III protocols in general needed improvement, innovation and simplification. Too much data was requested that was never analysed and did not contribute to the final outcome. There was no doubt about the reliability of data but some members could have performed much better if administrative help had been available to them. The great variability in handling cytotoxic drugs encountered is still of great concern. There is still a need for oncologists and pharmacists to come to a consensus and uniformity in this respect.

The work of the Data Centre may be threatened by economic restraints. This means that relations with the pharmaceutical industry must be improved to encourage sponsorship that does not influence the independence of the group in conceiving and developing protocols and the presentation of trial results.

The authors and the following are members of the Quality Control Committee of the EORTC Genitourinary Group: Ph. Smith, J. W. Hoekstra, M. Brausi, F. Keuppens, P. Fernandez, W. Jones, J.C. Carneiro de Moura and P. de Mulder.

Table 1. The 10 Commandments

1. Be a good clinician.
2. Organise your administration.
3. Never try to do more than you can handle.
4. Either take or turnover responsibility for trial administration.
5. Follow-up scheme in dossier of every trial patient
6. Keep the other specialists informed about the EORTC, if you want their cooperation.
7. Nothing is taken for granted that you have not made evident yourself.
8. Ask EORTC officers for help and advice.
9. See your medical, nursing and administrative staff regularly on EORTC matters.
10. Communicate any trial idea that crosses your mind to the CTC.

Table 2. How to preserve and improve quality

1. Extension of the work of the National Coordinators (to form new QCC).
2. Continuation of computerised checks and blacklisting by the Data Center.
3. Screening of 10–25% of the dossiers of all entered patients in any trial by the Study Coordinators and QCC.
4. Method of quality control to be mentioned in final publication of trials.
5. Think-tank (scientific committee?) to find new, innovative and imaginative subjects for clinical trials.
6. Improvement of patient dossiers (standardisation?)
7. Development of standard reports for operative, endoscopic and diagnostic procedures.
8. Administrative help for some members.

The question remains of how can the performance of individuals and the group as a whole be improved in the performance clinical trials in urological oncology and how can the quality be preserved? The QCC strongly advocates the theory of continuous improvement [4], which can be attained by choosing the right peer review method combining judgment of procedure and outcome [5].

To this end the QCC developed the '10 commandments' for members (Table 1) and a set of recommendations for the group (Table 2). A second phase will be devoted to reviewing these, making readjustments and the evaluation of a number of important procedures.

1. Donabedian A. The quality of care. *JAMA* 1988, **260**, 1743–1748.
2. Marder RJ. Measuring the quality of care for the cancer patient. *Cancer* 1991, **67**(Suppl. March), 1753–1758.
3. Laffel G, Blumenthal D. The case for using industrial quality management science in health care organizations. *JAMA* 1989, **262**, 2869–2873.
4. Berwick DM. Continuous improvement as an ideal in health care. *New Engl J Med* 1989, **320**, 53–56.
5. Brook RH, Appel FA. Quality-of-care assessment: choosing a method for peer review. *New Engl J Med* 1973, 1323–1329.

Acknowledgements—We are grateful to Professor D.W.W. Newling who kindly read the manuscript and gave some sound advice.

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APPENDIX

EORTC GENITO-URINARY TRACT GROUP

FORM 1
AUGUST 89

CHECKLIST FOR SITE VISITORS

HOSPITAL VISIT, INTERVIEW WITH (BOARD OF) DIRECTORS AND OTHER OFFICERS

Institution: .....
Address: .....
Visit made by: .....
Visit concerned with EORTC GU protocols: .....

1 |_|_| |_|_| |_|_| Date of visit (day, month, year)

2 |_|_|_| EORTC number of institution visited

INTERVIEW WITH MEDICAL SUPERINTENDENT

Ethical Considerations / **Code: 1 = No, 2 = Yes**

3 |_| Is there a central Ethical Committee?

4 |_| Is informed consent always obtained?

5 |_| Is written informed consent obligatory?

6 |__| Is minimal information on informed consent provided to all patients?

7 |__| Is patient privacy adequately protected?

Records/Organisation / **Code: 1 = No, 2 = Yes**

8 |__| Are patient records centralised?

9 |__| If patient records are decentralised, are they uniform?

10 |__| Are out-patient records always available?

11 |__| Are patient records computerized?

12 |__| Are patient records microfilmed?

