So... What Can I Do With Toxicology?

RISK ASSESSMENT

NURS 735

Anne Sergeant

National Center for Environmental Assessment

U.S. Environmental Protection Agency

In this module, we'll explore how to apply toxicology--along with other topics like chemistry, epidemiology, and ecology--in the real world. One thing toxicology can do is help us decide whether a chemical or a physical or biological agent might cause a problem. And once we know how large and dangerous the problem is, we can use that information to choose the best solution for it.

So **the purpose of risk assessment is to inform risk-management decisions**. Of course, it's always possible to mislead ourselves, even with such a fine tool as risk assessment. As the physicist Richard Feynman said, "The first principle of science is that you must not fool yourself--and you are the easiest person to fool." This module aims to explore the finer points of risk assessment--not only to prevent you fooling yourself, but to prevent others fooling you.

So let's have a look ...

Risk Assessment:

- A process that evaluates the likelihood that adverse effects (such as disease or injury) may occur as a result of exposure to a chemical, physical, or biological agent

Here's the official U.S. Environmental Protection Agency's (EPA's) definition of risk assessment. Let's break this down:

1. It's a **process--**in all but the simplest assessments, several people work together to evaluate risk ... because it takes a lot of specialized training.

2. We're talking about **likelihood**, or the chance that something might happen. In other words, we're making a prediction.

3. We're examining the possibility of **adverse** effects (such as disease or injury). You could also use this process to evaluate the chances of something good happening (but we don't at EPA, because we don't regulate those things).

4. **Exposure** is key. The most toxic or virulent thing in the world won't hurt anyone if they don't come into contact with it ... in other words, no exposure, no risk.

5. We can use this process to evaluate the effects of anything that might cause a problem--it could be a **chemical**, something **physical** such as dust or fibers, or a **biological** agent such as a disease-causing organism.

The term **risk** is used in different ways in different professions: For example, insurance people consider things such as swimming pools risks, and certain engineers think of the risk of structural failure. Here, we interpret risk as something that has not yet occurred.

Ecological Risk Assessment:

- A process that evaluates the likelihood that adverse effects may occur as a result of exposure to a stressor

The definition of ecological risk assessment (ERA) is similar:

1. It's a **process** that needs many kinds of expertise.
2. It's still a **prediction**.
3. We're still examining **adverse** effects.
4. **Exposure** is still critical--without it there can be no risk.
5. We use the term **stressor** to mean any chemical, physical, or biological agent that could cause an effect.
6. And of course, we're talking about **ecosystems**, not just people.

A Brief History

- Human-health risk assessment
  - EPA started in 1970
  - HHRA guidance in 1980s
- Ecological risk assessment
  - About 10 years behind HHRA
  - Similar at first, then ...
  - Models, holistic approach

Human-health risk assessment started in the 1970s. Initially we used it to separate the chemicals that cause cancer (carcinogens) from those that don't, and focused our regulations on getting things that caused cancer out of food, air, and water. Guidance (to make things more consistent) was developed in the 1980s and at first consisted of which techniques to use with varying amounts of data. Later it became more specific and went beyond carcinogenicity address other areas such as developmental, reproductive, and neurotoxic effects, the effects of chemical mixtures, and finally organisms other than humans (ecological risk assessment).

Ecological risk assessment started as a process similar to human-health risk assessment (using plausible exposure scenarios to generate risk predictions), but soon evolved into a more holistic approach.

Two Kinds of Risk Assessment

- Human-health risk assessment:
  - One organism
  - We know a lot about it
  - Easy to agree on what's bad
  - People value their health (or at least that of their children!)

The **human-health risk assessment** process is fairly straightforward: It's based on one very well-understood organism (and we have many ways to extrapolate from laboratory animals to humans), and there is good agreement not only on what effect is a bad effect, but that human health is important.

Since we tend to think of ourselves as important, it's easy to see why people would generally agree that humans are important.

Two Kinds of Risk Assessment

- Ecological risk assessment:
  - Many organisms
  - We know less about them
  - Not always clear exactly what's bad
  - Many people value humans more than other organisms

It's not so simple with **ecological risk assessment**: For one thing, there are a lot of organisms out there, and we've only studied a few of them. (And while we can be confident about extrapolating lab rat data to wild rodents, what about, say, reptiles? We have very little data about this.) And different organisms mean different things to different people--they might be considered valuable or beautiful, or they might be regarded as a nuisance (for example, there might not be much outcry if, say, a new bird disease wiped out all the starlings). So opinions about what is a bad effect are likely to vary. Finally, some people think that humans and their interests are more important than other organisms.

Less information, the variety of opinions about the value of other organisms, and the challenges of defining and understanding terms like "ecosystem resilience" and "sustainability" can make it hard to agree on what's important when it comes to ecosystems.

Risk Assessment

- A well-executed risk assessment is
  - planned
  - focused
  - flexible
  - informative

If you're doing it right, risk assessment (RA) is a holistic process with the attributes shown above. If we consider these attributes when planning, we can use them or the RA process itself to:

