A Small Dose of Connecting the Dots
or
Connecting the Dots:
Toxicological Decision-Making and Communication in 21st century

Chapter 6 in Third Edition of
A Small Dose of Toxicology - The Health Effects of Common Chemicals

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Supporting web sites
web: www.asmalldoseoftoxicology.org - "A Small Dose of Toxicology"
Overview
This book “A Small Dose of Toxicology” provides a science based introduction to the principals of toxicology and the health effects common chemicals. But there are other aspects that are important to consider such as history, ethics, and regulation. A subtext of this book is to turn knowledge into action. A new approach is needed for the process of making decisions to protect human and environmental health from hazardous chemicals, to have positive preventive approach. The approach is called “Connecting the Dots” (CtD).

The hazard evaluations and risk assessments typically used for decision-making and regulations involves consideration of standard studies of dose-response (mostly in animals), assumptions about probabilities, and safety factors. But risk assessment is only part of the answer. The challenge is not always to do more studies to generate more data, but to use the knowledge we have to make decisions today. A new framework should include prioritizing human and environmental health as well as preventing disease and disability. An alternative approach would bind together existing science along with a strong ethical foundation coupled with an examination of the historical decisions and uses of the compound in question. This proposed alternative approach to risk assessment uses the classic, assumption-based scientific tools, but goes deeper to examine historic uses, alternatives, vulnerable populations, and includes an ethical framework for balancing those at greatest risk with those who benefit with those who pay and better informs those who have the decision-making power.

One of the goals of the Connecting the Dots approach is to define an action and then provide information in a format that connects science, history, and ethics. This approach allows all parties to make and communicate information that can lead to effective actions an ultimate make better decisions.
Introduction

“It is not the truth that makes you free. It is your possession of the power to discover the truth. Our dilemma is that we do not know how to provide that power.”
Richard Lewontin
(New York Review of Books, Jan 7, 1997)

Scientists and public health professionals are in the business of exploring, developing, and communicating facts. But often the greatest challenge for those who use this information is not in identifying the facts, but rather in effectively communicating and acting on those facts in a way that puts information in context with the past and within the expectations of a civil society. This chapter describes one such strategy: “Connecting the Dots” (CtD), which places a desired action within a framework of scientific facts, history, and ethics, enhancing the effective use of old and new scientific information (Figure 1). Putting scientific facts within this framework provides scientists, as well as non-scientists, with the tools and ultimately the power to understand and use information. The goal is to provided individuals with a tool to help organize information around a specific action along with the power to persuade others to make changes and take action. CtD is designed to help tell a story that shows the benefits of taking action.

Figure 1 – Connecting the Dots (CtD)
Advances in science and technology have produced enormous benefits, but have also created undesirable hazardous effects that impact human and environmental health. Despite the increased scientific data and understanding, decision-making has become more difficult and complex. It is increasingly important to consider the ethical, legal, and social issues that confront toxicologists, public health professional, and decision makers. It is with these considerations in mind that developing a method to connecting the facts of science, historical analysis, and ethics together to promote or discourage a specific action.

The 'Connecting the Dots' tool consists of four primary “dots”: science, ethics, and history that surround the central core of desired action. The dots may be augmented, depending on the topic or need to go deeper into a specific area. The desired action also may influence exploration of a subtopic and require more research and discussion for a deeper understanding. The four areas are discussed on below. The CtD model is a strategy to bring together relevant information into a meaningful but parsimonious story or fact sheet, recognizing decision-makers often have limited time to review important information. The information collected is designed to be supportive of a particular action and should be parsimoniously completed in no more than four written pages (two pages back to back).

The Connecting the Dots (CtD) system is designed to apply a standardized approach to support a specific action. The four pages of a CtD fact sheet include: a cover page with overview points followed by three pages that provide supporting details for the action goal, including sections on the science, history (including relevant regulatory standards), and ethics. In developing and using a CtD fact sheet, users can specifically educate decision-makers, policy-makers, and the public, which may help lead to a consensus for action to address an environmental challenge. The front page is meant to provide highlights of the issue, identifies a specific action goal and a brief justification for the specified action. The remaining three pages provide information on the science, ethics, history, including current regulatory standards, and references. It may be further tailored to meet the needs of particular audiences, such as regulators, public interest groups, and members of the public, academics, legislators, or legislative staff.

