Hazard Analysis and Hazard-Control Hierarchy

Michael S. Wogalter

CONTENTS

Responsibility for Manufacturing a Safe Product	18
Foreseeable Misuse	18
Hazard Analyses	19
Government Regulations and Industry Standards	20
Data on Product Injury	20
Consumer and Usability Testing	21
Hazard-Control Hierarchy	22
Design Out the Hazard	23
Guarding against the Hazard	24
Warnings	24
Factors That Influence Decisions	25
Human Error	25
Product Stewardship	25
Issues About the Hierarchy	26
Training/Supervisory Control	27
Responsibility for Product Safety: Importers Need to Consider Safety	28
Distribution of Safety Communications	29
Discussion/Conclusions	30
References	31

This chapter is the first of two chapters concerning general methodologies and techniques frequently used in Forensic Human Factors and Ergonomics (HFE) analyses. This chapter concerns the topics of hazard analyses and the hazard-control hierarchy. The next chapter (Wogalter, 2019b, Chapter 3, in this volume) concerns the Communication-Human Information Processing (C-HIP) Model, which describes the flow of safety information (i.e., warnings) from a source to end users who process the information. The purpose of these two chapters is to provide greater detail on major concepts that are only briefly mentioned, or assumed, in some of the case study chapters that follow. In the legal world within which HFE professionals participate as consultants and expert witnesses, there are some fundamental concepts relevant to this work. In the next few sections, a few main ones are reviewed.

Forensic Human Factors & Ergonomics: Case Studies and Analyses

M. S. Wogalter (Ed.), Boca Raton, FL: CRC Press/Taylor & Francis Group, © 2019, pp. 17–32.

Responsibility for Manufacturing a Safe Product

In the U.S. and elsewhere, manufacturers are responsible for producing reasonably safe products. Manufacturers are assumed to have (or should have) sophisticated knowledge with respect to their product(s) compared to other entities, or at least relative to endusers. To produce reasonably safe products, manufacturers need to examine their product thoroughly to determine the hazards associated with it. The standard of producing a reasonably safe product means that manufacturers need to be aware of knowable and discoverable hazards of their product in order to control those hazards so that they do not injure people (and/or cause property damage).

Foreseeable Misuse

Given that manufacturers need to sell reasonably safe products, the hazards associated with their product need to be dealt with in effective ways. This usually means trying to design out the hazard, guard against the hazard, and/or warn about them—usually in that priority. Not only does the concern need to be directed to hazards associated with intended foreseeable use, but also *foreseeable misuse*. If a manufacturer does nothing to discover the hazards associated with their product (e.g., by ignoring or not considering consumer complaints or injury reports), then it might not discover foreseeable misuses until after injuries occur.

Companies are, of course, *not* responsible for *unforeseeable misuses*. A light bulb manufacturer might not be liable for their product igniting gas from a cut fuel line of a forklift that hit the light bulb. Consider that this event resulted in an explosion and fire that burned the operator and two bystanders in a warehouse. This type of event seems unforeseeable—and it may very well be. But sometimes there is more to the story than is apparent. Liability and responsibility can depend on information that is produced in the course of a lawsuit. Consider the difference in potential liability if any of the following details were found to be true: The manufacturer (a) did no testing to determine the bulb's capability to ignite flammable gas, (b) did testing but ignored the finding that it could ignite flammable gas, or (c) did testing, found that it can ignite flammable gas, and developed a different design that could be incorporated for a little extra cost per bulb, or (d) knew that it could ignite flammable gas but did not adequately warn about it. These are just a few examples of details that might be found in a lawsuit that could affect foreseeability-related decisions made by a judge or jury.

The reason manufacturers need to know how their product can be misused (foreseeably, of course) is so that they can control the associated hazards in one or more effective ways. A failure to look for hazards in the first place can be interpreted as a deficiency in the standard of care. Unfortunately, the strategy of not looking for hazards and not doing hazard analyses is not uncommon. The strategy of not looking for hazards that it did not know about or foresee. Manufacturers may be concerned that the analyses will uncover negatives about the product that marketing and sales departments do not want consumers to know about. Clearly, this is antithetical to safety and the notion that manufacturers are responsible for producing a safe product. Another common misstep is when a manufacturer does in fact do some hazard analyses but keeps the findings confidential

despite potential safety ramifications. These strategies can catch up with manufacturers or an entire industry if it becomes known that the entities involved knew about a hazard and did not do anything effective to try to limit potential injury during intended use and foreseeable misuse. It can be a problem when the hazard is known, or reasonably easy to discover, and easy and inexpensive to deal with, yet nothing was done and the hazard left uncontrolled. Lawsuits filed for product-related injuries often attempt to show defects in the design, manufacture, safeguarding, or warning—with plaintiffs (the injured party) arguing that the particular hazard was inadequately controlled and the product or property was unreasonably dangerous. The defendants take a different position. For example, the manufacturer may argue it produced (or other entities sold) a reasonably safe product and that the injury was exceptionally rare and unforeseeable and/or it was the injured party's own fault.

Hazard Analyses

Given the necessity of producing a reasonably safe product (including the fact that hazards need to be controlled in some way), manufacturers should invest time, money, and effort to determine the ways that people might use their product and how people might get hurt. Collectively, the methods employed to identify product hazards are called hazard analyses.

