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Why a Precautionary Approach is needed for Non-Ionising Radiation Devices

Victor Leach and David Bromwich

What is the Precautionary Approach?

- Simple **definition** of Precautionary Approach:

A risk management framework in the face of scientific uncertainty

- **Not** an admission of guilt

- **Implementation** of Precautionary Approach
  - Complex
  - Requires trust
  - Fair and reasonable
  - Transparent and open

- As Low As Reasonable Achievable (**ALARA**)
  As Low As Reasonable Practicable (**ALARP**)
  - Both historical Precautionary Approaches
  - Lack **structure** of proper Precautionary Approach

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Trigger Points

- Two main factors **trigger** a Precautionary Approach:
  - **Strength of evidence**
  - Potential **cost of doing nothing**

- Full **biological explanation** can take years:
  - **Asbestos,** (1898 till1999): 101y
  - **Water** with cholera – Dr John Snow, (1854 till1883): 29y

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ICRP and ICNIRP Philosophies

- **ICRP = risk managers (Insurance)**
  - Risk may exist
  - Low radiation doses → Risk

- **ICNIRP = Judge**
  - Certainty before action.
  - Low exposure levels → “No risk”
  - “People being protected”
    However not all children,
    the elderly, and some chronically ill

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ICRP vs ICNIRP Philosophies

- **ICRP – Risk management approach**
  - <100 mSv is a **Precautionary Approach** using ALARA
- **ICNIRP** (2002) **Non-Risk management approach**
  - ***But notes*"*…children***, *the* ***elderly***, *some* ***chronically ill*** *people …* ***lower tolerance*** *for one or more forms of NIR exposure"*
  - Precautionary Approach <u>not</u> applied for these at-risk groups

Waiting for established evidence of harm is <u>not</u> a recognised risk management approach

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Satellite Image of Victoria, 2009

2009 Victorian Bushfires – “Black Saturday”

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Evaluating the Strength of Evidence

- **ORSAA** - Not-for-Profit scientific association
- **Members** - non-industry scientists interested in EMR Health issues
- **Many disciplines** needed
- **Over 3000 papers** objective assessed and categorised
- **ORSAA database** - analytical tool to evaluate the strength of evidence