The process of developing and using the CtD process is also meant to stimulate critical thinking about an issue and proposed approach to addressing the issue. To take meaningful action requires an integration of range of information and by articulating an action and then setting out to collect relevant support from science, history, and ethics a more reasoned and effective action might be developed, refined, articulated, and undertaken. Some of the questions that might arise by undertaking this process might include: what are the underling scientific findings, what were some of the precipitating events that lead to the problem to be addressed, who are the vulnerable populations, who is or has benefited from the current status and why should that be changed. How the information, past positions, values of stakeholders, vested interests interact and connect is integral to decision making.

First a word about Risk Assessment and Risk Communication
The US Environmental Protection Agency (EPA) has been using risk assessment modeling since the mid 1970s as a process to estimate the human health risk of cancer from exposure to pesticides and other chemicals. Risk assessment and related risk communication strategies are increasingly being pushed to evaluate and discuss very low level effects (Gwinn et al., 2017). Risk assessment has been touted as the gold standard for setting regulatory limits to protect human health and is widely used in the US and elsewhere. The process involves four basic steps: 1. Hazard Identification, 2. Dose-Response Assessment, 3. Exposure Assessment, and 4. Risk Characterization.

**Hazard Identification** Examines whether a stressor has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances. **Dose-Response Assessment** considers the numerical relationship between exposure and effects. **Exposure Assessment** looks at data related to frequency, duration, and concentration of exposure. And, **Risk Characterization** examines how well data support conclusions about the nature of the health risk from exposure. This process involves making assumptions about the probability of various conditions or characteristics being present with little or no relationship to the actual people or communities who are trying to use the guidance.

While this approach is laudable and better than not considering these basic conditions at all, it is incomplete and outdated. What are not considered in this process are health outcomes other than cancer, such as reproductive, neurotoxic, developmental, and immunologic. Nor are individual susceptibilities, pre-existing conditions, gender, or genetic predisposition considered in this process. The unique susceptibilities of the very young or fragile elderly are not considered. The interactive effects of exposure to several compounds or environmental stressors are not considered. Nor are the health effects of chemical mixtures considered. Unfortunately, the US EPA risk assessment process often is a permission to pollute with the implication that exposures at the level assigned by risk assessment are ‘safe’ regardless of the unique exposures or underlying health issues of the individual or communities exposed. And equally important is the fact that the assumptions and incomplete data upon which a risk assessment is based are poorly or not communicated at all to the public. As William Ruckelshaus (the first administrator of the EAP) once said, "We should remember that risk assessment data can be like the captured spy: If you torture it long enough, it will tell you anything you want to know". A new approach is needed.

**Beyond Risk Assessment**

Given the uncertainties surrounding the EPA risk assessment models and the possible adverse consequences of exposures to harmful compounds to many if not most citizens, a more precautionary approach is needed. A precautionary assessment moves beyond the usual risk assessment approach to include the ethical construct to not only reduce risk by “doing no harm” or “minimize harm”, but to move to “doing good”.
The goal of a precautionary assessment is to allow communities and individuals to incorporate their knowledge, the unique needs and challenges of their communities, and their values into a more comprehensive evaluation of a hazardous condition. It combines the philosophy and ethics of the precautionary principle with the standard scientific evaluation of the hazards. A precautionary assessment contains three basic elements: a) community and social issues, b) exposure, and c) hazard and toxicity. Each element is broken down into a series of questions that are scored numerically and summed to produce a summary score for each element. In contrast to the traditional risk assessment, a precautionary approach is a more comprehensive way to evaluate the human and environmental health risks within the context of the community.

Recent scientific advances in our understanding of how DNA expression can be modified by environmental conditions, such as diet or stress, indicates that subtle changes in health outcomes are possible beyond the basic the DNA sequence. This is known as “epigenetics”. In keeping with the acknowledgement of the interactive and combined effect of genetics and environment, we suggest that a precautionary approach to risk assessment is a tool to implement the ethics of “epiprecaution”. We have an ethical responsibility to demand that our children have an environment that is supportive and nurturing and one in which they can reach and maintain their full potential, not just one that is free from exposure to chemicals.

Developing a ‘Connecting the Dots’ Fact Sheet

Action – Where we want to go

The desired Action can be big or small, but should be stated as simply and specific as possible. For example, according to the Occupational Safety and Health Administration (OSHA) a worker’s occupational lead exposure can reach 60 µg/dL before the worker is removed from the work place (Shaffer & Gilbert, 2017). A CtD Action may be “Reduce worker lead exposure so that blood lead levels are less than 5 µg/dL”. Other CtD Actions may be stated in the form of protecting children from lead-based paint or passing a bill to reduce the use a pesticide. Once an Action is clearly defined, the Dots of science, history, and ethics can be explored and developed to support and explain the stated Action.