According to the National Safety Council (1997), hazard analyses are an orderly process used to acquire specific hazard and failure data pertinent to a given system. It can uncover hazards that may have been overlooked in the original design, mock-ups or setup of a particular process, task, or product. Many methods are available to aid in the search, discovery, and evaluation of hazards. There are formal analytic procedures and/or tools (Frantz, Rhoades, & Lehto, 1999) such as failure mode effects analysis (FMEA), fault tree analysis, critical-incident analysis, and others (Israelski & Muto, 2012; Young, Shaver, Grieser, & Hall, 2006). Some involve the collection and evaluation of injury or adverse event reports. A brief mention of some of these methods is given below.

Failure Modes Effects Analysis (FMEA) is a formalized inductive method of hazard analysis in which consideration is given to different ways that a product or its component parts may fail and what the consequences may be (e.g., National Safety Council, 1989, 1997).

Fault tree analysis is another formalized method where product safety experts try to anticipate the ways that there could be a problem with the product or its components. It requires a thorough analysis of potential events and consideration of all known or potential sources of failure. One of the problems with this method is that some potential injury modes will be left out, thereby distorting quantitative predictions along with producing erroneous overconfidence that the analysis is complete (Wogalter, Brems, & Martin, 1993).

Critical incident analysis is a method in which persons with experience using the product are asked not only about potential injury but also about potentially negative events in which nothing bad happened (due to luck, or from someone noticing, identifying, and fixing the problem beforehand, etc.) such as in a "near miss." Critical incident data can reveal problems that almost occurred, but fortunately did not, which hopefully can be corrected before it results in a future injury. There are other kinds of hazard analyses, all of which have the goal of identifying potential causes of injuries and property damage. No method is perfect so it is generally advisable to use several kinds of hazard analyses.

Government Regulations and Industry Standards

For some products, there may be governmental regulations mandating certain aspects, features, and characteristics. For example, there may be a legal requirement that all reported adverse effects must be reported to a government agency, or that a particularly worded warning be used. Government regulations (i.e., law) are mandatory and must be followed.

Companies may also choose to comply with voluntary standards developed within their industry (such as the American Standards Institute [ANSI] or the American Society of Testing and Materials [ASTM]). These standards are not laws or mandatory requirements. Sometimes, an industry standard is adopted and incorporated into government regulations. In those cases, the industry standards made into law are mandatory requirements. However, most industry standards are not law and some manufacturers do not always comply with them. While industry standards are "voluntary," a jury in a lawsuit may consider a company liable if they did not follow a relevant standard. In this way, a standard becomes a requirement.

Even though a product may meet or exceed all applicable government regulations and industry standards, it does not mean the product is safe. Frequently, there is a need to do something more. Compliance with regulations and standards are considered the least that a responsible prudent manufacturer should do. They are the minimum level that a manufacturer needs to achieve; they are not maximums. There is an exception worth mentioning, which is when the law explicitly says that nothing more is needed. This preemption is sometimes applicable with hazardous chemicals and some other kinds of products, for example, explicit law prohibiting non-airbag warnings on sun visors (that might distract from the required airbag warning) in the U.S.

Complying with all applicable government regulations and industry-derived standards is usually insufficient to make a reasonably safe product. The reason is that only a relatively small number of product characteristics are addressed by regulations and standards. Foreseeable hazards that are not addressed by regulations and standards need to be dealt with in some way by the manufacturer so as to fulfill the goal of making their product reasonably safe.

That manufacturers are responsible for appropriate safeguards makes sense because manufacturers are more expert and knowledgeable about their product than governmental agencies and end-users of the product. There is little likelihood that that governments can keep up with rapid changes in product development. It is only when manufacturers are not doing the right thing (and usually only when they persist at doing the wrong thing) that government needs to step in to ensure public safety. Laws tend to lag behind product development. The U.S. Consumer Product Safety Commission (CPSC) is reactive in dealing with product hazards—usually acting only after noting problems cropping up in products already on the market for sale—unlike the U.S. Food and Drug Administration (FDA), which is more proactive, asking for valid demonstrations of safety and effectiveness before a new product is approved and marketed.

Data on Product Injury

Data are useful in determining product hazards. The U.S. CPSC monitors consumer product injuries by collecting data in a variety of ways, including newspaper reports of product involvement in injuries and through death notices and obituaries. They also track a representative sample of hospital emergency room entrances and make estimates of injury frequency and severity potential associated with different products.

Manufacturers can collect their own data through customer inquiries and various other methods of obtaining consumer comments, complaints, and injury reports. Unfortunately, consumer injury reports are often haphazardly recorded. To complain or report injuries is often difficult. Some companies make consumers "jump through hoops" to communicate with them, although certain specific ways may be available. Some manufacturers limit contact with consumers by not publishing (or making it easy to find) email addresses and phone numbers. In some cases, the only way to contact some companies is through postal mail. These difficulties discourage reporting. Even with successful contact, information may only go to the legal department and not be forwarded to other groups in a company. Some U.S. governmental agencies (for example, FDA and the National Highway Traffic Safety Administration [NHTSA]) require reporting of adverse events. Underreporting of adverse events is a problem. Commonly, the collected information is incomplete. If the manufacturer does not collect injury reports or does it in a slipshod way, or does not save the information it collects, it thwarts efforts that try to find out the extent of the problem and what the issues might be. It can lead to ambiguous and deceptive statements that there are no (or few) prior notices of a problem, which suggests there is a low rate of injury when the reality may be that there were poor processes to collect these data. Underestimation of injury rates and ineffective hazard control can have negative consequences. Good data collection can aid proper remedial action and prevent additional problems in the future.

