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Ref: H201700046

Dear [redacted]

Response to your request for official information

Thank you for your request of 9 January 2017 under the Official Information Act 1982 (the Act) for

"A copy of the paper refered to in 168th MARC meeting minutes".

The information relating to this request is itemised below, with copies of documents attached.

Request	Response
A copy of the paper referred to in the 168th MARC meeting minutes	Attached is: The paper: Risk Communication

I trust this information fulfils your request.

Yours sincerely

[redacted]

Medsafe

Medicines Adverse Reactions Committee

Meeting date	**1 December 2016**	Agenda item	3.2.2
Title	**Risk Communication**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For advice
Active constituent N/A	**Medicines**	**Sponsors**	
Funding	N/A		
Previous MARC meetings	N/A		
International action	N/A		
Prescriber Update	N/A		
Usage data	N/A		
Advice sought	**The Committee is asked to advise whether:** – There are any other factors that should be taken into consideration when communicating risk – Any changes need to be made to the example consumer information		

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1.0 PURPOSE

Statistical illiteracy is widespread among the general public and medical experts. For many people it is hard to accept uncertainty or understand basic numerical information. These problems are exacerbated when evaluating the benefits and harms of treatment options. This is a severe obstacle to informed treatment choice. It also makes it extremely difficult to provide useful information for healthcare professionals and consumers to help making informed choices.

In order to achieve better decision making by all parties it is necessary to understand the psychology involved in decision making and subsequently the best way of providing numerical data and information about risk.

The purpose of this paper to summarise some of the principles of decision making in general (and with respect to vaccination), risk communication and to provide an example using Gardasil 9.

2.0 DECISION MAKING

2.1 Factors involved in decision making

Psychologists have used the two system approach to describe differences in thinking in different situations.[1]

System 1 operates automatically and quickly with little or no effort and no sense of voluntary control. It is associated with intuitive thinking. System 1 thinking can be improved by education and experience.

System 2 allocates attention to effortful mental activities, including complex computations. It gives the subjective experience of agency, choice and concentration and is associated with reasoned thinking.

System 2 has some ability to change the way system 1 works by programming the normally automatic functions of attention and memory. However, system 2 requires mental effort and is easily distracted.

Cognitive illusions are a bias of system 1, and are not fully overcome by system 2.

It is possible to change which system is used to make decisions. In relaxed environments intuitive thinking predominates. Thinking under pressure invokes system 2. Frowning indicates the use of system 2, but consciously frowning will change thinking to system 2 as well.

In all situations thinking requires energy and effort and therefore whenever possible the easy method is taken. It has been proposed that this can lead to biases and mistakes.

The 2 systems proposal has been criticised since it is not predictive and therefore cannot be tested scientifically.[2]

Expert intuition [1]

Certain intuitions are acquired very quickly, for example when to be afraid. However the acquisition of expertise usually takes a long time to develop. Expertise in a domain is not a single skill but rather a large collection of mini-skills. It should be noted that the confidence that people have in their intuitions is not a reliable guide to their validity.

There are two basic conditions for acquiring a skill.

- An environment that is sufficiently regular to be predictable
- An opportunity to learn these regularities through prolonged practice.

For short term outcomes it is possible to gain knowledge and experience because the outcome can be linked to actions. Longer term predictions do not provide the opportunity for learning as there is no instantaneous feedback.

Taking the practice of medicine as an example anaesthesiologists benefit from good feedback and will develop good skills, whereas radiologists may obtain little info about the accuracy of their diagnoses. For example radiologists contradict themselves 20% of the time when they see the same picture on different occasions.

The line between what clinicians can do well and what they cannot do at all well is not obvious, especially to them.

Algorithms outdo clinicians in noisy environments because they are more likely to detect weakly valid clues and more likely to use the cues consistently. Experts try to be too clever and bring in unneeded complexity and are inconsistent in making summary judgements of complex information. Of course there is huge opposition to the use of algorithms.

Cognitive ease [1]

Writing in clear font will enable cognitive ease, in this state the reader is likely to be relatively casual and superficial in their thinking, but their creativity will be encouraged.

In situations of strain or stress people are likely to be vigilant suspicious and invest more effort in thinking. There may be fewer errors, but less creativity.

Anything that makes text easier to read – for example bolding, or use of bright blue or red makes the text more likely to be believed.

To be thought credible and intelligent it is best to use simple rather than complex language.

Determining causality [1]

The brain needs to create a coherent story to link fragments of knowledge. Even infants at 6 months see events as a cause effect scenario. Humans are programmed to have impressions of causality which do not depend on reasoning. It is the consistency of the information that matters for a good story not its completeness. Indeed less information makes it easier to fit what is known into a coherent pattern.

Jumping to conclusions is efficient if the conclusions are likely to be correct and the costs of an occasional mistake are acceptable and if the jump saves time and effort. However this is risky when the situation is unfamiliar, the stakes are high and there is no time to collect more information.

Extreme outcomes (both high and low) are more likely to be found in small than large samples due to random noise. There is no causal explanation and there is nothing to explain when these types of figures are found in small samples. The tendency to exaggerate consistency and coherence makes people insensitive to small numbers (small sample size).

Similarly regression to the mean has an explanation but doesn't have a cause. Any extreme group will move to the mean over time which can be misinterpreted as a causal effect.

Hence the need to provide sample size calculations and use control groups in clinical studies.

The human predilection for causal thinking exposes us to serious mistakes in evaluating the randomness of truly random events. Humans do not expect to see regularity produced by random events and when a person detects what appears to be a rule they quickly reject the idea that the process is random.

This is an outcome of the general vigilance inherited from our ancestors. It is safer to notice and respond to an apparent increase in the rate of lion appearances even if it is actually random.

To the untrained eye randomness appears as regularity or tendency to cluster. Even when processes have been proved to be random the tendency is for the public to disbelieve as the tendency to see patterns is more overwhelming than the results of a study.

Halo effect [1]

This is the tendency to like (or dislike) everything about a person including things not yet observed.

People let their likes and dislikes determine their beliefs about the world and subsequently their decisions. People's emotional attitude to technology drives their beliefs about their benefits and risks. Dislike promotes belief in high risk and negligible benefit.

Beliefs can change if the risk of a disliked activity is smaller than previously thought. However, the information about lower risks will also change opinions of the benefits, even if nothing was said about benefits.

Priming [1]

Priming effects take many forms. For example someone thinking about food will be quicker than usual to spot someone talking about food, or specific food types or to see words associated with food on a written page.

The idiomotor effect describes the influencing of an action by an idea. For example words associated with old age have been shown to prime people to walk slower.

Anchoring is a priming effect which occurs when people consider or are exposed to a particular value for an unknown quantity before estimating that quantity. The estimates stay close to the number people first considered. People adjust from anchors less when their mental resources are depleted.

Keeping score [1]

Humans carefully keep score of rewards, punishments, promises and threats. As a result people refuse to cut losses if that means having to admit failure. In addition people are biased against actions that could lead to regret.

Regret is an emotion and also a punishment. Regret is not the same as blame. The fear of regret is a factor in many of the decisions that people make.

Unusual events are easier than normal events to undo in the imagination. People have stronger reactions to an outcome that is produced by an action than to the same outcome when it is produced by inaction.

The asymmetry in the risk of regret favours conventional and risk averse choices. Hence consumers prefer brand names over generics. It is also common to be more loss averse in health than in money.

It is possible to reduce feelings of regret. The most useful is to be explicit about the anticipation of regret. If you can remember when things go badly that you considered the possibility of regret carefully you are likely to experience less.

Endowment effect and loss aversion [1]

The more you have of something the less value you place on having more. However, the amount that someone is willing to pay for goods/objects is much less than they are willing to sell for once they have the goods/object in their possession. This is the endowment effect.

When things change the disadvantages loom larger than the advantages. Making concessions hurts. This is loss aversion. Loss aversion is one of many manifestations of a broad negativity dominance in humans.

Tastes are not fixed they vary from a reference point which is the boundary between a 'good' and 'bad' choice.

The decision weights that people assign to outcomes are not identical to the probabilities of these outcomes. Outcomes that are almost certain are given less weight than their probability justifies. Humans tend to overweight small risks and are willing to pay more than the expected value to eliminate them altogether.

Similarly improbable outcomes are overweighed. The amount of worry about safety is not proportional to the probability of the threat. Reducing or mitigating the risk is not adequate to eliminate the worry, the probability must be brought down to zero. The probability of a rare event is most likely to be overestimated when the alternative is not fully specified.

Social dynamics [3]

Social interactions influence the spread of behaviours.

Perceptions and opinions on risk change when propagated from one person to another. When messages are propagated through the diffusion chains they tend to become shorter, gradually inaccurate and increasingly dissimilar between different chains. The perception of risk is propagated with higher fidelity due to participants manipulating messages to fit their preconceptions. Small judgement biases tend to become more extreme even when the message contradicts preconceived risk judgments.

2.2 Heuristics and biases

The term heuristic is of Greek origin meaning 'serving to find out or discover'.

Heuristics have been variously described as.

- Attribute substitution
- Effort reduction (through (a) examining fewer cues, (b) reducing the effort of retrieving cue values, (c) simplifying the weighting of cues, (d) integrating less information, and (e) examining fewer alternatives).
- A strategy that ignores part of the information, with the goal of making decisions more quickly, frugally, and/or accurately than more complex methods.

The use of heuristics has been associated with shoddy decision making. There is an ongoing discussion in the scientific literature as to whether heuristics are good or bad. For example Kahneman [1] and colleagues consider that the use of heuristics leads to mistakes and poor decision making because:

- heuristics are always second best
- heuristics are only used because of human cognitive limitations
- more information, more computation and more time for analysis is always better.

Whereas other psychologists [4] consider the use of heuristics enables better decision making and presenting numeric information correctly avoids bias and the need for nudges.[2]

Availability/ recognition heuristic [5] [1]

The availability heuristic is the process of judging frequency by the ease with which instances come to mind.

When estimating the frequency of an event humans use the impression of the ease (cognitive ease) with which instances come to mind. The ease of remembering can be influenced by salient events (eg, media reports - see table 1) that are attention grabbing, or a relevant personal experience.

The experience of familiarity has a simple but powerful quality of pastness that seems to indicate that it is a direct reflection of prior experience. This is an illusion. Things you have been exposed to before – words or ideas become easier to see again. If a judgement is based on an impression of cognitive ease anything that makes it easier for the associative machine to run smoothly will also bias beliefs. A reliable way to make people believe in falsehoods is frequent repetition, because familiarity is not easily distinguished from truth.

Listing ways to improve process can paradoxically improve ratings. Asking people to list a high number of improvements to a system for example makes people believe that the quality of the system is better than if a low number of comments is sought. This is because it took more effort to think up the longer list.

Availability cascade [1]

Describes a self-sustaining chain of events which may start from media reports of a relatively minor event and lead to a public panic and large-scale government action. This cycle is sometimes sped along deliberately by availability entrepreneurs who work to ensure a continuous flow of worrying news. Those who try to dampen the effect attract little attention, most of it hostile. The cascade resets public priorities other risks and other ways that resources could be applied for public good fade into the background.

Table 1 ***The 'size' of 11 hazards and media reporting about them (US data) [6]***

Hazard	Annual odds of dying (1 chance in . . .)[a]	Number of news articles[b]	Number of annual deaths[c]	Articles per death[d]
Skin cancer	29,500	102	9559	0.01
Food poisoning	55,000	257	5127	0.05
Bicycling	578,000	233	488	0.48
Heat exposure	950,000	229	297	0.77
Children (under 15) falling from windows	2,400,000	89	25	3.53
Fireworks	71,200,000	59	4	14.90
Amusement parks	72,300,000	101	4	25.89
Snake bites	19,300,000	109	15	7.46
Drowning while boating	400,900	1688	703	2.40
West Nile Virus	1,000,000	2240	282	7.94
Shark attacks	578,000,000	276	0.5	552.00

Fluency heuristic [7]

Fluency heuristic: If all alternatives are recognized but one is recognized faster, then infer that this alternative has the higher value with respect to the criterion.

Judgement heuristic [1]

When attempting to answer a difficult question without sufficient information a simpler question is substituted instead. For example how happy are you with your life these days is substituted with what is my mood right now.

Affect heuristic [1]

People make judgements and decisions by consulting their emotions, an instance of substitution in that the how do I feel about it substitutes - what do I think about it?

Consensus suggests that emotion is a psychological construct consisting of five components: (a) cognitive appraisal or evaluation of a situation; (b) the physiological component of arousal; (c) a subjective feeling state; (d) a motivational component, including behaviour intentions or readiness; and (e) motor expression.[8]

For humans frightening thoughts and images occur with particular ease and thoughts of danger that are fluent and vivid exacerbate fear. This provides a survival advantage. The media use these fears and thus warp people's risk estimates (Table 1).

The evidence supports a positive linear relationship between fear and attitude, behavioural intention, and behaviour change.

Early studies of the persuasive power of guilt demonstrated that guilt increases compliance with requests from strangers. However, interestingly, evidence from media-based studies suggests a negative linear relationship in that the stronger the guilt appeal in a media message (e.g., a telethon to raise money for flood victims), the less persuasive the message may be. This effect tends to be attributed to the fact that high levels of guilt are associated with high levels of anger, which short-circuits attitude change, especially if the anger is directed at the message's source.[8]

It has been argued that the use of emotion by the public creates a richer conception of risks than experts. Since the public distinguishes between good and bad deaths rather than just using figures.

Representativeness [1]

This describes the effect where details of an event or how representative (stereotype) a person or thing is for a category override statistical concerns/ probability. For example scouting for sports stars based on how they look rather than their achievements.

Narrative fallacy [1]

The explanatory stories that people find compelling are simple and concrete rather than abstract. They assign a larger role to talent, stupidity and intentions than to luck and focus on a few striking events that happened rather than on the countless events that failed to happen. A compelling narrative fosters an illusion of inevitability. It provides a comforting conviction that the world makes sense and rests on a secure foundation: everyone's almost unlimited ability to ignore our ignorance.

Hindsight bias [1]

The inability to reconstruct past opinions causes people to underestimate the extent to which they were surprised by past events.

Hindsight bias has a pernicious effect on the evaluations of decision makers. It leads observers to assess the quality of a decision not by whether the process was sound but by whether its outcome was good or bad. This makes it almost impossible to evaluate a decision properly – in terms of the beliefs that were reasonable when the decision was made.

The illusion of validity [1]

This is a cognitive illusion. In situations of low data and high noise when predictions are impossible, 'pundits' still make predictions with high confidence. High confidence only tells you that an individual has constructed a coherent story in their own mind, not that the story is true.