INTERVIEW WITH PHARMACOLOGIST IN CHARGE OF CENTRAL PHARMACY / **Code: 1 = No, 2 = Yes**

13 |__| Are cytotoxic drugs centrally stored and prepared?

14 |__| Is storage of cytotoxic drugs adequate?

15 |__| Is preparation and delivery of cytotoxic drugs adequate?

16 |__| Are new drugs and protocols discussed with pharmacologist?

Summary of interview:

.....

.....

.....

INTERVIEW WITH PATHOLOGIST IN CHARGE OF CENTRAL PATHOLOGY LABORATORY
***Code: 1 = No, 2 = Yes**

17 |__| *Are protocols discussed with pathologist before trial approval?

18 |__| *Are forms for biopsies or cytology always marked for EORTC GU trials?

19 |__| *Are biopsy and cytology materials marked for EORTC GU trials?

20 |__| Unstained sections are sent to the Referee Pathologist: **1 = Immediately, 2 = Later on request**

Name of responsible Pathologist for EORTC GU trials: .....

Local Pathology problems / **Code: 1 = No, 2 = Yes**

21 |__| Concerning the EORTC GU Referee Pathologist

22 |__| Concerning the quality of slides

23 |__| Concerning the quality of histology

24 |__| Concerning the G classification of bladder and prostate cancer. If yes, specify: .....

.....

25 |__| Does the pathologist know that he can claim financial compensation from the GU Group for preparation of extra slides?

Summary of interview with Pathologist: .....

.....

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.....

.....

RADIOLOGY AND NUCLEAR MEDICINE / **Code: 1 = No, 2 = Yes**

26 |__| Has there been an interview with the radiologist?

Who is in charge of radiology: .....

Who is in charge of Nuclear Medicine: .....

27 |__| Are they aware of the EORTC GU trials? Are there special difficulties in performing demands from these trials: .....

Summary of interview: .....

EORTC GENITO-URINARY TRACT GROUP

FORM 2
AUGUST 89

CHECKLIST FOR SITE VISITORS

INTERVIEW WITH PRINCIPAL INVESTIGATOR OF DEPT. OF UROLOGY AND OTHER DEPT. (ONCOLOGY, RADIOTHERAPY IF INVOLVED)

1 |__|__| |__|__| |__|__| Date of visit (day, month, year)

2 |__|__|__| EORTC number of institution visited

Chairman of dept. Urology: .....
Chairman of dept. Medical Oncology: .....
Chairman of dept. Radiotherapy: .....
Chairman of dept. Pathology: .....
Chairman of dept. Radiology: .....
Chairman of Nuclear Medicine: .....
Principal investigator: .....
Other investigators: .....

What is the total number of full time equivalents in:

	Urology	Urology involved in EORTC trials	Urology % of time for EORTC	Oncology involved in GU group trials
Specialists	3|__|.|__|	4|__|.|__|	5|__|.|__|	6|__|.|__|
Residents	7|__|.|__|	8|__|.|__|	9|__|.|__|	10|__|.|__|
Nurses	11|__|.|__|	12|__|.|__|	13|__|.|__|	14|__|.|__|
Admin. personnel	15|__|.|__|	16|__|.|__|	17|__|.|__|	18|__|.|__|

BEWARE OF THE "." WHICH IS MEANT FOR HALF TIME PERSONNEL

In-patient department Urology

19 |__|__| Number of beds for adult patients

20 |__|__| How many patients with urogenital cancer? Estimate

21 |__|__ In-patient files available?* ***Code: 1 = No, 2 = Yes**

22 |__|__ EORTC protocols at the department?*

Out-patient department Urology

Code: 1 = No, 2 = Yes

23 |_|_| How many visiting hours for patients during a week?

24 |_|_ Divided in how many days?

25 |_|_ Are all the staff members involved?

26 |_|_ Are all the residents involved?

27 |_|_ Are Nurses and Admin. Personnel involved?
If not, explain: .....

How is the unit set up for EORTC GU trials?

28 |_| Meetings to discuss EORTC GU trials: **1 = no, 2 = yes,** specify frequency: .....

Who does routine follow-up: .....
.....

Who ensures correct data for the data manager: .....
.....
.....

