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Prevention, communication and equity in environmental epidemiology: ethical issues

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Summary. In environmental epidemiology research, decisions about when and how to intervene requires adequate ethical reflection. In fact, different kinds of issues may arise about: research methods and knowledge production; management of the results in terms of their overall assessments or for the implementation of preventive actions; reclamation intervention. In this contribution we propose to consider three topics we regard as crucial to this ethical debate: the reporting of conclusive research data; the correct application of the precautionary principle; and the environmental equity issues.

Key words: precautionary principle, equity, environment, perception of risk, communication.

Riassunto *(Prevenzione, comunicazione ed equità in epidemiologia ambientale: una riflessione morale)*. Nell'ambito delle ricerche di epidemiologia ambientale le decisioni, riguardo all'agire e alle sue modalità, richiedono un'adeguata riflessione etica. Possono sorgere, infatti, diversi tipi di problematiche relative sia alle modalità di ricerca e produzione delle conoscenze, sia alla gestione dei risultati prodotti in termini della loro valutazione generale o ai fini di azioni preventive e interventi di bonifica. Nel presente contributo proponiamo di considerare tre questioni come fondamentali per questa riflessione etica: la comunicazione dei dati conclusivi della ricerca, la corretta applicazione del principio di precauzione e le problematiche di equità ambientale.

Parole chiave: principio di precauzione, equità, ambiente, percezione del rischio, comunicazione.

GENERAL FRAMEWORK AND POTENTIAL OUTCOMES

In environmental epidemiology, many aspects related to production of data, communication of results and to their implications for public health policies require a satisfactory ethical reflection. Different types of issues about methods of research and timing may arise, as well as concerning the use and communication of results, especially in the studies which, referring to circumscribed groups and small communities of specific interest, put the researcher in a direct relationship with the community and/or the individuals involved. In this paper three specific problems will be touched. The first is communication of data and transparency; the second is the issue of the value of the precautionary principle. Finally, that which concerns the role of researchers in relation to preventive action and reclamation which follows the production of the data. Ethical considerations concerning researchers' duties in the actual performance of a study (*e.g.* obligation to subjects of research, informed consent, obligation to colleagues, the morality of meeting scientific standards, etc) will not be examined in this paper since they are sufficiently discussed and defined in existing guidelines [1, 2].

COMMUNICATION AND TRANSPARENCY

The first issue which will be considered is the communication of results of epidemiological studies, mostly in relation to the problem of how and when to communicate this information to the individuals or communities involved.

Of course we are thinking of studies which are conducted in a scientific sound way, published and peer reviewed. It is worth remembering in fact that scientific soundness of a study, publication and peer review are requisites, also from an ethical point of view, not only for the communication to the involved communities or individuals, but also to colleagues and to the scientific community in general.

Concerning communication of results, therefore, the considerations are different in relation to the characteristics of the study results, *i.e.* whether: a) the final result is decisive and ascertains a risk for human health, such as the occurrence of pleural cancer in residents in areas contaminated by asbestos, b) results are uncertain as well as the health risk.

In the first case, the duty to report results with accuracy and transparency is clear because they are strongly relevant in the improvement of the conditions of community and/or individuals' life.

Where the data are certain and the health effects

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are univocal, the importance of a communicatory approach toward the community is clear and visible.

The acknowledgement of the positive value of self-determination, essential to protect personal autonomy (a core value in bioethics) implies in fact the obligation to inform as much as possible individuals, in order to make it possible the implementation of intentional and autonomous decisions. Autonomous decisions are, in fact, characterised by a deep understanding of one's own situation and not just by the lack of external constraints [3, 4]. Therefore, a non transparent attitude can be to the detriment of the principle of autonomy. It is clear that autonomy, in this context, can be understood in two ways: on the one side as the possibility given to a community considered as a whole to take decisions, knowingly, in order to defend the health of its members (*i.e.* putting in place monitoring programs and preventing actions or soliciting public actions of reclamation); on the other side, it can be understood as each individual's autonomy in relation to the kinds of choices each informed individual can take concerning his/her life or that of his/her beloved (*i.e.* monitoring of not his/her own health, following or not medical indications, leaving a defined territory and so on).