Organize project planning and data collection

Compare and select management or control options

Develop measures of success

Validate the "best professional judgement" approach

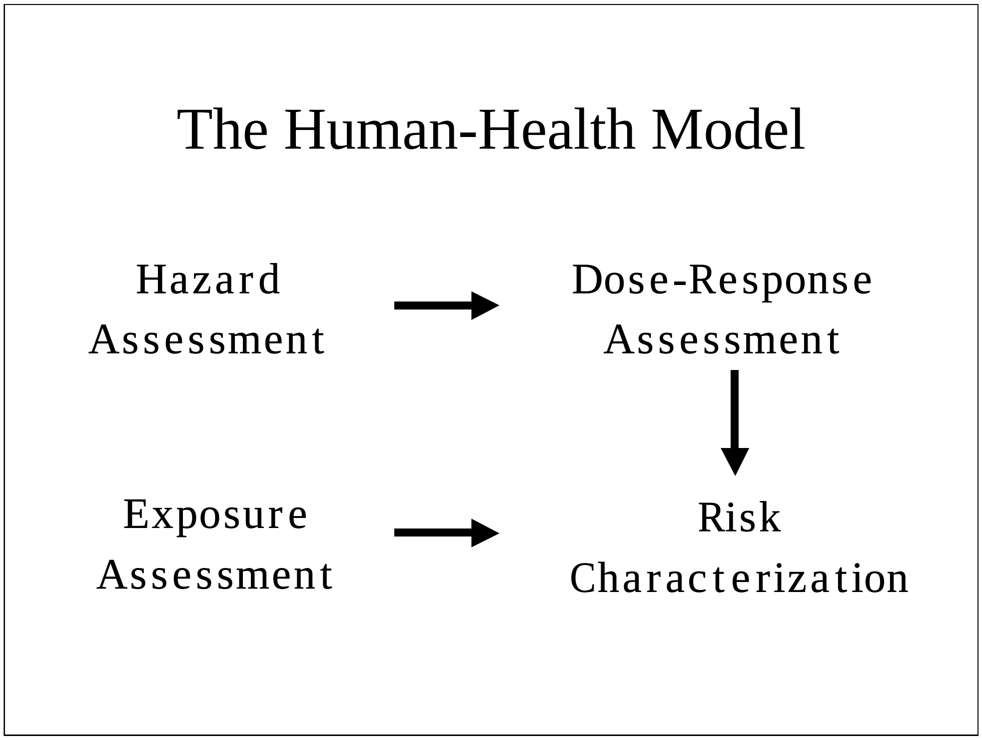
Do it right the first time

Risk Assessment

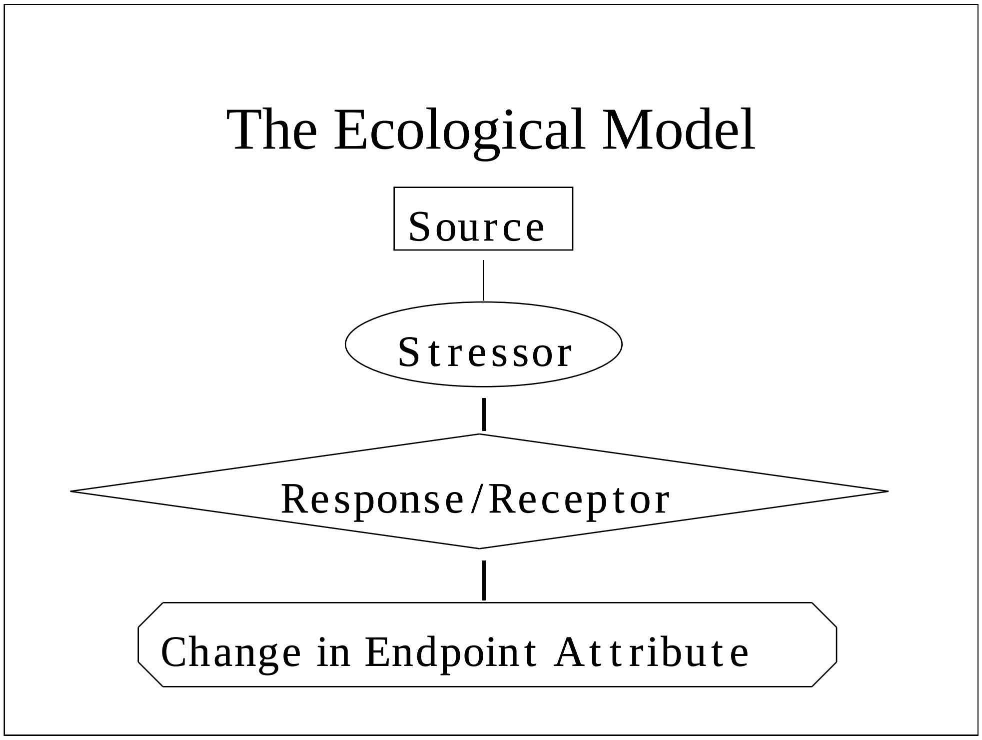
- Risk assessment is NOT
  - cost-benefit analysis
  - justification for already-planned activities
  - unfocused data collection

Risk assessment is a useful tool, but it's not always necessary. For example, it does not consider costs and benefits--that's a separate analysis in which risk-assessment data may be used. Nor should it be used to rubber-stamp decisions that have already been made. The purpose of risk assessment is to inform risk-management decisions, but if those decisions have already been made, simply explain what went into them and save yourself the trouble of all that data collection and analysis. Finally, just because you can collect data doesn't mean you should--that's why we include specific planning and problem-formulation processes.

We'll examine planning and problem formulation later, but first, let's take a look at two **risk-assessment models**.



In **human-health risk assessment**, we first determine whether a substance could harm organisms (**hazard assessment**). The next step is learning how much of that substance causes a given response (**dose-response assessment**). Anything can be toxic, but it depends on the dose, hence the old saying "The dose makes the poison." **Exposure assessment** determines how much of it people could have been exposed. All this information is combined in the final step of **risk characterization**, which describes what the substance can do, how much causes what effect, how people might have contacted it, and what effects might occur under those conditions. It may also place those effects in the context of other factors such as exposure to other chemicals or the body's compensatory mechanisms.



