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**

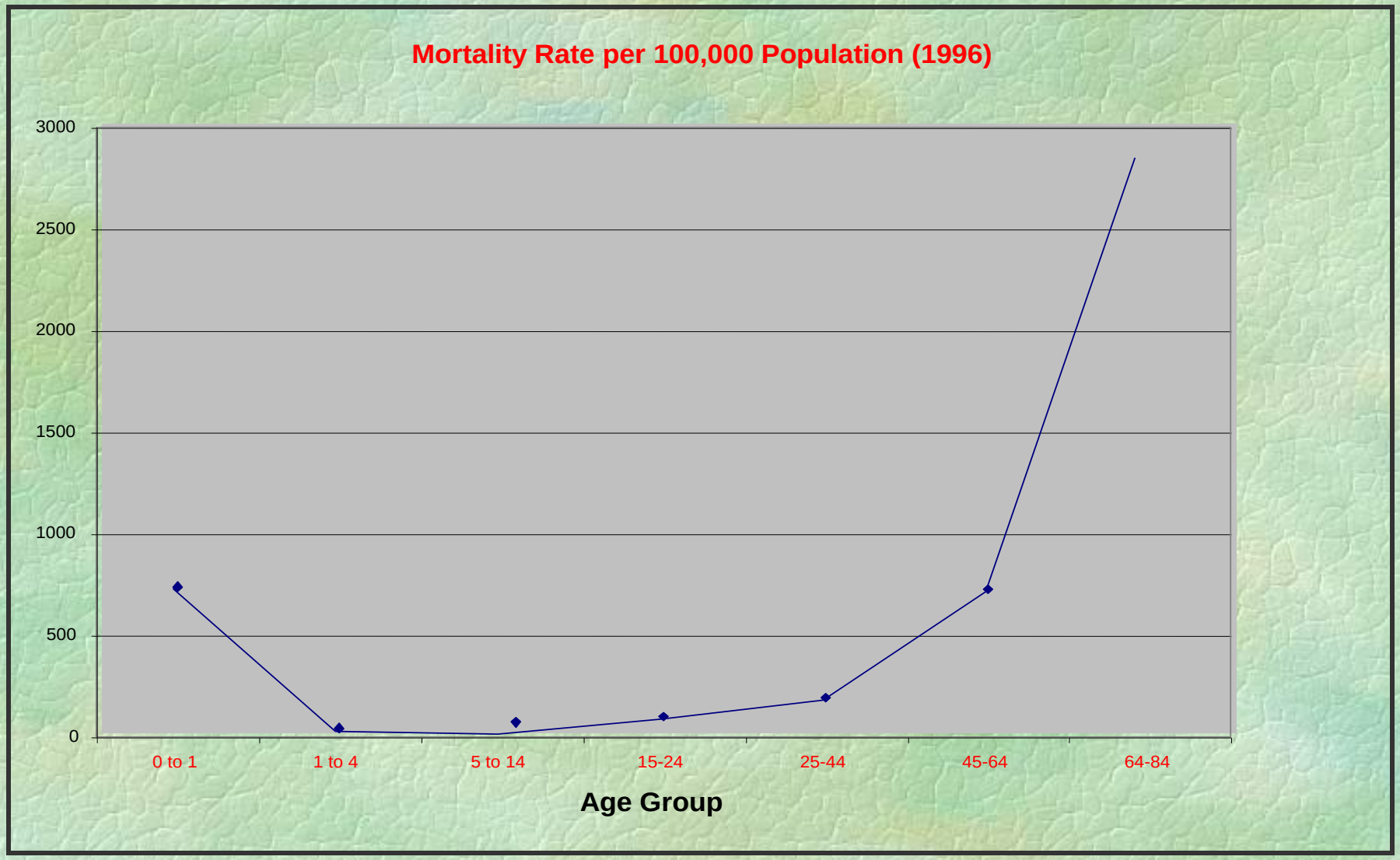
Types of Risk

- **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

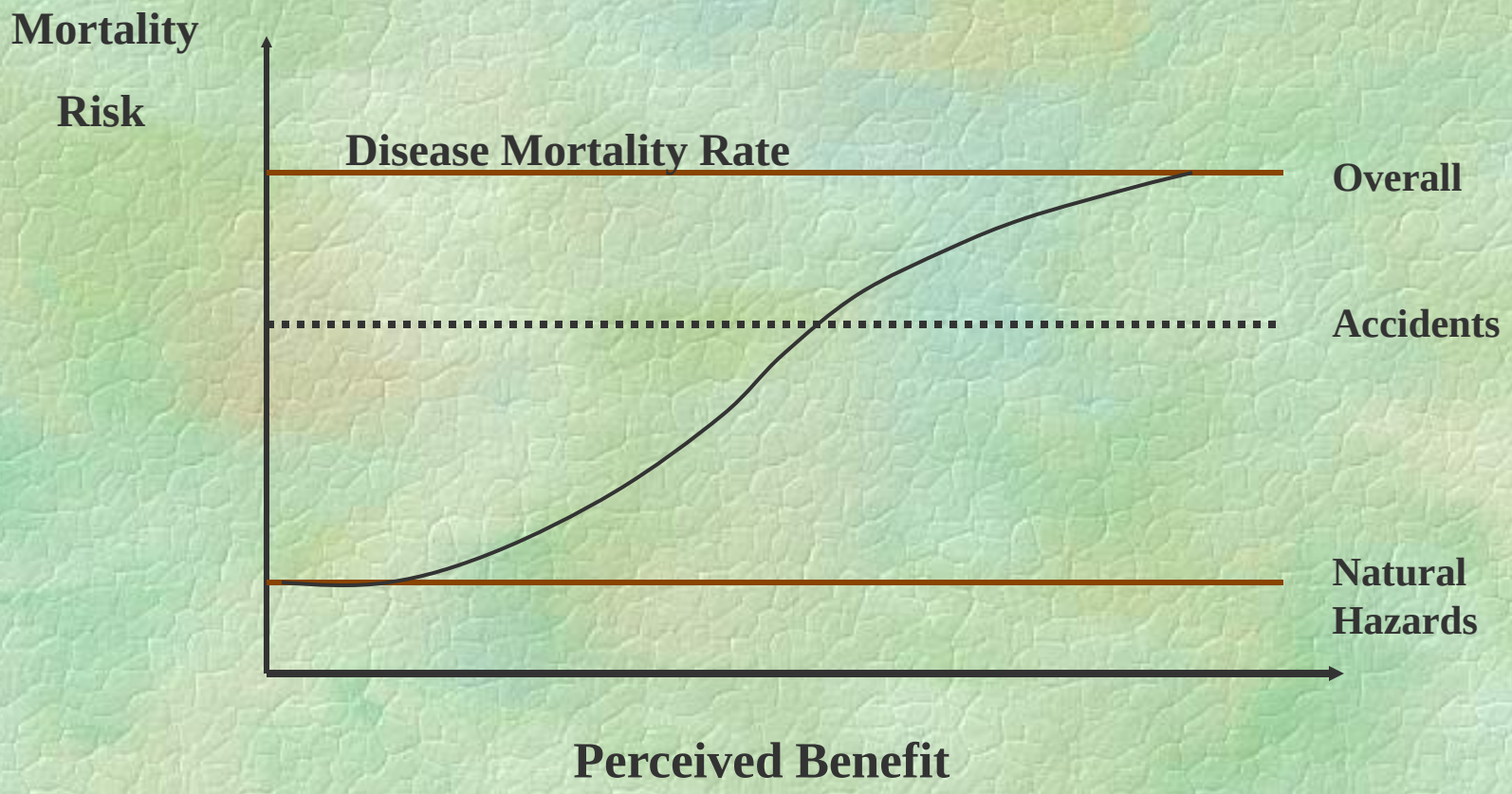
US Mortality Rate (per year)



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**
- **1/10 th 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: 0.1 per 100,000
  (fatal and serious)
- Commercial Diving: 200 per 100,000

