When is it legitimate for a researcher to go beyond means of scientific communication?

Quando è necessario andare al di là della comunicazione scientifica?

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Summary

Science and the information world have long been separated. The XXI century will be the one of constant interaction due to the development of novel, exceedingly efficient and fast technologies to share information, including coming from science. Whereas traditionally scientists did not interact with communication people, this is doomed to change. Therefore, nowadays, researchers face the dilemma of when and how to communicate outside the realm of purely scientific domains. The present paper, based on the experience of the author, will, through examples of tobacco, cannabis, hormones, as well as environmental pollutants, attempt to define the prerequisite for the legitimacy of such an approach in the specific case of cancer epidemiology and prevention. Eur. J. Oncol., 14 (4), 191-197, 2009

Key words: cancer, communication, epidemiology, ethics, prevention

Riassunto

La scienza e il mondo dell'informazione sono rimasti a lungo separati. Il XXI secolo sarà quello di interazione più stretta tra questi due mondi, dovuto allo sviluppo di nuove tecnologie, estremamente efficienti e veloci, per condividere informazioni ed in particolare quelle scientifiche. Tradizionalmente gli scienziati non interagivano con i professionisti della comunicazione. Ora questa situazione sta cambiando radicalmente. Pertanto, al giorno d'oggi, i ricercatori affrontano il dilemma di quando e come comunicare al di fuori del mondo puramente scientifico. Il presente documento, sulla base dell'esperienza dell'autore, attraverso gli esempi del tabacco, della cannabis, degli ormoni, e dell'inquinamento ambientale, tenta di definire i pre-requisiti per dare legittimità ad una tale communicazione in particolare l'epidemiologia e la prevenzione del cancro. Eur. J. Oncol., 14 (4), 191-197, 2009

Parole chiave: cancro, comunicazione, epidemiologia, etica, prevenzione

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1. Introduction

Science can be defined as the search for the truth (*veritas* as in the Harvard logo), independent of time and space. Such is the case when one considers fields such as mathematics, physics, chemistry or in general what is called "hard" science. By contrast, these conditions most often do not apply to biology, medicine and even less so to epidemiology or human and social sciences, quite derogatorily called "soft" sciences, or relinquished to the status of disciplines rather than real sciences. Are these distinctions of any relevance to our societies and more importantly to the populations of the world? My contention is that the answer will depend on our ultimate goal in life, as a scientist, but also more simply as a human being.

Rather than writing a philosophical or political piece on the topic, I shall build upon my own experience as a seasoned epidemiologist, having worked for more than 25 years almost exclusively in cancer etiology and prevention, following dual training and education, in medicine in Bordeaux and Toulouse, France and in public health at Harvard University School of Public Health in Boston, United States of America (USA). I worked at the international level, during most of my career (22 years) at the International Agency for Research on Cancer-World Health Organization (IARC-WHO), including 9 years as Group Leader and then Unit Chief of Epidemiology for Cancer Prevention, while being for 2 years acting chief of the WHO Programme for Cancer Control, thereby having to combine research and action in the field, before returning within the French research system, as a Director of Research belonging to the National Institute of Health and Medical Research (Institut National de la Santé et de la Recherche Médicale (INSERM). The present paper only reflects the opinion of the author (AJS) and cannot be considered an official position neither of the INSERM, the University of affiliation, nor of IARC-WHO.

2. Selected examples of controversial science in epidemiology

I shall briefly present three examples from cancer epidemiology, illustrating past or present controversies in the field of etiologic research in cancer epidemiology. As already mentioned above, this will be based on my own experience and is not a systematic review of selected domains.

2.1 Tobacco, cannabis and cancer

Readers in 2010 will be shocked to see "tobacco and cancer" put under the heading of "controversial science in epidemiology". Now, even the tobacco industry has to acknowledge the reality of the causal association. But, history shows that this was far from having always been the case. Such a link had been proposed for a very long time, before being accepted. The first serious documentation at the clinical level of an association between tobacco smoking and lung cancer came from Germany from the end of the XIX century to the 1940s. Several doctors repeatedly described occurrences of lung cancer in smokers. At the time, they did only case reports and series, and in addition published their observations in German, which at the time limited the dissemination of knowledge and was then even more detrimental for historical and political reasons, during the following decades, when all science coming from Germany would be considered as Nazi science and therefore systematically ignored (1).