How many patients newly admitted last year with:

	all cases seen in inst. of Urology	entered in EORTC GU trials
Bladder cancer	32 |_|_|	33 |_|_|
Prostate cancer	34 |_|_|	35 |_|_|
Renal cell cancer	36 |_|_|	37 |_|_|
Testicular cancer	38 |_|_|	39 |_|_|

40 |_| Has the investigator asked and received permission of the central Ethical Committee for all EORTC GU trials:
1 = No, 2 = Yes

In which GU protocols are patients entered: .....
.....

41 |_| + 42 |_| Reasons for not entering all eligible patients in the protocols you participate in: 1 = all eligible patients are entered, 2 = refusal of patients, 3 = limitation of time, 4 = limitation of hospital resources
Comments: .....
.....
.....
.....

Medical Oncology

43 |_| Is department Medical Oncology present in the hospital? **1 = No, 2 = Yes**

Oncologist for GU group trials: .....

How is the cooperation established? (narrative): .....
.....
.....
.....

Data Managers

44 |_|.|_| How many Data Managers work only with EORTC GU protocols?

45 |_|.|_| With other departments in the same institution?

46 |_|.|_| With other institutions?

What is the level of education of the Data Manager? **1 = No, 2 = Yes**

47 |__| M.D.

48 |__| Nurse

49 |__| Medical Secretary

50 |__| Other medical training

51 |__| No medical training

Data Managers' problems in institution (narrative): .....
.....
.....
.....
.....

EORTC Eurocode connection

52 |__| Is there a Eurocode connection: **1 = No, 2 = Yes**

53 |__| If not, reason: **1 = no PC available, 2 = not interested, 3 = not aware of the possibility**

54 |__| Was a request for 1000 ECU for connection addressed to M. BUYSE: **1 = no, 2 = yes**

EORTC GENITO-URINARY TRACT GROUP

FORM 3
AUGUST 89

CHECKLIST FOR SITE-VISITORS

VERIFICATION PROCEDURE OF PROTOCOLS INVOLVED

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1 |__|__| |__|__| |__|__| Date of visit (day, month, year)

2 |__|__|__| EORTC number of institution visited

3 |__|__|__|__|__| Protocol number

4 |__|__| |__|__| |__|__| Birthdate (day, month, year)

Patient name and/or identification number: .....

COMPLETENESS OF PATIENT RECORDS / **Code: 1 = No, 2 = Yes, 9 = Not applicable**

5 |__| Is eligibility noted in the patient's chart?

6 |__| Protocol summary and/or follow-up scheme present

7 |__| Are deviations in protocol follow-up noted in the patient's chart (if yes explain in comments)

8 |__| Dosages of drugs mentioned

9 |__| Toxicity asked for and noted

10 |__| Response to treatment noted

11 |__| Progression noted if applicable

Written reports available from: (check quality in random review of 1/3 of patients)

Code: 1 = No, 2 = Yes, 9 = unknown or not done

	Reviewed	Adequate quality	Agreement with forms
12 |__| CT-Scans	13 |__|	14 |__|	15 |__|
16 |__| X-ray	17 |__|	18 |__|	19 |__|

20 |__| Bone-scans	21 |__|	22 |__|	23 |__|
24 |__| Ultrasound exam.	25 |__|	26 |__|	27 |__|
28 |__| Chemical lab.	29 |__|	30 |__|	31 |__|
32 |__| Pathology lab.	33 |__|	34 |__|	35 |__|

Comments on completeness of files: .....

.....

.....

.....

.....

PROTOCOL COMPLIANCE / **Code: 1 = No, 2 = Yes**

36 |__| Follow-up in accordance with protocol

37 |__| Assessment of response in accordance with protocol

38 |__| Assessment of toxicity in accordance with protocol

AGREEMENT BETWEEN PATIENT'S HOSPITAL RECORDS AND EORTC FORMS

	Reviewed	Number of discrepancies per form
On-study form	*39 |__|	40 |__|__|
Treatment forms	*41 |__|	42 |__|__|
Follow-up forms	*43 |__|	44 |__|__|
Off-study form	*45 |__|	46 |__|__|

***Code: 1 = No, 2 = Yes, 9 = Not applicable**

47 |__| Are these differences due to incorrect interpretations? **Code: 1 = No, 2 = Yes**

48 |__| Are these differences due to incorrect transcriptions?

49 |__| LEGIBILITY OF PATIENT HOSPITAL RECORDS/FILES: **1 = good, 2 = fair, 3 = bad**

Shortcomings to be discussed with investigator: .....

