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Questioning the concept of risk in ethical guidelines for research in the humanities and social sciences in Public Health

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Abstract *This article discusses the use of the concept of risk in ethical guidelines directed to research in the humanities and social sciences (CHS), suggesting an alternative to that concept. In Public Health field (PH), risk assumes a peculiar semantics, closely linked to the idea of calculation and predictability, according to the disciplinary bases that support it. This circumstance makes incongruous its use in initiatives justified precisely by strong distinctions between biomedical and social research, as ilustrated by specific guidelines for CHS, especially to the qualitative approach. The authors do not seek to redefine risk, operating a conceptual transit, but to sustain an effective conceptual distance within these specific guidelines, keeping congruence with the objectives pursued by its construction. Taking risk in the quantitative sense, still hegemonic in PH, overlooks important dimensions, reifying the use of this concept in situations where uncertainty, unpredictability, intersubjectivity inherent to the processes beyond the calculation and measurement, as in the case of a significant portion of the research in CHS. Alternatively, it is suggested to replace the expression level of risk, as also appears in Brazilian resolutions.*

Key words *Ethical, Health research, Public health*

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Introduction

This paper stems from a discomfort facing the use of the term/concept *risk* in the context of specific resolutions for research in the humanities and social sciences in health (collective health), given that this is the foundation of qualitative health research focus. Such discomfort emerged throughout the process, still in progress, to build a specific resolution for research in Humanities and Social Sciences (CHS) health, complementary to 466/12, under the responsibility of the Working Group (WG) CHS, created within CONEP, in 2013, in which I have been acting as a representative of one of the 18 invited organizations. I manifested about this feeling in one of the first meetings of the group, and experienced it at various times, among other reasons, due to my inclusion in the Public Health field, in which, unlike other disciplinary fields of CHS, this concept has a central place.

The concept of field is being employed in this article according to the theory of social fields of Pierre Bourdieu in which field designates a space of struggle competition in which what is at stake are the monopoly of scientific authority [...] and scientific competence [...] socially determined[1]. As widely documented in literature[2-5] such a field is constituted by three *core areas of knowledge*[5] or spaces and *different disciplinary formations*[2] – Epidemiology; Humanities and Social Sciences; Policy, Planning and Management. This internal differentiation in the field causes an epistemological tension, especially between the epidemiological and qualitative approaches, the latter based on the conceptual theoretical framework of Humanities and Social Sciences. Thus, and in a unique way, or much more noticeable than in other fields, the concept of *risk* as we shall see later, takes in SC a peculiar semantics. This becomes problematic and somewhat makes incongruous its use in initiatives justified precisely by striking distinctions between the modalities of biomedical and social research in this field. Demand for building a specific resolution for research on CHS, largely referred to health qualitative research, is an example of this type of initiative.

Resorting to an analogy, the employment of risk in our discussions had been causing a kind of "noise", rather a "groove" like a grain of sand in the oyster in the witty metaphor of Rubem Alves[6]: *The creative act, whether in science or art, always arises from pain. There is no need to be a painful pain. Sometimes the pain appears like that itch that has the name of curiosity*.

Indeed, an "itch". This itch led me to embrace the challenge of questioning and even dare to seek alternatives to the use of this concept in an attempt to replace it in the text we had been building collectively. Not a simple challenge, as is often the case in reflective exercises, whose result, in the case, is still precarious and is expressed in this small contribution. I present it with the reservation that it represents a modest grant, aimed to stimulate the identification of a category that, without semantic loss, can present onto-epistemological congruence higher than that suggested by the concept whose use is questioned here.

I note that, for the purposes for which this article proposes, I summarized my argument as much as I could, aiming at only encouraging the specific discussion concerning the tensions that the use of the term entails (eg. in the expression *potential risk* that we continue incorporating in our discourse about ethics on research within the CHS interchangeably) and, in an exploratory manner, we propose, finally, a term/alternative concept. Therefore, I will start by recovering central elements in discussions about the concept of risk, pointing the meanings that it assumes in different disciplines, so that, in the sequence, we "risk" its replacement.

