Final Report

Project reference: 14

Applicant's name: Dr. Georg Neubauer

Project title: Study on the Feasibility of Future Epidemiological Studies on Health Effects of

Mobile Telephone Base Stations

1. State of Research

1.1 Research activities performed, milestones and deliverables accomplished

BACKGROUND: The introduction of mobile phones using the digital GSM 900 / DCS 1800 systems in the 1990s led to a wide use of this technology and subsequently to an increase in the environmental exposures to RF fields, the introduction of new technologies has intensified this process. Such installations are often situated close to dwellings or houses and have become the focus of concerns of parts of the population in recent years.

These concerns resulted in the demand for epidemiological studies on the potential health effects of the RF emissions of such base stations. Within the scientific community the usefulness of epidemiological studies to investigate health effects related to the RF fields from mobile base stations has been debated controversially due to a number of unsolved methodological problems. Up to now only a few cross sectional surveys on possible effects of base stations as well as several cluster investigations of populations residing near TV and radio transmitters were performed. These studies do not allow any conclusions and sound large scale studies are lacking. Several questions remain open, e.g. the adequate type of study design, the endpoints to be investigated, the adequate exposure metric and the methodology how to deal with the emissions from other RF sources.

OBJECTIVE: This research project brings together in a collaborative effort leading international scientists in RF-engineering/dosimetry and epidemiology to jointly assess the feasibility of epidemiological studies on health impacts of RF-exposure from mobile phone base stations.

METHODOLOGY: The project consists of three parts:

1) Analysis of existing study designs of epidemiological studies (January 2004 – March 2005)

Existing epidemiological studies on RF sources and health are analysed to describe existing study designs and to identify strengths and weaknesses. Existing epidemiological and human experimental studies on base station exposure are critically and systematically reviewed.

2) Comparison and analysis of dosimetric concepts (February 2004 – March 2005)

Existing exposure assessment methodologies are evaluated and the suitability for epidemiological studies is examined. The contribution from other RF sources to the total exposure is taken into account.

3) Expert workshop (October 2004)

In the last step the developed specifications were evaluated by experts in different fields in the frame of a workshop.

1.2 Findings

One has to be aware that biological relevant exposure circumstances in respect of RF exposure are unknown. Exposure from mobile phone base station may be relevant compared to other RF sources, if

- cumulative exposure time above a relatively low threshold
- or cumulative whole body exposure
- or the frequency and/or the signal characteristics

turn out to be biological crucial. In every case it is recommended to take contributions from other sources into account. Nocebo effects should be considered in particular when performing studies on soft outcomes. The Nocebo effect is the inverse of the Placebo effect and means that adverse symptoms are expressed by expectations (due to concerns).

It has been shown that data on individual's exposure is scarce and little is known to what extent different exposure sources contribute to a subject's overall exposure. For base station studies, no adequate exposure metric for studying long term effects is available at the moment (distance alone cannot be recommended, the use of analytical calculations is questionable, the use of monitoring systems and dosimeters is promising, but needs to be evaluated). One crucial question is whether a reliable method can be developed in order to assess exposure of large study collectives. The answer to this question is relevant for the feasibility of epidemiological studies on base stations. Possible approaches to assess exposure are given below:

- One concept could be the use of monitoring systems to assess variations in time of different contributions, in particular in studies where people are expected to stay at the same location.
- Another solution might be the use of dosimeters to determine individuals exposure where people are expected to change their location during their day.
- Numerical and/or analytical tools could be implemented to give crude estimates (for stratification) of exposures from specific fixed transmitting installations.

Each of these methods has strengths and weaknesses. Any exposure assessment methods has to be validated in a given collective. We have to be aware that we are at the beginning stages. In order to design a valid epidemiological study more knowledge about the contribution of different EMF sources to the total exposure on an individual and a population level is needed. Thus, systematic studies to evaluate individual exposure of different parts of the population are recommended. In addition, such studies allow to validate different exposure assessment methods for different population subgroups.

1.3 Problems

SCIENTIFIC PROBLEMS: One of the crucial aspects of epidemiological base station studies is the question whether base station exposure is relevant compared to exposure from all other EMF sources or whether it can be neglected in any circumstance. In order to answer this question one major problem is that we do not know which exposure circumstances might be biologically relevant or critical. Base station exposure might be relevant if one is interested in total exposure time above a very low threshold, e.g. > 0.5 V/m, it may be relevant for 24 hours whole body exposure, but seems not to be relevant for momentary exposure levels at a specific body site. If an effect is extremely frequency and/or signal specific, base station exposure might be relevant, too. In contrast, if the focus is on rather high and local exposure levels, mobile phone exposure or the contributions from other local sources might be most relevant.