Consumer and Usability Testing

An important hazard-analysis method is consumer testing. There are numerous kinds of consumer testing, but the general goal is to collect data from people using products. One rather simple way to perform this assessment is to ask and watch people (potential users) to try out the product.

Testing can be done in various places such as labs, offices, and in the field. Such testing helps in determining the kinds of errors that people may make and whether the instructions and warnings are effective. However, this method like other methods should be conducted in conjunction with other hazard analysis methods because any one method may or may not reveal foreseeable misuses and other potential problems (unless tasks are developed to pull out those problems).

Despite its potential utility, it is not uncommon for manufacturers not to do consumer testing. The exception, of course, is that marketing departments will do consumers tests but usually there is no interest in finding hazards and foreseeable misuses. Inadequate usability tests can lead to problems down the road if the manufacturer did not anticipate a usability-related hazard.

Consider the 95-gallon (360 liter) garbage carts that have populated neighborhoods across the U.S. The garbage bins were purposefully developed for automated pickup operations, where a robotic lift arm grabs the cart and dumps the contents into the truck and returns the cart to the curb. Consumers are supposed to roll out these large carts out to the curb and back. One aspect that cart manufacturers apparently did not anticipate was the likely situation that people will roll the carts with the lids open (opened all the way back on itself). When open and moved, the large lid will hang very close to the ground and may even drag against the ground. In walking with the tilted cart, the hanging or dragging lid can catch the user's foot and cause an unexpected trip and fall. Had consumer usability evaluations been conducted during the planning, design, and pre-release time periods, this problem would have been noted (and hopefully corrected). Apparently no consumer/user assessment testing was done on this product during its developmental stages to determine hazards to humans when people interact with the carts. The importance of considering the human-machine interface is discussed in the preceding chapter (Wogalter, 2019a, Chapter 1, in this volume).

At this point, it is difficult to change the garbage-cart design to make it less likely to cause a tripping hazard. The carts' design has become standardized, with different manufacturers producing the same or similar cart with minor physical differences. Also difficult to change are the trucks with mechanical/hydraulic arms to pick up the carts, dump the contents, and return them to the curb, as they have been standardized as well. Once things have been standardized, it is very difficult to change them. Nevertheless, there have been some attempted solutions to deal with the hazard in current garbage cart design. A device called a lid stop can be added to prevent the lid from swinging all of the way over. However, this device makes it difficult to add yard waste because the lid must be opened for each deposit. Some cart manufacturers have tried to use warnings and instructions as a method to control the trip and fall hazard, but most do a poor job of it. Frequently, the warnings are usually embossed (raised or lowered print) with the same color lettering as the background plastic. Some have added contrasting paint to the embossed letters to make them more visible and legible. Large colorful weather-resistant sticker labels to warn about the hazard would be better. While warnings might help reduce the incidents of tripping and falling, better designs and guarding are usually preferred as the next section discusses.

Another point to note is that hazard analysis is, or should be, considered during the early stages of product development, preferably during design stages, when it is usually easier to make changes compared to the completed product. It should be done after the product is completed as well. Indeed, hazard analysis ought to be an ongoing process even after the product has been marketed and sold. As seen in the garbage cart example, a hazard that is not recognized until the product has been released can be costly. Recalls and retrofits are not a good substitute for timely and competent hazard analyses at the early stages of product development. Once a product is already at people's homes, it is difficult to make changes. Nevertheless, on-going post-sale evaluations can reduce the negative impacts, such as future injuries, product recalls and defending lawsuits.

Hazard-Control Hierarchy

When a product or system has been determined to have hazards (e.g., as revealed by one or more methods of hazard analysis), manufacturers should try to control or limit their effects so that people do not get hurt or property damaged. There is a concept in safety, as well as in HFE, engineering and other disciplines, known as the hazard-control hierarchy, or alternatively, the safety hierarchy (Christensen, 1987; National Safety Council, 1989; Sanders & McCormick, 1993). It provides guidance on a set of strategies useful in reducing the hazard and preventing or limiting injuries.

There are many versions of the hierarchy as reviewed by several authors (Barnett & Brickman, 1985). While there are different conceptions of the hierarchy, fundamentally there are three basic prioritized strategies: design out, guard, and warn (Laughery & Wogalter, 2006; Lenorovitz, Karnes, & Leonard, 2014). Figure 2.1 illustrates the basic hazard control hierarchy. The strategies are ordered with respect to priority from top to bottom.



FIGURE 2.1 Basic hazard control hierarchy.

Design Out the Hazard

The first and best strategy for controlling hazards is to design them out, to eliminate or reduce the danger so as to avoid injuries. This method has primacy because its successful implementation results in the hazard being eliminated or substantially reduced.

