NTP
National Toxicology Program

NTP Presentation to the

New Hampshire Commission to Study the Environmental and Health Effects of Evolving 5G Technology

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Outline

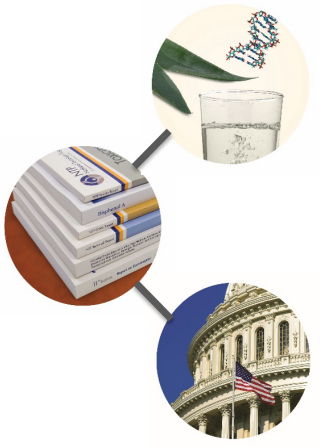
- About the National Toxicology Program (NTP)
- NTP studies on radio frequency radiation (RFR)
  - Brief background on RFR
  - Summary of findings
  - NTP's exposure system for studying RFR
  - NTP RFR research program
  - Summary of NTP RFR study results
  - Next steps

NTP

- An interagency program established in 1978
  - National Institute of Environmental Health Sciences (administrative headquarters)
  - National Institute for Occupational Safety and Health
  - Food and Drug Administration (primarily National Center for Toxicological Research)
- Mission: *Evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology*
- NTP has evaluated more than 2800 environmental substances for potential human health effects
- NTP website: *https://ntp.niehs.nih.gov*

Scope of NTP Activities

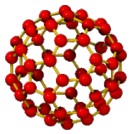
- Carry out **research and testing** activities on agents of public health concern
- Conduct **literature-analysis** activities to identify cancer and non-cancer human health hazards
- Develop **new approaches** to better predict how chemicals affect biological responses
- **Communicate results** broadly to multiple stakeholder groups through technical report series, monographs, journal publications, and NTP website



NTP's Portfolio

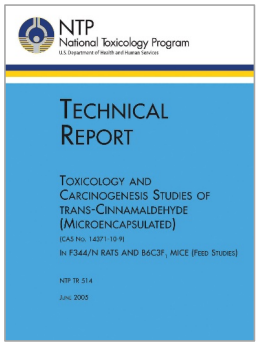
- AIDS therapeutics
- Botanical dietary supplements
- Complex occupational exposures
- Green chemistry
- Endocrine active compounds
- Flame retardants
- Food and drinking water contaminants
- Industrial chemicals
- Mold
- Nanoscale materials
- Per- and polyfluorinated alkyl substances
- Persistent environmental contaminants
- Personal care products
- **Radio frequency radiation**
- Sulfolane








NTP Publications



Technical Reports

- ~600 2-year cancer assays
- Reports published on 2-year NTP toxicology and carcinogenesis studies
- Provide NTP's policy decision on *level of evidence for carcinogenic activity* under the study conditions

Monographs

- Literature-based assessments on cancer and noncancer health outcomes
- Integrate human, experimental animal, and mechanistic data
- Provide NTP's opinion on whether exposure causes adverse health effects to identify potential hazards for humans or state of the science

Journal Publications

- ~125 per year

NTP reports are peer reviewed; reports and data are available for free download from the NTP website – https://ntp.niehs.nih.gov

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NTP Studies on Cell Phone Radio Frequency Radiation (RFR)

Brief Background on RFR

- The U.S. Food and Drug Administration nominated radiofrequency radiation (RFR) of wireless communications devices to NTP for study in 1999
- Cell phone usage has steadily increased
  - Estimated exposure: 5 billion people worldwide
- Some studies in humans have demonstrated elevated risk of tumors in heavy users of cell phones
- Biological effects have been reported in cell-based tests and in laboratory animal studies
- Animal studies have not consistently demonstrated increased incidences of tumors at any site associated with exposure to cell phone RFR in laboratory animals
- Challenges and logistical issues associated with studying RFR
- Regulatory RFR limit for cellular devices: 1.6 W/kg

Summary of Findings

- NTP's study on cell phone RFR is the most comprehensive assessment of health effects in rats and mice from exposure to 2G and 3G cell phone RFR
- There was **clear evidence** that exposure to cell phone RFR caused heart tumors in male rats
- There was **some evidence** that exposure to cell phone RFR caused tumors in the brain and adrenal gland in male rats

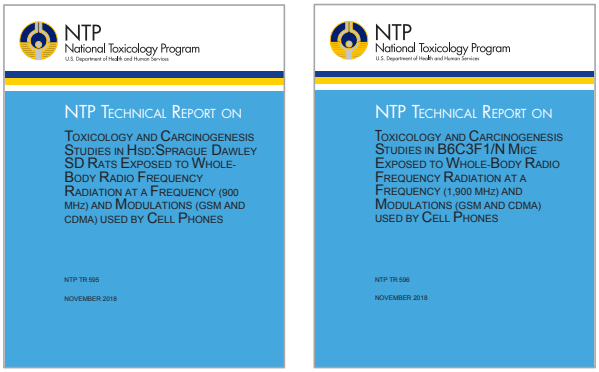
4-Level Scale

- **Clear evidence (highest)**
- **Some evidence**
- **Equivocal evidence**
- **No evidence (lowest)**

