

Dragon, Karen E. (CDC/NIOSH/EID)

From: Zumwalde, Ralph D. (CDC/NIOSH/EID) (CTR)
Sent: Thursday, February 07, 2008 3:52 PM
To: Dragon, Karen E. (CDC/NIOSH/EID); Miller, Diane M. (CDC/NIOSH/EID)
Subject: Doug Trout's PowerPoints-nano medical

Attachments: Trout 1_08 Pub Mtg.ppt

Here are Doug Trout's PowerPoints that he presented at the January 30 meeting on NIOSH Interim recommendations for medical screening of workers exposed to engineered nanoparticles.

From: Trout, Douglas (CDC/NIOSH/DSHEFS)
Sent: Wednesday, January 30, 2008 1:29 PM
To: Zumwalde, Ralph D. (CDC/NIOSH/EID) (CTR)
Subject: RE: PowerPoints-nano medical



Trout 1_08 Pub
Mtg.ppt (158 KB...)

Current Intelligence Bulletin - DRAFT November 2007

Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles

Public Meeting - January 30, 2008

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



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Background

- ❖ NIOSH Nanotechnology Research Center (NTRC)
- ❖ Need for guidance in area of surveillance and medical screening
 - ❖ NTRC Surveillance Working Group
 - NIOSH representatives
 - Federal Partners
 - Dept. of Defense, Dept. of Energy, OSHA, EPA
 - External Review

Basis for Concern

- ◆ Research on fine and ultrafine incidental particles
 - Epi studies - pulmonary and cardiovascular effects
 - Lab studies – given mass dose a/w increased toxicity as particle size decreases
- ◆ Research on engineered nanoparticles
 - Laboratory testing
 - Fibrotic and inflammatory responses
 - Pulmonary and cardiovascular systems
 - Potential for skin absorption
 - Translocation to brain

Purpose of Document

- ◆ Provide interim guidance concerning specific medical screening until further scientific information becomes available
- ◆ Generate discussion

Occupational Health Surveillance

Ongoing systematic collection, analysis, and dissemination of exposure and health data on groups of workers for the purpose of preventing illness and injury

- ❖ Hazard Surveillance

- ❖ Medical Surveillance – evaluation of group's health status through periodic collection, analysis, and reporting of data

- ✓ Primary prevention

Medical Screening (Monitoring)

- ◆ Can be considered one type of medical surveillance
- ◆ Medical testing/examination of individual to detect preclinical changes or changes that occur in the very early stages of disease
 - before an exposed person would normally seek medical care and when intervention is beneficial
- ◆ Prevention goals
 - secondary prevention – detecting adverse events at early stage

