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EUROPEAN LONGITUDINAL STUDY ON PREGNANCY AND CHILDHOOD (ELSPAC)

Report on a Meeting of Principal
Investigators

Bristol, 16–21 July 1994

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1994

EUR/HFA target 7

TARGET 7

HEALTH OF CHILDREN AND YOUNG PEOPLE

By the year 2000, the health of all children and young people should be improved, giving them the opportunity to grow and develop to their full physical, mental and social potential.

ABSTRACT

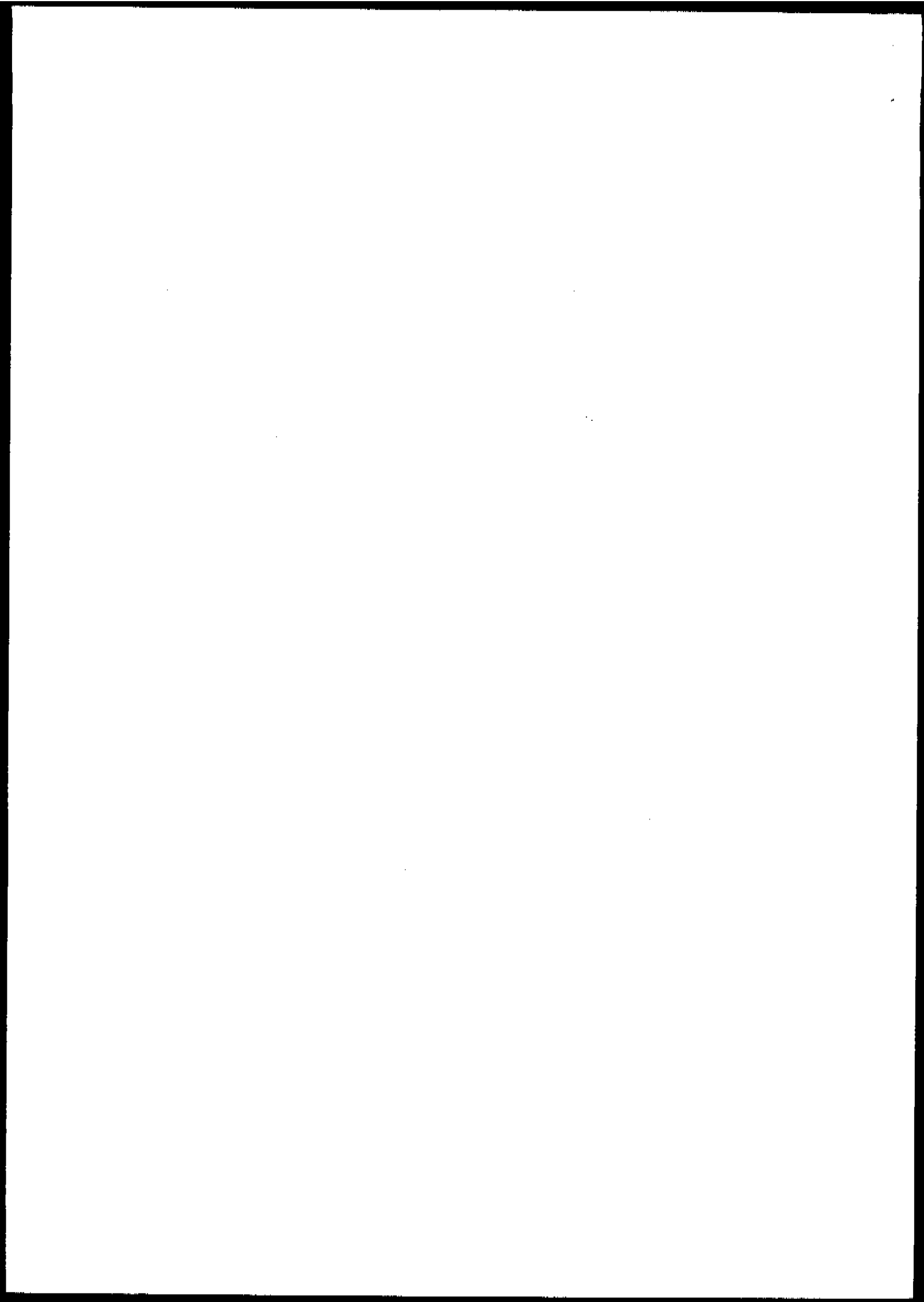
The European Longitudinal Study on Pregnancy and Childhood (ELSPAC) was initiated by the WHO Regional Office for Europe in 1985 to improve epidemiological knowledge about factors influencing child health in European countries. The study is designed to cover various aspects of the life and environment of the pregnant woman and child. The ninth ELSPAC meeting was mainly devoted to the first ELSPAC book, including the actual writing and/or finalization of the first drafts. The book is expected to be finalized by the end of 1994 and printed in 1995. Progress reports from participating countries were also reviewed and discussed. The study was cancelled in Mallorca (Spain) due to financial constraints. An additional centre in Ukraine was approved to join the study. At present, the study is running in six countries (Czech Republic, Greece, the Russian Federation, Slovakia, Ukraine and the United Kingdom). The Central Survey Office is located in the Bristol centre. The participants agreed that the next meeting should focus on the preparation of the second ELSPAC book.

