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Challenges of Drug Risk Communications in the Philippines

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Abstract

Risk communication in the context of patient care is about conveying balanced information on benefit and risk of medical products and procedures and developments in health. It is an integral part of pharmacovigilance and healthcare communications and involves stakeholders such as regulators, industry, health professionals and patients. In the Philippines, many factors can interfere with effective risk communication and affect the safety of patients when medicinal products are used: poverty, literacy, age, social media, practice and behaviour of health professionals, industry marketing, patient expectations and product quality. These factors must be taken into consideration when formulating effective risk communications to ensure patient safety.

Risk communication is defined as the exchange of necessary and appropriate information to promote better decision making by raising awareness and improving understanding of a developing situation. It must be characterized by balanced information on the benefits and risks of harm.[1] Two features that distinguish risk communication from public relations communication are accuracy of information and lack of spin.[2]

In the context of healthcare, industry, government and the health sector make decisions based on the potential of actual risk. At times, such decisions must take political and economic factors into consideration. In the case of a communicable disease such as severe acute respiratory syndrome (SARS), for example, travel and tourism were heavily curtailed in the interest of public safety.

The public, however, may base decisions on the perceived risk, which may be over- or underestimated. In addition, people imitate the behaviour of others, resulting in herd behaviour. Unfortunately, misinformation may proliferate, particularly in cases of relatively unknown infectious diseases, even before health professionals and government are able to respond. Confusion may result from new information as it is released in real time, especially with the advent of costless and instantaneous social media which compete with more traditional sources of information. All these lessons from the past should shape risk communication strategies of the future.[3]

Pharmacovigilance professionals know that there is no such thing as a totally safe drug; every drug prescribed or used comes with a level of uncertainty, a benefit-risk ratio, balancing the chance of harm with the supposedly greater chance of better health. But society is so inundated with clinical information that patients and even physicians can no longer keep up with the latest recommendations. For this reason, risk communication must be an integral part of risk management. Understanding and managing risk should be a culture and a value within every organization

(regulators, pharmaceutical industry, health professionals and providers).

In the Philippines, the situation is far from ideal. Many organizations prohibit employees from discussing risks for fear of potential repercussions. In the process, they erode their own credibility and alienate consumers seeking reliable information and fair treatment following a product crisis. Organizations need to be clear if their priority is integrity or 'spin' as corporate value.[4] Toolkits and techniques to address drug risk communications are available.[5]

Risk communication is traditionally used to react to crises when medicines pose a clinically significant risk which necessitates informing the public. But this science would be better served by quality products, a secure system to report drug reactions by clinicians, and better profiling of patients. The main objective of this article is to explore the various factors that directly or indirectly affect stakeholders' capacity to appreciate the benefit-risk of drugs in the Philippine context.

1. The Challenges

A review on the state of adverse drug reaction monitoring in five Asian/Pacific Rim countries (Australia, Japan, Malaysia, New Zealand and Singapore) showed that these countries have active pharmacovigilance systems in place. The positive features of these countries' systems include management by national regulators, the presence of active, independent, expert clinical advisory committees undertaking risk assessment of reports, and regular communications about risks from the national agencies to doctors and pharmacists through bulletins.[6]

The prevailing conditions in these five countries are far different from those in low- and middle-income countries such as the Philippines. In the Philippines, many distinctive factors contribute to the disregard for drug safety, rendering effective risk communication even more crucial.

1.1 Poverty

It is not unusual for poor people in the Philippines to buy retail drugs piecemeal without the information insert or even expiration notices because blister packs are cut to accommodate the few pills that they can afford. Patients have been known to underdose by cutting medicines in half in order to make them last longer. Oftentimes, patients do not receive the full course of treatment. However, health workers exert little effort to inform patients of the consequences of noncompliance, of possible adverse effects of the medicines or what to do in case adverse reactions develop.

