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Precautionary approaches and the SAGE experience

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ABSTRACT

The UK Department of Health hosted a stakeholder advisory group (SAGE) on ELF EMF since 2004, with a remit to make practical recommendations for precautionary measures. It reported its first interim assessment in April 2007.

ELF EMF has generated diverse assessments and views. This was also recognised in an EEA Workshop this year, which explored reasons for legitimate diversity. The SAGE report characterises the diverse views in a polarised way, using codes of the "WHO/HPA" view and the "California" view.

The two views of the science were not miles apart. They each agree with the IARC classification 2B as a "possible human carcinogen". An important difference was that the "WHO/HPA" view would confine precautionary considerations to childhood leukaemia, whereas the "California" view would take into account possible wider impacts where there was supporting (but not conclusive) evidence.

This difference is crucial to assessing proportionate precautionary options. The total impact on a population could differ by a factor of a hundred or more, because childhood leukaemia is so rare.

The SAGE experience raises interesting issues for stakeholder dialogue and government decision making more generally. Should a plurality of legitimate viewpoints be taken into account? Should statutory advisory bodies have a monopoly? This paper examines the plurality of views on ELF, RF and EHS and suggests approaches for addressing such plurality.

1. Introduction

This paper is about where we might go from here, given the apparent conflicts on EMF issues.

The SAGE experience of stakeholder dialogue in the UK is a fresh approach. There are lessons to learn from it. Can it be useful in other countries, or on an international scale?

The first part of the paper is to report briefly on the SAGE experience for the benefit of readers from other countries. This is a personal view from one of its sternest critics, internally, but one of its warmest advocates externally.

Beyond that, the paper examines the wider EMF issues, some underlying principles for evaluation of scientific evidence, key collision points between parties in conflict, and possible ways forward.

2. The SAGE Group

SAGE stands for Stakeholder Advisory Group on ELF EMF. At the time of its first report in 2007, it comprised 41 UK stakeholders from government, statutory bodies, industry, professions, academics and public concern groups.

The dialogue had been initiated and funded, in an earlier form between key parties, by National Grid, with a view to creating an independent basis for wider stakeholder dialogue.

SAGE is hosted by and reports to the UK Department of Health. It is jointly funded by the Department of Health, National Grid and Children with Leukaemia (a charity with concerns about EMF exposure).

Its agreed Aim is:

> "*To bring together the range of stakeholders to identify and explore the implications for a precautionary approach to ELF EMF (electric and magnetic fields) and make practical recommendations for precautionary measures*"

It has considered ELF EMF only at "sub-ICNIRP levels", that is below ICNIRP reference levels, for practical precautionary measures.

SAGE worked for three years to produce interim findings [1] in April 2007. It recommended low-cost measures for house wiring and appliances, and for transmission lines. It identified a "best available option" of a 60-metre corridor separating new lines and homes, but couldn't agree to make that a recommendation.

SAGE started well, but struggled later. In 2008, DH commissioned an external Appraisal of the SAGE process so far. The Appraisal is essentially concerned with *process*. It recommends including discussion (not evaluation) of the science and suggests questions to shape that discussion. The main SAGE process is due to resume in October 2008 after an 18-month gap.

3. SAGE considerations

Considerations of SAGE relate to four logical stages, as in Table 1, though the work was not done in that order. SAGE was not directly active in the first and last stages, but took account of them. It was acknowledged that SAGE was not constituted to evaluate science, and that the decision stage lay in the hands of government.

Account was taken of external evaluations (published reviews) of the science, in order to consider whether particular precautionary measures might be reasonable and

proportionate. Account was also taken of legislative requirements and consequences in order to consider whether measures might be practical.

1. Evaluation of science – Causation and end-points	Science not evaluated; refer to reviews Two views: CL and CL+ Uncertainty by what-if (& factors for CL+)
2 Risk & impact	Adopted published attributable risks Used government risk guidelines CL+ impact about 100 times CL impact
3. Options & recommendations	Recommend on either: • insignificant cost or • positive CBA(CL) CBA(CL+) noted, not agreed Alternative advice on 60-metre corridor option
4. Decision	Overlay advice from HPA Awaiting government response

Table 1 Four stages of considerations
(CL = childhood leukaemia alone; CL+ = other diseases also considered;
CBA = cost-benefit analysis; HPA = Health Protection Agency)

These four stages can be important for
- accessing different expertise and guidance
- integrating the implications across the four stages
- extension to a planning cycle with monitoring and review.

