Quality Risk Management

Mental Modelling

Examples of exposure in everyday life

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ÜMİT H. KARTOĞLU, MD, DPH

Foreword

James Vesper, PhD, MPH
Rochester, New York
March 2017

One of the best things in visiting a favorite place with someone who has never been there is having them point out things that you have never seen or forgotten about. The new visitor calls to your attention little details hidden in a shadow or something so obvious that you have unconsciously ignored it.

In this book, *Quality Risk Management Mental Modelling: Examples of Exposure in Everyday Life*, Dr. Umit Kartoglu provides that set of new eyes to help us identify hazards, hazardous situations, and ways that risks can be lessened. He invites us to take a different, fresh perspective as we look at a wide range of routine situations that we encounter daily. As we do this, we are constructing for ourselves a mental model of risk and factors that affect risk. While mental models are important in helping us comprehend complex situations, if we don't have a correct model or one that is limited, our understanding can be deficient. Dr. Kartoglu's wide range of examples helps us develop a rich, robust mental model that can assist us when we think about risk and how it can be reduced.

And, at the same time that he is helping us develop a powerful mental model, we have the side benefit of learning a variety of quirky facts about stairway design, thermodynamics, "sleeping policeman", and specialized protective equipment for men. After reading this book you will never look at the baskets of spoons and forks offered at some restaurants in quite the same way.

Dr. Kartoglu proves that there can be joy in learning. We thank him for that and also for sharing his work with us through a Create Commons license.

Behind the pages

Ümit H. Kartoğlu, MD, DPH
Collonge-Bellerive
February 2017

Every year I coordinate an exceptional WHO course - Pharmaceutical Cold Chain Management on Wheels, including its authentic e-learning version. This course has been conceived to be carried out entirely with a risk-based approach. On a bus tour of 700 km we offer a comprehensive learning journey across quality logistics by visiting different levels of supply chain facilities, where risk assessment of the used processes is mindfully scrutinised. The course brings together both experts and novices from all over the world, who learn and share their experiences during a phenomenal six-day journey across Turkey or Greece. Since its beginnings in 2004, the course programme has been a living concept evolving around the most critical on-going issues and challenges of quality logistics, which are brought to a learning discussion and moderated by a team of top experts in the field of pharmaceuticals and quality management. Both the bus course and its e-version help participants to build mental models of every single relevant process with a special emphasis on quality risk management. When it comes to complex processes, such as pharmaceutical manufacturing or supply chain management, the challenge is how to help learners to build robust mental models.

Mental models are a set of tools that we use to think. They offer us frameworks that we can use to look at a problem or a process. Mental models help us to shape our behaviour, set an approach to doing specific tasks, as well as explain our own thought process about how the 'real' world works. Through mental models we see the relationships between different steps of a process, causations, and consequences.

In our course, we use preliminary risk analysis as well as 'backwards' evaluations with a lot of examples from everyday life, which help participants to better understand the linkages between hazard, harm and risk. It is rewarding to see how participants improve with each new facility visit and how well they conduct preliminary risk assessments at the end.

This book suggests taking a look at some of our daily routines from a risk management perspective in order to better understand the process.

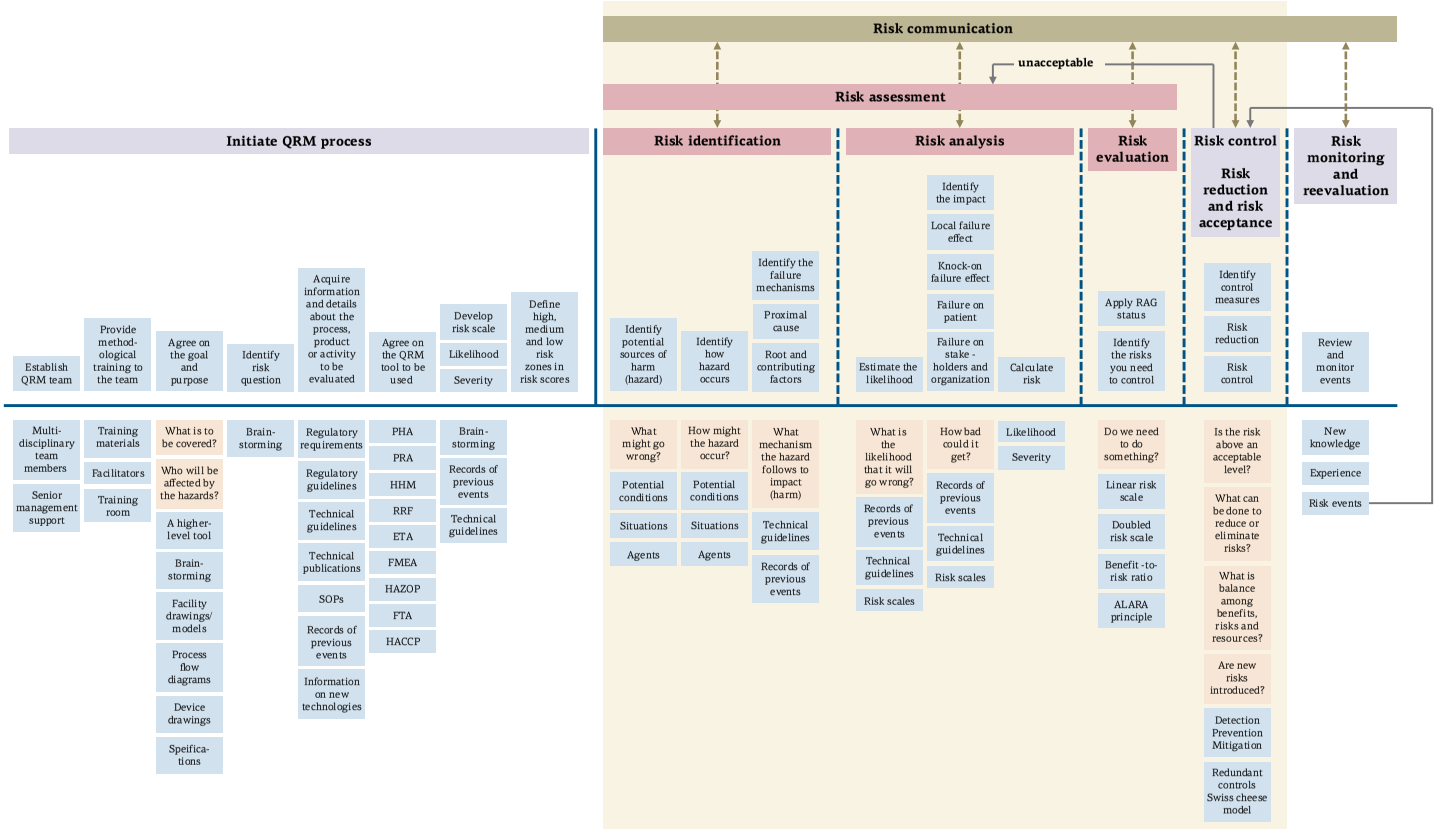
I worked on this book in the winter of 2016-2017 during weekends and after-office hours. Since all examples in this book are from everyday life, both my wife Nellie and my daughter Deniz Nala have kindly shared with me some of their reflections of quality risk management in everyday activities. I am grateful to both of them for their patience, love, support and especially their encouragement to go ahead with this publication. I am thankful to Jim, Kevin, Rafik, Ticky, Serge, Denis, Julie, the late Andrew, Henry, David, and Tom, my mentor colleagues from the wheels and e-learning courses, and the course participants who helped me build my own mental model in quality risk management. I am infinitely grateful to Amy and Ümran-Gökhan, who believe in the importance of this work.

Through the prism of risk assessment of simple examples of our daily routine, I am sharing a different approach in building mental models that have been proven to help others learn.

My mental model on quality risk management (QRM) is an analytical landscape that illustrates how I operate when working on quality risk management projects. It can be also regarded as a road map that ensures continuity in the QRM process.

My model, as all other mental models, has two parts. The steps that I follow are above the horizontal line, while the tools that I use as enablers are below. In addition, there are a few questions that I ask myself at certain steps.

In this book, I deliberate on the part of the process that is highlighted in the model on the next page, i.e. the control measures in place, the hazards they respond to and failure mechanisms, as well as illustrate how they relate to each other. I do not consider the *initiation of QRM process* nor do I refer to *risk monitoring and re-evaluation* because it would not be possible to elaborate on these stages unless you are a part of the team who comes up with the strategies relevant to these stages.


Risk communication
unacceptable
Risk assessment
Initiate QRM process
Risk identification
Risk analysis
Risk evaluation
Risk control
Risk reduction and risk acceptance
Risk monitoring and reevaluation
Establish QRM team
Provide method-ological training to the team
Agree on the goal and purpose
Identify risk question
Acquire information and details about the process, product or activity to be evaluated
Agree on the QRM tool to be used
Develop risk scale
Likelihood
Severity
Define high, medium and low risk zones in risk scores
Identify potential sources of harm (hazard)
Identify how hazard occurs
Identify the failure mechanisms
Proximal cause
Root and contributing factors
Estimate the likelihood
Identify the impact
Local failure effect
Knock-on failure effect
Failure on patient
Failure on stake - holders and organization
Calculate risk
Apply RAG status
Identify the risks you need to control
Identify control measures
Risk reduction
Risk control
Review and monitor events
Multi-disciplinary team members
Senior management support
Training materials
Facilitators
Training room
What is to be covered?
Who will be affected by the hazards?
A higher-level tool
Brain-storming
Facility drawings/ models
Process flow diagrams
Device drawings
Speifica-tions
Brain-storming
Regulatory requirements
Regulatory guidelines
Technical guidelines
Technical publications
SOPs
Records of previous events
Information on new technologies
PHA
PRA
HHM
RRF
ETA
FMEA
HAZOP
FTA
HACCP
Brain-storming
Records of previous events
Technical guidelines
What might go wrong?
Potential conditions
Situations
Agents
How might the hazard occur?
Potential conditions
Situations
Agents
What mechanism the hazard follows to impact (harm)
Technical guidelines
Records of previous events
What is the likelihood that it will go wrong?
Records of previous events
Technical guidelines
Risk scales
How bad could it get?
Records of previous events
Technical guidelines
Risk scales
Likelihood
Severity
Do we need to do something?
Linear risk scale
Doubled risk scale
Benefit -to-risk ratio
ALARA principle
Is the risk above an acceptable level?
What can be done to reduce or eliminate risks?
What is balance among benefits, risks and resources?
Are new risks introduced?
Detection Prevention Mitigation
Redundant controls Swiss cheese model
New knowledge
Experience
Risk events

Of course you will undeniably learn a lot by studying risk management publications related to your technical area, and excel by practice. But in my experience, one good way to build mental models is to read outside the norm. When I read or listen to something new and different, I always think of how this new information could connect with information I already know, or to my technical expertise. With my involvement in QRM, I have developed a habit of wearing 'risk spectacles' wherever I go and in whatever I do. Looking through such spectacles on the things that we typically consider as outside our technical areas reveals a deeper understanding about the issues around the risk management. I often look for answers in unexpected places.

In this book I invite you to wear my 'risk spectacles' at home, outside – on the way to your office, and at work. I hope you enjoy this book that is different from the classic risk management literature.

Contents

Abbreviations

°C	degree Celsius
£	British Pound
%	percent
$	US Dollars
AD	auto-disable
ANSES	The French Agency for Food, Environmental and Occupational Health and Safety
ASTM	American Society for Testing and Materials
A/V	audio/visual
BS	British Standards
CHF	Swiss Franc
CN	phenacyl chloride
CR	dibenzoxazepine
EN	European standard
EPELA	Extentio et Progressio – Authentic e-Learning
ESP	electrostatic precipitator
ETA	event tree analysis
FPP	finished pharmaceutical product
FMEA	failure mode and effects analysis
FTA	fault tree analysis
GLO	Global Learning Opportunities
GS	2-chlorobenzalmalononitrile
h	hour
HACCP	hazard analysis and critical control point

HAZOP	hazard and operability studies
HEPA	high-efficiency particulate arrestance
HIV	human immunodeficiency virus
HMM	hierarchical holographic modelling
ICH	International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IQ	installation qualification
ISO	International Organization for Standardization
IV	intra venous
kg	kilogram
km	kilometre
lb	pound
m	meter
m^2	square meter
ml	millilitre
MPCA	Minnesota Pollution Control Agency
mph	miles per hour
mK	meter kelvin
MSDS	material safety data sheet
NIR	near-infrared
NIOSH	National Institute for Occupational Safety and Health
OQ	operational qualification
oz	ounce
PCSO	Police Community Support Officer
PHA	preliminary hazard analysis
PQ	performance qualification
PQS	Performance, Quality and Safety (project of WHO)
PRA	preliminary risk analysis
QRM	quality risk management
RH	relative humidity
RRF	risk ranking and filtering
RMS	Royal Mail ship
SMS	short message service
UNICEF	United Nations Children's Fund
US	United States
USFDA	United States Food and Drug Administration
VVM	vaccine vial monitor
W	watt
WHO	World Health Organization

Glossary

For more information on definitions below,
visit http://epela.net/illustrated

CAPA (Corrective and preventive actions) system: A system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring *(ICH Q10)*. A structured approach to the investigation process should be used with the objective of determining the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, in line with ICH Q9 Quality Risk Management. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

Detectability: The ability to discover or determine the existence, presence, or fact of a hazard. *(ICH Q9)*

Fault tree analysis (FTA): A qualitative (and potentially quantitative), graphical, structured, deductive tool used to define a particular event and identify its causes. FTA uses Boolean logic to combine a series of lower-level events. FTA is most appropriate when trying to identify the potential root cause(s) of a real or hypothetical event. These root causes are called "basic events" in an FTA. The defined problem (unwanted event) for the FTA is the "top event".

Failure mode and effects analysis (FMEA): A qualitative (semi-quantitative or quantitative), structured, inductive risk assessment tool used to identify known and potential failure modes of facilities, systems, products, equipment, or components, as well as to identify the failure's impact. Failure mode, effects, and criticality analysis (FMECA) is a slightly expanded version of the FMEA with the main difference in the calculation of the "risk priority number".

Harm: Damage to health, including the damage that can occur from loss of product quality or availability. *(ICH Q9)*

Hazard: The potential source of harm. *(ISO 14971:2000)*

Hazard Analysis and Critical Control Point (HACCP): A systematic, proactive and preventive tool for the identification, assessment and control of safety hazards. It is a structured approach that applies technical and scientific principles to analyze, evaluate, prevent, and control the risk or adverse consequence(s) of hazard(s) due to the design, development, production, and use of products.

Hazard and Operability Studies (HAZOP): A qualitative, highly structured inductive tool used to identify, consider, and reduce risks related to the materials, equipment, and operation involved with a process or system. It is usually carried out by a suitably experienced multi-disciplinary team (HAZOP team) during a set of meetings. The amount of information needed to conduct a HAZOP is substantial; it is highly recommended that other risk assessment tools should be use prior to HAZOP to eliminate some of the more obvious risks. HAZOP is best suited for assessing hazards in facilities, equipment, and processes. It is capable of assessing systems from multiple perspectives such as design, physical and operational environments and operational and procedural controls. In this regard, very detailed process flows and instrumentation drawings or piping are needed to conduct a HAZOP. HAZOP could also be used for new processes and/or for facilities that are being designed.

Hierarchical holographic modelling (HHM): A methodological framework to identify, prioritize, assess, and manage risk scenarios of a large-scale system. The modelling includes both qualitative and quantitative aspects. It is usually used as the preparatory step to "risk filtering and ranking". S. Kaplan defines eight phases in HHM which reflect a philosophical approach rather than a mechanical methodology. In this philosophy, the filtering and ranking of discrete scenarios is viewed as a precursor to, rather than a substitute for, consideration of the totality of all risk scenarios.

Human error: All those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to some change agency (*J.T. Reason*). Action by human operators can fail to achieve the goal in two different ways: The actions can go as planned, but the plan can be inadequate or the plan can be satisfactory but the performance can be deficient (*E. Hollagel*).

Humidity (relative humidity (RH)): The partial pressure of water vapour in air to the vapour pressure of saturated air at a given temperature. In other words, the RH is the amount of water vapour present, divided by the theoretical amount of moisture that could be held by that volume of air at a given temperature.

ICH: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - ICH's mission is to make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.

Launched in 1990, ICH is a unique undertaking that brings together the drug regulatory authorities and the pharmaceutical industry of Europe, Japan and the United States.

Regulatory harmonization offers many direct benefits to both regulatory authorities and the pharmaceutical industry with beneficial impact for the protection of public health. Key benefits include: preventing duplication of clinical trials in humans and minimising the use of animal testing without compromising safety and effectiveness; streamlining the regulatory assessment process for new drug applications; and reducing the development times and resources for drug development.

Harmonization is achieved through the development of ICH Tripartite Guidelines. The Guidelines are developed through a process of scientific consensus with regulatory and industry experts working side-by-side. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.

ICH harmonization activities fall into four categories: Formal ICH Procedure, Q&A Procedure, Revision Procedure and Maintenance Procedure, depending on the activity to be undertaken.

Installation qualification (IQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems have been provided and installed in compliance with their design specifications. (*WHO*)

Last mile: Last mile is the final leg of the supply chain that is between a service point and a customer, as it is often the least efficient link in the supply chain. By definition, it does not need to be a mile. For example, when you order a product from an online distributor located in another country and the product is sent directly to you, this is the last mile. In another example, when you ask your pharmacy for your prescription to be delivered to your home, this is the

last mile. In health services, two approaches are used in last mile; active and passive. An immunization programme uses an active approach, when a child does not come for a scheduled vaccination session, the programme follows the person to reach and vaccinate. By contrast, retail pharmacies use a passive approach, they wait for patients to come with their prescriptions.

Operational qualification (OQ): The process of obtaining and documenting evidence, under controlled conditions, that the premises, equipment and supporting systems operate in accordance with their design specifications. (*WHO*)

Pallet: Wooden or plastic platform designed to be lifted by pallet jack or forklift truck. Typically used for storing and handling tertiary cartons.

Since pallets form an important part in the maritime industry, several norms and measures have been established by the ISO (International Organization for Standardization). Through such norms, it has been sought to bring the entirety of the freight operations which palletize their cargo consignments under a wider and common spectrum. The normative standardization for pallets has been regulated in their sizing. Pallet sizes matter hugely while loading on palletized cargo ships as depending on the nature of the cargo, the optimal sized pallet is utilised to support the cargo consignments.

Performance qualification (PQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications. (*WHO*)

Performance, Quality and Safety (PQS): A WHO project to establish performance specifications, test procedures and prequalify a comprehensive range of immunization equipment, injection devices and other products needed for safe and effective immunization delivery.

The PQS on-line catalogue includes details of all immunization-related products currently pre-qualified by WHO for procurement by United Nations agencies. The catalogue replaces the old WHO/UNICEF Product Information Sheets (PIS), the last edition of which was published in 2000. Only products included in the PQS catalogue are now recommended to be purchased by UN agencies. The catalogue and the individual product data sheets are available on the internet only at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx

There is no hardcopy version. Each edition of the catalogue is date-stamped. It is updated regularly to ensure that the information it contains is current.

Preliminary Hazard Analysis (PHA): A tool that is used to determine if a particular, potential agent could be a hazard – a source of harm to something of value such as the defined critical quality attributes of a product (*J. Vesper*).

Preliminary Risk Analysis (PRA): A qualitative, inductive, loosely structured tool that can be used to identify, consider, and reduce risks early in a new or changed process. A PRA can be done at early stages of conceptual design of a product or process. Because it is relatively easy to conduct and quite unstructured, it is the recommended first step in trying to assess risks in a new product or process. Results from a PRA may lead to the use of more extensive and specific risk assessment tools for more detailed analysis. The most common approach in PRA is to study existing hazards and then examine how the hazards could be expressed, what the impact would be and the probability of occurrence. On the contrary to FMEA/FMECA, detectability of the hazard is not taken into account in typical PRA/PHA.

Quality: The degree to which a set of inherent properties of a product, system or process fulfills requirements. (ICH Q9)

Quality management system (QMS): A set of policies, processes and procedures required for planning and execution in the core business area of an organization that can impact an organization's ability to meet customer requirements. QMS is not a group of documents; it is an entire system whose documents are used to describe the system. ISO 9001:2015 is an example of QMS. The eight QMS principles on which the quality management standards of the ISO 9000 series are based can be used by senior management as a framework to guide its organization towards improved performance. (*ISO*)

Quality risk management: A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle. (*ICH Q9*) Quality risk management is integral to an effective pharmaceutical quality system. It can provide a proactive approach to identifying, scientifically evaluating and controlling potential risks to quality.

R-value (insulation): A measure of thermal resistance, expressed as the ratio of the temperature difference across an insulator and the heat flux (heat transfer per unit area per unit time, Q_A) through it or $R=\Delta T/Q_A$. Although thermal resistance varies with temperature, it is usually treated as a constant value. The higher the value of R, the better is the insulation material's theoretical effectiveness.

Risk: The combination of the probability of occurrence of harm and the severity of that harm. (*ISO 14971:2000*)

Risk analysis: The estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms. In some risk management tools, the ability to detect the harm (detectability) also factors in the estimation of risk. (*ICH Q9*)

Risk assessment: A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards. Quality risk assessments begin with a well-defined problem description or risk question. When the risk in question is well defined, an appropriate risk management tool and the types of information needed to address the risk question will be more readily identifiable. (*ICH Q9*)

As an aid to clearly defining the risk(s) for risk assessment purposes, three fundamental questions are often helpful:

1. What might go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)?

Risk communication: The sharing of information about risk and risk management between the decision maker and other stakeholders. (*ICH Q9*)

Risk control: Actions implementing risk management decisions. (*ISO Guide 73*)

Risk evaluation: The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk. (*ICH Q9*)

Risk control might focus on the following questions:

- Is the risk above an acceptable level?
- What can be done to reduce or eliminate risks?
- What is the appropriate balance among benefits, risks and resources?
- Are new risks introduced as a result of the identified risks being controlled?

Risk identification: The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description. Risk identification addresses the "What might go wrong?" question, including identifying the possible consequences. This provides the basis for further steps in the quality risk management process. (*ICH Q9*)

Risk management: The systematic application of quality management poli-

cies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk. (*ICH Q9*)

Risk management framework: A set of components that support and sustain risk management throughout an organization. (*ISO 31000*) In risk management framework there are two types of components: foundations and organizational arrangements. Foundations include risk management policy, objectives, mandate, and commitment. Organizational arrangements include the plans, relationships, accountabilities, resources, processes, and activities used to manage organization's risk.

Risk management process: One that systematically applies management policies, procedures, and practices to a set of activities intended to establish the context, communicate and consult with stakeholders, and identify, analyze, evaluate, treat, monitor, and review risk. (*ISO 31000*)

Risk matrix: A matrix that is used during risk assessment to define the various levels of risk as the product of the harm probability categories and harm severity categories. The two-criterion model of severity and probability based matrix is a typical risk matrix. See *risk scales*.

Risk ranking and filtering (RRF): Risk ranking and filtering is a tool for comparing and ranking risks. Risk ranking of complex systems typically requires evaluation of multiple diverse quantitative and qualitative factors for each risk. The tool involves breaking down a basic risk question into as many components as needed to capture factors involved in the risk. These factors are combined into a single relative risk score that can then be used for ranking risks. "Filters," in the form of weighting factors or cut-offs for risk scores, can be used to scale or fit the risk ranking to management or policy objectives. (*ICH Q9*)

Stability budget: A stability budget considers long term, accelerated, and stress temperature exposure, as well as temperature cycling studies to determine the amount of time out of storage that a drug product may experience without any significant risk to its quality. (*PDA*) Temperature sensitive products may have limited time that they can be exposed to temperature outside label storage conditions and still meet quality attributes through expiry. The stability budget ensures product will meet shelf life specifications given end to end time out of storage requirements.

Swiss cheese model: Redundant barriers intended to minimize risk of human errors as defined by Dante Orlandella and James T. Reason of the University of

Manchester. It is widely used in aviation, engineering, healthcare, computer security and defence.

The control measures (barriers) that are put in place intended to minimize the risk do not provide complete prevention, this is why redundant controls are necessary to minimize the risk. Like slices of Swiss cheese, the control measures also have holes in them. The system produces failures when a hole in each slice momentarily aligns, permitting (in J.T. Reason's words) "a trajectory of accident opportunity", so that a hazard passes through holes in all of the slices, leading to a failure.