- *Alternative Designs.* Removal of sharp edges from surfaces that are touched by people is an example of eliminating a hazard. Substituting a safer chemical (e.g., nonflammable or nontoxic) for a more dangerous one (e.g., flammable or toxic) is another example. Less hazardous designs ought to be implemented when they are practically, technologically, and economically feasible. For example, hair sprays can be made with nonflammable delivery methods (carriers) instead of highly flammable ones such as butane and propane. Alternative-design decisions should also consider whether the use of the alternative chemicals could adversely affect other aspects of the product such as reliability and adequate function. If the alternative severely detracts from the effectiveness of the product, the alternative may not be an acceptable option, even though it may reduce the hazard. Likewise, if reduction of toxicity of a chemical cleaner makes it much less effective, the product might not be purchased and used.
- *Economic feasibility*. The economic feasibility is another factor when considering alternative designs. If the cost of eliminating a hazard with an alternative design is prohibitively expensive, it may not be an acceptable fix. Here again, the decision is more complex than meets the eye. The revision might create another hazard elsewhere—possibly a new and worse hazard. The harm could be to the environment, which could indirectly cause adverse health effects of users and others. A previous carrier in aerosol hairsprays was chlorofluorocarbons (CFCs), but its use was found to negatively affect the ozone layer in the atmosphere, and as a result, they were banned from use in the U.S. and in some other countries.

Any new hazard that is created to eliminate another hazard demands deliberate consideration about its tradeoff acceptability. Clearly, one should avoid using an alternative design that creates a worse hazard. Alternative designs that create more hazards as they decrease others should be avoided. The decision to ban CFCs was made to reduce a societal, environmental hazard, but it resulted in an increased personal-use hazard. Current hair sprays instead have highly flammable propellant such as butane and/or propane. Thus, a complex evaluation of alternatives is needed, not just at the product level, but also globally as a part of a broader system of interacting components.

Guarding against the Hazard

If the first strategy of hazard elimination or reduction is not used for whatever reason, then a second-best strategy is to guard against the hazard. Here, the hazard exists, but it is constrained by one of several kinds of physical or procedural barriers. One example of a physical guard is a locked door of an electrical transformer box; it is a barrier separating high-voltage equipment and people. The spinning blade of a lawnmower that cuts grass has the potential to cause bodily injury, but one method to reduce it is a cover or deck around the spinning blade(s) of a lawnmower acts as a physical shield to prevent bodily contact with the blades. Personal protective equipment such as rubber gloves and goggles, and barricades around a hole in the roadway are other examples of physical guards.

An example of a procedural guard is the "dead man's" switch (an unfortunate name derived from the railroad industry). If a person releases a switch on a handle of powered lawnmower, it stops the blades from rotating. The placement of the handle away from the spinning blade is an example of guarding by distance. The lawnmower works when the operator's hands grip the handle some distance away from the spinning blades. When the hands are released, the blades stop. A different example of a procedural guard is the requirement that prescription drugs need permission of a licensed health care practitioner.

Sometimes it is difficult to categorize design and guarding since a cover around a hazard can be part of a product's design as well as a guard. In general, the strategies of designing out and guarding against hazards are better ways to control hazards in products and environments as compared to the third level of hazard control, warnings (Sanders & McCormick, 1993).

Warnings

Hazards that cannot be completely designed out or guarded against should be warned about. Warnings guard against *residual* hazards after design and guarding work has been (or should have been) done. Warnings are in the third-place position in hazard control hierarchy and are sometimes called the strategy of "last resort" or "last line of defense." The reason for these designations is that warnings are generally considered relatively less effective than designs that eliminate or effectively guard against the hazard. Warnings are usually less reliable than the other two hazard control strategies.

To be effective, warning systems should be designed to influence users' cognition and behavior so that they and others do not get hurt or property damaged. Warnings "work" by affecting perception, cognition, and behavior. The reliability of warnings is affected by several factors. People may not see, read or comprehend them, or they may not alter incorrect beliefs that people might hold, or provide sufficient motivation to engage in appropriate behaviors. The next chapter (Wogalter, 2019b, Chapter 3, this volume) gives more specific details on the factors that influence the effectiveness of warnings as part of the presentation of the communication-human information processing (C-HIP) model.

Factors That Influence Decisions

There are several factors that may influence decisions regarding hazard control. One factor is what the consumer wants or will accept. This could be said differently: it depends on what the manufacturer believes the consumer wants or will accept. Consider an example that is discussed in detail by Laughery and Wogalter (2019, Chapter 20, in this volume). Most vehicles marketed in the U.S. have front seats (driver and passenger) that can be reclined. However, in many cases, reclining the seat will result in the shoulder belt not being in contact with the torso. This results in the restraint system losing its effectiveness in preventing injury (and could cause substantially greater injury). Virtually all manufacturers warn in the vehicle owner's manual not to recline the seat while the vehicle is in motion. Most people are unaware of this hazard; however, when this reduced restraint level is specifically called to their attention, people are cued to understanding it (Laughery & Wogalter, 2008; Leonard, 2006; Leonard & Karnes, 1998; Paige & Laughery, 2003; Rhoades & Wisniewski, 2004).