Two different views of the science emerged:
- "CL": that childhood leukaemia (classified by IARC as a possible carcinogen: class 2B) is the only health outcome to be considered, and
- "CL+": that other health outcomes (identified in some reviews, e.g. California DHS, but not classified 2B by IARC) should also be considered.

SAGE struggled with whether to allow either the California DHS review or the CL+ viewpoint into consideration.

The approach to uncertainty for CL was taken as "what-if". That is, causation was taken to be certain for the purpose of assessing the impact of exposure and the benefit of precautionary measures. An alternative approach to uncertainty, used with the CL+ viewpoint, was to use weighting factors from California's "Degrees of Certainty".

To consider risk and impact, SAGE closely followed published data and government risk guidelines. This led to an estimate of benefit of about £1,000 per home removed from (or avoiding) long-term exposure above 0.4μT, based on CL alone.

A detailed analysis [2] estimated that impacts of CL+ would be about 100 times more than those of CL alone. That was noted by SAGE but was controversial. By way of simple rationalisation, it was noted there were about 10 times more diseases in CL+ which were typically each about 10 times more common than CL.

Options were considered by "dominance analysis" against criteria for effectiveness, safety, cost, direct and indirect impacts, and implementation. Recommendations were agreed only at very low cost. Some stakeholders required positive cost-benefit analysis based on CL alone, so stronger options could not be agreed.

The most controversial area was on powerlines. Very-low-cost options would have little impact on public EMF exposures from powerlines. A "best available option for obtaining significant exposure reduction" was a 60-metre corridor option, which would restrict new developments, of either lines or homes, to 60 metres separation. Under the adopted assumptions, cost would outweigh benefit based on CL alone. However, the option could be considered cost-beneficial based on CL+.

Two alternative views were therefore presented, instead of a recommendation, on this corridor option. The report is still under consideration by government.

It was referred by government to the HPA for advice, thus giving one stakeholder an over-riding say on its conclusions. In its response [3] of 15 October 2007, the HPA noted its published position was "broadly in line" with one of the viewpoints identified in the report, and claimed "*The evidence to date suggests that in general there are no adverse effects on the health of the population of the UK caused by exposure to ELF EMFs below the guideline levels*", seemingly tantamount to IARC class 4 ("probably not" carcinogenic), contradicting IARC and WHO.

The 2008 external Appraisal suggests issues of "*trespassing on HPA territory*" (regarding science). The HPA [4, 5] gives second-stage occupational and public reference levels of 1800 and 360 μT, respectively, last revised 7 Dec 2007, relaxed from the ICNIRP levels of 500 and 100 μT.

4. Discussion points

Looking at the four stages in Table 1 raises the question of who should decide what. Many types of expertise are involved at different stages: a mixture of sciences, logic and philosophy early on; risk analysis, public health, economics and social science later on; and multi-disciplinary integration all along.

Views expressed on behalf of WHO and ICNIRP at the conference suggest that the science evaluation stage should be exclusively for scientists, who should then remain independent from the later stages. Labels "risk assessment" and "risk management" were sometimes used to distinguish the science from the next stage. It may be helpful, in the case of uncertain risks, to think of more stages:

- Evaluation of science to assess degrees of confidence in causation
- Application to assess likely attributable risk and impact
- Policy considerations for criteria for evaluating precautionary options
- Evaluation and recommendation of precautionary options against criteria
- Decision (equivalent of business risk management plan)
- Implementation of options
- Monitoring and review

Each of these stages might require different types of expertise. Yet the boundaries seem blurred and interaction and feedback seem desirable. Should the stages be independent, merely acting on reports from other stages? Or should there be active engagement across the stages to help frame the questions? How can different stages be joined up, with vertical integration?