Time-temperature integrators (TTIs): Are generally chemically impregnated onto a pulp or paperboard substrate. Their reaction rate or diffusion process is used to estimate a temperature equivalent integrated over time. Thus, TTIs provide a measure of accumulated heat rather than instantaneous temperature such as a spike or critical threshold (see chemical indicators). The reactions are irreversible - once a color change, color development, or diffusion process has taken place, exposure to low temperatures will not restore the indicator to its original state. They change color, or are marked by a hue progression in intensity (generally from light to dark) in response to cumulative changes in temperature, such as heat, at a rate dependent on the Arrhenius equation. A TTI accumulates all of the temperature conditions experienced by the product to which it is affixed. The color development can be customized based on the known stability of the product, and in much the same way that most biologicals and pharmaceuticals degrade when exposed to heat - faster at higher temperatures, and slower at lower temperatures.

Vaccine vial monitor (VVM): A label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the vaccine vial monitor to darken gradually and irreversibly. A direct relationship exists between the rate of color change and temperature: the lower the temperature, the slower the color change; the higher the temperature, the faster the color change. VVM is the only tool among all time temperature indicators that is available at any time in the process of distribution and at the time a vaccine is administered indicating whether the vaccine has been exposed to a combination of excessive temperature over time and whether it is likely to have been damaged.

Water-pack: Flat plastic container, filled with water, which can be used as a frozen water-pack (ice-pack), a cool water-pack or a warm water-pack. (*WHO*)

Introduction and Overview

Although the concept of risk has been studied for centuries in many fields and applied in various businesses over decades, its formal introduction to pharmaceutical industry is not so old. It was only in 2005 that the International Conference on Harmonisation (ICH) formally introduced Quality Risk Management (QRM) with the publication of ICH Harmonised Tripartite Guideline on Quality Risk Management Q9. The guideline provided principles and examples of tools for QRM that can be applied to different aspects of pharmaceutical quality. These aspects included development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substances, drug (medicinal) products, biological and biotechnological products (including the use of raw materials, solvents, excipients, packaging and labelling materials in drug (medicinal) products, biological and biotechnological products).

By the time ICH Q9 was introduced, there were some examples of the use of quality risk management in the pharmaceutical industry, but they were extremely limited and did not represent the full contributions that risk management had to offer. The ICH Q9 Guideline brought a systematic approach to QRM by providing guidance on the principles and some of the tools of QRM that can enable more effective and consistent risk-based decisions, both by regulators and industry, regarding the quality of drug substances and drug products across the product lifecycle. Although it was assumed by the industry that the intention was to create new expectations beyond the current regulatory requirements, this was not the case. The ICH Q9 brought discipline to the business by underlying two critical principles:

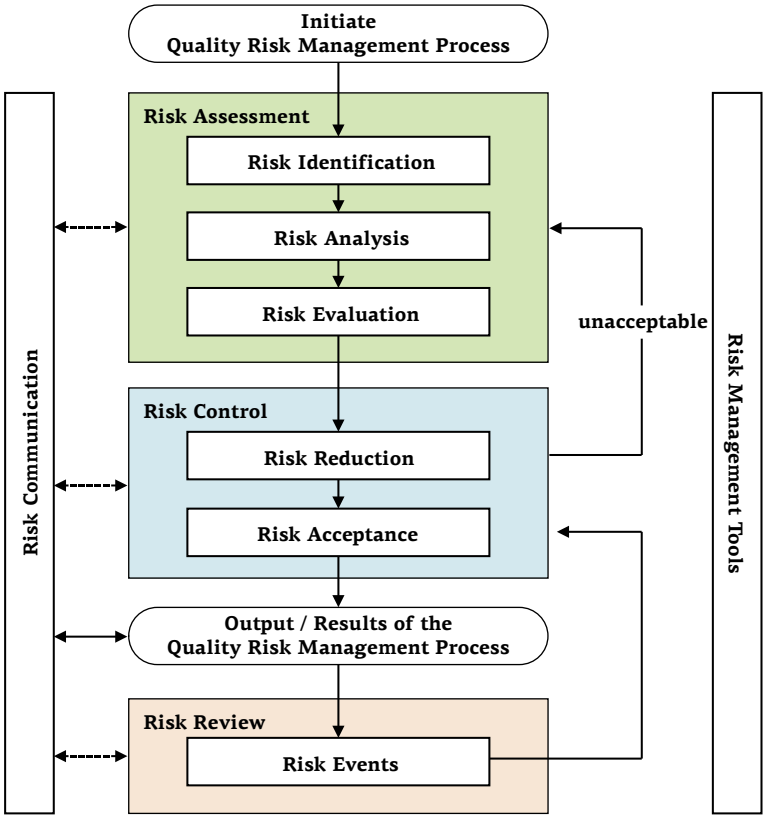
- Evaluation of risk to quality should be based on scientific knowledge and ultimately link to protection of a patient; and
- The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk.

Risk management process

The ICH Q9 defines risk management as a systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk.

As seen in the definition, quality risk management compromised of four major activities: assessing, controlling, communicating and reviewing the risk. This can be illustrated as shown in the following figure.

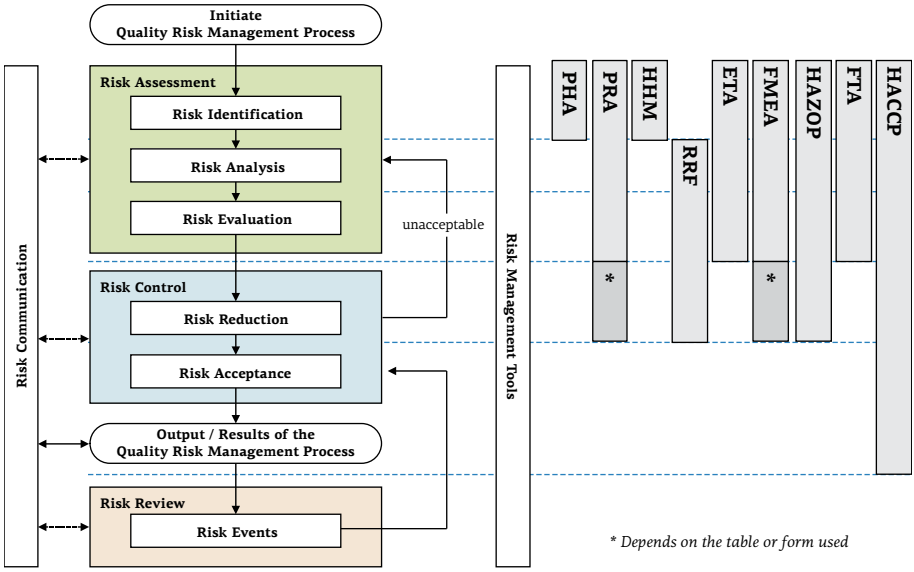
Overview of a typical quality risk management process (ICH Q9)



Quality risk management activities are usually undertaken by interdisciplinary teams. Teams should include experts from the appropriate areas (e.g. quality unit, business development, engineering, regulatory affairs, production operations, sales and marketing, legal, statistics and clinical) in addition to individuals who are knowledgeable about the quality risk management process. Although risk assessment can be done individually, interdisciplinary teams always bring invaluable benefits both to the process and the outcomes.

QRM includes systematic processes that are designed to coordinate, facilitate and improve science-based decision making with respect to risk. During risk assessment we identify the hazards and do the analysis and evaluation of risks associated with exposure to those hazards. The assessment begins with a well-defined problem description or risk question. This keeps the teams on track. For every new hazard that is identified and entered on the list, it is always a good practice to revisit the risk question to make sure the team is not off the track. When the risk in question is well defined, the most appropriate risk management tool and the types of information needed to address the risk question will be more readily identifi-

Risk management process and tools used (J. Vesper)



PHA (preliminary hazard analysis); PRA (preliminary risk analysis); HHM (hierarchical holographic modelling); RRF (risk ranking and filtering); ETA (event tree analysis); FMEA (failure mode and effects analysis); HAZOP (hazard and operability studies); FTA (fault tree analysis); HACCP (hazard analysis and critical control point)

able. Without relevant background information and/or data (historical data, theoretical analysis, informed opinions, and the concerns of stakeholders) on the potential hazard, harm or human health impact relevant to the risk assessment, the teams cannot base their decisions on evidence and science.

The figure on page 5 shows how risk management tools apply to different stages of risk management process.

In risk assessment, we ask three fundamental questions:

1. What might go wrong?
2. What is the likelihood (probability) that it will go wrong?
3. What are the consequences (severity)?

Although these are fundamental questions in any risk assessment, in some tools, the ability to detect the harm (detectability) is also considered in the estimation of the risk.

Risk is defined as a combination of the probability of occurrence of harm and the severity of that harm by ISO 14971:2000. Some tools, e.g. failure mode and effects analysis, FMEA, take "detectability" into account to calculate the risk priority number (probability x severity x detectability).

The output of a risk assessment is usually a quantitative estimate of risk, though a qualitative description of a range of risks can also be used. Regardless of how the risk is expressed, a risk matrix may be used to define the various levels of risk as the product of the harm probability categories and harm severity categories. The two-criterion model of severity and probability based matrix is a typical risk matrix.

Example of a two-factor risk matrix

		PROBABILITY		
		Low	Medium	High
SEVERITY	High potential impact	Medium risk	High risk	High risk
	Medium potential impact	Medium risk	Medium risk	High risk
	Low potential impact	Low risk	Low risk	Medium risk

Another way of using qualitative descriptors of risk estimation is to use linear or doubled risk scales. As same linear scales can be used for both likelihood of occurrence and severity of consequence, a doubled risk scale may be used especially for severity element as it gives more weight to risks with a high impact. A risk with a low probability but a high impact is thus viewed as much more severe than a risk with a high probability and a low impact. This avoids any averaging out of serious risks.

Linear and doubled risk scales used in PRA/PHA

		SEVERITY				
		1	2	3	4	5
PROBABILITY	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5

Linear risk scale

		SEVERITY				
		1	2	4	8	16
PROBABILITY	5	5	10	20	40	80
	4	4	8	16	32	64
	3	3	6	12	24	48
	2	2	4	8	16	32
	1	1	2	4	8	16

Doubled risk scale

In this regard, red risks are unacceptable and have priority in response strategy. Amber risks are moderate risks having secondary priority while green risks are acceptable (but this does not mean they can be ignored - they should be addressed at least through means of contingency).

Whatever scale is used, numbers should be explained clearly as to what they correspond to. For likelihood (probability), terms should be more observable and countable. As for severity, the impact needs to be spelled out. For example, for home injuries the following risk scales may be used.

	Scale				
	1	2	3	4	5
Severity	Minor non-immobilizing injury or trauma not requiring hospital treatment	Non-immobilizing injury or trauma but requiring hospital treatment	Immobilizing injury or trauma requiring hospital treatment	Severe injury or trauma requiring urgent hospital treatment	Very severe life-threatening event
Likelihood	One occurrence in more than one year	One occurrence every 6-12 months	One occurrence every 3-6 months	One occurrence every month	More than one occurrence every month

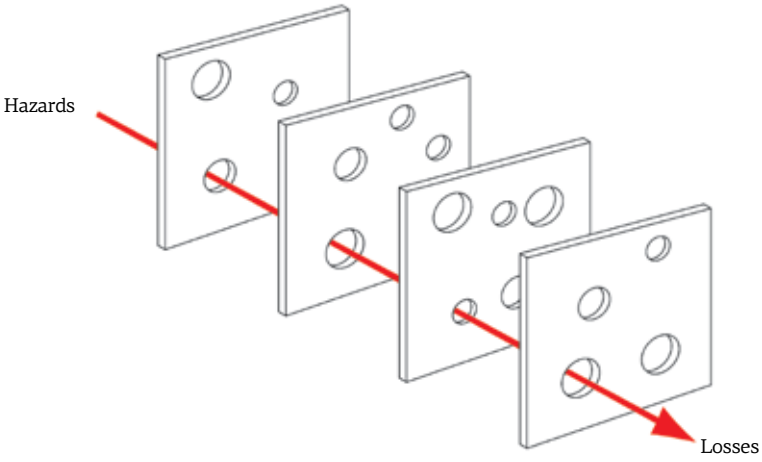
Risk treatment

Risk treatment is a process of selecting and implementing of measures to modify risk. Risk treatment measures can include avoiding, reducing, optimizing, transferring or retaining risk. Once the treatment is being implemented, it becomes a control and/or it modifies existing controls. ISO 31000:2009 gives a list on how to deal with risk:

- Avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk
- Accepting or increasing the risk in order to pursue an opportunity
- Removing the risk source
- Changing the likelihood
- Changing the consequences
- Sharing the risk with another party or parties (including contracts and risk financing)
- Retaining the risk by informed decision

The control measures (barriers) that are put in place intended to minimize the risk do not provide complete prevention, this is why redundant controls are necessary to minimize the risk. Similar to slices of Swiss cheese, the control measures also have holes in them. The system produces failures when a hole in each slice momentarily aligns, permitting (in J.T. Reason's words) "a trajectory of accident opportunity", so that a hazard passes through holes in all of the slices, leading to a failure.

Swiss cheese model



Here is a good example of redundant controls. The sun before you is so bright that you cannot see well. Of course the very first control measure that comes to mind is sunglasses. But do they always work?

Redundant controls to overcome impact of direct sun in viewing

In this photo you see four control measures, two of them failing. Of course both cap and the sunglasses may work perfectly, but we should not underestimate human errors in application of control measures.

Here, it would be worthwhile to discuss the nature of control measures. Some control measures automatically kick in when the hazard is present. For example, nobody needs to activate anything for airbags (mitigation control measure) to pop up in case of a car accident with impact (hazard). Another example would be warnings on the status of oil level, tyre pressure level, and so on. If we take low tyre pressure as an example, the monitoring tool (detection control measure) sends an alarm to the dashboard when the pressure level in the tyre is lower (hazard) than the normal value. Some control measures require compliance by the users. For example, headlights (detection control measure) in the car are for detection and must be switched on when it is dark (hazard), though some countries require headlights on all the time. If the headlights are not automatically switched on when you start the car, they need to be put on manually. Drivers without headlights on during twilight are a good example of demonstrating the compliance problem by the users.

Selecting controls is not an easy task. Every situation must be studied in depth completely and carefully. The following factors should always be considered when making decisions on which control measures to select:

- Feasibility
- Cost
- Benefits
- Residual risks
- Additional risks
- Sustainability
- Impact on stakeholders
- Compliance with regulatory requirements

In some cases, control measures may create new hazardous situations. Use of ice packs as coolant to keep the temperature of a cold box within the targeted range is a *preventive measure*, but at the same time ice packs turn into *hazard* for freeze-sensitive products.

Risk monitoring

Risk monitoring is the process of tracking and evaluating the levels of risk and effectiveness of risk management strategies. The outcome of risk monitoring can be used to create new strategies and removing older ones which may have proved to be ineffective. Risk monitoring ensures that introduced risk controls are achieving

their intended purpose. It also confirms that the assumptions used in the risk analysis were correct. Undetermined hazards could also become apparent and recognized during risk monitoring.

Risk communication

ICH Q9 defines risk communication as sharing of information about risk and risk management between the decision maker and other stakeholders. Risk communication is the act of conveying or transmitting information between parties about a range of areas that include levels of risks, significance or meaning of risks and decisions, actions or policies aiming at managing and controlling risks. It is an integral part of risk management process and brings transparency.

When to carry risk assessment?

Risk assessment should be carried out whenever a new process is introduced; a process is changed; or failed (as part of corrective and preventive action).

ICH Q9 defines the following areas as potential applications for QRM:

Main area	Activities	Potential uses
Integrated quality management	Documentation	• To review current interpretations and application of regulatory expectations • To determine the desirability of and/or develop the content for SOPs, guidelines, etc.
	Training	• To determine the appropriateness of initial and/or ongoing training sessions based on education, experience and working habits of staff, as well as on a periodic assessment of previous training (e.g. its effectiveness) • To identify the training, experience, qualifications and physical abilities that allow personnel to perform an operation reliably and with no adverse impact on the quality of the product
	Quality defects	• To provide the basis for identifying, evaluating, and communicating the potential quality impact of a suspected quality defect, complaint, trend, deviation, investigation, out of specification result, etc. • To facilitate risk communications and determine appropriate action to address significant product defects, in conjunction with regulatory authorities (e.g. recall)
	Auditing/ Inspection	• To define the frequency and scope of audits, both internal and external
	Periodic review	• To select, evaluate and interpret trend results of data within the product quality review • To interpret monitoring data (e.g. to support an assessment of the appropriateness of revalidation or changes in sampling)

Main area	Activities	Potential uses
Integrated quality management	Change management	• To manage changes based on knowledge and information accumulated in pharmaceutical development and during manufacturing • To evaluate the impact of the changes on the availability of the final product • To evaluate the impact on product quality of changes to the facility, equipment, material, manufacturing process or technical transfers • To determine appropriate actions preceding the implementation of a change, e.g. additional testing, (re) qualification, (re)validation or communication with regulators
	Continual improvement	• To facilitate continual improvement in processes throughout the product lifecycle
Regulatory operations	Inspection and assessment	• To assist with resource allocation including, for example, inspection planning and frequency, and inspection and assessment intensity • To evaluate the significance of, for example, quality defects, potential recalls and inspectional findings • To determine the appropriateness and type of post-inspection regulatory follow-up • To evaluate information submitted by industry including pharmaceutical development information • To evaluate impact of proposed variations or changes • To identify risks which should be communicated between inspectors and assessors to facilitate better understanding of how risks can be or are controlled (e.g. parametric release, Process Analytical Technology (PAT))
Development		• To design a quality product and its manufacturing process to consistently deliver the intended performance of the product (see ICH Q8) • To enhance knowledge of product performance over a wide range of material attributes (e.g. particle size distribution, moisture content, flow properties), processing options and process parameters • To assess the critical attributes of raw materials, solvents, Active Pharmaceutical Ingredient (API) starting materials, APIs, excipients, or packaging materials • To establish appropriate specifications, identify critical process parameters and establish manufacturing controls (e.g. using information from pharmaceutical development studies regarding the clinical significance of quality attributes and the ability to control them during processing) • To decrease variability of quality attributes • Reduce product and material defects • Reduce manufacturing defects • To assess the need for additional studies (e.g. bioequivalence, stability) relating to scale up and technology transfer • To make use of the “design space” concept (see ICH Q8)

Main area	Activities	Potential uses
Facilities, equipment and utilities	Design of facility/ equipment	• To determine appropriate zones when designing buildings and facilities (e.g. flow of material and personnel, minimize contamination, pest control, prevention of mix-ups, open vs. closed equipment, clean rooms, isolator technologies, dedicated or segregated facilities/equipment) • To determine appropriate product contact materials for equipment and containers (e.g. selection of stainless steel grade, gaskets, lubricants) • To determine appropriate utilities (e.g. steam, gases, power source, compressed air, heating, ventilation and air conditioning (HVAC), water) • To determine appropriate preventive maintenance for associated equipment (e.g. inventory of necessary spare parts)
	Hygiene aspects in facilities	• To protect the product from environmental hazards, including chemical, microbiological, and physical hazards (e.g., determining appropriate clothing and gowning, hygiene concerns); • To protect the environment (e.g., personnel, potential for cross-contamination) from hazards related to the product being manufactured.
	Qualification of facility/ equipment/ utilities	• To determine the scope and extent of qualification of facilities, buildings, and production equipment and/or laboratory instruments (including proper calibration methods)
	Cleaning of equipment and environ-mental con-trol	• To differentiate efforts and decisions based on the intended use (e.g. multi- versus single-purpose, batch versus continuous production) • To determine acceptable (specified) cleaning validation limits
	Calibration/ preventive maintenance	• To set appropriate calibration and maintenance schedules
	Computer systems and computer controlled equipment	• To select the design of computer hardware and software (e.g. modular, structured, fault tolerance) • To determine the extent of validation (e.g. Identification of critical performance parameters; selection of the requirements and design; code review; the extent of testing and test methods; reliability of electronic records and signatures)

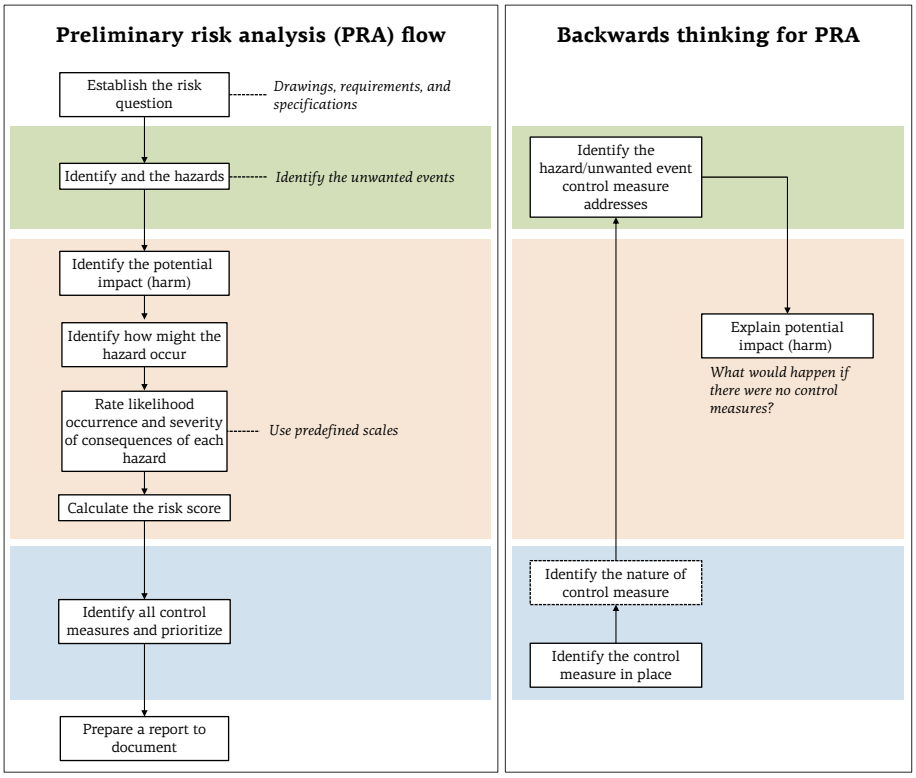
Main area	Activities	Potential uses
Materials management	Assessment and evaluation of suppliers and contract manufacturers	• To provide a comprehensive evaluation of suppliers and contract manufacturers (e.g. auditing, supplier quality agreements)
	Starting materials	• To assess differences and possible quality risks associated with variability in starting materials (e.g. age, route of synthesis)
	Use of materials	• To determine whether it is appropriate to use material under quarantine (e.g. for further internal processing) • To determine appropriateness of reprocessing, reworking, use of returned goods
	Storage, logistics and distribution conditions	• To assess the adequacy of arrangements to ensure maintenance of appropriate storage and transport conditions (e.g. temperature, humidity, container design) • To determine the effect on product quality of discrepancies in storage or transport conditions (e.g. cold chain management) in conjunction with other ICH guidelines • To maintain infrastructure (e.g. capacity to ensure proper shipping conditions, interim storage, handling of hazardous materials and controlled substances, customs clearance) • To provide information for ensuring the availability of pharmaceuticals (e.g. ranking risks to the supply chain)
Production	Validation	• To identify the scope and extent of verification, qualification and validation activities (e.g. analytical methods, processes, equipment and cleaning methods • To determine the extent for follow-up activities (e.g. sampling, monitoring and re-validation) • To distinguish between critical and non-critical process steps to facilitate design of a validation study
	In-process sampling and testing	• To evaluate the frequency and extent of in-process control testing (e.g. to justify reduced testing under conditions of proven control) • To evaluate and justify the use of process analytical technologies (PAT) in conjunction with parametric and real time release
	Production planning	• To determine appropriate production planning (e.g. dedicated, campaign and concurrent production process sequences)
Laboratory control and stability studies	Out of specification results	• To identify potential root causes and corrective actions during the investigation of out of specification results
	Retest period / expiration date	• To evaluate adequacy of storage and testing of intermediates, excipients and starting materials

Main area	Activities	Potential uses
Packaging and labelling	Design of packages	• To design the secondary package for the protection of primary packaged product (e.g. to ensure product authenticity, label legibility)
	Selection of container closure system	• To determine the critical parameters of the container closure system
	Label controls	• To design label control procedures based on the potential for mix-ups involving different product labels, including different versions of the same label

Thinking backwards

Although risk assessment is carried out by defining the risk question first and identifying the hazards, their likelihood of occurrence and severity and finally defining control measures either to detect, prevent or mitigate the risk, a backward

Typical flow of a risk assessment (based on PRA) and how backwards analysis work (Kartoglu)



thinking for already designed and implemented risk treatments can be effectively used to better understand how quality risk management works. In the EPELA authentic e-learning course on pharmaceutical cold chain management, participants practice risk assessments using a preliminary risk assessment (PRA) tool with various risk questions as well as watching a video to spot the control measures in place and think backwards to identify their nature (detection, prevention or mitigation) of the measure and the hazard they respond to. This helps participants to better define hazards in forthcoming tasks.