Indeed, this is not about seeking a redefinition of risk, operating a conceptual transit in contrast to dense work whose purpose was this questioning. It is an attempt, more radical, to support an effective distance to the concept, with epistemological and methodological consequences that seem to me consistent with the efforts made by the WG in charge of building a specific resolution by the CONEP. Effort corresponding to the complex task of designing new guidelines, different from those that guide health research, based on the model of biomedical and quantitative tradition. Thus, the latter route mentioned - concept distance, it sounded more "efficient" than the first, given the significant risk of force in the field of public health, an aspect that probably would remain operating, even if we could offer new meanings, more specific, in order to distinguish it from common use. More than that, marking a separation has the added advantage to illustrate with another example, the epistemological discontinuity that demands the effort toward a specific resolution and encourages great part of the undertaking performed by this GT.

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***Risk*: What do we mean?**

A first consideration to be made to open this topic is the realization of the existence of vast literature covering not only efforts aimed to define risk, but a rich discussion of the intrinsic difficulties with the concept, both within and out of CHS. The review carried out, it is worth recalling, preliminary and not exhaustive, due to the requests and limits of this exercise, retrieves a set of elements that we will try to summarize briefly. Let us begin, then, with a definition list using the following sources / most common authors.

In the Dictionary Houaiss of Portuguese[7], *risco*, from latim *risicu/riscu*, refers to:

1) *probability* of danger, usually with physical threat to man and/or environment [...] 2) *p. ext*. *probability* of failure in a particular enterprise, due to casual happening, uncertain, whose occurrence does not depend exclusively on the willingness of interested parties [...]. (words highlighted by me)

However, the Dictionary of Social Sciences of Getulio Vargas Foundation[8] inserts next to the entry risk, the complement "(and uncertainty)", defining risk, but placing it, ahead, on the interface with uncertainty. Despite such development, which certainly brings the concept of congruent readings with the uncertain and unpredictable nature of research in CHS, risk is also marked as:

"[...] b) a condition characterized by *knowledge of the parameters of a probability distribution* on a set of alternative events " (words highlighted by me)

Several other dictionaries were consulted in the fields of Philosophy; Sociology; Communication; Psychology, without location of the entry. In the Larousse Dictionary of Portuguese[9], I have located *risk* defined as: "1) possibility of occurrence" linked therefore more to uncertainty than estimated probability. I also found in Ferreira[10]: 1. Danger or possibility of danger.

Thus, and confirming what Areosa[11] claims, "the *risk* concept takes us both to probabilities and possibilities of occurrence of future events, arising from the various dynamics of the social world." According to him, assuming a categorization somewhat "simplistic", we might consider risk under two different points of view: quantifiable, based on occurrence probabilities and not quantifiable, admitting a high level of uncertainty[11]. Therefore, examining the concept, we observe a polarization that, in one of its aspects, not quantifiable, would fit the specific resolutions to qualitative research (or CHS), except - and that caveat is what moves this reflection – for the hermeneutical necessity of considering the context in which that concept moves, especially when it comes to the proposition of guidelines to be operationalized by an agency linked to the field of Health, the National Health Council. What would be the hegemonic prospect of risk in (collective) health, then? Would it be congruent with guidelines aimed at CHS and, in this scope, at qualitative research?

Notwithstanding the possibilities marked by Areosa[11], the answer to this question leads us to the observation of Neves and Jeolás[12] as for the movement/conservation concept in a relatively small domain restricted to a few *hard* spheres, thus linked to quantitative tradition, also pointing to the "inoculation "operated by the health sciences," [...] With regard to the Social Sciences, the risk theme was (is) quite connected to the Health Sciences, in our country. *Despite countless attempts to approach these two areas, the difficulties of research and debates on that interface are very large.* (my emphasis). In the specific field of Public Health, such circumscription refers to the domain of epidemiology.

Indeed, passing to the field of SC, which interests us here more closely and, more specifically, to the hard core (Epidemiology), it becomes evident, as I have already alluded to, that risk is a central concept. For modern epidemiology, the concept of risk is a key element, enabling to this course not only the study of transmissible and not transmissible diseases, but a significant expansion of its object of study[13]. Scrutinizing the literature in this domain in order to add to the definitions presented above many others conceived by authors considered classic in the field, numerous texts are located, roughly converging way to what prevails in the definitions already provided. Let us look at some:

Almeida-Filho[14], on the work *Epidemiology without numbers*, marks risk as "the *probability* that a member of a defined population develops a disease in a given time period." (emphasis added by us)

