Scientific basis of ISO standards on biomechanical risk factors

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DRAFT DISCUSSION PAPER

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Introduction

The International Standard Organization (ISO) is an independent, non-governmental, international organization that brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant standards that support innovation and provide solutions to global challenges [ISO 2015]. The main deliverables from ISO are the so-called "ISO Standards", which are prepared by Technical Committees according to a framework protocol [ISO 2017a]. According to ISO, "*A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purposes*". The ISO standards - more than 21,000 are presently available - deal with many unrelated topics, ranging "*from soaps to spacecraft, MP3 to coffee*" [ISO 2017b; ISO 2017c].

Although ISO standards are not conceived as a part of a national or international regulatory process, many countries have developed policies to facilitate, or even enforce, their application. For example, Brazil has recently adopted the ISO ergonomics standards (discussed below) as a regulation. In the European Union, the so-called "New approach to technical harmonization" is based on indirect reference to ISO standards in the EU Directives [ISO 2017d]. As a result, the technical and scientific communities generally consider the application of ISO standards as a good practice. However, ISO standards are actually "*voluntary agreements*" not necessarily developed according to a rigorous scientific process (Behind the scenes - The making of an ISO standard, accessed at the time of this writing at:

http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1550) [ISO 2017e]. Thus, problems might arise when ISO standards are adopted as governmental policy on topics that should be evidence-based.

This is relevant for the Journal readers because some ISO standards cover aspects of the work environment and workplace health and safety. For example, there are ISO standards on protecting workers from hand arm vibration, the design of safety glasses, workplace noise, and so on. If these standards are to be adopted as workplace health and safety policies, they should, to the extent possible, follow an evidence-based scientific approach.

As an example of ISO standards which cover aspects of the work environment and workplace health and safety, the Subcommittee "Anthropometry and biomechanics" (SC3) - part of the ISO Technical Committee 159 Ergonomics (ISO/TC 159/SC3) - prepared 26 published standards among which some recommended occupational limits of exposure to ergonomic risk factors (e.g. ISO 11228-1 presents a risk-assessment model to prevent musculoskeletal disorders among workers lifting and carrying loads [ISO 2000]) [ISO 2017f]. The validation of a risk-assessment method for biomechanical risk factors is essentially a multistep scientific process. At first, rigorous laboratory and epidemiologic studies are conducted and replicated by independent research groups. Then, all available evidence should be systematically evaluated and synthetized through a transparent review process. For instance, the threshold limit values proposed by the ACGIH, to assess the risk of hand/wrist disorders due repetitive/forceful movements, have been evaluated in large prospective studies and many smaller cross-sectional studies, and the findings have been published in international peer-reviewed journals [Harris-Adamson et al. 2015; Violante et al. 2016]; the available studies have been analysed in a systematic review published in a peer-reviewed journal [Kozak et al, 2015]. Furthermore, when multiple options are available for risk assessment methods, the choice of the risk-assessment method to be recommended should be based on systematic comparative evaluations considering both scientific and technical issues [e.g. Takala EP et al. 2010]. Scientists have become concerned by the diffusion of standards that are not the result of a rigorous synthesis of the available scientific evidence. In 2001, Fallentin and colleagues reviewed some technical standards (ISO, CEN) on physical workload and the exposure limits and commented "*…technical standards on ergonomics and physical workloads, for example, CEN (Committee for European Standards) and ISO (International Organization for Standardization) standards, continue to present very specific exposure limits and equations to predict acceptable workloads. Due to limited legal implications, the CEN and ISO standards have been "allowed" to present very specific and rather unsupported limits without much public debate. The question of scientific validity is essential for all researchers involved in the study of work-related musculoskeletal disorders…*" [Fallentin et al. 2001].

An example of the application of a transparent process for reporting of scientific evidence are the widely known and accepted guidelines developed by the EQUATOR network [Chang et al. 2017]. The development of most medical practice guidelines follows this approach using the Appraisal of Guidelines, Research and Evaluation (AGREE) checklist (Brouwers et al. 2016). The AGREE checklist considers key factors that may lead to bias, such as the reporting of members involved in the authorship, the reporting of their competing interests of those members, the methods applied to review the evidence, the methods to formulate recommendations, the external review process, the process for updating the guidelines, and funding sources. This sound approach to scientific evidence is currently a requirement in many fields (evidence-based medicine, evidence-based policy, evidence-based legislation, just to name a few).