There are several alternative approaches to addressing the seat recline hazard. One is to design out the hazard. This can be done by not allowing the seat to recline or to recline beyond an unsafe angle. This could be considered a guarding situation. However, one has to consider consumers' desire for the seat recline feature, as it is useful for resting (when the vehicle is stopped). There are also some other guarding approaches. One example is to design the seat-recline system so that (a) the vehicle cannot be driven from a stopped condition if the seat is reclined beyond some safe angle, and (b) if the engine is running, the seat will not recline past a certain point. For a complete description, see Chapter 20 by Laughery and Wogalter (2019) in this volume. Note, too, that there may be other solutions not mentioned here that could work. A primary one is to develop a restraint system that is effective while in a reclined position.

Human Error

Frequently, accidents are blamed on users/operators of a product—that the cause was human error. However, there is usually more to the story (Woods, Decker, Johannesen & Sarter, 2010). In many situations, the manufacturer set the stage for an injury event by employing inadequate hazard control. The operator might have played little or no part of the error event. A larger part may be due to human designers creating an error-prone design and who were not injured or in the situation at all. In other words, other aspects may be involved to produce the injury event, such as human designers creating a design that is susceptible to errors. Hazard analysis could be useful to anticipate errors or failures (i.e., foreseeable misuses) to fix them in advance.

Product Stewardship

Product stewardship (e.g., Jenson & Remmen, 2017; Lee, Mokhtar, Goh, & Hanafiah, 2015) is a risk control strategy that is gaining momentum in adoption and use, particularly in the chemical industry. This hazard control strategy considers the entire lifespan of the product, which notably includes post-sale processes relevant to safety. The manufacturer tries to

ensure that all of the downstream entities involved know and understand the hazards and limitations of the product. This means knowing not only how their direct customers are using the product, but also knowing how the customers of their customers are using the product to ensure the product is being used safely by them. Since manufacturers are considered the most knowledgeable about their product, it is critical that the manufacturer make sure that they are passing on all necessary hazard-related information to their customers, and that information gets to the customers of their customers, and so forth. This is one reason why placing warnings directly on the product or its container is frequently necessary for a manufacturer to reach ultimate users. These on-product warnings may be the only material that the manufacturer can expect end users have access to. Other information such as owner's manuals can be misplaced, lost, or not read, particularly if it is a re-sold product (Wogalter, Vigilante, & Baneth, 1998).

Issues About the Hierarchy

There has been some discussion on the utility and application of the hazard-control hierarchy (e.g., Hall et al., 2010; Laughery & Wogalter, 2010). A few points are worth mentioning. The main criticism relates to its simplicity, that is, that it does not adequately reflect the complexity of the hazard control process. The argument is that the real world is much more complex than the basic hazard control hierarchy. The counterargument to this perspective is that the best principles are often simple yet are powerful in prediction and applicability. The basic hierarchy enables a structuring of the ways hazards can be dealt with. Because products, tasks, situations, and environments are different, the way the hierarchy is used can be different. It is a building block that can be modified for particular products and circumstances. The hierarchy does not make a rigid decision about specific methods of hazard control that manufacturers should use. It is a guideline. Of course, a simple guideline can be made more complex. Figure 2.2 shows a more complex model of the hierarchy in comparison to Figure 2.1. Figure 2.2 shows a set of feedback loops



FIGURE 2.2 Basic hazard control hierarchy with feedback loops.

going in the reverse direction from later to earlier stages of the model, which can be used to describe a more complex decision process like those in the real world. For example, suppose that design and guarding have been considered, and the decision is now to use warnings as the method of hazard control. If warnings are tried and cannot be made to work sufficiently well (or if it is not desirable to use warnings), then a re-consideration (feedback as indicated by reverse arrows) of the current design and guarding is needed. In other words, the manufacturer may have to go back and relook at other design and guarding alternatives. Others have argued that warnings should only be considered as a supplement, not a substitute for good design and guarding (Lehto & Salvendy, 1995), and that warnings should not be the sole remedy to protect against serious hazards (Karnes, Lenorovitz & Leonard, 2010). Thus if warnings are used for the purpose of hazard control, then they ought to be designed so that can perform that role. Factors that influence warning effectiveness are described in the next chapter in the context of the C-HIP model (Wogalter, 2019b, Chapter 3, in this volume).

This model could be developed further. If none of the basic stages of the hierarchy work to control hazards, then other alternatives should be considered. One is for the manufacturer not to make it, import it, or sell it. The government (e.g., through the CPSC) might ban the product so that it cannot be made, imported, or sold. If the product is already in homes or businesses, a product recall program can be attempted. One example is the two-time recall of the baby seat described in Mayhorn and Wogalter (2019, Chapter 6, in this volume). Still another alternative strategy is to restrict sales to entities with appropriate safety training. For example, a medical device or a certain kind of pesticide might only be purchased by persons who are trained, certified and/or licensed. These alternatives are not in the basic hazard control hierarchy, but the hierarchy is a foundation for them.

With the addition of feedback loops, the hazard control hierarchy has greater utility. It is not a simple linear process or a unitary, directional priority scheme that always goes from design, guard, and then warn. It is extendable. Most products use a combination of design, guarding, and warning. Typically, one method is not used at the exclusion of the other two.

Considerations about warnings could affect design and guarding. Even with better design and/or guarding, warnings may still be needed. With safer designs, warnings may be unnecessary, or they could be very different than the warnings needed before a design or guarding change. Warnings complement good design and guarding.