Hacettepe University Hospitals pharma store

Defining the hazards correctly may sound an easy task, but it might be quite challenging especially for newcomers to QRM. Here is one example from the EPELA e-pharmaceutical cold chain management course:

We ask participants to watch a facility video of a university hospital in which they observe the cold chain operation at the main pharma storage area (refer to 00:54 to 01:33 sec for main pharma storage area operations).

https://vimeo.com/54547081

In addition to what they see in the video, we give the following information to participants:

- The storage facility is located in the basement of the hospital
- In-built digital thermometer is used for each refrigeration unit

- Alarms set for below 2°C and above 8°C for more than five minutes continuous excursion
- Alarm type is only audio (sound alarm) that can only be heard within the immediate area
- Storage facility works from 9am to 5pm, and closed at nights and weekends
- Temperature records are kept manually on a form that is attached in a transparent folder on each refrigeration unit
- Temperatures are recorded manually twice a day, morning and afternoon
- Temperature records are kept for three years in archive
- Storage facility is supervised by head pharmacist who works in the main hospital pharmacy

We give a "newly appointed head pharmacist" hat to participants to conduct a risk assessment of the current practices. We tell them that they are concerned about the way temperature is monitored in the storage facility for temperature-sensitive products. For the assignment, they are requested to conduct a detailed risk assessment using a PRA form on temperature monitoring of products at the storage facility. The risk question is also given to them as "what are the risks of using refrigerators that are equipped with non-recording temperature monitoring systems and with local sound alarms". Participants are asked to work in groups of three.

Many groups indicate "temperature excursion" as the first hazard in their PRA worksheet. Is temperature excursion really the hazard here? Let's revisit some definitions before we delve into this.

When it comes to hazard (unwanted event) and harm, we need to be very clear. ICH Q9 defines harm as "damage to health, including the damage that can occur from loss of product quality or availability" and hazard is defined as "potential source of harm" by ISO/IEC Guide 51. In simple terms, hazard is the ***banana peel*** on the floor, and the harm is physical injury if you stepped on it and slipped. When it comes to likelihood of occurrence, it will be much higher if the *banana peel* is along the way where everybody walks compared to a *banana peel* in a corner in a room. The severity will have various other factors to be considered – for example, older people might have more severe outcomes compared to younger ones should they slip and fall. Identifying the *banana peel* is critical, because the control measures will be addressing this very potential source of harm.

In this sense, temperature excursion is not an unwanted event/hazard. Here, hazard would be "alarm not being heard". The control measures you come up with to respond to temperature excursion may not be applicable to "alarm not being heard" in the storage. As a result, regardless of how good are the measures you introduce, the hazard will not be dealt with. Another approach in order to identify hazard correctly could be thinking otherwise instead of asking what could go wrong. If you ask "what do I want to happen?" your answer will be that you want alarm to be heard (so it can be attended) should there be one. So, the opposite of your answer would be the hazard: Alarm not being heard.

When we talk about harm, we usually are concerned about **immediate** or **"local" harm** or **impact**. What is the first thing that can happen if, for example, nobody hears the alarm (because it is downstairs and nobody is there)? The products may be exposed to unwanted temperatures. We do not know yet if the products have been affected – that COULD happen of course, but we will need more information about time and temperature exposure. Thinking about impacts as immediate and then longer-term can help you be more laser-focused when you think of control and mitigation activities.

Let's focus on some control measures dealing with the hazard. The table below discusses the applicability of different risk treatment options to our case (alarm not being heard):

Options	Meaning	Applicability
Avoid	To decide not to proceed with the activity likely to generate the risk, where this is practicable.	Not applicable. Time and temperature sensitive products must be stored under certain controlled temperatures. The activity must be undertaken.
Accept or increase the risk in order to pursue an opportunity	Accepting/increasing the risk may be considered as opportunity – though this is mostly applicable to financial related risk management. The only possible explanation for the pharma sector could be the research and development that all may be considered as opportunities but only few of them turn into commercial successes.	Not applicable.
Remove the risk source	Elimination of the hazard.	Not applicable.
Change the likelihood	You may need to adjust what is happening or might be planned: successfully altering the approach will depend on identifying the causes of the threat and the causal links between the threat and its impact – both of which should have been identified in the risk assessment phase.	Alarms do occur when the temperature goes beyond the recommended temperature range that is 2-8°C. If we can control the causes of such temperature violations, the likelihood of having an alarm, and therefore alarm not being heard, will be low. Temperatures may rise when there is power shortage. Therefore, having a backup power generator dedicated to storage area would be good control measure. Temperatures may also rise if the door of the fridge is left open mistakenly. Installing new alarm system to the storage with event logger (door openings) would be a good response (with warning going to hospital pharmacy as well). Temperatures may drop if the thermostat settings are wrong. To avoid such problems, thermostats can be arranged to optimum setting and then be sealed to prevent manipulation. One other thing that could be done is to make sure the alarm is heard. In this sense, an application that warns the pharmacy in the hospital (which works 24/7) would perfectly work well. In addition to alarms being visible/audible at the hospital pharmacy, an SMS message can also be sent to responsible people as a redundant control.

Options	Meaning	Applicability
Change the consequences	Contingency plans might be required to respond to a threatening event if it occurs. This planning may be undertaken in combination with other controls – that is, even if steps have been taken to minimize the likelihood of the risk, it may still be worthwhile to have a plan in place to reduce the consequences if the event actually occurs.	When the new alarm system that is linked to hospital pharmacy staff will be able to react on time, and this will cut the time products will be exposed to unwanted temperatures, therefore reducing the possibility of products being damaged. In addition, as for vaccines, vaccine vial monitors may indicate whether the vaccines are still usable. Using VVMs will eliminate the possibility of damaged products from being used. *See The little big thing: Vaccine vial monitor on page 30.*
Share the risk with another party or parties	Involving another party, such as an insurer or contractor, may help. Risk can be shared contractually, by mutual agreement, and in a variety of ways that meet all parties' needs. Any such arrangement should be formally recorded – whether through a contract or agreement or by letter. However, sharing the risk does not remove your obligations and does not avoid you suffering consequential damage if something unexpected happens or something goes wrong.	Managing the store could be given to another party with a signed quality agreement. Here, we may not be responsible in designing the control measures, but if anything goes wrong and the products are damaged, it will be us who will be suffering regardless of insurance policies we might have with the contractor.
Accept or tolerate	Sometimes, a decision is made to accept or tolerate the risk, due to the low likelihood or minor consequences of the risk event, or the fact that the cost of effectively controlling the risk is unjustifiably high or that the opportunity outweighs the risk.	The above suggested control measures are not unjustifiably high and risk can be effectively treated; therefore acceptance/tolerance of the risk is not an option here.

More on definitions

Hazard

ISO and ICH Q9 define hazard as "potential source of harm". The definition does not reveal the nature of the source. In our *banana peel* example above, hazard comes as an object. But in the Hacettepe University Hospitals pharma store example, hazard is a situation (alarm not heard). In this regard, hazard could be a condition, a situation or an agent. ICH Q9 defines harm as the damage to health, but here the implication could be to people, organization, system, equipment, property, or environment. In this regard, I very much like Dr James Vesper's clear and simple hazard definition that amalgamates all these factors:

Dr. James Vesper

> *"A real or potential condition, situation, or agent that could cause immediate or long term harm to people or an organization; damage or loss of a system, equipment, property, the environment, or other things of value."*

Vesper lists other aspects of a hazard (in addition to exposure and effect) that need to be considered as follows:

- A hazard is an intrinsic part of a substance or situation
- A substance or situation can have multiple hazards
- A hazard may not be immediately detectable or its effects not immediately observed
- A hazard can trigger a chain of effects or consequences
- A hazard can have consequences that affect various stakeholders differently

Risk

Dr. Paul Slovic, a founder and President of Decision Research and Professor of Psychology at the University of Oregon, studies human judgment, decision making, and risk analysis. He and his colleagues worldwide have developed methods to describe risk perceptions and measure their impacts on individuals, industry, and society. Dr. Slovic believes that risk concept contains elements of subjectivity that provide insight into the complexities of public perceptions. He further lists the most common uses as follows:

Dr. Paul Slovic

- Risk as a hazard. Example: "Which risks should we rank?"
- Risk as probability. Example: "What is the risk of getting AIDS from an infected needle?"
- Risk as consequence. Example: "What is the risk of letting your parking meter expire?" (answer: "Getting a ticket")
- Risk as potential adversity or threat. Example: "How great is the risk of riding a motorcycle?"

You may think that using risk with so many different meanings may often cause problems in communication. But regardless of the definition, we typically assume to objectively quantify the risk (probability and consequences) by conducting a risk assessment. Risk comes with the probability and the impact. "The risk" of being broken when dropping an egg onto the concrete floor is always a "virtual certainty".

What about the risk of your smart phone being broken when dropping onto a concrete floor?

Although it is very likely, there is no 100 percent certainty that it will get broken. Of course if you do not have any protective cover, the possibility of your phone being broken would be higher (and you also know that a protective cover does not provide full protection). For risks that do not fall under the virtual certainty category, predictive statistics based on historical data are used to determine risk levels. Odds ratio is a typical example of such predictive statistics. For example, S.D. Stellman et al. calculate the odds ratio (OR) for lung cancer in current United States smokers relative to nonsmokers as 40.4 [95% confidence interval (CI) = 21.8-79.6], which was >10 times higher than the OR of 3.5 for current smokers in Japanese relative to hospital controls (95% CI = 1.6-7.5) and six times higher than in Japanese relative to community controls (OR = 6.3; 95% CI = 3.7-10.9).

Is it possible to quantify the risk always objectively? We reach risk values through the process of risk analysis. This, in general, is assumed to be objective, and therefore, the risk values are to be correct. However, the risk assessment process involves subjectivity, and in some cases to a considerable extent. Even if all staff agree upon the hazard and know the processes, they filter information differently and may reach different conclusions. Even for experts, there cannot be any guarantee that the judgement will be made to a reasonable approximation. The need for judgement brings subjectivity and natural bias to the process. This is why risk assessment is preferably conducted by a team of interdisciplinary experts to reduce the subjectivity.

But is this really a problem? We do not refer to *time* in risk definition, but we have *future* in it implicitly. We do not define a current problem with risk analysis, nor a future certainty. We rather define the *potential for future harm.* As indicated by Robert N. Charette, *risk assessment is not about future decisions, but about the future of decisions that we must take now.*

We can conclude that *risk may be estimated but it cannot be measured* as we are reminded by Leroy C. Gould.

Risk perception and risk judgement

We all use what we know to interpret new information and make judgements about risks. Our mental models of risks and trust in sources that communicate risk related issues to us also affect how we interpret risk communication. Many times we use heuristics that may lead to biases.

More than 100 cognitive biases known to date shape our decisions regarding risks and they may result in negative outcomes in our everyday lives. Here are some examples of such biases:

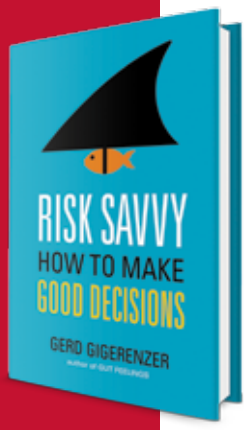
Availability of information (and experience): Tendency to give greater probability to events that we have been exposed to personally or through close friends.

Anchoring bias: A cognitive bias describing the common human tendency to rely on the first piece of information offered (or known) when making decisions. We think that we rationally analyse all factors before making a choice or determining a value, but in reality our first perception lingers in our mind, affecting later perceptions and decisions.

Overconfidence bias: A well-established bias in which a person's subjective confidence in his/her judgements is reliably greater than the objective accuracy of those judgements. Overconfidence comes in three distinct ways: overestimation (tendency to overestimate one's standing on a dimension of judgment or performance), overplacement (judgment of your performance compared to another), and overprecision (excessive confidence that one knows the truth).

Framing bias: A cognitive bias, in which people react to a particular choice in different ways depending on how it is presented. In general, we tend to avoid risk when a positive frame is presented but seek risk when a negative frame is presented. A study by Simon Gächter et al., showed that 93 percent of PhD students registered early when a penalty fee for late registration was emphasized, with only 67 percent doing so when this was presented as a discount for earlier registration. One another good example of framing bias comes from G. Gigerenzer on the 1995 pill scare case on third-generation oral contraceptive pills in Great Britain.

Pill scare



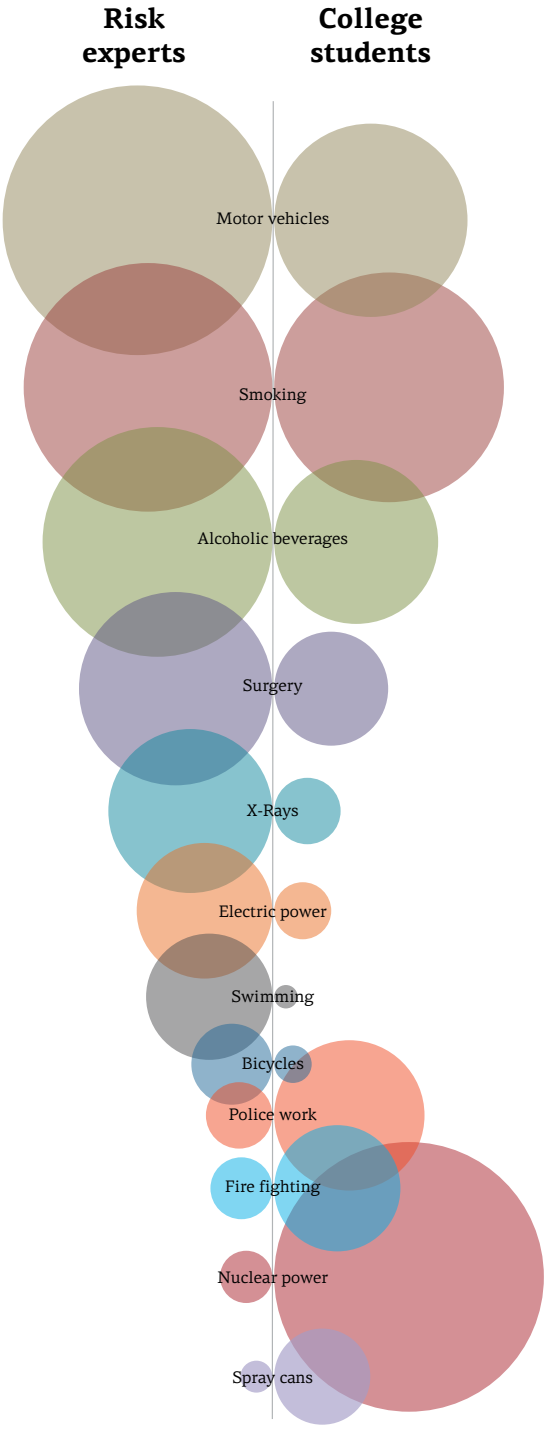
"Great Britain has many traditions, one of them being the contraceptive pill scare. Since the early 1960s, women are alarmed every couple of years by reports that the pill can lead to thrombosis, potentially life-threatening blood clots in the legs or lungs. In the most famous scare, the UK Committee on Safety of Medicines issued a warning that third-generation oral contraceptive pills increased the risk of thrombosis twofold – that is, by 100 percent. How much more certain can you get? This terrifying information was passed on in "Dear Doctor" letters to 190,000 general practitioners, pharmacists, and directors of public health and was presented in an emergency announcement to the media. Alarm bells rang around the country. Distressed women stopped taking the pill, which caused unwanted pregnancies and abortions.

Just how big is 100 percent? The studies on which the warning was based had shown that of every seven thousand women who took the earlier, second-generation pill, about one had a thrombosis; and that this number increased to two among women who took third-generation pills. That is, the absolute risk increase was only one in seven thousand, whereas the relative risk increase was indeed 100 percent. As we see, in contrast to absolute risks, relative risks appear threateningly large and can cause a great stir. Had the committee and the media reported the absolute risks, few women would have panicked and dropped the pill. Most likely, no one would have even cared.

This single scare led to an estimated thirteen thousand (!) additional abortions in the following year in England and Wales. But the fallout lasted for longer than a year. Before the alert, abortion rates had been steeply on the decline, but afterward, this trend was reversed and abortion rates increased for years to come. Women's confidence in oral contraceptive was undermined, and pill sales fell sharply. Not all unwanted pregnancies were aborted; for every abortion there was also one extra birth. The increase in both abortions and births was particularly pronounced among girls under sixteen, with some eight hundred additional contraceptions.

Ironically, pregnancies and abortions are associated with a risk of thrombosis that exceeds that of the third-generation pill. The pill scare hurt women, hurt the National Health Service, and even brought down the stocks of the pharmaceutical industry. The resulting increase in costs to the National Health Service for abortion provision has been estimated at £4-6 million. Among the few who profited were the journalists who got the story on the front page."

From the book Risk Savvy: How to Make Good Decisions by Gerd Gigerenzer (p. 5-6)



Confirmation bias: Tendency to search for or interpret information in a way that confirms one's preconceptions and to discount that which does not, thus leading to statistical errors. It is something like one hearing only the side of the debate that supports their viewpoint and seeing the faults in viewpoints contrary to their own.

Although there could be some overlaps, there are always discrepancies between expert assessments and lay perceptions of risk. One of the historical studies on risk perception was conducted by Slovic et al. (1980), which compared risk perception of study subjects from the League of Women Voters, a men's activity club, and college students to expert risk ranking. All were asked to rank 30 events. The results of ordering of perceived risks and technologies (comparing college students and risk experts) can be summarized with selected events in the graph on the left (bigger the circle higher the rank).

Titanic at the docks of Southampton.

Titanic: Retrospective risk assessment

In our GLO Pharmaceutical Cold Chain Management on Wheels course, we also bring in the Titanic disaster to explain how risk assessment works. Titanic is known by everybody and you open a different side of the story which none of the participants ever thought of. First of all, the example is considered as to be attention grabbing and helps participants to mentally model how things are interrelated in a typical risk assessment.

Here how it goes:

Royal Mail Ship (RMS) Titanic was a British passenger liner that sank in the North Atlantic Ocean in the early morning of 15 April 1912, after colliding with an iceberg during her maiden voyage from Southampton to New York City. She had 2,224 passengers and crew aboard. In the Titanic disaster more than 1,500 died, making it one of the deadliest commercial peacetime maritime disasters in modern history.

Newsboy Ned Parfett announcing the sinking of the 'Titanic' outside the offices of the White Star Line, Oceanic House, London on April 16, 1912

We then list what we know about the ship and the tragic accident:

1. Shipbuilders believed the Titanic was unsinkable because of its watertight compartments and doors. In the event of an accident, the captain could close these doors and prevent the boat from completely filling with water. The ship also was built to take on some water without sinking.
2. The Titanic received at least four warnings from other ships about icebergs in the area on the day of the accident. The final warning came an hour before disaster struck.
3. Despite iceberg warnings, the ship continued to steam at full speed, which was standard practice at the time. Although the ship was not trying to set a speed record, timekeeping was a priority, and under prevailing maritime practices, ships were often operated at close to full speed, with ice warnings seen as advisories and reliance placed upon lookouts and the watch on the bridge.
4. It was a moonless night.

5. There were lookouts but they did not have any binoculars. Actually, there were binoculars on board in a locker used by the Second Officer who sailed on the Titanic from Belfast to Southampton prior to its maiden voyage. However, for the maiden voyage, the Second Officer was not required to be on board and when he left the ship he did not inform anybody of the location of the binoculars. When lookouts spotted a massive iceberg less than a quarter of a mile off the bow of the ship, it was too late.
6. The design of the rudder was poor. When an iceberg was spotted, at the engine room, the engineers had to spend a few moments getting the ship's enormous engines to respond and switch to reverse - the steering gear as well, took time to respond as the steam-powered rudder moved into position.
7. Titanic's overlapping steel hull plates were held together by rivets that were hammered in by hand. Most of the rivets were steel, but some were made of wrought iron; according to some, the rivets were poor-quality and contained large amounts of slag. The actual holing of the ship was caused when she dragged over the surface of the iceberg, with the iceberg snapping/popping the rivets along the hull, allowing water to enter in between the hull plates. The hull plates themselves are alleged to have not been strong enough, with signs of stress fracturing; but this is disputed.
8. The Titanic had too few lifeboats to evacuate all those on board. The 20 lifeboats that she did carry could only accommodate 1,178 people, despite the fact that there were 2,224 on board. The Titanic had a maximum capacity of 3,327 passengers and crew. In addition, many lifeboats only carried half of their maximum capacity, allowing only women and children first.

Following presentation of these facts, we discuss the following questions:

- What was the hazard?
- What controls were in place? (detection, prevention, mitigation)
- Were they adequate?

Participants identify the *iceberg* as the *banana peel* for the Titanic. They discuss the adequacy of control measures, starting with iceberg warnings, speed, lookouts and lifeboats. They differentiate the nature of these controls as lifeboats are for mitigation - following the unwanted event happening, they were to be used to reduce the impact on loss of passengers' lives; and lookouts as detection, both inadequate. They use the contributing factors to explain the failing mechanisms that resulted in sinking the unsinkable - such as moonless night reducing the visibility and therefore increasing the likelihood of colliding with an iceberg; design of rudder that delayed the response for reversing; and inflexible rivets that resulted in watertight compartments to be damaged.

The little big thing: Vaccine vial monitor

Earlier, VVMs were mentioned as control measure when analysing the risk treatment options for Hacettepe University Hospitals pharma store. VVM is an important tool that addresses more than one hazard within the vaccine supply chain.

VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the vaccine vial monitor to darken gradually and irreversibly. A direct relationship exists between the rate of color change and temperature: the lower the temperature, the slower the color change; the higher the temperature, the faster the color change. VVM is the only tool among all time temperature indicators that is available at any time in the process of distribution and at the time a vaccine is administered indicating whether the vaccine has been exposed to a combination of excessive temperature over time and whether it is likely to have been damaged.

The principle purpose of the VVM is to warn health workers when the cumulative heat exposure of a vial of a vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. This is defined as the end point. Before the end point is reached, changes in the appearance of the VVM are used to alert health workers to the fact that heat exposure has occurred. Heat exposed vials can then be used in preference to those that have not been exposed. VVM is not a potency indicator. Therefore it does not directly measure vaccine potency, but gives

information about the main factor that affects potency: heat exposure over a period of time.

Let's summarize the VVM from the risk management perspective:

Feature	Function	Nature of control
Indicate the level of time/ temperature exposure of each vaccine vial	Whether the vaccine vial can still be used	Detection (of non-damaged vaccine) Prevention (of wastage) Prevention (of inaccessibility and low immunization coverage) Prevention (of inadvertent freezing)
	Whether it is likely to have been damaged (beyond end point)	Detection (of damaged vaccine) Detection (of cold chain problems) Prevention (of damaged vaccine from being administered)
Compare the level of time/ temperature exposure of vials of same type/manufacturer	Prioritization of certain vials with less color change to be used prior to others with higher color change	Prevention (of wastage)

As seen in the above table, this simple tool as a control measure can respond to many different hazards at the same time. First of all, when there is no VVM, you cannot make any judgement whether to use the vaccine should there be any temperature excursions. You would not know how the vials were handled before they have reached you. There will be no memory to explain this, but VVM. VVM is the *only* tool among all time temperature indicators that is available at any time in the process of storage and distribution and at the time a vaccine is administered.

