

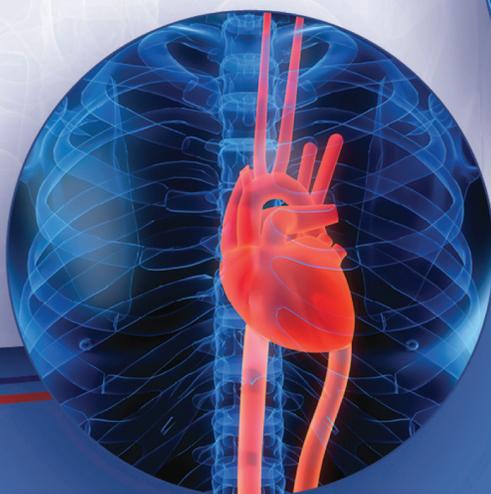
NEUROLOGICAL EFFECTS AFTER CHEMICAL NERVE AGENT EXPOSURES WORKSHOP

BETHESDA, MARYLAND | FEBRUARY 26–27, 2014

National Institutes of Health

Counter
ACT

Countermeasures
Against Chemical
Threats



Sponsored by:

CounterACT Program, Office of the Director, NIH, DHHS

National Institute of Neurological Disorders and Stroke, NIH, DHHS

Neurological Effects after Chemical Nerve Agent Exposures Workshop

February 26-27, 2014

Neuroscience Center Building (NSC)

6001 Executive Boulevard

Bethesda, Maryland

Sponsored by:

CounterACT Program, Office of the Director, NIH, DHHS

National Institute of Neurological Disorders and Stroke, NIH, DHHS

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INTRODUCTION

The HHS Office of the Assistant Secretary of Preparedness and Response (ASPR) and Department of Defense (DoD) have large multi-agency programs on the development of better medical countermeasures against chemical threat agents. NIH is charged with basic and translational research in this area. To this end, the NINDS¹ has led the NIH Countermeasures Against Chemical Threats (CounterACT) Program since 2006, with oversight from NIAID², and partnerships with several other NIH Institutes including NIEHS³, NIAMS⁴, NEI⁵, NICHD⁶, NIGMS⁷ and NLM⁸.

The ASPR develops Scenario-Based and Product-Specific Requirement Documents that help set the NIH research priorities. Currently, HHS is developing such documents for therapeutics that could prevent or reduce the short- and long-term effects of acute, non-lethal exposures to organophosphorus (OP) nerve agents including chemical weapons such as sarin, and pesticides such as parathion. Within ASPR, the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is exploring the existing clinical data of non-lethal nerve agent exposure and associated long-term neurological sequelae. The relevance of these anecdotal clinical reports is not known, but it is clear that in order for researchers in this field to adopt best practices, the animal models they develop and use to examine the non-lethal neurological effects of nerve agent exposure should be relevant to those observed in humans.

The goal of this workshop is to inform the scientific community on the availability of human and animal data supporting neurological effects after non-lethal exposure to nerve agents, and how these data could be used to develop the best animal models for testing therapeutics.

PRIMARY WORKSHOP QUESTIONS

1. What is the evidence in humans for neurological effects after sub-lethal exposure to OP nerve agents?
2. What animal models exist for neurological effects after sub-lethal exposure to OP nerve agents, and what is the evidence that these effects occur in animals?
3. How do we improve the validity of animal models used for testing potential therapeutics?
4. Can we learn more about appropriate assessment tools and animal models from other types of acute brain injury such as seizures, TBI, or large-vessel stroke?

¹ National Institute of Neurological Disorders and Stroke

² National Institute of Allergy and Infectious Diseases

³ National Institute of Environmental Health Sciences

⁴ National Institute of Arthritis and Musculoskeletal Skin Diseases

⁵ National Eye Institute

⁶ Eunice Kennedy Shriver National Institute of Child Health and Human Development

⁷ National Institute of General Medical Sciences

⁸ National Library of Medicine

ACKNOWLEDGEMENTS

The workshop organizers would like to thank the following people for their work and contributions to the meeting program:

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Marilyn Johnson | Operations Coordinator, NIH CounterACT Research, NINDS, NIH

