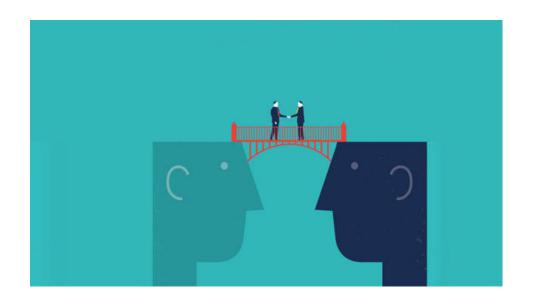
Using the Matrix to bridge the gap between epidemiology and risk assessment

Judy S. LaKind, Ph.D.

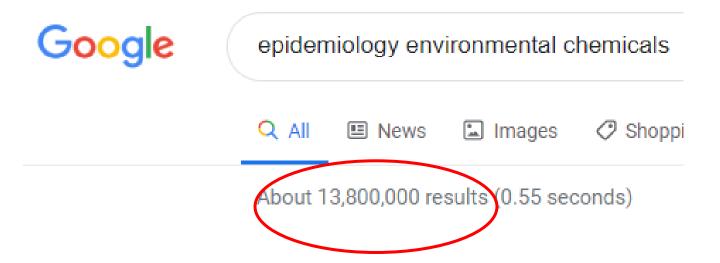
LaKind Associates, LLC

University of Maryland School of Medicine

Carol J. Burns, Ph.D.
Burns Epidemiology Consulting, LLC



Large number of epid studies....



...with many positive attributes....

Target species is directly relevant

Reduces need for high-to-low dose extrapolations

No/poor laboratory animal models for some health endpoints

Minimize the use of animals in chemical testing

....but often aren't used for risk assessment and public health decision-making.

Why?

Training and expertise barriers
Language barriers
Evolving systematic review process
Interest



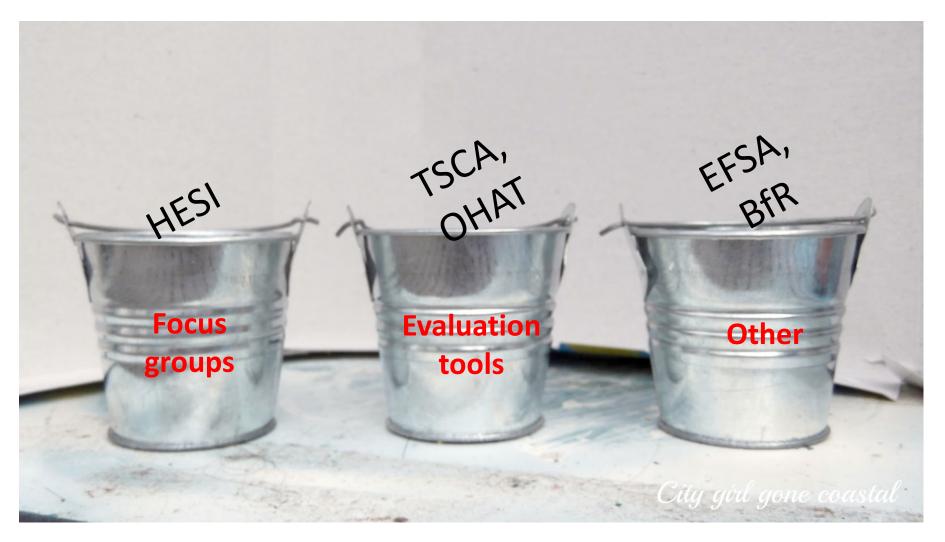
Is bridging the gap a new issue? A new awareness?

NO!

Since the 1990's there have been calls for improving suitability of epidemiology studies for risk assessment.