The first epidemiological investigations were carried out in the late 1940s and published in the early 1950s. Almost automatically among public health students, the name first associated to the epidemiological research on tobacco and cancer is the one of (later becoming Sir) Richard Doll with his landmark prospective study on medical doctors performed in the United Kingdom, the first results of which were published in 1954 (2) and the ones covering 50 years of observation in 2006 (3). Yet, the first convincing epidemiological investigations were of a different study design, namely case-referent studies. In fact, the very first one to be published on May 27, 1950 was a nation-wide US study. The principal investigator was a then young American researcher, Ernst Wynder. One has to know this man was a recent immigrant to the USA, having with his parents fled pre-war Germany, changed his name and decided to work in cancer research. Having spent his early years in Germany, he knew the work done by the German physicians and of course had no language barrier. Ernst Wynder had the chance in the USA as a new comer and young brilliant researcher to be given the opportunity to set up a large study, including 684 lung cancer cases and 780 referents without cancer. A positive, statistically significant association of lung cancer with tobacco smoking was found (4). A few months later, on September 20, 1950 Doll and Hill published their results from a similar study, based on less than 500 cases and more than 700 referents with similar results (5), and then four years later the confirmation with a cohort study design (2). The first case-referent study carried out in France and funded by the French tobacco industry was published in 1960 (6).

Since that time, thousands of studies have been published from all over the world, making the causal nature of the association between tobacco and cancer undisputable. Over the years, the number of cancer sites associated with tobacco lengthened from 8 (7) to attain 13 cancer sites at a more recent IARC Monograph on the carcinogenicity to humans (8, 9). This list keeps on growing with recent evidence, for example on a role for tobacco smoking on colorectal cancer and mucinous tumours of the ovary but also on breast cancer occurrence when the exposure takes place in young women, between puberty and first term-pregnancy (10).

The role of passive smoking has been much slower to be recognized and is still not accepted by the tobacco industry as well as part of the public, not to mention some public health researchers themselves. Of course, the lung cancer relative risk linked to passive exposure to tobacco smoke is small, of the order of 1.2 to 1.3, going up to 2 for the most heavily exposed as compared to around 20 for active smokers. Yet, the evidence is consistent, backed up by observations in experimental animals but also in pets, and considered sufficient to classify tobacco as a human carcinogen (8). Resistance to some role for exposure in utero or/and passive smoking in childhood is still encountered despite evidence of effect (11). Similarly, one had to conduct big metaanalyses, in particular of exposure to passive smoking in the occupational setting (12), to finally see action being taken to prevent such exposure in places of work, but also public living, including places of leisure and entertainment.

Therefore, we can conclude it took almost a century to see strong measures being implemented

under the current umbrella of the Framework Convention for Tobacco Control, established by WHO, under the leadership of a determined woman, WHO Director around 2000, Gro Harlem Brundtland, MD, MPH.

If one compares tobacco and cannabis, we are now, for cannabis, at the stage we were in the early 50-60s for tobacco smoking. I was the first, at least in France, to officially ask the question of the carcinogenicity of smoked cannabis in the late 1990s. I directed a MD thesis on that topic, which was published in 2000 (13). I then tried to convince the French authorities that the question was serious enough to conduct a formal epidemiological investigation in young cases of cancer of the lung or the upper aero-digestive track. Despite encounters with the highest authorities of the Mission InterMinistérielle des Drogues et des Toxicomanies, and the support of the then Directeur Général de la Santé, such a project was judged "politically incorrect" and not funded. I therefore decided to carry out the study outside France, in countries of North Africa, where cannabis smoking had been a tradition, at least for men, for a long time. Studies in Morocco (14) and Tunisia (15), as well as a meta-analysis (16), have been published and detailed results from Algeria are under way. The resistance to the idea that cannabis is a carcinogen is wide spread. In fact, the active principle of cannabis, delta-9-tetra-hydro-cannabinol does not seem to be an animal carcinogen, whereas we have clear evidence in humans for the carcinogenicity of smoked cannabis (17). The question of the carcinogenicity and other detrimental effects of other forms of cannabis remains, as it already was in 2000, totally unanswered and will remain so unless decision is taken to address formally the issue, through epidemiological studies, backed up by complementary toxicological investigations.

Controversy should mean "more research is needed", especially when the exposure is frequent in human populations. Such is the case for cannabis use among young people, in particular in our countries.

2.2 Hormones and hormonal-like compounds

Hormones are essential to life. They make us what we are, be it on biological or even social grounds. Yet, endocrinology teaches us that hormonal

systems may be the most intricate and delicate ones, where slight imbalance or wrong timing may have long lasting negative consequences. This is true for all hormonal systems, and in particular for steroid sexual hormones.