The illusion of skill is not only an individual aberration it is deeply ingrained in culture. Facts that challenge basic assumptions are simply not absorbed.

The planning fallacy [1]

Describes plans and forecasts that are unrealistically close to best-case scenarios and are highly unlikely to come true.

Denominator neglect [1]

If people's attention is drawn to the numerator they do not assess the denominator with any care. Helps explain why different ways of communicating risks vary so much in their effects.

Using the frequency approach of 1 in 10000, the one becomes very vivid. A disease that kills 1,286 in every 100,000 was judged more dangerous than one that kills 24.4 out of 100.

Framing [2]

A framing effect occurs when people's choices differ depending on how two logically equivalent statements are framed. A bad outcome can be more acceptable if it is framed as a cost rather than a loss. Similarly stating that the one month survival rate is 90% sounds better than the one month mortality rate is 10%.

For example:

In an experiment a full glass (A) and empty glass (B) are placed on a table. The experimenter asks the participant to pour half the water into the other glass and then to place the half empty glass at the edge of the table. Most people choose glass A.

The framing of the request encodes surplus information (the past state of the glass) that serves as a reference point that is intuitively understood (social intelligence).

Consider the medical example:

Five years after surgery, 90% of patients are alive.

Five years after surgery, 10% of patients are dead.

If patients are given the first statement they are more likely to accept surgery than if they are given the second statement, although both statements are equivalent. This has been used as an example to show that humans are illogical. However, to make a rational decision the patient needs to know whether the survival rate is higher with or without surgery. It has been argued therefore, that the patient infers that the doctor considers that surgery is beneficial or not depending on the statement used.

The size of the population involved in a framed message is also important.[9] Framing effects wax and wane in response to changing size of the target group. The framing effect (i.e., the irrational reversal in risk preference) occurs only when a problem is presented in a large, anonymous, and thus ambiguous group context involving 600 lives or more. The framing effect was absent when the size of the endangered group was within a two-digit number. The small size of a social group signals a higher interdependence between group members and evokes a kith-and-kin rationality. Guided by this rationality, respondents showed a live-or-die together risk preference. In contrast, risk preference of a decision maker becomes erratic when prioritized group cues are absent in a large, anonymous, group context. When the risk preference is ambiguous, secondary cues, such as verbal framing, are used to direct choices.

Experienced utility [1]

There is more utility in reducing 6 injections to 4 than 20 to 18. Even through 2 injections are removed in each case.

Memory is important in experience. The peak end rule describes how a global perspective rating of an experience is defined by the average at the most intense period and the end. The duration has no effect on the rating of the experience. Confusing experience with the memory of it is a cognitive illusion.

Focusing illusion [1]

Nothing in life is as important as you think it is when you are thinking about it.

2.3 Models of decision making

The decision environment can be represented graphically (figure 1). The requirements of the decision maker are represented by goals: the status quo and a minimum requirement. The outcomes of the decision are therefore success, if a goal was achieved or bettered, gain if the outcome was better than status quo but the goal wasn't achieved, loss if the outcome was worse than the status quo but better than minimal requirements and failure if the outcome was worse than minimal requirements. Various models attempt to explain how the decision process operates in this environment.

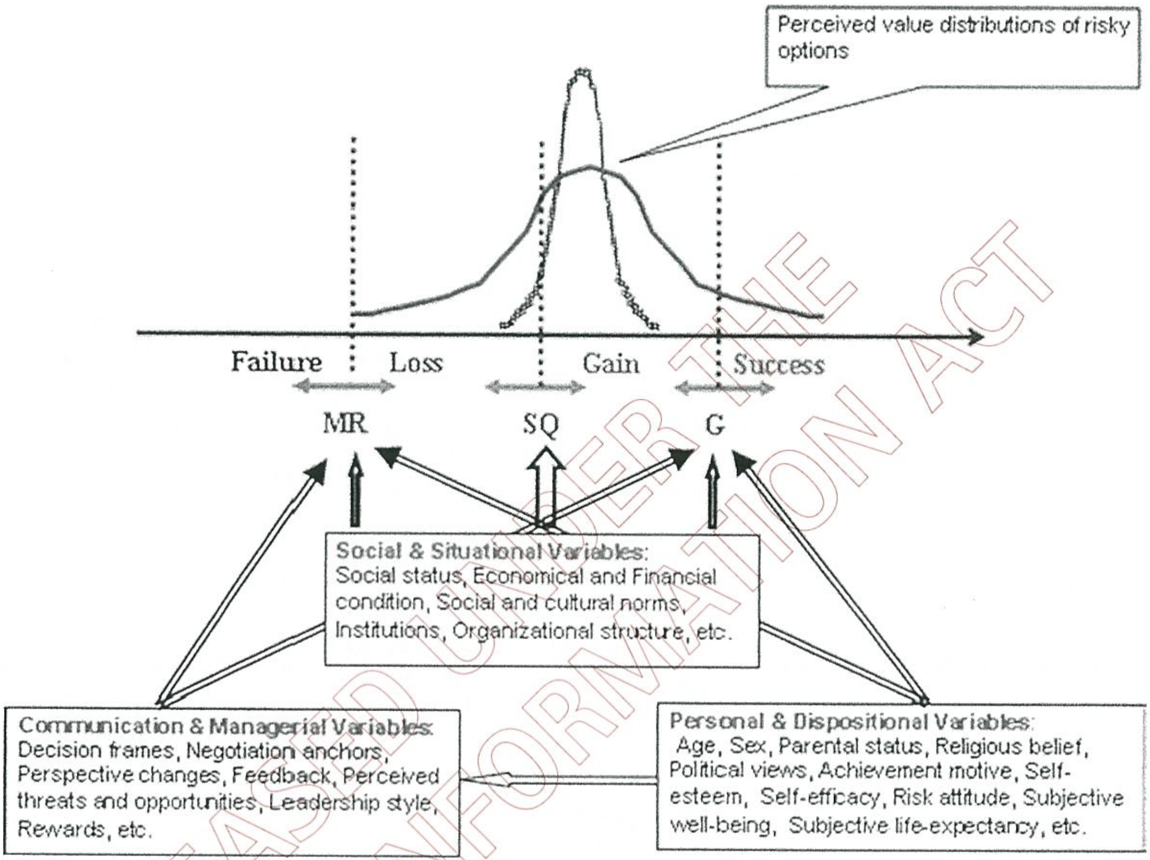

Figure 1 A framework for risk communication and risk preference. MR= minimum requirement, SQ= status quo, G= goal[9]

2.3.1 Heuristic decision making

Using heuristics for decision making is not necessarily bad, but there is a need for awareness that this process is being used, and the limitations need to be acknowledged.

In order to deal with an uncertain world, the brain relies on an adaptive toolbox of heuristics. Accordingly, intelligence is defined as the degree of knowing in which situation to use which heuristic (ecological rationality).

There is broad experimental evidence that humans and other animals rely on a toolbox of heuristics (Table 2). These are based on evolved and learned core capacities and include.

- *Recognition-based heuristics:* Recognition heuristic (RH), fluency heuristic.
- *Equality-based heuristics*: 1/*N*; tallying (weight reasons equally).
- *One-good-reason heuristics:* take-the-best, fast-and-frugal trees.
- *Social heuristics*: tit-for-tat; imitate-the-majority.

Recognition heuristic (RH): If one of two objects is recognized and the other is not, then infer that the recognized object has the higher value with respect to the criterion. RH-based decision processes go beyond automatically choosing the recognized alternative and are guided by judgments about the ecological rationality of the RH.

Table 2 ***Ten well studied heuristics for which there is evidence that they are in the adaptive toolbox of humans.***

Heuristic	Definition	Ecologically Rational If	Surprising Findings (examples)
Recognition heuristic (Goldstein & Gigerenzer, 2002)	If one of two alternatives is recognized, infer that it has the higher value on the criterion.	Recognition validity >.5	Less-is-more effect if $\alpha > \beta$; systematic forgetting can be beneficial (Schooler & Hertwig, 2005).
Fluency heuristic (Jacoby & Dallas, 1981)	If both alternatives are recognized but one is recognized faster, infer that it has the higher value on the criterion.	Fluency validity >.5	Less-is-more effect; systematic forgetting can be beneficial (Schooler & Hertwig, 2005).
Take-the-best (Gigerenzer & Goldstein, 1996)	To infer which of two alternatives has the higher value: (a) search through cues in order of validity, (b) stop search as soon as a cue discriminates, and (c) choose the alternative this cue favors.	See Table 1 and main text	Often predicts more accurately than multiple regression (Czerlinski et al., 1999), neural networks, exemplar models, and decision tree algorithms (Brighton, 2006).
Tallying (unit-weight linear model, Dawes, 1979)	To estimate a criterion, do not estimate weights but simply count the number of positive cues.	Cue validities vary little, low redundancy (Hogarth & Karelaia, 2005, 2006)	Often predict equally or more accurately than multiple regression (Czerlinski et al., 1999).
Satisficing (Simon, 1955; Todd & Miller, 1999)	Search through alternatives and choose the first one that exceeds your aspiration level.	Number of alternatives decreases rapidly over time, such as in seasonal mating pools (Dudey & Todd, 2002).	Aspiration levels can lead to significantly better choices than chance, even if they are arbitrary (e.g., the secretary problem, see Gilbert & Mosteller, 1966; the envelope problem, see Bruss, 2000).
1/*N*; equality heuristic (DeMiguel et al., in press)	Allocate resources equally to each of *N* alternatives.	High unpredictability, small learning sample, large *N*.	Can outperform optimal asset allocation portfolios.
Default heuristic (Johnson & Goldstein, 2003; Pichert & Katsikopoulos, 2008)	If there is a default, do nothing.	Values of those who set defaults match those of the decision maker; when the consequences of a choice are hard to foresee.	Explains why mass mailing has little effect on organ donor registration; predicts behavior when trait and preference theories fail.

Tit-for-tat (Axelrod. 1984)	Cooperate first and then imitate your partner's last behavior	The other players also play tit-for-tat; the rules of the game allow for defection or cooperation but not divorce	Can lead to a higher payoff than optimization (backward induction).
Imitate the majority (Boyd & Richerson, 2005)	Consider the majority of people in your peer group and imitate their behavior	Environment is stable or only changes slowly; info search is costly or time-consuming	A driving force in bonding, group identification, and moral behavior.
Imitate the successful (Boyd & Richerson, 2005)	Consider the most successful person and imitate his or her behavior	Individual learning is slow; information search is costly or time-consuming	A driving force in cultural evolution.

Take the best Heuristic. If both objects are recognized, the RH is not applicable, but the take-the-best heuristic (TTB) is. Like the RH take-the-best model show people infer which of two objects has a higher value on a criterion based on cue values retrieved from memory. The heuristic is defined by three building blocks:

(i) Search rule: search through cues according to their validity.

(ii) Stopping rule: stop search on finding the first cue that discriminates between the objects.

(iii) Decision rule: infer that the object with the positive cue value has the higher criterion value.

Note that take-the-best implies a lexicographic step-by-step process with limited search. This process is quite different from weighting-and-adding all cues, which is assumed in models that postulate the integration of all cues, such as in value-based decision models. Experimental studies have provided strong evidence that many people's memory-based inferences are consistent with the predictions of take-the-best (and inconsistent with those of adding-and-weighting models) in situations where its use is ecologically rational. Specifically, experts appear to rely on simple search and stopping rules more often than novices.

Tallying. Whereas take-the-best ignores cues (but includes a simple form of weighting cues by ordering them), tallying ignores weights, weighting all cues equally. It entails simply counting the number of cues favouring one alternative in comparison to others.

1. Search rule: Search through cues in any order.

2. Stopping rule: Stop search after m out of a total of M cues (with $1 < m \leq M$). If the number of positive cues is the same for both alternatives, search for another cue. If no more cues are found, guess.

3. Decision rule: Decide for the alternative that is favoured by more cues.

Prediction error

Prediction error is the sum of bias, variance and noise.[3, 5]

Bias here is the difference between the true answer and the answer generated by a system or process for example an algorithm. There is a trade-off between bias and variance.

An unbiased algorithm may suffer from high variance due to excess variance in the data, which is a function of the number of data observations available. Across samples, bias is the difference between the mean prediction and the true state of nature, and variance is the expected squared deviation around this mean. Variance decreases with increasing sample size, but also with simpler strategies that have fewer free parameters.

Thus even an unbiased algorithm may be poorly predictive. Combating high bias requires using a rich class of models while combating high variance requires placing restrictions on this class of models. Using heuristics reduces the effect of variance on prediction error.

2.3.2 Fast and frugal heuristics [7, 10, 11]

The fast and frugal heuristics framework has developed an ecological view of rationality to try and understand how and when reliance on simple decision heuristics can result in smart behaviour. Being rational means that a heuristic is successful with regard to some outside criterion. For example over diagnosing and over treating patients is considered undesirable but is a rational response in a highly litigious environment.

Studies have shown that when used in the correct environment, simple decision heuristics can surpass the accuracy of more sophisticated, information-greedy classification and prediction tools, including that of regression models or neural nets.

How physicians make diagnostic decisions is potentially modelled by fast-and-frugal trees, a branch of heuristics that assumes decision makers follow a series of sequential steps prior to reaching a decision (see figure 2 for an example). Such trees ask only a few yes-or-no questions and allow for a decision after each one. Like most other heuristics, fast-and-frugal trees are built around three rules; one that specifies in what direction information search extends in the search space (search rule); one that specifies when information search is stopped (stopping rule), and one that specifies how the final decision is made (decision rule).

- Search rule: Look up predictors in the order of their importance.
- Stopping rule: Stop search as soon as one predictor variable allows it.
- Decision rule: Classify according to this predictor variable.

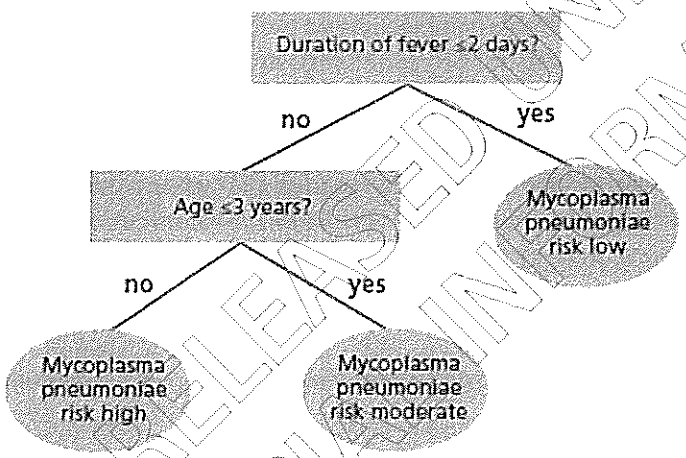

Figure 2 *Fast and frugal tree for making decisions about macrolide prescriptions*

Sequential heuristics can predict the classic violations of gambling choices identified by Kahneman.[1]

In these problems the decision maker is given four reasons[12]:

- maximum gain
- minimum gain
- probability of maximum gain
- probability of minimum gain

The resulting choices are decision from description and not decisions from experience.