Ecological risk assessment looks different but contains the same elements:

The **source** is where the stressor originates--for example a factory, an organism, or a landscape. You will recall that a **stressor** is any chemical, physical, or biological agent that could cause an adverse effect. The **receptor** is the organism or ecosystem component that contacts or co-occurs with (is exposed to) the stressor and the **response** is its reaction to it, and the **change in endpoint attribute** is the adverse effect of interest. These items may be identified in any order.

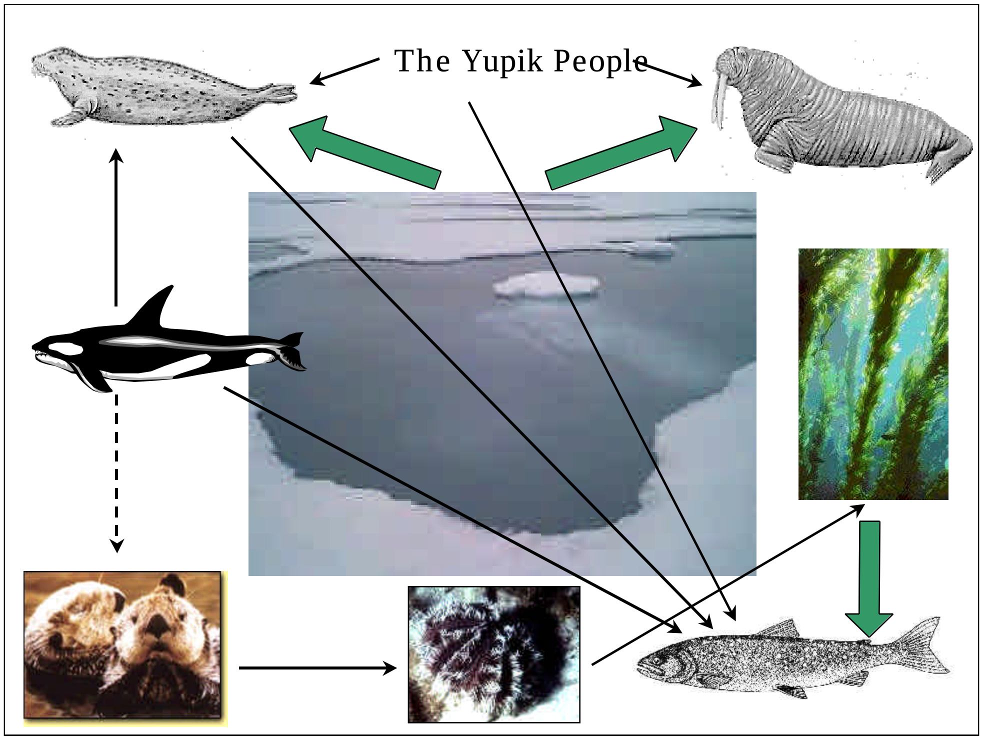
Things to Notice:

In human-health risk assessment model, the source is not necessarily specifically called out.

The "response" attribute in ecological risk assessment embodies the concept of hazard assessment.

We'll cover exposure in more detail later, but for now, observe that the connection between source, stressor, and receptor is equivalent to an exposure pathway as used in the human-health model.

Note to engineers: The shapes shown above have no relation to standard engineering flow diagrams--for example, the "response/receptor" diamond does not represent a decision.



“Everything is Tied to Everything Else” - A Lesson From Alaska*

Caleb Pungowiyi is a Yupik Eskimo who lives in the Arctic, moving back and forth from Alaska to Siberia in pursuit of walrus and other sea mammals. Gathering food directly from the land and the sea makes the Yupiks very careful observers of what is going on around them. In recent years they have noticed, for example, that the walrus are looking thinner and their blubber is less nutritious, and that they have had to go further and further from shore to reach the icepack where young seals are being fed fish by their parents. The Yupiks have even noticed that some killer whales have begun eating sea otters, an unusual shift in their diet apparently brought on by the reduced number of fish and seals. But are all of these changes connected, and, if so, what do they portend for the future?

Satellite observations confirm that the sea ice retreat noticed by the Yupiks is happening much more widely, as temperatures warm over most of the Arctic region.

Because the edge of the sea ice is further out to sea in deeper water, walrus--which rest on the ice and feed on the bottom--must dive deeper to feed and find less food, causing their weakened condition. Because sea ice is melting back earlier in the year, the seal pups being raised on the edge are smaller when they must leave the ice, worsening their chance of survival. With fewer seal pups, sea otters become an alternative food source for whales. Because a favorite food of sea otters is sea urchins, fewer sea otters will mean more sea urchins. Sea urchins' favorite food is the kelp that provide the breeding grounds for the fish, so more sea urchins will mean less kelp and thus fewer fish. And with walrus and seal populations declining, it is these very fish that the Yupik need more than ever to feed themselves.

It may seem like only a little warming in a very cold place, but for the Yupiks, the warming is significantly disrupting their traditional food sources because as Caleb Pungowiyi says, in their environment, like all environments, “everything is tied to everything else.”

Conceptual model courtesy of Susan Herrod-Julius, U.S. EPA Global Change Program.

*National Assessment Synthesis Team, US Global Change Research Program, 2000. Climate Change Impacts on the United States: The potential consequences of climate variability and change. Cambridge University Press, Cambridge.

This is a great example of the “Eco 101--it's all connected” observation mentioned earlier. It also shows how we can integrate human-health concerns into an ecological conceptual model.

First: Planning

- What are we trying to do here? E.g.,
  - What caused this effect we see?
  - What will happen if we do nothing?
  - What can we do to prevent effects in the future?
  - What risks does this population face?
  - Can we reduce those risks?

Planning is important in any risk assessment. Different people will want to use its results for different purposes, so it's critical to coordinate with them from the beginning. Possible audiences include the decision maker, those who will be affected by the decision (neighbors, regulated parties), those who must take some action (regulated parties, other agencies), other analysts (economists, engineers, lawyers), and colleagues.