The main function of VVM as indicating the level of time/temperature exposure of each vaccine vial can be taken to a next level by comparing the level of time/temperature exposure of vials of same type/manufacturer. This allows health workers to decide on using more heat exposed vaccines prior to ones with less exposure, therefore preventing wastage. This facilitates better management of stocks for dispatches as well as deciding which vials to be used first in fixed immunization sessions and outreach programmes. VVM also becomes a critical tool to rely on for storage and transportation of freeze-sensitive vaccines where the risk of freezing is greater than the risk of heat exposure (thus preventing inadvertent freezing). VVM is also a good example of a control measure that has both detection and prevention features.

Examples of exposure in everyday life

In this book, I'd like to take you through a regular day but wearing quality risk management glasses. We shall look into details at home, in an apartment block, in a vehicle, on a road, in a café/restaurant, at work and so on... We shall focus on things we see every day but do not think/analyze from the risk management perspective. We shall practice more and more backwards risk management thinking to better understand the linkages between the risk question, hazard, harm, likelihood, severity and control measures.

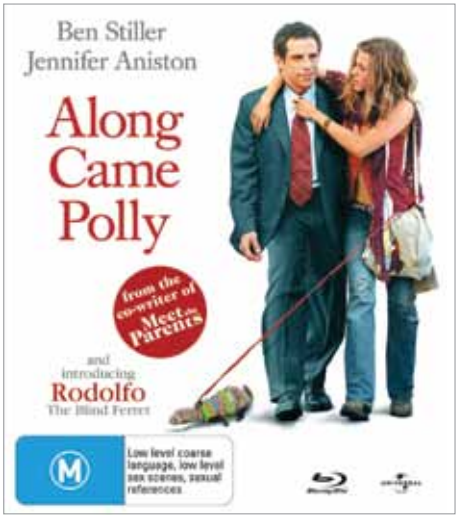
When we say that life is full of risks, it may sound like a cliché. Many of such daily risks in life are mostly dealt with reactions and are "damage control" in nature. But, here we shall focus on things that even many of us never think of from a risk perspective. For example, I do not think that any of the cafe owners have thought from the risk management perspective whether to heat the coffee cups before they serve coffee. And I bet airlines have a lot to learn in this regard, since they all serve coffee in freezing cold coffee cups.

I live in Collonge-Bellerive (12.5 km from my office), and take public transport. This was not a risk management decision I made, it was simply the most convenient mode of transport for me. I believe I would choose the same if I did the risk thinking. First I list my options for transport:

- We have a car; it is driven mostly by my wife for daily routines. Of course, asking my wife to drop me to office and then pick me up at the end of the day is not fair and cannot be justified at all. So, driving to office is not an option.
- I do not have a motorbike and I do not have any license for riding a motorbike, so this is not an option for me.
- Though I do not have a bicycle, I know how to ride a bike. I can buy a bicycle and can cycle to the office; it would also help me keep my weight down, and moreover, it does not produce any pollution.
- I can take public transport; it takes me around 45 minutes to reach office.

If I drive, I could cut this time by 15 minutes but only if I leave the house at certain hours – otherwise crossing the bridge could take much longer. From the risk perspective, despite all the benefits it provides, the bicycle is the most risky one regardless of Geneva being a bike friendly town. The car would be safer, but public transport is the safest. In 2015, there were 253 deaths on the roads in Switzerland, 57 percent less compared to 2010 figures. The majority of these cases are motor vehicle users, but we know if involved, pedestrians, cyclists and moped and motorcycle riders have a much higher risk (high likelihood and high severity) of death per kilometre travelled. Public transport in Geneva was not involved in any of the deaths on the road. So, continuing to take public transport to work is both a practical and sound decision based on the risk thinking. In addition, public transport share in passenger transport performance in Switzerland is increasing, despite 4.5 million stocks of passenger cars; public transport share increased three percentage points in 2015. I am happy to be part of this.

Film critic Roger Ebert says he will never eat free nuts from the bowl on the bar again, having seen "Along Came Polly." Not after hearing the expert risk-assessor Reuben Feffer (Ben Stiller) explain who has already handled them, what adventures they have had, and, for all we know, where they might have been. Do not misunderstand me, I am not asking you to become Reuben in your everyday life. But if you are a newcomer to risk management and you'd like to excel in risk management and do better than Reuben, then this book is for you. If you think you are a risk management expert (which Reuben is), and would like to do better than him, then this book is for you as well.



Remember, it is not only newcomers, but also risk management experts who mix up the hazards with failure modes and/or harm. Here is an example from a respected health and safety public agency on risk assessment for office-based business (the original table includes seven rows in total, below only first two rows are given as an example):

What are the hazards?	Who might be harmed and how?	What are you already doing?	Do you need to do anything else to control this risk?	Action by who?	Action by when?	Done
Slips and trips	Staff and visitors may be injured if they trip over objects or slip on spillages	General good housekeeping is carried out All areas well lit, including stairs No trailing leads or cables Staff keep work areas clear, e.g. no boxes left in walkways, deliveries stored immediately.	Better housekeeping in staff kitchen needed, e.g. on spills Arrange for loose carpet tile on second floor to be repaired/ replaced	All staff, supervisor to monitor Manager	From now on xx/xx/ xx	xx/xx/ xx xx/xx/ xx
Manual handling of paper, office equip-ment etc.	Staff risk injuries or back pain from handling heavy/ bulky objects, e.g. deliveries of paper	Trolley used to transport boxes of paper and other heavy items when collecting deliveries etc. High shelves for light objects only	Remind staff that they should not try to lift objects that look or appear too heavy to handle	Manager	From now on xx/xx/ xx	xx/xx/ xx xx/xx/ xx

Are "slips and trips" really hazards? Definitely not! Something else (hazard) causes you to slip or trip, no? If you look at the second column where "who might be harmed and how" is questioned, you will find the hazards there: objects (for trip) and slippage (for slips).

Let's move on to the second row. Are manual handling of paper, office equipment, etc. really hazards? Or real hazards again hidden in the second column heavy/bulky objects in the office?

In order to design robust control measures, it is critical that the hazards are clearly identified. If not, then the control measures that may result will be general and not really specific and focused to eliminate, prevent, detect and/or mitigate the hazard. For example, do you really believe that by continuing to use trolleys for transporting heavy items, dedicating high shelves for light objects and intro-

ducing reminding staff that they should not try to lift objects that look or appear too heavy to handle would reduce staff injuries due to manual handling of heavy objects in the office?

What is missing in the above table? Do you see any references to likelihood and severity and therefore any risk scoring? No. If you were the manager, would you decide to do something or simply accept the risk without having such information? And if you were to take any action, how would you prioritize your risk treatment options?

Though there are not standard spreadsheets for risk assessment tools, the following examples incorporate all hazards, failure mechanisms, harm, likelihood, severity, (in some cases) detectability, risk score and prioritization options.

Preliminary risk assessment (PRA)

Risk question:							
Risk ID#	**Hazard/ unwanted event**	**Harm/consequences**	**Potential causes**	**Likelihood of occurrence (L)**	**Severity of consequence (S)**	**Risk score**	**Possible controls/ actions**
Assign each entry a unique tracking number	What is the hazard/ What could happen?	What might be the potential impact?	How might the hazard occur?	What is the likelihood that the hazard and harm will occur (rating scale)	How significant is the impact (rating scale)	(Calculated) L x S	What might help to detect, prevent and control the hazardous situation?

Failure mode and effects analysis (FMEA)

Risk question:									
Process step	**Potential failure mode**	**Potential failure effect**	**Severity of consequence (S)**	**Potential causes**	**Likelihood of occurrence (L)**	**Current process controls**	**Detectability (D)**	**Risk priority number**	**Actions recommended**
What is the step?	In what ways can the step go wrong?	What is the impact?	How severe is the effect? (risk scale)	What causes the step to go wrong?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	(Calculated) S x L X D	What are the measures for reducing the occurrence of the cause for improving its detection, likelihood of occurrence and reduce the severity impact?

William G.T. Shedd said that "a ship is safe in harbour, but that is not what ships are for." We will not go anywhere if we keep it in harbour. If we want to move ahead, we need to take risks but with limiting the likelihood and severity through well thought and designed control measures.

Test your risk thinking

Here you will find photographs from the forthcoming chapters in which I discuss the control measures, redundancies and hazards in detail. You may analyze the photographs first before moving on to chapters and test your risk thinking.

Can you mark a control measure that is for mitigation, redundant control measures for detection and at least one control measure that is for prevention in this photo? In that case, try to list the hazards these control measures correspond to.

For a more detailed discussion, please refer to chapter *Car: Sea of control measures and redundancies* on page 95.

Can you mark a hazard and a control measure in this photo? Discuss the adequacy of the control measure.

For a more detailed discussion please go to chapter *Down the stairs* on page 59.

Can you mark control measures that are both for prevention and mitigation in this photo?

For a more detailed discussion please go to chapter *Under construction* on page 75.

Can you spot a hazard in this photo? Do you also see any control measure that is in place for such a hazard?

For a more detailed discussion please refer to chapter *Pedestrian liberation* on page 67.

If you complain about not having hot coffee or tea during flights, can you spot a hazard in the photo? What control measure would you bring as a response against this hazard?

For a more detailed discussion please refer to chapter *A cup of coffee* on page 47.

Would you ever consider a champagne flute as a control measure? If yes, what would be the hazard then?

For a more detailed discussion please see chapter *Gloriously bubbly* on page 53.

Can you spot the hazard in this photo? What control measure is in use? How adequate is it?

For a more detailed discussion please see chapter *Mask on* on page 119.

What is the hazard in this photograph? What types of control measures could you suggest either to eliminate the hazard, or reducing the likelihood of the exposure?

For a more detailed discussion please see chapter *Keeping kids safe* on page 137.

Can you spot three control measures in this photo? If it was a cold environment, what would the adequacy of these measures be? What different hazards do they correspond to?

For a more detailed discussion see chapter *Protect from freeze* on page 83.

Can you spot a control measure in this photo? What hazard is it taken against?

For a more detailed discussion see chapter *Nutcracker* on page 143.

Can you identify a control measure that could also be hazard itself in this photograph? Can you discuss how a control measure can be a hazard at the same time?

For a more detailed discussion please see chapter *Sleeping policeman* on page 101.

Do you see anything hazardous in the photograph on the left? How would you define the hazard? What control measure would be the best response?

For a more detailed discussion please see chapter *Plastic habit* on page 105.

Can you spot control measures in this photograph? What is the hazard they respond to? Can any of these control measures be also turned into a hazard? Can you explain how?

For a more detailed discussion please see chapter *Last mile: at the pharmacy* on page 111.

Can you spot control measures in this photograph? What is the hazard they respond to?

For a more detailed discussion please see chapter *Sharing a bench* on page 129.

In meetings, when everybody wants to plug in their devices, power supply may become an issue. What hazard do you see in the photograph on the left? What would be the harm? What control measures can you introduce?

For a more detailed discussion please see chapter *How was your trip?* on page 147.

A cup of coffee

I am not a coffee person. I prefer tea. But when it comes to drinking coffee or tea, the same rule applies. It must be *hot*, and I mean *hot*, not warm. Since both drinks are prepared with boiled water, before they are served, they are hot supposedly. In a café, you ask for a cappuccino and you get a warm one. If it is not hot enough by your standards, you call the waiter to complain. If you are lucky, the waiter might put the cup in a microwave (that I do not like), otherwise

he/she will argue with you that it comes from the machine like this and nobody has ever complained that it was not hot. You ask the waiter to heat the cup before pouring the coffee, and the waiter looks at you with empty eyes. And at that moment you decide not to come there anymore. They've just lost a client.

My wife has a kind of ceremony when she prepares her coffee. First of all she refuses to have a coffee machine, and there are a number of subtleties that would make a book to describe. But to cut a long story short, she says that the taste of coffee evolves over slow cooking in old-style percolator. While the water boils in her percolator, the cup is placed upside down in another small pot where the milk is heated to boil. The cup naturally becomes very hot; you can only hold it by its handle.

When I make tea, I always heat my mug first. I add boiled water to the mug and wait for thermodynamics to do its job. Clearly, this is not needed for fine porcelain or Turkish tea glasses.

A fastidious tea/coffee drinker will definitely suffer in the air. The majority of airlines serve drinks in plastic cups in economy class – if the tea/coffee is served is hot, you may have your tea/coffee hot. If the airline is using ceramic cups instead of plastic ones, you will hardly have any chance of having a cup of hot tea or coffee. When the tray is brought to you, the empty cup is almost at freezing temperature, especially with breakfast trays. Why is that so? Well, the trays are all refrigerated with the food, cutlery and [ceramic] cup on it. It is only hot food that comes refrigerated separately and gets heated before going on the tray. It really does not matter how hot the coffee or tea they serve, the moment it is poured into your freezing cup, the thermodynamics do not work in your favor. One is no longer surprised with the irritability that flight

attendants, even in business class, might show when you ask for your cup to be heated before serving tea/coffee.

What control measure are we dealing with here if we want a really hot cup of coffee?

Heating the cup...

This is a *preventive control measure* in nature.

Cold cup is the hazard here.

Harm is having a warm and not hot coffee. This impact is the *immediate impact*, which may manifest itself with dissatisfaction of the customer if we are speaking of a café. Later on, this may result in *losing a client* - that is *knock-on failure effect*. I am sure, if café owners had had risk management glasses to review the processes they have, they would have caught the *cold cup* as the *banana peel*.

Who knows, maybe clients do not complain much when they are not served really hot coffee or tea. Such complaints would correspond to *risk events*. Risk management is conducted especially with new, changed, and failed processes. Though QRM is not in the dictionary of cafés, they will not think about changing the process by adding a simple *heating the cup* as a preventive nature control measure unless the majority of their clients complain that the coffee is not hot.

Dealing with the same problem as a passenger in an aircraft has a bit of different challenge. Because of the food content they have, trays (many at a time, the

cup is already on the tray) are kept at refrigerated temperature. This is why the cup is freezing cold when the tray is placed on your table. Heating the cup in your hands is not possible. The only option is to call the flight attendant, but this may not be very helpful. I must confess that I stopped drinking tea or coffee on board airlines. I might be more optimistic about cafés introducing *heating the cup* notion as a preventive control measure, but have almost no hopes how to have really hot coffee or tea on board.

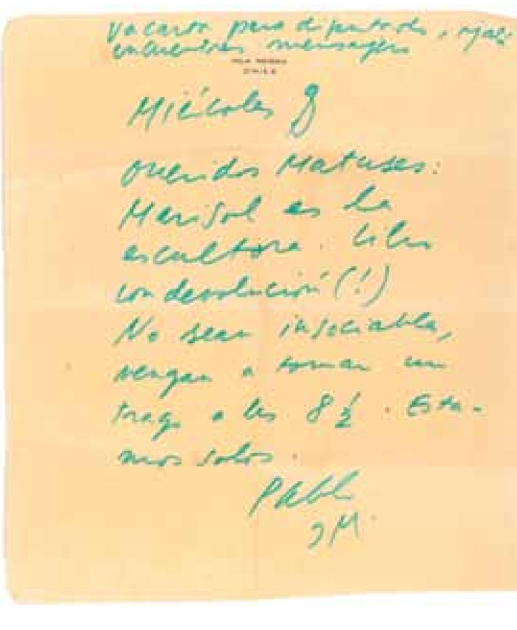
The opposite of this example could be the frosted beer mug to serve really cold beer. In busy bars, you may get a beer (though it is cold when they pour into the mug) in a mug that just came out from a dish washer. Customers appreciate it more when the beer is served in frosted mugs. Bars serving beer in frosted mugs are smart, even though they have not conducted any formal risk assessment; they know what the customer satisfaction is about.

In this example, *warm mug* is the hazard and *frosting the mug before use* is the preventive control measure.

Enjoy...

Gloriously bubbly

The great Chilean poet Neruda always wrote in with the green ink. Green wine glasses sat on the dining room table at all times in his house Casa de Isla Negra. Neruda used to say that wine tasted better from colored glasses. Though this might need some explanation by a psychologist, I am sure Neruda had his own elucidation. But when it comes to the shape of a glass, does it really impact the taste? In 2015 scientists in Japan showed that glass geometry controls where and how vapor rises from wine, influencing taste - through a camera system that maps out the concentration distribution of ethanol leaving the glass. But we know that wine glass designs come from the times when such camera systems did not exist. The design was fully based on experience, mainly by wine connoisseurs.


Miércoles 8
Queridos Matuses:
Marisol es la escultora
con devolución (!)
No sean [illegible],
vengan a tomar un trago a las 8½. Estamos solos.
Pablo

Selection of a particular wine glass for a wine style is important, as the glass shape can influence its perception. The appropriate way to hold a wine glass, especially when drinking chilled wine, is to grip at the base or by the stem, in order

to prevent the temperature of the wine being affected by body heat (here comes thermodynamics again). As for the red wines, the tendency is to sit the bowl into your palm.

But seriously, does this matter? Though the last thing you should be worried about is being judged by how you hold your wine glass, wine connoisseurs suggest always holding it at the base or by the stem not to leave any greasy hand prints on the bowl regardless of the color of your wine. That makes sense...

Most of the celebrations in our family are marked by a bottle of champagne. I prefer champagne flutes to coupes.

Attic black-figure mastos cup
attributed to Psiax, ca. 520-510 BCE

Human anatomy and the coupe

The rumor has it that the coupe design begins with human anatomy. The very first example of coupe design comes from Greeks; the glass is often thought to be modelled on a breast – that the shape was inspired by Helen of Troy's breast. This mastos cup had even an articulated nipple at the bottom. More recent designs of the same kind said to be inspired by Marie Antoinette. The original designs from late 18th century also come with nipples as to complete the cup (called as "breast bowl").

Nipple-cup known as the Breast bowl
(Jatte-téton, dite bol sein) 1788, Sèvres Porcelain
Manufactury Painted by Fumez after a design by
Jean-Jacques Lagrenée & Louis-Simon Boizot
Material: hard-paste porcelain
Photo: M. Beck-Coppola (Musée National de la
Céramique, Sèvres, France)

Here is the physics around the design of champagne flute: The bowl is designed to retain champagne's signature carbonation by reducing the surface area at the opening of the bowl. Nucleation in a champagne glass helps to form the bubbles seen in champagne. Too much nucleation will cause the carbonation to fizzle out quickly. A smoother surface area will produce fewer bubbles in the glass and thus more bubble texture in the taster's mouth. Flutes, with their deep bowl, allow for greater visual effect of bubbles rising through the liquid to the top. The flute also helps regulate and reduce the oxygen-to-wine ratio, which both enhances the aroma of the wine as well as the taste. As for the champagne coupe, if you leave it at rest, the drink in the coupe will go flat faster than in a flute. But coupe enthusiasts handle sacrificing a few bubbles for a bit of tradition and a lot style, and they claim if you have to worry about your bubbles, maybe you're just not drinking it fast enough.

Well, the other side of the coin for carbonation is that carbonation speeds up alcohol absorption, people therefore get drunker faster and have a worse hangover – but of course this fact does not make flat champagne likeable.

Now, you may ask how we are going to move into risk assessment mode with the champagne glasses. Well, the special design of the glass itself is a control measure.

If we take the champagne flute, it is designed in its shape *to reduce the surface area at the opening of the bowl* as a preventive control measure to retain champagne's carbonation longer. If you prefer a champagne coupe, then *drinking faster* would be your preventive control measure. Here we see a *redundant control measure* that is *to hold the glass by the stem or at the base*, which applies to both glass selections.

All these measures help us to enjoy the cold and carbonated champagne. Then what is the hazard?

Since *champagne becoming flat* is what we do not want to happen as the immediate effect (this is harm), then the hazard is the *surface area at the opening of the bowl.* You can reduce it by selecting a champagne flute. If you selected the champagne coupe, then you have got to drink it faster. *Your body temperature* (through your grip of the glass) is the second hazard and you hold the glass by the stem or at the base (control measure) to reduce its impact on the temperature of your champagne.

Cheers!..

Down the stairs

Remember that famous scene in ***Gone With The Wind*** when Scarlett O'Hara falls down the stairs? What triggered the fall of Scarlet O'Hara was Rhett Butler's sarcastic remark about her pregnancy and him moving away when Scarlet reacted. As a result, she lost her balance, fell and lost their second child.

You might wear protective gear when riding a bicycle, but not when you need to use stairs. Staircases are everywhere: In apartment buildings, in homes, in commercial establishments, in restaurants, bars, and in workplaces. Although in many commercial establishments, workplaces and in many apartment buildings there are elevators, many still use the stairs. We live in a duplex apartment and use stairs day and night.

Stairs are the place where most deaths and serious injuries happen inside a building. Naturally, elderly people are at a greater risk hurting themselves on the stairs. UK statistics show that more than 100,000 elderly people are treated for such injuries every year, and of these, more than half end up in hospital with serious injuries. Staircase accidents constitute the second leading cause of accidental injury, second only to motor vehicle accidents.

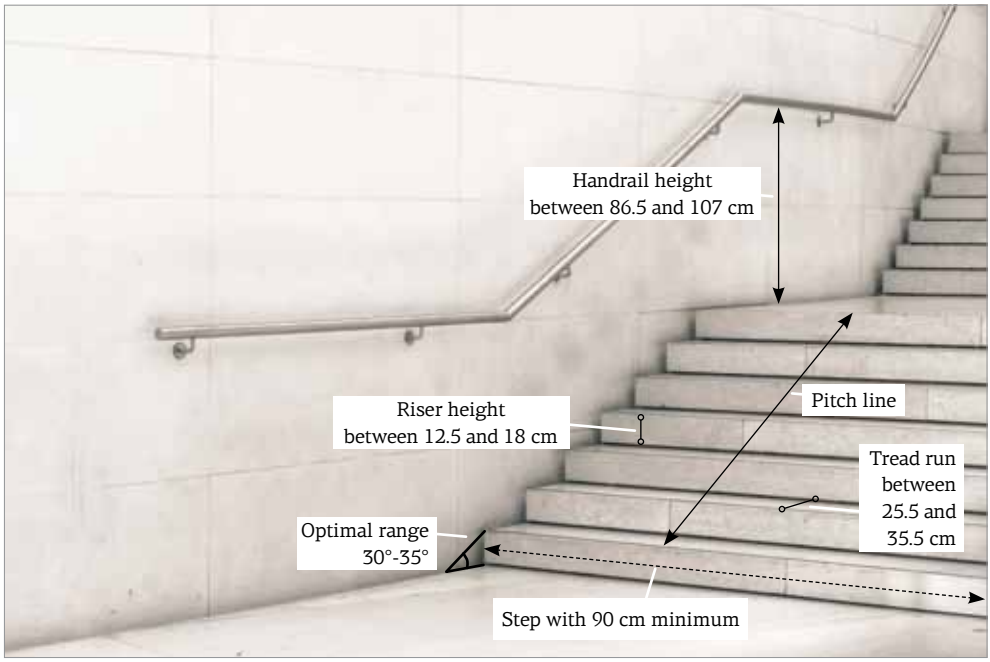
In elderly people, reduced strength, poor balance and impaired vision increase the *likelihood* of staircase related accidents.

In general, the *likelihood* of accidents increases if you are going down the stairs. From the scientific point of view, more force goes through the patella (3.5 times of your body weight) when you are going down the stairs compared to when you climb (only 0.5 times of your body weight). This is a contributing factor for increasing the likelihood of an accident. It may sound and look weird that some people always walk up the stairs but wait for the elevator to go down (this is what I do most of the times in my office).

Last year, colourful new posters and messages have appeared around WHO, especially where the lifts are located and on the riser surface of the staircases. It was the signal for the start of the Step up! campaign to encourage staff to take the stairs instead of the elevator between floors, as one easy way to get more physical activity during the work day.

What do I see when I examine a staircase with risk management glasses?

Well, first of all, there is a lot science behind the good design of a staircase. I mean the pitch line, tread depth (run) and rise height. We all know that when the tread depth is short and rise height is tall (steep stairs), it is more prone for tripping. The opposite of this is also possible; people also trip more in staircases with very short rise height and long tread depth that are not synchronized with the flow of a normal person's walking pace.



