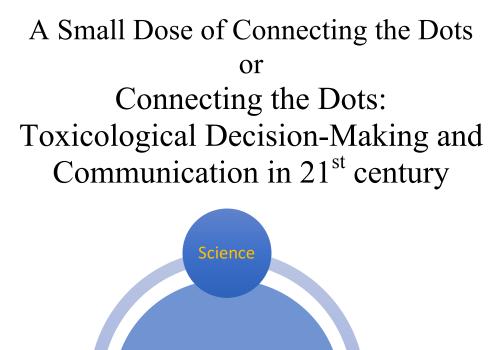
Chapter 6 - Connecting the Dots: Third Edition - New: 07/05/20



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

Ethics

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Supporting web sites web: <u>www.asmalldoseoftoxicology.org</u> - "A Small Dose of Toxicology"

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History

Abstract

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 problem solving and policy decision-making when protecting human and environmental health from hazardous chemicals. Often when communities or organizations are working to undertake chemical policy reform, they are hampered by challenges of communicating the problem(s) and desired actions to policy makers. On the other hand, policy makers may fall back on old formulaic approaches to addressing community concerns about chemical exposures, not taking into account the historic issues related to the use of a chemical or even ethical guidance with regard to protecting vulnerable populations. Communications are often at cross-purposes and confusing. We are proposing a new, standardized way to collect, collate, and communicate the background science, history, and ethical principles that address a chemical exposure problem and the desired action needed for chemical policy reform.

The hazard evaluations and risk assessment typically used for decision-making and regulations involves consideration of standard dose-response studies (mostly in animals) and assumptions about probabilities and safety factors. But risk assessment is only part of the answer. The challenge is not only to continue to generate more data to refine our understanding of dose-response, but also to use the knowledge we already have to make decisions to protect human and environmental health today. This new framework, called Connecting the Dots (CtD), broadens the decision-making framework to provide a more nuanced approach to policy making. CtD takes the concerns of the impacted individual, community, and environment into account and does not focus only on dose-response studies. The proposed alternative approach links existing science with ethical principles and a review of historical decisions and uses of the chemical(s) in question. The framework is designed to help all parties, those desiring action, and those tasked with policy development, to better communicate and make sensitive and equitable decisions about actions that need to be taken to address exposure problems.

Key Words Communication Risk assessment needs improvement Transparency, veracity Community-based ethics Connecting the dots

Introduction

"It is not the <u>truth</u> 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, public health professionals, and policy makers are in the business of exploring, developing, and communicating facts, and making decisions and even policies. But often the greatest challenge for those who use this information is not in identifying the scientific 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 a new strategy: "Connecting the Dots" (CtD), which takes an identified problem, develops a framework of scientific facts, history, and ethics that supports and guides suggested action(s) to address the problem (Figure 1). Putting scientific facts within this framework provides concerned citizens, communities, organizations, scientists, and policy makers with the tools to understand and use information. The goal is to provide a tool to help organize information to address a problem and persuade policy makers or others to make changes and take action. Ultimately this can enhance everyone's ability to carefully explore an approach to a problem, concisely communicate that information, and ultimately direct and take action.



Problem Identification:

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 also important to consider the ethical, historical, legal, economic, 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. Developing a CtD story is a multi-step effort starting with identifying the problem, doing research on the science, history, and related ethical principles, then developing an action designed to address the identified problem and finally crafting it all into a succinct story. The CtD is a tool to present fact-based information in transparent manner that is designed to support an action to address a specific problem.

The 'Connecting the Dots' tool consists of four primary "dots": science, ethics, and history that surround a desired action. The dots may be augmented, depending on the topic or need to delve deeper into a specific area. The four areas are discussed in more detail below. The three dots (science, ethics, and history) were chosen because they represent general areas of content that are helpful, if not necessary, to consider with developing an approach to a problem. Legal considerations were not included because laws and regulations are often captured in a review of history and may be further address and explored once an action is identified. Another topic, or dot, that might be considered, may be economics, which is often an important consideration in developing approaches to problems. While economics is not specifically included in the proposed CtD framework, the model is meant to be flexible and the inclusion of additional dots is encouraged while maintaining a concise presentation of the most relevant issues. The information collected should address the identified problem, be supportive of a suggested action, and should be parsimoniously presented in no more than four written pages (two pages back to back) in order to recognize the limited time policy makers, have to review information. If this compiled information is used in testimony in front of a government committee, it needs to brief but as complete as possible.