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FINAL REPORT (SUMMARY OF IMPRESSIONS):

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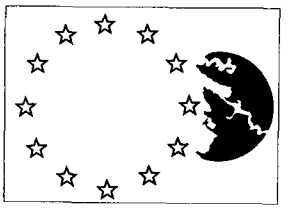

First Annual European Residential Course on

CANCER CLINICAL TRIALS

Organised by ESO - EORTC

in collaboration with BODMA, CKVO, CRC, DVMD, FNCLCC, MRC, SAKK

18th - 22nd October, 1993, Bruges, Belgium

Chairpersons: J.G. McVie and M. Baum (London), C. Molin (Stockholm), D. Riley (London)

Programme Coordinator: K. Vantongelen (Leuven)

Discussion leaders: C. Arrigo (Brussels), F. Montinari (Monza), N. Rotmensz (Milan)

Faculty: Blackledge (GB), Castiglione (CH), Dalesio (NL), Denis (BE), Dubbelman (NL), Fallowfield (GB), Franklin (NL), Gall (NL), Hill (FR), Houghton (GB), Marsoni (IT), Meunier (BE), Parmar (GB), Pavlidis (GR), Sylvester (BE), Tagnon (BE), van der Schueren (BE), Van Glabbeke (BE), Van Oosterom (BE), Webb (GB)

This 5-day full-immersion course in English is designed at advanced level and oriented towards medical doctors, specialists in oncology, experienced data managers, oncology nurses and people working in the pharmaceutical industry, involved in cancer clinical trials. Teaching methods will include formal lectures, panel discussions on controversial issues, individual sessions for the different groups of participants and a visit to the European Organization for Research and Treatment of Cancer (EORTC) - Central Office / Data Center in Brussels. The Commission of the European Communities has made ***30 fellowships*** available to nurses and data managers to attend this course.

The need for science in medicine

Clinical trials versus standard treatment

Multidisciplinary approach

How to translate an interesting question into a clinical trial

The role of statistics in clinical trials

Protocol review

Ethical issues: legal constraints, informed consent, privacy of data, doctor/patient relationship

EORTC Data Center visit

Role of the Data Center

Design of clinical trials: design, sample size, randomisation, stratification

Data analysis: basic principles, analysis techniques, models, prognostic factors, interim analysis, early stopping rules

Nurses' role and contribution in observation, interpretation and recording of adverse events

Patient and family information and education

Response evaluation, reporting toxicity, patient documentation, audits

Reporting results

Interpretation of published results

Meta-analysis

Quality-of-life assessments

Cost evaluation of clinical trials

Implementation of good clinical practice

Impact of trial results on clinical practice

Priorities in cancer clinical trials

For all further information contact (B1):
ESO Brussels Office
Av. E. Mounier 83/13
1200 Brussels, Belgium
Tel: (+32 2)7724621 Fax: 7726233

Mechanisms of Carcinogenesis

The forum on mechanisms of carcinogenesis is being presented by the Baptist Memorial Hospital and the University of Tennessee, Memphis, U.S.A. on 23 April 1993. As in the past 6 years, it will address state-of-the-art cancer research. For further information contact Dr J.E. Hamner, Forum Director, The University of Tennessee, Memphis, 62 South Dunlop, Room 511, Memphis, Tennessee 38163, U.S.A. Tel: (901) 528–6354.

European Association of Science Editors

The EASE 5th general assembly and conference on editing, ethics, electronics and economics will be held on 24–28 April 1994 in Budapest, Hungary. Topics covered will include editorial freedom, ethics in the economic era, design from desktop publishing and economics of journal production. For further information contact M. O'Connor, EASE Secretariat, 49 Rossendale Way, London NW1 OXB, U.K. Tel: 071 388 9668, Fax: 071 383 3092.

Stereotactic Radiotherapy/Radiosurgery

The Departments of Radiation-Oncology and Neurosurgery, Free University Hospital, in close co-operation with the Meta Elisabeth Foundation and Bureau PAOG Amsterdam, will be holding an international conference and course on stereotactic radiotherapy/radiosurgery on 6–8 May 1993 in Amsterdam. For futher information contact Ms A. Sol, Ms G. Luysterburg, VU-Ziekenhuis, Postbus 7057, 1007 MB Amsterdam, The Netherlands. Tel: (31) 20 548 6163/20 548 6164, Fax: (31) 20 548 6160/20 548 6101.