For human-health analyses, much of the process is implicit: People take it as a given that cancer, birth defects, and things like liver toxicity are undesirable and to be avoided. But it's still worth examining the possible range of effects, and whether they interact with or are counteracted by other environmental factors such as air pollution.

Ecological risk assessment must consider many topics, including what is to be protected (remember that not everyone considers all organisms valuable enough to warrant spending money to protect them), to what extent it should be protected (is it okay if half of them die?), whether predicted effects will really be a problem, and whether effects on one organism might cause problems for another (cascading effects) and if those secondary effects matter.

In either case, you will want to consider **what decision needs to be made and how the risk assessment can inform it**. Example risk-management decisions include whether to: grant a permit to build an incinerator, clean a site up or leave it alone, allow an exotic organism into the country, or allow development on highly erodible soils.

Now let's look more closely at human-health risk assessment. Parallels to ecological risk assessment are shown as needed.

Hazard Assessment

- Is this stuff bad?
- Types of stressors
- Types of effects

Hazard assessment identifies what adverse effects the substance in question might cause. For example, a biological **stressor** like a virus could cause illness, a chemical stressor could cause deformities, organ damage, or cancer, or a physical stressor such as excess sediment could make it impossible for a fish to find its food. **Effects** (also known as **responses**) can include injury, deformity, illness, and reproductive or neurological changes.

In ecological risk assessment, this concept is generally covered under the "response" portion of the conceptual model.

Dose-Response Assessment

- How much of it does it take to cause a problem (adverse effect)?
- Does it cause other problems (adverse effects) at other doses?

Dose-response assessment examines how much of a stressor causes how much effect. And it's not always a case of more stressor causing more of a given effect: For example, some compounds induce weight loss at low concentrations, embryo malformations at higher concentrations, and death at the highest exposures. And some exhibit a threshold concentration below which no effect is seen.

A stressor may not cause adverse effects at all doses: Selenium is an essential nutrient at very low concentrations, but at high concentrations it causes cancer and deformities in developing animals. And Vitamin A is an essential nutrient a low concentrations, but induces embryo malformations at higher concentrations.

Potential Dose

- The amount of a substance contained in the material ingested, air inhaled, or the material applied to the skin

Potential dose is how much of the substance gets **to** the organism, while ...

Absorbed Dose

- The amount of a substance penetrating an absorption barrier (exchange boundary) of an organism, by either physical or biological processes
- Also known as Internal Dose

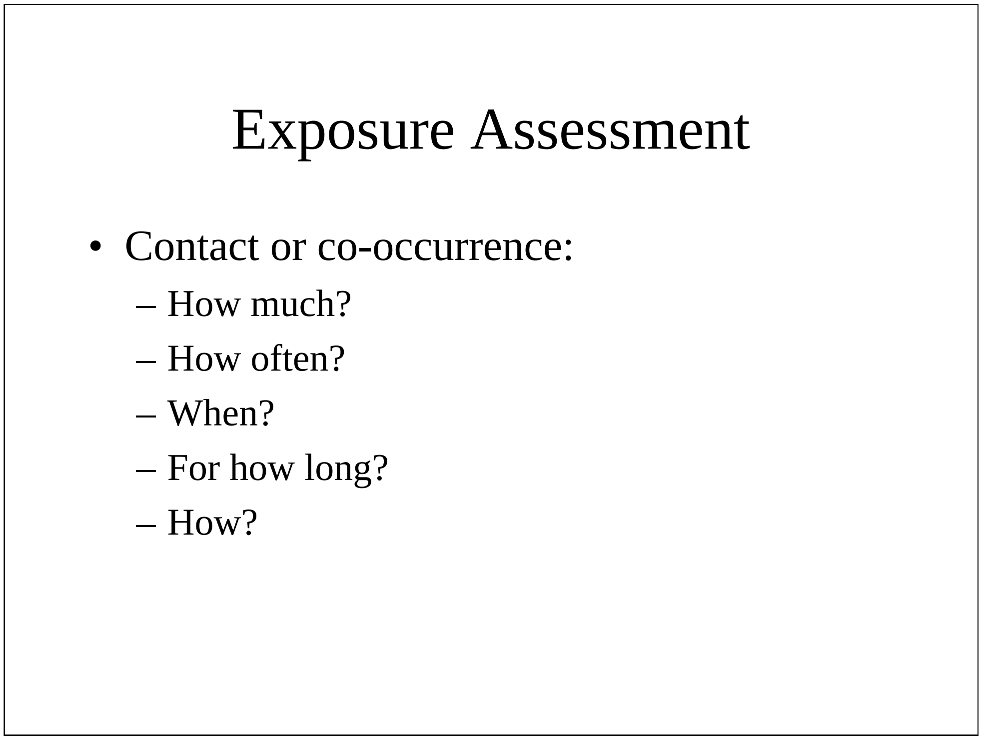
... **absorbed dose** is the amount of a chemical absorbed and available for interaction with biologically significant receptors; it's also called **internal dose**.

Once absorbed, a chemical can be metabolized, stored, excreted, or transported within the body. The amount transported to particular organ, tissue, or fluid is called **delivered dose**.

Doses are presented as **dose rates** and expressed:

per unit of time (e.g., mg/day) or

per unit of body weight (e.g., mg/kg day)



Exposure assessment asks these questions: Acute exposure might, for example, exacerbate asthma or cause effects such as lung irritation, while long-term low-dose (chronic) exposure could cause cancer.

How much? - Usually, a large amount has more of an effect than a small amount.