The Connecting the Dots (CtD) Process:

The Connecting the Dots (CtD) process is designed to apply a standardized approach to address an identified problem and 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 action goal, including sections on the science, history (including relevant regulatory standards), and ethics. The CtD process really starts with acknowledge that there is a problem that need to addressed. Typically, this requires research into the scientific facts, history, and ethics. This generally leads to a first draft of action statement and the CtD fact sheets. The first page is meant to provide a very brief summary of the stated problem and an introduction to key points. In developing and using a CtD fact sheets, users can specifically educate decisionmakers, policy-makers, and the public, which may help lead to a consensus for action to address an environmental of human health challenge. The front-page bullet points are 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, and history, including current regulatory standards if applicable, and references. It may be further tailored to meet the needs of particular audiences, such as regulators, public interest groups, members of the public, academics, legislators, or legislative staff (Legislature, 2019).

The process of developing and using the CtD process is also meant to stimulate critical thinking about a problem and proposed approach to addressing the issue. The process starts with clearly articulating the problem, doing research on the science, history, and ethics, which leads to formulation of the action. Developing an action is really an evolving and iterative process. 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? 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.

It is also important to consider that audience of the CtD fact sheet. Once the general structure of science, history, and ethics are addressed the CtD fact sheet can be modified to suite a specific audience or presentation. For example, a CtD fact sheet directed toward the general public may have slightly different language than a CtD fact sheet directed toward legislative policy makers. For example, the ethics or history dot may be expanded to include more information on policy approaches over the last few decades. The CtD process is meant to be flexible and easily adaptable to different situations or audiences.

The author of a CtD fact sheet has several important responsibilities. One of the most important considerations is to know the audience. For example, the knowledge base of students is very different from a group of scientists. One should also consider and acknowledge the personal biases and conflicts of interest or relevant financial relationships of the authors (Maurissen et al., 2005).

Three example CtD fact sheets are included in the appendix (childhood lead exposure, lead shooting ranges, and fluoride). CtD fact sheets also are being developed for many of the chapters of the book "A Small Dose of Toxicology" and will be available on the web site www.asmalldoseoftoxicology.org.

First a word about Risk Assessment and Risk Communication

Risk assessment and risk management has been around for 1000's of years, after all it was important to judge the probability of becoming a meal of the resident saber tooth tiger (Aven, 2016). The last 100 years has seen risk assessment and risk management become a recognized science (Hansson & Aven, 2014) (Hansson & Aven, 2014). 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 (Embry et al., 2014; Faustman & Omenn, 2013). Risk assessment methods 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 (Faustman & Omenn, 2013).

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. (NRC, 1983).

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. Risk assessment asks "How much harm can we tolerate." Instead of focusing on the actions should we take to reduce human and ecological harm (Gilbert, 2005).

Beyond Risk Assessment

Current biological and toxicological knowledge now allows us to look beyond basic risk assessment in our effort to protect human and environmental health. It is time to consider whether or not risk assessment, as it is currently applied, meets the needs of the community and the new demands of chemical regulation. One demand that must be met concerns Environmental Justice (EJ) define by the EPA as the "fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations and policies" (Eaton & Gilbert, 2013). Given the uncertainties surrounding the EPA risk assessment models and the possible adverse, non-cancerous, consequences of exposures to harmful compounds, a more precautionary approach is needed. The foundation of Connecting the Dots was built with a desire to strengthen the fundamental of the toxicological sciences, risk assessment, ethics, and other essential elements of how we define harm. (Eaton & Gilbert, 2013).

When chemical exposures yield non-cancerous outcomes that are sometime subtle or differentially affect vulnerable populations, the precautionary principle should be incorporated in the review of the science. The most widely accepted definition of the precautionary principle is from the Wingspread Conference of 1998: "When an activity raises threats of harm to human health or the environment, precautionary measures should be take even if some cause and effect relationships are not fully established scientifically" (Raffensperger & Tickner, 1999). Central components of the precautionary principle can by stated as: establish public health goals; taking preventive action in the face of uncertainty; shifting the burden of responsibility (proof) to the; proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; increasing public participation in decision making (Gilbert, 2005).

Broadly defined, the goal of a precautionary assessment is to allow communities and individuals to incorporate the unique needs and challenges of specific communities, and to include their values into a more comprehensive evaluation of a hazardous condition. It combines the philosophy and ethics of the precautionary principle with a 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 and contextual way to evaluate the human and environmental health risks

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. 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". 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". We have an ethical responsibility to our children to 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 (Gilbert, 2015).

Developing a 'Connecting the Dots' Fact Sheet

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 the scientific community; 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 the life sciences such as biology and then toxicology. 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. 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, in fact, 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 biases, conflicts of interest, 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) (Faustman & Omenn, 2013) (Eaton & Gilbert, 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 and used by profitmaking companies (Maurissen et al., 2005).

