Mathematical Modeling of Risk Acceptability Criteria

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Objectives

- To compare various risk acceptability concepts
- To explore various potential mathematical models to estimate acceptable or tolerable risk
- To illustrate risk communication problems and potential acceptable and negligible risk exposure ranges through asbestos exposure examples

Perceptions and Problems that Make Risk Communication Difficult

1. Involuntary risks are unacceptable.
2. Once minds are made up, it’s hard to change them.
3. Trust and credibility require long-term effort.
4. Unfamiliarity breeds contempt.
5. Health risks may be secondary in environmental controversy.
6. Community values/beliefs/perceptions can outweigh science in shaping public policy.
7. The best communication cannot reverse bad risk-management decisions.

-- Thomas A. Burke, PhD, MPH, Johns Hopkins University

Potential Criteria for Risk Acceptability

1. Estimated Disease Incidence (per year or lifetime)

2. Relative Risk
   - *Attributable Risk Fraction*

3. Cost-Benefit Analysis

4. Life Expectancy Analysis

World Health Organization (WHO). *Water Quality: Guidelines, Standards and Health*. Edited by Lorna Fewtrell and Jamie Bartram. Published by IWA Publishing, London, UK (2001) and Others

1. Lifetime Risk Approach

Acceptable Environmental Risk (USEPA)

- One-in-a-million lifetime risk: “So small as to be negligible.”

- Between one-in-a million and one-in-ten thousand lifetime risk: “Generally considered to be acceptable.”

http://www.epa.gov/region8/r8risk/hh_risk.html

Asbestos: No Safe Level of Exposure?

- Statement commonly included in regulatory and health agency statements.
- What does it mean?
- No threshold?

Common Definitions

Hazard: Potential to do harm

Risk: Probability of that harm occurring for a particular exposure scenario (Probability times the severity of the outcome.)

Safety: Acceptable Risk

(Danger): Unacceptable Risk)

ISO/IEC Guide 51:2014

OSHA, "Guidance for hazard determination," https://www.osha.gov/dsg/hazcom/ghd053107.html

Acceptable Risk in the Workplace (OSHA)

In the Benzene Decision, the Supreme Court stated:

"…if the odds are **one in a thousand** that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it."

Negligible Risk In Radiation Protection

Negligible individual dose corresponds to cancer mortality of 0.03 cases per 1,000
(30 cases per 1,000,000)

NCRP (1993). National Council on Radiation Protection and Measurements. *Limitation of Exposure to Ionizing Radiation,* NCRP Report No. 116 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

Data from ICRP (1991). International Commission on Radiological Protection. *1990 Recommendations of the International Commission on Radiological Protection,* ICRP Publication 60, Annals of the ICRP **21** (1-3) (Pergamon Press, Elmsford, New York).

European Union (REACH)

Tolerable lifetime cancer risk levels:

- 1 case per 100,000 for workers
- 1 case per 1,000,000 for general population

Occupational Exposure Level (f/cc, 45 years starting at the age of 18) Yielding One Case of Cancer per 1000