AGENDA, Wednesday, February 26

7:00 AM ***Welcome and Registration***

General Session I (Conference Room C, 1st Floor)

8:00 AM ***Welcome***
Story Landis, PhD
Director, NINDS

Goals and Objectives
David Jett, PhD
Program Director, NIH CounterACT Research, NINDS, NIH

8:20 AM ***HHS Research Requirements***
Susan Cibulsky, PhD
Office of the Assistant Secretary for Preparedness and Response

8:40 AM ***FDA Perspective***
Luciana Borio, MD
FDA Assistant Commissioner for Counterterrorism Policy

9:00 AM ***The Animal Rule***
Andrea Powell, PhD
FDA CDER Office of Counter-Terrorism and Emergency Coordination

9:45 AM ***Break***
Coffee and refreshments available in the NSC Cafeteria, 1st floor.

10:00 AM ***Overview of Human Effects of Nerve Agents***
Steven Bird, MD
University of Massachusetts Medical School

10:30 AM ***Overview of Animal Studies***
Pamela Lein, PhD
University of California, Davis

11:00 AM ***Panel Discussion with Morning Presenters***
Moderator: David Jett, PhD

AGENDA, Wednesday, February 26– cont'd

12:00 PM **Lunch**
Pre-ordered boxed lunches available in Conference Room E.

Breakout Sessions

1:00 PM **Breakout Session I (Conference Room 2172, 2nd Floor)**

Evidence for Neurological Effects in Humans

Discussion of the evidence for short- and long-term sub-lethal effects from OP exposures in humans, including neuropathological effects and functional deficits (cognitive, sensory, motor). What is the evidence, and what is the relationship between these chemical exposures and the effects observed (causal, correlational, association, none)?

Session Chair: Steven Bird, MD

Breakout Session II (Conference Room D, 1st Floor)

Evidence for Neurological Effects in Animals

Discussion of what animal models exist for short- and long-term sub-lethal effects from chemical exposures, including neuropathological effects and functional deficits. What is the predictive value of animal models, both in terms of the effect of the chemical toxin, and the efficacy of potential therapeutics in humans?

Session Co-Chairs: Douglas Cerasoli, PhD and Pamela Lein, PhD

2:45 PM **Meeting of Workshop Session Chairs (Conference Room 2172, 2nd Floor)**

2:45 PM **Break**
Coffee and refreshments available in the NSC Cafeteria, 1st floor.

General Session II (Conference Room C, 1st Floor)

Breakout Session Reports

3:15 PM **Evidence for Neurological Effects in Humans**
Steven Bird, MD

AGENDA, Wednesday, February 26– cont'd

3:25 PM ***Evidence for Neurological Effects in Animals***
Douglas Cerasoli, PhD and Pamela Lein, PhD

4:00 PM ***Comparison of Human and Animal Data***
Discussion of differences and similarities between the effects seen in humans, and the data from animal models of OP toxicity. These will be discussed in the context of developing animal models that are more predictive of the effects seen in humans.

Session Co-Chairs: W. Kent Anger, PhD and Mark Kirk, MD

5:00 PM ***Lessons Learned from a Neuroprotectant Study: Neuregulin***
Byron Ford, PhD
Morehouse School of Medicine

5:30 PM **Adjourn**

6:30 PM **Workshop Dinner**
Timpano Italian Chophouse

AGENDA, Thursday, February 27

7:00 AM ***Welcome and Registration***

General Session I (Conference Room C, 1st Floor)

8:00 AM ***Tokyo Video and Discussion***

Tetsu Okumura, MD, PhD
Superintendent Chief of the doctor's office,
Metropolitan Police Academy, Tokyo Metropolitan Police Agency
Tokyo, Japan

8:30 AM ***Welcome***

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
Rear Admiral, U.S. Public Health Service
U.S. Department of Health and Human Services

8:35 AM ***Global OP Poisonings***

Nicholas Buckley, BMed, MD, FRACP
Professor, Prince of Wales Clinical School
University of New South Wales
Sydney, Australia

General Session II (Conference Room C, 1st Floor)

