

Probabilistic Risk Assessment

- **Design Requirements**
- **Test Programs**
- **Field Information**
- **Uncertainty, Legal & Regulatory**

Safety

Safety:

- ◆ **Freedom from unacceptable risk of harm**
- ◆ **Probability of a hazardous event:**
 - ◆ Probable, occasional, remote, improbable, incredible
- ◆ **Severity of the consequence of the hazardous event:**
 - ◆ Negligible, marginal, moderate, major, critical

Probability Labels

- **Qualitative labels signals a vague or uncertain probability**
- **Interpretation of Qualitative labels depends on context**
- **Users prefer quantitative data**
- **Quantitative data may result in unwarranted assumptions about precision of the data**
- **Interpretation unduly influenced by absolute numbers**

Types of Risk

- ◆ **Voluntary Risk:**

- ◆ Rock climbing, race car driving, horse jumping, smoking, diving

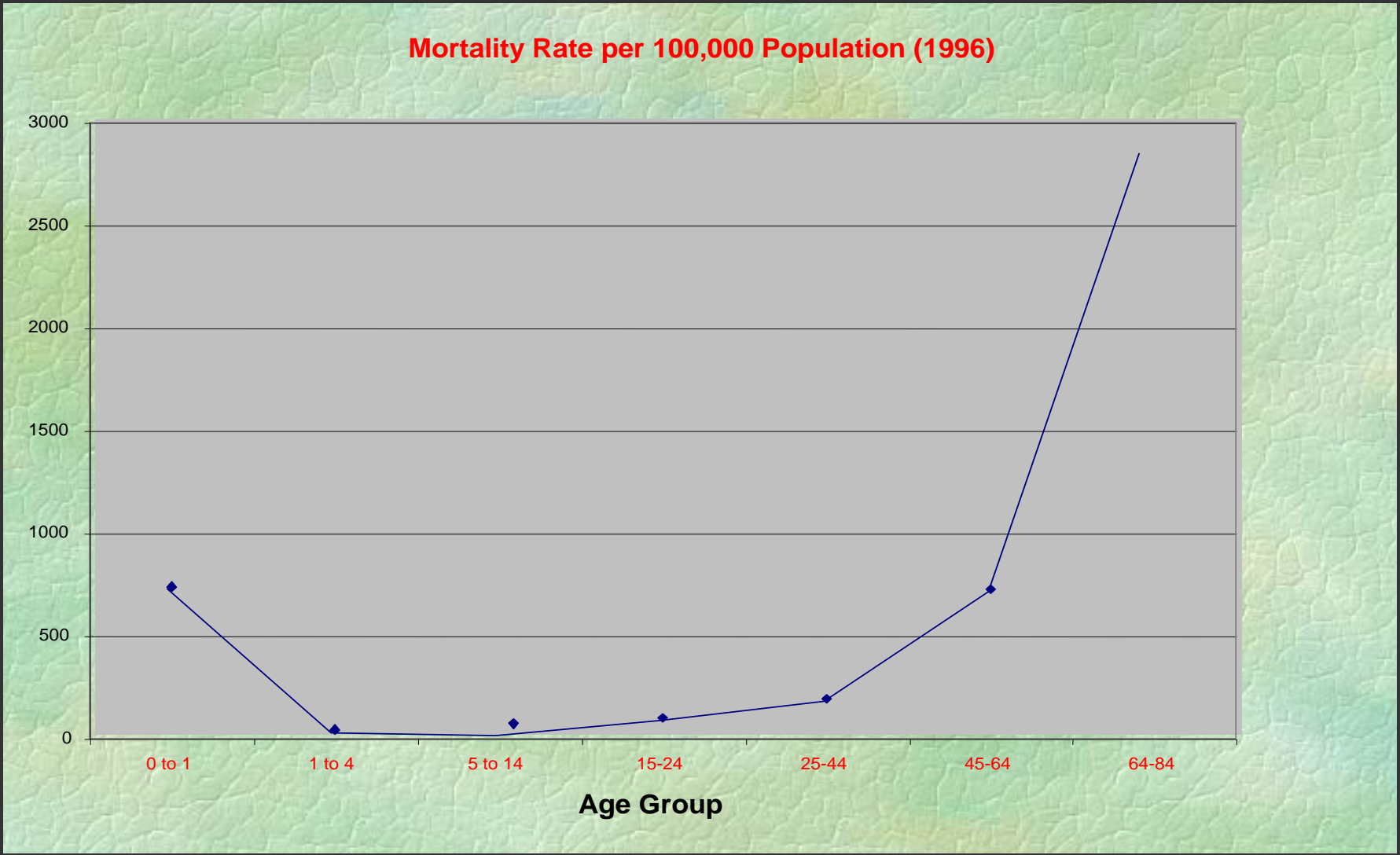
- ◆ **Involuntary Risk:**

- ◆ Natural disasters, sickness

Risk and Fear

- Woody Allen's definition of major surgery:
 - “Anything being done to me”
- Greater fear of Human made risks than natural risks
- Voluntary risk less threatening than other
- Highly personal