Of course, it is different to communicate the results of an epidemiological study to the community of involved individuals as whole, from communicating them to each individual as such. In the latter case the modality of communication can be more difficult, if not impossible, for an epidemiologist [5].

In the latter case, in order to behave coherently with the principle of autonomy, epidemiologists should illustrate with clarity this specific difficulty (*i.e.* the impossibility to achieve/communicate individualized data) to the individuals involved, both at the beginning and at the end of the study. Conversely, where and when is possible to use individual analysis, there will be space for the moral question about the duty of the researcher to inform; i.e. if he/she must inform each individual on his/her health or not.

In our opinion, in this case, if the researcher wants to act respecting the autonomy and decision-making capacity of the individual, he/she must consider among his/her tasks either to inform directly each individual, or to provide relevant information to other subjects able to reach the individuals (by promoting a plan for health monitoring on the territory or referring to the local health care system).

In both cases (communication to communities or individuals) the moral problem of transparency, however, does not consist only in the decision about whether to inform or not, but requires, in the case of a positive decision, a careful analysis of times and methods of communication and management of the information which will be communicated. In this situation it can be necessary to refer to competent figures (with expertises in communication) [6].

Moreover, in the case of studies producing clear-cut evidence of the existence of a risk, in addition to the issue of the protection of individual and community autonomy, it can be considered part of the researcher's duty the study of solutions about reclamation or to advocate for their implementation, as it will be discussed in the next sections of this paper.

In the second case, instead, when the results are uncertain and the effects on health are not clearly defined, the theoretical space for the hypothesis of not to say and not to act may emerge. But even in this case, this is not the right attitude. In fact, the uncertainty of the final results of a study does not preclude the possibility that the studied factors may cause the development of one or more diseases and so it does not preclude the possibility, mainly for a community, but even for single individuals, to consider these factors and to decide to act accordingly. Uncertainty is in fact radically different from the certainty of absence of risk. Therefore, results should be communicated to the population or to competent authorities also in this case, being sure of communicating as well the degree of uncertainty which characterises them (to decide to withdraw an information is in fact in any case a paternalistic attitude).

Personal knowledge, autonomy and therefore freedom must in fact be protected in any case, certain or uncertain that the results are.

Science must, necessarily, consider freedom of the subjects as fundamental: if it does not, believing to be able to exclude it and forgetting the limits that surround its same cognitive procedure it, ceases to be science [7].

In fact, without liberty there would not be science: the researcher's freedom and that of the enrolled subjects are two instances of the same liberty of action and thus they are strictly intertwined.

The point we are making, is that freedom of the enrolled subjects should not be protected only at the beginning of a study (asking consent, etc.) but also at the end: communication is, in fact, a fundamental part in protecting their freedom.

Finally, a last problem, concerning transparency and communication and autonomy, is that inherent to the biological material collected in the course of some studies. In fact, when a study requires the sampling and conservation of biological material, the deposited materials could be subsequently used for other studies and, moreover, there is the possibility that it can be modified and patented. So, in relation to this problem: first of all the persons involved in the studies should be informed about the possible future use of their biological material (in addition to the information related to the way in which it will be used in the study); secondly, if they agree to participate in the study, it will be necessary to establish when and how they can decide to make the biological material available for the conservation in data banks and for future uses. For instance it should be made clear if they will be asked a specific consent for any single future use or if their participation tacitly implies a consent for any possible use.

In conclusion a strong attention to the quality of information which will be offered and of the mode of communication, both in the phase of request of the

initial consent (enrolment) and during the communication of the results, should be considered as a moral commitment for environmental epidemiologists.

Particularly about the final phase of communication there are two further recommendations to be considered: first, researchers should wonder about their real possibility to communicate and about their ability to explain clearly the results reached, the data and their degree of certainty, keeping in mind the difficulty of this last aspect. Where opportune, it can be recommended that the team would be endowed with an expert in communication.

Secondly, in the communication of results, researchers must be able to express the role that their own personal beliefs play in the interpretation of the produced datum, both the beliefs moved by their own previous experience and the beliefs which derives from their personal moral position. This is always important, but it is especially so when there is a degree of uncertainty in the results.

There has been a wide debate about the importance and role of moral values in scientific production and particularly in epidemiological research [8]. Given this reality, the duty to make available the data to the community requires that the researcher behave consistently with his/her ethical-scientific position and is able to express it. On the basis of this awareness, at the same time, the researcher may have a critical attitude toward this same position and know its limits, when and if it is necessary.