- Samet et al. 1998. Am J Epidemiol 148(10):929-36.
- Goodman et al. 2010. Environ Health Perspect 118:727–734.
- Burns et al. 2014. Environ Health Perspect 122:1160–1165.
- European Food Safety Authority. 2017. EFSA Journal. doi: 10.2903/j.efsa.2017.5007

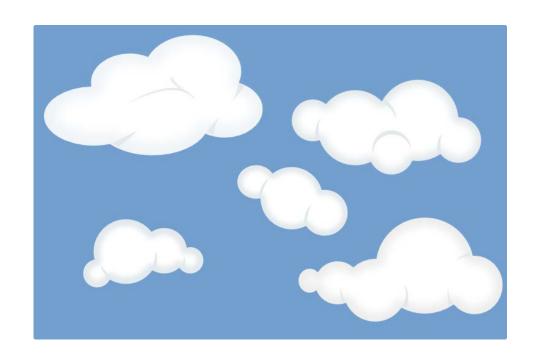
Current activities on bridging epi/risk assessment gap



What are we hearing?

Get off my cloud!

How can I learn more?





Fresh thinking

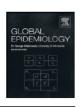
Workshop attendee	Affiliation		
Alcala, Cecilia	Department of Global Environmental Health Sciences, Tulane University School of		
	Public Health and Tropical Medicine		
Branch, Francesca	Risk Assessment Division, Office of Pollution Prevention and Toxics, US		
	Environmental Protection Agency		
Burns, Carol	Burns Epidemiology Consulting		
Camacho, Iris	Risk Assessment Division, Office of Pollution Prevention and Toxics, US		
	Environmental Protection Agency		
Castillo, Juan	Clean Air Institute		
Clark, April	BP		
Clougherty, Jane	Department of Environmental and Occupational Health, Dornsife School of Public		
	Health, Drexel University		
Darney, Sally	Environmental Health Perspectives		
Erickson, Heidi	Chevron		
Goodman, Michael	Department of Epidemiology, Emory University Rollins School of Public Health		
Greiner, Matthias	Department of Exposure, German Federal Institute for Risk Assessment (BfR)		
Jurek, Anne	The Dow Chemical Company		
LaKind, Judy	LaKind Associates; University of Maryland School of Medicine		
Luben, Thomas	National Center for Environmental Assessment, US Environmental Protection		
	Agency		
Mattison, Donald	Risk Sciences International; McLaughlin Centre for Population Health Risk		
	Assessment, University of Ottawa		
Miller, Aubrey	National Institute of Environmental Health Sciences		
Rooney, Andrew	Office of Health Assessment and Translation, National Institute of Environmental		
	Health Sciences		
Thayer, Kristina	Integrated Risk Information Division, National Center for Environmental Assessment,		
	US Environmental Protection Agency		
Weis, Christopher	Office of the Director, National Institute of Environmental Health Sciences		
Zidek, Angelika	Existing Substances Risk Assessment Bureau, Health Canada		

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Methodology article

A matrix for bridging the epidemiology and risk assessment gap*

Carol J. Burns ^{a,*}, Judy S. LaKind 2^b, Donald R. Mattison ^c, (April Clark ^g, Jane Ellen Clougherty ^h, Sally P. Darney ⁱ, Hei Anne M. Jurek ^m, Aubrey Miller ⁿ, Andrew A. Rooney ^o, Ar





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In Press, Journal Pre-proof ?



Methodology

Bridging the Epidemiology Risk Assessment Gap: An NO₂ Case Study of the Matrix

Judy S. LaKind ^a A ⊠, Carol J. Burns ^b, Heidi Erickson ^c ⊠, Stephen E. Graham ^d ⊠, Scott Jenkins ^d ⊠, Giffe T. Johnson ^e ⊠



Focusing on important concepts

Improved dialogue, communication



A nudge, not a shove



Risk Assessment Asks



The Matrix

	Asks for risk assessment		
Hazard ID	Confirm outcome?	Confirm exposure?	Report methods fully and transparently?
Dose Response	Include information on shape of the curve?	Harmonize exposure categories?	Describe direction/ magnitude of error?
Exposure Assessment	Describe source-to- intake pathways?	Provide complete exposure data?	Report on quality assurance/quality control?

The Matrix is:

- communication tool
 - advance an understanding of risk assessment
 - increase the translation of epidemiology data
- includes elements that have impact
- not intended to supplant current best practices
- forward looking

Case Study of NO₂ epidemiology literature

- Scope: 14 mortality studies of long-term NO₂ exposure.
- Why: Does the *existing* epidemiology literature meet the needs of risk assessment(s)?
- What: Examples of providing high/low confidence for each Matrix element
- Conclusion: Epidemiology studies weren't conducted and reported with risk assessment in mind...but they could be.