1.2 Literacy

The literacy rate in the Asian region is between 62.8% and 97.5%.[7] In the Philippines, the adult literacy rate is 95.4%, but level 3 literacy, referring to the ability to read, write and comprehend, is only 65.8%.[8] Although this may suggest a respectable capacity to absorb risk communication messages, it does not always translate to safety. Most Filipino patients defer to their clinical doctors' advice and rarely deviate from medical orders. Perhaps because of this, many choose not to read or pay attention to information about potential risks. Moreover, small font sizes in printed drug product inserts make information completely unreadable. Drug package inserts can be improved with the use of colour and larger print; the diligence of pharmaceutical companies to inform users, evidenced by making the inserts legible to all, would imply a level of product stewardship that is not readily evident. As it is, although the small-print inserts comply with the letter of the law, they do not address the spirit and original intention of the law – patient safety.

Even with a literate population and legible product inserts, no risk communication would be effective unless it is expressed in a language understood by the general public. In the Philippines, food supplements are required to carry the warning "No approved therapeutic use". In 2010, the Philippine Secretary of Health attempted to require the industry to translate the warning into the vernacular on their products in an effort to promote safety and educate the Filipino public.[9,10] Her advocacy was successfully undermined by the association of herbal industries

which initiated legal proceedings and won an injunction to block her endeavour.

1.3 Age

For elderly patients in general, the increased likelihood of visual and auditory disabilities, as well as physical and mental complications, make it difficult to communicate complete care instructions, resulting in inadvertent non-compliance. In studies, general reasons given for non-compliance among the elderly include poor recall of medication regimen, seeing numerous physicians, use of numerous medications and believing that medications are expensive.[11] The Philippines is no exception. The author has had many encounters with the children of elderly patients who complain that their parents were unclear regarding the instructions given to them by their various doctors, and that the medications prescribed were overlapping.

1.4 Misinformation through Modern Means of Communications

Technology can derail the rational release of information. Anyone can endorse products without scientific basis through social media. Patients access information and purchase products from unregulated internet sites. Inaccurate information about risk may be presented out of the context of clinical care or as part of advocacy against taking medicines. Regretfully, biased or erroneous information are mistaken for facts. Meanwhile, regulatory agencies are hard-pressed to ensure that the public has consistent access to correct information.

In 2011, after the tsunami in Japan struck, an anonymous hoax text (SMS) message informed the Philippine public that the radioactive dust particles from the failed Fukushima nuclear reactor would reach the Philippines and would affect the water and food supplies, as well as contaminate people. This misinformation of the public led to a massive panic buying of povidone iodine antiseptic solution to be swabbed on the neck in an erroneous attempt to prevent radiation-related thyroid cancer. The solutions quickly sold out in drugstores. In this instance, no corrective advice was ever provided by the drugstores or public authorities.

In the 1980s, also in the Philippines, tetanus vaccines were rumoured to be adulterated with human chorionic gonadotropin (HCG) hormones which would cause female infertility.[12] The news came from a religious group that was against the family planning movement of the government. Although the claim has since been debunked, the damage to public perception was done and a few local government agencies refused to procure tetanus vaccines.

1.5 Clinical Behaviour

Rising population in some areas affects doctor-patient ratio and time spent in consultations. Limitations of consultation time between physicians and patients may potentially affect quality of care; with history taking, physical examination and answering patients' questions, there does not seem to be time left to talk about therapeutics.

In Japan, mean consultation time is 6.12 minutes per patient, compared with European countries where the mean clinical consultation time is 10.7 minutes per patient, and the US where the average consultation time is 16.3 minutes per patient.[13,14] The author participated in previous medical mission work for poor villages in the Philippines, where the approximate consultation time per patient was often less than 5 minutes. With too many patients and too few physicians, there was no opportunity to provide extensive public health education or discuss drug effects or risks. Although medicines were provided for free, comprehension of the proper use of medicines was a major concern.

Moreover, the distribution of doctors in the country is uneven. Seventy percent of Filipino health professionals serve only 30% of the population, and 60% of Filipinos who die, die without health professional attendance.[15] Patients can and do self-medicate without medical supervision. Pharmaceutical companies do not always exercise product stewardship, particularly in remote villages, as evidenced by the absence of product monitoring.

In one unfortunate incident in the year 2000, five emergency hysterectomies were performed postpartum in a Philippine government provincial hospital following the failure of a batch of methylergometrine maleate. The women suffered uncontrolled bleeding and uterine atony even after multiple doses of the medicine were administered, resulting in one death.[16,17] There was no official risk communication to inform the public of this potential risk.