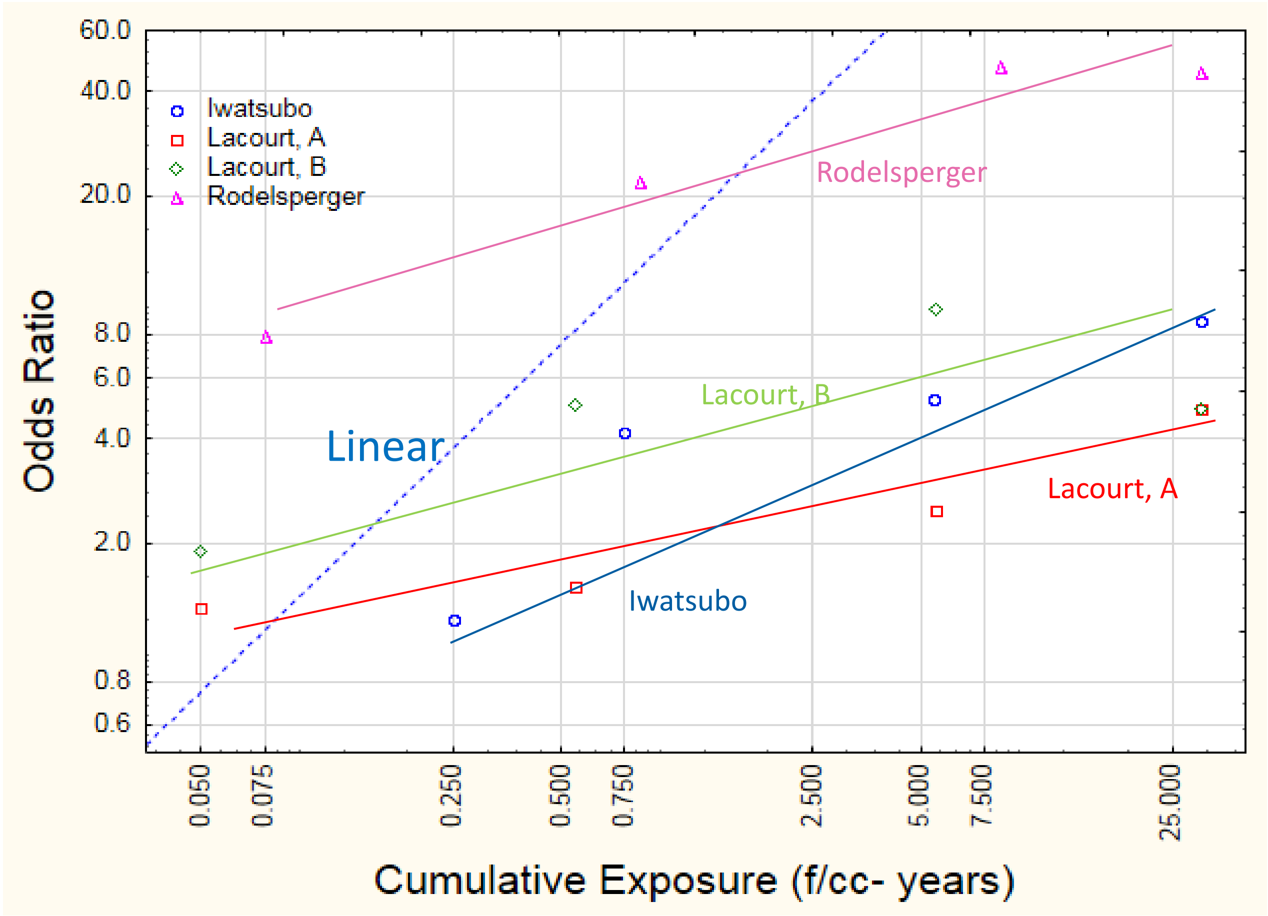
Mineral Type	U.S. EPA IRIS	Berman, Crump (2008)	Hodgson, Darnton (2000, 2014)
PCM	0.032	-	-
Chrysotile	-	0.13	0.48
Amphiboles	-	0.0045	-
Crocidolite	-	-	0.0018
Amosite	-	-	0.014

The Precautionary Principle is not Always Precautionary

Occupational Exposure Level (f/cc, 45 years starting at the age of 18) Yielding One Case of Mesothelioma per 1000

Mineral Type	U.S. EPA IRIS	Berman, Crump (2008)	Hodgson, Darnton (2000, 2014)
PCM	0.063	-	-
Chrysotile	-	5.5	1.4
Amphiboles	-	0.0058	-
Crocidolite	-	-	0.0019
Amosite	-	-	0.026

Low-Level Exposure Mesothelioma Response, Four Case-Control Studies, Based on Cumulative Exposure Estimation



Shows significant, but inconsistent sub-linear dose-response down to quite low estimated mixed fiber type cumulative asbestos exposure levels

2. Relative Risk and Attributable Risk Fraction

Attributable Risk Fraction

$$ARF = \frac{RR - 1}{RR}$$

Where,

ARF = Attributable Risk Fraction

RR = Relative Risk

Attributable Risk Fraction Examples

When RR = 2, ARF = 50%

When RR = 1.1, ARF = 9%

- In this example, there is a 9% chance in a population with an exposure that yields a RR of 1.1, that an individual case is related to the exposure.
- Conversely, there is a 91% chance that the case is not related to the exposure.