A danger, particularly for long-standing and more exclusive groups, of becoming "anchored" is recognised by the IPCC Uncertainty Guide [6]:

> *"6. Be aware of a tendency for a group to converge on an expressed view and become overconfident in it [3]. Views and estimates can also become anchored on previous versions or values to a greater extent than is justified. Recognize when individual views are adjusting as a result of group interactions and allow adequate time for such changes in viewpoint to be reviewed."*

How should evaluations, at the various stages, be reported? Sometimes there is a dichotomous evaluation: accepted or rejected, for example with peer-reviewed studies or with established cause. Sometimes there is a narrative report, with undefined terms like "weak evidence". Systematic classification schemes may have narrative categories, such as the IARC approach to carcinogenicity of agents; alternatively they may have quantified categories, such as the California DHS approach to ELF or the IPCC approach to climate change. Table 2 outlines a selection of approaches to reporting evaluations of various different things in different ways.

Individual studies: intrinsic quality	peer review; good laboratory practice; IARC ungraded qualitative assessment
A body of evidence: quality relative to an estimate or hypothesis	GRADE 4-point scale; IARC 3+1 point scale separately for studies in animals and humans
Causation: specific or broader harm	IARC 4+1 point overall human carcinogenicity scale; CDHS 7-point degree of certainty scale
Scientific understanding relevant to an issue	IPCC 2x2 or 3x3 table
Correctness of a model, an analysis or a statement	IPCC 5-point confidence scale
Events: past and future; forecasts and predictions	IPCC 7-point likelihood scale
Options: precautionary measures	SAGE Cost-Benefit Assessment and other criteria
Recommendations	GRADE 2-point scale (strong and weak)

Table 2 Some approaches to reporting evaluations [6-9]

When considering criteria for evaluating policy options, have we thought about underlying ethical assumptions, and clearly stated them (e.g. a utilitarian basis, or other ethical objective function)? For example, see the four policy frameworks

described in the Policy Options section of the California DHS report [7]. What of the distribution (as well as magnitude) of "public good", protection of the susceptible, short-term versus long-term, and the perennial ethical problem of a metric for the common good?

5. Some underlying principles for evaluation of science

Table 2 above mentions a number of evaluation bodies which differ in their method of overall evaluation; in who makes the overall assessment; and in how the overall assessment is described and reported.

Some suggested underlying principles for evaluating science are:

- *There is no unique "correct" Weight-Of-Evidence approach [10]. Different methods may lead to different verdicts, especially where there is uncertainty.*
- *Hypotheses underlying assessment of evidence for causation may be sharp (specific exposure/endpoint/population) or blunt (any exposure metric and any harm in any population subset), and should be clearly stated. Blunter hypotheses may be more relevant to public health.*
- *Systematic and formal methods of aggregating disparate evidence, where available, should be used to inform evaluations [11]. Simple statistics may often be used where studies are too disparate for meta-analysis. Examining studies only individually may tend to "fragment-and-dismiss" evidence.*
- *Continuous probabilistic scales for credibility of causation can be useful in assessing potential attributable impact. They're not the same thing as incidence-based risk probabilities but can be used in combination with them.*
- *An indication of variation of assessment (subjective or otherwise) contains more information than a single central (consensus) value. Consensus will be valuable if obtained across a breadth of valid scientific viewpoints, but where there is uncertainty a range of viewpoints may be more appropriate.*

Bio-effects may sometimes be recognised but dismissed if harm is not established. Mike Repacholi seemed to suggest to conference that that is how WHO and ICNIRP see it: exposed people are expected to have compensatory mechanisms which cope with the bio-effects, given that general population studies find no statistical harm. People are nevertheless subjected to a bio-effect which they might reasonably prefer to avoid, on the basis that minor stresses which are normally compensated can possibly accumulate to levels beyond the capacity of compensation, particularly at times of illness and particularly in sensitive people. Although one exposure, and one bio-effect, may be tolerated in isolation, its potential contribution cumulatively to harm is not zero. That contribution may be realised in susceptible subsets of the population while not appearing in general population studies. Hence

- *The bio-effects principle: bio-effects of exposure (established or uncertain-but-plausible), given general population studies finding no statistical harm, should not thereby be zero-weighted in assessing causation, risk and precautionary measures.*

Most EMF evaluations seem to concentrate on possible human effects, with some (limited) attention to effects on plants and animals as related studies by analogy. In leading wide-ranging reviews of EMF science, large well-researched relevant fields

are not mentioned. Following the work of Warnke and others, brought to attention in the conference, such effects, for example on bees, may be sufficient to be regarded as harmful to the environment. Here two principles are suggested:

- *The analogy principle: evidence from contingent areas (such as solar and geo-magnetic activity, animal navigation, and plant magneto-reception) should be thoroughly considered for indications of biological capability for signal detection and response.*
- *The environmental effects principle: effects (established or uncertain-but-plausible) likely to be harmful to the environment other than to human health should not be excluded when assessing risk and precautionary measures.*

6. Possible collision points of views on EMFs

At the extremes, the EMF debates sometimes seem to polarise into opposing views:

(a) Public exposures are far too low for any scientifically feasible harmful effect, and concerns are irrational.

(b) Evidence is so extensive that harmful effects are beyond reasonable doubt, and deniers are dishonest.

The "low-exposure" mindset seems to have been cast in a context of comparisons like the earth's static field, quantum energies of ionising radiation, and macroscopic effects like heating and induced currents. Since then, understanding of the possibility of low-intensity frequency-related effects on hyperfine structures, spin states, complex large-molecule bio-chemical processes, cellular function, etc. has developed, and continues to develop with new knowledge and techniques.

On the other hand, the "extensive evidence" mindset seems to have been built on particular studies giving a piecemeal and still uncertain and incomplete picture of potential mechanisms. Although there are many such studies, it is easy to gain a strong impression from selected positive results taken out of the full context.

It seems to be a natural human trait to find it easier to get attached to a perception than to relinquish it. (See also the quote from IPCC in section 4 above.) Here there is a double perception: the judgment of potential risk and the judgment of the opponent. Surely it will be unfair to attribute those extreme characteristics – irrational or dishonest – to everyone arguing a different point of view, even if they might apply exceptionally to some. It may help to examine some possible collision points giving rise to such views.

Possible collision point 1: plausibility

"*Plausibility*" is the sixth "*aspect*" described by Hill [12] of an association for considering whether "*causation*" is the most likely interpretation. Incidentally, he used the word "*aspect*" rather than either criterion or guideline. He used the word "*causation*" rather than causality; that is my preference too, when referring to a specific relation, since causality can refer to a philosophy about the universe.

Hill referred to what was "*biologically plausible*", not just the biological plausibility of a specific mechanism. The distinction is important in that it can allow overall

biological plausibility even if all identified specific mechanisms, when tested in detail, seem implausible at some point. He also adds "*But this is a feature I am convinced we cannot demand*".

The idea of plausibility is discussed in WHO EHC238 [13] with a general definition and particular reference to signal-to-noise ratios (SNR) for ELF EMF. "*Degrees of plausibility*" were mentioned but not elaborated.

Bio-physical plausibility, with reference to SNR *in situ* in biological tissue, was examined in WHO EHC238 for a number of potential mechanisms of interaction of ELF EMF. See also Swanson & Kheifets [14], who argue bio-physical implausibility below about 5μT, albeit with assumptions and uncertainties. This is interesting scientific analysis which deserves consideration.

Yet in Table 2 of section 7 of the Bio-Initiative report [15], Martin Blank lists eight studies showing thresholds for several different biological effects at ELF exposures in the range 0.2 – 2 μT. EHC238 cites three of the eight references, Swanson & Kheifets none of them. I could add other such studies which are not cited by WHO or Swanson & Kheifets. There seems to be scope here for detailed dialogue to test the validity of such studies on the one hand and the scope for such effects within the uncertainties and qualifications of the biophysical plausibility analysis on the other hand.

Turning to RF exposures, the IEGMP (Stewart) Report [16] says in its Main Conclusions 1.17-118: "*The balance of evidence to date suggests that exposures* … (below guidelines) *do not cause adverse health effects to the general population*" and "… *scientific evidence suggests … that there may be biological effects* (below guidelines)". Since then more evidence has accumulated on bio-effects. The "Bio-effects Principle" suggested in section 5 above may be another collision point.