In these decisions, the outcome is more important than the probability of the outcome. Emotional outcomes override the impact of probabilities; in the extreme, people neglect probabilities altogether, and instead base their choices on the immediate feelings elicited by the gravity or benefit of future events. For example lottery buyers focus on the big gains rather than their tiny probabilities.

The frequent observation that people tend to be risk-averse in the gain domain is consistent with ranking the minimum outcome first. This is because the reason for focusing on the minimum outcome is to avoid the worst outcome. This is consistent with people trying to avoid disappointment and regret.

It has been proposed that the following order is the way decisions are made.

Priority rule: Consider reasons in the order: minimum gain, probability of minimum gain, maximum gain.

Stopping rule 1: Stop examination if the minimum gains differ by 1/10 (or more) of the maximum gain.

The hypothesis is that 1/10 of the maximum gain, that is, one order of magnitude (or near enough), is "good enough" or meets the aspiration level. For example in the choice between winning $200 with probability 0.5 or otherwise nothing and $100 for sure, most people choose the $100.

Stopping rule 2: Stop examination if probabilities differ by 1/10 (or more) of the probability scale.

Decision rule: Choose the gamble with the more attractive gain (probability).

2.3.3 Melioration [13]

Melioration is defined as choosing a lesser local gain over a greater longer term gain. In most complex environments the relationship between actions and future outcomes is uncertain and must be learned from experience.

For example after a long day at work the choice may be between exercising or watching TV. Whilst the short term benefit of watching TV may be preferred there are long-term consequences of adopting a sedentary lifestyle which meaning that this choice may not be considered rational.

According to rational choice theory, humans act in a manner that seeks to maximize the overall achievement of subjective utility. By contrast, melioration theory asserts that the driving force underlying decision making is not the attempt to maximize global utility but rather a process of continually shifting behavioural preferences towards alternatives with higher local rates of reward. The implications of the debate between melioration and rational choice theory are both important and widespread, impacting fields as diverse as training and education, criminal justice, and the treatment of substance abuse and addiction.

Melioration theory has been offered as an explanation for phenomena as diverse as impulsivity and self-control, delayed reinforcement, and natural selection.

In most simple decision environments without delayed or indirect consequences, melioration theory predicts behaviour that is similar to or indistinguishable from global utility maximization.

However in more complex environments decisions appear to follow melioration principles and long term gain is not maximised according to rational behaviour (as determined by the experimenter). However, to date, no one has examined whether a rational decision maker could, in principle, learn an appropriate representation of the task environment in a melioration experiment. Without this key piece of information, it is not clear whether documented instances of melioration reflect irrationality in human decision making under risk or whether they point to a rational agent acting optimally in the face of significant environmental uncertainty.

It has been found that even an unbiased rational learner could be led to believe that melioration will be of higher long-term value than the supposedly optimal strategy, despite extensive experience in the task environment.

Melioration can be interpreted not as irrational behaviour under risk but instead as rational choice under uncertainty.

2.3.4 Fuzzy Trace Theory [14]

Fuzzy-trace theory makes predictions regarding memory, judgement and decision making. The concepts of gist (essential meaning) and verbatim (surface form such as exact wording) representation are extended beyond verbal information to numbers, images and events.

In this theory meaningful inputs are assumed to be encoded into memory in two forms: a verbatim representation (the objective stimulus or what actually happened) and a gist representation (the subjective interpretation of information or interpretation of what happened). Gist is not derived from verbatim representations, both representations are encoded roughly in parallel as a person perceives a stimulus.

For example for the following information:

In a study of 791 healthy children aged 1–15 years, post-vaccination fever was noted among 12% of those aged 1–5 years, 5% among those aged 6–10 years, and 5% among those aged 11–15 years.

Verbatim representations would include memories for exact words and numbers (eg, fever was noted among 12% of those aged 1-5 years).

Gist interpretations could include that the risk is low and that risk goes down with age. However gist interpretations are different for different people. Gist depends on a person's knowledge, culture, life experience, prejudices and beliefs. For example one person may view fever as a mild side effect, whereas another might view it as serious. Similarly 12% may be viewed as high or low.

People have a fuzzy-processing preference; they rely on gist (a fuzzy or vague representation relative to precise verbatim representations) rather than verbatim representations whenever they can.

Gist representations support intuitive processing, which is generally unconscious, parallel, and impressionistic. Verbatim representations, in contrast, generally support conscious, analytical, and precise processing. Ironically, the preference for fuzzy, or gist-based, processing tends to improve reasoning, judgment, and decision making because gist memory is more stable and less subject to interference, compared to verbatim memory

Most reasoning, judgment, and decision-making tasks can be accomplished to a high standard of performance using simple gist. Although, tasks, such as exact recall, might appear to require verbatim representations, they are often accomplished accurately by reconstructing items (e.g., studied words on a long list) from vague gist representations. However, taking advantage of the robustness of gist representations hinges on having sufficient background knowledge to be able to extract a meaningful gist. Such background knowledge is often lacking in medicine and public health, in particular, regarding vaccinations.

Gist based approaches are different to fast-and-frugal approaches as gist involves meaning to apprehend the essence of the information or experience. Experience and knowledge facilitate connecting the dots, producing systematic biases that generally improve performance, but they also have predictable pitfalls. For example, "false" memories that go beyond actual experience are typically the product of gist-based interpretations and inferences—and they increase from childhood to adulthood.

According to fuzzy-trace theory, there are four aspects of decision making:

- knowledge (having background information or experience needed to understand the gist of options)
- representations (especially appreciating the meaning of key facts—the gist—of options)
- retrieval of values (recognizing the relevance of key values or knowledge in context)
- processing (understanding how values apply to the options).

Obstacles to good decision making exist for each of these four aspects. For example public health messages mainly warn and persuade but do not explain.

Fuzzy-trace theory predicts that decision makers begin with all-or-none categorical distinctions, the simplest gist. This can be illustrated with the classic decision dilemma:

Which do you choose?

Receive $100 for sure or have a 50% chance of $200 or nothing.

Using gist this is represented as receiving some money versus taking a chance on receiving some or no money. In the gist, the sure option is pitted against a gamble. Receiving some money is better than no money so most people choose the sure thing.

2.3.5 Health Belief model

The Health Belief Model (HBM) specifically identifies five factors – susceptibility, severity, benefits, barriers, and self-efficacy – that predict whether people will perform a particular health behaviour.

- Perceived susceptibility addresses the extent to which the person perceives they are vulnerable to the particular health problem.
- Perceived severity refers to an individuals' belief that not acting to prevent the health problem will lead to severe consequences. Lower perceived severity reduces intentions to enact a health behaviour.
- In terms of perceived benefits, if individuals believe that the health behaviour will reduce the threat, they are more likely to adopt the behaviour.
- Perceived barriers to performing the behaviour also play into the decision, as those who believe the costs of adopting the behaviour to be too high will not perform the behaviour.
- Perceived self-efficacy refers to a person's belief in his or her ability to perform the behaviour.

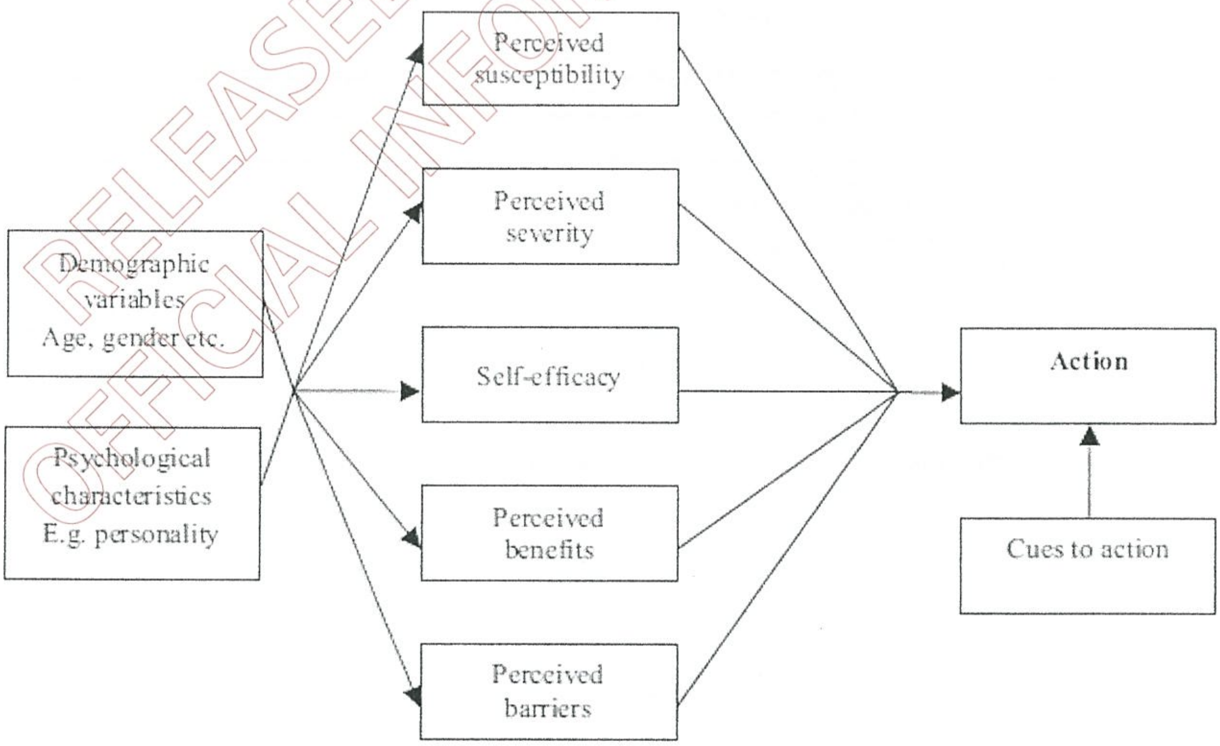

Figure 3 ***Health belief model [15]***

2.3.6 Emotion [16]

The emotion-as-frame model suggests that discrete emotions, like fear, anger, and hope, once evoked by message content, selectively direct cognitive efforts by

(a) making emotion-related information accessible from memory,

(b) directing attention to information expected to relieve negative emotions and perpetuate positive ones, and

(c) differentially influencing risk perceptions and, in turn, attitudes and behaviours.

Once evoked, those emotions would direct decision making based on the emotion-relevant information made accessible from memory (e.g., knowledge of personal risk factors, awareness of protective actions), as well as information from the story itself. Although related to other forms of framing that incorporate the notion of valence (e.g., gain/loss or positive/negative attribute framing), emotion-based framing is unique in its focus on discrete emotional states, which, unlike less differentiated affect-based constructs, have evolutionary-derived motivational goals and action tendencies that direct thought processes and behaviour.

2.4 Vaccination decisions

Zingg measured general knowledge about vaccinations in the German and French speaking populations in Switzerland. They found that most respondents had little knowledge and many misconceptions about vaccination. For example more than half of respondents thought that children would be more resistant if they were not always vaccinated against all diseases.[17] This lack of general knowledge means that people lack the ability to make sound gist assessments of information they are given on vaccination. It also leaves them open to the messages of the anti-vaccination lobby.

An analysis of social media (called Web 2.0 in a series of publications) in the context of the vaccination debate was performed by Witteman et al. [18] Stories and testimonials are powerful influences on risk perception and decision making, including in the context of vaccination Thus, evidence-based narratives hold significant potential for conveying information. Stories are authoritative because they are very concrete and they have the inherent credibility of the "anti-authority", the person with personal experience who provides "living proof" of the message.

Stories contribute to risk perceptions by shaping perceptions of incidence and by conveying and provoking emotion. The number of positive or negative stories to which a reader is exposed helps to shape his or her sense of incidence of positive or negative outcomes. Indeed, specifically in the context of vaccination, someone who is exposed to more stories about vaccine injuries can easily develop a sense that such injuries are more common than someone unexposed to such accounts of adverse events.

The emotionality of stories about vaccination may serve to further amplify these effects via transportation, a mechanism by which a reader may become engrossed in a narrative (or transported, as it were, into the story) and such absorption in the story can influence beliefs. This amplification has also been supported empirically in the context of vaccination, with more emotional narratives leading to higher risk perceptions.

Fuzzy trace theory [14] proposes that the vaccination decision can be framed as feeling okay (do nothing) versus either feeling okay (no side effect to vaccination) or not feeling okay (side effect to vaccination). In this scenario the choice is not to vaccinate, because vaccinating is the only option that has not feeling okay as a possible outcome (vaccinating is seen as the gamble).

There are of course other reasons why people may not vaccinate, they may be unaware of the vaccine, unaware of the cost, or they may think they can get the disease from the vaccine.

The gist changes if one perceives the risks of vaccination as nil (not necessarily as no side effects, but that the side effects are negligible). In this case the options are protection against the disease or a gamble that you will not get the disease. In this case the decision is to vaccinate.

The gist also changes if the perception of catching the disease is high or the consequences of catching the disease are serious. In this case the gamble is again seen as not vaccinating.

Vaccination decisions are made on a complex array of factors including doctor's recommendation, social norms, previous experiences, trust in individuals and organizations and other cognitions. [20]

The decision process can be described as occurring in three stages.

In the pre-decisional phase, individuals consider their options, usually to either vaccinate within the recommended time frame, with delay or not at all.