This attitude will be able to give a more functional and available information for all involved subjects and it will allow an open dialogue and a true participation, so favouring aware and conscious choices.

PRINCIPLE OF PRECAUTION

Among the ethical basic attitudes, for those who operate this kind of studies, a particular value should be given to a precautionary attitude, and to the reference to the precautionary principle.

The value of this principle in risk evaluation is internationally recognized and it has been considered as a guiding principle in different international Conferences and Guidelines (the universal recognition of the precautionary principle is reached in the 1992 UN Conference in Rio de Janeiro on Environment and Development. See also: The Cartagena Protocol on Bio safety in 2000. The 2001 Stockholm Convention on Persistent Organic Pollutants (POPs). The London Convention of 2001 on anti-fouling paints) [9, 10].

As a first consideration, it is necessary to distinguish among the principle of precaution and the principle of prevention. Difference resides in the degree of uncertainty that surrounds the probability of an adverse effect: while the principle of prevention presents itself against ascertained risks, the principle of precaution is finalized to the difficult management of uncertain risks.

The precautionary principle is, in fact, characterized precisely because it states that the lack of a full scientific certainty should not be a reason for postponing the adoption of appropriate preventive measures in relation to a specific risk factor, when there is a reasonable but not certain reason to consider it so.

According to the precautionary principle, the uncertainty of data loses a big part of its paralyzing power, because the principle reverses the burden of proof [10-12]. Indeed this principle does not ask to show that there is a certain risk in some exposures to those who wish to intervene with preventive action, but instead it asks to those who don't want to intervene to show that there is no risk.

Obviously it should not be given an absolutist or naive reading of this principle, as it has been in some debates, for instance that about Genetically Modified Organisms (GMOs) [13, 14].

It is well known that "zero risk" hypothesis does not exist and that to require it would be absurd and crippling, but we must consider that there is not even always the certainty of risk and that to wait for it, before intervening, could be equally absurd. In any case, in a correct understanding, precaution should still be based on data, although uncertain (but uncertainty can be scientifically measured) and cannot be invocated on the basis of presumed risks, biases and opinions. In environmental epidemiology, moreover, uncertain risks are still risks which are individuated by scientific procedures, and the degree of uncertainty of the results does not always undermine the risk of the occurrence of adverse effect on human health (uncertainty may regard the ability of a study to measure the risk, not the existence of the risk itself).

It should be considered, moreover, that in this particular area of research, the precautionary principle can be invoked also in relation to problems which are different from that of uncertainty, and concern instead situations in which a well defined risk factor regards a very small number of individuals: often, societies give precedence to the benefits (not just on health but also economic) of a wider community against small high risk communities. In this situation, the precautionary principle requires instead to consider the particular value of those few cases [15].

This point is worth an articulation.

To develop a scientific act in a way which is consistent with human wellbeing, it is necessary that the foundations of the act are thrown beginning from the protection of the each individual case, since community is nothing but a whole of individuals.

Moreover, even if we are in search of human wellbeing on a large scale, the attention paid to particular individuals or to small communities can be relevant or beneficial.

Attention paid to the particular demands coming from a few cases or a small community, may allow the definition of procedures and bring to results which could be applied afterward to a larger community or be to advantage for the whole community. This kind of considerations is essential for a wider consideration of the practice of analysing, preventing and where possible, solving the problems coming from the relationship between environment and health.

The precautionary principle should thus be understood, as asking to take into consideration and protect as much as possible the health of subjects exposed to high risks even when they are few in comparison to the whole of the community or of the population. The numerical sparseness of the possible cases, in fact, should not be a deterrent agent that finds its reason in some naïve cost/benefits analyses, such as those in which the value of human life inexorably succumb to the factors of economic interest [16]. Where is a reasonable risk for the health it will be morally remarkable that the different possibilities of intervention are valued. And in this evaluation the vulnerability of some groups of individuals (or classes) and the possibility to be particularly penalized should be highly considered.

A common argument that has been brought on to object to this understanding of the precautionary principle, or in general to its assumption, is the contrast, that many find, between "precaution" and "development". But this contraposition does not always hold true.