1.6 Doctors as Dispensers and Owners of Drug Stores

In Zimbabwe, quality of healthcare was compromised because drug-dispensing doctors prescribed more drug products compared with their non-dispensing colleagues.[18] In the UK, clinics that dispensed drugs prescribed more items per patient than non-dispensing counterparts.[19] As dispensing doctors tend to prescribe more medicines to their patients, the likelihood of drug-drug interactions also increases.

Although in some countries such as the Philippines doctors are not allowed by law to dispense and sell medicines, it does happen in actual practice. Doctors in the public health sector in the Philippines tend to refer patients to pharmacies that they own, raising questions of conflicts of interest.[20] These behaviours may disregard patient safety and raise doubts as to whether prescribers actually communicate the benefit-risk of drugs to their patients.

1.7 Role of Pharmacists in Retail Outlets

Although, in the Philippines, prescription medicines cannot be legally purchased without prescription, the law is not strictly enforced. In addition, the migration of licensed pharmacists to other countries in pursuit of job opportunities has resulted in a lack of licensed pharmacists willing to work in local community dispensaries and the necessity for hiring pharmacy aides (non-regulated, non-licensed sales clerks) to staff drugstore counters. Some are inadequately trained; proper advice to patients purchasing medicines is left wanting. In one instance of failed communication, the author personally witnessed a retail outlet aide wrongly assure a woman with muscle pain (a patient) that NSAIDS had no adverse effects and would not cause abdominal pain.

1.8 Drug Regulatory Agencies

Even in a country with a robust regulatory risk communication system such as the US, advisories are not guaranteed to change behaviour, as evidenced by a report which showed that US FDA warnings have delayed, unintended or no effect on prescribing behaviour.[21] In the Philippines, where drug risk communication is less developed, there is an opportunity to learn from the lessons of others and craft a more responsive and targeted strategy.

It is generally accepted that health professionals have a public obligation to report adverse drug events (ADEs) to authorities. The current method widely used by countries is spontaneous reporting, which is based on trust; that is, there is a presumed guarantee of confidentiality for those reporting. If such a basic tenet is compromised, it is feared that both quantity and quality of ADE notification to authorities will likewise be compromised.

Last year in the Philippines, a group of specialist doctors from different hospitals reported that a particular brand of a peri-operative medicine, imported by a local company from another Asian country, was prone to discolouration and precipitation and did not exhibit effectiveness. The doctors refused to use it and reported their observations in ADE reports, which were sent to the hospital therapeutics committees and then forwarded to the national drug regulatory agency. The information somehow reached the company, which decided to sue the reporting doctors individually for libel. Doctors have since expressed real concerns for their continued support to pharmacovigilance programmes.

A similar incident has been cited in Australia[22] where a doctor was sued for lodging a complaint against a company for overstating the benefits of a health product. The weakness of any pharmacovigilance programme caused by the inability of the system to protect those who report would render drug risk communications irrelevant.

1.9 Industry Marketing Behaviour

Marketing principles can adversely affect risk communications. While an ethical code of marketing practices through self-policing is implemented in a country, the ability of drug regulatory agencies in monitoring and enforcing this code is weak. Not all in the industry follow the code; some companies practice unethical marketing, highlighting benefits while downplaying the risk and safety profile of the product. Based on personal accounts from medical colleagues, the author believes that many companies still offer junket trips to influence doctors' prescribing behavior.[23,24] Vigilance to product safety may be dangerously ignored.

In 2011, a marketing code was accepted by the heads of Asia Pacific nations – the new Asia-Pacific Economic Cooperation (APEC) Mexico City principle code for ethical business practices for the biopharmaceutical industry.[25] These initiatives contribute to the awareness of drug safety by promoting transparency and governance and, in some respect, assist in drug risk communications.[26] Although not specifically addressing risk communication, these documents state that the marketing information must be balanced and truthful, giving equal weight to benefits as well as risks.