Asbestos Lung Cancer Example, Nicholson, 1986 Approach (IRIS)

For lung cancer:

RR = 1 + K_L*Cumulative Exposure

where

K_L = 0.01, the increase in RR risk of lung cancer per f/cc year of cumulative exposure.

Therefore, at RR =2, ARF = 50%, for example, a 100 f/cc year asbestos lung cancer standard would be appropriate (~ 2 f/cc for 45 year exposure)

Mesothelioma Amphibole Example, Berman and Crump (2008b,

For Mesothelioma, the risk equation is somewhat more complex and relies on lifetables:

Assuming:

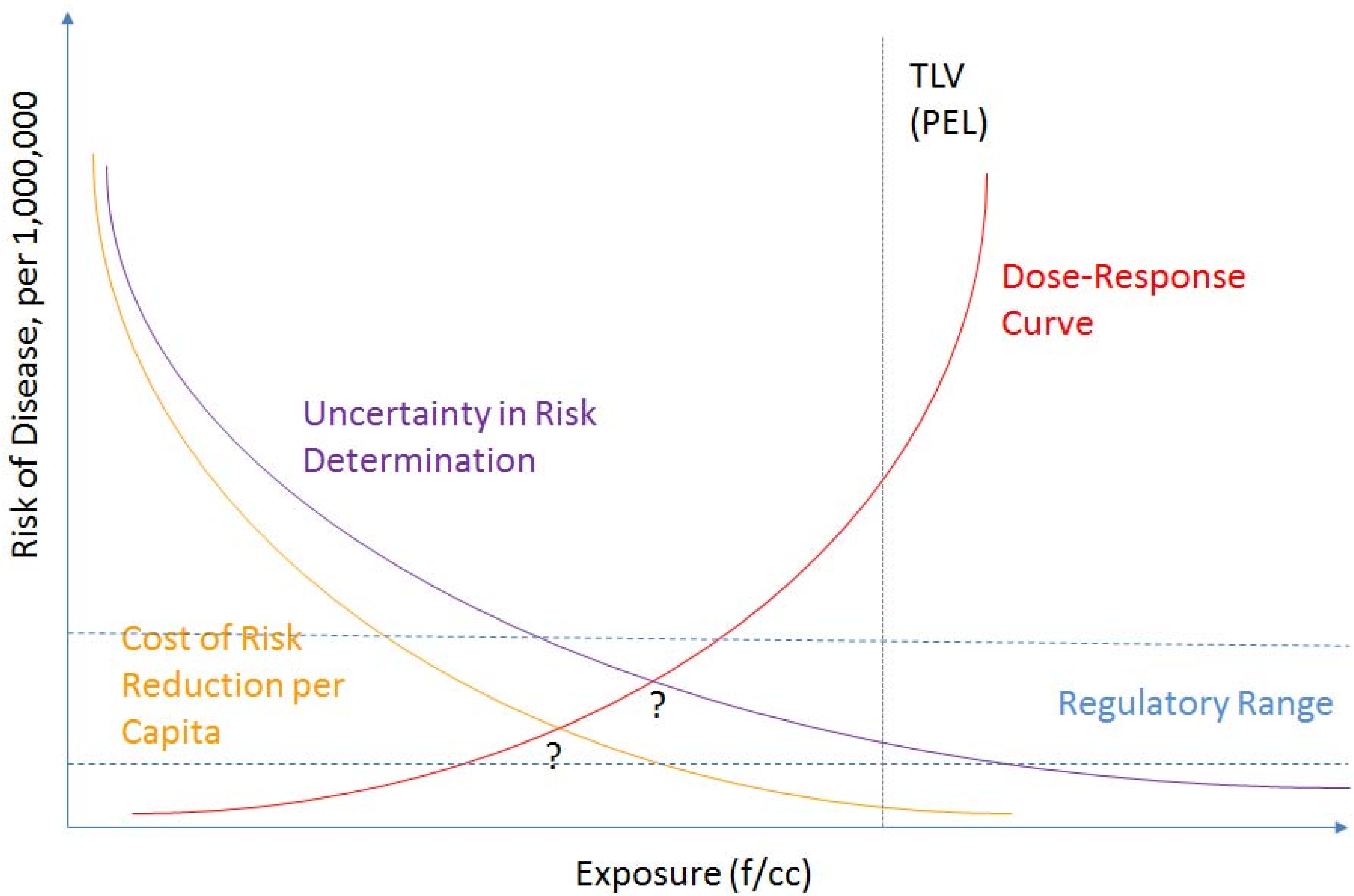
- A lifetime mesothelioma background incidence of 70 per million
- Exposure starts at age 18 and lasts for 45 years