Individuals in the decisional phase then evaluate potential outcomes of alternative actions (such as vaccinating or not) based on the obtained information. Current theories of health behaviour assume that individuals must first perceive themselves as being at risk before they will take protective action. Risk perception has been conceptualized as a combination of one's beliefs about the likelihood of being affected by a negative event (e.g., contracting HPV) and the severity of the negative event (e.g., cervical cancer can be lethal). In addition, the benefits of vaccination arise in the future and are thus typically intangible to individuals at the time of the decision, especially since they refer to an event that will not occur, i.e. not contracting a disease. Further, individuals also benefit when others get vaccinated and herd-immunity increases, which makes free-riding attractive. Vaccinations may also be followed by adverse events that are either correctly or falsely attributed to them (e.g., causally established outcomes such as anaphylaxis or disproven outcomes such as autism). Individuals may find it easier to visualize that vaccinations are harmful, especially since such links are suggested by vivid anti-vaccination messages and possess face-value biological plausibility

In the post-decisional phase, individuals again receive unbalanced feedback regarding their decision: while vaccination costs such as pain, time, money and potential adverse events are immediate and tangible, the benefits are typically delayed or less tangible. As with all types of prevention, the difficulty with vaccinations is that individuals can never know whether they would have contracted the disease had they not been vaccinated – the prevention is unobservable. In contrast, adverse events are easily connected to the vaccination, even those that are actually unrelated and would have occurred anyway.

2.4.1 How interest groups seek to influence decision making

The factors that seem to contribute to anti-vaccine sentiment have been reviewed. [19] It has been argued that current culture has become intolerant of risk such that when harm occurs someone must be blamed. The culture of widely available information (accurate or otherwise) through the internet is exploited by anti-vaccine groups.

First it must be acknowledged that vaccines can and do cause harm and may even theoretically carry unknown risks. It is impossible to know all the risks until a vaccine has been widely used.

Anti-vaccine concerns include.

- The idea that vaccines are foreign material injected into the body of otherwise healthy people.
- There is an increasing number of antigen and injections by virtue solely of the number of vaccines and this is thought to carry additional risks.
- Vague ideas of an increased risk of cancer or autoimmune disease.
- Disease had already begun to disappear prior to the use of vaccine.
- The majority of people who get a vaccine-preventable disease were previously immunised.

- There are 'hot' lots of vaccines associated with a greater frequency and/or severity of adverse events.
- Vaccines cause illness and deaths.
- Vaccine preventable illnesses have been eliminated already.
- Multiple vaccines overload the immune system.
- Vaccines are not natural, disease-induced immunity is preferred.
- Any variety of political/economic conspiracy theories regarding manufacturer profits, minority issues and even genocide issues.

An inadequate scientific knowledge base within the media and an irresponsible tendency toward the sensational contributes to public fears and concerns. Anti-vaccine groups have been successful in finding outspoken and articulate spokespersons for their cause.

According to fuzzy-trace theory, [14] anti-vaccine messages are expected when people do not understand vaccination (which is widespread) and when mysterious adverse events occur in close contiguity to vaccination. The search for meaning and the tendency to interpret events—to connect the dots—provides a powerful impetus to generating strident anti-vaccine messages under the right conditions. Superstitious behaviour is evident in humans, for example, when baseball players continue to wear a lucky hat or use a lucky bat in the hope of recreating home runs. Connecting events that merely co-occur randomly is a rote or verbatim strategy because it does not depend on understanding. Thus, individuals with very low levels of causal knowledge are likely to engage in superstitious behaviour. Most adults attempt to understand associations and try to test hypotheses about why the events occurred in order to predict future occurrences. Whilst humans are able to detect non-random patterns when they occur they are woefully inadequate at understanding that events are random.

Anti-vaccination messages attempt to create a highly coherent gist, but official sites often do not. Because of the drive to extract meaning, the widespread lack of knowledge about vaccination creates fertile ground in which misleading "explanations" can take root.

Hence, in addition to low knowledge, strident anti-vaccination messages are predicted when: (a) specific ideas have a priori plausibility (that the government would deliberately infect people with a dread disease; that authorities are untrustworthy) and when (b) adverse outcomes occur that are poorly understood (e.g., autism, multiple sclerosis, and fibromyalgia). Anti-vaccine messages that make sense of unexplained events and associations, that satisfy that longing for clarity, are apt to diffuse more rapidly through the internet and social media.

Anti-vaccination messages which connect rare and unexplained diseases such as MS or autism to vaccinations exploit a human bias towards identifying something as meaningful signal or pattern rather than random noise. Social media amplifies these processes and charged personal narratives allow anti-vaccination messages to spread rapidly particularly as they provide more coherent accounts of the gist of vaccination relative to official government sites.

16% of people searched online for vaccination information, and of this group, 70% say what they found influenced their treatment decisions. Surveys indicate the Internet now rivals physicians as the leading source of health advice. As many as 72% of American users trust health information they obtain on the Internet. [19]

Also, around 75% of American users evaluate the source and status of online health information only sometimes, hardly ever or never. Further, lots of important information is missing when individuals conduct web searches: A recent study showed that approximately one third of websites obtained in a Google search on the relation between autism and the MMR vaccination do not contain key information regarding the absence of a link between autism and vaccinations and about a quarter of websites contain inaccurate information.

Recent research has identified characteristics that could increase users' vulnerability to obtain non-reliable information in Internet searches:

- lower socioeconomic status
- lower cognitive ability and older age
- lower literacy or health literacy (the ability to read and understand written or verbal (health) information
- less understanding of how to search the Internet (i.e., digital literacy)
- less knowledge about vaccination
- lower numeracy (the ability to understand and use numbers.

Larger anti-vaccination groups (e.g. National Vaccine Information Center, Australian Vaccination Network) also actively use Web 2.0 (social media) by coordinating their presence in online polls and on parenting discussion boards, Twitter, Facebook and YouTube. This increases the availability of material opposing vaccination that is often vivid, emotionally arousing and personal.

While scholars are reluctant to recommend the inclusion of narratives in decision aids, online debates about vaccination are filled with personal stories of patients and parents who describe in vivid language the health problems they believe (correctly or incorrectly) to be the result of vaccination. The person-centered technique of Web 2.0's information creation is particularly well suited for collecting and disseminating personal stories in anti-vaccination messages. Narratives have inherent advantages over other communication formats. Narratives of purported vaccination injuries include all of the key elements of memorable messages: They are easy to understand, concrete, credible in the way in which a first person story of victimization is always credible ("I was there!") and highly emotional. These qualities make this type of information compelling; in risky situations, individuals prefer to know how consequences might be if they do occur, rather than how likely a consequence is to occur. Whether or not these stories represent verifiable vaccination risks is immaterial.

The existence of narratives about adverse events on websites increases the perceived risk of adverse events, especially via the elicitation of emotional reactions Further, lab experiments showed that the greater the number of narratives that people read, the higher the perception of risk was, regardless of the information contained in simultaneously presented statistical information.

In addition to being individually persuasive, the broad distribution of stories of perceived vaccine-related negative outcomes via the Internet distorts users' perceptions of the actual likelihood of such events. Individuals consider how often they see such narratives in order to estimate how often different events will occur in real life.

2.4.2 Tactics used by the anti-vaccination movement [20]

A new postmodern paradigm of healthcare has emerged, where power has shifted from doctors to patients, the legitimacy of science is questioned, and expertise is redefined. Together this has created an environment where anti-vaccine activists are able to effectively spread their messages.

Web 2.0 has furthered postmodern ideals by "flattening" truth; the infinite personalized truths presented online are each portrayed as legitimate. This is supported by the postmodern characteristic of relativism – that there are no objective facts, but rather multiple meanings and ways of "knowing". This is demonstrated by anti-vaccinationism on the Internet, where self-proclaimed "experts" tout conflicting messages; with the notion that multiple "truths" based on different worldviews are equally valid, evidence-based advice from qualified vaccine experts becomes just another opinion among many (table 3).

Table 3 ***Tactics used by the anti-vaccination movement***

Tactics	Description
Skewing the science:	Denigrating and rejecting science that fails to support anti-vaccine positions; endorsing poorly-conducted studies that promote anti-vaccine agendas.
Shifting hypotheses:	Continually proposing new theories for vaccines causing harm; moving targets when evidence fails to support such ideas.
Censorship:	Suppressing dissenting opinions; shutting down critics.
Attacking the opposition:	Attacking critics, via both personal insults and filing legal actions.

The anti-vaccination movement often denigrates scientific studies (and the scientific method in general), while simultaneously craving scientific legitimacy for their theories that vaccines are harmful. The movement constantly demands more research. Various obstacles – e.g. the ethics of leaving children unvaccinated, or the logistics of recruiting enough subjects to sufficiently power a study – make conducting such a study virtually impossible. These obstacles are not mentioned when making such demands. Properly conducted work on the issue that already exists, yet comes to the "wrong" conclusion, is rejected.

Scientific studies have repeatedly refuted allegations that vaccines are harmful, forcing the anti-vaccination movement to continually propose new theories. When various studies failed to find a connection between MMR and autism, the culprit then became thimerosal and autism was rebranded as mercury poisoning. When the mercury hypothesis floundered, the new culprit became aluminium. The targets established by anti-vaccine activists are continually being redrawn in order for their key messages to endure in the face of contradictory evidence.

The anti-vaccination movement is extremely disparaging of those criticizing them, to the point of censoring dissenting opinions. Posts opposing anti-vaccination views or supporting vaccines are removed, apparently due to "agenda-focused behaviour". More underhanded methods have also been used to silence vaccine advocates (Table 4).

Table 4 ***Tropes used by the anti-vaccine movement***

Tropes	Description
"I'm not anti-vaccine, I'm pro-safe vaccines":	Denying one opposes vaccination, instead claiming they are for safer vaccines and further research.
"Vaccines are toxic!":	Listing potentially toxic vaccine ingredients while providing disingenuous explanations of their dangers (a.k.a. the "toxin gambit").
"Vaccines should be 100% safe":	Because absolute safety cannot be promised, vaccination is therefore flawed and dangerous.
"You can't prove vaccines are safe":	Demanding vaccine advocates demonstrate vaccines do not lead to harm, rather than anti-vaccine activists having to prove they do.
"Vaccines didn't save us":	Attributing improvements in health over recent decades to factors other than vaccines (e.g. better sanitation).
"Vaccines are unnatural":	Designating something "natural" to be the better option (e.g. naturally acquiring immunity from diseases rather than from vaccination).
"Choosing between diseases and vaccine injuries":	Framing vaccination choices as restricted between undesirable outcomes (e.g. catching a disease versus serious vaccine side-effects).
"Galileo was persecuted too":	Invoking the names of those persecuted by scientific orthodoxy, implying ideas facing close-mindedness will eventually gain acceptance (a.k.a. the "Galileo gambit").
"Science was wrong before":	Citing prior instances of scientific errors to imply the scientific evidence supporting vaccination is also in error.
"So many people can't all be wrong":	Implying anti-vaccine claims are true because many people support such ideas.
"Skeptics believe...":	Ascribing false motives to vaccine supporters, which are then easily attacked.
"You're in the pocket of Big Pharma":	Claiming those supporting vaccines do so because they are hired by pharmaceutical companies (a.k.a. the "pharma shill gambit").
"I don't believe in coincidences":	Rejecting that health problems can occur coincidentally after vaccination.
"I'm an expert on my own child":	Redefining expertise, where parents are the experts on their own children while medical authorities are discounted.

Anti-vaccine activists have filed legal actions against their critics. Some anti-vaccine activists attack their detractors in more personal ways. Moving beyond verbal attacks, for Thanksgiving 2009 the Age of Autism blog posted a Photoshopped image showing vaccine advocates sitting down to a dinner of a dead baby.

Many websites list toxic ingredients supposedly in vaccines (e.g. ether, anti-freeze, formaldehyde, aborted fetal tissues, animal viruses, and foreign DNA). This is known as the "toxin gambit". While some ingredients listed are technically present, explanations of their dangers are often disingenuous. Their risks are frequently emphasised in terms of larger or prolonged exposure, not acknowledging that "the dose makes the poison". Nor is it mentioned that some substances occur naturally in the human body (e.g. formaldehyde), or accumulate in greater amounts through acts such as breastfeeding (e.g. aluminium).

"You can't prove vaccines are safe" This accusation demands vaccine advocates demonstrate vaccines do not lead to harm, rather than anti-vaccine activists having to prove they do. This involves arguing based on a lack of evidence – not knowing something is true is taken as proof it is false, or not knowing something is false is proof it is true. Likewise, because there have been no studies conducted with the specific conditions anti-vaccination groups ask for, this lack of knowledge means vaccines are not safe. Lists of questions to ask vaccine proponents are circulated with the intention of stumping them, with the inability to answer taken as evidence against vaccination.

Rather than acknowledge the role vaccines played in improving health over recent decades, those gains are instead attributed to factors such as cleaner water, better sanitation, and less crowding. This claim is usually accompanied by graphs showing deaths from vaccine-preventable diseases were declining before vaccines were introduced. That mortality rates would have been decreasing due to improving medical and supportive care is not explained. Graphs showing decreasing disease incidence after vaccine introduction would be evidence of their efficacy, and are omitted.

"Vaccines are unnatural" This designates something "natural" as being inherently good or right, while what is "unnatural" is bad or wrong. Vaccines are unnatural and therefore bad. Acquiring immunity from diseases is natural and therefore the better approach. This logic overlooks higher risks from natural infection while fixating on comparably minute risks from vaccination.

Vaccination may be portrayed in terms of misleading dichotomies – e.g. the unlikelihood of catching a disease versus the supposedly greater likelihood of a vaccine injury, or the possibility of vaccine side-effects more serious than the diseases prevented. Such framing restricts the possible outcomes when others exist (e.g. vaccination without side-effects).

"So many people can't all be wrong" Asserting that many children have been harmed by vaccines, that many people do not vaccinate, or that many doctors question vaccination, does not make such claims true. The constant repetition of this and other tropes on various websites can fool readers into thinking anti-vaccination opinions expressed are shared by many.

Genuine authorities on vaccines are denigrated for supporting vaccination and belittled as not having appropriate expertise. Alternatively, appeals may be made to authorities who are not experts on the particular subject. Doctors criticizing vaccination despite no training in immunology, or doctors noticing certain reactions in their patients after vaccinating or not vaccinating, implying they have special insight into the issue. Authorities are invoked when they support the desired opinion.

The techniques used by the anti-vaccination movement are cunning, for not only are their protests camouflaged in unobjectionable rhetoric such as "informed consent", "health freedom", and "vaccine safety", they take advantage of the current postmodern medical paradigm. Calls to "do your own research before vaccinating" dovetail with the postmodern characteristics of patient empowerment and shared decision-making, where individuals play a more involved role in their healthcare. Some anti-vaccine arguments may at first seem reasonable and to hold a grain of truth; the various tropes encountered, particularly when repeated through various channels, may make vaccinating seem like an extremely risky proposition. Rather than creating "informed patients", Web 2.0 is used by the anti-vaccination movement to spread fear, uncertainty, and doubt, thereby creating "misinformed patients".