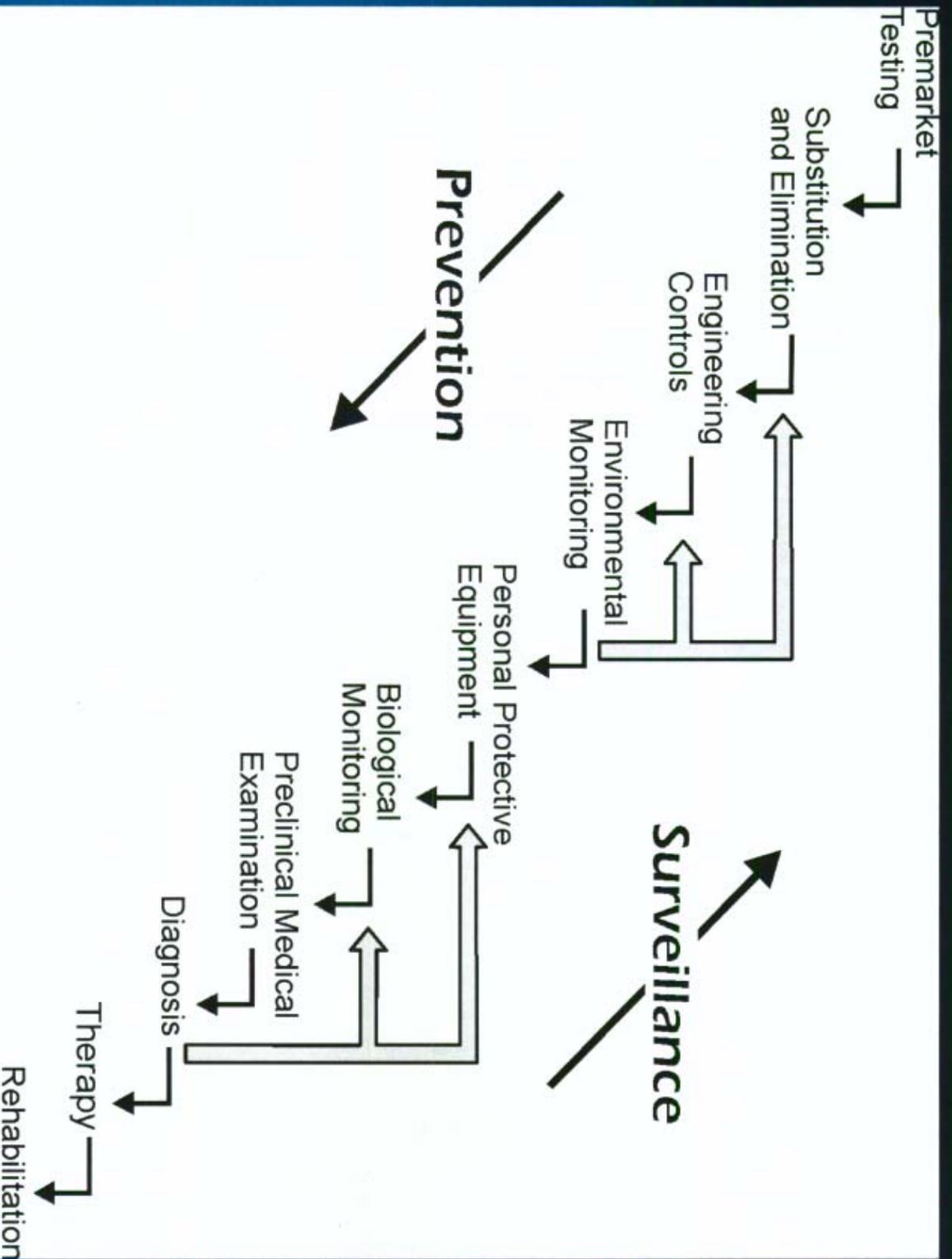


Figure 1. The cascade of occupational health prevention with examples of surveillance feedback (Adapted from Halperin 1996)¹⁴

Frequent Use of Medical Screening

- ◆ Medical screening is a component of many complete safety and health management programs
- ◆ Preplacement medical examinations
 - Fitness for job
 - *Defacto* baseline
- ◆ Ongoing medical screening
 - Mandated by law or voluntary
 - ~ 32 OSHA standards require medical surveillance (*screening*)
 - NIOSH documents recommend medical surveillance (*screening*)

Elements of a Medical Screening Program

1. An initial medical examination and collection of medical and occupational histories
2. Periodic medical examinations at regularly scheduled intervals, including specific medical tests when warranted by the hazard
3. More frequent and detailed medical examinations as indicated on the basis of findings from these examinations
4. Worker training to recognize symptoms of exposure to a given hazard
5. A written report of medical findings
6. Employer actions

Medical Screening - Benefits

- ◆ Information concerning individuals
 - Data may be aggregated across groups of workers
- ◆ May aid:
 - Early recognition of exposure/disease relationship
 - Assurance of safety of new substances

Medical Screening - Benefits

- ◆ Evaluate sentinel events
 - Disease, disability, or untimely death, which is occupationally related and whose occurrence may:
 - provide the impetus for epidemiologic or industrial hygiene studies; or
 - serve as a warning signal that materials substitution, engineering control, personal protection, or medical care may be required.

Medical Screening - Concerns

- ◆ Adverse effects of testing (e.g., radiologic studies)
- ◆ Generation of “uninterpretable” data
 - Application of medical testing poorly understood
 - Detection of common illness/symptoms warranting follow-up vs. those of multi-factorial etiologies
 - Lack of occupational medical evaluation criteria for the interpretation of health findings with respect to workplace
- ◆ Potential follow-up of “false positive” tests
 - Invasive testing, distress related to testing
- ◆ Resources

Medical Screening - Nanotechnology

- ◆ Information available
 - Toxicological research at early stage
 - Exposures characterization at early stage
 - No useful biomarker or medical tests specific for health effects related to exposure to engineered nanoparticles
- ◆ Concerns > Benefits

Conclusions - Medical Screening & Nanotechnology

- ✓ Issues of hazard and exposure have been raised
 - ✓ Assessing potential toxicity is at an early stage
 - ✓ Amount of information is limited
-
- Inadequate data relating specific exposures to specific adverse health effects
 - Insufficient evidence at this time to recommend medical screening based solely on exposure to engineered nanoparticles
 - Need continued reassessment of information

Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles

Recommendations

- Take prudent measures to control exposures**
- Conduct hazard surveillance
 - Identify presence of engineered nanoparticles in workplace and in work tasks