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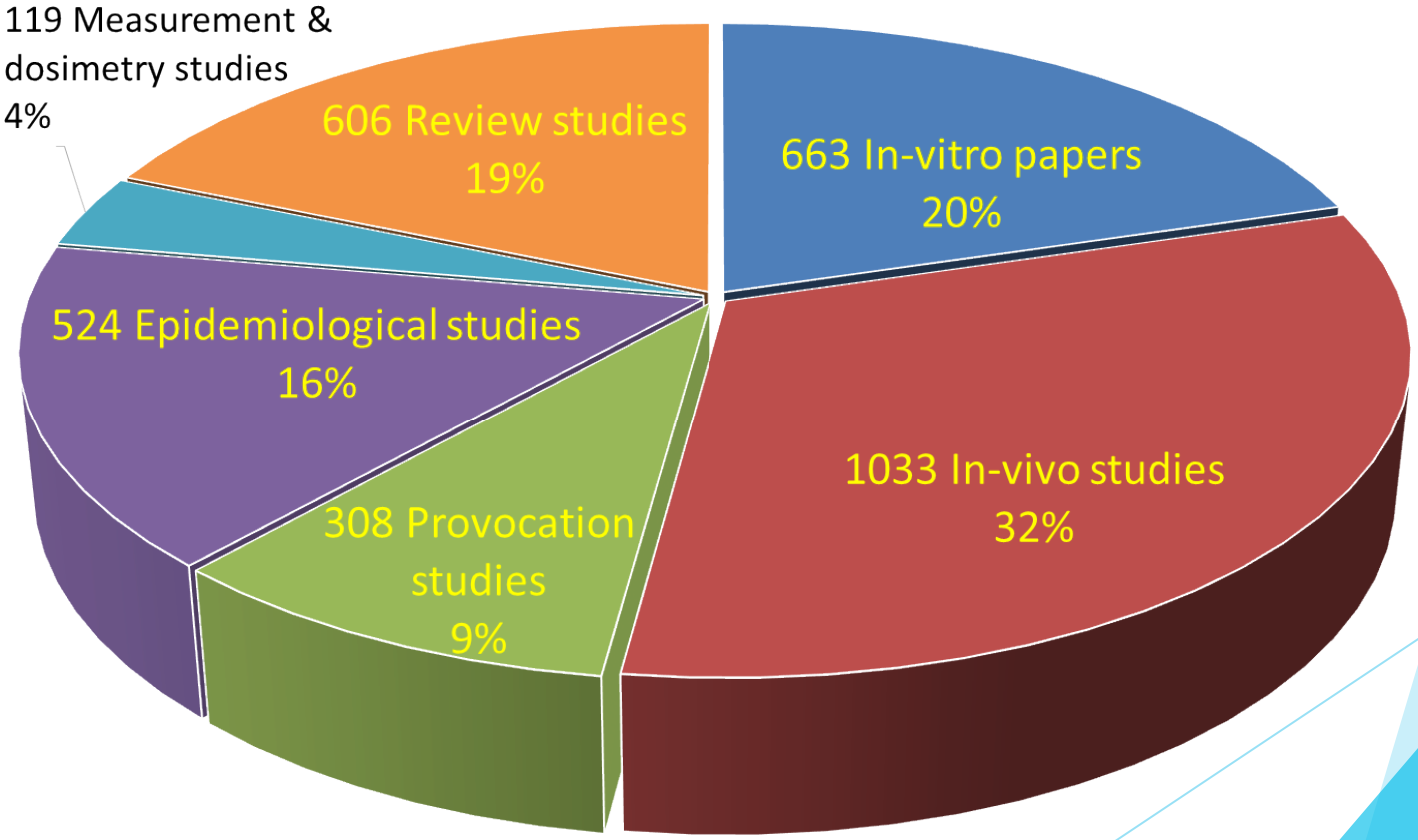
ORSAA database ELF to SHF (radar freq) publications

- Includes ARPANSA papers (1354) and Emeritus Prof Henry Lai papers (937)