As a woman, I naturally have a strong interest in breast cancer and hormonal determinants, not only of the disease, but also of all phases of life, including the total reproductive period. The IARC classified for the first time, some hormones as carcinogens back in the late 70s (18) and most recently in 2007 (19). Since I came to IARC, and every time I was asked to discuss hormones and breast cancer, I clearly stated that both oral contraceptives and hormonal menopausal replacement therapy were most likely to be human carcinogens, increasing modestly but rather consistently the risk of breast cancer. Needless to say, I was accused to be an "antihormone fanatic". I kept on repeating that the evidence was clear with most studies finding small and most of the time not statistically significant increased risks of breast cancer among hormone users as compared to non users. Faced with the opposition of the French gynecological community and other menopause specialists who were arguing products as used in France were different and safer, I was systematically encouraging them to actually conduct studies and demonstrate it. More than 30 years later, good valid data has only recently emerged from our country. In fact, it is easier to say there is no problem when there is no data rather than taking the chance the data may not be favorable to the product. Now, most women accept the idea that hormonal products such as oral contraceptives and hormone replacement therapy increase the risk of breast cancer. The change in public opinion came from the headlines in the general and feminine press, following the realization of meta-analysis on the topic. Meta-analysis has been originally developed to make small improvements in clinical trials statistically significant through mere large numbers. The pharmaceutical industry needed the tools to be able to say a 2% improvement in survival was statistically significant and used the meta-analysis to do exactly that. Of course, this totally ignores the issue of biological rather than statistical significance, as well as side effects and quality of life, not to mention financial costs. But the same tool may be used to

demonstrate risk and this is what happened with oral contraceptives and even more with hormone replacement therapy. The Americans did not stop there and decided to look for the formal proof by conducting randomized controlled trials and again the answer came out positive. Now even the French health authorities recommend caution in using these products, although part of the gynecological community is not yet convinced and keep on relying on the poorly substantiated French exception.

Taking or not taking hormonal products should be a matter of informed choice by women, and no one else. Unfortunately, there is a *proviso* to the notion of choice, namely the availability of hormone free products in terms of contraception. Besides barrier methods, other alternatives which existed, such as hormone free intra-uterine devices are disappearing from the market and consequently some women who decide to use intra-uterine devices precisely to avoid hormonal contraception are exposed, sometimes even without knowing it. This is not acceptable.

Analogous considerations may be made for exposures to other hormonal products. This is of paramount significance with the ever more fashionable topic of pharmacoprevention. In the field of breast cancer, tamoxifen has been the first such drug proposed in the 1990s. At that time, it was known to be a good therapy for breast cancer, in particular among menopausal women with estrogen-receptor positive breast tumors. The use of tamoxifen increased survival and decreased the occurrence of second breast cancer. Unfortunately, it had the side effect of being carcinogenic, increasing in exposed women the risk of endometrial cancer. Whereas the risk-benefit ratio was good for women already having breast cancer, this was not the case for healthy women even if they were at high risk of breast cancer. Again, I was the first in France asking the question of the ethical use of a carcinogen as a cancer preventive (20). That time, I succeeded in being the one to start the first case-referent study specifically designed to evaluate the carcinogenicity of tamoxifen for the endometrium (21) and for a long time the only one insisting on the fact that risks were much higher for women exposed in premenopause (22). As a scientist, I realized my task did not stop there. I went on as an expert, being instrumental in the classification of tamoxifen as a group 1 human carcinogen, both by IARC (23) and also by the US Environmental Protection Agency (US EPA). This led to several countries, including France not starting chemoprevention trials (24). But a battle is never for ever won. A report from the *Académie nationale de Médecine* again recommended chemoprevention of breast cancer, a few years ago, with hardly any discussion of the potential side effects, including but not limited to carcinogenicity.

2.3 Some topics for the years to come

I shall only mention three specific topics, which illustrate the general issue of exposures of populations to environmental carcinogens. The preceding two points were dealing at least in part with use of tobacco or cannabis and medicinal drugs, *i.e.* individual exposures linked with life-style and behavior, in which the individual may have some freedom of choice. However, when exposures are present in the air, water, food, soil and objects of daily living, the ethical considerations differ (25, 26).

The first such example is the one of the potential effects for human health of the use of growth promoters in animal husbandry. I got involved with that topic, often referred to as "hormones in meat" back in 1996, first as a national expert for France and then as a European expert. The issue came about when the USA and Canada filed a complaint against Europe in front of the World Trade Organization (WTO) for unfair barrier to trade. Europe had years before decided to ban the use of natural (17 beta estradiol, progesterone, testosterone) as well as synthetic hormones as growth promoters in meat animals. USA and Canada, along with several other beef producing countries in the world continued using these products. It is undeniable that demonstrating risks for human health is exceedingly difficult, as we are attempting to evaluate the effect of an added quantity of already existing hormones in humans. Scientists on both sides of the controversy agree that the risk, if any, is likely to be small. Yet, over the years, more and more data accumulated, in favor of the carcinogenicity of some molecules and of specific metabolites, as well as effects on puberty. Confronted with the limitations of quantitative risk evaluation, Europe carried out a riskbenefit exercise and concluded that in the absence

of any benefit whatsoever for the consumer, it was better to avoid any risk, thereby adopting the precautionary principle. On the contrary, North America concluded that the risk was "acceptable" and refused to ban the use of these products. The exchanges in front of WTO on this topic have been going on for more than 10 years with several rounds (27-29). For the first time in 2008, Europe finally convinced WTO and is therefore no longer condemned to paying heavy fines to the USA and Canada. I regard this as a clear example of the way economic and trade considerations far outweigh health concerns and matters and may prevent for years actions to be taken.