It would be helpful to develop the idea of "degrees of plausibility" mentioned in EHC238. This is not the same as degrees of credibility of causation; plausibility is just one of Hill's aspects. Considerations for degrees of plausibility might include:

- Challenge to fundamental scientific principles
- Physical signal-to-noise ratio of the external signal
- Bio-physical signal-to-noise ratio *in situ* in cells and tissues
- Evidence for bio-effects and the Bio-effects Principle
- Evidence for biological capability from contingent areas

Possible collision point 2: exposure limits

Different views have been expressed about when and whether exposure limits (sometimes called restrictions or standards) should be applied as a precautionary response to uncertain harmful effects.

The WHO EHC238 says:

> *"Therefore the use of precautionary approaches is warranted. However, it is not recommended that the limit values in exposure guidelines be reduced to some arbitrary level in the name of precaution. Such practice undermines the scientific foundation on which the limits are based and is likely to be an expensive and not necessarily effective way of providing protection."* (1.1.12)

"However, the evidence for a causal relationship is limited, therefore exposure limits based upon epidemiological evidence are not recommended, but some precautionary measures are warranted." (12.6 conclusions)

From the Bio-Initiative Report:

"These proposals reflect the evidence that a positive assertion of safety … cannot be made." (Summary for the Public)

"However, proof of mechanism is not … mandatory to set new guidelines or limits if adverse health effects occur …" (overall conclusions)

"ELF limits should be set below those exposure levels … linked in childhood leukemia studies to increased risk of disease, plus an additional safety factor." (overall conclusions)

"Both bodies [ICNIRP and IEEE] *require proof of adverse effect and risk before amending the exposure standards."* (section 4, page 2)

"… *prevention is used to justify the restriction of exposure to an IARC Category 1 carcinogen whereas precaution is necessary to justify restricting exposure to a Category 2A or B carcinogen"* (section 16 - David Gee)

The Benevento Resolution [17] suggests:

"Precautionary strategies … may not necessarily define numerical thresholds because such thresholds may erroneously be interpreted as levels below which no adverse effect can occur."

Those words were dropped in the 2008 successor Venice Resolution, which called for reduced and biologically relevant standards.

There seem to be different (implied or express) principles at work. The idea of when exposure limits might apply surely lies in the province of social policy and not science. As social policy, exposure limits might involve pragmatic aspects like cost and reasonable achievability, rather than scientific determination.

Possible collision point 3: plurality versus monopoly

This is not about the sort of "plurality" that would include irrational or dishonest views. Consider only what can be agreed as scientifically valid. Can there be different rational and scientifically valid views?

We have already seen "alternative views" from the SAGE report. They were derived from different external reviews by official bodies. When adopted by stakeholders and applied to options such as the 60-metre corridor in the UK context, they were no longer the express views of the external review bodies. However, the original evaluations made by various bodies like HPA, WHO, NIEHS and California DHS did show material (if slight) differences. Does that mean some of them were "wrong" or scientifically invalid, or is there a genuine plurality of valid views?

The SAGE report shows disagreement together with recognition of legitimacy of opposing viewpoints, albeit with discomfort with the ensuing alternative advice:

"The other view, again with variants, has been set out in a number of places, for instance … (NCRP) … (EPA) … (NIEHS) … supported this view in part. However, this view has perhaps been most clearly expounded in the Report from the California Department of Health Services …" (page 13)

"Although we disagree over which view to adopt, we are able to recognise each as a legitimate viewpoint and we respect each other's right to come to different conclusions based on interpretations of the science and we all support more research to clarify these issues." (page 52)
"… stakeholders take different views on the "WHO/HPA" and "California" views of the science and have consequently not been able to reach a consensus on the advice that stems from these views. Therefore SAGE needs to set out alternative advice to Government, depending on which of these views is followed through, recognising that not all stakeholders are comfortable with each piece of advice." (page 52)
"Other stakeholders do not wish to identify with either view in particular, but believe Government should be aware of both." (page 53)

I was one of the "other stakeholders" preferring to inform government of both views, without aligning with either. How would that work? Government would have a freer choice, since the view of its statutory advisor would be acknowledged as important but not exclusive. On the corridor option, taking political factors into account, government could decide either:

- "no", with support from one legitimate (but not exclusive) scientific analysis and from its statutory advisor, or
- "yes", with support from another legitimate (but not exclusive) scientific analysis but against the advice of its statutory advisor (in which case government should give good reason for such departure).

In the event, referring to HPA for (in effect) over-riding advice, casts doubt on the legitimacy of the alternative advice, thus negating the essence of the SAGE process.