In the work *About the Risk*, by José Ricardo Ayres[15], a classic text on the subject in the field of public health, the author confirms our understanding of the concept of risk corresponding to: "[...] *probabilistic chances* of susceptibility, attributable to any individual in individualized population groups, defined according to the exposition to agents (aggressors or protectors) of technical or scientific interest "(emphasis added by us). By extension, the construction *risk fac-*

tors in investigations "[...] *makes use of stochastic and probabilistic procedures*, that is, by characterizing a phenomenon of health and disease, it describes the affected populations according to certain characteristics whose *probabilistic association with the disease* under study seem relevant. Population subgroups are defined and there is an attempt to identify *regular probabilistic and statistically significant associations* between such groups and the disease under study".[16] (emphasis added by me)

According to Guivant[17], also in agencies definitions such as the *Environmental Protection Agency* (EPA); *Food and Drug Administration* (FDA) and *Occupational Safety and Health Administration* (OOSHA) risk is "regarded as an adverse event, an activity, a physical attribute, with certain *objective probabilities* of causing damage, and *can be estimated using statistical calculations* of levels of acceptability which allow to establish standards through various methods [...]". (emphasis added by me)

What do these definitions have in common?

Exploring quickly the definitions with which we, very briefly, illustrate this semantic analysis on how risk is understood in the field of health (collective), and which is reiterated in vast literature, it becomes evident there has been a preponderance of the idea of calculation and predictability, according to the highlights/emphasis placed on content analysis of the selected definitions, we reiterate, with no claim to an exhaustive exercise, although "representative". As emphasized in the literature, it is observed, as in the other "hard" subjects (hard sciences), which, for the Epidemiology, hard core of public health, as alluded to, still hegemonic in the epistemological configuration of the field, the concept of risk values precision, accuracy and predictability, involving calculations and probabilities, according to their disciplinary bases (especially mathematics and (bio) statistics). The concept of risk has obtained legitimacy in several areas and the field of health is not an exception, precisely because it acquires a scientific coat, according to the canons of modern scientific rationality, guaranteed by the claim of "truth" supported by accurate calculations, increasingly sophisticated, aiming not only to meet, but to play/control the phenomena with which it associates[18].

As Ayres[19] argues in his article *Epidemiology, health promotion and the risk paradox*, among "the first traces which permit identify the discursive character, proper of Epidemiology, among health speeches" one is "quantitative variation as a language that most authentically expressed the ability to seize and intervene in collective phenomena and their technical control".

Rodrigues da Silva[20], discussing the evolution of Epidemiology, indicates that epidemiology of risk factors is the contemporary hegemonic model, allowing, among other advances, to leverage studies related to chronic degenerative diseases. This model rests on the foundations of quantitative tradition, more precisely, in empiricism that resonates in the biomedical model, to which our efforts are directed to build ethical provisions more congruent with the field of CHS. Here we retake an important warning from Guilam[13]: *Modern epidemiologists, when trying to theoretically think their discipline, seem to retake the empiricist thought, which could be summarized by the aphorism of John Locke:. 'No direct measurement, no basic concept'[21]. This statement brings explicitly the question that only what is measurable is susceptible to scientific treatment*. Assertion according to the author[13], confirmed by Rothman, author of the well-known text Modern Epidemiology (1986) which gives primacy to the empiricist tradition stating: "When you can measure what you refer to, ... then you will know something about it"[22]".

In the same direction, Minayo et al.[23] argue: "[...] the confusion between science and quantification in the field of Epidemiology, is not a privilege of this subject. The positivistic statistical approach was equally privileged from the classic works of Durkheim, especially in Rules of sociological method [...] and come to the present social analysts, here and elsewhere".

Almeida Filho[14], commenting on the influence of Geenwood, first professor of Epidemiology at London School, says he was responsible for the introduction of statistical reasoning in epidemiology, rejecting the comprehensive nature of the investigations.

Circumstances are established, therefore, that still stand nowadays in the debate pertaining to research in health, and by extension, to the resolutions operating in ethics committees, as we have witnessed in the collective work developed with CONEP.