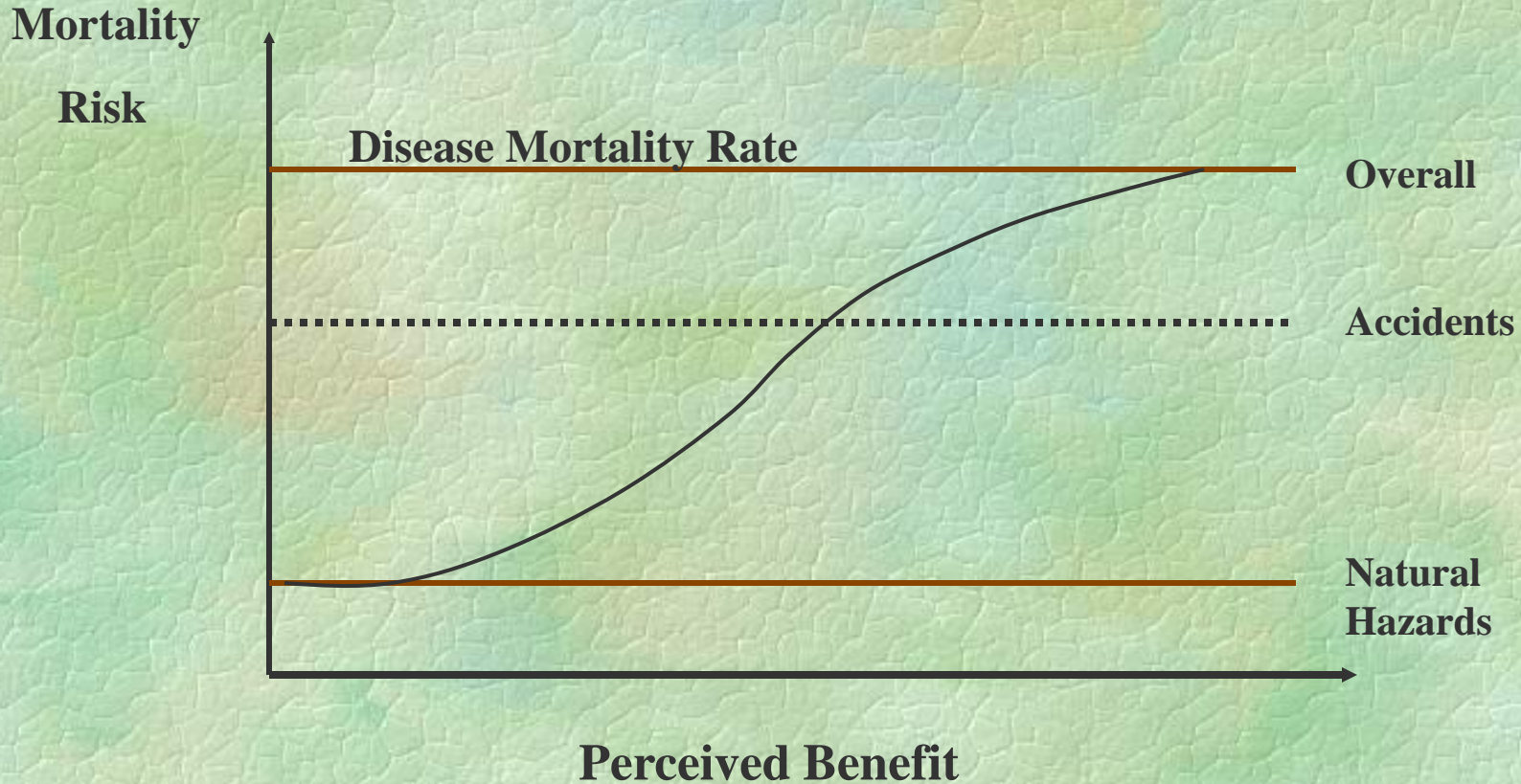
US Mortality Rate (per year)



Frequency Scales

- **Yearly mortality rate for 25-44 year olds in the US: 192 per 100,000**
- **Risk of accidental death: 33 per 100,000**
- **1/10th Risk of accidental death: 3.3 per 100,000**
- **Average mortality rate: 1000 per 100,000**

Risk Tolerance



Natural Hazards

- Lightning death Rate: 0.041 per 100,000
- Tornadoes: 0.027 per 100,000
- Natural “Ave”..... 0.1 per 100,000

One Per Million

US Mortality Rates

- Lung Cancer 56 per 100,000
- Traffic Accident (Car): 22 per 100,000
- 10 Aircraft trips/yr:
(fatal and serious) 0.1 per 100,000
- Commercial Diving: 200 per 100,000