Typically, any scientific discipline can be broken down to a common set of studies with defined methodology. It should be noted that toxicology is one of the few scientific disciplines that have developed a large and vibrant for profit business that supports data development and report generation. Toxicology has both studies with defined methodology and studies with far more flexible methods that allow the exploration of mechanism of action and effective dose. These laboratories conduct contract a prescribed set of studies with primary variable being the dose of the test compound. The studies are done to determine at what dose an adverse effect is apparent. As a general rule the greater the exposure to humans or distribution of a compound the more well studied the compound and the larger number of ecological reports produced. The focus of the scientific dot is to summarize the scientific information that is accessible. Data or certain reports may not be accessible because they are not publically available and considered to be confidential information. There are a number of examples were scientific information has been hidden or distorted to facilitate advantage conclusions about a product's safety (EEA, 2002, 2013). It may also be a situation were on side of dispute focuses on uncertainty in the scientific process instead of taking a more precautionary approach as

documented in Late lessons from early warnings (EEA, 2002, 2013). These two EEA reports examine in detail the human life consequences of failing to take a precautionary approach in chemical management.

The last 10 to 15 years have seen many scientist working to summarize the scientific literature related to childhood exposure to an array of chemical compounds. These review papers can serve as examples of supporting literature for a CtD process. A particularly good example is the consensus statement on the neurotoxic effects of chemical exposure in childhood (Bennett et al., 2016). In addition, there are several authors who have a long track record of publications on the health effects of chemicals (Lanphear, 2015) and (Axelrad, Bellinger, Ryan, & Woodruff, 2007).

Using the Science Dot

The Science Dot focuses on scientific data and reported findings of research related to the identified problem and possible policy or action efforts. 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 can be used as part of the Science Dot and leads to 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. It will typically take the most room and require the most referenced information. It is important to remember that you are building a story so that people can understand the scientific facts within the context of ethics and history and understand how this information addresses the stated problem and leads to possible action alternatives.

History – Looking back to go forward

Understanding the historical perspective on an issue is a critical part of making good decisions. History helps us to 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. Toxicological history

goes back hundreds of years (Gilbert, 2011), (Gilbert & Hayes, 2006), (Hayes & Gilbert, 2009) (Gallo, 2013). 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 (EEA, 2002, 2013).

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 (Shaffer & Gilbert, 2017).

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), a 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 (Hayes & Gilbert, 2009).

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 (Gross & Birnbaum, 2017).

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 (Lane et al., 2008).

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 or policy approaches 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, environmental justice, and concerns (Gilbert, 2015) 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 (Figure 2).



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.

"It is the public that is being asked to assume the risks...the public must decide whether it wishes to continue on the present road and it can only do so when in full possession of the facts...""

"Only within the moment of time represented by the present century has one species -- man -- acquired significant power to alter the nature of his world."

Rachel Carson (Carson, 1994)

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 (Gilbert, 2005; Kriebel et al., 2001). Many countries, states, and organization have since adopted the Earth Charter. Lessons can be learned from this approach when it comes to addressing problems and identifying actions related to human health.

"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."

- Wingspread Statement on the Precautionary Principle, Jan. 1998

The concept of epigenetics also provides the scientific and biological foundation for the importance of "doing good". This concept 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.

Action – Addressing the Problem

A desired action is at the center around which to rotate the supporting information of science, history, and ethics, and other 'dots' such as economics. The Action dot works to address the stated problems and is the conclusion of the research and effort that went into understanding and linking the relevant science, history, and ethics. The Action is a desired effort to address or resolve the problem. A good example of this is the Action of crafting a bill to be considered through the legislative process and hopefully will ultimately lead to a vote of approval. In this situation, the goal and audience are well defined. Another approach, perhaps a little more forthright, would to conduct organized and structured research on the content of the three dots, science, history and ethics, to explore what might be possible actions to take to meet a specific goal or to determine whether a goal needs to be narrowed. The CtD approach is a tool for linking, organizing, evaluating, and communicating existing knowledge. The CtD can be used as a tool support advocacy for the action.

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 ug/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 μ g/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. See the action dot in the three examples in the appendix.

Conclusion

The Connecting the Dots (CtD) paradigm is designed to facilitate systematic exploration of an identified problem and to communicate with and between the public and decision makers. The CtD approach encourages people to think more deeply abut the relationship between science, history, and ethics while supporting an Action to address a specific problem. The CtD approach was developed with the understanding that there is tremendous amount of information available on a given topic, but it is not often presented in a concise format neither does it regularly capture the values of parties involved nor does it provide clear rationale for a suggested Action. By selecting highly specific examples from science, history, and ethics relevant to support 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. We need more time and effort placed in realm of scientific communication and education.

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.

Garrett Hardin in his paper "The Tragedy of the Commons" (Hardin, 1968) concluded that "It is our considered professional judgment that this dilemma has no technical solution." The vast majority of our problems in the complex world we have created must be managed or prevented. The Connecting the Dots (CtDs) is meant to help us move forward to create a healthier world for all of our children.

Appendix – Three Examples of Connecting the Dots (CtD) in Separate Document

Childhood Lead

Shooting Ranges ß Fluoride

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