In many countries, including the Philippines, prescription drugs are not allowed to be directly advertised to the public, but over-the-counter (OTC) drugs can be advertised generally. Violations of marketing claims for OTC drugs are frequently observed. For instance, the off-label use of ascorbic acid tablets promoted as a cure for cancer and SARS is a gross exaggeration not supported by scientific validation. An example of subliminal promotion in a billboard suggesting the off-label use of an OTC medicine can be seen in this illustration (see figure 1). The mission to provide countervailing information becomes a difficult risk communication task for drug regulators, as well as for health providers, who generally have fewer resources to reach the public than companies do.

The unethical marketing practices of nutraceuticals and food supplements are also on the rise. What is labelled as natural does not guarantee absence of harm; therefore, appropriate regulation has been urged to ensure consumer safety.[27] Unlike registration for drugs, the Philippines FDA registers food supplements without stringent evaluation. If companies should choose to market these products unethically, as some of them do, an FDA registration would inadvertently lend credence to their exaggerated claims.

Some multinational pharmaceutical companies practice differential marketing. In the Philippines, a statin was promoted to prevent and cure heart disease, as stated on brochures distributed to doctors. However, the dedicated information website for the product explicitly stated that the company could not claim that the drug prevents and cures heart disease. When challenged, the company directed the regulator's attention to the very fine print on the website, which indicated that the information was ''for US residents only''. Upon further investigation, it was also discovered that the company used relative versus absolute risk reduction information and the results claimed were laboratory outcomes rather than real patient outcomes. The duplicity of product claims and the use of misleading statistics took advantage of lapses in the health sector's monitoring of product claims.

1.10 Patients' Perception

In the author's clinical experience, enlightened patients exhibit low tolerance for unsafe drugs. Some doctors prefer to fully disclose the adverse effects of drugs so that patients may decide whether or not to take the medicine based on their own benefit-risk assessment. However, if patients overestimate the risk, they may choose to forego the benefit in order to sidestep the potential harm, leaving chronic illnesses untreated.

While some patients choose not to take certain drugs because they believe the medicines are not efficacious, still others choose to take them because of the adverse effects. Anecdotally, some Filipino women look for certain adverse effects of oral contraceptives, such as weight gain, to ascertain the efficacy and benefit of the pills.[28]

Lack of public confidence can damage public health programmes, and if government and/or industry fail to address concerns in a timely manner,