Summary of Findings

- The final conclusions represent the consensus of NTP and a panel of external scientific experts who peer reviewed the studies at a public meeting on March 26-28, 2018
- Findings published in NTP Technical Reports
  - NTP Technical Report on the Toxicology and Carcinogenesis Studies in Hsd:Sprague Dawley SD Rats Exposed to Whole-Body Radio Frequency Radiation at a Frequency (900 MHz) and Modulations (GSM and CDMA) used by Cell Phones. TR 595 (2018)
  - NTP Technical Report on the Toxicology and Carcinogenesis Studies in B6C3F1/N Mice Exposed to Whole-Body Radio Frequency Radiation at a Frequency (1,900 MHz) and Modulations (GSM and CDMA) used by Cell Phones. TR 596 (2018)

***Note**: These findings should not be directly extrapolated to human cell phone usage*



Key Players in Exposure System Development

- National Institute of Standards and Technology (NIST, Boulder, CO)
  - Suggested **reverberation chamber** concept of exposure
  - Conducted feasibility studies
  - Conducted independent validation of specific absorption rates (SARs) and chamber RF field strengths and homogeneity prior to initiation of the NTP studies
- IT'IS Foundation (Zurich, Switzerland)
  - Modelled whole-body and organ-specific specific absorption rates (SARs)
  - Built and tested a prototype reverberation chamber based on the technical parameters obtained and optimized in the NIST studies
  - Constructed the reverberation chambers and exposure system

Exposure System Development

- Reverberation chamber exposure system for animal studies of RFR
  - Large shielded room with RF antenna and two paddles to create a homogeneous electromagnetic environment
  - Field exposure is from all directions, all polarizations
  - Field distributions are well characterized and easily monitored

NTP RFR Research Program

- Three-phase toxicology and carcinogenicity studies in rats and mice
  - **5-day** studies to characterize the effects of exposure on body temperature (10 studies)
  - **28-day** toxicology studies
  - **2-year** toxicology and carcinogenicity studies
- In all studies, daily exposure to RFR (2G signals) in reverberation chambers for 9 hrs 10 min (18 hr 20 min per day in 10 min on/10 min off cycles)
  - Rats exposed starting *in utero* to 1.5, 3, or 6 W/kg either GSM- or CDMA-modulated signals at 900 MHz
  - Mice exposed starting at 5 weeks of age to 2.5, 5, or 10 W/kg either GSM- or CDMA-modulated signals at 1900 MHz

Summary of NTP RFR Study Results

Rat studies

- Clear evidence of carcinogenicity based on increased incidences of malignant schwannomas (**heart tumors**)
  - Some evidence of carcinogenicity based on increased incidences of malignant gliomas (**brain tumors**) and pheochromocytomas (**adrenal gland tumors**)
- Greater survival in all groups of exposed **males** compared to controls

4-Level Scale

- **Clear evidence (highest)**
- **Some evidence**
- **Equivocal evidence**
- **No evidence (lowest)**

Summary of NTP RFR Study Results

Rat studies cont.

- Effects observed in pregnant dams and their offspring
  - SAR-dependent decrease in body weights of dams and pups
  - Decreased pup survival at higher exposures tested
- Positive findings for DNA damage in the brain (hippocampus) and equivocal findings in frontal cortex in males

Summary of NTP RFR Study Results

Mice studies

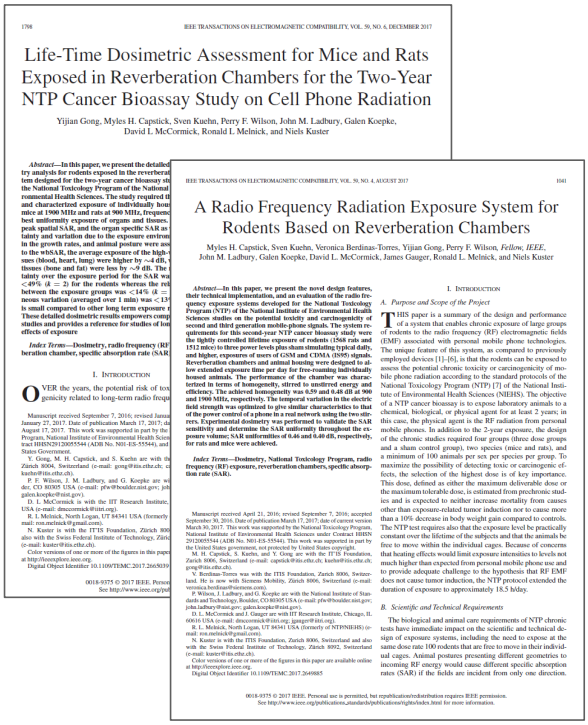
- Equivocal evidence of carcinogenic activity in male and female mice for both GSM and CMDA modulations
- Positive findings for DNA damage in the brain (frontal cortex) in males and blood cells in females