To determine the degree to which workplace health and safety related ISO standards followed an evidence-based scientific approach, we applied the AGREE checklist to ISO standards dealing with ergonomic issues (i.e. ISO 11226, 11228-1, 11228-2, and 11228-3) and discuss the possible consequences of the lack of compliance with the AGREE checklist [Brouwers et al, 2016; ISO 2000; ISO 2003; ISO 2007a; ISO 2007b].

Selection of ISO standards for review and the review process

In August 2017, we read the "scope" paragraphs of all ISO documents produced by the subcommittee "Anthropometry and biomechanics" (ISO159/SC3) to identify guidelines on risk assessment methods for occupational biomechanical factors. Published standards (the main deliverable from ISO) were identified along with other types of documents - such as technical reports - as possible sources of additional information. We selected ISO standards 11226 (static postures), 11228-1 (lifting and carrying), 11228-2 (pushing and pulling), and 11228-3 (handling low loads at high frequency) for review, as they cover important biomechanical risk factors in the workplaces. ISO technical report TR 12295 - Application document for International Standards on manual handling (ISO 11228-1, ISO 11228-2 and ISO 11228-3) and evaluation of static working postures (ISO 11226) - and ISO Technical Specification TS 20646 - Ergonomics guidelines for the optimization of musculoskeletal workload - were consulted as further sources of information, as they present additional details on the application of relevant standards. All the consulted documents were defined "in effect" (i.e. published and not withdrawn) by ISO at the time this paper was drafted. These documents are referred to as the "ISO ergonomics standards" in this paper.

AGREE II is a widely used approach for assessing the methodological quality of practice guidelines (Brouwers et al. 2016). The checklist comprises 23 items (each presenting specific reporting criteria) grouped into the following six domains: 1) Scope and purpose; 2) stakeholder

involvement; 3) Rigour of development; 4) Clarity of presentation; 5) Applicability; 6) Editorial independence. The AGREE guidelines are mainly aimed at being applied prospectively during the drafting process of a practical guideline; however, they can also be used retrospectively as a quality assurance step. Of note, the checklist was developed to be sufficiently flexible to fit different contexts, independently from the specific protocols and methods used to support the practical guideline (Brouwers et al. 2016). We *a priori* decided to focus on three out of the six domains of the AGREE checklist (e.g., Domain 2 - Stakeholders involvement, Domain 3 - Rigour of development, and Domain 6 - Editorial independence) as they convey fundamental information on bias and the scientific bases of any practical guideline.

Application of AGREE checklist to ISO ergonomics standards

The compliance of selected ISO ergonomics standards, to three domains of the AGREE checklist, is presented in Table 1. The ISO standards do not fulfil the items of interest. One of the most relevant issues is the absence of information about the subcommittee members (with the exception of the chair): their identity is undisclosed and their scientific profile is not described. Stakeholders' involvement is a cornerstone of ISO procedures [ISO 2017a] and identified as an important criterion on the AGREE checklist, but the involvement of key stakeholders (e.g., labor authorities, companies, ergonomics professionals, knowledgeable scientists) is not clear. One of the potential *caveats* of every risk assessment method is the level of knowledge/expertise necessary to apply it properly and efficiently in a real-world setting [Takala et al, 2010]. The ISO ergonomics standards do not present specific information on this aspect.

Rigour of development of the ISO ergonomics standards

The production of the ISO ergonomics standards differed substantially from the writing of evidence-based practical guidelines. According to the limited information provided in the published documents, the ISO ergonomics standards were not based on a systematic search and appraisal of the available literature. It is not clear why the ISO subcommittee preferred one method of risk assessment over others. For instance, the ISO 11228-3 identified three detailed risk assessment methods for repetitive hand exertions at high frequency, OCRA [Occhipinti and Colombini 1996], ACGIH HAL [ACGIH 2017], and Strain Index [Moore and Garg 1995]), but preferred the OCRA methods without providing a scientific basis or comparison (e.g. intra- and inter-observer reliability, strength of association with MSDs, etc.) even though such comparisons are available in the literature [Takala et al, 2010; Eliasson et al, 2017]. As a result, some statements in ISO 11228-3 appear to be based on personal opinions and are in contrast with scientific evidence from the literature. For

instance, the ISO Standard includes a statement - "*in many epidemiological surveys it (OCRA) has shown itself to be well related with health effects (such as the occurrence of UL-WMSD)*". This statement was not supported by well-designed epidemiological study at the time the ISO Standard was published (2007). Indeed, in 2010, Takala and colleagues noted the absence of longitudinal studies on the association between the OCRA index and the risk of musculoskeletal disorders [Takala et al, 2010]. They also pointed out the absence of studies on the repeatability of the OCRA method [Takala et al, 2010].