Science – the bedrock of knowledge

Science is an ongoing and continual process that builds knowledge and facts following a systematic study of testable predictions. The scientific method is well described and agreed upon by scientists; it is the systematic observation and experimentation to test a prediction of hypothesis. The Oxford Dictionaries Online define the scientific method as "a method or procedure that has characterized natural science since the 17th century, consisting in systematic observation, measurement, and experiment, and the formulation, testing, and modification of hypotheses". Scientific findings are divided into many categories and subcategories as knowledge has expanded and continues to evolve. To this list can be added

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the life sciences such as biology. Disciplines such as medicine and toxicology are often considered to be applied sciences that use the scientific method. When there is controversy regarding the interpretation of scientific findings, it is important to develop an agreed upon process for examining the scientific information or at the very least understand why there is disagreement.

Over the past few years the “sciences” have been used to justify a variety of personal opinions. Also, some have focused on the uncertainty inherent in science as a strategy to discount science or deflect the use of science in policy decisions. While it is true that the very nature of the scientific method includes the recognition of uncertainty, one of the beauties of science is that quest for knowledge is always evolving. Scientific findings, like most human endeavors, are influenced to some degree by the biases of the scientists conducting the research and the individuals interpreting published findings. More effort is needed to transparently acknowledge individual bias and research funding sources. The toxicological science were not immune from labeling and there developed a branch called evidence-based toxicology (Stephens et al., 2013) (Silbergeld & Scherer, 2013). The toxicological sciences are particular susceptible to controversy about particular findings because of the money that can be made, or lost, from the way scientific findings are interpreted.

Using the Science Dot

The Science Dot focuses on scientific data and reported findings of research related to the desired Action. For example, one scientific fact around childhood lead exposure is that children absorb more lead than adults and because they are smaller than adults, they receive a bigger dose for the same exposure (Gilbert & Weiss, 2006). This information is used part of the Science Dot and supports an Action to establish policy to reduce childhood lead exposures. Ironically the Science Dot can be the most difficult and complex to write because of the range of scientific research findings and the ongoing evolution of the science.

History – Looking back to go forward

Understanding the historical perspective on an issue is a critical part of making good decisions. History helps us understand how humans have shaped the environment and how the environment has shaped humans. But is also gives us a chance to learn from our mistakes and apply the knowledge and experiences that can inform current circumstances. The thoughts and arguments that went into current regulatory approaches to protecting human health and the environment are by nature historical and as time, culture, expectations, and science evolve we can use these historical records to help make better decisions and take better actions.

Why study history?

History provides a framework upon which we can better understand current issues, rules, regulations, and behaviors (Stearns, 1998). Understanding and using historical discoveries, reports, and experiences is an important, even necessary, element of implementing toxicological information in the present day. Historical references can help provide a
foundation for current practices and policies, help predict future experiences, explain the evolution of scientific thought, and help us learn from mistakes of the past.

It helps us predict and even anticipate the future by reflecting on and learning from the ideas, and mistakes, of researchers, teachers, and advocates who have gone before. Understanding how things have changed, why they changed, and what stayed the same despite the efforts at change helps anticipate and even predict how future actions and activities will play out.

Often people from the past inspire us with their ideas, their work, and their thoughts about how they addressed challenges similar to our own. Reviewing historical activities for lessons learned, or for ways humans have faced difficulty situations, or for examples of things that worked well can inspire us to continue along similar paths and may even provide guidance in an increasingly complex world.

History is a study in trial and error and a view on what worked, and what did not. Science too is a process of continual exploration and evolution of information and observations. Science and history both build on the work of the past to help understand the present day and even the future. Even research conducted 50 years ago can make important contributions to addressing current problems. Science incrementally approaches a better understanding of why things are the way they are and how things work. From this standpoint history and science go hand-in-hand to help decision-makers continually progress towards better solutions to problems we face.