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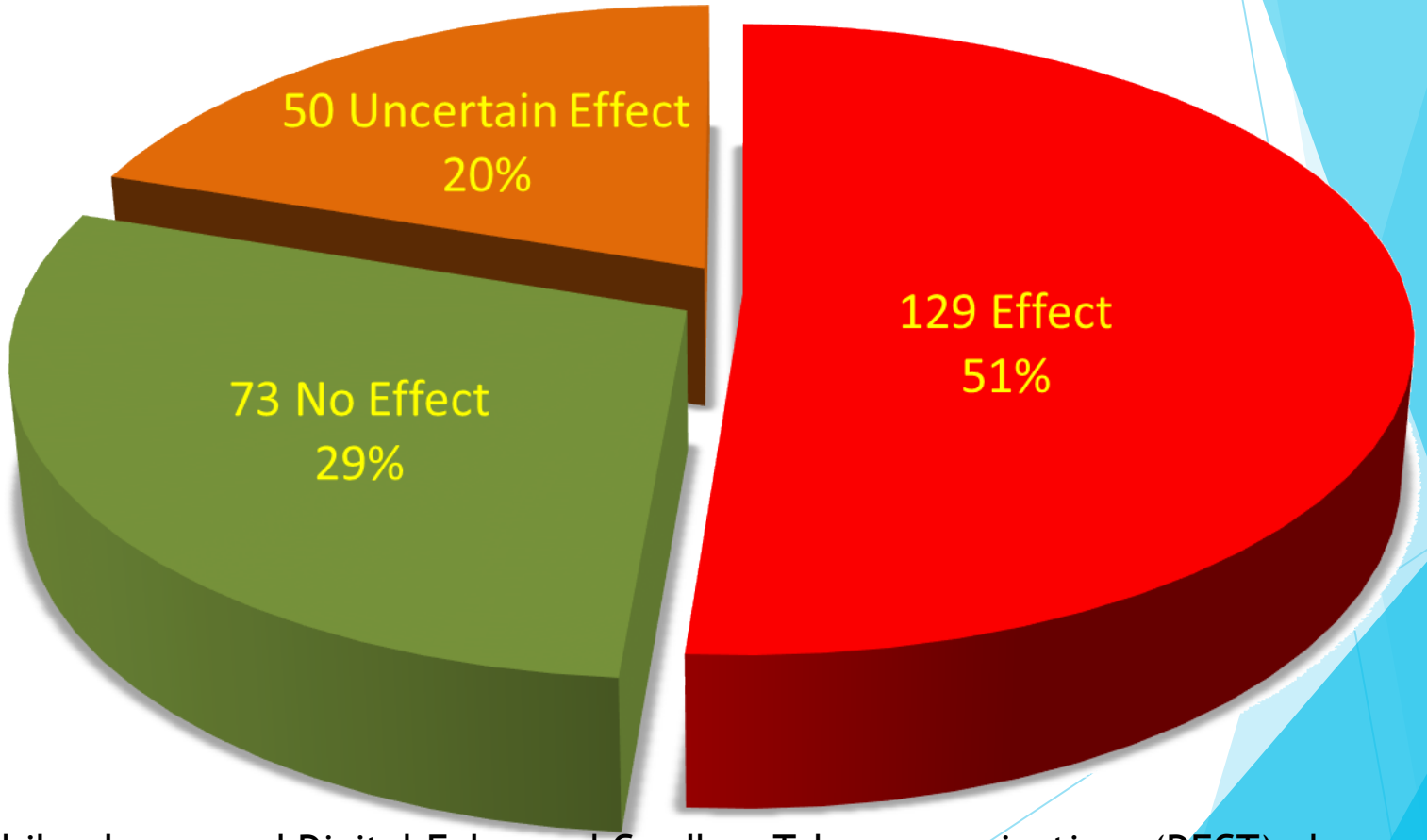
ORSAA Database Epidemiological UHF Studies



Mobile phones and Digital Enhanced Cordless Telecommunications (DECT) phones

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Bradford Hill System – Moving from Association to Causation

- **Temporal Relationship:** Exposure must precede the effect
- **Strength:** Strength of the association – Relative Risk
- **Dose Response Effect:** Biological gradient
- **Plausibility:** Biological plausibility
- **Experimental:** Reproducibility with repeated studies
- **Specificity:** Specificity of the association
- **Coherence:** Coherence between cause-to-effect interpretation with generally known facts about disease
- **Consistency:** Consistency between independent studies

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Bradford Hill System of Causation

Bradford Hill indices for epidemiological studies for UHF studies using ORSAA database

Find Search Summary Totals for Bradford Hill Criteria

Number of records used : 129

	Total No
Temporal Relationship	18
Strength	69
Dose Response Effect	72
Consistency	43
Plausibility	122
Experiment	120
Specificity	6
Coherence	1

EXIT

ORSAA.org screen grab

IARC - RF-EMR

Group 2B

"Possible human carcinogen"

May 2011

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In-vivo testing from Human UHF studies

Organ or fluids sampled	Studies			Top 6 major Bio-Effect categories
	Effect	No Effect	Uncertain Effect	
Saliva; Blood (Haemoglobin, chromosomes & lymphocytes); Sperm; Skin; Auditory system; Core Temperature; Pituitary Hormones; Urine; Faeces; EEG studies' ECG studies	51	10	7	DNA damage, Biochemical changes Altered Enzyme Activity; Cell Irregularities/ Damage/ Oxidative Stress; Cardiovascular/ Vascular Effects

Source : ORSAA database

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In-vivo animal studies - All UHF studies