The basis for formulating the recommendations of the ISO ergonomics standards did not follow the AGREE criteria. Relevant scientific studies were not evaluated for strengths and weaknesses and assigned a formal grade. Without such a review, it is not possible to establish relative merits or priorities. Also, when dealing with exposure assessment methods, a practical guideline should try to establish achievable goals; the ISO standards do not provide any information on the reduction (or increase) of the risk of musculoskeletal disorders expected for any given level of exposure. Furthermore, statements in the ISO ergonomics standards are not referenced and linked to a scientific study that supports the statement as would be expected in a scientific paper or review. Although ISO standards are not conceived to be part of the scientific literature, the transparency of the creation process would be greatly enhanced if the scientific rationale was presented in a supporting documentation.

A strength of the ISO standard process is the thorough and transparent flow of the updating procedure, such that the users have clear knowledge of the state of the standard writing timeline.

Authorship of the ISO ergonomics standards

Scientific reviews, public health and medical guidelines, and scientific papers are the responsibility of the authors who are clearly identified in the publications. Since the scientific process is an open one, anyone reading the publication can check the competence and bias of the authors by retrieving previously published papers, resumes, institutional information, and so on. In addition, authors of guidelines are required to report any conflict of interest (financial and other interests), which may be related to the issue on which they are writing. Competing interests are a major concern in the scientific community. The ISO standards, on the other hand, do not publish the names and affiliation of the members and their possible conflicts of interest and there is a lack of transparency on funding. There may be advantages for keeping the ISO authorship anonymous. Committee members may change frequently, some people may not participate if their name is publically listed, and independence may be facilitated by hiding the identities. However, this approach is counter to transparency and the recommendations by AGREE.

External review of the ISO ergonomics standards

The ISO ergonomics standards did not undergo an external peer-review by key stakeholders, relevant professional societies, or interested scientists. Therefore, the ISO ergonomics standards should not be considered as widely accepted by these other bodies. All other medical practice guidelines, or public health standards, undergo external reviews as recommended by AGREE. The quality of evidence-based guidelines is enhanced by the review process. The process may not be perfect, but it ensures that scientific endeavors are a self-correcting and self-improving activity. After the publication, it is the scientific community at large who will corroborate (or not) the recommendations of guidelines by direct critique, by independent reanalysis of the same data (thanks to the "open data" initiative), or by new studies. The issue of the quality of public health guidelines is of paramount importance; no one wants effort and resources wasted on a large scale on actions that have dubious public health value. This important external review process is not undertaken during the development of ISO standards.

It is noteworthy that the scientific community has directed relatively little attention to the ISO ergonomics standards. At the time of this writing, PubMed (search string: "11226" AND ISO) identified only three papers which reference the ISO Standard 11226, none of which is a validation study or otherwise provides support to the limits and other recommendations included in the standard. Also, a literature search for articles citing ISO Standards 11228 (search string: "11228" AND ISO) identified only 16 pertinent papers (9 of which originating from the same group of Italian coauthors). Again, none of the retrieved papers is a formal validation study or otherwise provides support to the reference values included in the standard.

Conclusions

There are several methodological aspects that make the ISO process very different from the processes used for developing medical practice guidelines, including public health guidelines. The purpose of public health or medical practice guidelines is to recommend approaches to treatment or prevention of injuries or diseases that are based on systematic and transparent scientific reviews of the literature. An ISO standard has a different purpose, in that it is an effort by a self-identified committee of interested people to agree on "how something should be made" in order to facilitate exchange of goods, services, or other similar endeavors. This is a key distinction between a scientific review on a topic and an ISO standard on the same topic; the former will have to abide by the accepted peer review process for scientific publications and development of recommendations

whereas the latter can use any approach that will suit the purpose, without having to take into account scientific method, evidence or even transparency.

The development of the ISO ergonomics standards reviewed (e.g., 11226, 11228-1, -2, -3) did not involve transparent and evidence-based scientific review processes that are widely used in public health and in the health care field. The names and affiliations of the authors of the ISO standards were not identified (except for the chair) and there was no review of conflicts of interest. It was not evident that critical stakeholders, who will be impacted by the standard (e.g., labor organisations and safety professionals) or even scientific specialists in the field (e.g. research ergonomists and epidemiologists) were represented. The methods used for selecting the recommended force limits and risk assessment tools were not presented. Some risk assessment methods are recommended over others without providing an explanation of the criteria used to differentiate them. Overall, the lack of an evidence-based approach leads us to recommend that the ISO ergonomics standards should not be adopted as policy by companies or governments.

