

What Is Missing In Post-Market Surveillance of Wireless Technology?

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Washington, D.C.**

**Radiation Research Trust Conference
London, UK**

September 8-9, 2008

Post-Market Surveillance Basics

- **Regulatory Paradigm to Protect Consumers**
- **Goal: Early detection and treatment**
 - **Government and industry joint responsibility**
 - **Pre-Market Testing – “Keep dangers out...”**
 - **Post-Market Surveillance – “Safety net...”**
 - **Historically, it has worked....**
- **Hypothesis testing research is not quite Post-Market Surveillance**
- **The Precautionary Principle is not Post-Market Surveillance**

What Is It Supposed to Be?

- **Monitoring wireless technology for changes that could impact consumer safety**
 - **Both devices and infrastructure**
- **Monitoring people who use the technology or who are otherwise exposed for signs of adverse effects**
 - **Seek out data on illnesses**
 - **Put it into the prevention/therapeutic realm**
- **Two functional components:**
 - **Passive Post-Market Surveillance – Registries**
 - **Active Post-Market Surveillance – Surveys**

Where Is The Protection for Users Of Wireless Technology?

- **1984: Wireless industry was exempted by government from pre-market testing and post-market surveillance**
- **1993 -- 1999: \$28.5 million to fill in missing pieces of the regulatory framework including Post-Market Surveillance**
- **1999 – 2008: ‘More Research’ has taken the place of Post-Market Surveillance**
 - **In reality, both are necessary**
 - **Without both, consumers are left unprotected and science is left without an important tool**

Example of How It Works: Safe Wireless Initiative

Ongoing Technology Monitoring

- **New wireless product assessments and field measurements**

Health Effects:

- **Passive Post-Market Surveillance Registry**
- **Clinician Network – Data sharing**
- **Active Post-Market Surveillance**
 - **UK Electro-Sensitivity Prevalence Survey**

Technology Monitoring Findings

- **Wireless Devices**
 - **SAR excursions**
 - **Could bring both thermal and non-thermal disease mechanisms into play**
 - **iPhone appears to have signal repeater functions**
 - **Could make ‘users’ part of the transmission infrastructure**
- **Infrastructure – Masts, towers, antennas, bases...**
 - **In U.S., thousands of un-registered, unregulated masts/antennas**

Health Effects Monitoring Findings

- **Clinical symptoms and the array of reported conditions are consistent with pathological mechanisms centered on abnormally persistent cell-membrane oxidative stress and ion channel impermeability**
- **Clinician reports suggest that patients with non-EMR conditions require higher doses of meds to achieve desired outcomes**
- **Detoxification protocols appear to work better for patients in non-EMR environments**

UK Electro-Sensitivity Survey

- **Conducted January-March 2008**
- **Questionnaire distributed through ES-UK related networks**
- **256 participants (95 males; 161 females)**
- **Ages 16 to 82**
- **To be published soon as a case series**
 - **Very modest as ‘research’**
 - **But, critically important to those suffering from ES and their clinicians**

UK Electro-Sensitivity Survey

- **Etiology clues:**
 - **Cases have significant wireless device exposure**
 - **Note: Microwave ovens do not appear to be causal factors**
 - **Cases have a precipitating event: bacterial or viral infection, post-traumatic stress, a severe chemical exposure event, automobile accident, snake or bug bite....**
 - **More frequent in women than in men**
 - **Effect threshold lower with increasing age**

A Progressive Medical Condition?

Phase I: Functional Impairment

- **fatigue; sleep problems; tingling in extremities; pain in head and neck**

Phase II: Debilitating Progression

- **Headaches; heart palpitations; inability to focus; light headedness; dizziness; memory loss; poor concentration; sensitivity to noise and light**

Phase III: Requires Clinical Intervention

- **Dry, painful, bleeding eyes; excessive sweating at night; extreme irritability; fits of anger; persistent nausea; blood in stool; ringing in ears; skin rashes and bumps; vision impairment; heavy metal toxicity**

Clinician Feedback Pursuant to Surveillance: Evaluation Tools for Phase II

- **ICRW exposure documented; symptoms subside when out of exposure**
- **Cervical (neck) inflammation and tenderness**
- **Extremely tight shoulder muscles**
- **EKG to evaluate heart rhythms**
- **Cognitive challenge batteries to test short term memory and focus**
- **Ocular and auditory sensitivity assessments**
- **Blood pressure adaptive variability assessments**

Laboratory Markers for Phase III

- **TBARS (thio-barbiturate reactive substances) – serum**
 - **Malondialdehyde as direct marker for cell and mitochondrial membrane oxidative stress (lipid peroxidase reaction)**
- **Total Anti-oxidants (including Glutathione) – serum**
 - **Free radical load in interstitial space**
- **DHEA – saliva**
 - **Oxidative stress induced inflammation**
- **Cortisol – saliva**
 - **Systemic stress response**
- **Interstitial/intracellular metals ratio – longitudinal; hair and feces**
 - **Degree of functional ion channel impermeability**
- **Neuro-transmitter panel (monoamines: norepinephrine, dopamine, serotonin) – serum or urine**
 - **Gap junction intercellular communication function**

Intervention Protocols Now Being Tried Based on These Data

- **Neurological re-balancing**
- **Ion Channel Opening**
- **Mitochondrial Enhancements**
- **Methylation Support**
- **Detoxification**
- **Cell Membrane Repair**