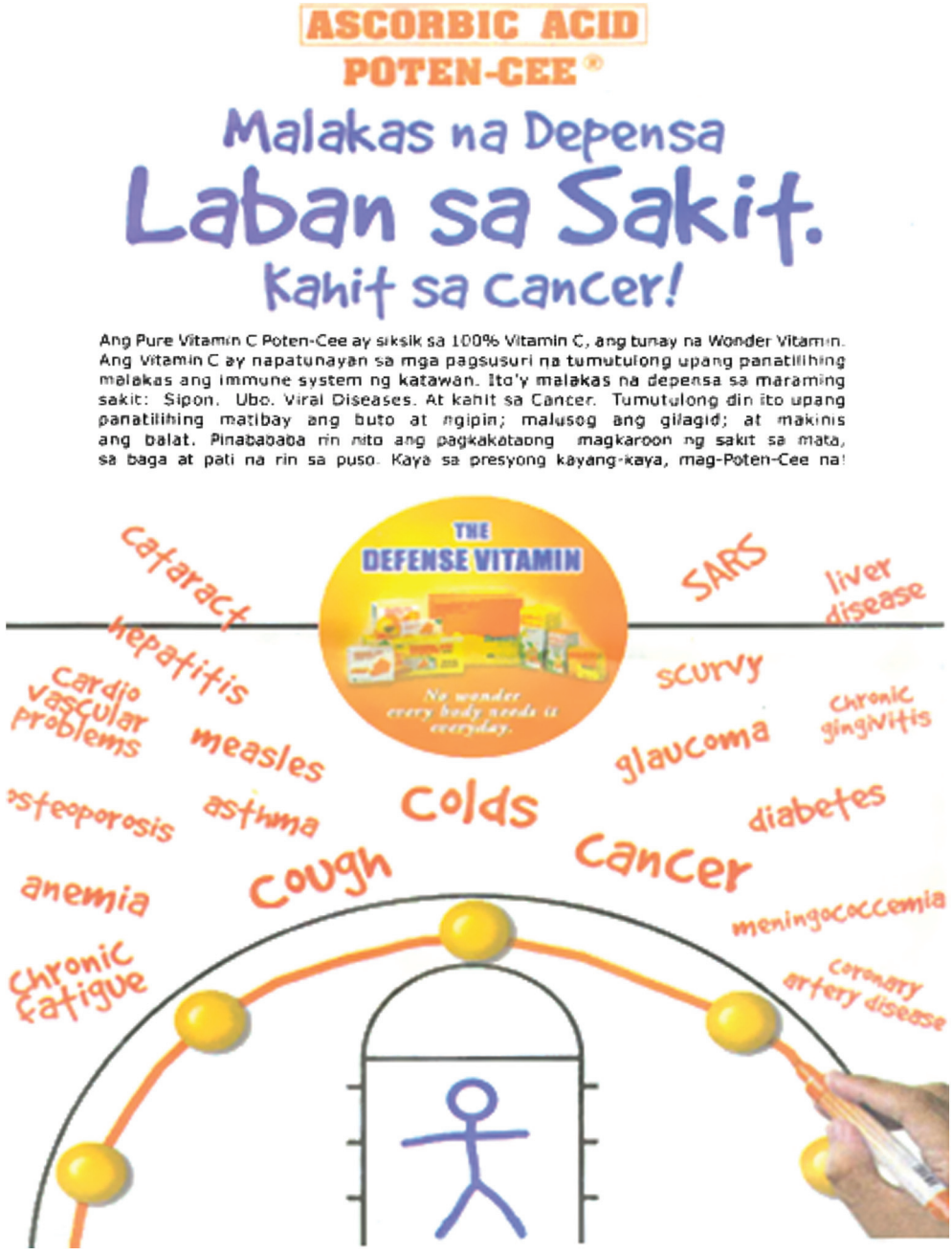

Fig. 1. Billboard suggesting the off-label use of OTC medicine. [Translation: Ascorbic acid Poten-Cee®. Strong defense against sickness. Even for cancer! The pure vitamin C Poten-Cee is filled with 100% vitamin C, the true wonder vitamin. Vitamin C has been proven in studies to help maintain immune system strength in the body. It is a strong defense against many diseases: colds, cough, viral diseases, and even for cancer. It also helps to maintain strength in bones and teeth, healthy gums and smooth skin. It also lowers probability of diseases of the eye, the lungs, and also the heart. So, at affordable prices, take Poten-Cee now!] Photograph taken by author, year 2007.

there is no win-win scenario to be gained. Reluctance to address and communicate the correct information can exacerbate distrust and increase fear.[29]

1.11 Products

Substandard medicines may cause harm in unpredictable ways.[30] The problem is exacerbated because national regulatory authorities find it self-incriminating to acknowledge their existence.

In 2006, the Philippines' bioequivalence analysis of an anti-tuberculosis fixed-dose combination of drugs used in the government programme and a commercially available rifampicin failed during testing.[31] This was a missed opportunity to undertake risk communication to address a systemic problem suspected of causing multidrug resistance tuberculosis.

There are also counterfeits which can lead to treatment failure and exacerbation.[32] Industry has refused to share critical information about counterfeit medicines with regulators for fear that their reputation and the reputation of their product will be adversely affected (author's personal experience).

In a case in Singapore in 2002, a slimming product made in China called Slim 10 caused headline news when a celebrity developed liver failure after taking it.[33] Authorities later determined that it was adulterated with weight-reducing agents such as nicotinamide, fenfluramine and thyroid hormone,[34] and can cause death.[35]

This is reminiscent of a similar drug that entered the market earlier in the Philippines. Unregistered slimming products called 'Bangkok pills' dominated the underground market and were tested to contain fenfluramine, dexfenfluramine, bisacodyl and furosemide.[36-39]

The problem with these faulty products is that they cannot be managed with conventional drug risk communications, which only comes into play when a legitimate, quality pharmaceutical product demonstrates serious and unexpected adverse drug reactions. There is a need to expand the coverage of drug risk communications to include counterfeit, substandard or complementary health products.