The second example will be cell phones. These apparatus have been in use for a limited amount of time and on a very large scale for the last 5 years, with now an estimated 60% of the world population using cell phones. It is much too early to see a finally demonstrated carcinogenic risk but the question is "should we wait for it before saying anything?" A lot of evidence is already available on the effects of exposure to ElectroMagnetic Fields (EMF). Cells, be they animal or vegetal, react when exposed to EMF, in particular producing heat stress proteins. Animal experiments have been carried out. Moreover, epidemiological results are already available. Many studies have been performed in different countries. Results are available and tend, although somewhat inconsistently, to show increased risk of benign tumors, such as acoustic neurinomas, or, most importantly, malignant ones such as gliomas for long term exposures. The risk appears double for long term (more than 10 years) heavy users. Even if again results taken individually are often not statistically significant, they are rather consistent and although biases are advanced to explain the positive association, the possibility of a causal link cannot be rejected. In these conditions, and faced with the long time clear reluctance of the IARC to release the results from the largest ever conducted study on this topic, Interphone, partly financed by the cell phone industry and operators, I decided to participate to the awareness document known as the French Appeal of 20 experts on cell phones in 2008. It is a simple document, reminding everyone of the necessity, in face of uncertainty, to use the precautionary principle and avoid as far as possible any unnecessary exposure (30). It later after being translated became known as the University of Pittsburgh appeal, leading to US Congressional hearings on the topic.

The last example will be the one where most clearly research is needed. It concerns the fact that Martinique is experiencing a very high incidence rate of prostate cancer, twice as high as metropolitan France. The reasons for this excess are not known. Multifactorial causes are likely to include racial components, mitigating potential gene-environment interactions, life-style (in particular sexual habits and nutrition) and finally environmental exposures, including pesticides. All these factors are likely to contribute to the existing cancer burden. Yet, quantification of respective factors remains to be done (25). Many teams are attempting to work on this issue, but unfortunately in complete isolation. This is likely not to be productive. The issue is complex enough to warrant a concerted effort to reduce a significant population health problem. Is this going to be the case? Future will tell.

3. Synthesis and discussion

In my experience and opinion, the objective of population health experts and actors should be to find the best way to get information across to people in need of it. This includes the general population, the medical and research community as well as decision makers and politicians.

The question then becomes: when is it legitimate to speak? I shall draw a historical parallel with John Snow. All epidemiologists know the story. During a cholera epidemic in London, Snow was asked to evaluate the problem. He drew a map of London and indicated there the homes of the cases. It became clear that cholera did not occur at random but seemed to concentrate around a pump from which part of the London population drew water. At the time, Snow had no idea cholera was water born and the agent responsible for the disease had not yet been isolated. Nevertheless Snow decided to act and he removed the handle of the pump. One would say nowadays that he acted in the name of the precautionary principle (evidence of harm but no proof of cause) and the epidemics dwindled down.

What do we need to act today? People and institutions will disagree. Some, like the Académie nationale de Médecine will insist on waiting for the final proof, i.e. thousands of deaths later. Others (and I count myself among these, as a scientist, a MD, but also more basically as a woman, a mother and a citizen of the world) will speak up in the name of the precautionary principle and will request action in favor of prevention. This means the need to use beyond and on top of scientific peer-reviewed publications, other means in order to be heard when knowledge is enough, evidence is good even if not yet definitive, and when institutions and organizations whose mission it is to advise and protect people do not do it the reasons which may go from lack of culture of prevention, economic or career interests, failure to stand up to threat and lack of commitment to population health goals. If the route of scientific research and communications fails to attend to these goals, other routes may and should be taken.

How can we be most efficient in terms of communications? We need to turn to the right experts, the ones whose job consists in informing people. Scientists do not have to be ashamed to talk to the press. Media by definition reach out to people. Charismatic and well introduced opinion leaders may be instrumental in getting a message across and it is possible to work with some of them, in the best complementarities and mutual respect. I believe scientists can and should also talk to activists, as a doctor talks to her/his patients. If our goal is population health, we do not have any reason not to work with the ones fighting for it. We will quite often have to educate them but they are the ones in the field, the ones carrying out the task and field action. Without them, nothing will change. I see no opposition in being a scientist, a MD, a citizen and "just" a woman.

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