The Matrix: some positive examples

	Asks for risk diagnos		Online supplements
Hazard ID	Confirm ou come?	Confirm exposure?	Report methods fully and transparently?
Dose Response	Include information on shape of the curve?		Describe direction/ magnitude of error? Histograms, ox plots, etc.
Exposure Assessment	Describe source-to- intake pathways?	Provide complete exposure data?	Report on quality assurance/quality control?

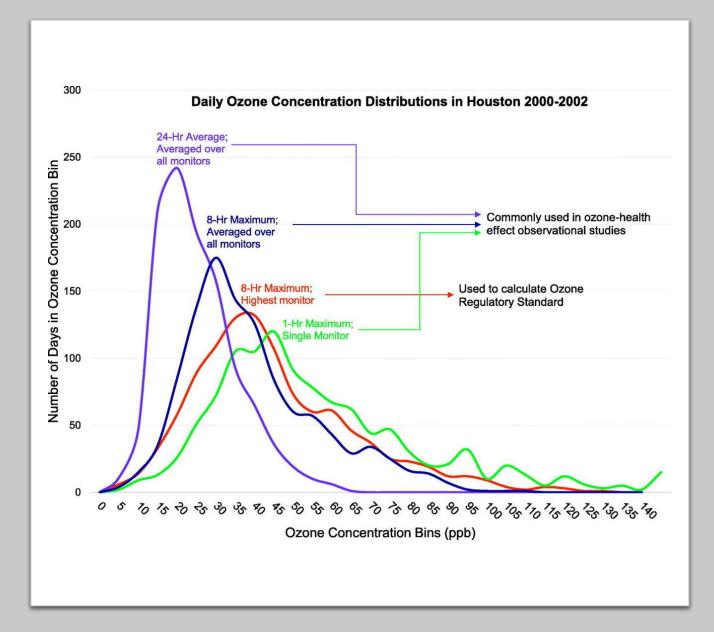
The Matrix: some examples for improvement

	Asks for risk assessme	nt		
	ASKS TOT TISK dSSESSITIETIC			
Hazard ID	Confirm outcome?	Confirm exposure?	Report methods fully	
	Assume lin models	(
Dose	Include info	пarmonize	pescribe direction/	
Response	on shape of the	exposure	magnitude of error?	
	curve? Mobile or stationary? gories?			
Exposure	Describe surce-to-	Provide complete	Report on quality	
Assessment	intake pathways?	exposure data?	assurance/quality control?	

Apples and Oranges

Lange S. Sci Total Environ, 644 (2018) 1547-1556

Example: Ozone



Burns/LaKind - Matrix - 2020

Matrix Refresher

Does not include:

- Confounding
- Study design
- Types of bias

Focuses on:

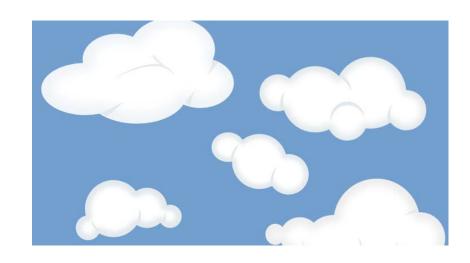
- Risk language
- Elements with "impact"
- Current regulatory thinking

Matrix provides a constructive template

 Can a study be improved in the following stage(s)?
 Design – Reporting - Analysis

• If more research is needed...
Tell me more. Be specific.





Temporal trends of reviews

 Past: Compared results across studies, focus on consistency

 Recent: EPA concluded..."evidence is suggestive of, but not sufficient"...

 Future: Attention on quality, completeness and integration



Matrix Users







RESEARCHERS



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Coauthors

Judy LaKind

Heidi Erickson

Stephen Graham

Scott Jenkins

Giffe Johnson

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Questions?

The Matrix

	Asks for risk assessment			
Hazard ID	Confirm outcome?	Confirm exposure?	Report methods fully and transparently?	
Dose Response	Include information on shape of the curve?	Harmonize exposure categories?	Describe direction/ magnitude of error?	
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