How often? - The body may have a chance to recover from intermittent or occasional exposures. For example a loud rock concert or explosion may leave your ears ringing, but they're generally OK the next day. But perform in too many concerts or fire too many Howitzers, and you'll probably be quite hard of hearing by the time you reach old age.

When? - Some compounds only cause effects during a certain time, for example, as far as deformities are concerned, alcohol affects the developing fetus during the first few weeks of pregnancy (before most women even know they're pregnant). It also affects adults, but in different ways.

For how long? - Some stressors cause temporary effects with short exposures, but their effects become permanent with long exposure. For example, people can become sensitized to lung irritants over time.

How? - Something that's toxic by one route may not cause a problem (or may cause an entirely different effect) by another. Asbestos fibers cause cancer if inhaled, but not if ingested.

In ecological risk assessment, we also consider whether the presence of a stressor could affect an organism (we call this co-occurrence). For example, ground-nesting birds need a clear view of their surroundings (you may be familiar with the killdeer, which will feign a broken wing to lure predators away from its nest), and will not nest in an area if clear ground is not available. So if vegetation has colonized a nest area they will choose another place, or if obstructions have been added near the nest they will abandon it. Even though the vegetation or obstruction is not toxic, it can adversely affect the bird by reducing its nesting success.

Elements of Exposure

- Source
- Pathway
- Receptor

A complete **exposure pathway** includes a stressor **source**, the **pathway** it takes to the receptor, and the **receptor** (exposed organism) itself. If an exposure pathway is incomplete (say, the ground water is contaminated but no one drinks from the well), exposure cannot occur and there can be no risk.

This is similar to the conceptual model used in ecological risk assessment, which, as you will remember from slide 10, shows the path a stressor takes from source to receptor to change in endpoint attribute.

Source

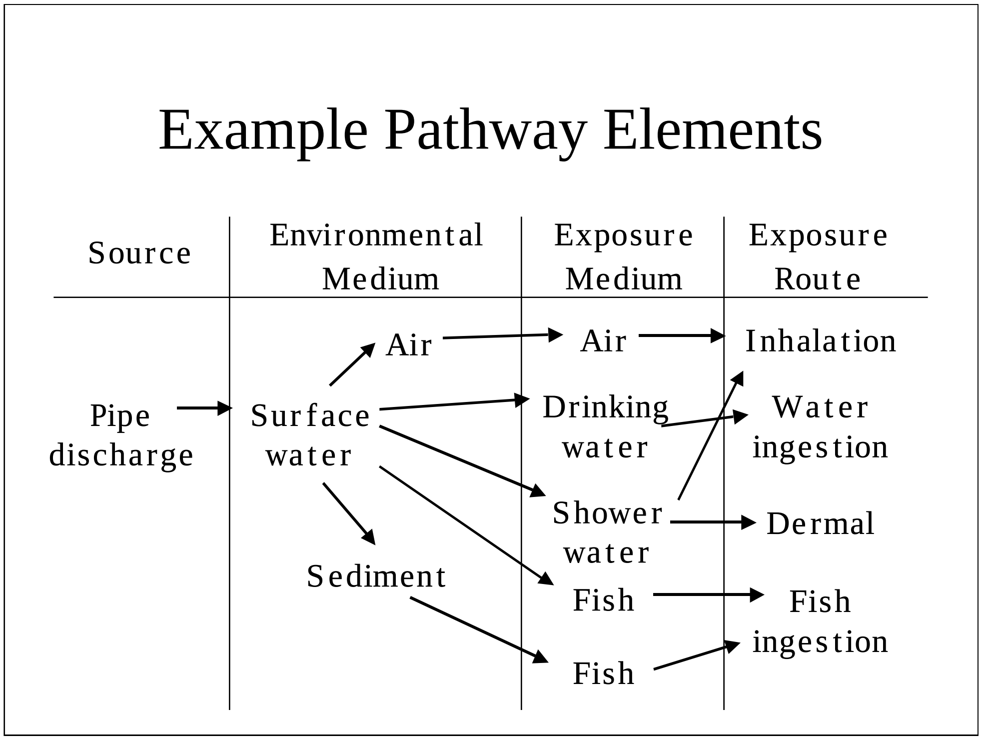
- Existing
- Residual
- Intermittent
- Secondary

An **existing source** is one that is currently emitting or releasing chemicals.

A **residual source** is one that remains after the original source is gone or has been removed, but something remains, perhaps in another form or medium(say, a factory has been torn down, but the contaminated soil at what used to be the loading dock continues to erode into a stream).

An **intermittent source** is an occasional, episodic, or accidental release, such as spills that occur when transferring cargo.

A **secondary source** is one in which the original stressor causes a change in a receptor, which in turn causes a change in something else. For example, a tree parasite may change the character of a forest community and leave the habitat unsuitable for a certain birds.



Here's a simple (yes, really) illustration of how a contaminant in a single discharge might find their way into several exposure pathways.

You'll notice that this (hypothetical) contaminant, once discharged into the surface water body, could stay in the **water**, adsorb to **sediments**, or volatilize into the **air**.

The portion that stays dissolved might be piped into someone's home and be **drunk** after it's mixed with orange-juice concentrate, **absorbed through the skin** when bathing, or **inhaled** after it volatilizes from that nice hot shower water. It could also be **directly taken up by fish** that live in the water body.

The portion that goes into sediments might get into **fish as they clean stirred-up sediments from their gills**. Or it may be **taken up by invertebrates** that are in turn eaten by the fish. And those **fish may be eaten by anglers** who use that water body.

Those same anglers, or people who live nearby, or people who use the water body for boating, sightseeing, or birdwatching, may also **inhale** the portion that volatilizes.

This diagram illustrates how humans can be exposed; we could prepare a similar (but more complicated) diagram for ecological exposures.