Transparent and scientifically supported methods have been used by national and international organizations to develop work-place health and safety standards. For example, the ACGIH lists the committee members and considers their conflicts of interest. The ACGIH TLVs include published background documentation that reviews the literature and provides a basis for the selection of action limits or threshold limit values. Even with this greater transparency and evidence-based approach, ACGIH declares that the TLVs "*are not developed for use as legal standards and ACGIH does not advocate their use as such*" [ACGIH 2017].

Safety practitioners and regulators might perceive ergonomic standards as highly accurate because most of them include exact formulas to assess the level of exposure or risk [Takala et al, 2010]. However, cutoffs of continuous variable (e.g. times, angles, or loads) are usually based on simple *a priori* classifications; for instance, scores usually range on 0 to 10 and quantitative measures are classified on rough discrete scales. Thus, the formulas are actually based on approximations and their discrimination value may be low. This fact is the obvious consequence of the difficulty to collect highly accurate measures with observational methods and should be clearly acknowledged to avoid an excessive confidence in observational methods due to "false accuracy".

The purpose of this Discussion Paper is not to critique the ISO process, per se, but to clarify that the ISO process is based on the opinions of the subcommittee's participating members and not on evidence-based scientific methods. Therefore, if ISO standards are referenced as an approach for the prevention of work-related injuries or illness, they should be used with caution. As repeated in the ISO documents, ISO standards are intended to be voluntary standards. Mandatory policies

adopted by governments or companies for the prevention of work-place injuries or illness should, instead, be based on evidence-based scientific methods.

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Table 1. Compliance of selected ISO standards (11226, 11228-1, 11228-2, 11228-3, and TR 12296) to specific items relevant to bias from AGREE reporting guidelines (numbering of items corresponds to the AGREE checklist).

Checklist item and description	
Domain 2: Stakeholders Involvement	**Summary of compliance**
4) Group Membership	No information on subcommittee members is provided (e.g., name, expertise, institution, geographical location, role in the standards development, funding, conflict of interest). The names of the current chairperson and secretary of ISO 159/SC 3 are presented on the ISO website with no additional information.
5) Target Population Preferences and Views	Stakeholder engagement is a part of ISO procedures [ISO 2017], but the role of stakeholders in the development of each standard is not described. It is not specified if, and how, feedback from stakeholders were integrated in the standards. Possible stakeholders for ergonomic guidelines are not defined or identified.
6) Target Users	The intended guideline audience (i.e. who should perform the risk assessment) is not described. Instructions on how to apply the risk assessment methods are provided within the standards and in additional technical reports (e.g. TR 12295 [ISO, 2014]).
Domain 3: Rigour of Development	
7) Search Methods	A systematic literature search is not described in the standards. It is not clear if a (systematic) review of available evidence was conducted.
8) Evidence Selection Criteria	Inclusion or exclusion criteria of studies are not described. It is not clear how data were extracted from the original articles.
9) Strengths & Limitations of the Evidence	The review of the studies are not based on a formal or informal appraisal of evidence and bias. The quality of studies referenced are not assessed. Heterogeneity between studies is not evaluated or addressed. The guidelines do not present quantitative information on reliability and validity of risk assessment methods. Internal and external validity is not discussed.
10) Formulation of Recommendations	The methods used to formulate the recommendations is not described. Disagreement among subcommittee members is not presented. It is unclear how disagreement, if present, was handled.

12) Link Between Recommendations and Evidence	There is no process for linking evidence to recommendations (e.g. grade of recommendation based on available evidence/expert opinion). Not all the recommendations are directly supported by referenced studies. Recommendations are not preceded by a summary of evidence.
13) External Review	No process for external review is identified.
14) Updating procedure	The ISO website clearly defines the stages of development (e.g. publication, review, withdrawal) of each standard according to a harmonized coding system (available at https://www.iso.org/stage-codes.html). All the standards are meant to be reviewed or confirmed every five years. All changes to ISO standards are tracked.
Domain 6: Editorial Independence	
22) Funding Body	There is no statement about funding to support subcommittee members.
23) Competing Interests	A competing interests statement of all subcommittee members is not available to the public. It is unclear how competing interests are or might be addressed.