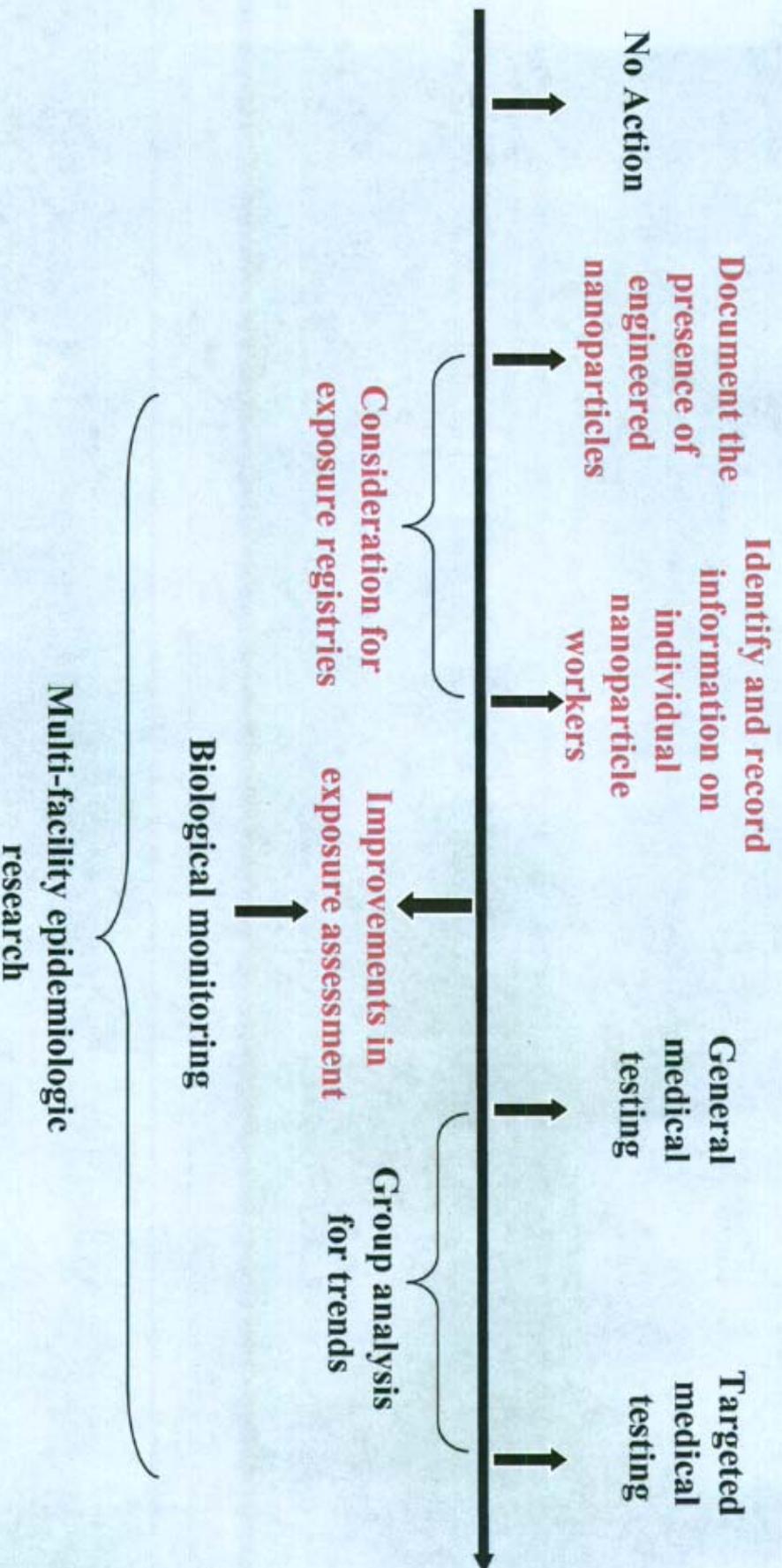
** Approaches to Safe Nanotechnology: An Information Exchange

Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles

Recommendations

- Consider taking advantage of established medical surveillance approaches
 - Established medical surveillance may be useful for workers exposed to nanoparticles despite not being specifically focused on them
 - NIOSH seeking comments on strengths / weaknesses of exposure registries

Continuum of hazard and medical surveillance and related research approaches for nanotechnology workers



Future Research

➤ Improved knowledge of potential hazard and exposure

- in vivo and in vitro studies of toxicity
 - can broad categories of engineered nanoparticles be identified as having similar properties?
 - is particle size a pre-eminent factor?
- epidemiologic studies
 - improve understanding of exposure histories
 - standardized exposure metrics
 - identify exposed groups of adequate size
- exposure assessment
- advances in biological monitoring

Current Status of Draft CIB

- ◆ NIOSH is seeking public review and comment on the draft document
- ◆ Public meeting January 30, 2008
- ◆ The document is posted on the NIOSH Web page, <http://www.cdc.gov/niosh/review/public/115/>
- ◆ Deadline for public comment is February 15, 2008.

Is There a Hazard ?

Are toxicologic data available?

Are epidemiologic data available?

Is There Exposure?

Assessment of exposure

Evaluation of Controls



Risk Determination

[Risk = Hazard & Exposure]



Potential for Residual Risk Exists



Consideration of Medical Surveillance
Types of Surveillance