Within a staircase, treads should have a uniform run and tread depth should not vary more than 0.5 to 1 cm. (Values are from the National Building Code of Canada, 2015)

Putting aside the details of engineering of the staircases, I find three major control measures in our staircase at home.

The very first one is part of the design, the *handrail* that is offered for us to use. Although this feature is added to the design as a *preventive measure* against accidents, it requires *compliance* from our side; we may or may not choose to hold the handrail. In addition to its preventive nature, if you are holding onto it and lose your balance for whatever reason, it will either prevent you from falling or help you to land more softly. In this regard, if losing your balance is the *unwanted event*, handrails also have a *mitigation* nature in addition to their preventive nature.

The second one is the *light* on the wall. Another preventive measure... So, you see better and do not miss a step.

If you do not see any objects on the staircase that means the control measure (*eliminating the hazard*) is already in effect. This is also a preventive measure.

Let's see where the *banana peels* are for these control measures.

The handrail will help us not to fall when we lose our balance for various reasons. So, *lost balance* is the hazard here. Here, with this control measure (*holding the handrail*), we are *changing the likelihood* of falling. There could be some cases that despite your intentions of holding the handrail, you simply cannot prevent

falling. Remember, the handrail is for *holding* as support while going up or down the stairs. If you cannot hold it, most likely its aesthetically pleasing design compromises the functionality. Handrails must be graspable. When you are about to lose your balance, it is extremely critical that you should be able to grasp the handrail easily, quickly and firmly. The best designed handrails are called *tennis-racket grip*. You should be able to run your hand smoothly along the entire length without adjusting your grip. In this regard, the diameter of the handrail should be between 4-5 cm. Even though it would be considered as a *control measure,* if its design compromises the functionality of the handrail, its adequacy will be questionable.

The handrail design above allows you to grasp it easily, while the one on the next page is a compromised design of its functionality, and cannot be grasped fully. In this regard, regardless of how much we like the aesthetic design, we can question its adequacy.

Lights on the stairs help with the visibility. Improving visibility on stairs significantly reduces the risk for common mishaps caused by misjudging distances. Otherwise you can trip on a step or miss it completely. Such mishaps are a routine cause of twisted ankles, sprained knees or more serious injuries incurred by a total fall. Here the hazard would be *poor lighting (or low visibility).* By turning the lights on, we are actually *removing* the source of harm; the stairs are no longer

dark... Of course, we can go into a deeper discussion here regarding the adequacy of the control measure. If you have stairs in your home, what is the lux level of the lamp you use for lighting? If you have a lamp that is less than 50 lux level, you would not have sufficient illumination. In this case, even you have a control measure in place; its adequacy will not be enough. Like in the Swiss cheese model, this layer of measure will have a big hole in it.

Removing objects from the staircase and *keeping it clean* is a preventive measure, and whatever is placed on the stairs would be the *banana peel*. Similar to *turning the lights on* measure, if the stairs are clean and clear, we are removing the source of harm here.

Although you may come up with avoidance, changing the likelihood or consequences type of options for control measures, if possible, the best control measure would be to *remove the source of harm*. In our staircase example, turn-

ing the lights on (but with over 50 lux level illumination) and clearing the objects from the stairs are in that nature. You simply eliminate the source of harm.

In addition to all these, you may always add additional layers as redundant controls: Non slip socks...

Be careful and hold the handrail...

Pedestrian liberation

Although they are to enhance pedestrian space on sidewalks, we do get annoyed with bollards, don't we? There are cases that pedestrians do not pay attention and trip over them, especially on lower model bollards such as stone cubes or semi globes.

But hold on. Why are we complaining?

Would we be happier if we had to find our way through parked cars on the sidewalk and walk out into the road and be at risk of being hit by other traffic? And the situation would be more challenging and in many cases almost impossible for people with sight loss or mobility impairment.

Although there are many cases that bollards present visual clutter and degraded character of street architecture, they are primarily there to protect a sidewalk area from access by vehicles. Mainly, they prevent cars from parking on spaces that belong to pedestrians. Depending on the installation locations, bollards may also be used to guide moving vehicles and protect pedestrians at junctions and crossovers. But, here we shall focus on the bollards that are solely to protect sidewalk area from access by vehicles.

On the morning of 8 August 1969, John Lennon, Paul McCartney, George Harrison and Ringo Star gathered at EMI Studios for one of the most famous photo shoots of their career. Photographer Iain Macmillan took the famous image that appeared Beatles' last-recorded album, Abbey Road. The shot was Paul McCartney's idea and was sketched by him.

McMillan took six photographs with the help of a policeman holding up the traffic. The shot that was used was number 5 shot.

In 1969, it was not an offense for cars to park on sidewalks. There was not any legal regulation to this effect. As you see, the white beetle is parked on the sidewalk as well as some other cars on the left up the Abbey Street. Five years after this shot, only in London, it became an offense for motorists to park on sidewalks.

The street we live in Collonge-Bellerive is a small side street, the sidewalk on the left has narrow pencil bollards.

Bollards are *preventive* control measure.

The *banana peel* is the *car parked on the sidewalk.*

Bollards physically block access of cars to sidewalks. If not installed, inconsiderate parked vehicles shall cause a hazard and limit the freedom of all pedestrians and especially people with sight difficulties as well as elderly and families with baby trolleys.

But, do bollards only help pedestrians giving them more freedom? Do they not also prevent sidewalks from being damaged by cars? Sidewalks are not designed for cars to ride on them, and cars climbing on the kerb gradually cause damage. In this regard, bollards as a control measure address two different hazardous situations, one for pedestrians and one for the sidewalk itself.

The narrow pencil bollards in my street will not allow cars to park on the sidewalk because the distance between them is not big enough even for a small car. However, there are no regulations regarding the distance that should be required between the bollards.

Of course, there is another control measure here that we do not see. Parking on a sidewalk is an offence under Swiss Federal Law (Article 43, paragraphs 1 and 2, CRL/741.031 Order of 4 March 1996 on fines of order/228.1) and results in a fine of CHF 120. Once there are bollards and cars cannot get onto sidewalks, the traffic fine will be redundant. Here, you need another control measure to *detect* whether this offence has actually taken place. We know of two control measures in Geneva that are for *detection* in nature: *Municipality police* who walk around the city to *detect* such violations and *public cameras.* We can even add a third control measure as *residents* report such violations to authorities.

Bollards can also be portable. The sidewalk in front of the World Health Organization main building has portable bollards that are removed during special events such as World Health Assembly or Executive Board meetings, letting cars

to park on the sidewalk. At such a time, walking on the sidewalk becomes a challenge for everybody; as a result, the majority walk on the road. Since the *speed limit* on the street within the WHO premises is only 20 km (another preventive control measure), the likelihood of being hit by a car while on the road is very slim (though this assumes that all drivers would observe the speed limit and remain vigilant in general).

Portable bollards removed to allow cars park on the sidewalk at the WHO

There are many discussions around the world whether bollards should be removed. Some say that there should be a presumption against installing bollards unless absolutely necessary. Some argue that stronger laws (higher fines) would do the job. Some suggest higher kerbs would prevent cars climbing on them. Of course raising the sidewalk height using a double kerb is a good control measure, but it will become a hazard at the same time. It will prevent cars from climbing on the sidewalk but the raised height of the sidewalk will be a hazard for people and yet again especially for the elderly and people with sight difficulties.

We should always think about the control measures we suggest and whether they would pose any *additional risks*. This is quite critical in QRM. Just like ice-

packs that are introduced as coolants for passive packaging as a preventive control measure to keep the pharmaceutical goods within a certain temperature range. Icepacks become a hazard for freeze-sensitive products. If you do not run additional analysis for each and every control measure that is suggested (before they are implemented), you may create harm that may come from your control measure.

Amsterdammertje

Bollards date back to 17th century, when old cannons were often used as bollards on quaysides to help moor ships alongside. Mooring as permanent structures are used to secure vessels. Around 1800, many people in Amsterdam started to use bollards to protect the sidewalk in front of their houses. From 1915 onwards there was a standard bollard of cast iron, weighing 70 kg, with three Saint Andrew's Crosses from the coat of arms of Amsterdam. This bollard already looked like the modern Amsterdammertje, although, amongst other differences, it was thinner and heavier. As trucks ran over the Amsterdammertjes more and more frequently, cars were able to pass between, and the bollards were no longer effective. In their place, the sidewalks were elevated slightly in the 2000s. Around two thousand Amsterdammertjes are being removed every year. In 2003, there were 37,616 Amsterdammertjes left.

Pavement parking around Coverdale Road in Alphington

In October 2016, following problems with cars parking on the pavement and serious reservations on behalf of residents relating to loss of quality of living and safety in Aplington, Police Community Support Officer Ben Jones distributed the following letter to all residents in the area:

Dear local residents,

It has come to my attention that there are many residents' cars who park on the pavement in the vicinity of Coverdale Road.

It is an offence to park on the pavement and is dealt with via a fixed penalty notice and a fine. I am appealing driver's better nature initially to avoid from parking on pavements.

Parking on pavements causes a high risk to members of the public who have to step into the road and also road users whose view may be inhibited.

I am currently monitoring the situation and prolific offenders will be dealt with via the means above.

I understand that the parking situation is not ideal for those households with more than one car; however I'm sure you will appreciate how serious this could become.

Many thanks for your cooperation with this issue.

Kind Regards,

PCSO Ben Jones 30716

Alphington Neighbourhood Police Team

Under construction

It is always difficult to understand why the public find construction sites irresistible to explore. You would not be surprised to see a crowd of people watching a crane in operation. Curiosity could be one reason, drawing not only teens and children, but adults as well.

Construction sites create risks not only for a construction worker, but also for members of the public who live near or passers-by. There are situations where you need to walk through a passage with overhead protection nearby a construction site or be guided through barriers. It is common that we all come across such construction sites in our everyday life.

Preventing public access to such construction sites is extremely important and lies within the responsibility of the construction site owner. Having a *gateman* to prevent public access may not be an effective measure. Remember the movie *Baby's Day Out (1994)*? Bink, a mischievous baby, manages to crawl through a skyscraper construction site passing by a [dozed off] gateman, pursued by his kidnappers in the middle of downtown Chicago.

Recently, in front of my house the Mayor's Office started a new construction of a two-story building. The property will include a three-level underground parking facility. You can imagine the scene with heavy machinery excavating and pounding all day with the noise and the dust penetrating your privacy! We learned to enjoy rainy days, because even though construction goes on, there is no dust. What a wonderful *protective control measure* Mother Nature has offered us! Here how the site looks like (see photograph on the next page).

I see many control measures in place, especially targeting the general public.

First of all, the whole site is separated from the public to isolate the hazard (the *construction site* in general) using physical separation (fencing and hoarding). In addition, signage is used: *Chantier interdit au public* (Public access forbidden). The same signage also contains a message to construction workers reminding them of the minimum obligatory equipment to wear. This also applies to those – not nec-

essarily construction workers - who visit the site for various reasons. In principle, nobody enters the site without wearing the minimum obligatory equipment.

Here, we pointed out the *construction site* as a hazard in general since, for example, *physical barriers* prevent public access to the site. In this regard, *fences* and *hoarding* are preventive in nature. The fencing is locked when the work ceases for breaks and at the end of the day. During working hours, for staff and machinery access, the main fence is open. This naturally increases the *likelihood* of baby or adult Binks to sneak in. In addition, the site could have a *gateman*. A gateman might prevent people from coming closer to danger zones or walk in, but they need to be vigilant.

In the signage we have a safety helmet, safety boots, and high-visibility vest. Though this does not apply to general public, again such personal gear is for protection. Let's analyse each of them separately:

Safety helmet is for hazards such as *falling material* and *debris*. In this regard, *safety helmet* is a *mitigation* measure to prevent/reduce the impact of such falling materials on the heads of the workers. Similarly, it also helps workers to protect their heads from injuries by bumping their heads to low level constructions.

Safety boots are similar to safety helmets; they are *mitigation* measures to prevent/reduce the impact of falling materials and debris onto feet during operations.

High-visibility vest is a *detection* nature control measure. With its reflective feature and bright colors, workers become more visible on a construction site. By this detection, others may divert the operation and/or warn the person to move – once

the worker is detected, the same control measure becomes *preventive* in related unwanted situations.

In the photo above, you see a worker operating a loader. You can also clearly see that the worker is wearing a safety helmet and high-visibility vest. Though you cannot see his safety boots, he is wearing them.

There is one another control measure seen in the photo. The barricades are erected adjacent to the road, although they have not attached warning lights to alert motorists of the hazard during the night or inclement weather, they have a portable reflective traffic safety sign next to the entrance. This *detection* control measure warns motorists of the construction site hazard.

Currently, the work on our construction site is the foundation structure. As the construction progresses; additional control measures for the public might be required.

Here is another construction site in Geneva.

The photo was taken during off-hours and you can see the chain lock on the fence. Here we see additional control measures.

Reflective warning signs are attached permanently on the fence and hoarding. These are for *detection* of the construction site by motorist during night or inclement weather. Here, the hazard is the *construction site* itself.

The signage with *Entree interdite a toute personnes non autorisées* (Entry forbidden for all non-authorized people) warning has additional safety reminders for workers to wear protection equipment, safety gloves and dust mask. They are all *preventive* in nature and serve to warn workers to minimize or prevent adverse effects resulting from exposure to specific hazards such as *noise* (ear protection), cuts from *woodwork* (safety gloves) and *dust* (dust mask).

Although not attached quite properly, on the top left side we see a *security camera*: a control measure for *detection*... As for the hazard, I would opt for *theft*. It is mainly to detected *unauthorized people* for security purposes. However, on the other hand, it may also serve as a *record* should there be any incidents and/or non-compliance by any of the workers. In this regard, it still serves as *detection*.

Also on the left side of the photo, we also see a *covered scaffold*. In general, scaffolds can be utilised to provide public protection. A scaffold can be constructed to ensure that no materials will leave the working platform. You can also see a *catch platform* that is placed at an angle of around 45 degrees. Both *scaffolds* and *catch platforms* are to prevent materials falling on people, be it on the site or in the vicinity. In this regard, *scaffold* is for *prevention*.

When there is a danger of an object or material used in construction work falling down, whether from a crane or otherwise, the ultimate preventive control measure is erecting a *gantry* in the area. A gantry is capable of withstanding all intended loads and is used for the overhead protection of people as well as for the support of materials and people.

Here we can bring the *adequacy* issue to scaffolds/gantries. As mentioned, the scaffold/gantry is a preventive measure, but if not securely constructed it would turn into a hazard for those who are nearby and/or under it.

One other control measure, for such construction sites, although we cannot see it, is *first aid training* (and supplies). Every construction site should have the required number of emergency response trained individuals. When an accident happens (involving construction workers or public), there must be always one or more individuals who are capable of administering first aid immediately, while waiting for paramedics to arrive. This would be a *mitigation* measure, activated when the unwanted event (accident) occurs to minimize the negative health impact on involved individuals.

Examples of (mandatory) precautionary pictograms (European Union)

Despite all control measures installed to keep the public from hazardous situations created by construction sites, it is recommended to avoid being in the vicinity of the construction site whenever possible.

We may not be as lucky as baby Bink.

Protect from freeze

In January 2014, the coldest temperatures in almost 20 years rocketed over the central U.S. toward the East Coast, threatening to topple temperature records, ignite energy demand and damage Great Plains winter wheat. I was in New York that week freezing under my warm clothes and heavy coat.

Walking in the 40E Street, I saw a pallet sitting on the sidewalk with a sign on it *Protect from freeze.*

I was in a rush for an appointment so I continued walking. In the afternoon, going back to my hotel along the same street, I was shocked to see the same pallet at the same spot, still waiting. This time, I took my phone and took a photo. I also took a screen shot of my iPhone showing the temperature at that moment.

Minus 16 °C!.. I had no idea how long the pallet had been left on the sidewalk, unattended like this, whatever it contained, it was sure frozen. This is what I call "temperature violation"...

It might have been that the delivery agents came to the address and there was no one in. They simply dropped the pallet on the sidewalk to complete their delivery. Of course we do not know if there was any quality agreement between the party who ordered the shipment and the supplier. But such details are typically specified in quality agreements with provisions.

Let's take a closer look at the situation with the risk management spectacles.

First of all, the *pallet* itself sitting on the sidewalk is a *hazard*, especially for people with sight loss and who are mobility impaired. Here again, we see an example of how a control measure *(pallet)* can also become a hazard.

There are two important warnings on the pallet:

"This side up"

"Protect from freeze"

The other sign *MSDS enclosed* is printed on one of the side flaps of each box. It means that special documents are secured and protected using pressure sensitive envelopes. MSDS (material safety data sheet) envelopes are generally used for documents that are attached outside surface of the shipment. They *protect* documents from *inclement weather* (hazard) by isolating the paperwork through pressure sensitive envelopes.

Let's start with the *this side up* warning.

This side up caution is usually applied to a fragile material shipment as well as to shipments where the product might be damaged (e.g. pressure, leakage) if transported otherwise. I see indication of oz and ml on the boxes under the stretch wrap, thinking that the product is either liquid or in a cream form. There are a total of 16 boxes in two sizes (10 big and 6 smaller) on the pallet – could be two different types of product. It is not clear whether the four boxes that are identical to the other six boxes do not contain any warnings on them. If they contain the same product, these two boxes are placed incorrectly on the pallet. The warning sign is printed on the box, meaning that it is not an attached sign. This eliminates personnel forgetting to apply the sign for such shipments. In this regard, *use of pre-printed boxes with warning signs* becomes a control measure against the hazard of *forgetting to attach it*. Of course, warning signs require *compliance* by workers, there is always a risk of workers not paying attention to the signs (this is the hole of the control measure) and either pack the material upside down but placing the box correctly, or packing the material cor-

rectly but placing the box upside down. I do not know what the product is and whether they were packed correctly.

Protect from freeze is a similar cautionary sign, and can only warn workers that the shipment should not be exposed to freezing temperatures. But what is freezing temperature? Freezing temperature is a point at which a liquid freezes. For example, the freezing point of water is 0°C. But what do they have in these boxes? What is the freezing temperature for that particular product? We do not know this. In pharmaceuticals and vaccines, although the freezing point for products varies, 0°C is taken *operationally* as the cut off point for freeze-sensitive products. This is why, in general, the threshold freeze indicators are set to 0°C. World Health Organization (WHO), Performance, Quality and Safety (PQS) project prequalified devices are required to set to -0.5°C for freeze alarm (the logic behind this is with the ±0.5°C accuracy, when there is a freezing alarm all possible *real* temperature would be below 0°C, otherwise if the set point is 0°C, in half of the cases, the real temperature could be between +0.1 to +0.5°C). Going back to our photo, if we assume 0°C as freezing point for this product, at -16°C, it should have been long frozen.

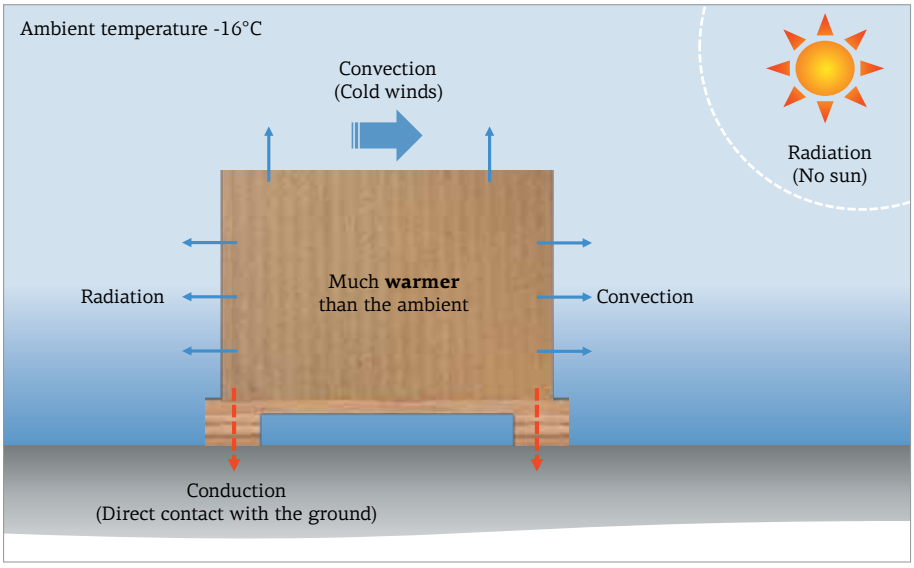
For freeze protection, thermal insulation boxes (preventive control measure) are used with special coolants. Coolants (ice packs, cool packs, water packs, warm packs) are used to regulate the temperature in these passive containers. In this regard, coolants are control measures. However, the use of ice packs, unless the loading design is specially engineered, may become a hazard for freeze-sensitive products. Some passive containers have specially engineered anti-freeze features and they use fully frozen ice packs. Otherwise, you need to bring the ice packs to latent phase before you load the box with freeze-sensitive products to prevent freezing. Conditioning the ice packs to 0°C is found to be NOT practical, time consuming and requiring serious compliance by users. This has proven to be the biggest problem in the field. Consequently, the *cool water packs* concept was developed by a research team to remove ice packs from in-country transport of freeze-sensitive vaccines. Today, WHO PQS demand cool life to be displayed on the lid for each cold box. *Cool packs* as a control measure *eliminate the hazard* (ice packs) to prevent freezing.

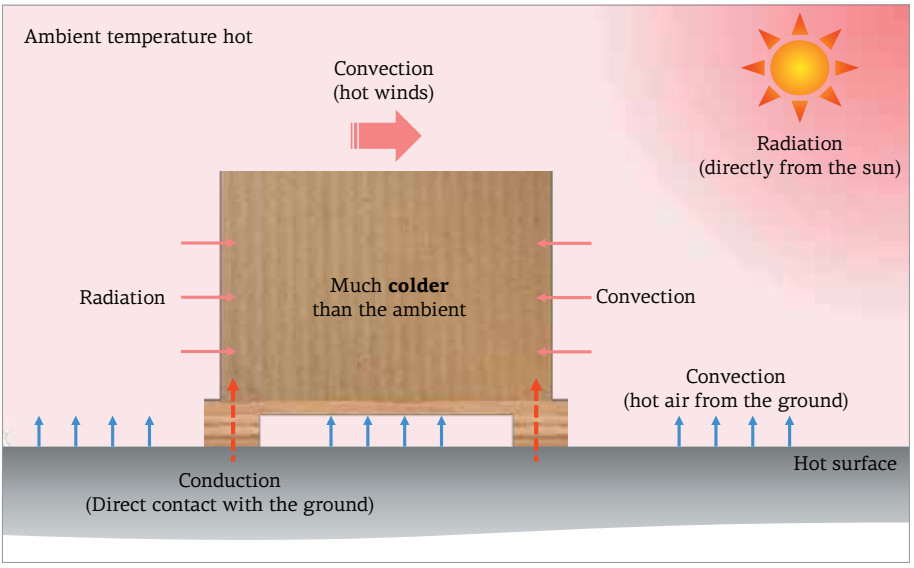
There are two other control measures we see with this pallet.

The *wooden pallet* itself is a control measure for the shipment. A pallet is a flat transport structure that supports goods in a stable fashion while being lifted by a forklift, pallet jack, front loader, work saver, or other jacking device, or a crane. It also helps to delay the impact of temperature from the surface on which it is

placed in preventing direct contact with the ground. Here the hazard is the *ground* (cold or hot). When pallets are placed on the ground, all three ways of heat transfer - conduction, convection and radiation - start working. Conduction works because of the direct contact with the ground, dolly or loader. We should keep in mind that wood has low conductivity (0.17 W/mK). Convection works with the hot air from the ground, convection currents, warm or cold winds. The severity depends on the conditions and increases significantly at high wind-speeds. Radiation can come from the ground around the pallet, nearby hot objects and directly from the sun. In bright hot weather, solar irradiance can be up to 1200 W/m^2. As for the thermodynamics, we should keep in mind that the heat moves from a region of high temperature to another region of lower temperature. In very cold weather such as in our example in 40E Street in New York, the heat transfer will follow from the pallet to the environment. Since there is no sun, radiation from the sun will not work.

The following two graphics illustrate the heat flow in a cold and a warm ambient temperature.