9:00 AM ***Working Groups and Workshop Deliverables***

David Jett, PhD

9:05 AM ***Working Group on Animal Model Best Practices***

Session Co-Chairs: Pamela Lein, PhD and John McDonough, PhD

10:30 AM ***Break***

10:45 AM ***Working Group on Research Gaps***

Session Co-Chairs: Maria Braga, DDS, PhD, and Mark Kirk, MD

12:15 PM ***Wrap Up and Way Ahead***

David Jett, PhD and Margaret Ochocinska, PhD

12:30 PM ***Adjourn Workshop***

LOGISTICS

Breakout Sessions | Breakout sessions are planned to convene at 1:00 PM on the first day of the workshop. **Breakout Session I: Evidence for Neurological Effects in Humans** will meet in Conference Room 2172 on the 2nd floor. Signs will guide you to the session.

Breakout Session II: Evidence for Neurological Effects in Animals will meet in Conference Room D, just next to Conference Room C where the main session will take place.

The roundtable participants for the sessions have been pre-assigned; please refer to the **Roundtable Assignments** section of this program booklet. Participants who have not been pre-assigned are welcome to attend the session of their choice, space permitting.

Lunch and Refreshments | The following food options have been made available for your convenience:

Boxed lunches: If you pre-ordered a boxed lunch through the NIH website, you can collect it in Conference Room E (where you checked in) at 12:00 PM on the first meeting day.

NSC Facilities: The NSC Cafeteria, located on the first floor, will be open for breaks and coffee until 4 PM on Wednesday, and through the entire duration of the meeting on Thursday. Please note that the NSC Cafeteria will only accept cash; there is an ATM in the lobby. Additionally, the convenience store on the first floor operates from 7:30 AM to 3:30 PM and also accepts credit cards.

Workshop Dinner | A dinner will take place Wednesday night, 6:30 PM, at Timpano Italian Chophouse, located at 12021 Rockville Pike, Rockville, MD 20852. The meal will cost \$36 including tax and gratuities. Participants must bring cash for payment; **credit cards and checks are not accepted.** Please also note that seating is limited in the dining area and may not be available to participants arriving late.

NSC Parking | If you wish to request a parking pass and were not provided one at check-in, please inform a staff member at the Welcome Desk.

Return to Airport | Staff at the Welcome Desk will be available to assist you in booking any necessary return transportation to the airport.

LOGISTICS– cont'd

Shuttle Service Between Hotel and Meeting Venue | For participants staying at the Bethesda North Marriott Hotel and Conference Center, there will be a shuttle to take you from the hotel to the meeting site each day. Please refer to your hotel welcome materials for the schedule indicating which shuttles you should take. The shuttle schedule is as follows:

Day 1, February 26:

7:15 AM – Shuttle 1 from Marriott to NSC

7:30 AM – Shuttle 2 from Marriot to NSC

5:45 PM – Shuttle 1 from NSC to Marriott

6:00 PM – Shuttle 2 from NSC to Marriott

Day 2, February 27:

7:15 AM – Shuttle 1 from Marriott to NSC

7:30 AM – Shuttle 2 from Marriot to NSC

There will be no return shuttle to the hotel on the second day, so please remember to bring your luggage to the meeting. We will watch your bags at the Welcome Desk in Conference Room E.

ROUNDTABLE ASSIGNMENTS

BREAKOUT SESSION I: EVIDENCE FOR NEUROLOGICAL EFFECTS IN HUMANS

Conference Room 2172

Session Chair: Steven Bird, MD

Roundtable Assignments:

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Francesca Bosetti, PhD

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Tetsu Okumura, MD, PhD

Michael Rogawski, MD, PhD

Diane Rohlman, PhD

David Siegel, MD

Shedra Snipes, PhD

Ernie Takafuji, MD

Paul Wax, MD

BREAKOUT SESSION II: EVIDENCE FOR NEUROLOGICAL EFFECTS IN ANIMALS

Conference Room D

Session Co-Chairs: Douglas Cerasoli, PhD

Pamela Lein, PhD

Roundtable Assignments:

Edson Albuquerque, MD, PhD

Mike Babin, DVM, PhD

Jim Blank, PhD

Maria Braga, DDS, PhD

Philip Bushnell, PhD

Anthony Choo, PhD

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