Keywords

LONGITUDINAL STUDIES
PREGNANCY
CHILD HEALTH
CZECH REPUBLIC
GREECE
RUSSIA
SLOVAKIA
UKRAINE
UNITED KINGDOM

CONTENTS

	<i>Page</i>
1. Introduction	1
2. Country reports	1
3. ELSPAC protocol	3
4. Study rules	3
5. New study centres	4
6. Cross-cultural analyses and authorship	5
7. First report from ELSPAC	6
8. Children's right in Croatia	7
9. The 1995 meeting	8
Annex 1 List of participants	9



1. Introduction

The 1994 meeting of ELSPAC (European Longitudinal Study on Pregnancy and Childhood) Principal Investigators was mainly devoted to the first ELSPAC book, including the actual writing and/or finalization of the first drafts. Country reports and other issues were discussed at the plenary sessions and are summarized below. The meeting was attended by 24 participants from 10 countries.

2. Country reports

Isle of Man - Ms Stephanie Goodfellow reported that the study on the Isle of Man was proceeding satisfactorily. The 3-year questionnaires were currently being administered and the response rate she thought was reasonable. Data from the early questionnaires are keyed and ready for analysis.

Information from the **Czech Republic** indicated that the 3-year questionnaire was administered from 1 April in Znojmo and 1 March in Brno. The questionnaire about the child being very long, they have split it into 2 questionnaires. The 3-year questionnaires have photographs of mothers and children inserted. This was viewed as a brilliant idea by all participants.

There had been a problem at one stage in Znojmo because of an administrative failure with the administration of the study, but this has now been corrected. Currently there are data from all antenatal questionnaires on computer together with those administered postnatally. These comprise 3570 and 3901 questionnaires for each sweep from Brno and 1 022 to 1 312 for Znojmo. In addition, the delivery questionnaire has been collected for 5 478 births in Brno and 1 844 births in Znojmo and this is also on computer.

From **Russia**, Professor Ignatyeva reported that the financial situation in regard to the research was under grave difficulties. Although the study had proceeded with the administration of the questionnaires and their safe return, there was a large back-log of coding and keying. In addition, the study had run out of paper and was unable to print the 3-year questionnaires. The question was raised as to whether she should use her resources to code and key the data that was available and abandon the 3-year data collection and this was briefly discussed. No conclusion was reached in the hope that she would be successful in raising appropriate money. It was pointed out later that compliance with the ELSPAC protocol would necessitate a 3-year contact. Just after the end of the meeting news was received that the US State Department had awarded funds to support the 3-year data collection.