The *stretch wrap* is also a control measure; the elastic recovery keeps the items tightly bound. Stretch wrap is frequently used to unitize pallet loads but also may be used for bundling smaller items which is the case in our photograph. It provides a film around one or more products with the aim to stabilize, protect and secure the cargo from *tampering* or *theft* (hazards). Here, we have an unattended pal-

let, loosely stretch wrapped. Anyone can easily lift the boxes from the top opening of the stretch wrap. Stretch wrap does not have good performance in terms of thermal protection. In the case of cold weather, the contents of the pallet might be warmer than the outer temperature, and *loss of heat* (therefore risk of freezing) results from inside the pallet to outside colder environment. If you want to temperature protect the pallet, you must use thermal blankets to cover it.

DuPont Protection Technologies conducted a study on cargo cover performance under real environmental conditions. They used the following cargo covers in this study:

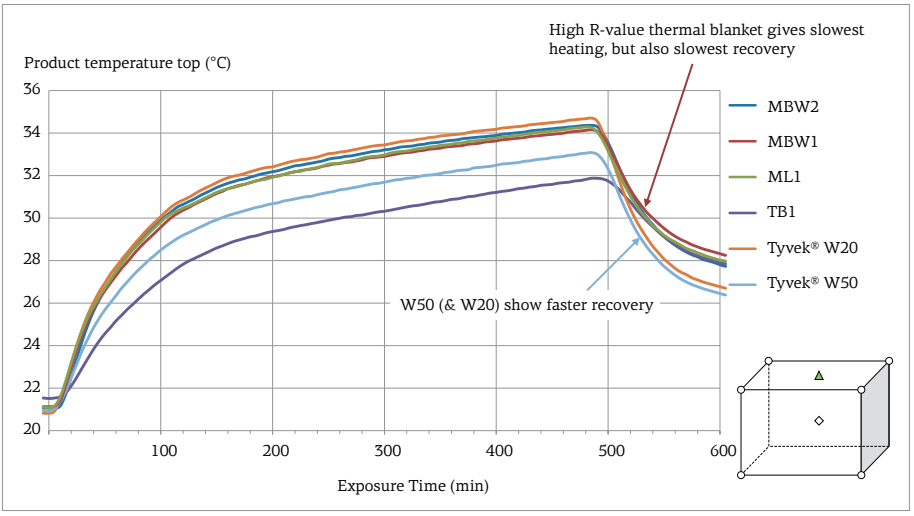
	Basis weight ASTM D646 g/m²	Thickness mm	Reflectivity 400-1050 nm %	Thermal conductivity ASTM C518 W/mK	R-value ASTM C518 M²K/W	Air permeable	Description
W20	60	0.17	93.4	0.0720	0.002	Yes	Flash-spun Tyvek®, metallic layer inside
ML1	166	0.3	81.4	>0.100*	<0.003*	No	Reinforced metallised film
MBW1	325	6.5	84.6	0.419	0.155	no	Double bubble film laminated to metallised film both sides
MBW2	370	8	79.9	0.0400	0.190	No	Double bubble film, aluminium foil both sides
W50	330	10	91.3	0.326	0.267	Yes	Flash-spun Tyvek®, metallic layer + insulation fleece
TB1	517	40	75.0	0.0326	0.447	No	Five layers double bubble film + four layers metallised fleece

*Out of instrument range

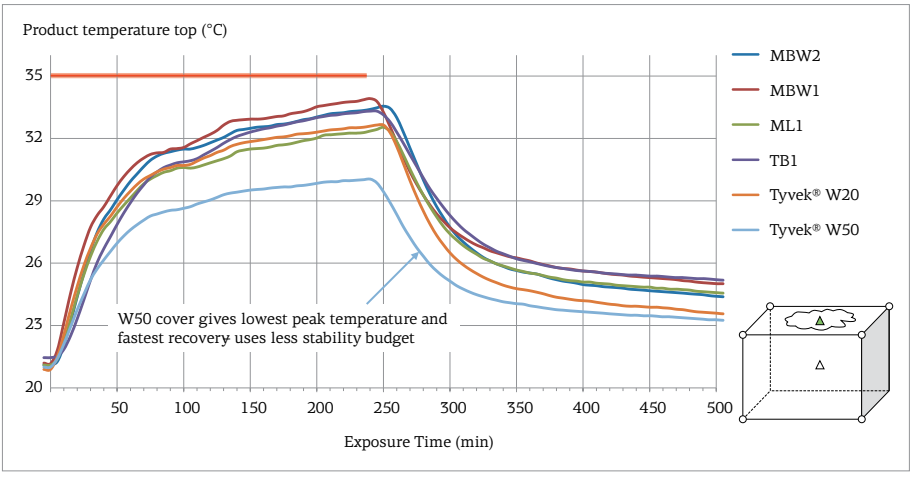
Identical pallets were loaded with 18 carton boxes (three layers of six) and low thermal mass (approximately 100 kg of water) was distributed through each pallet. Fifteen data loggers were placed at identical positions. Each pallet was then covered with a different type of cover. In first experiment, all pallets were conditioned at 20°C, then placed in a pre-heated environmental chamber at 40°C for eight hours, then returned to the 20°C warehouse. In the second experiment, all pallets were conditioned at 20°C, then placed outside in strong solar exposure (Florida) at midday (ambient temperature 34-36°C) for four hours, then returned to the 20°C warehouse.

In first experiment (environmental chamber 40°C), high R value thermal blanket gave the slowest heating but also slowest recovery, while low R value thermal

blanket showed the fastest recovery. Performance largely correlated with the R-value (TB1 > W50 > MBW1 > MBW2 ≈ ML1 ≈ W20).



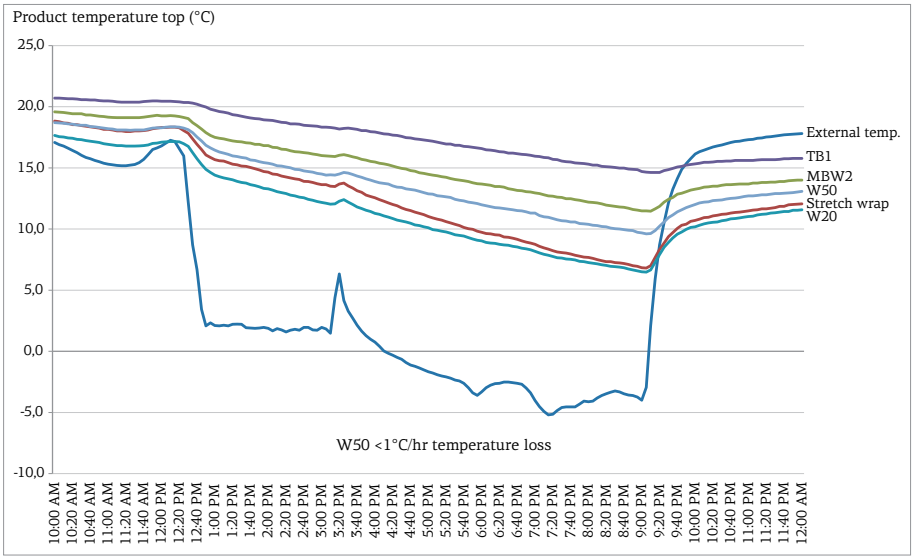
In the second experiment (solar exposure), low R value thermal blanket gave the lowest peak temperature and fastest recovery, therefore using the less stability budget. It should be noted that these blankets have high reflectivity. In this experiment, performance strongly improved by high visable/near-IR reflectivity (W50 > W20 ≈ ML1 > TB1 ≈ MBW2 ≈ MBW1).



In a real example of transport validation, DuPont shipped identical pallets as general cargo by air from Hydarabad, India through Dubai, UAE to Oslo, Norway. In this experiment, carton boxes with water bottles to give 10 percent thermal mass were used. Twelve data loggers per pallet were used to record the temperatures. It was also arranged with airlines to have unusually long handling times to simulate real world problems. In this study five different covers were used:

- Stretch-wrap
- Laminated, double metallised bubble-wrap cover (MBW2)
- Laminated, multi-layer metallised thermal blanket (TB1)
- Tyvek®Solar™ W20 cargo cover
- Tyvek®Xtreme™ W50 cargo cover

Unfortunately, in Dubai, conditions were not sufficiently severe to discriminate between covers, though stretch wrap resulted in giving the highest product temperature. Unloading and cold exposure in Oslo showed that covers with higher R values offers between protection against the cold.



MBW2

TB1

W20

W50

Stretch wrap

The authors concluded the following from these three experiments:

- Datasheets for cargo covers used during IQ should be read with caution as test methods used to evaluate physical properties can vary.
- Tests carried out during OQ & PQ need to reproduce real conditions expected during operations identified as high risk for cold-chain breaks.
- Thermal chamber results may not predict performance where solar exposure is a factor.
- High R-value materials give protection from excursions involving high or low ambient temperatures.
- High reflectivity in the visible/NIR spectral range is needed where solar exposure is a significant risk factor

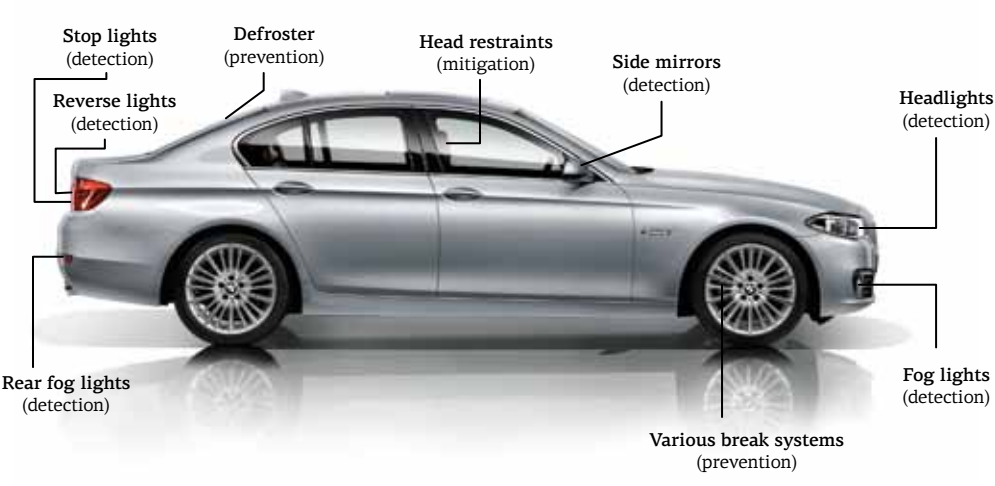
If we go back to our example of the pallet left outside unattended at 40E Street in New York, a high R value thermal blanket would be the most preferred control measure. Of course this alone would not solve the problem if you just leave the pallet unattended in a street.

We can only hope that whatever got frozen in those boxes did not cause any harm to the people who used it.

Car: Sea of control measures and redundancies

Even though I take public transport to commute to and from the office, when we travel outside Geneva, it is my turn to drive. I like driving... Nowadays, driving is filled with redundant control measures.

Let's look at it first from outside before getting in.



Even though there are many features in the car that make it *safe* based on the design such as car body; I'd like to focus only on the features that we use when we drive.

Headlights are for *detection*, both for you and for other vehicles in the opposite direction ahead of you. Here we have several hazards. First of all, we all know that we must turn headlights on at night; after all, we cannot exactly drive safely if we cannot see anything. In this case, the hazard is *darkness*. Headlights might also be required by law during the day time as well. Headlights automatically turn on when you start the engine in some models, which removes *compliance* issue and makes the control measure permanent when the car is in operation. This is an important feature in controls.

Some controls may require *compliance* by users that they have to initiate it. For example, before auto-disable (AD) syringes were introduced, we had either disposable or reusable syringes. Disposable syringes must be discarded after use. We are faced with a *compliance* issue here. If all users comply with this safety rule, it would be 100 percent safe, wouldn't it? Worldwide, each year, the overuse of injections and unsafe injection practices combine to cause an estimated 8 to 16 million hepatitis B virus infections, 2.3 to 4.7 million hepatitis C virus infections and 80,000 to 160,000 HIV infections[1]. Among unsafe practices, the re-use of syringes and/or needles without sterilization is of particular concern. Following a joint call by the WHO and UNICEF, several types of syringes have been designed to prevent reuse: AD syringes automatically become disabled after one use. WHO and UNICEF now recommend that auto-disable syringes should be used for administering vaccines. As adapted from ISO 7886-3, auto-disabling is a feature or characteristic of the syringe or device that passively and automatically activates upon administration of the intended dose in order to prevent subsequent re-use of the syringe. In order to avoid inadvertent or intentional re-use in the event such action is not taken, no secondary or additional action on the part of the user shall be required.

Now, let's look into different auto-disabling mechanisms.

The timing of the activation of AD feature may vary by design, typically within the range indicated below. Today, there are three auto-disabling mechanisms exist among the AD syringes:

Type 1. The auto disable feature is automatically activated and remains effective from the time that injection is commenced.

Type 2. The auto disable feature is automatically allowed and returns effective from the point when 50 percent of the intended fixed dose has been delivered.

Type 3. The auto disable feature is automatically activated on completion of delivery of the intended dosage.

1 Syringes engineered to prevent reuse are not suitable for certain medical procedures e.g. when administering multiple medicines, maintenance of IV lines, local anaesthesia and nasal feeding. Conventional disposable syringes should be used safely in these and similar instances.

Technically, it is possible to reuse the AD syringes with second and third auto-disabling mechanisms simply by overfilling and delivering sub-optimal dose (until just before the point where auto-disabling mechanism triggers and draws additional doses). In this regard, the first auto-disabling mechanism stands like the headlights switching on automatically once you start the engine in a car. There is no compliance issue with this measure. It is automatic, and it becomes active once you start using the device.

In quality risk management, compliance is an important aspect when it comes to control measures. If you are coming up with measures that are to be initiated by users, you should always keep in mind the risks of non-compliance.

Let's go back to our car.

In some countries, you may come across some signs reminding you to turn your headlights on along certain parts of the road (such as mountainous roads or tunnels). The primary reason for daytime headlights is inclement weather – rain, sleet, snow, hail, or fog. Here, we have another hazard, *low visibility*. In case of snow or fog, regular headlights can reflect off the fog or snow in the air, causing glare impacting the eyes of drivers so that they cannot see the road adequately.

The below photograph illustrates how important it is to have headlights on during the day time. The photo was taken December 2016 at 13:30 day time on D965 (France). About less than a kilometre ahead, you will recognize two cars approaching you, one overtaking the other. If it was not for the headlights, it would

have not been possible to detect these two cars at such a distance. The overtaking vehicle has enough distance to move back to his lane, but as a preventive measure you may want to reduce speed to make sure that it really happens at a safe distance.

Fog lights, as their name suggests, were developed for use in dangerously thick fog. They can also be used for other conditions in which visibility is severely limited. Fog lights are for detection purposes, addressing the hazards such as snow and fog, so that you can identify the road clearly. When you put the rear fog lights on, it is again for *detection* purposes, but also for the cars behind you. In such a case, the *cars behind you* are the hazards.

Let's take one more control measure, which is actually inside but can also be seen from outside: *head restraints*. They are not designed for comfort, they are designed to limit the movement of your head and provide support in case of an accident. In this regard, they are a *mitigation* measure while the hazard is the impact created by the accident. A properly adjusted head restraint will help to protect you against whiplash and potentially save you from injury. If not properly adjusted, the control measure will not be effective. Most head restraints can be adjusted for height and fore/aft and locked into position. In order to adjust the head restraint, you need to adjust it in a way so as the top of the restraint is levelled with or above the top of your head and stays as close to the back of your head as possible.

Since the impact created by an accident could affect everybody in the car, it is not only the driver; all passengers need properly adjusted head restraints.

Before we move to another reality of an everyday life, let's take a close look to a road/traffic related control measure that is also a hazard itself.

Drive carefully.

Sleeping policeman

Speed bumps (or speed breakers) are the common name for a family of traffic calming devices that use vertical deflection to slow motor-vehicle traffic in order to improve safety conditions. Vertical deflection is to raise a portion of a road surface to create discomfort for drivers travelling at high speeds. Both the height of the deflection and the steepness affect the severity of vehicle displacement. Speed bumps' heights typically range between 7.6 and 10.2 cm.

Speed hump is another traffic calming device and is placed across the road to slow traffic and are often installed in a series of several humps to prevent cars from speeding before and after the hump.

In all situations, speed bumps/humps require additional signalization to warn drivers of the approaching bump.

In addition to such signs, warnings can also be painted on the road such as *SLOW* or *BUMP AHEAD*. In most cases, a bump itself is also painted to attract attention.

Statistics show that *speed bumps/humps* reduce both the traffic volume and collisions. They are introduced as a prevention control measure against *high speed* (hazard).

The same preventive control measure becomes a *hazard* from the beginning. There are cases of cyclists being killed in a crash while attempting to avoid a speed bump.

Some humps cause the front and end of cars to hit the ground (and therefore exhaust damage) even at optimal speed. Suspension damage in cars is also often reported. In 2008, a study in Sweden analysed the public service bus drivers' health risks due to repeated exposure to mechanical shocks when frequently riding over traffic speed bumps. The paper published by J. Granlund and A. Brandth presented the results from an investigation of vibrations imposed on the driver from some 20 speed bumps in the Stockholm area (Sweden). The vibrations have been evaluated in accordance with the new standard ISO 2631-5. It defines a method of quantifying whole-body vibration containing multiple shocks (such as bumpy rides) in relation to human health. Peak vibration (shock) values were used to predict compression stress in the spine, and reports equivalent daily static compression dose, S_{ed}. The results showed high S_{ed} -values with high health risks even at low speeds. This finding made the Swedish Work Environment Administration prohibit line bus traffic on the related streets until some speed bumps were altered. The health risk depended on the number of daily shock exposures. On investigation of the worse road the speed limit was 50 kmph (30 mph), while the maximum acceptable speed was 10 km/h (6 mph) assuming 150 bumps per day.

One other criticism of speed humps is their effect on emergency vehicles. Response time is slowed by 3–5 seconds per hump for fire trucks and fire engines and up to 10 seconds for ambulances with patients on board. Alternative and more advanced traffic calming devices have now been developed to allow emergency vehicles not to reduce speed. For example, speed cushions are designed to alleviate the negative impacts that vertical deflections have on emergency vehicle response times.

Plastic habit

We have a lot of meetings at WHO. Some of them short, some take the whole day. When a meeting is at least half a day, we usually have a coffee break. The WHO catering services fix our coffee breaks, offering tea, coffee, sometimes fruit juice and some cookies. Though some people do not take any sugar, many still do, and need to stir their drink and therefore require a tool (usually a plastic spoon or a plastic/wood swizzle stick). Many times these spoons or swizzle sticks are not in individual packages, but on a holder or tray, all open. The picture would be very similar to the cafeteria.

This reminds me of Rueben from *Along Came Polly*. Just imagine what people have been up to (resulting in dirty hands) before they would pick up the cutlery. It is hard to understand why such cutlery is never placed upside down. If cafeteria managers think that people will confuse forks and knives, would it be so difficult to mark the trays?

When the cutlery is placed in the cup upside down, the users can only pick them up by the handle without touching the bowl, prongs or blade.

What would be the best control measure for the hazard of *unwashed hands of other users*? In this regard, placing the cutlery in a way to allow users only to touch the handle part is a preventive control measure. You cannot control that everyone wash their hands before. Even if they wash their hands, whether they are really clean is another question.

During coffee breaks we usually use plastic disposable food ware. Are there any other risks involved in general in using disposable utensils in cafeterias?

These disposable utensils end up in the trash. Food contamination makes it unlikely that they are recycled. From here the used cutlery is most likely transported by garbage truck to its final resting place in a big hole in the ground, the landfill – or in some cases they are incinerated. They may seem to be a convenient option, but they add unnecessarily to the earth's growing problems. On average 300 million tons of plastic is produced globally every year and half of it is for dis-

posable use. Manufacturing plastics requires fossil fuels, and, unlike organic materials such as wood and paper, it doesn't biodegrade. Of course there are exceptions of a miniscule share of bioplastics designed to be composted, but those also have their own problems. More than 180 species of birds, marine mammals, and other animals have been documented as having ingested plastic debris.

Wouldn't it be fair to conclude that *plastic utensils* are *hazards* harming the earth? In this regard, could replacing plastic utensils with *heavy duty utensils* be a control measure in saving the earth?

Switch from disposable to reusable food ware

You might think that purchasing reusable utensils for cafeterias would increase water consumption as well as costs. In 2014, two Minnetonka middle schools, in coordination with TonkaGreen (the parent volunteer organization), received a grant from the Minnesota Pollution Control Agency's (MPCA) Environmental Assistance Grant Program to switch from disposable to reusable food ware and improve their cafeteria waste sorting stations. The purpose of the project was to address the most significant source of non-recyclable, non-compostable waste from the school cafeterias: disposable plastic flatware and Styrofoam bowls. The schools used the grant funds to purchase washable durable utensils and bowls, custom-made waste sorting stations, and a few needed racks and carts to store, move, and wash the reusable food ware. In addition, the project included educating over 2,000 students, staff, and visitors about the benefits of eliminating the disposables and how to properly sort everything from the trays after lunch. The project team analyzed the waste diversion benefits and, with help from MPCA staff, the overall lifecycle environmental footprint change from the source reduction of the disposable items – including carbon emissions, water consumption, and air emissions.

In the first year, the schools saved approximately $3,000 combined by buying the reusable utensils and bowls. The annual per student costs for food-ware dropped from $6.89 to $4.83.

Environmental impacts included prevention of about 6,000 lb of on-site solid waste in the first year. Instead of buying 700,000 plastic utensils, the school purchased just 12,000 metal reusable utensils. In addition, in the first year of use, the change to reusable utensils and bowls are estimated to result in a 44% reduction in life cycle greenhouse gasses and similar reductions in water withdrawals and air pollution emissions versus the disposables. Taken alone, the metal utensils resulted in a 77% reduction in greenhouse gases and water consumption over disposable plastic utensils.

The benefits of reusables increase the longer they are in use. Over three years of use, the schools could anticipate saving an estimated $23,000. Environmental benefits accrue as well. Over three years of use, the reusable utensils (not the bowls) would result in an estimated life-cycle reduction of 88% of greenhouse gasses, air pollutants and water consumption over the disposables. On-site impacts to water and electricity use were found to be negligible and did not change the net overall magnitude of the lifecycle benefits of the reusables. Changes to staff routines were easily accommodated. Several tips for implementing use of reusables in schools were developed.

This case study shows that a return to reusable utensils in schools can be good for the bottom line and the environment. Moreover, the case study shows that common concerns about reusables – that on-site water and electricity use will undercut environmental benefits – are unfounded.

In 2016, a new law was passed in France to ensure that all plastic cups, cutlery and plates can be composted and be made of biologically-sourced materials. With this move, France has become the first country in the world to ban disposable plastic cups and plates. The law, which comes into effect in 2020, is part of the Energy Transition for Green Growth – an ambitious plan that aims to allow France to make a more effective contribution to tackling climate change. Although some ecologists' organisations are in favour of the ban, others argue that it has violated European Union rules on free movement of goods.

Last mile: At the pharmacy

The term *last mile* was originally used in the telecommunications field as a colloquial phrase referring to the final leg of the telecommunications networks that deliver telecommunication services to customers (retail end-users). It has also been applied to supply chain management to refer deliveries from a service point to a customer. In this regard, the *last mile* does not need to be a mile by definition; it can even be thousands of miles.

If I order a book from a bookstore (service point) and ask the book to be delivered to my home address (customer), the delivery courier takes care of the last mile distribution. If I did this with FNAC in Geneva, this would be 7.8 km. If I order the same book on internet, say from Amazon.co.uk (service point), the same last mile distribution would be over 1000 km.

Pharmacies are also considered as last mile service points. Even though the majority of the time, customers go to the pharmacy to purchase the products prescribed by their doctors, it is still considered as the last mile, though from the customer perspective this may also be taken as the *first mile* problem.