3.0 COMMUNICATING RISK

Information has been published on risk communication and is summarised below. To date there is no good advice on communicating uncertainty and in general these sources recommend avoiding this topic at present.

3.1 Numerical information

3.1.1 What is probability?

Probability statements are ubiquitous in the clinical medical literature. They are essential to how clinical trials are understood and interpreted. They form the core of how health risks are understood and diagnosis and prognosis are communicated to patients. So ubiquitous is the use of probability claims that its application in this variety of contexts is virtually unquestioned.[21] As it turns out, there is considerable disagreement on the foundations and interpretation of probability. There are three distinct and in some cases, conflicting interpretations of probability: mathematical, subjective and frequency.

Probability can be understood as a mathematical theory. The axioms of the mathematical interpretation of probability hold that a probability is a non-negative integer that takes a value between 0 and 1, with 0 connoting impossibility and 1 certainty.

The subjective notion of probability holds that probability statements are merely measurements of the strength of one's belief in a proposition. That is, the probabilities are not measured quantities of events in the real world, but reflect the subjective beliefs of a person on what the probability or the likelihood of an event would be. Two people may have divergent subjective probabilities regarding the same event. For example, two clinicians may express contrasting subjective probability estimates regarding the prognosis or occurrence of events in the same patient. So there can be as many subjective probabilities as there are humans expressing judgments regarding events in the real world.

The frequentist interpretation of probability admits to a variety of different constructions. Frequency interpretations of probability are familiar to anyone who has taken an introductory class in statistics. There are two varieties of frequentism: finite and infinite frequency.

Finite frequency is best represented by problems related to gambling or any context in which there is a well-defined class of events and finite number of possible events.

Infinite frequentism applies to situations where the reference set is not countable. In this case, infinite replications or repeated trials are necessary to fix the value of probability. Probability is determined as the limiting frequency as the series approaches infinity.

If uncertain medical events are meant to be regarded as probabilities, how do such claims attach to or relate to reality?

For the mathematical interpretation of probability, the issue does not arise. In a mathematical conception of probability, the notion of probability is an entirely abstract set of procedures that follow certain rules of derivation and deduction. As long as consistency is not violated and contradictions do not arise, it does not matter in any way whether or not any of the probability theorems that are derived from the axioms relate to the real world.

For the subjective interpretation of probability, probability statements do not 'attach' to events in the real world. They attach rather to the belief structure of the individual(s) making the probability statement. Again, as long as they do not contradict themselves and are consistent in their application, there is no necessity that these probability statements actually attach to reality.

The frequentist interpretation of probability requires events to occur in some space. In the case of medicine, this is likely in the life world of clinicians and patients. Probabilities to be useful in medicine must in some way relate to these events.

Thus in fact the meaning of *a 16% probability of developing cardiovascular disease in the next 10 years* is remarkably unclear.

Using the language of probability, creates the veneer of something objective and scientific, but really conceals greater uncertainty and error.

3.1.2 Communicating numerical information

Treatment benefits and harms are often communicated as relative risk reductions (RRR) and increases, which are frequently misunderstood by doctors and patients.[22] People's numeracy skills play an important role in correctly understanding medical information.

People often overestimate treatment benefits when they are communicated as RRRs: Interpreting a relative reduction as an absolute reduction results in an overestimation of a treatment's effectiveness. For example a scenario in which the baseline risk is 30% and the RRR is 20%. This implies that the event rate in the treatment group is 24%, but misinterpreting the information as an absolute decrease reduces the number to 10%.

Overall, communicating treatment benefits and harms in the form of relative risk changes remains problematic, even when the baseline risk is explicitly provided.

Communicating baseline risk in a frequency format facilitated correct understanding of a treatment's benefits and harms, whereas a percentage format often impeded understanding. For example, many participants misinterpreted a relative risk reduction as referring to an absolute risk reduction. Participants with higher numeracy generally performed better than those with lower numeracy, but all participants benefitted from a frequency format.

Table 5 Relative and absolute risk changes

Type of Change	Risk Reduction (RR)	Risk Increase (RI)
Relative (R)	$RRR = \frac{ER_{Control} - ER_{Treatment}}{ER_{Control}}$	$RRI = \frac{ER_{Treatment} - ER_{Control}}{ER_{Control}}$
	Example:	Example:
	$RRR = \frac{0.5\% - 0.4\%}{0.5\%} = 20\%$	$RRI = \frac{0.028\% - 0.014\%}{0.014\%} = 100\%$
Absolute (A)	$ARR = ER_{Control} - ER_{Treatment}$	$ARI = ER_{Treatment} - ER_{Control}$
	Example:	Example:
	$ARR = 0.5\% - 0.4\% = 0.1\%$	$ARI = 0.028\% - 0.014\% = 0.014\%$

Note: The risk reductions are based on the mammography example (breast cancer mortality reduction from 5 in 1000 to 4 in 1000 when participating in screening). The example for the risk increase measures is based on the "pill scare" (increase of thrombosis from 1 in 7000 to 2 in 7000 when taking the third-generation contraceptive pill). $ER_{Control}$ = event rate in the control group (baseline risk); $ER_{Treatment}$ = event rate in the treatment group.

Highly numerate individuals appear to pay more attention to numbers, better comprehend them, translate them into meaningful information, and ultimately use them in decisions. Decisions of the less numerate are informed less by numbers and more by other non-numeric sources of information, such as their emotions, mood states, and trust or distrust in science, the government, and experts. Careful attention to information presentation, however, allows the less numerate to understand and use numbers more effectively in decisions. As a result, the challenge is not merely to communicate accurate information to the public but to understand how to present that information so that it is used in risky decisions.

If risky decisions are to be informed by numeric information, it appears that information providers need to show only the most important information (or at least highlight it), make that information easier to evaluate (for example, by using well-tested symbols), and present data in accordance with cognitive expectations (i.e., higher numbers mean better performance). For those with poor numeracy skills, the effect of information presentation on comprehension and choice is even more marked. Taking steps to present information in accordance with these recommendations will reduce disparities in the ability to use numeric information effectively in decisions and may assist risk communication efforts.

3.1.3 Natural frequencies [23]

The use of natural frequencies for numerical data has been recommended. The power of using natural frequencies is illustrated in the following example.

After a positive haemoccult screening test, which signals hidden blood in the stool, a patient asks his doctor: "What does a positive result mean? Do I definitely have colon cancer? If not, how likely is it?"

When 24 experienced physicians, including heads of departments, were asked this, their answers to the third question ranged between 1 and 99%. All these physicians had the same information: a prevalence of 0.3%, a sensitivity of 50%, and a false positive rate of 3%. Only one physician gave the correct answer. When another group of physicians were given the same information in natural frequencies 16/24 gave the correct answer. A further example is shown in table 6 and figure 4 below.

Table 6 An example task comparing probability to natural frequencies

Probability version	Natural frequency version
The probability of breast cancer is 1% for a woman at age 40 who participates in routine screening. If a woman has breast cancer, the probability is 80% that she will have a positive mammogram. If a woman does not have breast cancer, the probability is 9.6% that she will also have a positive mammogram. If a woman has breast cancer, the probability is 95% that she will have a positive ultrasound test. If a woman does not have breast cancer, the probability is 4% that she will also have a positive ultrasound test.	100 out of every 10,000 women at age 40 who participate in routine screening have breast cancer. 80 out of every 100 women with breast cancer will receive a positive mammogram. 950 out of every 9900 women without breast cancer will also receive a positive mammogram. 76 out of 80 women who had a positive mammogram and have cancer also have a positive ultrasound test. 38 out of 950 women who had a positive mammogram, although they do not have cancer, also have a positive ultrasound test.
What is the probability that a woman at age 40 who participates in routine screening has breast cancer, given that she has a positive mammogram and a positive ultrasound test?	How many of the women who receive a positive mammogram and a positive ultrasound test do you expect to actually have breast cancer?

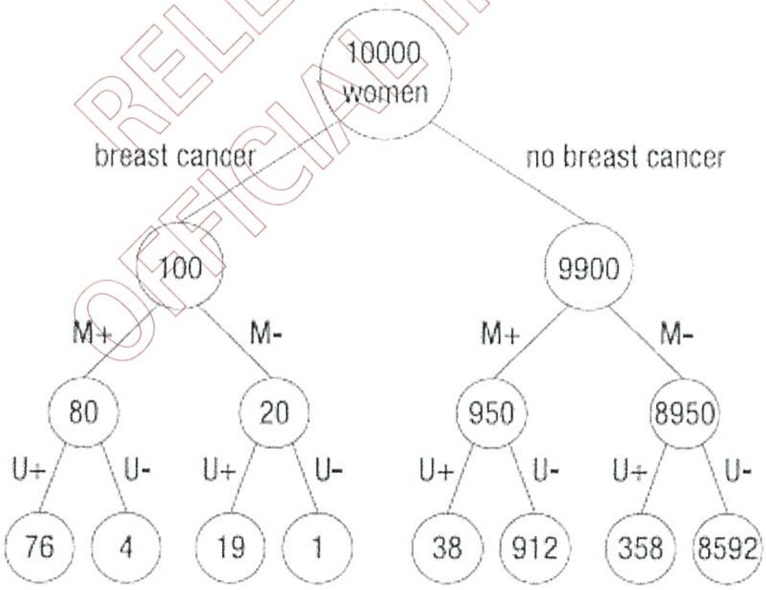

Figure 4 Visual representation of the information provided in the natural frequency version in table 6 above

Other options for reducing cognitive effort have not been tested with numeracy but are likely to be effective. For example, with small probabilities it is tempting to present them as one chance out of a larger number (eg, 1 of 50, 1 of 1000); keeping the denominator constant, however, will reduce effort and increase comprehension (eg, 20 of 1000, 1 of 1000).

The use of visual cues, such as stars, to highlight the meaning of information is also likely to help, as is ordering and summarizing information.

Results are mixed as to whether percentage (13%) or frequency (13 out of 100) formats promote greatest understanding. There is general agreement that decimals (0.03) should not be used. Finally, individualized risk estimates rather than general population figures may increase efforts to reduce risks.

3.1.4 Use of graphs and diagrams [24]

The use of graphs can improve comprehension of numbers. However, just as not all people are numerate, not everyone can understand graphs either.

Tree diagrams

Trees with natural frequencies foster insight because the natural frequency representation does part of the computations. If one wants to compute the probability p(HIV|positive) from the relative frequency tree, one would have to perform the following mental calculations:

$$p(\text{HIV}|\text{positive}) = p(\text{HIV})p(\text{positive}|\text{HIV})/[(p(\text{HIV})\,p(\text{positive}|\text{HIV}) + p(\text{noHIV})p(\text{positive}|\text{no HIV})]$$

$$0.01\% \times 99.9\%/(0.01\% \times 99.9\% + 99.99\% \times 0.01\%) \approx 50\%.$$

In contrast, the natural frequency tree reduces these computations to:

$$p(\text{HIV}|\text{positive}) = 1/(1 + 1)$$

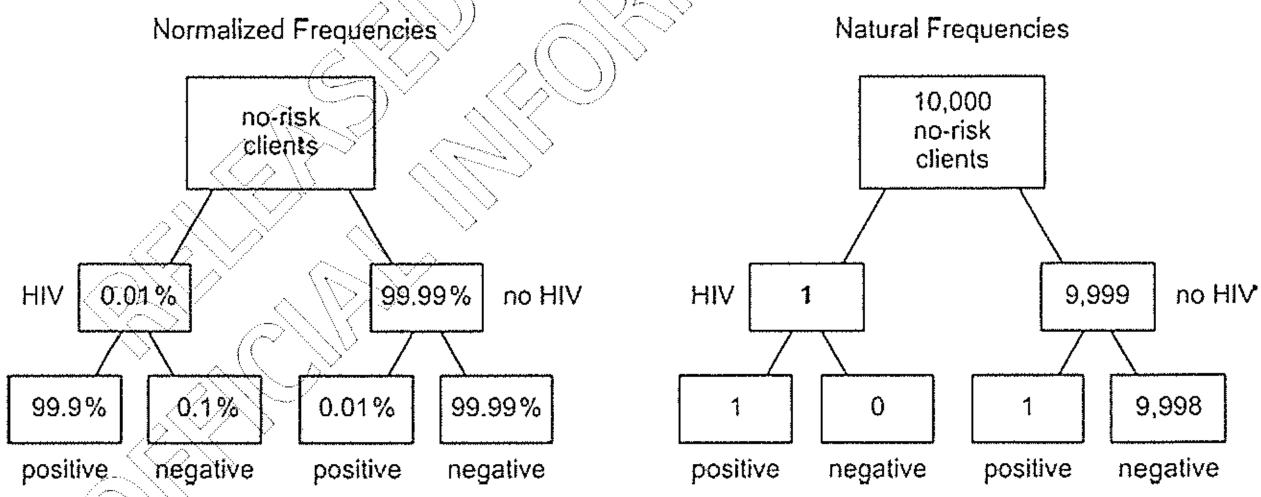

Figure 5 Two kinds of frequency trees for HIV testing: relative frequencies (left) which are non-transparent for many people and natural frequencies (right) which are transparent

Natural frequency trees can be extended without much difficulty to situations in which the co-occurrence of more than two binary variables is considered.

Bar graphs

Technically, a bar graph represents the frequency of the events in question by the height of the bars in the graph. A histogram, by comparison, represents frequency by area. Bar graphs strongly afford a fairly automatic and precise kind of perceptual comparison of heights that comes with a high degree of subjective confidence. Nevertheless, this capacity can be exploited; for example, bars can be constructed in a way that differences appear much larger than they are.