Hyperthermia in Oncology

An introduction and refresher course on hyperthermia in oncology is to be held on 13–15 May 1993 at the Royal Postgraduate Medical School, London, U.K. For further information contact C.C. Verman, Wolfson Conference Centre, Royal Postgraduate Medical School, Hammersmith Hospital, Du Cane Road, London W12 0NN, U.K. Tel: 081 740 3117/3245, Fax: 081 740 4950.

Monoclonal Antibodies in Clinical Oncology

The 10th international Hammersmith conference on advances in the applications of monoclonal antibodies in clinical oncology will be held on 3–5 May 1993 in Paphos, Cyprus. The programme will cover all aspects of monoclonal antibodies, highlight the breakthroughs of the past 10 years and discuss future avenues. For further information contact Mrs R. Chandler, Department of Clinical Oncology, Hammersmith Hospital, Du Cane Road, London W12 0HS, U.K. Tel: 081 740 3149, Fax: 081 746 2021.

International Society for Radiation Oncology

The International Congress for Radiation Oncology 1993 (ICRO '93) will be held on 21–25 June 1993 in Kyoto, Japan. The programme will cover all areas of radiation oncology, biology, physics, diagnostic imaging and nuclear medicine related to radiotherapy, and interventional radiology devoted to cancer treatment. For further information contact ICRO '93, Department of Radiology, Faculty of Medicine, Kyoto University, Shogoin-Kawaharacho, Sakyo-ku, Kyoto 606–01, Japan. Tel: 81-75-751-3417, Fax: 81-75-771-9749.

Lung Cancer Congress

The international congress for lung cancer will be held on 22–26 June 1994 in Athens, Greece. The congress will cover all relevant fields in basic cancer research and clinical oncology; also, special problems in the care of cancer patients, which is directed at young doctors and nurses. For further information contact Olympic Sun, International Congress Organisers, 7 Voulis Str, 105 62 Athens, Greece.

DNA Damage

The New York Academy of Sciences is holding a symposium entitled DNA damage: effects on DNA structure and protein recognition. This will take place from 31 July to 4 August 1993 in Vermont, U.S.A. For further information contact the Conference Department, New York Academy of Sciences, 2 East 63rd Street, New York, NY 10021, U.S.A. Tel: (212) 838 0230, Fax: (212) 838 5640.

CA 125 Ten Years Later

An international symposium on CA 125 ten years later: biology and clinical applications – present and future will be held on 10–13 October 1993 in San Remo, Italy. For further details contact M.A.F. Servizi, Via G.B. Vico 7, 10128 Torino, Italy. Tel: 39 11 505 900/598 383/5992 626, Fax: 39 11 505 9766.

Clinical Trials in Oncology

A conference on clinical trials in oncology: improving their design and analysis will be held on 28–30 October 1993 in Toronto, Canada. For further information contact Continuing Education, Faculty of Medicine, University of Toronto, Medical Sciences Building, Toronto, Ontario, M5S 1A8. Tel: (416) 978 2718.

Therapy of Colorectal Cancer

The University of Texas MD Anderson Cancer Center is holding a conference on advances in the biology and therapy of colorectal cancer on 4–7 November 1993 in Houston, Texas, U.S.A. For further details contact the office of Conference Services, HMB 131, U.T.M.D. Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, TX 77030-4095, U.S.A. Tel: 713/792 2222, Fax: 713/794 1724.

Localised Prostatic Carcinoma

The Xth Grenoble Cancer Research Workshop (under the patronage of INSERM) on localised prostatic carcinoma will be held on 8–9 April 1993 in Grenoble, France. For further information contact Unite de Concertation et de Recherche pour le Traitement des Affections Cancereuses, Hopital A. Michallon, BP 217X, 38043 Grenoble Cedex, France. Tel: 76 76 54 36, Fax: 76 54 17 82.

International Association of Cancer Registries

The 1993 meeting of the association will be held in Bratislava, Slovakia on 13–15 September 1993. The conference centres around the topic of poverty and cancer, with sessions on cancer in an aging world (in collaboration with the National Institute of Aging, NIH, U.S.A.), control and prevention, environmental pollution and cancer, and methodological problems in cancer registration. For further information contact Secretariat, Annual meeting of IACR, Slovak Medical Association (Mrs Sona Kozáková), Legionárska ul. 4, 813 22 Bratislava, Slovakia.