All pharmaceutical products are time and temperature sensitive. Some may require more strict temperature range than others. Although different pharmaceutical products have different stability budgets, WHO recommends the following labelling statements for both active pharmaceutical ingredients and finished pharmaceutical products:

Testing condition under which the stability of the API has been demonstrated	Recommended labelling statement [a]
25°C/60% RH (long-term) 40°C/75% RH (accelerated)	"Do not store above 25°C"
25°C/60% RH (long-term) 30°C/65% RH (intermediate, failure of accelerated)	"Do not store above 25°C" [b]
30°C/65% RH (long-term) 40°C/75% RH (accelerated)	"Do not store above 30°C" [b]
30°C/75% RH (long-term) 40°C/75% RH (accelerated)	"Do not store above 30°C"
5°C ± 3°C	"Store in a refrigerator (2°C to 8°C)"
-20°C ± 5°C	"Store in freezer"

[a] During storage, shipment and distribution of the API, the current good trade and distribution practices (GTDP) for pharmaceutical starting materials are to be observed..
[b] "Protect from moisture" should be added as applicable.

In addition to these recommendations, WHO recommends extra labelling statements for use where the result of stability testing demonstrates limiting factors:

Limiting factors	Additional labelling statement, where relevant
FPPs that cannot tolerate refrigeration	"Do not refrigerate or freeze" [a]
FPPs that cannot tolerate freezing	"Do not freeze" [a]
Light-sensitive FPPs	"Protect from light"
FPPs that cannot tolerate excessive heat, e.g., suppositories	"Store and transport not above 30°C"
Hygroscopic FPPs	"Store in dry condition"

[a] Depending on the pharmaceutical form and the properties of the FPP, there may be a risk of deterioration due to physical changes if subjected to low temperatures, e.g., liquids and semi-solids. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.

I'd like to share an experience from Volos, Greece to see how the products requiring transport under certain temperature range are handled.

Let's look at the labelling first:

The temperature requirement for this product (Tetravac® – Acellulaire) is be-

tween 2ºC to 8ºC. The product comes in a secondary box that contains the primary product. Though every product has its own stability budget, we do not have such information on the label. This may appear in the product insert or may not be mentioned at all.

The pharmacist uses a compact insulated pouch (Igloo) with a slim blanket cooling gel pack to maintain internal temperature at between +2°C and +8°C for up to one hour. The pouch is big enough to accommodate the vast majority of time and temperature sensitive pharmaceutical products on the market while remaining sufficiently compact to be easily transported by the patient inside a handbag or a briefcase. Insulation is rigid *high-density polyurethane panels* (control measure to keep product between +2°C and +8°C).

The slim cooling gel is used not frozen; it is kept in the refrigerator as a cool pack to *eliminate* inadvertent risk of freezing. There are also warnings on the cooling pack that it should not be frozen (ne pas congeler). The *cooling gel* is the preventive control measure to keep the product cool during transport, while the *hazard* would be the *ambient temperature* (be it warm or cold). The pouch closure is a *zip lock* (another control measure).

I observed how Vasilis Birlirakis (the responsible pharmacist) prepared the pouch for the client. Typically, he takes the slim blanket cooling gel and the pouch from the refrigerator. He rolls the blanket gel around the product, and places it in the pouch. Then he zip locks the pouch. He tells the client to come to his consultation room to explain more. He says that he can carry the pouch in his briefcase if he wants to, but should not leave it in the boot of the car or next to the windshield since with radiation such places may become extremely hot and this is not good for the medicine. He further explains to the client that he has one hour to transport the product. The patient tells him that he has to take it to doctor's office where his wife and the child are waiting for vaccination. He asks him whether he has any questions. Finally he reminds the patient to return the pouch so it can be reused. He explains to the patient that the pouch may be reused up to 50 times.

If we are to conduct a preliminary risk analysis for this operation for the pharmacy, we would need to identify the risk question: *What are the associated risks of using an insulated pouch for cold chain medicines?* As for the scales for likelihood and severity of consequences, we establish the following rating first:

	Scale				
	1	2	3	4	5
Severity	Increase out-of-storage time without any impact on product quality at all	n/a	Increase out-of-storage time without any significant impact on product	n/a	Lost product quality
Likelihood	One occurrence in more than 1 year	One occurrence every 6-12 months	One occurrence every 3-6 months	One occurrence every month	More than one occurrence every month

Risk question: What are the associated risks of using an insulated pouch for cold chain medicines?

Risk ID#	Hazard/ unwanted event	Harm/consequences	Potential causes	Likelihood of occurrence (L)	Severity of consequence (S)	Risk score	Possible controls/actions
Assign each entry a unique tracking number	What is the hazard/What could happen?	What might be the potential impact?	How might the hazard occur?	What is the likelihood that the hazard and harm will occur (rating scale)	How significant is the impact (rating scale)	(Calculated) L x S	What might help to detect, prevent and control the hazardous situation?
1	Frozen cooling gel	Freezing of product	Cooling gel is kept in the freezer instead of refrigerator	1	5	5	Pharmacist checks that the cooling gel packs are always kept in the refrigerator
2	Prolonged transport time	High temperature excursion (in warm ambient)	The pouch is validated for 1 hour - extended time in transport could pose potential risks to unwanted temperatures	3	1	3	Pharmacist explains to the patient to carry the pouch with protection from direct sun and not place it in the boot of the car and to transfer the contents to a refrigerator within one hour
3		Low temperature excursion (in cold ambient)	The pouch is validated for 1 hour - extended time in transport could pose potential risks to unwanted temperatures	1	3	3	Coldest average temperature in Volos is never below zero. Pharmacist explains to the patient to transfer the contents to a refrigerator within an hour
4	Forgetting pouch somewhere	High temperature excursion (in warm ambient)	The patient may forget the pouch for an extended period of time	1	5	5	If the patient informs the pharmacist, the manufacturer could be contacted to check whether stability budget allows product to be used after such exposure
5	Unzipped pouch	High temperature excursion (in warm ambient)	Pharmacist forgets to zip the pouch and/or the patient unzips it	1	3	3	A second person could check that the zip is locked and pharmacist must explain to the patient not to unzip the lock until he/she reaches his/her destination

Now, let's mark all these in a linear risk scale (bold and circled ones are our scores):

		SEVERITY		
		1	3	5
LIKELIHOOD	**5**	5	15	25
	4	4	12	20
	3	**3**	9	15
	2	2	6	10
	1	1	**3**	**5**

It is routine that Vasilis checks on a daily basis to make sure that no slim cooling gels are placed in the freezer. Therefore, the likelihood of accidently freezing them is extremely low. Although the pharmacist explains to the client that the contents of the pouch should be transferred into a refrigerator within one hour, there is always a possibility that this may take longer. On the other hand, the majority of the clients of the pharmacy are from the vicinity and they reach their homes/offices in less than an hour. If it takes longer than one hour, high temperature excursion is a greater concern than cold exposure since Volos does not experience freezing ambient temperatures. In this regard, the biggest hazard would be the patient forgetting the pouch somewhere. In such a case, if the patient comes back to Vasilis and explains what he has done, the best *mitigation* measure would be for Vasilis to *call the manufacturer* to explain the exposure and to question whether the product still can be used safely. When the product is prepared by an assistant, the head pharmacist always *checks* the preparation before it is handed over to the client – which is another *control measure* that is in place.

Although Volos does not experience freezing ambient temperatures, in such places with low temperatures, prolonged transit times could be a concern for freezing. Placing warmer cooling packs could be a solution (e.g. keeping the cooling packs at room temperature).

Next time you go to your pharmacy for purchasing a cold chain medicine, check how your pharmacist prepares the package and what warnings he/she explains to you if at all!

Mask on

I travel a lot for official purposes and have been to China on several occasions. But I have never experienced anything like the *airpocalypse* case in January 2012 in Beijing. Since then heavy air pollution has dramatically increased public awareness and promoted serious discussion not only in China, but all over the world. The typical sight of a pedestrian in videos and photographs emerging from China is with an anti-pollution mask.

In the photograph below you see the lady, who covered her nose and mouth with her hand – another solution to protect and hence becoming a preventive control measure.

The *hazard* is clear: *air pollution.* Air pollution is the introduction of particulates, biological molecules and other harmful substances into the atmosphere. Air pollution causes diseases, allergies, deaths to humans as well as creating damage to other living organisms such as animals and plants. In this regard, though we consider air pollution as a hazard in general, we can be more specific with the pollutant.

Of course hand protection, regardless of whether you have your gloves on, is less efficient than the anti-pollution mask. But, do air pollution masks as individual intervention actually help to protect you? The effectiveness of air pollution masks has not been included in the ongoing Cochrane systematic review, and has not been systematically evaluated before. Agency for Food, Environmental and Occupational Health and Safety (ANSES) is currently assessing the efficiency of using masks under different scenarios - this was meant to be completed by the end of 2016. In the absence of such evidence by systematic reviews, what other information have we on the benefits of anti-pollution masks?

There is no doubt that the size of the particle is the main determinant of where in the respiratory tract the particle will come to rest if inhaled. Cilia and mucus in nose and trachea will filter larger particles, but particles less than 10 micrometre can easily settle in the bronchi/lungs and cause health problems. Fine particles, smaller than 2.5 micrometre, can reach and rest in the bronchioles and alveoli. If you think of a construction site, it can be filled with dust, heavy metals and/or dangerous gases. Construction workers have been using protective masks for decades. The most common facemask for workers is the N95 respirator. An N95 respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The N95 designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. However, even a properly fitted N95 respirator does not completely eliminate the risk of illness or death.

When it comes to facemasks, they are loose-fitting, disposable devices that create a physical barrier between the mouth and the nose of the wearer and potential contaminants in the immediate environment. Facemasks may be labelled as

fitted surgical, isolation, dental and/or medical procedures. As indicated by the USFDA, if worn properly, a facemask is meant to help block large-particle droplets, splashes, sprays or splatter that may contain germs (viruses and bacteria), keeping them from reaching your mouth and nose. Facemasks may also help reduce exposure of your saliva and respiratory secretions to others.

In the situation of airpocalypse, for individuals, facemasks (plain surgical masks) may seem the best control measure against the hazardous particulates in the air. Such masks do not carry a NIOSH (National Institute for Occupational Safety and Health) rating. Although they are recommended to prevent seasonal flu and filter out larger particulate matter, they are not proven to be effective. They will only filter larger particles if worn tightly. WHO, Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association for Professionals in Infection Control and Epidemiology, and the American College of Occupational and Environmental Medicine still recommend these except in cases of "high risk". Although developed and recommended for construction workers, the general public also have access to purchasing N95 masks for personal use – which provide better protection compared to plain surgical masks. Ministry of Health in Singapore promotes use of N95 masks for elderly people, people with chronic lung diseases, heart disease or stroke, and pregnant women if they feel uncomfortable while breathing.

If you think from risk management perspective, in order to be effective, the mask must be tightly fitted. Here is a better pictogram on how to properly put on a disposable respirator. It warns users that nothing should prevent proper placement or come between your face and the respirator - such as facial hair – which was the case with me.

When it comes to control measures, proper and detailed explanation should be provided if *compliance* by the user is required. Otherwise, it will not be effective and will create a false security for the individual.

California Department of Public Health also recommends NIOSH rated N95 or P100 masks against wildfire smoke (hazard). From the risk management perspective, the leaflet that is released includes all necessary points for effectively applying the mask. Though masks are to protect the wearer from the hazardous particle and gasses in the imminent

environment, they can be considered as *mitigation* measures. From the risk management perspective, other *mitigation* measures to reduce wildfire smoke impact on health that can be applied by individuals at home. Conditions can be summarized as follows:

Staying indoors - The most common advisory issued during a smoke episode is to stay indoors. The usefulness of this strategy depends on how well the building limits smoke from coming in from outdoors and on minimizing indoor pollution sources. Staying indoors may therefore provide some protection, especially in a tightly closed, air-conditioned home in which the air conditioner re-circulates indoor air.

Reducing activity - Reducing physical activity is an effective strategy to lower the dose of inhaled air pollutants and reduce health risks during a smoke event. During exercise, people can increase their air intake as much as 10 to 20 times over their resting level. Increased breathing rates bring more pollution deep into the lungs. Furthermore, people tend to breathe through their mouths during exercise, bypassing the natural filtering ability of the nasal passages, again delivering more pollution to the lungs. They also tend to breathe more deeply, modifying the usual patterns of lung particle deposition.

Reduce other sources of indoor air-pollution - Many indoor sources of air pollution can emit large amounts of pollutants, some of which are also present in wildfire smoke. Smoking cigarettes, using gas, propane and wood-burning stoves and furnaces, spraying aerosol products, frying or broiling meat, burning candles and incense, and vacuuming can all increase particle levels in a home and should be avoided when wildfire smoke is present.


Environmental Health Investigations Branch • California Department of Public Health

Protect Your Lungs from Wildfire Smoke

Wildfire smoke can irritate your eyes, nose, throat and lungs. It can make you cough and wheeze, and can make it hard to breathe. If you have asthma or another lung disease, or heart disease, inhaling wildfire smoke can be especially harmful.

Staying indoors and reducing physical activity are the best ways to protect your lungs from wildfire smoke. Wearing a special mask called a "**particulate respirator**" can also help protect your lungs from wildfire smoke.

How to Choose the Correct Mask to Protect Your Lungs

- Choose a mask called a "**particulate respirator**" that has the word "**NIOSH**" and either "**N95**" or "**P100**" printed on it. These are sold at many hardware and home repair stores and pharmacies.
- Choose a mask that has **two straps** that go around your head. **DO NOT** choose a mask with only one strap or with straps that just hook over the ears.
- Choose a size that will fit over your nose and under your chin. It should seal tightly to your face. These masks do not come in sizes that fit young children.
- Do not use bandanas (wet or dry), paper or surgical masks, or tissues held over the mouth and nose. These will not protect your lungs from wildfire smoke.

N95 particulate respirators WILL protect your lungs from wildfire smoke. Straps must go above and below the ears.

How to Use a Mask

- Place the mask over your nose and under your chin, with one strap placed below the ears and one strap above.
- Pinch the metal part of the mask tightly over the top of your nose.
- The mask fits best on clean shaven skin.
- Throw out your mask when it gets harder to breathe through, or if the inside gets dirty. Use a new mask each day if you can.
- It is harder to breathe through a mask, so take breaks often if you work outside.
- If you feel dizzy or nauseated, go to a less smoky area, take off your mask and get medical help.
- If you have a heart or lung problem, ask your doctor before using a mask.

A one strap paper mask will NOT protect your lungs from wildfire smoke.

For more information about protecting yourself from wildfire smoke, call your local health department.

A surgical mask will NOT protect your lungs from wildfire smoke.

Air conditioners and filters - Little is known about the impact of using various types of room air conditioners and air filters on indoor smoke concentrations in homes. However, homes with central air conditioners generally have lower amounts of outdoor particles indoors compared to homes that use open windows for ventilation. Most air conditioners are designed by default to re-circulate indoor air. Those systems that have both "outdoor air" and "re-circulate" settings need

to be set on "re-circulate" during fire or smoke events to prevent smoky air from being drawn into the building.

Room air cleaners - HEPA filter air cleaners and ESPs can help reduce indoor particle levels, provided the specific air cleaner is properly matched to the size of the indoor environment in which it is placed.

Another situation where various kinds of masks are used as personal control measure is at demonstrations. Regardless of how peaceful a demonstration might intend to be, we have seen many cases of authorities taking severe measures against crowds. For example, when *tear gas* (hazard) is used, the individuals apply various control measures to mitigate the impact of the tear gas. Of course, the protestors do not conduct fully-fledged risk assessment prior to their participation to such demonstrations; they can still be prepared for such aggressive measures authorities may take. The *gas mask* (control measure) is the best solution, though some countries prohibit protestors wearing gas masks with the claim that they hide their identity.

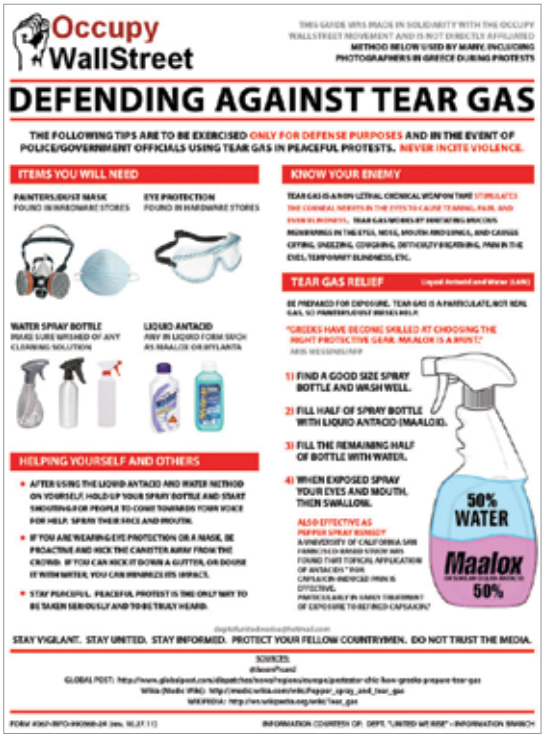
With protests occurring almost daily in many places in the world, and with law enforcement commonly using *chemical weapons* (hazard) against protestors, activists naturally take time to better prepare themselves for the inevitable tear gas attack.

Tear gas (formally known as lachrymatory agent) is a chemical weapon that causes severe eye, respiratory, and skin irritation, pain, vomiting, and even blindness. In general types include pepper spray (oleoresin capsicum), GS gas (2-chlorobenzalmalononitrile), CR gas (dibenzoxazepine), CN gas (Phenacyl chloride), novivamide (pelargonic acid vanillylamide), bromoacetone, xylyl bromide (methylbenzyl bromide), syn-propanethial-S-oxide, and chemical mace. The effects of tear gas could be fatal if canisters are fired from close range and directly target the protestors. There are many documented cases of protestors with lost eyes, bone fractures in skull and extremities; and even death.

The best control measure is the *gas mask* followed by *escape hood*. Using builder's respirator that covers mouth and nose may provide some degree of protection. Homemade masks provide very limited protection.

In 2011, a flyer and web page made its way around Facebook and other social media recommending a solution of Maalox or other liquid antacids (mitigation control measure) as an antidote to the eye pain, blindness, and respiratory distress related to tear gas attacks. This same flyer has been translated into other languages throughout the world. The flyer recommends particle filters and dust masks for keeping tear gas out of the nose and mouth, and safety goggles to protect the eyes.

It also urges nonviolent protest, saying, "Peaceful protest is the only way to be taken seriously and to be truly heard."



Sharing a bench

Benches are long seats on which several people may sit at the same time. Just like "old friends" in Simon and Garfunkel's fourth studio album, Bookends in 1968.

"Old friends, old friends
Sat on their park bench like bookends
A newspaper blown through the grass
Falls on the round toes
Of the high shoes of the old friends

Old friends, winter companions, the old men
Lost in their overcoats, waiting for the sunset
The sounds of the city sifting through trees
Settles like dust on the shoulders of the old friends

Can you imagine us years from today
Sharing a park bench quietly
How terribly strange to be seventy
Old friends, memory brushes the same years
Silently sharing the same fears"

Benches come in many shapes, some with arms and back rest, some without; some to be seated only from one side, some from both sides. They are typically made of wood, but sometimes made of metal, stone, fiberglass, or recycled plastic.

You will always find a bench to sit on in a park. At some bus stops you will also find benches, but not always.

Let's look at a bus stop moments before the bus arrives. I have chosen two examples. In the first example, people are waiting at State University of New York at Purchase.

Do you see any control measure here?

What about the shelter? Stops at busy locations usually have shelters, seating, and many times electronic (or just manual display) passenger information systems with ticketing machines. *Shelter* is a *preventive control measure* for the bus stop. The *hazard* is the *wind, snow* or *rain*. For a bright sunny day, a *reflective top* would also serve as a *control measure* against the sun by providing shade. The side panels of the shelter are ideally made of transparent material for riders to see through.

But what about the *seating*? Though seen through the side panel in the above photograph, here is the second example, this time from Geneva, Switzerland: UIT bus stop on Avenue Giuseppe-Motta just in front of the International Telecommunication Union.

The bus stop also has *shelter* (control measure), though its top side cover is transparent and will not create any shade during bright sunny times. The seating is made of metal. Geneva's high altitude results in pleasantly warm summers and mild winters, in January average maximum temperature is around 2°C, minimum average is around -5°C. What do all these mean for a metal bench?

Well, in general the temperature of the seating unit is in equilibrium with the air temperature. The day I took the above photograph, it was -3°C. If we look at the design of the seating units with risk assessment spectacles, we would consider "metal" seating units as hazards. In extreme cold weathers, you would freeze your bottom if you sit there. Non-metal applications and especially wood, would make a good control measure for seating (hazard being the cold).

Let's see the thermal conductivity of main materials used in benches.

Material/substance	Thermal conductivity W/mK
Aluminum	205
Concrete lightweight	0.1-0.3
Concrete medium	0.4-0.7
Concrete dense	1.0-1.8
Concrete stone	1.7
Fiberglass	0.4
Stainless steel	16
Plastic	0.03
Wood	0.07-0.1

It is all about thermodynamics. When you sit on a cold surface, you start losing heat from your body to the cold surface on which you are sitting. As a result you feel cold. If the thermal conductivity is high, like in the case of metals, heat loss will be faster. Think about holding a wooden and metal spoon. The metal spoon feels colder than the wooden spoon. In reality, they are at the same temperature. Because of high thermal conductivity, you will be losing heat from your hand faster when holding a metal spoon compared to a wooden spoon, thus feeling as if the metal spoon is colder. It is the same for benches.

You can tell from the above list that metal is definitely not a good choice for benches, especially where the temperatures go down the freezing point in winter.

Park benches are better thought over. But still we come across benches in parks where you would not like to sit. Here is one example:

I find this one more inviting:

No matter where, if you are to share a bench with a friend, young or old, like bookends, and ponder how it feels, pick a wood bench.

Keeping kids safe

In 2014, Safe Kids Worldwide surveyed 1,185 grandparents in the U.S. aged 50 and over who regularly take care of young children. Grandparents worries in terms of keeping kids safe, identified more with electrical outlets than medications. During the same period, 36 times more children visited emergency rooms due to medication poisoning than electrocution.

In 2016, Tox Info Switzerland received 39,543 calls related to poisoning, which was a record. Every day, 30 people are victims of drug poisoning and nearly half of them are children under school age. The number of visits to the hospital emergency departments increased by three percent compared to 2015 figures.

Child-resistant packaging (preventive control measure) is a special packaging used to reduce the risk of children ingesting hazardous items. This is often accomplished by the use of a special safety cap. It is required by regulation for prescription drugs, over-the-counter medications, pesticides, and household chemicals. In some jurisdictions, unit packaging such as blister packs is also regulated for child safety.

It should be noted that child resistant packaging is not child proof, and therefore it cannot be considered as the first line control measure to prevent children access to various hazards. There is always a possibility that such closures could be opened by children. Since such control measure is not 100 percent safe, there should be redundant measures to protect children. The best option would be *cutting access of children to medicines.* Placing and keeping all medicines, including your own, up and away and out of sight, would be a good measure. Almost 90 percent of all cases of child poisoning are from an adult medicine. A redundant measure would be using child-safety lock for cabinets and drawers. Again keeping wallet or purses (where we also keep some medicines) away from reach of children would be another additional control measure.

Child resistant packaging could become a challenge for elderly people.

What Is Child Resistant Packaging? (British Plastics Federation)

Child-resistant packaging is packaging that is difficult for a child younger than 52 months to open (or gain access to the contents) in a reasonable period but not difficult for an adult — up to and including seventy years old — to use properly.

These packs may be split into reclosable and non-reclosable and each may use one of a variety of ways to achieve child resistance. A reclosable pack defined by the international standard BS EN ISO 8317:2004 is " (A) package which, after it has been initially opened, is capable of being reclosed with a similar degree of security and is capable of being used a sufficient number of times to dispense the total contents without loss of security."

Reclosable packs employ a number of different methods to ensure child resistance. All are based on the fact that children younger than 52 months are unable to accomplish two simultaneous actions. The three most popular child resistant mechanisms are, push and turn, a two-piece moulding that has the added advantage of presenting the child with a false affordance. Squeeze and turn packs, usually single piece mouldings are extremely popular for household products. Finally, 'line up the arrows' packaging, where two fixed points on the container and closure must be aligned for the pack to open. All reclosable child resistant packs consist of a container and clo-

sure, in other words the complete pack. Hence there are child resistant packs but never child resistant closures or child resistant containers.