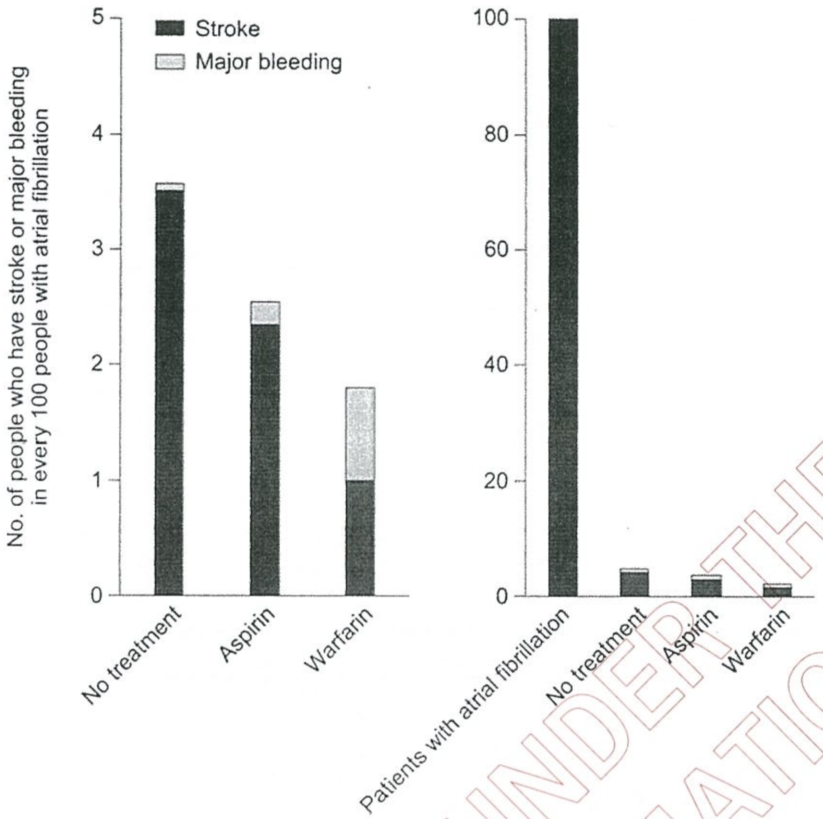

Figure 6 Two bar graphs representing the same benefits of treatment in two ways. The absolute effect of aspirin and warfarin becomes transparent in the bar graph on the right when the reference population is included.

For example in figure 6, the graph on the left-hand side suggests comparisons of incidences with and without treatment. Specifically, it turns out that the bars for the categories "no treatment," "Aspirin," and "Warfarin" show perceptually comfortable, that is, clearly differentiable, differences in height. However, this representation invites the same confusion as when reporting relative risk reduction. The bar graph on the right-hand side, in contrast, gives a visualization of absolute risk reduction.

Analogues

Population diagrams represent frequency in analogue fashion, e.g., by using a population of analogous icons, each representing an individual, rather than by using number symbols or bar height. By this one-to-one match between individual and icon, population diagrams invite identification. To a greater extent than with trees and bars, the reader can imagine being one of the individuals in the diagram.

In figure 7, individuals are represented by circles and squares. One step beyond this is to use icons that resemble the objects represented; for instance, when people are the objects to shape the icons using salient properties, such as identifiable clothing for a professional group or a particular body shape for small children.

Population diagrams allow individuals to "see" what their chances are. This type of seeing is backed by human understanding of group membership and intuitions about what it means to stand out from a crowd.

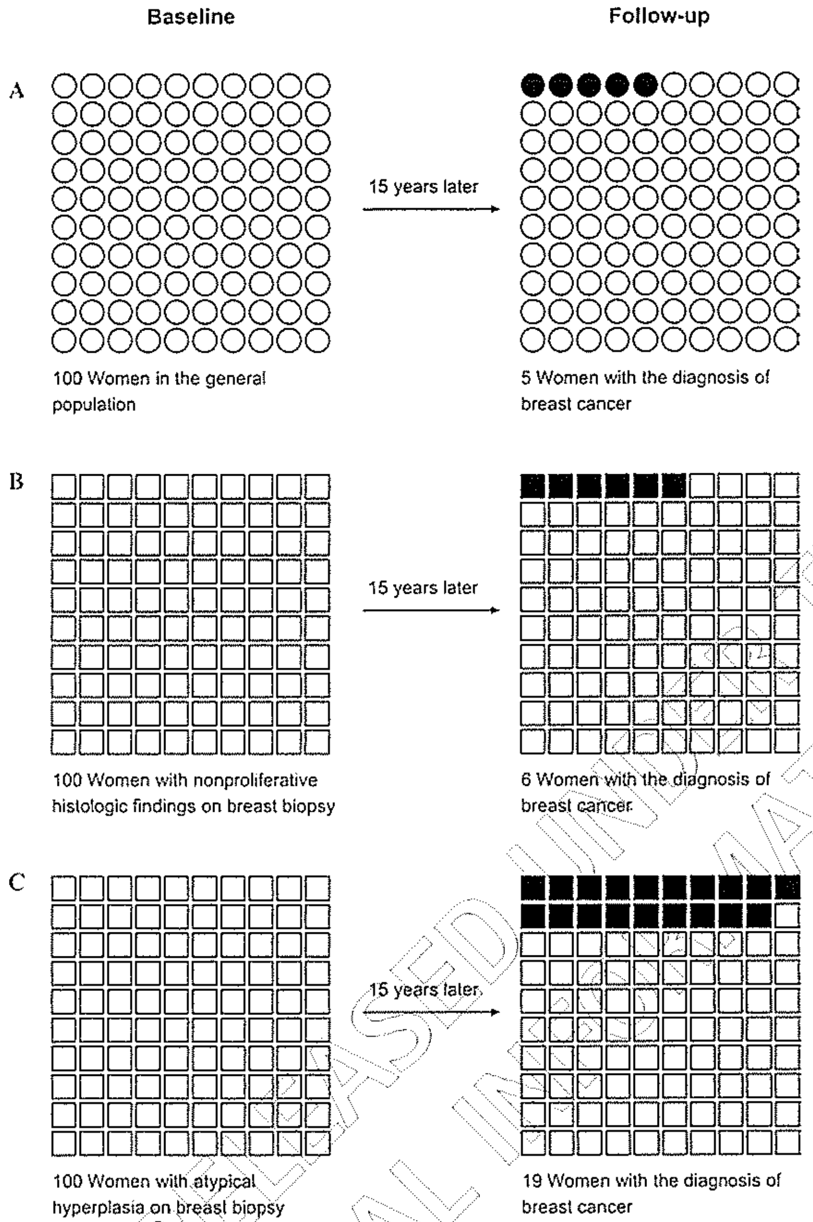

Figure 7 A population diagram representing the number of women who will be diagnosed with breast cancer in the next 15 years. Illustrates the data that 'As compared with women in the general population, women with non-proliferative findings on breast biopsy had a relative risk of breast cancer of 1.27 and those with atypical hyperplasia a relative risk of 4.24'.

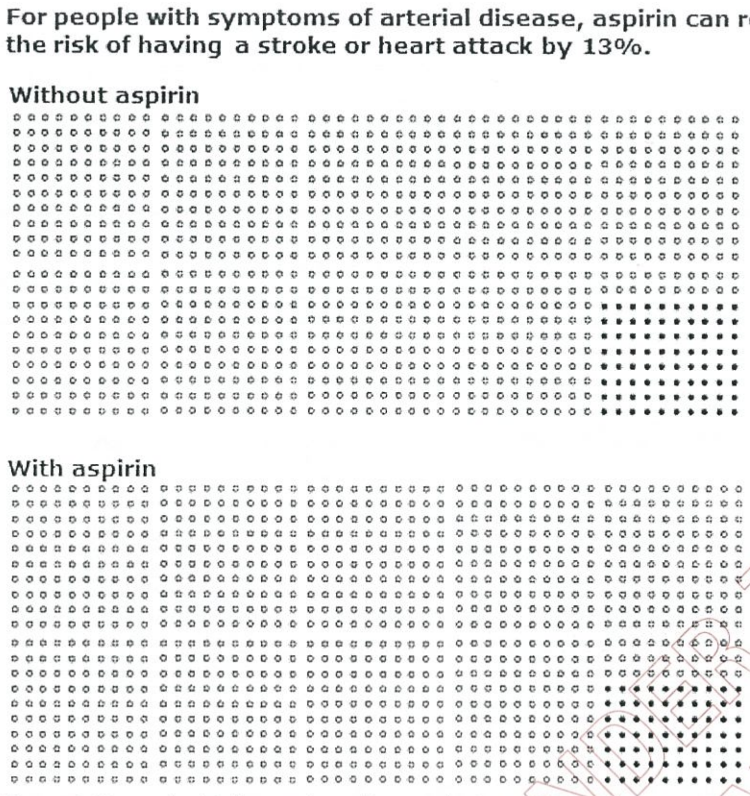

Figure 8 Numerical information about relative risk reduction involving icon arrays

Tinker cubes are a medium for representation that is also used in the mathematics classroom. As with population diagrams, tinker cubes can represent frequency in analogue fashion; cubes represent individuals.

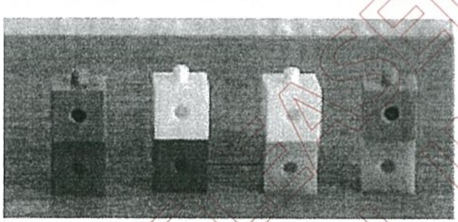

Figure 9 Conjunctions consisting of two tinker cubes. The colour is used for coding two binary variables, each conjunction represents an individual

3.2 Non-numerical information

3.2.1 Framing in communication [25]

"Framing manipulation" is the presentation of logically equivalent information in different ways. It can be further subdivided into "attribute framing" and "goal framing." Attribute framing is the positive versus negative description of a specific attribute of a single item or state. Interventions are perceived as more beneficial when presented using positive framing messages, but there is little evidence that framing affects patients' understanding or behaviour.

Goal framing describes the consequences of performing or not performing an act, presented as a gain versus a loss. Patients perceived screening as more effective when presented with a loss message, but again there was no evidence of an effect on patients' understanding or behaviour.

3.2.2 Use of emotion in communication [8]

When unintentionally evoked, supplementary emotions are viewed as noise or error. However, when intentionally generated, they may facilitate desired attitude and behaviour change.

An emotional shift message's enhanced influence may be due to its ability to reduce defensive processing, and in the case of negative–positive shifts, to boost perceptions of self-efficacy.

Fear appeal messages typically first present information regarding perceived threat severity and susceptibility, followed by response and self-efficacy information. Thus, the target audience should first experience fear and then receive information to adaptively respond to that fear. Not only might level of fear decline after receiving efficacy information but, more importantly, fear is likely replaced by a different emotion, like relief or hope, which would have its own unique action tendency. Not only might fear–hope appeals be effective at generating health behaviour change, but they may also be more effective than fear-relief appeals, as relief is more likely associated with inaction.

Although guilt appeals have a less defined structure than fear appeals, they, too, may logically generate emotional flow. The awareness of having committed a norm transgression for which one is to blame (e.g., putting loved ones at risk by smoking) should generate feelings of guilt. The opportunity to make amends (e.g., protecting loved ones by smoking outside the home or quitting) and thus alleviate the guilt state should generate relief. Thus, theoretically, "guilt-relief" appeals may offer a more persuasive message design than, say, guilt alone. However, if guilt appeals mistakenly generate the perception of manipulative intent, anger directed at the message source due to reactance is likely. Evidence suggests that "guilt-anger" appeals are likely to fail.

Unlike fear and guilt appeals, it is difficult to identify a clear message structure for humour appeals in light of both the great diversity in types of humour and its infrequent study in health promotion contexts.

Anger, often generated from perceptions of demeaning offenses, is associated with approach behaviour and, some evidence suggests, deeper information processing. However, its attack motivation, when directed at a message source, can be counterproductive.

Sadness, resulting from perceptions of irrevocable loss, is associated with deeper thinking about and elaboration on a problem or situation. However, its action tendency is to inaction. Therefore, those who are sad and thus perceive a situation as unchangeable are unlikely to take remedial action.

Pride is associated with a positive self-image as a result of taking credit for an achievement, which is highly useful for those who experience self-doubt. Indeed, pride may facilitate sustained effort and performance attainment, though its reputation as a vice may limit its expression.

Hope, or fearing the worst yet yearning for better, is an enjoyable state and highly desirable as it is associated with perseverance toward a goal, even in difficult circumstances. Although false hope may be detrimental, one is hard-pressed to find other downsides to hope.

The initial images or sentences in a message should reflect the underlying theme of the emotion deemed most appropriate to capture attention in the particular health context at hand. Importantly, the emotions that are well suited to capture attention may not be as efficient or productive at generating the deeper message elaboration deemed crucial to promote meaningful shifts in beliefs and attitudes. Thus, though we may have a frightening statistic about the severity of impairment caused by texting and driving, for example, we may find sadness to be a more effective frame than fear through which to provide more detailed information and educate the audience.

In addition to considering the full course of a message's emotional flow, a second way to harness the power of emotional shifts is to place a message's key take-away message at the point of an emotional shift.

3.2.3 Avoiding Linguistic uncertainty in communication [6]

Language is often overlooked as a source of uncertainty, but linguistic uncertainty may be pervasive in language-based settings where it can result in misunderstanding and arbitrary disagreement.

Most risk assessments assume uncertainty may be decomposed into variability (naturally occurring, unpredictable change) and incertitude (lack of knowledge about parameters or models). Incertitude in model parameters and functional relationships may be reduced by acquiring additional data. Variability may be better understood and more precisely characterized but is not reduced by additional data.

There are several types of linguistic uncertainty, including the following.

- Ambiguity—words have two or more meanings, and it is not clear which is meant.
- Vagueness—words allow borderline cases. For instance, the words low and remote.
- Underspecificity—definitions include unwanted generality. For example, in the expression "there is a 70% chance of rain," the absence of a specified reference class allows for differing interpretations including rain during 70% of the day, rain over 70% of the area, or a 70% chance of at least some rain at a particular site within the area.
- Context dependence—a failure to specify context.

Arbitrary language-based differences in qualitative risk assessments may be minimized by using iterative re-assessment of likelihoods and consequences, interspersed with facilitated discussion to identify, describe, and resolve language-based misunderstandings.

To avoid ambiguity, definitions should be provided, risks defined as precisely as possible, use of categories may be helpful and context should be specified.

3.3 Recommendations for communicating

A partial prescription for practical risk communication might include:[26]

- Describe the population at risk in such a way that the communication recipients can easily infer the relationships between those at risk and themselves.
- Scale and present a risk problem in different group size situations to help decision makers gain insights into the nature of the problem.
- Be aware that different individuals have different minimum requirement, status quo, and goals and thus different preferences. One perception of the risk does not fit all.
- Experienced communication recipients are less susceptible to framing effects from secondary cues.
- Communicate clearly to avoid ambivalence resulting from ambiguity.
- Beware conflicting emotional and rational responses to risk as these lead to susceptibility to framing effects from secondary cues.

An expert consensus group of fourteen researchers from North America, Europe, and Australasia identified eleven main issues in risk communication.[27]

The eleven key components of risk communication were.

1) Presenting the chance an event will occur.
2) Presenting changes in numeric outcomes.
3) Outcome estimates for test and screening decisions.
4) Numeric estimates in context and with evaluative labels.
5) Conveying uncertainty.
6) Visual formats.
7) Tailoring estimates.