Areosa[11], in the article R*isk in social sciences: a critical view of the dominant paradigm* (2010), introduces an important note which is worth quoting:

As probabilistic assessment object, risk is a mathematical expression that varies between the

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range of 0.0 (occurrence impossibility) and 1.0 (occurrence certainty), excluding both those values. [...] *Currently, the probabilistic concept of risk is the subject of considerable criticism, both for its improper application in certain situations and for the biased use that some experts confer to it*. He concludes with a timely warning by Granjo[24]: *As much as any risk analyst knows that the theory of probability does not intend to make predictions about each individual occurrence, but on a very high number of repetitions of occurrences (as a very likely event may never take place, while another one with very low probability may occur at the first opportunity), it is not in this modest and abstract perspective that applications of this theory are presented to the 'general' public, or are erected before it on a rational basis for choice-making*.

CHS posture on public health: why is the concept problematic?

From the 80s, the risks problem has constituted a central object in social theory. Acting, and I can say, carrying the conformation of what is now known as Public Health, I have been witnessing, in that same period, alongside the widespread use of the concept, a criticism to it and to epidemiology of risk factors within Epidemiology, although restricted to a small portion of the epidemiological literature. Criticism which appears in a major production, worth mentioning that it is based on CHS benchmarks, following the movement of the concept in this field. In this context, the vigorous analyzes of authors such as José Ricardo Ayres, Naomar de Almeida-Filho and Luis David Castiel deserve special attention for the relevance and impact in this (sub) field of science, and we cannot help but comment, albeit briefly.

Almeida-Filho[21] advocates that risk factors epidemiology does not account for the complexity surrounding the object health/disease. The author suggests that Epidemiology make use of a new paradigm, which must transcend the limitations of previous paradigms: the modes of transmission and risk factors. In the same direction, Castiel[25] points to a series of limitations of risk factors epidemiology, such limitations that, in the author's view, reveal an epistemological crisis of Epidemiology. On the one hand, the author seems to admit the complexity as a new paradigm (*If we face complexity as characteristic of self-organizing systems, this needs to be considered in epidemiology*). On the other, it suggests that the crisis does not lie in the need of paradigmatic replacement, but the epidemiological spirit, in the Epidemiologist worldview. There would be necessity to establish a new relationship between object and subject, *so as to make the first less elusive and second less obsessive in his or her fruitless effort to control the first*.

Such criticism, developed in the Epidemiology core, advances a dialogue in health in the CHS interface, returning to what we intend to argue here. For that, it is helpful to recover Guilam[13] when he establishes an important contrast between "hard and soft culture", pointing out that: "For social scientists, risk assessments cannot ignore subjective factors (ethical, moral, cultural) that direct the decisions of individuals".

Despite the interdisciplinary dream so often alluded to in the field, it is unnecessary to argue about the dialogue difficulties between the hard and soft cultures, especially for researchers who develop research in CHS health. The "negotiation" work of specific guidelines for research in this tradition reveals, surprisingly, that such goal is still a quite bold utopia in modern times. Thus, I suspect that whatever explanations and reformulations related to the concept of risk, and despite the broad concept in social theory, its role in health (collective) will follow immersed in the precepts that constituted it, in its origin, that is, those of the exact or physical and natural sciences.

Unable to examine the extent of risk analysis in the scope of social theories, it is worth mentioning the importance of the contributions of Ulrich Beck[26] and Anthony Giddens[27,28], who gave new direction to risk analysis, influencing a debate that is unfolding impressively in the work of many authors nowadays. It is not my intention to recover, in this space, the richness of this debate. However, I must at least mention as a synthesis that serves the purposes of this exercise what marks Guivant[17] in her thought-provoking article *The trajectory of risk analysis*: *From the periphery to the center of Social Theory,* in which, as the title announces, she conducts a major review of the subject of risks, especially in view of Beck and Giddens. In this text, the author states that, despite the different theoretical trends present in the debate about risks in the social sciences and the dispersion of arguments, analysis dimensions and other aspects, there is a consensus point: the authors [...] *share criticism to the dominant technical and quantitative analysis of risks for (these) ignore that both the causes of the damage and the magnitude of its consequences are mediated experiences and social interactions* [...].

Therefore, considering risk in its purely quantitative sense, as prevails in SC, leads to neglect of key dimensions, advising against the employment of the concept in situations where uncertainty, unpredictability, the processuality and intersubjectivity inherent to the processes and/or procedures prevent its measurement. It seems to be the case for social research in health, with emphasis on the qualitative tradition, space where the reflection on "risks" moves in the working group where I am now, with the mission to build specific guidelines for this type of research.