Relevance of historical toxicology

Humans have long been interested in how plants and minerals affected the human body, long before there was an actual scientific discipline called ‘toxicology’. Human reactions to ingesting herbs, spices, fermented liquids, and various concoctions were often closely observed and reactions, positive and negative, were noted and passed on to ensuing generations. Experimentation and trial and error became the foundation for future advances as those historical experiences were passed on by oral tradition or eventually in writing. Even fatal effects informed future users; the father of Chinese medicine and pharmacology Shen Nung (2696 BCE) (Gilbert & Hayes, 2006) (Hayes & Gilbert, 2009) died sampling an herbal remedy – a great lesson for his followers.

One example of how history informs and impacts the present day is the use of the metal lead. The human health consequences of exposure to lead dust and fume were recognized more than 2000 years ago with observers noting that “lead makes the mind give way” (Gilbert & Weiss, 2006). Despite this ‘scientific’ observation, future users of lead in metal-working, roofing, cooking, paint, gasoline, and ammunition often ignored this historical knowledge regarding the adverse health effects of exposure to lead, to the detriment of the lives of many. However, this evolution of scientific knowledge eventually influenced the regulation of the use of lead in a variety of products, though regulatory and policy decisions were often based more on economics and practicalities than health effects. It wasn’t until the 1920s that lead-based
paint was banned in Europe and not until 1978 in the United States. Lead exposure was found to be particularly worrisome for children as research increasingly demonstrated that lead exposure had a highly negative impact on early childhood intellectual development (Gilbert & Weiss, 2006). Unfortunately, leaded gasoline is still used in most parts of the world, as are many other lead-based products. Even historic uses of lead that are seemly in a ‘safe’ form can have health impacts in present day. The recent fire at the ancient Notre Dame cathedral in Paris vaporized the lead-based roof of the structure, resulting in deposits of exceedingly high levels of lead fume and dust across the city and beyond.

One of the early practitioners of what is now called ‘toxicology’ is Paracelsus (1493-1541), physician, alchemist, and astrologer. The classic (and historic) principle of toxicology, ‘the dose makes the poison’, has been attributed to Paracelsus. This quote reflects the historic evolution of scientific observations that all substances have the potential to be poisonous, depending on the amount of exposure. In the 1700’s the understanding of the link between exposure and effect was advanced by Percivall Pott (1714-1788) who documented and reported that chimney sweeps, who were regularly and frequently cleaning the inside of Victorian England chimneys full of coal dust and soot, were susceptible to scrotal cancer due to their regular and cumulative exposure to the fireplace soot, or as the causative agent was later identified, polycyclic aromatic hydrocarbons.

The scientific process and scientific understanding is one of building on a history of observations, discoveries, successes, and failures, it also puts current problems within a context of years of evolution of scientific of thought.

**Using the History Dot**

Reading and understanding history gives us a chance to learn from past mistakes and apply the knowledge and experiences that can inform current circumstances (EEA, 2002, 2013). The thoughts and arguments that went into current regulatory approaches to protecting human health and the environment are by nature historical and as time, culture, expectations, and science evolves, we can use these historical records to help make better decisions and take better actions.

History is an important part of making ethical decisions. History provides an opportunity to see how past decisions may have unfairly or disproportionately affected certain groups of people. The perspective of history provides a clearer view of who benefited and who was harmed and what information were people given when it came to making decisions. If people did not obtain sufficient, or correct, information or if information was withheld, then decisions may have been poorly made and harm was done needs to be addressed and changed with present day decisions and actions. Without the perspective of history, many of these injustices cannot be recognized or modified.
It is important that we look back to go forward and consolidate our experiences into useful practices that allows use to learn from our mistakes. Using the opportunity to review the history of past actions, research, successes, and failures and incorporate those things into present day thinking is a critical part of educating decision-makers and moving towards better practices and actions for everyone.

**Ethics – a framework for Decision Making**

Ethics is a philosophical approach to considering concepts of right and wrong. As such ethics can provide a framework or guide to decision-making so that Actions incorporate the values of the recipients, the proponents, and other concerned parties to an action. The Ethics Dot section provides an opportunity to explicitly explore the perspective, values, interests, and concerns of impacted populations and individuals, identify who is at greatest risk, who benefits from the Action, and at what costs.