8) Formats for understanding outcomes over time.
9) Narrative methods for conveying the chance of an event.
10) Important skills for understanding numerical estimates.
11) Interactive web-based formats.

Guiding principles from the evidence summaries advise that risk communication formats should reflect the task required of the user, should always define a relevant reference class (i.e., denominator) over time, should aim to use a consistent format throughout documents, should avoid "1 in x" formats and variable denominators, consider the magnitude of numbers used and the possibility of format bias, and should take into account the numeracy and graph literacy of the audience (table 7).

Table 7 ***Recommendations for risk communication***

Communication Issues In Presenting Quantitative Information	Key Messages

Presenting the Chance an Event Will Occur	• Ideal formats depend on the task that the recipient faces.
	• Use simple frequency (e.g., x in 100) or simple percentage (e.g., x%) formats that explicitly specify the reference class over time.
	   ○ Using both formats together does not appear to provide benefits.
	• When comparing two independent events, the simple percentage format appears to be better understood than the simple frequency format, possibly because fewer numbers are simpler to process.
	   ○ Specifying the reference class over time is essential.
	   ○ Format biases may exist with very small numbers and for the less numerate. These may be partly corrected by use of appropriate visual display formats (see Section 6).
	   ○ Use consistent denominators with simple frequency formats (i.e., no "1-in-X" formats").

Presenting Changes in Numeric Outcomes	• Use absolute risk presentations (either simple frequencies or percentages) rather than relative risk presentations (e.g. "30% lower risk"), as the latter tend to magnify risk perceptions and decrease understanding. ○ Maintain constant denominators across statistics. • Incremental risk formats (absolute risk increase or decrease) may be valuable if accompanied by visual displays.
Outcome Estimates for Tests and Screening Decisions	• Use of "natural frequencies" (frequency representations that use a common, fixed reference class of cases) can improve peoples' understanding and estimates of joint occurrence risks (e.g., the probability of having breast cancer given an abnormal mammography result). ○ Representations of the calculated "post-test probability" may be communicated as percentages if that simplifies the user's task.

Numerical Estimates in Context and with Evaluative Labels	• Contextual data (e.g., providing the risk of conditions other than the target condition) can help users get perspective on their risk of disease.
	  ○ Providing such data should be considered when feasible.
	• Directly interpreting the meaning of risk data (e.g., by providing evaluative labels such as "poor") has a substantial impact on people's reactions.
	  ○ Because the appropriateness of such reactions varies, evaluative labels should be applied carefully.

Communicating Uncertainty	• Care should be taken to distinguish between the randomness of future events and "ambiguity" (a lack of knowledge needed to predict the likelihood of future outcomes). • Many people exhibit "ambiguity aversion," avoiding decision making and showing affective responses to situations described as having epistemic uncertainty. • Little consensus exists regarding how best to communicate these concepts.

Visual Formats	• Visual displays such as pictographs/icon arrays and bar charts can improve understanding, especially among the less numerate
	  ○ People vary in their graph literacy, i.e., their ability to extract data and meaning from visual displays.
	• Visual displays convey essential or "gist" information more than precise information.
	  ○ Bars and pictographs are perceived most accurately and easily, especially when they depict the part-whole relationship by showing the entire population.

Tailoring Estimates to Individual Characteristics	• Research is mixed regarding the effect of tailoring risk information.
Formats for Understanding Outcomes Over Time	• Efforts to estimate risk over time are often hampered by a lack of data. • Multiple approaches can show risk over time, including chance of a specific outcome at a single point in the future, mortality or survival graphs, and lifetime risk estimates. ○ Research is needed to assess the relative strengths and weaknesses of different approaches
Narrative Methods for Conveying the Chance of an Event	• The proportion of favorable vs. unfavorable narratives can influence perceptions of risk and treatment choices. ○ When used to present risk or benefit information, they should be accompanied by a visual display such as pictographs. • Narratives should be used with caution until research better clarifies their effects (both positive and negative).
Important Skills for Understanding Numerical Estimates	• Higher numeracy facilitates computations, interpretations of numbers, information seeking, depth of processing and, trust in numerical formats. ○ Lower numeracy is associated with overestimation of risk probabilities, higher susceptibility to other factors such as format, and denominator effect. • Both objective and subjective measures of numeracy are now available.
Interactive, Web-based Formats	• While interactive, web-based formats can use motion cues or game-like interfaces to potentially reinforce risk messages, they may degrade knowledge unless these elements reinforce the most critical gist message.

Findings in relation to people with low health literacy are shown in table 8. [16]

Table 8 Findings on supporting users to understand health information

Health Information Design Features that Improved Comprehension for Lower Health Literacy Individuals in at Least One Study
• Presenting essential information by itself or first [25]
• Presenting numerical information in tables or pictographs rather than text [19,21,26]
• Presenting numerical information so that the higher number is better (i.e. "nurses per patient"(more is better) rather than "patients per nurse" (less is better)) [25]
• Presenting numerical information with the same denominator [21]
• Using natural frequencies (e.g. 1 out of 100) to help individuals understand the probability of disease following testing [20]
• Adding video to verbal narratives to improve the salience of information about health states [27]

Patients with lower health literacy may be less able to use patient decision aids (PtDAs) effectively and to engage in shared decision making unless special attention has been paid to low health literacy in the PtDA development process.

It has been consistently observed that patients with lower health literacy desire less involvement in decision making. This may in part be a consequence of a lack of awareness that they can be involved and a lack of confidence in sharing the decision process with health care providers. In patients with higher health literacy, desire for involvement has been found to increase when patients are shown the PtDA tools that are available.

Table 9 Expert-opinion based principles for successful health literacy interventions

Principles	Rationale (based on broader health literacy literature) [1]
Use high intensity interventions	Use multiple literacy-directed strategies to support knowledge acquisition and understanding. For example, design PtDAs using plain language, simple numbers, and a range of visual and linguistic techniques. Delivery of the PtDA requires multiple reinforcing contacts to support active decision-making.
Use theory-based interventions when appropriate	Theory can be used to maximize the impact of PtDAs. For instance, behavioral and communication theories applied in PtDAs can motivate engagement with the PtDA or, if appropriate, engagement in specific behaviors.
Pilot test before full implementation	Pilot testing a PtDA involves examining the information needs and communication preferences of lower literacy populations, and examining the *whole* process of decision making among lower health literacy patients. This means checking not only understanding of the language and content, but also whether the PtDA helps users to clarify values, communicate with health professionals, and implement a decision.
Increased emphasis on skill building	PtDAs should be designed to help with skill building. This suggests that demonstrating and modeling values clarification and physician interactions in PtDAs may improve outcomes among low literacy users of PtDAs.
Delivery by a health professional	Deliver PtDAs by a health professional (e.g., pharmacist, health educator, nurse, physician) rather than by non-clinicians. This also suggests that delivery of PtDAs in the context of clinical care might result in the best outcomes.

Table 10 Recommendations from the Montauk risk communication symposium [26]

Practical:

- Use natural frequencies and avoid single event probabilities, relative frequencies, and percents. (Kurz-Milcke, Gigerenzer, and Martignon)
- Beware group-level differences in number ability (numeracy) and mental models of risk. (Bostrom, Anselin, Farris; Kurz-Milcke, Gigerenzer, and Martignon; Peters)
- Incertitude (ambiguity) is not perceived in the same way as variability. Uncertainty is often interpreted as worst-case. Risk estimates presented as exact values are perceived as less risky than when presented as variable. Risk estimates presented as uncertain are perceived as riskiest of all. Analyze and communicate each explicitly. (Carey and Burgman; Sanfey and Chang; Slavin, Tucker, and Ferson; Tucker and Ferson; Vorhold; Wang)
- Fairness, justice, and equity can trump utility. The risk of social contract violation must be analyzed and communicated. (Sanfey and Chang; Stirling; Tucker and Ferson; Watson; Bingham)
- Hyperbolic (non-exponential) discounting reverses short term preference in the long term. Design communication to expect time-dependent perception. (Tesch and Sanfey; Kable).
- Risk cannot be divorced from choice. Risk perception cannot be predicted outside of a choice context that includes minimum requirements, goals and needs, and current status, in addition to expected value and variance. Benefit and cost, risk and risk, must be communicated. (Finkel; Stirling; Wang)
- Uncertainty due to disagreement (experts, opinions, language) must be analyzed and disclosed. (Carey and Burgman; Finkel; Slavin, Tucker, and Ferson; Stirling)

3.3.1 Recommendations for communication about vaccines [15]

Trivializing or glossing over complexity and uncertainty in situations where knowledge is evolving may negatively affect credibility. In particular, people who have more background knowledge and expertise in a topic will recognize when important elements are missing, damaging their trust in the message source. People who have a sense of these complexities are therefore unlikely to be moved by artificially simple messages about protecting one's child, for example.

Decision aids that present facts about the risks and benefits of vaccines and discuss relevant issues such as omission bias have shown promise for helping parents make informed decisions about childhood vaccinations. Randomized trials of decision aids have demonstrated that full and open disclosure of risks both of vaccinating and of choosing not to vaccinate can increase vaccination intentions.

The network effects that characterize Web 2.0 mean that, overall, online resources become more powerful as more people interact with them. Additionally, the connections formed and strengthened within online networks increase the power of personal stories. People afford greater credibility to content authored by someone who had experienced their personal situation and are more likely to follow the lead of someone with whom they have more of a connection. Uncertainty can drive people to seek out information from anti-authorities, i.e., people who have, 'been there, done that.' This social reality, combined with the rise of social media, has led to an increase in pass-it-along marketing techniques that can be harmful to health.

Efforts to provide high quality health information sometimes try to separate online health information from authoritative sources from less credible content like stories. Avoiding narrative-based content may be counter-productive to such sites' aims, however. People react more emotionally to individual stories than they do to statistics about large numbers of suffering people and statistics in general have limited influence on individual decisions.

A well-crafted message could start by making effective use of a personal story, such as a highly emotional public service announcement promoting vaccination created by the New York State Department of Health featuring the mother of a 5 year old boy who died of influenza. Yet, to be effective in the Web 2.0 environment, such a message should encourage broad sharing of the message to enable network effects to boost dissemination and potentially enhance the impact of the message. Unfortunately, in this case, while the videos are embedded on the Department of Health's Website, the site provides with no easy functionality to take users to the YouTube source where they might comment or share the link. Nor does the site use any common tools to facilitate easy sharing via Facebook, Twitter, Google+ or other platforms.

Thus, in this Web environment, effective communication about vaccinations is not about controlling what is available but rather, it is about responding and participating in an interactive, user responsive environment. Efforts to accomplish this could benefit by investigating, for example, the effects of more complex sets of narratives on vaccination risk perceptions and intentions.

4.0 EXAMPLE OF GARDASIL 9

4.1 Published research on Gardasil indicating consumer communication needs

Foster et al [13] investigated girls explanations for being unvaccinated against HPV. Around 74 % of un-/under vaccinated girls in the sample taken from London, provided a reason for their vaccination status (n = 259). Among unvaccinated girls, the most common reasons related to lack of perceived need for vaccination, concerns about safety and lack of parental consent. Girls who were under vaccinated gave practical reasons, including the need for more information (e.g. not knowing that multiple doses were needed), administrative issues (e.g. school absence), health and procedural concerns (e.g. fear of needles). Girls from Black and Asian backgrounds more commonly thought that the vaccine was not needed. Lack of parental consent without providing further explanation was most often cited by girls from Black backgrounds.

Reasons for not vaccinating included:

"My mum didn't trust the vaccine because it was new"

"My family wanted to wait for further research"

"Because I am not sexually active so I wouldn't need it"

"Because I am not going to have sex before marriage"

"My mother never had it, so I didn't need it"

"The cancer looked very rare, cancerous diseases don't run in my family"

"My mum did not think it was necessary for me to have the vaccine since I won't be sleeping around"

Madden et al [28] systematically analysed the HPV vaccine information returned by online search engines. The content of 89 top search results were analysed with respect to source, tone, and information on specific content.

In the content analysis, the authors found 74% of websites made the connection between HPV and cervical cancer, while 26% of websites failed to provide a link.

The majority of the top websites returned by search engines indicated a high level of susceptibility to HPV, but more than a third of the websites did not include information about susceptibility, despite the fact that HPV is the most common sexually transmitted disease. A survey study found that nearly half of young women were unaware of the prevalence of HPV and considered themselves not at risk to contract the virus. If a third of the websites returned by top search engines fail to provide information about susceptibility, young women may continue to be misinformed.

Certain types of sources provided more information than other types of sources in terms of self-efficacy. Governmental agency websites, the second largest source category, were the most likely to provide steps to get the HPV vaccine.

Fu et al performed a systematic review on educational interventions to increase HPV vaccination. They identified 33 studies: 7 tested the effectiveness of interventions with parents, 8 with adolescents or young adults and 18 compared the effectiveness of different message frames in an educational intervention. They concluded that there is no strong evidence to recommend any specific educational intervention for widespread-implementation.[29]

The Spanish Association of Vaccinology offers a personalised service called 'Ask the Expert'. Questions can be posed by the public or healthcare professionals about vaccines and vaccination. Questions are initially received by a coordinator and then forwarded to a member of website's expert group. Questions are answered within 2 weeks and if considered of special interest are published online.[22]

Wegwarth et al conducted a survey of German HPV vaccination leaflets. [30] In the authors opinion none met the standards of balanced risk communication. The following criteria were considered the criteria for good risk communication.

1. Completeness (baseline risk of cervical cancer, benefit and harms of vaccination).

2. Transparency (presentation of all risk information in absolute numbers, not relative numbers; provision of a reference class).

3. Correctness (evidence-based information).

None of the studied leaflets provided correct and transparent numbers on the effectiveness of HPV vaccination, and more than 60% did not mention any harms at all related to the vaccine.

The authors investigated the difference in vaccination intention after exposure to balanced and unbalanced leaflets.

Table 11 Information provided in the unbalanced leaflet

Criteria for balanced risk communication	What does the leaflet report?	What is unbalanced about it?
Completeness		
Base risk	6700 women are diagnosed every year 1800 women die of cervical cancer per year	Is mute about the references classes for incidence and mortality (out of 43 million German women – incidence: 0.01% mortality: 0.004%)
Benefit	Vaccine is 98% effective for HPV types 16 and 18, which cause 70% of cervical cancer	Suggests that the vaccine would prevent almost 70% of all cervical cancers. Approval studies demonstrated an effectiveness of 29% at most, which is not reported
Harms	Redness at injection site	Does not mention any other harms and provides no numerical information
Transparency	–	Provides neither absolute numbers nor the reference class
Correctness/Evidence-based information	–	Does not mention the evidence from the approval studies Future I or II Does not report that outcome measures were surrogate markers, not actual cervical cancer

There was no difference in vaccination rates between those who read the balanced versus unbalanced leaflets. However there was a difference in the concordance between stated intention to vaccinate after reading the leaflet and vaccination.