2. Discussion and Recommendations

Drug surveillance serves an important purpose to managing risk communications. It translates information to action through prevention measures or clinical intervention. It can also modify health policy and strengthen health systems. However, if no action is taken or a hostile attack on the general principles of surveillance is made, then appropriate risk communication is also threatened.

The main goal of risk communication and pharmacovigilance is drug safety. Risk communication provides a balanced drug information picture and is reliant on pharmacovigilance. These two systems are mutually reinforcing and must not be fragmented or compartmentalized. If there are no reliable drug safety data to begin with, what risk will there be to communicate?

By convention, drug risk communications the world over are undertaken by the pharmaceutical industry with oversight from national regulatory authorities. However, in countries such as the Philippines, one cannot assume that risk communications will be initiated by an industry that does not always provide quality, effective or safe drugs, undertake postmarketing surveillance or promote products ethically to begin with. Likewise, because of limited resources and the lack of an integrated system for drug safety, one cannot presume that drug regulatory authorities can ensure medicine quality and safety.

Most countries have regulations to cover the behaviour of drug companies, such as compliance to good manufacturing practice. For products, quality tests such as bioequivalence for generic products are needed. In addition, marketing and therapeutic claims for such drug products must be examined for accuracy. Because there is no guarantee of safety, postmarketing surveillance or audits is necessary. Translating the findings into a public understanding of the likelihood that an adverse reaction will occur is at the heart of risk communication.

Industry can be persuaded or compelled to practice balanced and transparent marketing. Messages from marketing, advertising and promotions of medicines should undergo more stringent checks and balances. Perhaps it is timely that

regulators initiate an office for monitoring market communications. Drug risk communications will benefit if a social marketing approach is applied, both as a public health policy and an industry strategy, to influence behaviours toward better choices for the public good. Techniques for developing a social marketing campaign plan are well elucidated in recent literature.[40]

But drug risk communication should go beyond simply releasing appropriate information. Stakeholders must be able to access and understand the information in order to make better decisions and act to safeguard their own health and well-being, as well as those of their communities and constituents.

Much can be done to empower patients to be able to discuss health issues and medicines. The government, the academe and consumer advocate organizations can counter the existing information asymmetry with information campaigns to educate the public. Social media can be harnessed to open a dialogue among stakeholders. Selective mass media leaders can be enjoined to be advocates for patient education. Patients can do their part by reporting harms through a citizens' watch, an official avenue set up for them to share their experiences. Clinicians must be reminded to allocate more time to talk to patients about proper drug use and to solicit feedback on medicines they prescribe.

Authorities must establish stronger regulatory implementation to ensure compliance to pharmaceutical safety guidelines. Regulatory systems and normative standards are important when discussing pharmaceutical safety profiles. An integrated pharmacovigilance system to proactively detect quality defects, adulteration, contamination and potential harm is badly needed. Regulation is inherently a complicated process, covering pharmaceutical companies, product registration and prescribing/dispensing behaviour. Unfortunately, clinical misuse is oftentimes not as vigilantly evaluated. Adverse event reporters' confidentiality must be protected so that there will be better capture of the problems of drugs and their use. These are necessary components for regulators and industry to craft a responsive risk communications strategy.

Innovations in technology can provide solutions, such as information communications technology in healthcare. It is imperative to assist in developing people and community empowerment by imparting proper information.[41] However, a system is needed to depict health risks in an understandable and non-threatening format by framing them in the context of a person's ordinary life experience.[42]

3. Conclusions

The ultimate goal of risk communication is to decrease potential harm. If risk communication is not done well, patients ultimately suffer and will seek other forms of information. It pays to attempt to share the same language among stakeholders when communicating the risk of drugs.

Furthermore, it is important to keep in mind the kind of audience the message is meant to target. Health benefits and risk information must be framed succinctly and in a balanced manner so as to include patients in the decision making process. In addition, external factors that may render such messages ineffectual must be considered. Given the limited resources countries such as the Philippines face, it can be challenging. But even within existing constraints, much can already be done to improve the public's understanding of drug risk.

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