Citing Jasanoff[29], Guilam[13] says there is a consensus among the various risk studies on issues such as the following: *the risk assessment is not a scientific process, objective, which can be reduced to a quantitative assessment; facts and figures often intermingle when dealing with high uncertainty matters; cultural factors affect the evaluation that individuals make of risk situations: experts and laymen perceive risk differently* [...].

These two dimensions tend to send us to different paradigms on the approach to the risk theme which met the categorization somewhat "simplistic" suggested by Areosa[11], as alluded to before, but it serves the purposes of this analysis. A first one associated with mathematical and statistical calculations, such as prevails in Epidemiology and, by extension in the health field (collective), while the second one would be closer to some perspectives related to social sciences and humanities, conforming, in the words of Guilam, an "emerging paradigm".

Such a paradigm extends risk analysis beyond the mere measurement with a view to predict, recognizing the increasing complexity of social processes (among which we can situate research processes), encompassing relationships between people and institutions. It is about recognizing the uncertainty (rather than prediction and control) and the open nature that imposes surprises, even when you plan and anticipate steps and procedures. More than that, it imposes constant reflexivity[30,31], to identify new forms of damage, sometimes invisible, subtle, but no less harmful, and the health field is a space that exemplifies this condition:

These new forms of risk, sometimes unobservable until they take effect, are presented as additional difficulties to our understanding, whether by our ignorance about them, either by our lack of experience in dealing with such situations concretely. Certain types of risk are themselves uncharted territory or little known to mankind.

Aerosa[11] reminds us of the dissolution of certainties, giving space to the contingency and uncertainty, defying science and technology, and reminds us that "the more men try to colonize the future, the greater the possibility of causing us surprises".

To conclude: The necessity of another terminology in the area of research in health from CHS perspective

In the brief visit exercised in this text, along with a now classic debate within the core of Epidemiology, started another one, even stronger, towards my epistemological discomfort. The contributions of classic authors on risk analysis in social theory, together with the comments present in various other texts examined here, although meaning to a distant vision of the specific object of which we are concerned (building a resolution), reinforced my initial inclination to postulate the search for the other (s) significant (s) that would allow us to replace the heading "risk" in constructions directed to the scope of CHS, in the health field.

In that direction and after a series of steps taken in the reflective method, I started working with the possibility, more than that, with the feeling of need for the use of another term. By examining a large number of possible classifications, it occurred to me to exercise this replacement with the proposal, I reiterate, by means of illustration, the term "potential harm" rather than "potential risk", as stated in the Draft Resolution on the point we arrived, as it follows.

Contrasting *risk* with *harm*

If risk, under the hard sciences and epidemiological perspective, hegemonic in the health field, refers, as we have seen, to an established meaning linked to occurrence probabilities, speaking, therefore, a quantitative language, founded in empiricism, harmfulness denotes quality, being defined as the "characteristic which is harmful"; it remains, then, to know what harmful designates in order to check for semantic loss in an eventual replacement. From Latin, *nocivus* – refers to what causes damage, which impairs, is harmful, pernicious (as opposed to useful, helpful, advantageous). It corresponds, in most settings to *infesto*, it's bad; damaging[7]. This definition is reiterated

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in other sources consulted[9,10], though, just as risk, the entry does not appear in the specialized dictionaries that were consulted. In addition, it fits precisely into what we want to safeguard with the construction of guidelines.

As noted, harmfulness - term which evidently is only a suggested alternative to foster debate - refers to a feature, rather, a quality; none of the definitions found for this entry makes use of the idea of probabilities, as in the case of "risk". Thus, the language of "qualities" guards onto-epistemological congruence with the qualitative approach, recovering partly what is stated on extensive critical literature on the concept of risk in quantitative terms, from the perspective of CHS. Employing expressions such as potential harm rather than potential or risk level, term that now figures in the Draft and resolutions, would translate the latter concept for the qualitative language without semantic loss.

As an additional advantage, as already alluded to, I conjecture about the "educational" potential by allowing a favorable strangeness to new syntheses, especially considering the strong biomedical audience in the environment of ethical regulations, to illustrate with another conceptual example, the distance and the epistemological ruptures between the biomedical and CHS paradigms. In my oppinion, this goal is included in GT's mission constituted by CONEP and, more than that, as I pointed out early in the beginning, such distances are what justify the construction of a specific resolution, the effort of its operation in Brazil Platform and, above all, its dissemination and consolidation in instances related to the ethical assessment of research on CHS in the country.

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