Another crucial aspect of epidemiological base station studies is the way exposure is assessed. Past residential RF exposure assessments were based on the distance to the source and in a few cases simple analytical calculations or spot measurements. Distance is poorly correlated to exposure levels and, therefore, the use of distance as an exposure metric is not recommended. Analytical tools and spot measurements are problematic in studies involving retrospective exposure assessment approaches and might lead to severe exposure misclassification. Reasons for exposure misclassification are the contribution from other RF sources and the exposure variations in time and space and variations due to changing weather conditions. In many countries measurement campaigns have been performed using different protocols. Spot measurements have been most common, but, in some cases monitoring equipment was used as well. All of these measurements have been stationary, and usually broadband equipment was used which does not distinguish contribution from different RF sources. These measurements have usually been made as a result of public concern about base station exposures or other specific sources, and do not reflect the RF exposure in the general population. No information on personal exposure was found in any of the examined studies. Thus, at present, little information on individuals' exposure in the general population is available, making it problematic to estimate the exposure from all radio frequency sources in the general population. A better knowledge of the distribution of total exposure, as well as a contribution from different sources would allow for a design of more efficient studies.

Hence, more measurement campaigns focusing on exposure in samples representative for general population are urgently needed. An attempt should also be made to develop good proxies. It is not the first

priority to obtain an exact value for the total exposure, but rather to know factors which can be relatively easily obtained and allow to divide the study collective accurately in exposed and non exposed groups or in groups which are exposed to a varying degree. A suitable proxy has to capture all relevant sources of exposure in the radio frequency and microwave frequency range. Given the limited knowledge at present, a single exposure assessment approach can not be recommended. There may exist specific populations which have only one dominant exposure source (e.g., in occupational settings or people living close to strong transmitters), however this will rarely happen for base stations. The importance of co-exposure to other sources depends on the assumption of effect specificity and the proportion of their contribution to the overall exposure. Neglecting of such sources will introduce exposure misclassification. If only a low proportion of the study population is exposed, a high specificity (truly unexposed) is more important than a high sensitivity (truly exposed).

Possible dosimetric approaches are summarized below:

- One approach might be the use of monitoring systems to assess variations in time of different contributions, in particular in studies where people are expected to stay at the same location
- Another approach might be the use of dosimeters to assess individuals exposure where people are expected to change their location
- Numerical and/or analytical tools could be used to provide crude estimates (for stratification) of exposures from specific fixed transmitting installations

Regarding selection of relevant outcomes, it needs to be stressed that there is little scientific evidence for specific candidates. Given paucity of data, selection of the outcome may be based on anecdotal reports and/or on analogy from ELF research. Physiological measures can be objectively measured and are useful to evaluate biological mechanisms. On the other hand, soft outcomes, e.g. sleep, headache, well-being are more difficult to assess. Soft outcome measurements are primarily based on questionnaires and are only occasionally complemented by objective methods. Long term measurements of soft outcomes and between subject comparisons can be problematic. For "electromagnetic hypersensitivity" there are currently no diagnostic criteria, objective signs, or measurement instruments available. The concept "electromagnetic hypersensitivity" is in itself problematic as the exposure is included in the definition of the condition. The concept relies solely on the subject's own attribution of his/her symptoms to electromagnetic fields. Chronic diseases can be objectively diagnosed, however, investigating such diseases need long term follow up and often rely on a retrospective exposure assessment.

In the context of base station research, researchers also have to be aware of Nocebo effects. The Nocebo effect is the inverse of the Placebo effect and means that adverse symptoms due to expectations (due to concerns). The Nocebo effect has to be addressed when designing studies on soft outcomes. The development of study designs including truly exposed subjects, subjects who perceive exposure but are unexposed, subjects who don't perceive an exposure but are exposed, and truly unexposed subjects is encouraged, as it is then possible to separate between physical and psychological effects. It is furthermore recommended that, for soft outcomes, diagnostic methods are used which are as objective as possible, e.g. actigraphs for sleep or validated questionnaires for assessing well-being. Note that the use of questionnaires is always very problematic if study participants are aware of their exposure status.

FINANCIAL AND SCHEDULE PROBLEMS: No major financial problems occurred in the frame of this project; there was a need to extend the schedule of the project due to two reasons: the amount of scientific information to be evaluated was larger as expected and, also due to the larger amount of scientific data, the date of the workshop had to be postponed from June 2004 to October 2004.