Many sources of divergence in scientific evaluations by different formal review bodies have been characterised in papers by David Gee for the EEA [18]. The sources range from constitution through evidence-base and evaluation-process to frameworks for expressing decisions, which vary from one review body to another. Examples include both ELF and RF exposures.

7. Differences in where key parties stand now

In order to look for ways forward, it is helpful to summarise where the parties stand now. Naturally there is a range of views both among official bodies and among public concern groups. For example, on mobile phones the UK Stewart Report was more precautionary than the Dutch Health Council report; and on power-frequency fields the California DHS review was more precautionary than the WHO and IARC. Public concern groups like RRT, ICEMS and the Bio-Initiative are unified in calling for more precaution, but differ in some details. Out of all this there seem to be clear differences between relatively "more permissive" and "more precautionary" positions adopted with respect to controlling public exposure, drawing from their respective interpretations of the science.

Different views on ELF are clear from the UK SAGE report as discussed above. There the key difference stemmed from associated health end-points other than childhood leukaemia (CL). Several countries have adopted precautionary measures,

including sub-ICNIRP conditional exposure restrictions; their concerns might derive from CL alone, given its IARC 2B classification.

Views on RF raise questions of precaution for phones (voluntary usually-higher exposure) with limited establishment support and with debate on emerging Interphone studies; and for masts (imposed usually-lower exposure) without establishment support and with debate on plausibility. There is growing evidence for various bio-effects, acknowledged but not fully assessed by official bodies.

Mobile phone use is becoming ubiquitous, as is a usually-lower environmental exposure from a mixture of EMF. In its (draft) Precautionary Framework, WHO recognises the case for precaution for uncertain hazards where they are ubiquitous with potentially large impacts. In risk management, particularly in business and governance, similar situations can be assessed as Moderate or High risk, even when they are extremely unlikely to happen.

Both the "more permissive" and "more precautionary" views recognise the reality of EHS symptoms, but are divided on cause: physical or psychological. It may be that a mixture of physical and psychological causes is confounded, making provocation studies more difficult.

8. Ways forward

In conference discussion, Mike Dolan nicely observed that policy is national, science international. Where the aim is to formulate precautionary policy options and advice, it may be sensible to focus stakeholder dialogue at national levels. Given the nature of practical policy options, separate dialogues for ELF, RF and EHS would seem appropriate. In seeking to draw from science, SAGE found a need to discuss the science and its evaluation. It can be difficult to do that on a national basis.

International scientific dialogue takes place through conferences and the peer-reviewed literature. Sometimes different factions survive within this framework, with conferences and journals inclining one way or another. Scientific dialogue *between* opposing viewpoints would be helpful. This RRT conference is one example, bringing together presentations from different perspectives.

Workshops and study groups provide for greater depth of scientific dialogue. It would be helpful for official workshops, such as those of WHO and ICNIRP, to reach out to include scientists of opposing views. They do already invite leading scientists from a range of specialisms and countries, though leading well-published scientific dissenters have been noticeably absent. There were some late invitations to give a ten-minute presentation to the WHO Geneva ELF conference in 2007, in a session on stakeholder perspectives; the invitations were declined, partly because they did not seem to cater for meaningful scientific input. It would be a pity if this experience deterred WHO from engaging with dissenting scientific views in future.

Still greater depth of discussion may be possible with structured continuous dialogue between scientists with opposing perspectives. The participants would best be on an equal footing, and the dialogue managed jointly or independently. That is rather more

than a short workshop. Such a structured process might be feasible with internet communication, occasional plenary conferences and agreed position statements.

General objectives might include:

- Jointly examining conflicting scientific views in detail
- Recognising which are scientifically valid or invalid views
- Identifying and extending common ground
- Identifying scientifically legitimate differences of opinion

Specific issues might include

- Plausibility for ELF effects at low exposures
- Updating evidence on "CL+"
- Masts and base-stations: exposures and epidemiology
- Analysis of Interphone study designs and results
- Problems with and re-design of provocation studies for EHS

In summary, more intensive international *scientific* discussion, engaging opposing scientists on an equal footing in structured continuous dialogue, is recommended, along with *stakeholder* dialogue to investigate practical precautionary measures at national level.

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