An exposure of 0.018 f/cc years yields a RR of 2, ARF of 50%.

This is equivalent to an average occupational amphibole exposure of only 0.0004 f/cc!

3. Cost-Benefit Approach

Where is the Acceptable Risk Level?



Mathematical Model of Acceptable Risk Exposure Level

$RT = \alpha \, BC \, MR/(LE * GDP)$,

where RT is a risk tolerance level,

α – Coefficient (or elasticity of the risk acceptability),

BC – Background concentration of the parameter of interest,

MR – Background mortality rate or incidence of disease,

LE –Life expectancy,

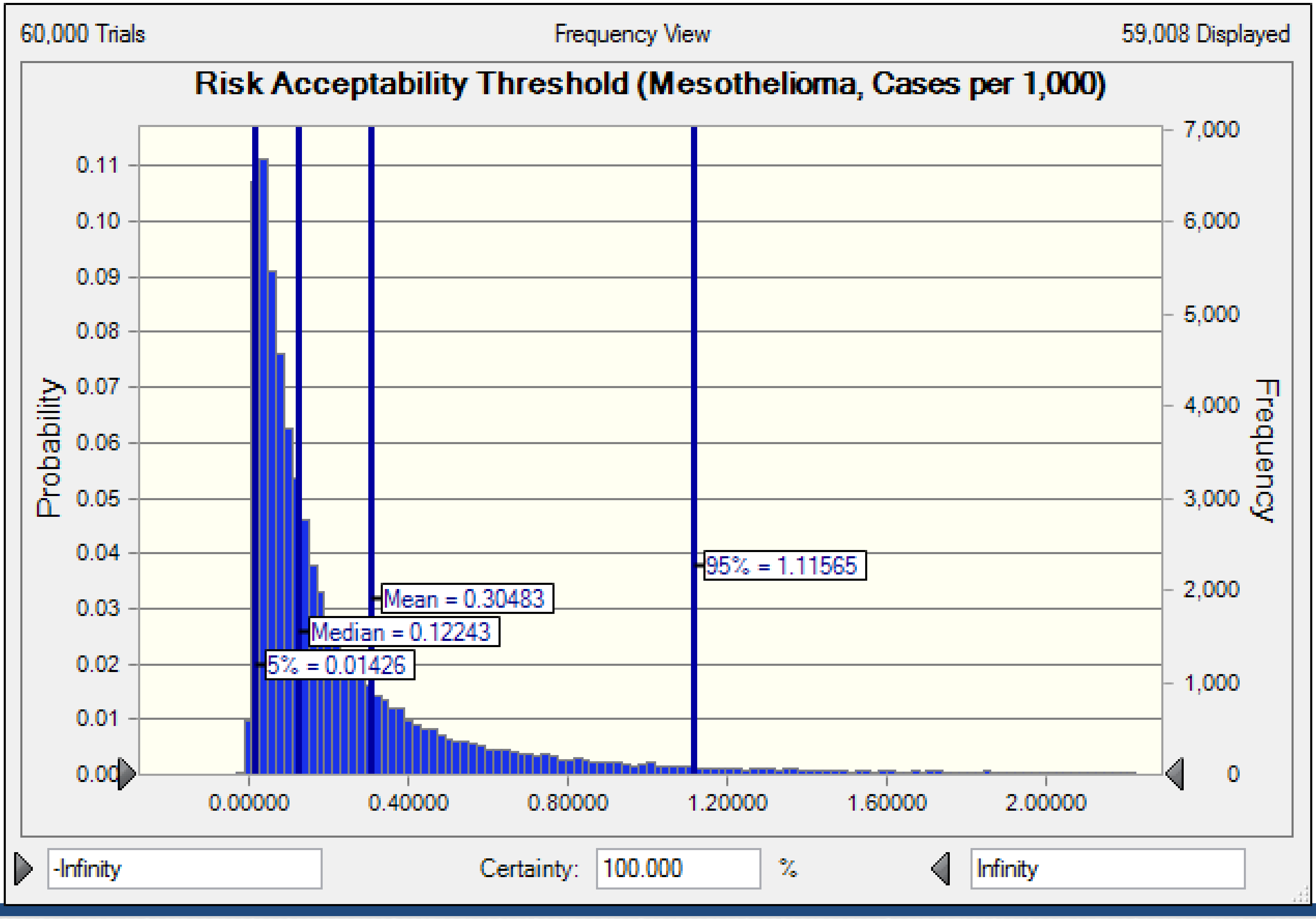
GDP – Gross domestic product per capita.

