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Health impact assessment should be based on correct methods

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Summary

The methodology of health impact assessment (HIA), originally proposed by WHO, is widely used to predict the potential health effects in a community living in a place in which a new project (e.g., an industrial plant) will be implemented. One of the key quantities to calculate the impact (i.e., the number of attributable cases) is the baseline (i.e., before the project implementation) rate of selected diseases in the community. In a recent paper on this journal, this methodology has been challenged. Specifically, the use of baseline rate has been questioned, proposing to use only the fraction of the baseline rate due to the exposures related to the project, and not the rate due to all risk factors for the disease. In this commentary, we argue that the proposal is logically and epidemiologically unsound, and devoid of scientific motivation. The conclusion that the traditional approach overestimates the health impact should be rejected as based on flawed assumptions. On the contrary, the proposal may produce a (seriously biased) underestimation of attributable cases.

We have read the recent paper authored by Carlo Zocchetti "Epidemiologic health impact assessment: estimation of attributable cases and application to decision making" [1]. We have serious concerns about the rationale of the paper, which in our opinion is flawed in relation to the new methodology proposed for health impact assessment (HIA).

We skip the many technical details in the paper to go directly to the critical point (the second objective of the paper: "to discuss which rate at baseline could be used for the estimation of attributable cases") [1] (Abstract). For the readers, we remind that attributable cases are calculated by multiplying four quantities: 1) the *baseline rate*, i.e., the rate in the population living in the area in which a new industrial plant will be open; 2) the *excess relative risk (ERR)* for a unit (or 10 units) increase in exposure (e.g., particulate matter, PM_{10} or $PM_{2.5}$), where ERR = (relative risk minus 1) = (RR – 1) [2]; 3) the *size* of the exposed

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population; and 4) the *additional exposure* due to the plant [1] (first formula and formula 1, p. 2).

The Author argues (and *de facto* proposes) that "the baseline rate to be used for the computation of the cases attributable to the project under evaluation" (e.g., a new industrial plant) is "the rate due to the exposures only related to the project, and not […] the rate due to all risk factors for the disease." [1] (formula 10, p. 4). His conclusion is that "In the case of pollution and lung cancer" the use of the traditional approach "will cause an overestimation of the attributable cases of the order of around ten times." [1] (p. 5). We definitely disagree with this proposal, for the reasons discussed below.

First, the baseline rate in a given population is due to a constellation of risk factors (e.g., age, genetic predisposition, individual habits, environmental factors). For example, a community with many elderly people and smokers (population A) has a higher baseline rate (say, 10 cases per 100,000 person-years) of respiratory diseases than another population B on average younger and with less smokers (say, 5 cases per 100,000 person-years). These are facts existing prior to the implementation of the new project. The new additional exposure (e.g., $PM_{2.5}$) due to the project will act on the existing conditions: we see *no logical rationale* in considering only "the rate due to the exposures only related to the project". The plant will impact on *all individuals*, each with his/her profile of risk factors (age, smoking and so on).

Moreover, we see *no statistical/epidemiological basis* in support to the proposal. The RRs for a given disease to be used for HIA are considered (based on valid previous research) to be causally related to the exposure. They usually come from systematic reviews and are in general *adjusted* for the main confounders under a multiplicative model, where the relative effect of the exposure is assumed to be *constant* across strata of confounders (and therefore applies equally to *all individuals* independently of their characteristics) [2].

For example, let's assume that: a) the scientific consensus is that the frequency of respiratory diseases increases 10% for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ (i.e., RR = 1.10, ERR = 0.10); and b) the new plant will cause a 10 $\mu g/m^3$ increase in $PM_{2.5}$. ERR = 0.10 will apply to everyone in the community, young or old, smoker or non-smoker, and so on. As a consequence, in the example above, the impact of the same additional exposure on the incidence rate would be higher in population A ($0.10 \times 10 = 1$ case per 100,000 person-years) than in population B ($0.10 \times 5 = 0.5$ cases per 100,000 person-years). Therefore, the proposal conflicts with basic epidemiological concepts. Our conclusion is that the new formula in some circumstances may produce a (seriously biased) underestimation of attributable cases.

To illustrate the point, we make a numerical example with hypothetical data. Let's assume a new plant will be built in a place where a population of 200,000 people live, with a baseline incidence rate of respiratory diseases of 50 per 100,000 person-years. Let's assume that RR = 1.10 for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ and that the new plant will cause a 10 $\mu g/m^3$ increase in $PM_{2.5}$. Under the formula currently used [1] (formula 1, p.2), the number of cases attributable to the new project (AC) would be: $AC = (1.10 - 1) \times 50/100{,}000 \times 200{,}000 \times 10/10 = 10$ cases (per year).

The new proposed formula [1] (formula 10, p. 4) makes use of "the rate due to the exposures only related to the project". Let's assume that respiratory diseases in that population had been caused 90% by tobacco smoking (i.e., baseline rate 45 per 100,000) and 10% by $PM_{2.5}$ (i.e., baseline rate 5 per 100,000). Under the new formula, $AC = (1.10 - 1) \times 5/100{,}000 \times 200{,}000 \times 10/10 = 1$ case (per year).

We believe that the formula proposed by the Author is incorrect because it is based on the unrealistic assumption that $PM_{2.5}$ has an effect only on a subset of individuals (non-smokers), with the consequence of producing an underestimation of the number of attributable cases.

Second, no scientific references are provided to support the proposal. It is argued that: "it makes sense to discuss which value has to be chosen for the baseline rate […] because such a choice has a strong numerical effect on the number of cases attributable to the intervention." [1] (p. 4). It appears that the only reason for choosing only a small piece of a baseline rate is just "the strong numerical effect". We believe this is a poor motivation for proposing changes in HIA methodology, lacking the necessary scientific support.

Third, and not less important, HIA methodology includes a body of consolidated techniques that has a long tradition [3,4] and is applied by WHO [5,6], the Global Burden of Diseases working group [7], and the European Environmental Agency [8], to name just a few. It is not unknown for authoritative institutions all to be wrong. However, strong scientific justification is needed to dismiss their shared approach.

In conclusion, we hold the proposal of using as baseline "the rate due to the exposures only related to the project" is logically and epidemiologically unsound and devoid of scientific motivation, insufficient to dismiss the current approach. Therefore, we maintain the proposal cannot be accepted by the scientific community and the conclusion that the traditional approach produces a "large overestimation as in the case of lung cancer" should be rejected as based on flawed assumptions. On the contrary, the new formula can in realistic circumstances produce a (seriously biased) underestimation of attributable cases.

Declaration of Interest: All Authors have been experts of HIA activities for public institutions; some of the Authors (AB, FB, FF) have been experts for the Judge or the Prosecutor in courts. None of the Authors had financial or other interests.

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