A non-reclosable child-resistant pack is defined by the European standard BS EN 14375:2003 as: " (A) child resistant package or part of a child resistant package which, when all or part of the contents have been removed, cannot be properly closed again." Typical non-reclosable packs are blister and strip packs, popular for packaging medicines and single use household products. Blister packs consist of a polymer tray whose open side is sealed to aluminium lidding foil during the filling process. Designing child resistance into a non-reclosable pack is usually accomplished by making opening a two-step process for example, "peel and push" or using a paper label, impervious to children's soft fingernails, which is applied to the lidding foil.

On the photographs below is one example of *child-resistant blister packaging.*

Locked4Kids consists of a carton and a plastic tray that holds the product, e.g. medicines in blister strips. To access the product, the tray should be pulled out like a drawer. To secure child safety this only works if two hooks on the top of the carton are pressed simultaneously. Looking closely at the Locked4Kids carton, you will find two push points with hooks sticking out. These push points are located diagonally across each side of the carton. And that's why children have difficulties opening the cartons. They simply don't understand how it works. And if they do, they are not able to handle it physically because their hands are too small.

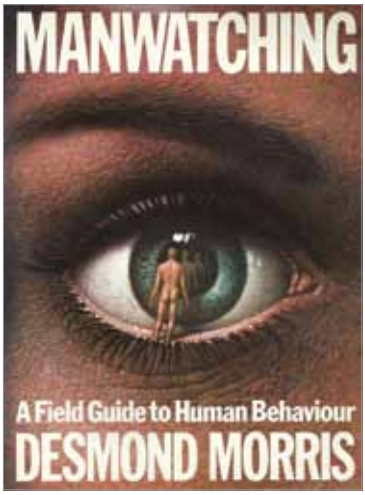
During the testing of the this product, in the first five minutes, out of 300, only two children were able to open the packaging, resulting in 0.6 percent of the children against the allowed maximum level of 15 percent. In the second five minutes of testing, after a demonstration by the auditor, out of 300, only 11 children were able to open the packaging, this time giving 4.4 percent against the allowed maximum level of 20 percent.

Here is another example from Keystone Folding Box Co., Key-Pak blister Card, a child resistant solution, which is also senior-friendly and eco-friendly control measure for safety. In addition, the package does not include any plastics, and is made from 100 percent recyclable material with the highest CR rating (F=1).

If you do not want to end up calling an ambulance (mitigation measure), you need to keep all the following preventive control measures in mind:

- Keep medicines and chemicals out of sight and reach of children, preferably in a locked high cupboard
- Where possible, buy products in child resistant containers
- Place cold-chain medicines in the fridge, on high shelves that are not accessible to children
- Always store chemicals in their original containers
- Dispose of unwanted medicines and chemicals safely (follow your regions safe disposal instructions)

Nutcracker



Desmond Morris in his book Manwatching (1978) describes the protective behaviour of humans as follows: *"Like any other species, the human animal tries to protect itself when danger threatens. The human body is extremely vulnerable to damage and lacks almost any kind of natural 'armour'. The nearest approach we have to this is the hard, bony casing around the brain, and the five bony projections – the eyebrow ridges, the cheek bones and the bridge of the nose – which surround the eyes. These help to lessen the damage done by blows to the head and increase the chances that we will be able to think and see clearly following a physical attack."*

Morris further explains the *startle pattern* in every healthy human that is present from the age of four months onwards, when sudden danger appears to be imminent: closing of the eyes, widening the mouth, thrusting forward the head and neck, raising and bringing forward of the shoulders, bending of the arms, clenching of the fists, forward movement of trunk, contraction of the abdomen, and slight bending at knees. This protective pattern that has evolved over millions of years is the very first stage of a defensive crouching action (control measure) to make the body smaller, more compact, holding tight and stiff, and shoulders and arms preparing to protect the head against an expected blow (hazard).

Players of certain sports developed specific protective behaviour against specific hazards. The football players *clamp their hands together in front of their genitals* (control measure) when forming a wall to block their goal against a free kick (*hazard = ball*). In such a position, the crotch region is the most vulnerable one since

Steve Perryman, Cyril Knowles, Phil Beal and Roger Morgan line up in the Spurs wall for a Leeds free-kick, in their January 1972 clash.

the footballers can watch the direction the ball takes, and quickly lower their heads if needed. In women's league, footballers clamp their hands together in front of their breast – the most vulnerable region in the body by the *ball* (hazard). But if you think of some other sports, take baseball for example, the *hazardous nature* of the ball is much higher. Baseball is solid compared to football, and average bat speed is 110-130 km/h. Well, they all wear *helmets (preventive control measure),* but we do not see anyone covering their genitals. Do they have a secret control measure that we do not see?

Catchers in baseball wear a *cup (control measure)* to protect their genitals. The protective cup is worn in many other contact sports (cricket, martial arts, boxing, lacrosse, hockey, and paintball) and is made of hard plastic or steel, perforated for ventilation. But although not that often, we hear stories of outfielder baseball players being hit in their sensitive region with fastballs up to 150 km/h. That hurts... The ones who do not wear the cup complain that they find it uncomfortable and restrictive. New technologies emerge and come up with better designed control measures, providing better protection as well as comfort. The following video provides testing of a certain brand cup by Sport Science and is worth watching to understand how "severity" of a high speed baseball can be reduced dramatically.

https://www.youtube.com/watch?v=yV831oPwG8M

How was your trip?

In all our face-to-face learning events, we do require 3-4 flipcharts to be available for the room. A learning event involves a lot of movement from participants to form groups, work together and present. *Legs of the flipchart* stands become a *hazard.* We all trip. There is very little that you can do about it except being very careful yourself. Although there are different models with different design legs, they still continue to be a *hazard.*

There are flipcharts that are hanging; naturally they do not have any legs. Although, here, *legs (hazard)* are removed, you lose the *portable* feature. With the *re-*

moval of flipchart legs (control measure), the *likelihood* of tripping goes down to zero. But, depending on the design and how protruded the platform is from the wall, there could be other types of accidents.

When you are using a flipchart with legs, you may think of other control measures to reduce the likelihood. You may remove them from the trainer's space when not in use. Likewise, you may also remove them during the breaks as well as other activities in the room that do not require use of flipcharts.

Tripping in training rooms happen all the time. Both participants and facilitators may trip on bags (hazard) that are dropped here and there... Many hotels decorate U shape tables with skirts that reach to the floor, all attached with pins – and in some cases, these skirts get loose, and become a hazard.

The photograph below is taken on the day 1 introduction session of the pharmaceutical cold chain on wheels course: I am explaining the flow of the course. What are the control measures and/or hazards we see in this photo?

First of all, one flipchart is moved to the back of the room and is kept away from participants' space. This is a good control measure.

The second flipchart on the right side of which we see only one leg of it is also not in use at the moment. It is placed to the corner, outside the facilitator's

space. This *placement at the corner (control measure)* also reduces the *likelihood* of me tripping over.

We see the *skirt* at the tables. It is mainly on the inner side for decorative purposes, but still if it becomes loose, especially at the corners, participants may get stuck when getting up and may easily trip.

Do you see something else?

The extension cable from the wall to the small table in the middle of U table (for data projector and computer) is very *well sealed to the floor carpet (preventive control measure).* Such sealing does not remove the risk for good; the tape may get damaged by participants/facilitators walking on it and may get loose, increasing the likelihood of tripping. In all courses, we always *check* that the cords are well sealed during each break and at the end of the day *(another control measure).*

In high-tech, well designed meeting rooms, we may see solutions with redundant control measures to keep attendees safe. Here are four examples of hiding the connections and cables with creative control measures:

	Overfloor raceway	Smallest, lowest and narrowest profile overfloor raceway is attached directly to floor covering, giving access to a wide range of power, communications, and A/V connectivity options
	Floor box (other options include wall box, ceiling box, hinged-wall box)	Floor boxes provide easy access for reconfiguring services, hiding connections under the floor
	Poke-through devices	Poke-through devices provide recessed connections through a cover that opens a full 180 degrees - with ingenious sliding doors - keeping wires, connections, and people safe
	Ceiling mounted data projector	Ceiling mounted data projector removes the cables from the learning space

If you do not want to lose your participants in a learning event or a meeting, you need to remove hazards and constantly check them on a daily basis. Remember, none of the control measures, unless you eliminate the hazard, could provide full control.

Afterword

Everyone has heard the famous adage, *"Anything that can go wrong, will go wrong."* That is known as Murphy's Law. Is Murphy's Law inevitable? Is it the cause of an unavoidable loss? Is it really a part of our lives? Did Titanic have to sink as per Murphy's Law because it was built to be unsinkable?

Murphy's Law

"According to history, the term was coined inadvertently in the late 1940s when Captain Murphy of the US Air Force made a statement about a technician making an error that could cause a problem with the manufacturing and operation of aircraft.

This statement later went on to be applied to most things having to do with engineering, mechanics, and aviation science, accompanied by the pessimistic thinking that, "If there's a way to do something wrong, it will be."

Here are the most known examples of Murphy's Law:

If anything can go wrong, it will.

Corollary: It can

Corollary: It should

Corollary: At the most inopportune time

Extension: it will be all your fault, and everyone will know it.

If there is a possibility of several things going wrong, the one that will cause the most damage will be the one to go wrong.

If anything just cannot go wrong, it will anyway.

If you perceive that there are four possible ways in which something can go wrong, and circumvent these, then a fifth way, unprepared for, will promptly develop.

Corollary: It will be impossible to fix the fifth fault, without breaking the fix on one or more of the others.

Left to themselves, things tend to go from bad to worse.

If everything seems to be going well, you have obviously overlooked something.

Nature always sides with the hidden flaw.

No matter how perfect things are made to appear, Murphy's Law will take effect and screw it up.

You cannot successfully determine beforehand which side of the bread to butter.

The chance of the buttered side of the bread falling face down is directly proportional to the cost of the carpet.

A falling object will always land where it can do the most damage.

http://www.murphys-laws.com/murphy/murphy-laws.html

Murphy's Law uses the rules of *probability* to dwell on the negative. As a result, it makes us overlook the positive. We may not be able to *eliminate hazards* nor *substitute* them in all cases, but we may *uncouple a process* or *reduce the number of steps or risk exposures* that could occur. We may *isolate the hazard* so it presents fewer potential risks. We may also *change conditions.* More importantly, we may *decrease the frequency of an event* happening as well as *decreasing the consequences* should an event occur.

Vernon Grose says that "Risk is not guaranteed by Murphy's Law – instead, it can be managed more effectively by employing that famous canon!"

Everything begins with the risk thinking:

If anything can go wrong, we'll fix it!

Ümit H. Kartoğlu

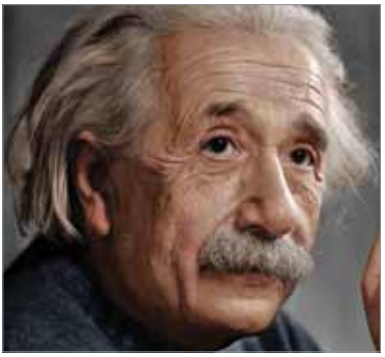
Risk management quotes

"Risk management is not about future decisions, but about the future of decisions that we must take now."

Robert N. Charette

"The fear of death is the most unjustified of all fears, for there is no risk of accident for someone who's dead."

Albert Einstein

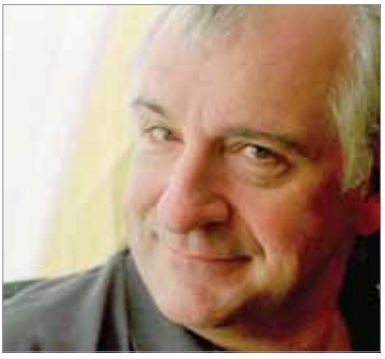


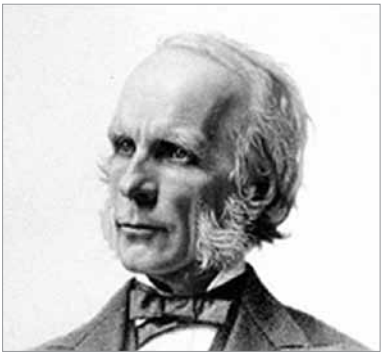
"It is the part of a wise man to keep himself today for tomorrow, and not venture all his eggs in one basket."

Miguel de Cervantes

"A COMMON MISTAKE THAT PEOPLE MAKE WHEN TRYING TO DESIGN SOMETHING COMPLETELY FOOLPROOF IS TO UNDERESTIMATE THE INGENUITY OF COMPLETE FOOLS."

Douglas Adams





"A ship is safe in harbor, but that's not what ships are for."

William G.T. Shedd

"Risk is not guaranteed by Murphy's Law – instead, it can be managed more effectively by employing that famous canon!"

Vernon L. Grose

"The greatest hazard in life is to risk nothing."

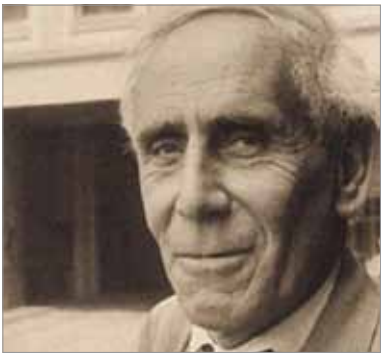
Leo Buscalia

"Plans based on average assumptions are wrong on average."

Sam L. Savage

"It's impossible that the improbable will never happen."

Emil Julius Gumbel



"Fear of harm ought to be proportional not merely to the gravity of the harm, but also to the probability of the event."

Peter L. Bernstein

"If you treat risk management as a part-time job, you might soon find yourself looking for one."

Deloitte white paper (Putting Risk in the Comfort Zone)

"We will not rest until we have controls that are as watertight as possible."

Carsten Kengeter

"Risk management should be an enterprise wide exercise and engrained in the business culture of the organization."

Julie Dickson

"A good rule of thumb is to assume that everything matters."

Richard Thaler

"Doubt is not a pleasant condition, but certainty is absurd."

Voltaire

"One of the greatest contributions of risk manager – arguably the single greatest – is just carrying a torch around and providing transparency."

Anette Mikes

"If you don't invest in risk management, it doesn't matter what business you're in, it's a risky business."

Gary Cohn

"Reality is that which, when you stop believing in it, doesn't go away."

Philip K. Dick

"Even a correct decision is wrong when it was taken too late."

Lee Iacocca

"When our leaders accept the status quo, we run the risk of disaster."

Max Bazerman

"We have no future because our present is too volatile. We have only risk management."

William Gibson

"Risk is a function of how poorly a strategy will perform if the 'wrong' scenario occurs."

Michael Porter

"Luck is unreliable."

Amanda Ripley

"One thing that makes it possible to be an optimist is if you have a contingency plan for when all hell breaks loose."

Randy Pausch

"Risk comes from not knowing what you`re doing."

Warren Buffet

"The best decision under risk is not the best decision under uncertainty. Heuristics are indispensable for good decisions under uncertainty; they are not the product of flawed mental system. "

Gerd Gigerenzer

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Recommended videos

Breaking down risk *by Steve Fisher*

https://goo.gl/gdyYnl

running time: 15:58 min (2014)

Steve Fisher tells us that this was this was the most nervous he's ever been for anything! He was invited to the TEDxAthens speakers conference where the theme was "Uncharted Waters". In his talk he explains how he breaks down challenges on the river and how his method has become a metaphor for his life.

Five senses: Vaccine Vial Monitors *by World Health Organization*

https://vimeo.com/51505939

running time: 20:46 min (2007)

A movie, produced for the 10th year anniversary of the introduction of vaccine vial monitors (VVM). The movie focuses on how this simple tool expands the horizon of the immunization programme and empowers health workers serving people at the very periphery of the health system. The theme and the goal are specific but there are scenes, human conditions, and different livings for everybody to see and think about. Shot in Niger, Vietnam and Indonesia in 2007.

Hacettepe University Hospitals – Facility tour
https://vimeo.com/54547081
running time: 04:26 min (2010)

Facility tour video for EPELA authentic Pharmaceutical cold chain management e-learning course participants.

Imagined and Real, Risks and Value *by David Miller*
https://goo.gl/bM4P0X
running time: 17:32 min (2016)

In a literal sense, risk in study abroad is about understanding the reality of mortality. There is no such thing as safety, and every risk can be quantified by multiplying the likelihood of it happening with the severity of the consequences if it does. But without careful management of perceived risks, the possibility of global studies programs being eliminated would be very real. In this talk, David Miller explores the real risks of study abroad for high school students—but, more importantly, he explores the risks of NOT studying abroad.

Introduction to Quality Risk Management *by James Vesper*
https://vimeo.com/51441324
running time: 12:28 min (2011)

Risk management involves a series of activities that are sequenced so that one step informs or shapes those that follow. James Vesper provides a high-level overview of the entire process.

Last Mile *by Umit Kartoglu*
https://vimeo.com/51442652
running time: 11:15 min (2011)

Umit Kartoglu reviews the critical last mile between the service point and the end user. He further discusses the best solutions for storage and transport of products and best practices for temperature monitoring.

Nothing stands still *by World Health Organization*
https://vimeo.com/51505482
running time: 17:50 min (2008)

The video of the WHO-PDA Pharmaceutical cold chain management on wheels course conducted during 2-7 June 2008 in Istanbul, Ankara, Konya, Eskisehir and Bursa (1,400 km route) in Turkey.

Risk assessment methods *by James Vesper*
https://vimeo.com/51441322
running time: 18:23 min (2012)

James Vesper goes into details of methods frequently used in risk assessments and gives first hand advice on when and how best to use them: Preliminary risk assessment, failure mode effects analysis and fault tree analysis.

Risk literacy *by Gerd Gigerenzer*

https://goo.gl/qwZkSG

running time: 16:13 min (2013)

In this world, nothing is certain except death and taxes. We learn to read and write but not how to deal with uncertainty: we are risk illiterates. Why do we fear what's unlikely to kill us? Is it true that people are basically hopeless when it comes to managing health and wealth? Some experts have concluded that Homo Sapiens ("man the wise") is a misnomer, and that John and Jane Q. Public need continuous guidance, as a child needs a parent. Against this pessimistic view, Gerd Gigerenzer argues that everyone can learn to deal with risk and uncertainty, and that experts can be part of the problem rather than the solution. A democracy needs risk-savvy citizens who cannot be easily frightened into surrendering their money, their welfare, and their liberty. We should begin to teach risk literacy to everyone.

Risk Management *by Chris Davenport*

https://goo.gl/BCO3aH

running time: 10:33 min (2012)

Is there a method to the madness of skiing all of Colorado's fifty-four 14,000 ft peaks? Is there a real way to mitigate the inherent dangers of climbing and skiing Mt. Everest? As one of the world's foremost and celebrated ski-mountaineers, Chris Davenport understands risk better than most. In this powerful talk, Chris goes into detail about his strategy in the hills, what makes him tick, and how climbing peaks relates to overcoming challenges.

Risk - the anatomy of chance and uncertainty *by Grant Statham*

https://goo.gl/CTLXh4

running time: 12:11 min (2013)

Every day, every one of us makes choices and decisions in the face of uncertainty. Guided by a blend of intuition and logic, we spend a large part of our lives navigating the murky waters of chance. This is the space between 0 and 1; this is risk, and we confront it daily. But how many of us really understand the underlying constructs of risk? What is risk, and how do we break it down to better understand the decisions we face? How do probability, consequence, exposure and vulnerability play out in the choices we make and they impacts they have? In this captivating presentation, Grant Statham takes us on a journey into the heart of risk by weaving stories, ideas and concepts together with stunning images from a lifetime spent in high places.

Sled dogs, serum run and saved lives *by James Vesper*

https://vimeo.com/58976346

running time: 20:08 min (2012)

In January 1925, a diphtheria outbreak struck a remote Alaskan town near the Arctic Circle. Severe weather had isolated the town with ice, snow, and strong winds. Only a very limited amount of diphtheria antitoxin was available. The town's physician feared many residents would die.

Getting the medicinal supplies to the town was more than a challenge and clearly required a collective, collaborative effort. Dog sled teams were put together for the "serum run". Twenty "mushers" and 150 dogs risked their lives and covered nearly 1000 km in a record five and one-half days, passing off a package of glass-sealed ampules in a day and night relay.

Looking at this heroic event 90 years after lets us see how the decision makers identified and controlled the risks. Through the lens of our relatively recent knowledge of the product, we can see risks that those involved at the time did not know of.

What Can Economists Know? *by Gerd Gigerenzer*

https://goo.gl/WDxw7F

running time: 21:43 min (2012)

Gerd Gigerenzer discusses how to make good decisions in panel entitled "What Can Economists Know: Rethinking the Foundations of Economic Understanding" at the Institute for New Economic Thinking's (INET) Paradigm Lost Conference in Berlin, April 12, 2012.

Credits

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About the author

Ümit Kartoğlu is a medical doctor and a scientist at the World Health Organization Headquarters in Geneva. Ümit began his career in Turkey, where he served at all levels of the national health system for over 10 years. He joined UNICEF in 1994 and has been with WHO since 2001.

Ümit brought to life the WHO-UNICEF Effective Vaccine Store Management initiative; Global Training Network for Vaccine Management; and the Performance, Quality and Safety (PQS) project. Currently Ümit is coordinating the Global Learning Opportunities (GLO) network.

Ümit has developed a variety of courses, tools and games for learning. He received several international awards in the field of research and communication, including the 2010 IQPC Cool Chain Excellence Award and the 2011 and 2013 Ludwig Rajchman Public Health Award. Ümit was also named one of the "Temperature Controlled Logistics Leaders for 2012" by the IQPC's Temperature Control Logistics & Quality Network, an international industry peer group recognizing 15 of the most influential and inspiring thought leaders in global pharmaceutical supply chain. He also received 2015 Golden Award in e-learning category of the Hermes Creative Awards for e-Pharmaceutical Cold Chain Management course and 2016 Platinum Award in e-Book category of Marcom Awards for his latest book *Pharmaceutical and Vaccine Quality Illustrated.*

Quality Risk Management

Mental Modelling

Examples of exposure in everyday life

"One of the best things in visiting a favorite place with someone who has never been there is having them point out things that you have never seen or forgotten about. The new visitor calls to your attention little details hidden in a shadow or something so obvious that you have unconsciously ignored it.

In this book, *Quality Risk Management Mental Modelling: Examples of Exposure in Everyday Life*, Dr. Umit Kartoglu provides that set of new eyes to help us identify hazards, hazardous situations, and ways that risks can be lessened. He invites us to take a different, fresh perspective as we look at a wide range of routine situations that we encounter daily. As we do this, we are constructing for ourselves a mental model of risk and factors that affect risk. While mental models are important in helping us comprehend complex situations, if we don't have a correct model or one that is limited, our understanding can be deficient. Dr. Kartoglu's wide range of examples helps us develop a rich, robust mental model that can assist us when we think about risk and how it can be reduced."

James Vesper
Director, Learning Solutions, Valsource, USA

"Pablo Neruda wrote that 'The books that help you most are those which make you think the most.' This innovative book will make you think, albeit never in a ponderous or heavy way. Through the engaging thinking stimulated by the images and words in this creative volume, your mental model of risk management and related topics will be improved and strengthened."

Thomas Reeves
Professor Emeritus, Learning, Design and Technology, The University of Georgia, USA

"In this excellent book, Dr. Kartoglu recognises the difficulties and problems in risk assessing and managing complex processes such as pharmaceutical supply chain management. While the application of quality risk management principles to supply chain control has been the subject of much work in recent years, the focus Dr. Kartoglu gives in this work to understanding the cognitive processes that relate to risk assessment, and that relate to how hazards and risks are perceived, render this work an important new approach in this area. He teaches readers how to actually think about hazards, not only in terms of their relationship with harm and risk, but also in terms of how human behaviour and cognitive processes can influence one's perception of those hazards, and the risks they may present. This is a very welcome development in this field, and it has definite relevance to the application of quality risk management principles in efforts to secure the supply chain of vaccines and other important medicines."

Kevin O'Donnell
Market Compliance Manager, Health Products Regulatory Authority, Ireland

"This book provides an engaging and practical way to apply risk assessment and risk management techniques to a variety of situations. The use of everyday examples gives the reader the opportunity to practice the techniques in real life, and also discusses specific applications for medicinal products."

Richard Johnson
President and CEO, Parenteral Drug Association, USA

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