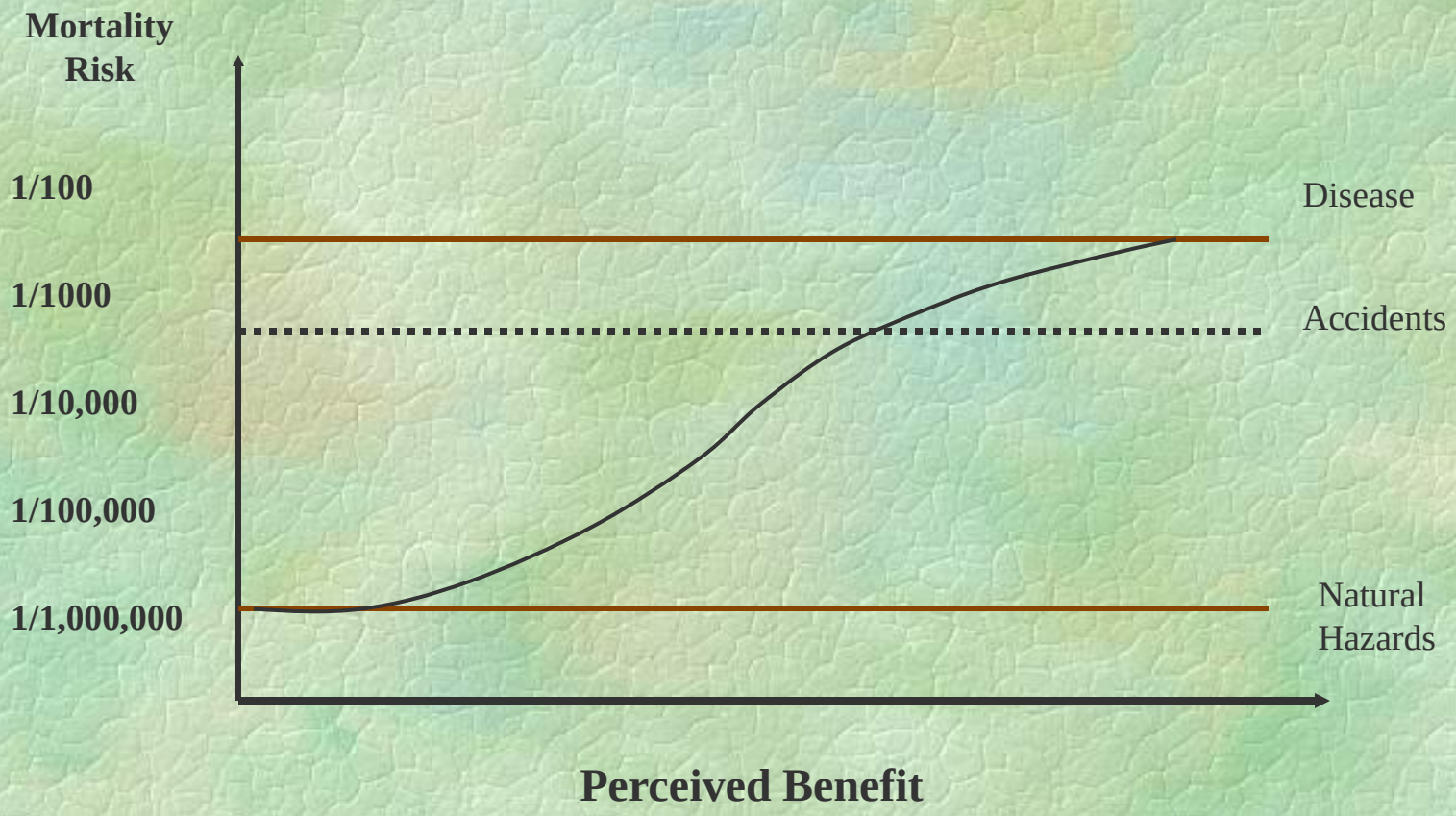
Consumer/Producer Risk

- **Patients/Consumer**
  - Acute
  - Chronic
  - Pediatrics, geriatrics…..
  - Donor
- **Manufacturer**
  - # of Devices
  - # of Procedures

Devices
F_D = 1/10,000 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