Cumulative Exposure (h)	Studies			Top Six Bio-Effect categories (# studies in brackets)
	Effect	No Effect	Uncertain	
Group 1 ≤ 100 h (≤ 4.2 d)	366 (79%)	85 (18%)	14 (3%)	1. Biochemical changes (167) 2. Altered Enzyme Activity (144) 3. Oxidative Stress (122) 4. Cell Irregularities/ Damage (82) 5. Neuro-behavioural Effects/ Cognitive Effects (53) 6. DNA damage/ Mutagenic /Genotoxic (42)
Group 2 100 to ≤ 750 h (4.2 d to 1 month)	76 (76%)	21 (21%)	3 (3%)	1. Biochemical changes (35) 2. Altered Enzyme Activity (33) 3. Oxidative Stress (29) 4. Cell Irregularities/ Damage (18) 5. Apoptosis (Programmed cell death) (12) 6. DNA damage/ Mutagenic /Genotoxic (11)
Group 3 >750 ≤8700 h (<1 yr)	19	11	1	1. Biochemical changes (7) 2. Altered Enzyme Activity (6) 3. DNA damage/ Mutagenic /Genotoxic (4) 4. Oxidative Stress (4) 5. Sperm effects (4) 6. Apoptosis (Programmed cell death) (3)

Source : ORSAA database

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Simulated vs Real Mobile Phones Signal

Table 3. Number of bio-effect Mobile phone studies with Signal Type and Wave-form

Research Categories	Real Mobile Phone used in Experiments			Simulated Mobile Phone Signals used in Experiments					
Wave form	Pulsed			Pulsed			Continuous		
Outcome	#Effect	#No Effect	#Uncertain Effect	#Effect	#No Effect	#Uncertain Effect	#Effect	#No Effect	#Uncertain Effect
in vivo	120	18	11	69	49	8	6	4	0
in vitro	28	8	1	60	63	7	10	17	2

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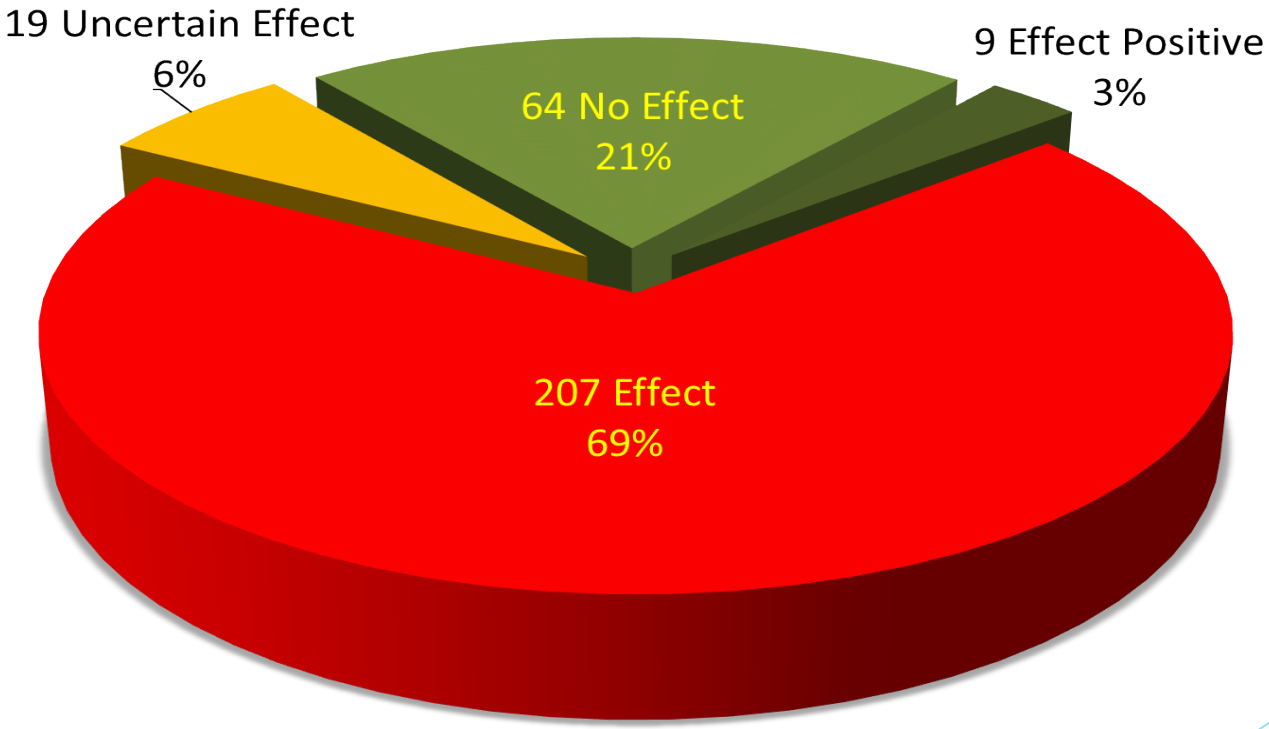
Non-thermal Effects exposures - In-vivo animal studies ≤ SAR 2 W/kg