So there are many possible ways humans and other organisms can be exposed to contaminants. How do we figure it all out? Well, this is usually the time to consult our friendly local environmental chemist, but here are a few chemical rules of thumb to get us started:

Chemical Parameters

- K_{ow} - octanol-water partition coefficient
- K_{oc} - organic carbon partition coefficient
- K_d - soil-water distribution coefficient
- BCF - bioconcentration factor
- H - Henry's Law constant

Here are some chemical properties we use to estimate where compounds will go in the environment:

K_{ow} - octanol-water partition coefficient - tells us how much will dissolve in organic solvent (octanol) vs. water. It's expressed as

equilibrium C of compound in octanol

equilibrium C of compound in water Typical range: 10^{-3} to 10^{+7} L/kg or cm^3/g

K_{oc} - organic carbon partition coefficient - concentration in organic carbon vs. concentration in water - also tells us where compound will go. It's independent of soil properties, lab-derived, and can be estimated based on K. This one is expressed as

mg absorbed/g of organic carbon

mg/ml of solution Typical range: (1E+8) to (10E+8)

K_d - soil-water distribution coefficient - is a soil or sediment-specific measure of chemical partitioning between soil or sediment, unadjusted for dependence upon organic carbon. To adjust for fraction of organic carbon (foc), use Kd = Koc x foc

BCF - bioconcentration factor - Measure of the tendency for a chemical in water to accumulate in fish tissue via the water column. Typical BCF range for organics in water = 1 -> 10^5 BAF includes all media

H - Henry's Law constant - The relative measure of volatility of a pure chemical in water

H = Vapor pressure (atm) x MW (g/mole)

Water solubility (g/m) Typical range: 10^{-5} to 300 mm Hg

Rules of Thumb - Chemicals

low	(parameter)	high
	K_{ow}	soil
water	K_{oc}	sediment
	K_d	biota (fat)
	BCF	
water	H	air

And here's how we use them (warning - some sweeping generalizations here):

Organic compounds with higher K_{ow}s, K_{oc}s, K_ds, and BCFs tend to gravitate toward organic matter and lipids, so look for them in soil, sediment, and critters (and to a lesser extent in plants). Those with lower K_{ow}s, K_{oc}s, K_ds, and BCFs are generally found in water.

Organic compounds with low H tend to be found in water, and those with high H in air.

Receptor

- Who is in the way?
- Who has unique characteristics that influence exposure?
- Who is especially vulnerable?

Who is in the way? - Who is just there - someone who drinks the water, who lives downwind and breathes the air, who fishes in this river, etc.

Who has unique characteristics that influence exposure? - Small children who are creeping or toddling and exhibit mouthing behavior are especially likely to be exposed to lead paint and contaminants in dust, smokers' lungs may be less able to clear inhaled contaminants (due to malfunctioning cilia), and workers may be exposed to several chemicals at once.

Who is especially vulnerable? - The elderly, asthmatics, and immune-compromised people may be especially susceptible to toxic effects. Young or yet-to-be-born (or hatched) organisms are susceptible to developmental toxins. Medicines can affect either exposure to chemicals or the body's response to them.

Please take a moment to think about how each of these factors influence our opportunity to reduce risks.

Ways to Describe Exposure

- Point-of-Contact Analysis
- Scenario Evaluation
- Dose Reconstruction
- Integrative Assessment

Point-of-Contact Analysis measures the chemical concentration at the interface between a person and the environment. An example: Researchers have applied adhesive tape to small children's hands to measure how much dust and dirt sticks to their fingers to get an idea of how much of dust- or soil-borne contaminant they might ingest. You could also use this method to estimate how much of the chemical is available for direct absorption through the skin.

Scenario Evaluation uses a set of facts, assumptions, and inferences about how exposure occurs to estimate exposure and calculate risk. For example, we could create a hypothetical day for a person based on what they eat, drink, touch, and inhale to determine their total exposure to a particular chemical.

Dose Reconstruction measures chemical or other indications of change and relates these measurements back to internal dose or exposure. For example we might start with a metal concentration in hair and extrapolate to blood or other tissue levels.

Integrative Assessment is useful when we need to determine total exposure to all chemicals by way of a particular route. Units are concentration x time.

Risk Characterization

- What's happening here?
- Under *x* conditions, what might happen?
- Might there be secondary effects?
- Does any of this matter?
- Can anything be done to reduce the risk?

This is where the rubber meets the road ... somebody's going to have to make a decision based on this and other information. The risk characterization might not necessarily answer all these questions, but they're a sample of what's commonly covered.

Note that sometimes risk assessors forget that their information does not trump everything else (it's easy to get wrapped up in your own field, simply because you know more about it than others).

If you're reviewing someone else's assessment and can't figure out what they're talking about, ask ... it's the risk assessor's job to explain risks in useful terms. And remember: If you want the decision maker to use the fruits of your labor, make it easy for her/him by linking your conclusions to the decision that needs to be made.

Risk characterization may use central-tendency or high-end estimates (or both) depending on what is needed. Central-tendency estimates are useful if you want to know how a contaminant generally affects a population. If you are concerned about specific sensitive subgroups, the high-end estimate is better provided that the estimate is still plausible (for example, you would not use an adult food-consumption or inhalation rate for a child, but you probably would choose an adult inhalation rate on the high end of the normal range to estimate exposure to workers in a physically active job setting).

Simplified Dose Calculation:

Calculation of Absorbed Dose From Potential Dose:

$$\text{Potential Dose} = \frac{C \times IR \times ED}{AT \times BW}$$

Absorbed Dose = Potential Dose x AF

Where:

C = Contaminant Concentration IR = Intake Rate

ED = Exposure Duration AT = Averaging Time

BW = Body Weight

AF = Fraction of Potential Dose Absorbed

Concentration (C), intake rate (IR), surface area (SA) and body weight (BW) vary with time. Absorbed fraction is AF.