Table 12 Information provided in the balanced leaflet

Criteria for balanced risk communication	What does the leaflet report?	What is balanced about it?
Completeness		
Base risk	15 women in 100,000 are diagnosed per year 3 women in 100,000 die of cervical cancer per year	Provides the base rate and the reference class
Benefit	Incidence reduction: from 15 to 11 in 100,000 per year (−4 less in 100,000) Mortality: from 3 to 2 in 100,000 per year (−one less in 100,000)	Provides the base rate and the absolute risk reduction
Harms	Very common (>10,000 in 100,000): fever, redness, pain, and swelling at the injection site Common (1000–10,000 in 100,000): seasonal allergies Rare (100–1000 in 100,000): unspecific arthritis	Provides numerical information on the most common harms
Transparency	Yes	Each section provides information about the base rate, reference class, and risk reduction/increase. Information is provided as absolute numbers and the same reference class of 100,000 is used for all benefits and harms
Correctness/Evidence-based information	Yes	Numbers are based on the approval studies, and on data from the German Federal Agency of Statistics and the German Standing Vaccination Committee (*STIKO*)

Nabi and Prestin [16] examined the effect of emotional health news coverage of HPV infection. 175 students read news stories designed to evoke fear or hope about HPV infection, followed by different levels of response efficacy information on HPV vaccine. Understanding the news story structure that best promotes healthy behaviours, then, would be of great benefit to both news organizations and public health advocates.

Results indicated no main effects for emotion frame or response efficacy, but a significant interaction suggested that emotionally-consistent presentations (fear/low efficacy; hope/high efficacy) boosted intentions to engage in protective actions relative to emotionally-inconsistent, sensationalized presentations (fear/ high efficacy, hope/low efficacy). Consistent with the emotion-as-frame perspective, this effect was moderated by perceived knowledge about HPV prevention.

The psychological challenges to Gardasil 9 vaccine update are considered to be.[15]

- Distrust of 'combination' vaccines- will the nonavalent vaccine overload the immune system?
- Uncertainty about long-term efficacy.
- Uncertainty about the safety of a new and untested vaccine.

Parents' potential concerns about the safety and efficacy of the nonavalent vaccine may be clarified by explaining what testing has been done and why efficacy is likely to be sustained. Parents' preferences to delay vaccination to maximise the time that their child is protected against HPV (because they are concerned about long-term efficacy and safety coupled with their belief that their child will not be sexually active soon) may be challenged by explaining that the vaccine leads to a better immune response if delivered when an individual is younger.

4.2 Proposed consumer information for Gardasil

Medsafe proposes publishing the following 'Questions and Answers' on Gardasil 9 vaccination on the Medsafe website.

What is human papillomavirus (HPV)?

Human papillomavirus (HPV) is a virus that infects the skin. There are over 150 different types of HPV. Around 40 HPV types can infect the genitals of males and females.

You can catch HPV through skin to skin contact, for example through vaginal, anal or oral sex with someone who has the virus. Not everyone who has the virus has symptoms such as genital warts.

Comments

To provide background information to support decision making.

How common is infection with HPV?

HPV is the most common sexually-transmitted infection. More than half the population are infected during their life. It is possible to be infected with more than one type of HPV.

Comments

To provide information on need for vaccination. Use of red to emphasise the main message.

Why is infection with HPV a problem?

For most people HPV infection causes no symptoms. In 9 out of 10 infected people the infection goes away in two years.

For 1 out of 10 people the infection does not go away and may eventually cause cancer.

HPV infection can cause:

- Cervical, vaginal and vulva cancer in women
- Cancer of the penis in men
- Cancer of the anus, throat/mouth and tonsils in men and women

[www.theguardian.com/film/2013/jun/02/michael-douglas-oral-sex-cancer]

The risk of an HPV infection causing cancer is higher if you smoke or are infected with more than one cancer-causing HPV strain.

Cancer	Incidence per 100,000 per year	Number of registrations 2013
Cervical cancer	6.3 (Mortality rate 1.4)	158
Vulvar cancer	1.5	56
Vaginal	0.7	23
Anal	1.0 in men, 1.2 in women	32 in men, 38 in women
Penile	0.6	19
Oropharyngeal	0.4 in men, 0.1 in women	11 in men, 5 in women
Tonsil	1.6 in men, 0.3 in women	48 in men, 9 in women

Comments

To provide information on the need for vaccination. Link to a personal interest story to illustrate personal risk. Use of red to illustrate the main risk of HPV infection.

How does HPV infection cause cancer?

After HPV infects skin cells it starts to make copies of its self. Two proteins made by cancer-causing HPV types interfere with the normal functions of the skin cells. These proteins stop the normal processes that prevent skin cells growing too much. When these infected skin cells grow more quickly they can develop mutations which help them change into cancer cells.

Comments
To provide information on how HPV causes cancer to help counteract myths that the vaccine causes cancer.

How is HPV infection treated?

There is no treatment for HPV infection.

Genital warts can be treated with Condyline, Aldara, cryotherapy or laser therapy (www.hpv.org.nz/hpv-genital-warts).

Pre-cancerous cervical cells can be removed by cryosurgery (freezing), LEEP (removal of cervical tissue with a hot wire loop), conisation (surgery with a scalpel or laser to remove cervical tissue).

Around 153 of these procedures are performed per 100,000 women per year in New Zealand (around 3,500 in total).

Comments
To provide information on the seriousness of HPV infection.

How can I protect myself from HPV infection?

You can protect yourself by.

- Using condoms (condoms protect against all strains of HPV, but may not cover all areas infected by HPV).
- Getting vaccinated (more information below).

Women can protect themselves from cervical cancer by attending their cervical cancer screening appointments. There are no screening programmes for other HPV cancers. (www.nsu.govt.nz/national-cervical-screening-programme).

Comments
To provide transparent information about alternatives.

What HPV vaccines are available?

There are three HPV vaccines approved for use in New Zealand:

Cervarix protects against HPV types 16 and 18 (cause up to 7 out of 10 cases of cervical cancer)

Gardasil protects against HPV types 6, 11, 16 and 18 (cause up to 9 out of 10 cases of genital warts and up to 7 out of 10 cases of cervical cancer)

Gardasil 9 protects against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 (cause up to 9 out of 10 cases of genital warts and up to 9 out of 10 cases of cervical cancer)

From 1 January 2017 Gardasil 9 is the funded vaccine.

Comments
To ensure that the difference between the vaccines is understood.

How are HPV vaccines given?

HPV vaccines are given by injection into the muscle of your arm. Most people get their vaccine at school, but you can also go to your GP. The vaccine is free for people under the age of 26 years.

(www.health.govt.nz/your-health/healthy-living/immunisation/immunisation-older-children/changes-hpv-immunisation-1-january-2017).

If you are under 15 you need two doses given 6 to 12 months apart.

If you are over 15 you need three doses given at 0 months, 2 months after the first dose and 6 months after the first dose.

Comments
To support self efficacy.

How do HPV vaccines work?

Your immune system is made up of cells and tissues that work together to protect you. One of the important cells are called white blood cells (leukocytes). White blood cells can eat up bacteria and viruses or they can produce antibodies. Antibodies stick to bacteria, viruses and toxins (antigens) to help to neutralise and kill them.

HPV vaccines contain a small part of the HPV virus called an antigen. This antigen activates your immune system to produce antibodies. This works in the same with the vaccine as when you get an infection. These antibodies are then ready in case you do get infected and make sure you can get rid of the HPV virus before you get sick.

Comments
To provide general information on how recombinant vaccines work. To help counter anti-vaccination messages about vaccines being unnatural

How effective are HPV vaccines?

In clinical trials all people given Gardasil 9 made protective antibodies to all the HPV strains in the vaccine.

However, Gardasil 9 does not protect against all strains of HPV and does not work if you have already been exposed to the HPV strains in the vaccine.

The effectiveness of Gardasil was estimated at around 43% if it is given before first sexual contact (prevents precancerous changes in the cervix in 43 out of 100 women).

In studies comparing the efficacy of Gardasil 9 with Gardasil:

- 2.4 in every 1,000 women per year experienced precancerous changes in the cervix after Gardasil 9 vaccine.
- 4.2 in every 1,000 women per year experienced precancerous changes in the cervix after Gardasil vaccine.
- 10 in every 1,000 women per year who have not been vaccinated have abnormal smear test results.

The length of time that Gardasil and Gardasil 9 are protective for is not yet known. Gardasil has been shown to be effective for 9 years so far. The long term effectiveness is being monitored. It is possible that a booster dose may be needed.

Cervical screening is still recommended for women who are sexually active, even if you have had the HPV vaccination

Further reading
Dochez, C., et al., HPV vaccines to prevent cervical cancer and genital warts: an update. Vaccine, 2014. 32(14): p. 1595-601.

Koutsky LA, and the FUTURE II study group 2007 'Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions' NEJM 356: 1915-27

Joura, E.A., et al., A 9-valent HPV vaccine against infection and intraepithelial neoplasia in women. N Engl J Med, 2015. 372(8): p. 711-23.

www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/cervical-cancer

Comments

To provide information on efficacy to help inform choice.

Why is Gardasil 9 vaccination given at such an early age?

Gardasil 9 is given at an earlier age than needed because:

- It works better in younger people so only 2 doses are needed (more protective antibodies are made by younger people).
- The vaccine only works if you haven't been exposed to the HPV strains in the vaccine (through sexual contact).

Giving the vaccine at a young age does not mean that health authorities or parents are saying you are ready to start having sex.

Comments

To address concerns about vaccine timing.

What is in the Gardasil 9 vaccine?

Gardasil 9 contains a copy of one of the proteins found in each of the HPV strains 6, 11, 16, 18, 31, 33, 45, 52 and 58. These proteins are known as the antigens. They cannot cause HPV infection and do not cause HPV-cancer.

Each vaccine dose also contains:

- 500 micrograms aluminium (known as the adjuvant).
- 9.56 milligrams sodium chloride (table salt).
- 780 micrograms L-histidine (an amino acid used in your body to make proteins).
- 50 micrograms polysorbate 80 (also used in food like ice cream).
- 35 micrograms sodium borate (used here to stabilise the vaccine, also found in some vitamin supplements).
- Traces of yeast (used to make the protein antigens).

Gardasil and Gardasil 9 are made in a similar way to other medicines such as insulin.

How safe is the Gardasil 9 vaccine?

The safety of Gardasil 9 has been looked at in the clinical trials which included 15, 875 people who had at least one dose of Gardasil 9.

Overall, the type of reactions people had to Gardasil 9 were very similar to Gardasil.

More people had injection site reactions with Gardasil 9 than Gardasil.

The most common side effects with Gardasil 9 are.

- 9 out of 10 people had an injection site reaction such as redness, pain or swelling.

- 5 out of 10 people had increased temperature
- 4 out of 10 people felt nauseous (felt sick)
- 3 out of 10 people felt dizzy for a short time after vaccination
- 2 out of 10 people felt tired for a short time after vaccination

You can find a summary of possible adverse reactions in the consumer medicine information and the data sheet.

www.medsafe.govt.nz/Consumers/CMI/g/gardasil9.pdf

www.medsafe.govt.nz/profs/Datasheet/g/gardasil9inj.pdf

Serious adverse effects:

There is no difference in the number of people who get Guillain-Barre Syndrome if they are vaccinated or not.

1 to 3 people in every 100,000 who are vaccinated have a serious allergic reaction.

During the clinical studies there were 7 deaths. These deaths were not related to vaccination and represent unfortunate circumstances that can occur in teenagers and young adults.

- One woman committed suicide.
- One woman died in a car accident.
- One woman died unexpectedly nearly two years after completing vaccination.
- One woman with previous ovarian cancer died.
- Three women with leukaemia, one had been diagnosed before being vaccinated and one was diagnosed nearly 4 years after completing vaccination.

Read more
Moreira, E.D., Jr., et al., *Safety Profile of the 9-Valent HPV Vaccine: A Combined Analysis of 7 Phase III Clinical Trials.* Pediatrics, 2016. **138**(2)
www.medsafe.govt.nz/Consumers/CMI/g/gardasil9.pdf
www.medsafe.govt.nz/profs/Datasheet/g/gardasil9inj.pdf

Comments
Transparency regarding adverse effects. Frequency given to change feelings of regret if an adverse effect is experienced.

Have there been any reactions to Gardasil 9 in New Zealand?

You can check for reports of suspected adverse reactions to all medicines using the Suspected Medicines Adverse Reaction Search (SMARS).

www.medsafe.govt.nz/projects/B1/ADRDisclaimer.asp

Additional information is also published on the Medsafe website.

www.medsafe.govt.nz/publications/OIAContents.asp

Comments
Information provided for transparency

What do I do if I think I've had a reaction to Gardasil 9?

Please contact your doctor.

You can also report your experiences to the Centre for Adverse Reactions Monitoring (CARM).

Reporting your suspicions of an adverse reaction after having a vaccine or taking a medicine helps CARM and Medsafe monitor the safety of medicines and to take action if a problem is identified.

www.medsafe.govt.nz/safety/report-a-problem.asp

If I've been vaccinated with Gardasil can I be vaccinated with Gardasil 9?

Yes. A clinical study has been done to show that Gardasil 9 worked in women who had previously had Gardasil. There were no unexpected safety problems in this study.

Read more
Garland, S.M., et al., Safety and immunogenicity of a 9-valent HPV vaccine in females 12-26 years of age who previously received the quadrivalent HPV vaccine. Vaccine, 2015. 33(48): p. 6855-64.

Knowledge

Find out if this information helped you to understand about Gardasil 9 vaccination.

Which option has the lowest chance of getting HPV-cancer?

A Vaccine before high school (correct)

B Vaccine later

C Decline vaccine

D Don't know

Which option has the lowest chance of a serious side effect?

A Vaccine before high school

B Vaccine later

C Decline vaccine (correct)

D Don't know

Do you feel sure about the best choice?

If not talk to your healthcare professional

5.0 ADVICE SOUGHT

The Committee is asked to advise whether:

- There are any other factors that should be taken into consideration when communicating risk
- Any changes need to be made to the example consumer information

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