Source : ORSAA database

All Microwave (UHF-SHF) Studies

Find Search Summary Totals

Peer Reviewed Studies Showing Biological Effects Number of records used : 1173 of 3063

Auditory Dysfunction / Hearing loss / Tinnitus	29	Apoptosis (Programmed Cell Death)	90	Brain Tumours	39
Blood Brain Barrier Permeability Changes	15	Breast Cancer	6	Cellular Stress	56
Brain Development / Neuro Degeneration	47	Biochemical Changes	307	EEG changes / Brain Waves	93
Neuro Behavioural Effect / Cognitive Effects	152	Cell Irregularities/ Damage/ Morphological Changes	174	Effects on Mitochondria	34
Calcium Influx / Efflux	16	Fatigue	30	Altered Enzyme Activity / Protein Levels / Protein Damage	326
Circadian Rhythm Disruption	12	Altered Gene Expression	127	Headaches/Migraines	46
DNA Damage / Mutagenic / Genotoxic	137	Altered Glucose Level / Glucose Metabolism	18	Inflammation	21
Endocrine / Hormone Effects	59	Cardiovascular/Vascular Effects	52	Hepatic Effects (Liver)	20
Miscarriage / Spontaneous Abortion / Foetus Resorption	2	Immune System Effects	56	Impaired / Reduced Healing/ Bone Density Changes	4
Memory Impairment	51	Oxidative Stress / ROS/ Free Radicals	223	Speech Impairment	4
Sperm /Testicular Effects	83	Sleep Effects	47	Haematological Effects	44
Tumour Promotion	28	Neurotransmitter Effects	31	Synergistic/Combinative Effects	45
Thyroid Effects	12	Visual Disturbances/ Ocular Effects	34	Autism	6
Leukemia	3	Parotid Gland Malignancy	4	Neoplasis/ Hyperplasia (Abnormal Tissue Growth)	2
Depression	18	Induced Adaptive Response	46	Dizziness / Vertigo / Vestibular Effects	18

May have a role in disease pathway/ well-being A known cause in disease Continue

Source: ORSAA Database – RF Bioeffect summary

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Identified Risks

- Brain Tumours
- Other Cancers
- Cardiovascular Disease
- Diabetes
- Neurodegeneration
- Mental illnesses
- Pregnancy Complications, Developmental Problems
- Immune Disorders
- Infertility/Sterility
- Chronic Illness
- Nuisance Effects
- Sleep Disorders

Biology vs Physics views of EMR Interaction

- **Biology**: microwave radiofrequency transmissions → Cancer
- **Physics**: photon energy cannot break ionic bonds → No DNA damage

Bad biology

<u>We know</u>

- **Chronic inflammation → cancer**
- **Cigarette smoke → cancer**
- **Toxins and autoimmune disease → cancer**

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Conclusions

- Converging evidence on health effects.
- Non-thermal bio-effects are **real**
- Enough SMOKE to say we have a FIRE
- Devices need a higher safety design standard
- Stronger consumer advice on safe use
  - especially **children**
  - Advice on **safer use is hidden**
  - Needs to be very **obvious**
- As Radiation Protection Scientists we must ask the question :

Has a trigger point been reach for adopting a proper Precautionary Approach to this new RF-EMR technology?