These kinds of arguments are brought on by those who square the concept of development only with the demands of industrial or technological advancements, considering this development limited by the call to precaution.

A reasoning of this kind, often, starts from an analysis that rewards only the positive factors of a determined element of technological advancement, underestimating or justifying the costs of it; but the same idea of "development" should contain in itself the necessity of a balance among technological advancement and reduction of the risk, even when considered from the economic point of view.

Moreover it must be considered that a scientific search able to identify the possible damages for human health is equal to any other type of "technological advancement", and − as such − it should be considered as a beneficial tool for everybody. An accurate study on the possible damage coming from certain exposures, for instance due to certain industrial or technological situations, allows not only to protect the population at risk and the more stricken groups, but it allows also a knowledge of which everybody or the entire community can benefit, in greater or smaller measure, and should be considered therefore a collective good.

In conclusion, it should be the constructive critical tension among development reasons on the one side, and those of the prevention on the other, that shows the possible limits of both and to favour a profitable balancing that goes to the advantage of an ethical application of the technologies and, therefore, to the quality of human life. This does not mean to find either/or solutions, but to find case by case compromises and strategies for the protection of these subjects.

The use of resources and technologies with the purpose to improve the quality of life is an integral part of scientific work; therefore, the latter will certainly be enriched from a correct use of the principle of precaution.

Besides, being a careful scientific analysis a *condicio sine qua non* which lies behind a reasonable assumption of the same Principle, a first form of precaution will indeed consist in performing and favouring epidemiological research which will in turn reduce the uncertainty of the data.

The theoretical-conceptual basis from which the principle of precaution and its assumption are originated, does not foresee nor, therefore, implies a deceleration of the research, even if it envisages an idea of development compatible with the problems of a territory and with the demands of those who live in it [17].

And it is evident, finally, that the precautionary attitude against possible risks does not require an interruption of the technological progress, but it may require additional costs related to measures of containment of the risks and an investment of energies and resources for the definition of strategies of alternatives development.

ENVIRONMENTAL EQUITY AND TIMING PROBLEMS

The moral issue of the relation between activities of prevention and land reclamation and the practice of researchers who investigate the relationship between environment and health should be considered.

Beyond the debated question, whether the researcher must or must not take a stand in the debate concerning preventive activities (risk management, advocacy, priorities in prevention and reclamations etc.), or if should limit him/herself to the mere production of data, it is necessary to deepen a different issue. In fact, the first question has been, generally answered in a positive way, since epidemiological research finds its place, at least in majority of cases (for instance when it is publicly funded and produced by governmental institution), in a wider practice of public health protection.

Taken for granted the idea that environmental epidemiological studies find their place within a more general preventive strategy, a different issue emerges in relation to their role, that is the following.

Usually, the elaboration of satisfying epidemiological data is considered a necessary condition for the planning and adoption of preventive measures and land reclamation; but the elaboration of conclusive results (above all if uncertain), and the same epidemiological search, do take time, and may lengthen the times of action, adding delay to other delaying pressures, different in nature. So the question is: is it always necessary to wait for epidemiological results before to give rise to actions of prevention or land reclamation? And how to manage the problem of the expansion of time?

A possible answer to this question can be found in the adoption of a different point of view, namely to consider considerations of "environmental equity" as a sufficient base for preventive interventions and reclamation, considering, so to say, environmental studies as a part of preventive intervention.

The concept of environmental equity refers to a wider sphere of action inside of which to intervene for a good

development of the relationships between human beings and environment (which may not include the production of data on the direct influence of specific risk factors on human health), which should be understood as a constitutive element of a broader idea of human health.

To our notice, the kind of elements considered to move what can be broadly described as a demand for environmental equity, in a given circumstance, are sufficient to motivate starting measures of prevention and reclamation, and to justify the employment of resources for a suitable epidemiological research in environmental field, as part of this effort [15].

On this we would want to offer some further considerations.

The slowness or inadequacy in the management of activities of remediation of contaminated sites and/or of environmental degradation, do not exclusively derive from the scarce yield of the technology adopted but it may depend also from temporal and financial ties that make it difficult to meaningfully reduce the concentrations of polluting materials. In this context, as mentioned above, the time needed to establish, through a sound epidemiological research, a possible risk for human health may cause a shift to long term of the environmental remediation.