2. Annex

2.1 Publications

Neubauer,G.¹, Röösli, M.², Feychting, M.³, Hamnerius, Y.⁴, Kheifets, L.⁵, Kuster, N.⁶, Schüz, J.⁻, Wiart, J.˚s: "Feasibility of Future Epidemiological Studies on Possible Health Effects of Mobile Phone Base Stations", Platform Presentation at the 26th annual meeting of the Bioelectromagnetics Society, June 20-24, 2004, Washington DC, USA, Abstract Book pp. 16-17.¹Seibersdorf research, Austria, ²Univ. Bern, Switzerland, ³Karolinska Institutet, Sweden, ⁴Chalmers Univ., Sweden, ⁵UCLA, USA, ⁶ITIS, Switzerland, ¬Univ. of Mainz, Germany, ¬France telecom research center, France

2.2 Documents

Submitted and accepted as oral presentation at the BEMS 2005 Annual Meeting in Dublin, session 11, the abstract can be found in the annex:

Neubauer,G.¹, Röösli, M.², Feychting, M.³, Hamnerius, Y.⁴, Kheifets, L.⁵, Kuster, N.⁶, Schüz, J.⁻, Wiart, J.˚s: "Feasibility of Future Epidemiological Studies on Possible Health Effects of Mobile Phone Base Stations", Platform Presentation at the 27th annual meeting of the Bioelectromagnetics Society, June 20-24, 2004, Washington DC, USA, ¹Seibersdorf research, Austria, ²Univ. Bern, Switzerland, ³Karolinska Institutet, Sweden, ⁴Chalmers Univ., Sweden, ⁵UCLA, USA, ⁶ITIS, Switzerland, ¬Univ. of Mainz, Germany, ⁶France telecom research center, France

Two peer reviewed publications one on epidemiological the other on dosimetric aspects are in preparation.

The ARC Report ARC – IT – 0124 includes a detailed description of the project and its results.

Date and Signature

13.4.2005

Dr. Georg Neubauer

ANNEX

REPRINT of the Abstract Book of the 26th Annual Meeting of the BEMS 2004: Abstract 2-5

FEASIBILITY OF FUTURE EPIDEMIOLOGICAL STUDIES ON POSSIBLE HEALTH EFFECTS OF MOBILE PHONE BASE STATIONS

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BACKGROUND: The introduction of mobile phones using the digital GSM 900 / DCS 1800 systems in the 1990s led to a wide use of this technology and subsequently to an increase in the environmental exposures to RF fields. Latest developments in mobile communications, e.g. UMTS, will intensify this process. Today about 1 billion people are using mobile telephones world-wide, about 400 million people of them in Europe. The frequent use of mobile phones has necessitated an increased deployment of base stations. Such installations are often situated close to dwellings or houses and have become the focus of concerns of parts of the population in recent years. These concerns resulted in the demand for epidemiological studies on the potential health effects of the RF emissions of such base stations. However, several scientific problems, e.g. availability of reliable estimates of exposure have to be solved before feasibility of such studies can be determined. Within the scientific community the usefulness of epidemiological studies to investigate health effects related to the RF fields from mobile base stations has been debated controversially. Up to now only a few cross sectional surveys on possible effects of base stations were performed. These surveys do not allow any conclusions and sound large scale studies are lacking. In addition, several cluster investigations and other studies that looked at the potential health effects of populations residing near TV and radio transmitters have to be considered. Several questions remain open, e.g. the adequate type of study design, the endpoints to be investigated, the adequate exposure metric and the methodology how to deal with the emissions from other RF sources.

OBJECTIVE: This research project brings together in a collaborative effort leading international scientists in RF-engineering/dosimetry and epidemiology to jointly assess the feasibility of epidemiological studies on health impacts of RF-exposure from mobile phone base stations.

METHODOLOGY: The project consists of three parts:

1) Analysis of existing study designs of epidemiological studies

Existing epidemiological studies on RF sources and health are analysed to describe existing study designs and to identify strengths and weaknesses. The current scientific evidence of a relationship between RF fields arising from base stations and health effects is investigated.

2) Comparison and analysis of dosimetric concepts

Existing exposure assessment methodologies are evaluated. More data on individual's exposure is urgently needed; little is known to what extent different exposure sources contribute to a subject's overall exposure. The suitability of existing concepts of dosimeters for epidemiological studies is examined. Present day exposure assessment techniques and existing data on exposure of the population are analysed. The contribution from other RF sources to the total exposure is taken into account.