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Extra Slides Follow

SLIDES NOT USED TO FOLLOW

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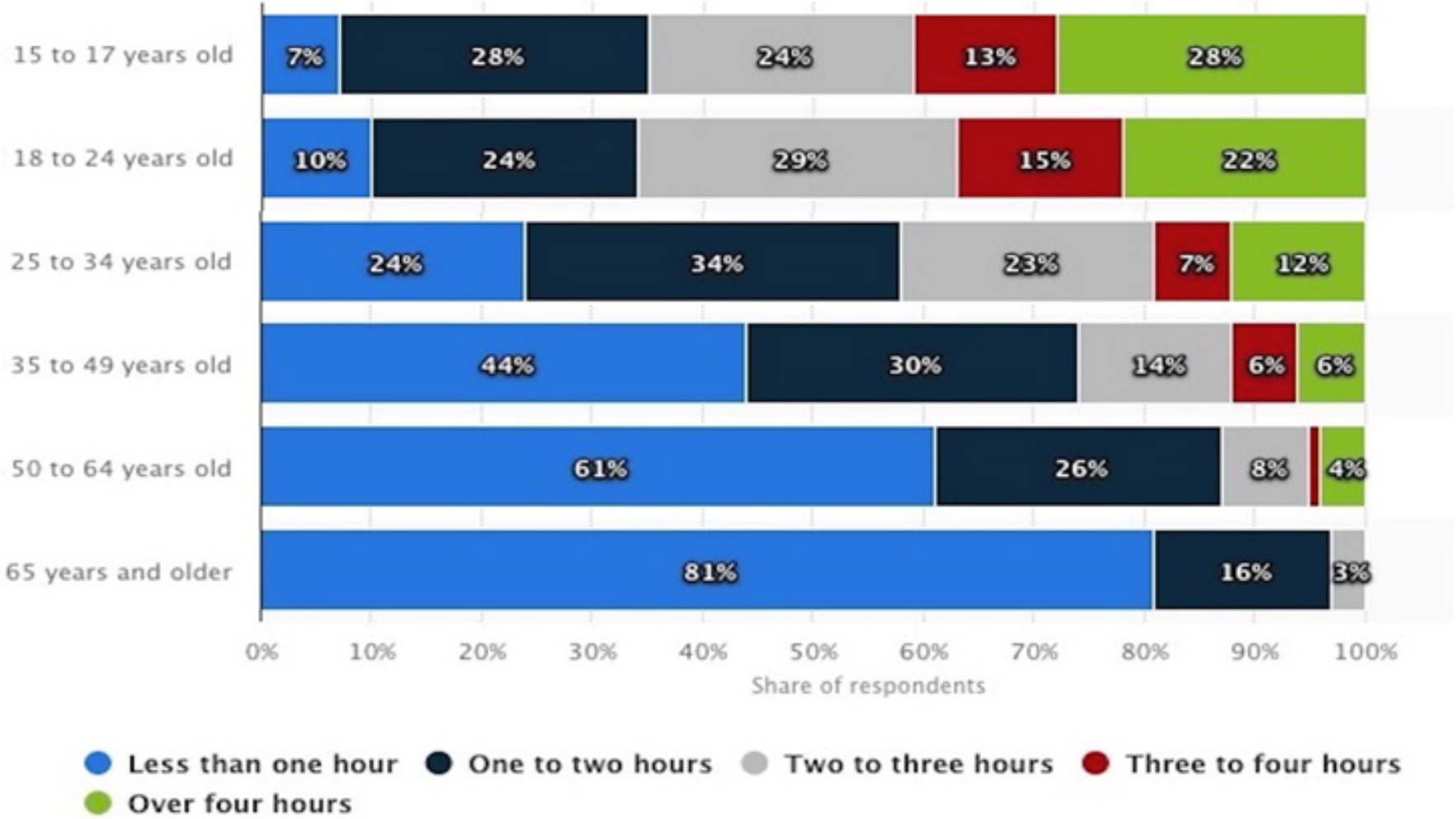

Source Statista.com

Epidemiological Studies of Note

- Interphone → glioma in the group with the longest duration of use (≥1640 h) (OR=1.40; 95% CI 1.03to 1.89), higher for ispsilateral use and temporal tumours.