Consumer/Producer Risk

- **Patients/Consumer**

- Acute
- Chronic
- Pediatrics, geriatrics.....
- Donor

- **Manufacturer**

- # of Devices
- # of Procedures

Devices

$$F_D = 1/10,000 \text{ Procedures}$$

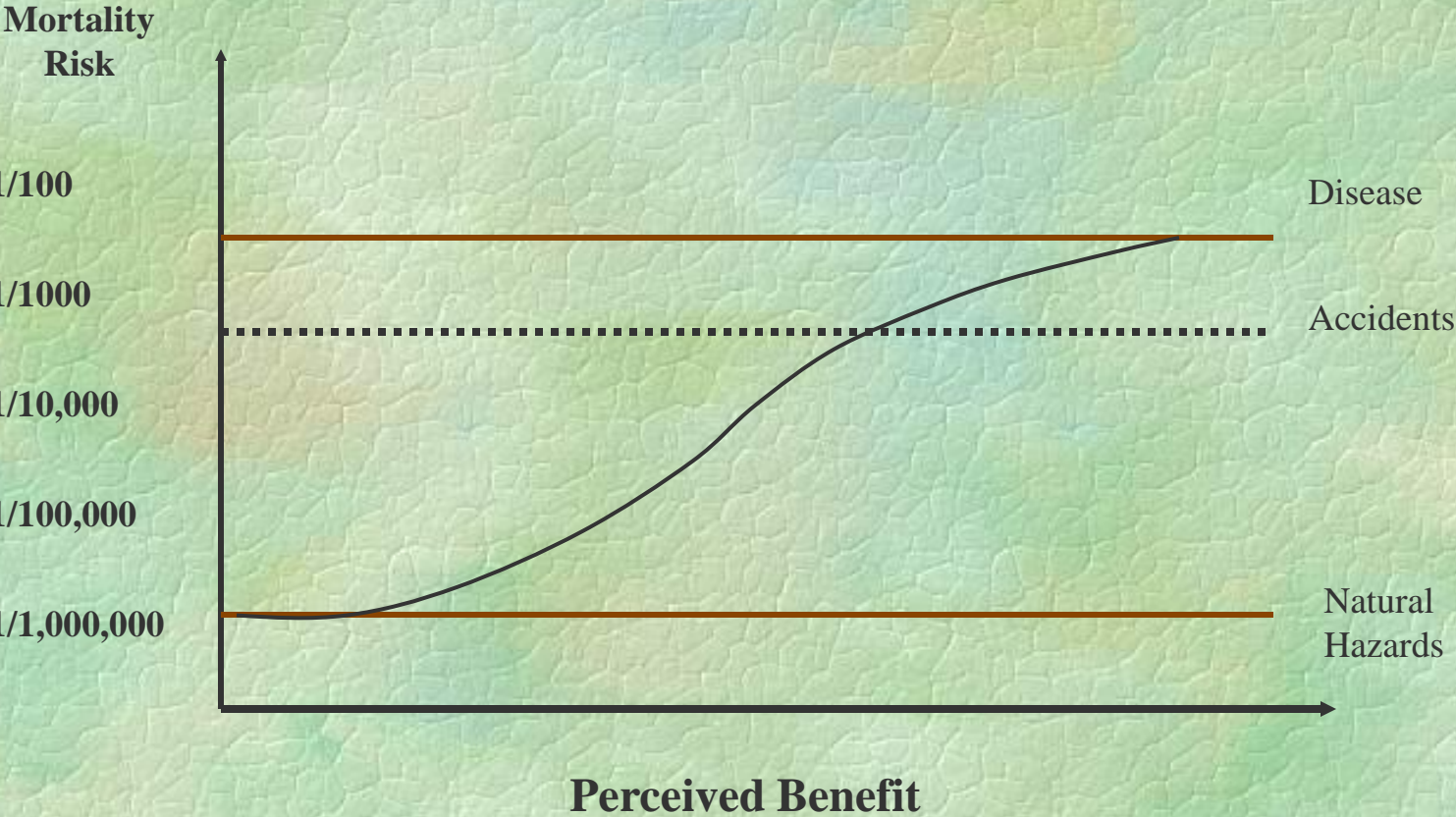
■ Patient/Consumer

- Acute 1/10,000
- Chronic (/yr) 3.65/100
- Pediatrics, geriatrics..... ??
- Donor ??

■ Manufacturer

- # of Devices: 2500
- # of Procedures/Device/yr: 100
- $P(F_D) = 1/10,000 * 2500 * 100 = 25$

Risk Tolerance



Summary

- Systems, not Components
- Systematic failures hard to predict
- Manufacturers burden to determine acceptable risk levels, probability and severity
- Life Cycle
- Use environment