<Photograph about here>

**Why include ethics?**

Consideration of ethics includes principles of conduct and how we choose to live. It identifies ideal activities or behaviors and includes discussions and consideration of justice and fairness. There are several approaches to ethics such as utilitarianism (a proper course of action is one that maximizes a positive effect), deontology (goodness determined by examining actions), consequentialism (rightness based on consequences), or pragmatism (moral correctness evolves) for the purposes of this chapter ethics is considered to be a thought process that includes identification of values and how they related to the action goal. Governments use laws and regulations to motivate ‘good’ behavior; ethics implicitly addresses behavior that lies beyond governmental control. Some have refined the ethical approach to addressing environmental issues (Environmental Ethics; Brennan & Lo, 2016) or through combining ethics with legal and social issues into ELSI – Ethical, Legal, and Social Implications.
The fundamental ethical principles with regard to toxicology may be summarized as: 1) dignity and respect for the autonomy of human and animal subjects; 2) veracity, an adherence to transparency and presentation of all the facts; 3) justice, an equitable distributions of the costs, hazards, and gains; 4) integrity, an honesty and forthrightness; 5) responsibility, an acknowledgement of the accountability of all parties involved; and 6) sustainability, consideration that actions should be maintained over a long period of time (Gilbert & Eaton, 2009).

The more explicit use of ethical principles increasingly entered into policy discussions. Aldo Leopold, considered by many to be America’s first bioethicist, summarized ethical responsibilities in a simple statement in 1949.

"A thing is right when it tends to preserve the integrity, stability, and beauty of the biotic community. It is wrong when it tends otherwise." (Leopold, 1949).

Some believe that this ethical statement suggests that exposing people, particularly children, to harmful agents robs them of their “integrity, stability, and beauty”, indeed their potential, and is therefore wrong. Health, ecological, and ethical concerns about chemical exposures were highlighted by Rachel Carson in Silent Spring (Carson, 1994), first published in 1962. Carson sounded one of the first alarm about the effects of environmental contaminants and catalyzed numerous regulatory changes related to chemical use.
The idea for an Earth Charter (Earth Charter, 1997) was first proposed in 1987 as an approach to creating a broad ethical statement with the goal of establishing a global civil society. The Earth Charter took a step forward in 1992 at The Earth Summit in Rio de Janeiro, also known as the Rio Summit, which produced the 27 Principles of the Rio Declaration. Principle 15 defined the Precautionary Principle as an approach, some would say an approach based in the ethical principle of ‘do no harm’ to protect human health and the environment. In January 1998 Wingspread Conference on the Precautionary Principle was held in Racine, Wisconsin to further define the Precautionary Principle (Steven G. Gilbert, 2005; Kriebel et al., 2001). Many countries, states, and organization have since adopted the Earth Charter.

"When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

The concept of epigenetics provides the scientific and biological foundation for the importance of “doing good”. This concept also could be called “epiprotection” or “epiprevention” to signify the need to move above and beyond preventing exposures to harmful material to one that is nurturing and supportive (Gilbert, 2015). We have an ethical responsibility to ensure that our children have an environment in which they can reach and maintain their full potential, not just free of exposure to chemicals but an environment that is supportive and nurturing.

Using the Ethics Dot

A consideration of ethics and ethical principles when constructing the Ethics section of a CtD document encourages an evaluation of available information from the framework of values, identifying possible harms or costs, and obtaining input from all concerned parties with a goal of doing no harm to achieve the best possible outcome.

Incorporating an ethical component into the CtD document will require thoughtful development and articulation of fundamental ethical principles upon which the suggested action should be based. This approach may be time consuming when working with stakeholders
to articulate their values and goals, some of which may not be transparent even to them. It requires a move beyond what is legally required toward an exploration, discussion, and incorporation of the values of all parties.

**Conclusion**

The Connecting the Dots (CtD) paradigm is designed to facilitate communication with and between the public and decision makers using a systematic and consistent format. The CtD approach was developed with the understanding that there is tremendous amount of information available on given topic, but it is not often presented in a concise format neither does it regularly capture the values of parties involved nor provide clear rationale for desired actions. CtD approach uses a basic structure of the interaction and contributions from science, ethics, and history that support a specific desired action. By selecting highly specific examples from science, history, and ethics relevant to the desired action the author can keep the CtD document to four pages (two pages front to back), which increase the likelihood that the information will be read and used by target audience.

The CtD approach was developed with the acknowledgement that despite the complexity of the many issues there is a real need to give people at all levels concise, methodical, and well supported information to help them make effective policy decisions and take action to ensure a safe and healthy environment. The CtD approach puts scientific information in the context of history, society, culture, and values to help people connect the dots to collectively make better decisions.

“It is our considered professional judgment that this dilemma has no technical solution.”
The Tragedy of the Commons
By Garrett Hardin, Science, 1968

**References**