In **Greece**, Dr Eleni Adam reported a poor response rate at 6 months (i.e. of the order of 50%) and that she had therefore decided not to send reminders when administering a questionnaire at 18 months, but rather use her resources elsewhere. Consequently her response rate at 18 months is around 25%. The third year contract is not being administered.

The study team had received a message from Dr Sergio Verd in **Mallorca** that his study had run out of finances and that he was therefore stopping it. The meeting expressed regret at this decision and emphasised that the data already collected should nevertheless be transferred to Bristol for cross-cultural analyses.

The study in **Ukraine** was now well in the field with over 1 000 questionnaires having been coded and keying about to start. In addition, 1 000 delivery questionnaires had been coded and keyed. Professor Shkiriak-Nizhnik reported that the promulgation of the study had been so excellent that other centres within the Ukraine were asking to join. She asked permission for a sixth centre, Krasny Louch, in the east of the Ukraine to join the study and the meeting referred this to Coordinating and Executive Committee (CEC) for approval.

Slovakia was not represented at the meeting, but a report received indicated that the study was still progressing there, although the response rate was not very high. Unfortunately Dr Marcela Barova is ill and the study has been taken over by Dr Ida Valkyova.

The Study in **Avon** (ALSPAC) was reported on by Mr Hugh Simmons. The response rates were still high and the number of projects mounted within the ALSPAC study was quite extensive. Analyses have not yet taken place concerning the bias in those mothers who did not respond, but this will proceed in the future.

Three of the countries that initially expressed a wish to join the ELSPAC study were represented. Dr Britt-Mari Lindqvist (Sweden) reported that she was still unable to find funding although now there was a major grant proposal which should be heard by the end of the year. Dr Sophie Alexander (Belgium) reported on a pilot study in the French-speaking part of Belgium, which was designed such that 5 different maternity hospitals were selected with varying degrees of success. The piloting was particularly carried out with deprived social groups including a large immigrant population who found self-completion questionnaires difficult to complete. The Belgian study team has therefore decided not to continue with the full ELSPAC survey.

Piloting is progressing, however, in Croatia. Translations and back-translations have been carried out and the pilot study has involved 100 questionnaires of 13 different types (i.e. 1 300 in all) being administered to the population. Dr Lili Mikecin presented her intentions of returning to Bristol with the results of the pilot when they were ready so that final preparations could be made for the full study, which would take place in Varajde on the Austrian border. Professor Golding reported that Professor Mai Maser from Estonia had sent her apologies, but had recently received money from her government for piloting, and is to begin piloting shortly.

3. ELSPAC protocol

The development of the ELSPAC protocol proceeded speedily. Participants supplied suggestions, corrections and additions, and a revised version should be ready for distribution by 31 July.

4. Study rules

It was felt very strongly that Collaborating Centres should be reminded of the overall rules for the study, with due attention being paid to the imperative of sticking to the study design of a geographic population, data to be forwarded to Bristol, and all core components of the study being undertaken.

The full rules comprised:

- * The study should cover all pregnant mothers resident in a defined geographical area with expected date of delivery between identified dates.
- * The mothers should be contacted as early in pregnancy as possible.
- * Both livebirths and fetal deaths occurring after 20 weeks gestation to residents of the area should be included.
- * Mothers resident in the area at the time of delivery should be followed up as far as possible, even if they move out of the area.
- * The children should be followed up until the age of 7 years.
- * Data collection should use self-completion questionnaires filled in by the mother and her partner and linked to information obtainable from health records.

- * All information should be deemed highly confidential and kept in such a way that the name of the parent or child cannot be linked with the statistical information.
- * All study centres should ask the same questions in the same way - with the exception of a few defined questions for which appropriate culture-specific questions should be used. Obvious examples are educational level, ethnic origin, socio-economic group.
- * Each study centre could add as much detail as it liked to the overall study strategy, but should not omit any of the core data set.
- * A copy of the collected data should be cleaned using instructions provided by the Coordinating Centre at Bristol and sent to Bristol within 1 year of completion of the particular data sweep.