Another criticism leveled at the basic hazard control hierarchy is that different authors have published different versions of it (Barnett & Brickman, 1985). For example, some models include training or supervisory control as separate levels or stages of the hierarchy. These stages are applicable for employers with respect to employees, but not usually for ordinary consumers in their home. And yet, employee training and supervision can be considered a form of warning or safety communications. While different authors have different versions, the basic structure of the hierarchy is similar (Laughery & Wogalter, 2010).

Training/Supervisory Control

In the U.S., employers are responsible by law for keeping employees safe according to Occupational Safety and Health Administration (OSHA) (U.S. Department of Labor, 2017) 29-CFR-1910 regulations. There are several ways that employers can take care of this responsibility, including supervising and providing safety training for their employees. With consumers and consumer products, there is usually little or no opportunity to supervise or train about safety. Employers hold employees "captive" to supervise and train so that their employees to carry out tasks safely. Supervisors can set and enforce rules.

Unfortunately, employee supervision and training can be quite poor, and while responsible for employee safety, employers are generally not experts on the equipment that they are supplying to their employees to use. This again means that product manufacturers need to supply adequate safety information to entities at risk, which includes not only employees, but also employers who could supervise and train about relevant safety concerns. Thus, manufacturers as well as distributors should ensure adequate safety information is supplied to employers to assist them in carrying out their hazard-control responsibilities. With respect to their product, manufacturers should tell employers what safety rules to enforce and to train.

Even with adequate information supplied by manufacturers and distributors to employers, it is not uncommon for safety training to be substandard. Often, training is given without any assessment of its effectiveness, both in training quality and whether employees benefit from it. A common training method is on-the-job training (OJT) given to junior employees by more skilled and seasoned employee(s), but not everything important for safety will come up in OJT training. These gaps need to be filled in some way, such as requiring the reading of pertinent material or giving classroom-type and/or video training based on a checklist of relevant safety-related concepts and procedures. These extra steps will provide more complete coverage than OJT alone. Also, re-training at some interval basis might be necessary, particularly when certain hazardous situations do not come up very often and may be forgotten or revised over time. Another important aspect of training is tests given after training. Testing is important to determine whether employees understand the trained information and can also reveal inadequacies in the instruction, which then can be corrected in future training. Testing methods can be poorly implemented as well. In particular, the tests should not be so easy that someone who were never adequately trained can get a passing score. In many safety-training programs, no formal testing is given, and in some cases, employees are only asked to sign an attendance sheet indicating that they received training.

Responsibility for Product Safety: Importers Need to Consider Safety

In the U.S., responsibility for adequate warnings is usually focused on the product manufacturer. Other do not have the same liability rules as the U.S. In world-wide open markets, products are commonly imported from other countries. U.S. courts have no jurisdiction outside of the U.S.; that is, non-U.S.-based manufacturers are usually out of reach from lawsuits filed in U.S. courts. As a consequence of this restriction, the entities that bring products made in other countries into the U.S., i.e., importers, are designated as the manufacturers in lawsuits—even though it did not physically carry out the process of putting the product together.

Thus, it is the importers' responsibility to check whether the product is safe for foreseeable and intended use by U.S. consumers. If it is not safe upon entry into the U.S., then importers need to decide whether to continue importing it or modify it in some way to make it safe. A common corrective method by importers is to add to or modify the instructions and warnings although not always. This seems reasonable because the non-U.S. company may not know the English language well or the U.S. culture with respect to product safety (including U.S. consumers' expectations and beliefs). However, it is sometimes forgotten that warnings cannot fix a defectively designed product. Thus, importers should do a hazard analysis with an awareness that design and guarding solutions are preferred over warning fixes.

Consumer who were not warned adequately could hold prior sellers responsible. Usually the manufacturer (or importer) is the most responsible for hazard control, but not always.

Sometimes, the distributor or seller could be considered responsible. Example is if the distributor or seller did not transfer necessary warnings issued by the product manufacturer to customers/ultimate users.

Thus, importers need to ensure that the products they are selling are safe, and if not, to correct the safety problems or decide not to put the product on the market. The Restatement of (Second) Torts (1965), which is a summary of the general principles of common law in the U.S. by the American Law Institute, makes a relevant point for this discussion: If a product needs warnings and instructions in order for it to be used safely, then the warnings and instructions are considered an inherent part of the product. It follows from this that if the necessary warnings are defective or absent, then the product is defective.

Importers, commonly, but not always, have products tested by one or more third-party testing laboratories to assess their compliance to U.S. laws and standards. However, importers cannot assume that a product is safe after a third-party testing laboratory gives it all passing scores. These testing labs hardly ever do user testing; they simply assess compliance to a limited set of regulations and standards that only cover certain aspects relevant to safety and other characteristics. The testing labs do not test what they are not asked to test. The fact that a product passes a set of tests may not be an adequate assessment for assessing aspects necessary for user safety.