Illustration for Mesothelioma: "Negligible" and "Acceptable" Risk Levels

RT_n =LCL(α BC MR/(LE *GDP), 5 %) –negligible risk
RT_a =UCL(α BC MR/(LE *GDP), 95 %) – acceptable risk

where RT is a risk acceptability threshold (excess mesothelioma cases per 1,000,000 per year),
α – coefficient,
BC – background exposure to asbestos, considering indoor and outdoor fraction (f/cc),
MR – background mortality rate of mesothelioma (cases per 1,000,000 per year),
LE –life expectancy (years),
GDP – gross domestic product per capita (thousands $).

Modeling of Current Risk Acceptability Threshold



It means that…

If we can tolerate risk of 1,000 cases per 1,000,000,

negligible risk will be 10 cases per 1,000,000.

Rule of Thumb?

Negligible risk level is 1 % of tolerable risk level

Approach 4.
Life Expectancy as a Metric

Life Expectancy Criteria…

We can assume, for example, that risk is acceptable if

$$|\Delta LE| < 0.01\ \%\ LE$$

(where LE – life expectancy of exposed population,

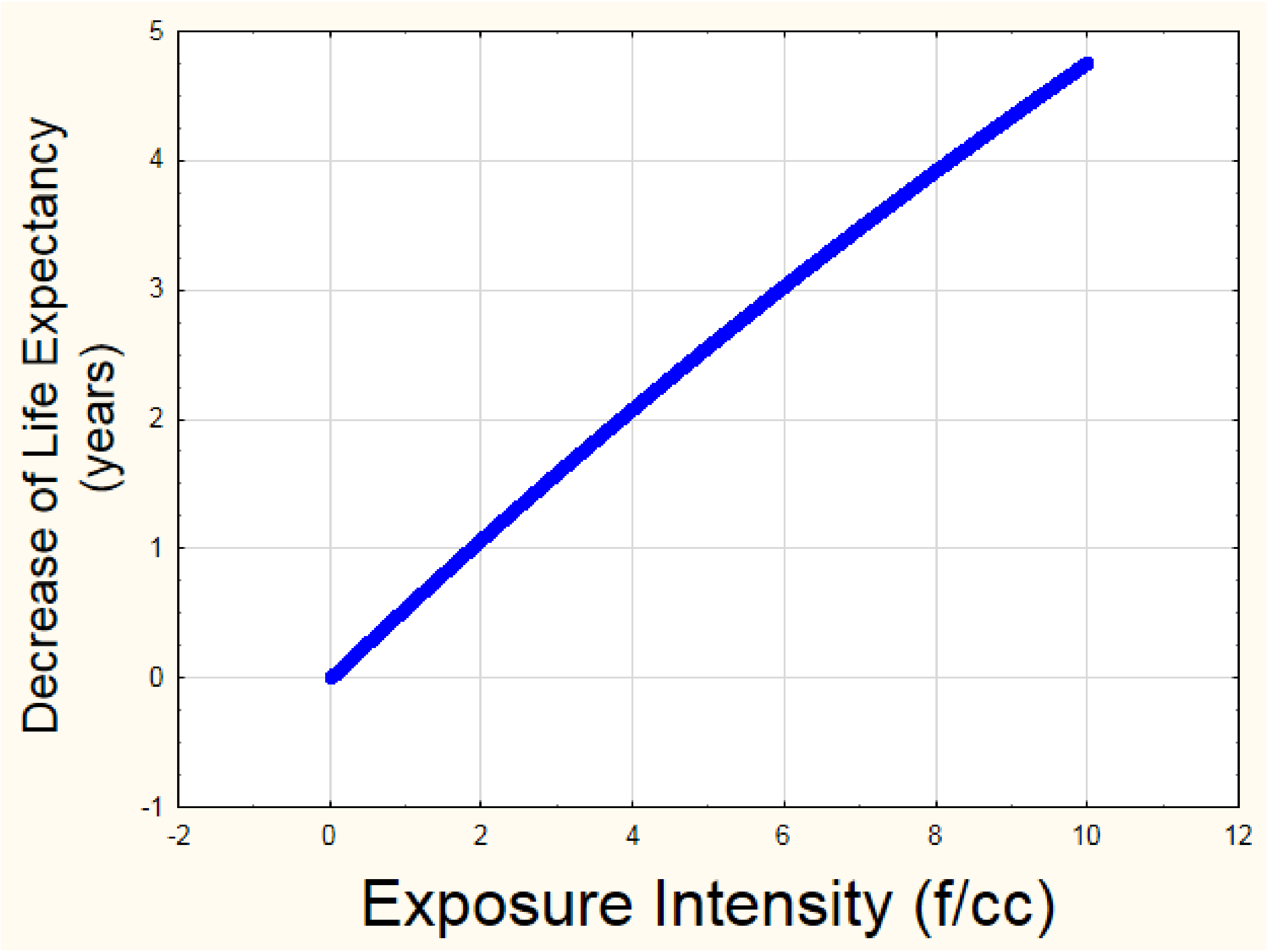
$|\Delta LE|$ - absolute value of life expectancy decrease

because of a risk factor in that population)

Life Expectancy Decrease for Different Levels of Cumulative Exposure (Nicholson, 1986 Model, 2009 Lifetables)

Cumulative Exposure, PCM fibers, f/cc-years	Life Expectancy Decrease (45 years of Occupational Exposure, Started at Age of 18 Years)		Excess Cancer Risk, per 1,000,000
	Years	%	
0.01	0.000124	0.00016	12
0.1	0.0012	0.0015	123
1	0.01	0.016	1,226
10	0.12	0.16	12,261
25	0.3	0.4	30,653
66	0.79	1.0	80,924

Life Expectancy Decrease for Different Levels of Exposure Intensity(Nicholson,1986 Model, Lifetables 2009)



Conclusions and Opinions

- There is no unified approach to determination of acceptable risk level
  - Risk communication method probably more important than exact method
- Risk-based standards are preferable to more arbitrary standards
- However, other factors, such as cost-benefit analysis need to be incorporated, especially in third world countries.