It was regretted that Spain had dropped out of the ELSPAC study, although it was pointed out that their conformity to the study design had not been good. It was arranged that Professor Baum and Professor Jean Golding would follow this up, however, to ensure that the data were deposited in Bristol.

5. New study centres

Anyone wishing to start the study should be approved by the CEC, and be asked to give a progress report at annual intervals. Persons making contact and beginning to attend meetings should be allowed a maximum of 3 years to get the study underway. After this point in time, it was felt that they should no longer be included in ELSPAC meetings.

In regard to the study centres that are new - the fact that Ukraine had included an extra centre should be formally approved, with a note of warning that the problems involved with coal mines being closed may result in migration out of the area. The new study area must be encouraged to follow the rules applying to each participant.

The interest expressed from Professor Anatoly Ustinovich and Dr Victor Dombrovsky in Byeloruss was greeted with interest. It was thought most appropriate for Professor Ignatyeva to discuss with them the problems involved in carrying out such a study and ensuring that they understand the full extent of the costs and commitment. Bristol should make such assessments within 1 month of receipt of the back-translations.

Similarly the interest expressed by Cyprus and Denmark should be fostered, but with full description of the rules. In particular:

1. Questionnaires must be translated and back-translated according to the rules set and these translations must reach Bristol and be assessed and any corrections made by Bristol before the proper study starts. Bristol should make such assessments within 1 month of receipt of the back-translations.
2. Piloting must be on sufficient numbers and the same methodology must be followed as the one to be employed on the proper study.
3. There is a minimum core of questions that must be included in the questionnaires and the actual format of the questionnaire must be the same as the original, as far as possible. The same codes must also be followed for reasons of comparability.
4. Data must be collected at the same time points as designated.
5. New study centres must budget for the costs of validation of questionnaires, central data analysis, etc. with £4000 per year being due to Bristol from each centre.
6. Centres which wish to join are welcome to participate at meetings and go through a trial period of 3 years when they will be looking for funds, for administrative support and undertake piloting. After this time period of 3 years they will be no longer considered as potential centres.

6. Cross-cultural analyses and authorship

Collaborative international studies of this type sooner or later face problems related to the ownership of the data, its transfer to other centres and authorship of joint publications. Therefore it is extremely important to agree beforehand, on the main principles of data sharing and authorship to avoid possible conflicts and misunderstandings. The purpose of such rules is to minimise data misuse and maximise international utilisation of the data. Too strict rules and too strong data ownership usually causes the situation when comprehensive international data analysis is not possible or takes too much time and effort. This is a rather common situation. On the other hand, it is not acceptable for data to be used and published by a person outside the study team without agreement and appropriate acknowledgement of people who worked hard to produce the data. However, the former case is much more common than the latter one.

In the case of ELSPAC the following rules should be used for guidance:

1. The ELSPAC study was planned as an international study and therefore each centre is automatically committed to provide a copy of the national data set to the Central Survey Office (CSO) for international comparisons. The CSO should not release this data to any third party or other ELSPAC centres without prior agreement of centres owning the data. The CSO should analyse and use the data within the general limits and purposes commonly agreed by all the study centres.
2. Otherwise, each centre is the full owner of its own data and can use it in any way it likes, including publication.
3. It is common for the running of the study to consume all the time and resources of the study team, thus not enabling enough time and effort for analysis of the data and preparation of publications. In such cases, when there is not enough time, resources or expertise in a particular field among the ELSPAC teams, the use of intellectual potential and experience of non-team members should be encouraged. However, permission from the relevant centres to use national data should be agreed beforehand together with authorship and acknowledgements. Data analysis in such cases should be performed by the CSO. If the need occurs, data analysis can be delegated to other ELSPAC centres or third parties but written permission from centres concerned to release the data should be obtained. Data analysed outside the CSO should be destroyed after the analysis is completed.
4. Authorship of joint publications should be discussed and agreed upon in each case separately. The main principle is to acknowledge equally the work done, on one side to collect the data, and on the other side, to analyse it, interpret and write the actual paper.