3) Expert workshop

In the last step the developed specifications are evaluated by experts in different fields in the frame of a workshop. Specifications not suitable are identified, cost analysis are undertaken. Finally (a) reliable concept(s) should be available describing the methods and the equipment which have to be used to describe exposure from base stations in a way that is useful for epidemiological studies.

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EXPECTED RESULTS: The purpose of this study is to investigate the feasibility of future epidemiological studies on health effects, or effects on well being, of mobile communication base stations by evaluating existing studies and dosimetric concepts, contributions from other RF sources have to be taken into account. If possible a list of recommendations and specifications for such studies will be developed and a cost analysis will be performed. A comprehensive rationale for the conclusion will be given in any case.

This project is sponsored by the Swiss Research Foundation on Mobile Communication, the Swiss Agency for the Environment, Forests and Landscape and the Swiss Federal Office of Public Health

Submitted and accepted as oral presentation at the BEMS 2005 Annual Meeting in Dublin, session 11

FEASIBILITY OF FUTURE EPIDEMIOLOGICAL STUDIES ON POSSIBLE HEALTH EFFECTS OF MOBILE PHONE BASE STATIONS

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INTRODUCTION: The increasing use of mobile phones in the last decade triggered an important deployment of mobile telephone base stations worldwide and in particular in Europe. Base stations are already ubiquitous, e.g. around 18,000 base stations are operated in Austria. Concerns of parts of the population and decision makers about potential health effects of emissions from base stations resulted in needs for society to have information on exposure and the effects of exposure, leading to the demand on epidemiological studies on potential health effects.

OBJECTIVE: This research project brings together in a collaborative effort leading international scientists in RF-engineering/dosimetry and epidemiology to jointly assess the feasibility of epidemiological studies on health impacts of RF-exposure from mobile phone base stations. The feasibility of epidemiological studies on possible health effects of mobile phone base stations depends on finding solutions to scientific problems, e.g. reliable estimates of exposure, control for bias and confounding, selection of health outcomes, therefore these aspects were analysed. Because studies using inadequate design could lead to wrong conclusions and/or increasing concerns in the population, we include recommendations and quality criteria for such studies.

METHODS: Based on the evaluation of existing knowledge in that field epidemiological study designs for the investigation of potential health effects of RF exposure were developed. Types of health outcome to be investigated, basic principles of exposure assessment, definition of metrics, and the relevance of other RF sources, proxies and exposure blinding were considered. The relevance of control for bias and confounding was discussed. Suggested methods are given for immediate, short term and long term effects. Because exposure assessment is crucial requirements on future assessments are given. Calculations, spot measurements, monitoring of exposure and the use of dosimeters are discussed.

RESULTS: Possible dosimetric approaches are summarized below:

- One approach might be the use of monitoring systems to assess variations in time of different contributions, in particular in studies where people are expected to stay at the same location
- Another approach might be the use of dosimeters to assess individuals exposure where people are expected to change their location
- Numerical and/or analytical tools could be used to provide crude estimates (for stratification) of exposures from specific fixed transmitting installations

Regarding selection of relevant outcome, one important finding is that it does not exist a specific outcome driven from scientific evidence. Given paucity of data, selection of the outcome may be based on anecdotal reports and/or on analogy from ELF research. Physiological measures can be objectively measured and are useful to evaluate hypothesized biological mechanisms. On the other hand, soft outcomes, e.g. sleep, headache, well-being are more difficult to assess. Soft outcome measurements are primarily based on questionnaires and are only occasionally complemented by objective methods. Long term measurements of soft outcomes and between subject comparisons can be problematic. For "electromagnetic hypersensitivity"

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there are currently no diagnostic criteria, objective signs, or measurement instruments available. The concept "electromagnetic hypersensitivity" is in itself problematic as the exposure is included in the definition of the condition. The concept relies solely on the subject's own attribution of his/her symptoms to electromagnetic fields. Chronic diseases can be objectively diagnosed, however need long term follow up and often a retrospective exposure assessment.

Dealing with different types of outcomes we have to be aware that Nocebo effects are in general very relevant in the context of base station exposure. The Nocebo effect is the inverse of the Placebo effect and means that adverse symptoms are expressed by expectations (due to concerns). The Nocebo effect has to be addressed when designing studies. It is recommended that methods are used which are as objective as possible, e.g. actigraphs for sleep, validated questionnaires for assessing well-being. Note that the use of questionnaires is always very problematic if study participants are aware of exposure status.

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