Some notes about averaging time (AT) in particular:

Must be in same units as exposure duration (ED)

Acute Effects: AT = 1 day

Cancer: AT = 70 years

Noncancer chronic effects: AT = ED

Constants averaged over the ED simplify analysis and can provide adequate estimates of exposure and dose. But information may be lost, or exposure conditions may be oversimplified. If you need something more detailed or with percentile distributions, try probabilisitc risk analysis (PRA). EPA's Superfund program has PRA guidance at http://www.epa.gov/superfund/programs/risk/rags3a/index.htm

Example Problem

Calculate the lifetime average daily potential dose of PCBs that a person would get from a daily average intake of 30 g of fish containing 2.5 mg/kg of PCBs for 30 years.

Express potential dose in units of mg/kg-day (concern is cancer risk).

Solution

Potential Dose =

$$\frac{2.5 \text{ mg/kg} \times 30 \text{ g/day} \times 365 \text{ days/yr} \times 30 \text{ yrs} \times 10^{-3} \text{ kg/g}}{70 \text{ kg} \times 70 \text{ yrs} \times 365 \text{ days/yr}}$$

$$= 5 \times 10^{-4} \text{ mg/kg-day}$$

Here's the answer.

Where do you think those PCBs in the fish came from?

How Do We Know What's OK?

- Reference Dose - RfD
- Reference Concentration - RfC
- Cancer Risk Range

A **reference dose** (RfD) is an estimate of daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. The ratio of the site-specific dose estimate to the RfD is called the hazard index (HI).

A **reference concentration** (RfC) is the estimated concentration in a particular medium that is likely to be without an appreciable risk of deleterious effects for the human population (including sensitive subpopulations) during a lifetime; for RfC, the HI is the air concentration divided by the RfC

Cancer risk range: Since it's usually impossible (or prohibitively expensive) to completely eliminate risk, EPA usually tries to reduce cancer risks to the 10^{-4} - 10^{-6} range.

A **slope factor** is an upper-bound estimate of the slope (for low doses) of the carcinogenic dose-response curve ... also known as **potency factor**

Adding Risks

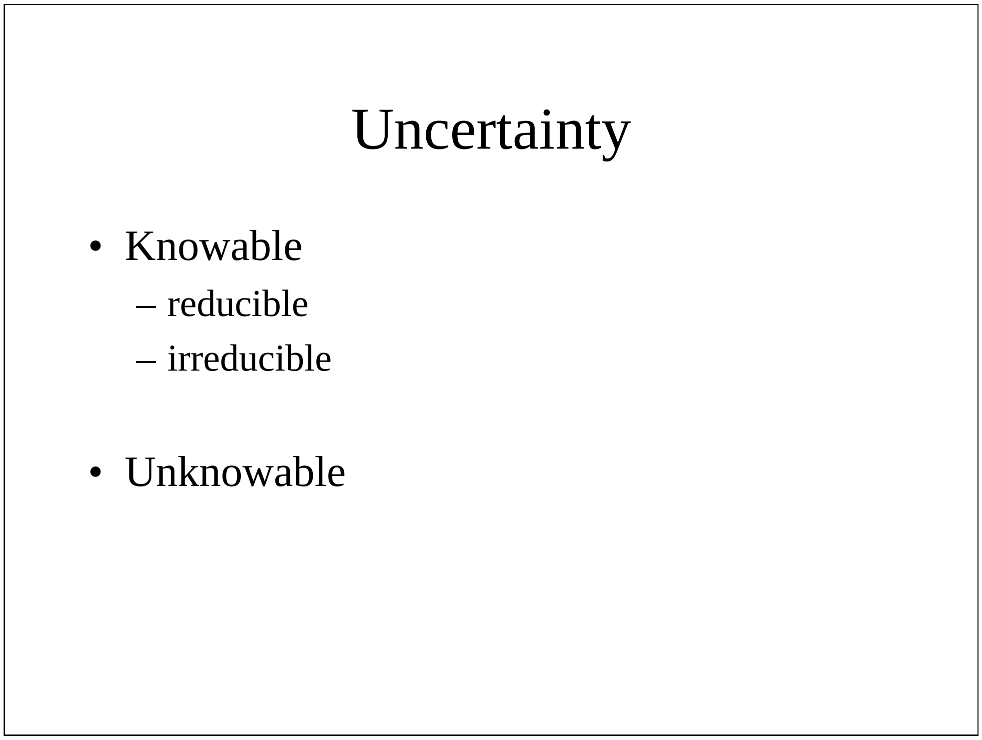
- By endpoint (toxic effect)
- By exposure route (e.g., drinking water)
- By whole person or population

By **endpoint** - This is OK if you're working with the same target organ or effect ... also OK if you're examining cancer, since we don't usually distinguish between different types.

By **exposure route** - You may want to do this for a medium-specific integrated assessment, e.g., what pesticides are in all the different foods eaten, what toxics are in the air breathed at work, while commuting, and at home. Just make sure one person could actually experience all the exposures you add up!

By **whole person or population** - For a cumulative risk assessment, e.g., what risks does a particular population face as a whole, to what risks from all media is a person exposed in the course of their day ... again, make sure your assumptions are reasonable.

We can also evaluate **populations** by location, demographics, activities, or medical condition.



There are two basic types of **uncertainty**, that which we can learn more about (the "knowable" type) and that which we can't (unknowable).