7. First report from ELSPAC

A number of features of the book were discussed. The final recommendation of the participants was that rather than particular authors being attached to each chapter, at the beginning of the book there should be a list of the collaborating countries listed in alphabetical order with a list of participants in each study centre (the persons, their titles, and their roles in the ELSPAC study). There should then be a list of participants at the meeting held to write the book. Each chapter should have a footnote stating that 'This chapter was summarised by'.

After some discussion it was thought that it was most appropriate to name the members of the CEC as the editors. This has the major advantage of the representation of the east and the west, the psycho-social components, the epidemiological and medical, academics as well as WHO. It was agreed that the book be called either:

'Pregnancy in the Nineties: The First Report from the European Longitudinal Study of Pregnancy & Childhood'

or

'European Longitudinal Study of Pregnancy & Childhood: The First Report: Pregnancy in the Nineties'

The data to be used in the book had to be data that were available. Priority was given to highlighting the information from the data that are part of the whole population study - and this includes Avon, Isle of Man, Czech Republic and Russia. The data from Greece should be included where appropriate, due account being made of the retrospective nature of this data. The fact that the data from the Ukraine was pilot data should be emphasised in all chapters however. There is a possibility that data from the full Ukraine study might be available within 3 weeks and thus able to be included.

It is expected that the book will be a joint publication with WHO/EURO but the details and process have to be discussed and agreed upon with the Publication Unit at WHO/EURO. It is suggested that the initial draft of the book should go to WHO as soon as possible to start the process. It is important to try and have the book published by summer 1995.

8. Children's rights in Croatia

Dr Lili Mikecin presented the document prepared by Professor Grguric on Children's Rights in Croatia. The group viewed this with great sympathy, and have suggested to each participant that they forward a copy of this document to the paediatric associations in their own country. They have promised to do this.

9. The 1995 meeting

It is proposed that the next meeting takes place for one week in the period June-July.

It is important that a decision be made as to whether there be 5-year questionnaires. There was a strong feeling by some centres that this should happen - but others felt that a gap should take place allowing consolidation of the data collected. One option would be to have an optional 5-year contact. The Bristol office will, therefore, prepare and distribute draft questionnaires well in advance of the next meeting, and a decision as to whether or not they are obligatory will be made at the meeting.

Detailed discussion of the proposed examination of the children at the age of 7 should conclude with plans for piloting and validation.

It was suggested that a similar exercise should be conducted as at the July 1994 meeting, writing the Second ELSPAC Report. This could be concerned with Labour, Delivery and the First Weeks of the Child's Life. Much had been learned about the ways to facilitate such an exercise:

- (1) The computerised data should be deposited in Bristol by December. It will comprise the first 3 antenatal and the first 3 postnatal questionnaires, the delivery and neonatal admissions questionnaires, the death questionnaires completed for all late fetal deaths, stillbirths and neonatal deaths.
- (2) The strategy should be continued of descriptive data only, with about 10 key variables for each chapter.
- (3) Authors should familiarise themselves with the literature prior to the meeting.
- (4) The authors for each chapter should be acknowledged in the same way as for the First Report.
- (5) At the meeting, each author will compare back-translations of the key questions, to ensure comparability of data.

A list of possible chapters will be circulated to study directors in August - to firstly ascertain with which chapters they would like to be associated. Later a decision will be made as to the other authors to be involved.

ANNEX 1

LIST OF PARTICIPANTS TEMPORARY ADVISERS

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Mr. Hugh Simmons
ALSPAC Manager

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