Patients interviewed	Tumour	Organ
2708	Glioma	Brain
2409	Meningioma	Brain
1100	Acoustic Neuroma (Vestibular Schwannoma)	Acoustic nerve
400	Parotid gland	Salivary gland

- **CERENAT** multicenter French case-control study 2004–2006.
- Among heaviest users (cumulative duration ≥896 h), time since first use was occasionally less than 5 years (11%) but mostly 5– 9 years (49%) and 10 years and more (40%).
  - 33 % commercial agents or sales people
  - 22% chief operating officers, production & operation managers
  - 62% reported occupational mobile phone use.
- **COSMOS** Study (75,993) – Self reported *vs* Telco usage figures
  - 14% reported health effect following use

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Current Australian EMF- RF Regulation

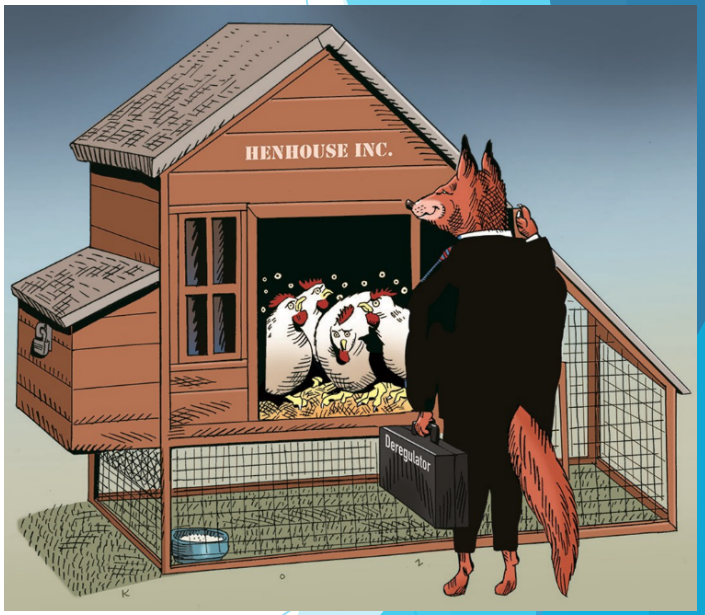
- Regulator =Australian Communications Media Authority (ACMA)

- *Radiocommunications Act 1992*. S162 (3) (f)

- "health and safety protection to persons who operate, work with or use wireless equipment via the establishment of standards"

- "Inclusion of the precautionary principle in the ACMA regulatory instruments would place a regulatory burden on industry which would require strong justification."

- The ACMA does not discern that justification



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Bradford Hill System of Causation

- **ORSAA database**
  - Uses Bradford Hill (BH) indexes for causation of cancer
- BH **Criteria for causation**
  - Minimal conditions necessary to provide adequate evidence of a causal relationship between an incidence and a possible consequence

Article | Exposure | Study Categories | Effects Categories | Study Statistics | **Bradford Hill Criteria**

Temporal Relationship	Exposure must precede the effect, taking into account the latent period of the condition	● N ○ Y
Strength	Strength of the association, commonly expressed in terms of relative risk *i.e.* the factor by which the probability of developing the disease is increased in the exposed over the non-exposed population groups.	○ N ● Y
Dose Response Effect	Biological gradient. An increasing amount of exposure increases the risk. If a dose-response relationship is present, it is strong	○ N ● Y
Plausibility	Biological plausibility, *i.e.* whether it is reasonable to postulate that the cause acts through a mechanism which corresponds to biological knowledge of the adverse effects of the agent.	○ N ● Y
Experimental	Reproduction of the condition experimentally (either in animals or in man).	○ N ● Y
Specificity	Specificity of the association (although it has become obvious that the rule "one cause – one effect" is hardly applicable for conditions with a multi- factorial aetiology (Aetiology- the cause, set of causes, or manner of causation of a disease or condition)	● N ○ Y
Coherence	Coherence of the cause-to-effect interpretation with generally known facts on the natural history and biology of the disease.	● N ○ Y
Consistency	Consistency of results between independently performed studies.	○ N ● Y