4-Level Scale

- **Clear evidence (highest)**
- **Some evidence**
- **Equivocal evidence**
- **No evidence (lowest)**

Publications

- Exposure system method, validation, and dosimetry were published in *IEEE Transactions on Electromagnetic Compatibility* (2017)
- Pilot study results published in *Bioelectromagnetics* (2018)



1708 IEEE TRANSACTIONS ON ELECTROMAGNETIC COMPATIBILITY, VOL. 59, NO. 6, DECEMBER 2017

Life-Time Dosimetric Assessment for Mice and Rats Exposed in Reverberation Chambers for the Two-Year NTP Cancer Bioassay Study on Cell Phone Radiation

Yijian Gong, Myles H. Capstick, Sven Kuehn, Perry F. Wilson, John M. Ladbury, Galen Koepke, David L. McCormick, Ronald L. Melnick, and Niels Kuster

IEEE TRANSACTIONS ON ELECTROMAGNETIC COMPATIBILITY, VOL. 59, NO. 4, AUGUST 2017 1041

A Radio Frequency Radiation Exposure System for Rodents Based on Reverberation Chambers

Myles H. Capstick, Sven Kuehn, Veronica Berdinas-Torres, Yijian Gong, Perry F. Wilson, *Fellow, IEEE*, John M. Ladbury, Galen Koepke, David L. McCormick, James Gauger, Ronald L. Melnick, and Niels Kuster

Next Steps

Goals for investigative studies

- Further clarify and fill knowledge gaps from the NTP studies on RFR
- Address issues/criticisms raised during the peer review
- Probe potential biological mechanisms for RFR-induced effects
- Further evaluate DNA damage in rats and mice
- Establish biomarkers of exposures to apply to studies of newer and emerging RFR-based communication technologies

Follow-up investigative studies

- Smaller-scale exposure facility
- 10 animals per group
- Series of multiple short- to medium-term studies
  - Expect to publish first set of data in 2020
- GSM and CDMA, 900 and 1900 MHz
  - Newer technologies (3G and 4G) at appropriate frequencies

- Stress and behavior
- Organ-specific effects
- Exposure factors
- The role of heat
- Conduct more robust and targeted assays for DNA damage
- Evaluate newer technologies (3G, 4G, and potentially 5G)

Applying Knowledge to Newer Technologies

- Newer technologies utilize different modulation scheme
- 5G will also utilize higher frequencies (up to 60 GHz)

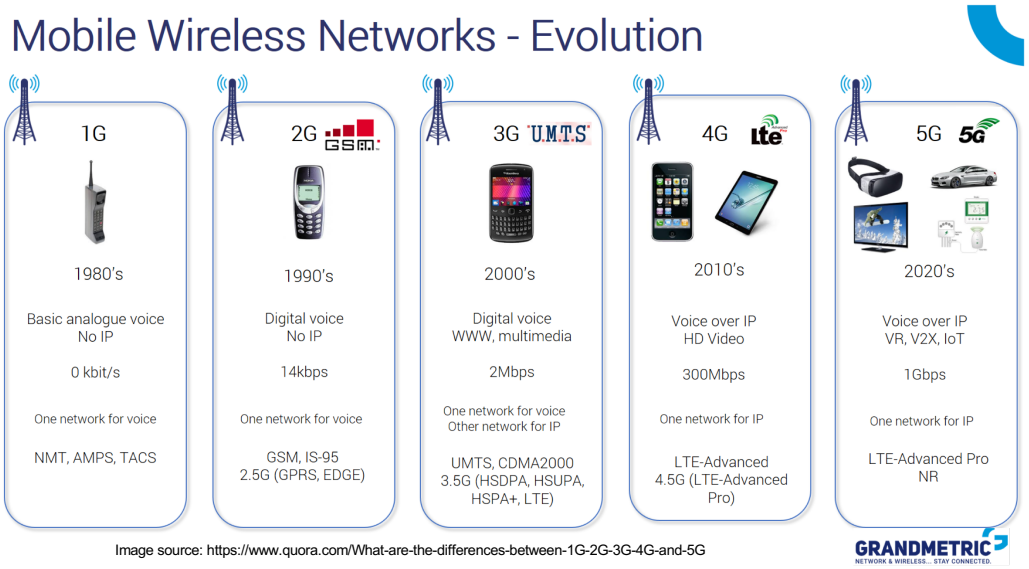


Image source: https://www.quora.com/What-are-the-differences-between-1G-2G-3G-4G-and-5G

Questions