The situation of polluted sites and/or in sites in environmental decline, however, contains in itself matters of immanent character which, if appraised by the point of view of environmental equity, evaluation which has smaller time constraints, may offer an optimal starting point for interventions of territory maintenance and reclamation.

We are suggesting that an application for reclamation may be acted before the production of epidemiological data on the basis of environmental equity considerations, that are wider and different in nature than the considerations about health.

In polluted sites and in the surrounding zones, in fact, besides the presence of elements that can represent a risk factor for human health, there are other elements of remarkable environmental degradation that are more easily detectable, in comparison to the measure of the damage to the health as such. Even if one does not want to stick at those philosophical/ecologist currents of thought which attribute a value to the environment in itself [18-21], nobody can avoid to recognize a value to the relationship between humans and the environment that surrounds them [22]. If this relationship is positively assumed, it may be seen that every modification and/or damage inflicted to the environment will cause an alteration in the interaction between humans and the territory/environment itself.

This relationship does not imply the necessary negative or unjustifiable nature of every human intervention that can somehow modify or damage the environment, but it implies the need of an evaluation of the environmental impact and of the different degrees of alteration that every intervention involves.

The constitutive elements of this evaluation are: the possibility to enjoy the benefits, economic and not, deriving from a correct development (or recovery) of urban areas and from the natural conformation of the territory, if this is adequately maintained; the protection of health and the comfort of human beings which derives, for instance, from a rate of discharge and pollution compatible with the local systemic ability to absorb and to transform harmful substances; the protection of biodiversity and of the quality of the local system in order to sustain life and welfare of animals and vegetables in way which is suitable to head off damages for food and agricultural patrimony [25].

In a cost/benefits analysis of a single intervention it must be considered, therefore, among the possible costs, also the alteration and the worsening of the relationship with the environment and the consequential development of an inequity which can damage people living in the contexts, even if a direct influence on their health is not present or already measured.

When an area is strongly characterized by environmental degrade, the local community is found in a disadvantaged situation in comparison to those who live in non damaged sites and benefit of a healthier and balanced relationship with the surrounding environment [23]. It is evident, in fact, that this kind of situations produces social and environmental disparities among different territories and communities, often strengthening existing social gaps. It should be considered, in fact, that what we could define like "collateral effects" of the economic/industrial development, varying from the atmospheric and hydrogeologic pollution to the epidemiological impact of heavily industrialized areas, in fact, falls with great facility on the most disadvantaged classes. Issues in environmental equity and issues related to the social justice inevitably overlap.

As a clear example of this fact one can consider the damage to food wealth frequently found in highly polluted and highly industrialized areas, such as in Campania and in Sicily [24].

The damages brought to these areas are a clear example of how environmental degrade may affect the relationship between human beings and their territory, directly and negatively. In these cases, in fact, the problems caused by the missing disposal of pollutants, the dumps, the contamination of the water-bearing layers etc. compromise the quality of agricultural and food production, damaging one of the most important relational balance between humans and a territory, independently from the effect on the health, which can be considered in a second time.

Another relevant issue concerns the benefits coming from the opportunities of economic-social growth offered by the tourism, if one does not want to consider the role of green spaces and of the aesthetics of the environment for a positive development of human life in all its aspects and qualities.

In the light of these factors, it is impossible to maintain that there is environmental equity among areas characterized by industrial or technological interventions with a low environmental impact and those characterized by degrade.

Coming back to the relationship between environmental equity, the practice of environmental epidemiology and that of prevention and land reclamation, it should be considered that in the majority of the cases, the presence of the elements just highlighted is more easily verifiable and requires a smaller employment of time in comparison to that necessary for the detection of possible risks for health through epidemiological studies, thus it can be thought as a first motor (and justification) for the request of reclamation and preventive actions. Moreover it can be considered as a sound justification for the employment of resources in epidemiological studies as part of the same practice of prevention.

Environmental inequity represents, therefore, in itself, a first sufficient reason to increase rapid and effective interventions of maintenance and reclamation of the territory. But, as we have already said, in motivating interventions of maintenance or reclamation of a territory on the basis of this kind of evaluations, one is at the same time offering a valid justification for the investment of resources for a suitable epidemiological environmental search, that becomes part of the preventive action or of the same reclamation.