Bradford Hill Summary Report

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In-vivo long-term (Near Field) animal studies - UHF study

- The US FDA - nominated cell phone RFR emission for toxicology and carcinogenicity testing in 1999
  - Took a decade to start
- NPT study - 2-year study on rats & mice
  - Huge $25 million study is the world's largest most carefully done study ever done on long term wireless health risks. Reporting started in 2018.
  - Near-field exposure intensity was at low non-thermal or non-heating levels
  - Evidence of Carcinogenic activity was rated as:
    - Clear evidence;
    - Some evidence;
  - Equivocal evidence of carcinogenic activity is demonstrated by studies that are interpreted as showing a marginal increase of neoplasms that may be test agent related;
    - No evidence;
    - Inadequate study.
- Mice Study showed no effects
- Exposure to Sprague Dawley (SD) Rats different
  - Occurrence of these rare nerve sheath tumours were statistically significant and others where not
  - Rare nerve tumours were found being malignant schwannoma in the heart of male rats
    - Same cells in nerves of the human ear.
- Significant positive trends were found for gliomas in male rats exposed to CDMA-modulated RF radiation
  - Ditto heart Schwannomas in male rats exposed to GSM or CDMA-modulated RF

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In-vivo long-term (far-Field) animal studies - UHF study

- Ramazzini Institute in Italy.
  - Long-term animal study - just concluded
  - Interim paper:
    - Same rare nerve tumours were found in *male* rats as in the NPT study.
    - These rare nerve tumours also present in control *male* rats
      - Same findings as NPT study.
    - Results less convincing than NPT study.
- **Does rat research inform human health risk?**
  - Rats are the preferred animal models for carcinogenicity studies
  - Regulatory agencies rely on rodent carcinogenicity bioassay data → a given chemical → cancer in humans.

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Prof Henry Lai's life-time collection

- ORSAA database incorporates:
  - ARPANSA database
  - Prof Henry Lai's personal collection of 937 papers:
    - 1. ELF-EMF-Apr1-comet-assay.docx (46 papers)
    - 2. ELF-oxidative-effect-11-21-2017.docx (186 papers)
    - 3. RFR-12-14-neurological-effects-2007-2017.docx (325 papers)
    - 4. RFR-Apr1-comet-assay.docx (76 papers)
    - 5. Electrohypersensitivity-50pg-2017.docx (124 papers)
    - 6. Final RF oxidative stress papers (180 papers)
  - Lai classified studies as "Effect" or "No Effect"
  - ORSAA classification different only 27 / 937 times
    - 7 in new category "Uncertain Effect"
    - 10 "Effect" to "No Effect"
    - 10 "No Effect" to "Effect".
    - **Good agreement** on the final bio-effect category for each paper.

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Chronic Diseases. Does EMR have a Role?

Top Health Burdens

- Cardiovascular Disease
- Cancer
- Neurodegenerative diseases
- Mental illness
- Allergies

RF-EMR bio effects with evidence

- Cardiac and vascular effects, oxidative stress and effects on voltage-gated Ca2+ channels
- DNA damage, altered cell metabolism, altered gene expression, oxidative stress, inflammation.
- neuronal damage (evidence of functional and histopathological changes), oxidative stress, metabolic changes, blood brain barrier damage.
- Neurobehavioural changes - anxiety, cognitive impairment, changes in neurotransmitters
- Serological evidence of elevation of IgE antibodies and Th2 cytokines, lowering of cytotoxic activity of white blood cells, mast cell degranulation

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ANRES research

Table 1. Environmental Sensitivity Conditions		
Environmental Sensitivity Conditions	**Number**	**Percentage %**
MCS	144	75.8
Fragrance Sensitivity	142	74.7
EHS	80	42.1
Food Sensitivity	131	68.9
CFS/ME	84	44.2
Fibromyalgia	54	28.4
Lyme Disease &/or it's co-infections	18	9.5
Biotoxin-related illness	13	6.8
Other	46	31.9

As registrants can select more than one condition, the percentages do not add up to 100%

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