Generally, retailers (sellers to consumers) are not responsible for end-user injury. Retailers rely on manufacturers and distributors to provide end users with a safe product (Williams, Kalsher, & Laughery, 2006). The exception is when the retailer has sophisticated knowledge about the product's deficiencies but does little or nothing to rectify the problem to prevent further harm. For example, a big-box retailer might receive complaints about young children falling out of a baby seat (e.g., see Chapter 6 by Mayhorn & Wogalter, 2019, in this volume) but never pass these reported adverse events on to the manufacturer (or importer). Another example is if a retailer does not remove the product from their shelves or does not post notices in stores that consumers who own the product would likely see. Moreover, the retailer may need to take reasonable steps to contact customers owning a recalled product for whom they have contact information. Sometimes, too, the manufacturer, importer, wholesaler, distributor, and retailer are the same entity.

Distribution of Safety Communications

Figure 2.3 illustrates a safety communication model representing the distribution of warning material from the manufacturer (sender) by way of other entities to consumers or users. In the case of a consumer product, the intervening entities might be wholesalers/ distributor and retailer/sellers. Thus, warnings may be passed on through each of these entities to get to the users of product or environment. To discharge their warning communication responsibility, each entity needs to pass on warning material so that appropriate safety information gets to the end user. There are also other routes—it may go from the (a) manufacturer to the distributor/retailer to the user, or (b) directly from the manufacturer to the user (as with a label attached to the product). Each of the intervening entities needs to discharge their responsibility for selling a safe product by effectively warning their customers and ultimate users at risk. Consumers/users who were injured and allege they were not adequately warned could claim the previous sellers in the chain of commerce including the distributor or seller are responsible if they did not adequately transfer warnings to the next entity in the chain of commerce. U.S. manufacturers, importers, distributors and other sellers need to ensure that ultimate users receive necessary safety warnings.



FIGURE 2.3 Distribution of warning information for consumers.



FIGURE 2.4

Distribution of warning information for employees.

A similar type of warning distribution model is applicable to employees at work (see also Laughery & Wogalter, 2010). Figure 2.4 shows that model with "employer" and "employee" in place of "seller/retailer" and "purchaser or user," respectively.

Discussion/Conclusions

Manufacturers need to identify hazards associated with foreseeable use and foreseeable misuse, then to control those hazards in effective ways; several methods were discussed.

The hazard control hierarchy (aka safety hierarchy) provides <u>some</u> principles and/or guidelines based on what is likely to be the more effective in preventing injury; that is, the basic design, guard, and warn priority scheme. As indicated with the seat recline example (Laughery & Wogalter, 2019, in this volume), decisions about whether and how to seek solutions based on alternative design, guarding, or warning may be complex. In addition to technological and economic feasibility, other factors come into play, such as secondary safety effects and customer preferences.

The hierarchy should not be viewed strictly as a priority scheme consisting of three options from which a selection can/must be made. It is more of a general preference scheme; it is based on what is likely to be most effective from a safety perspective. It is not an exclusion principle. Consider the situation where guarding involves a high fence around an electrical power station. If the guarding situation were perfect, then warnings would be unnecessary. However, this level of control is usually not attainable. Warnings are needed, at least, at entrances conveying (a) the danger of high voltage, (b) the potential for electrical shock and burn hazards, and (c) that unauthorized personnel not to enter. Even with excellent design and guarding, warnings may still be needed to deal with residual hazards not otherwise controlled.

References

Barnett, L. B., & Brickman, D. B. 1985. Safety hierarchy. Safety Brief, 3, 2. Niles, IL: Triodyne, Inc.

- Christensen, J. M. 1987. Comments on product safety. *Proceedings of the Human Factors Society*, 31, 1–12.
- Frantz, J. P., Rhoades, T. P., & Lehto, M. R. 1999. Practical considerations regarding the design and evaluation of product warnings. In M. S. Wogalter, D. M. DeJoy, K. R. Laughery, & K. R. (Eds.), *Warnings and risk communication* (pp. 291–311). London: Taylor & Francis.
- Hall, S. M., Young, S. L., Frantz, J. P., Rhoades, T. P., Burhans, C. G., & Adams, P. S. 2010. Clarifying the hierarchical approach to hazard control. In W. Karwowski, & G. Salvendy (Eds.), Advances in human factors, ergonomics and safety in manufacturing and service industries (pp. 1057–1064). Boca Raton, FL: CRC Press.
- Israelski, E. W., & Muto, W. H. 2012. Human factors risk management for medical products. In P. Carayon (Ed.), *Human Factors and Ergonomics in Health Care and Patient Safety* (2nd Edition), (pp. 475–505). Boca Raton, FL: CRC Press.
- Jenson, J. P., & Remmen, A. 2017. Enabling circular economy through product stewardship. *Procedia Manufacturing*, 8, 377–384.
- Karnes, E. W., Lenorovitz, D. R., & Leonard, S. D. 2010. Reliance on warnings as a sole remedy for certain product hazards: Some circumstance where that just does not work. In W. Karwowski, & G. Salvendy (Eds.) Advances in human factors, ergonomics and safety in manufacturing and service industries (pp. 1017–1027). Boca Raton, FL: CRC Press.
- Laughery, K. R., & Wogalter, M. S. 2006. Designing effective warnings. In R. Williges (Ed.) *Reviews* of human factors and ergonomics vol. 2 (pp. 241–271). Santa Monica, CA: Human Factors and Ergonomics Society.
- Laughery, K. R., & Wogalter, M. S. 2008. On the symbiotic relationship between warnings research and forensics. *Human Factors*, 50(3), 329–333.
- Laughery, K. R., & Wogalter, M. S. 2010. The safety hierarchy and its role in safety decisions. In W. Karwowski, & G. Salvendy (Eds.), Advances in human factors, ergonomics and safety in manufacturing and service industries (pp. 1010–1016). Boca Raton, FL: CRC Press. Also on CD ROM: ISBN-13: 978-0-9796435-4-5: ISBN-10_0-979-6435-4-6.