There is, in fact, a wide agreement between those who are involved in environmental rehabilitation about the fact that the estimate of health risk can be inferred through the application of appropriate models beginning from the data related to the contamination of the environmental matrixes. Therefore in general terms, there are no reasons for justifying the deferment of the interventions of environmental improvement on the basis of the absence of clear epidemiological data.

The question should be formulated in a different mode. Epidemiological studies are in fact needed, as they offer and added value under two different aspects, even it is not necessary to wait for their results to start a preventive action.

First of all, beyond a function of confirmation of the expected estimates (developed in the above mentioned broader way), specific studies in environmental epidemiology can detect previously underestimated adverse effects or effects not anticipated or predictable. Secondly, if the epidemiological investigation leans on a protocol that assures it enough specificity, it can put in evidence causal connections among particular exposures and defined diseases, thus allowing more specific kinds of interventions or to the possibility to individuate priorities for intervention and an optimization of resources.

FURTHER CONSIDERATIONS ON NATIONAL REGULATION

Italian national regulation concerning the criteria of priorities in the identification of reclamation's areas deserves a comment regarding its relationship with the issue of environmental equity.

The Italian regulation requires consideration of the following issues: economic impact caused by pollution; the compromising of all environmental matrixes (ground, water, air); the evidence (adequately evaluated) of a potential health risk; the perception of risk by the local population (determined by historical-social or environmental reasons, regardless the actual health risk factor) [26].

These issues overlap with those of environmental equity at least for what concerns: 1) socio-economic impact; 2) alterations of the environmental matrices. Considerations in environmental equity stem in fact from both sets of issues.

These factors, in addition to be the consequence of process with a strong environmental impact, can contribute to the impairment of the health and welfare of individual and/or community, but do not necessarily constitute a specific and imminent sanitary risk [27].

The socio-economic impact should be evaluated with attention. Changes in a given area can restrict the development of an economy based on tourism and favour automated systems with a low absorption of manpower, which can lead to conflicts within the local community. This conflict will see a contrast between the need for workplaces and the worsening of the quality of life.

In this context, investments in the maintenance and recovery of territory, as well as new technologies directed to reduce and/or to eliminate pollution, are a way to increase the occupation and to favour economy. Moreover, in a reclaimed territory, the cohabitation of two different types of local economy becomes possible: one aiming at the reduction and the introduction of techniques of low environmental impact, the other developing around tourism. Such a condition would allow the preservation and restoration of the local environmental patrimony (including all the environmental matrices and the whole production agricultural-food that follows).

Thus, considerations of environmental equity and criteria stated by the Italian Regulation go in the same direction for what concern setting priorities.

A different issue derives, instead, from the 18th article of the decree quoted above, *i.e.* that concerning an elevated perception of risk by the community as a factor to be considered in setting the priorities of intervention in polluted sites. The acknowledgment of the importance of risk perception by the community (regardless the real presence of the same risk) suggests thoughts about the origins of the idea of precaution that has structured and developed the homonym principle. Concept of precaution, in fact, develops from common sense, that is from the ability of a single or a community to perceive the risk and from the feeling of the necessity to act with the purpose of preventing such a risk. Of course, it implies an evaluation of the immediate benefits and future costs, but always maintaining a priority for human health (in dubio, pro salute) [28]. So, the perceived risk may be an alarm bell triggering prevention, which includes and asks first of all for an accurate

assessment of risk by the community and authorities.

As it has been said, we are not suggesting that the precautionary principle's application and the analysis of the possible risk should be interpreted as an obstacle to the technological development, but we notice the possibility that the same technological development foresees precaution as a constitutive elements [29].

Finally, the latter considerations about the perception of risk suggest further thoughts about the importance of the relationship between epidemiologists and local communities during the studies. Such a relationship may bring to a better reciprocal understanding of the perceptions and demands of the population which lives in an area, contributing therefore to the acquisition of a more complete vision of the situation that will help the researcher and will improve evaluations and decisions about land reclamation.

In conclusion, ethical issues in research and activities concerning the relationship between environment and human health require an interdisciplinary effort which should be able to identify the many faces of the complex relationship between environment and human beings and therefore between environment and health.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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