Knowable uncertainty come in two forms itself: That which we can reduce by collecting more data or using better analytical techniques (i.e., the **reducible** kind), and that which we can learn more about, but not reduce (the **irreducible** kind ... also known as variability). An example: We use an average human body weight of 70 kg in most risk assessments. That number is well known (millions if not billions of people have been paraded onto scales and their weight recorded at various times in their lives). But we might not be sure (i.e., we might be uncertain) if that's a good number to use for a specific group of people. One way to find out would be to weigh every person in that population--then we'd know for sure if 70 kg was the correct average body weight ... so we'd reduce our uncertainty about whether 70 kg was the correct average body weight (and we'd even be able to come up with our own population-specific average). But what we would NOT be able to do is change the fact that some people weigh 50 kg and others weigh 150 kg--the variability of body weight within that population. So we can get a handle on variability, but not reduce it.

Unknowable uncertainty is ignorance--we don't know, and we don't even know that we don't know. Think of a risk assessment in which we don't even have a scale and we've never seen the people ... and they all happen to weigh 300 kg. Since this a very extreme human body weight, it might not even occur to analysts that it was possible for everyone to weigh this much, and without a scale no one would even have a way to check.

Risk Characterization

- Clear
- Transparent
- Reasonable
- Consistent

A good risk characterization will tell the reader what the risks are and how important they are. And the ideal risk characterization will be:

Clear - It will be brief, avoid jargon, be written for an informed lay person, and explain unusual issues.

Transparent - It will separate science from policy, articulate differing scientific viewpoints, explain the risk assessment's purpose, and explain assumptions and biases.

Reasonable - It will integrate all components into conclusion, acknowledge uncertainties, describe data (generally accepted, state-of-the-art, experimental, etc.), identify reasonable alternatives and conclusions, describe the level of effort involved, and explain the assessment's peer-review status.

Consistent - It will describe how risks associated with one stressor compare with those associated with similar stressors or conditions, and compare strengths and limitations with other assessments.

Getting the Message Out

- Audiences:
  - decision maker
  - those affected
  - those who must take action
  - other analysts
  - colleagues

Ideally, you've already coordinated with all these people during the planning process, they've been able to articulate what they want, and you are at this point prepared to deliver each of them exactly what they need. Each group will have different information needs, perspective, timeframe, and attention/hand-holding requirements. This of course is the ideal--personnel, needs, and circumstances can change over time, and you may need to adapt. Written records can help address personnel changes, and can help show others who have become interested well into the process how things have evolved.

Decision makers will want to know whether the risks you identify will require them to take action; they'll have questions like “Are exposure levels higher than standards?” “Will predicted effects be visible?” “What organisms will be affected?” and “Which remedy is most effective?” (They'll also want to know about things like cost, practicality, and legal issues, but that information comes from elsewhere.)

The **people who are directly affected** will of course be concerned about their own personal health, and things like safety for their children and pets, property values, and inconvenience.

The **people who must take action** (regulated parties, people who want to voluntarily protect themselves or the environment) will want to know which actions are most likely to be effective, and how much they will cost (the latter is not part of a risk assessment).

Other analysts such as economists, engineers, and lawyers will probably want information about risks to specific organisms to plug into the reports they're preparing (and you already got together on this in the planning stage, right?).

Finally, **colleagues** may be interested in your results and how they fit into their work.

The main thing is to **know your audience**(s) and tailor your presentation to its needs. This may require more than one document, or even more than one format (for example, a lengthy tome for regulators who need all the details, handouts and posters for a public meeting, and a series of press releases for the local media).

Risk Communication

- Plan and evaluate communication
- Coordinate and collaborate with other credible sources
- Accept and involve the public as a legitimate partner

Plan and evaluate communication - Have a specific objective, know your information, target messages, train staff, and pre-test messages. There is no single "public"--there are many publics, and different goals, media, and audiences need different strategies.

Coordinate and collaborate with other credible sources - Allies help. Build bridges, work with intermediaries, release information jointly. Few things make risk communication harder than conflicts with other credible sources.

Accept and involve the public as a legitimate partner - Demonstrate respect and sincerity, involve all, and remember that you are accountable ... and if you work for the government, they pay your salary. The goal is to develop an informed public that is involved, interested, reasonable, thoughtful, solution-oriented, and collaborative. If all you try to do is diffuse public concerns or replace action, you're not doing risk communication.

Risk Communication

- Listen to people’s specific concerns
- Be frank, honest, and open
- Speak clearly and with compassion
- Meet the media’s needs

In no particular order ...

Listen to people’s specific concerns - People are usually more concerned about things like trust, credibility, competence, control, voluntariness, fairness, caring, and compassion than statistics and details. Don't make assumptions about what people want to know, listen to all , recognize emotions and other factors such as hidden agendas, use reflective listening

Be frank, honest, and open - Trust and credibility are hard to gain and easy to lose. State credentials, admit uncertainty/ignorance and get back to people, don't “spin” answers, avoid speculation, and explain how you got your estimate

Speak clearly and with compassion - No matter what you do, some people will be dissatisfied. Acknowledge that any death or illness is a tragedy. People can understand complex risk information. Use non-technical language, vivid images, examples. Acknowledge emotions, describe that is being/can be done, and make sure you keep your promises.

Meet the media’s needs - Why bother with this? Because if you don't, they will do it for you! Reporters and journalists may be more interested in politics than risk, simplicity than complexity, danger than safety. PREPARE. Be open and accessible, tailor information to their needs, follow up, and establish long-term relationships.

Helpful Sources

- Kammen, D.M. and D.M. Hassenzahl. 2001. Should We Risk It? Princeton University Press, Princeton. (Chapter 10)
- http://socrates.berkeley.edu/~dkammen/swri/
- Ross, J.F. 2000. Living Dangerously. Perseus Publishing. (Chapter 3)
- http://www.atsdr.cdc.gov/HEC/primer.html