- Laughery, K. R., & Wogalter, M. S. 2019. Don't recline that seat (Chap 20, pp. 303–314). In M. S. Wogalter (Ed.), Forensic Human Factors & Ergonomics: Case Studies and Analyses. Boca Raton, FL: CRC Press.
- Lee, K. E., Mokhtar, M., Goh, C. T., & Hanafiah, M. M. 2015. A conceptual framework for the adoption and implementation of product stewardship in the chemical industries. *Procedia Environmental Sciences*, 30, 50–55.
- Lehto, M. R., & Salvendy, G. 1995. Warnings: A supplement not a substitute for other approaches to safety, *Ergonomics*, 38, 2155–2163.
- Leonard, S. D. 2006. Who really knows about reclining the passenger seat? *Proceedings of the Human Factors and Ergonomics Society*, 50, 855–859.
- Leonard, S. D., & Karnes, E. W. 1998. Perception of risk in automobiles: Is it accurate? *Proceedings of the Human Factors and Ergonomics Society*, 42, 1083–1087.
- Lenorovitz, D. R., Karnes, E. W., & Leonard, S. D. 2014. Mitigating certain hazards with just warnings: When and why such warnings are likely to fail. *Human Factors and Ergonomics in Manufacturing & Service Industries*, 24, 275–297.
- Mayhorn, C. B., & Wogalter, M. S. 2019. Case of the baby sitter with no restraint (Chap. 6, pp. 91–104). In M. S. Wogalter (Ed.), *Forensic Human Factors & Ergonomics: Case Studies and Analyses*. Boca Raton, FL: CRC Press.
- National Safety Council. 1989. Accident prevention manual for industrial operation (5th ed.). Chicago, IL: Author.
- National Safety Council. 1997. Accident prevention manual for business and industry: Administration and programs (11th ed.). Chicago, IL: Author.
- Paige, D. L. & Laughery, K. R. 2003. Risk perception: The effects of technical knowledge—or lack of it. *Proceedings of the XVth Triennial Congress of the International Ergonomics Association*. Seoul, Korea: International Ergonomics Association.
- Restatement (Second) of Torts § 390. 1965. American Law Institute.
- Rhoades, T. P., & Wisniewski, E. C. 2004. Judgments of risk associated with riding with a reclined seat in an automobile. *Proceedings of the Human Factors and Ergonomics Society*, 48, 1136–1139.
- Sanders, M. S., & McCormick, E. J. 1993. *Human factors in engineering and design* (7th ed.). New York: McGraw-Hill.
- U.S. Consumer Product Safety Commission. 2008. National Electronic Injury Surveillance System (NEISS) On-line. January 1, 2008—December 31, 2008. Product code 1842: Stairs, steps. https:// www.cpsc.gov/cgibin/NEISSQuery/home.aspx. Washington, DC: U.S. Consumer Product Safety Commission.
- U.S. Department of Labor. 2017. Occupational Safety and Health Administration (OSHA) Code of Federal Regulations, 29-CFR-1910.
- Williams, K. J., Kalsher, M. J., & Laughery, K. R. 2006. Allocation of responsibility for injuries. In M. S. Wogalter (Ed.), *Handbook of warnings* (pp. 617–628). Mahwah, NJ: Lawrence Erlbaum Associates (Boca Raton, FL: CRC Press).
- Wogalter, M. S. (Ed.). 2019a. Introduction (Chap. 1, pp. 3–16). In M. S. Wogalter (Ed.), Forensic Human Factors & Ergonomics: Case Studies and Analyses. Boca Raton, FL: CRC Press.
- Wogalter, M. S. (Ed.), 2019b. Communication-human information processing (C-HIP) model (Chap. 3, pp. 33–50). In M. S. Wogalter (Ed.), Forensic Human Factors & Ergonomics: Case Studies and Analyses. Boca Raton, FL: CRC Press.
- Wogalter, M. S., Brems, D. J., & Martin, E. G. 1993. Risk perception of common consumer products: Judgments of accident frequency and precautionary intent. *Journal of Safety Research*, 24, 97–106.
- Wogalter, M. S., Vigilante, W. J., & Baneth, R. C. 1998. Availability of operator manuals for used consumer products. *Applied Ergonomics*, 29, 193–200.
- Woods, D. D., Decker, S., Cook, R., Johannesen, L., & Sarter, N. 2010. *Behind human error* (2nd ed.). Burlington, VT: Ashgate.
- Young, S. L., Shaver, E., Grieser, B. C., & Hall, S. M. 2006. Hazard analysis as part of the safety development process (Chap. 32). In M. S. Wogalter (Ed.), *Handbook of warnings* (pp. 431–436). Mahwah, NJ: Lawrence Erlbaum Associates.