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Reducing waste in nutritional epidemiology: review and perspectives

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We discuss efforts in improving the value of nutrition research. We organised the paper in five research stages: Stage 1: research priority setting; Stage 2: research design, conduct and analysis; Stage 3: research regulation and management; Stage 4: research accessibility and Stage 5: research reporting and publishing. Along the stages of the research cycle, varied initiatives exist to improve the quality and added value of nutrition research. However, efforts are focused on single stages of the research cycle without vision of the research system as a whole. Although research on nutrition research has been limited, it has potential to improve the quality of nutrition research and develop new tools and instruments for this purpose. A comprehensive assessment of the magnitude of research waste in nutrition and consensus on priority actions is needed. The nutrition research community at large needs to have open discussions on the usefulness of these tools and lead suitable efforts to enhance nutrition research across the stages of the research cycle. Capacity building is essential and considerations of nutrition research quality are vital to be integrated in training efforts of nutrition researchers.

Nutrition assessment: Epidemiologic research design: Nutritional sciences

Poor diets are a risk factor for global health and mortality. In 2016, the United Nations General Assembly declared a Decade of Action on Nutrition, which provides an unprecedented momentum to drive concerted action and improve diets and malnutrition in all its forms⁽¹⁾. Nutrition research plays a pivotal role in this process as it provides evidence-based recommendations to guide interventions, policy, practice and rational allocation of resources towards achieving the best possible health outcomes.

However, understanding what constitutes an optimal diet, remains a challenge⁽²⁾. The human diet presents a complex exposure for health with many interacting components⁽³⁾. Furthermore, nutritional epidemiological research relies on different types of study designs including experimental and observational designs, each with important limitations. Well-designed studies powered to assess long-term health outcomes are rare⁽⁴⁾.

Substantial concerns regarding the quality and credibility of nutritional epidemiological research findings have

recently emerged^(5,6). The nutrition science is fraught with concerns about private sector influences in agenda setting, design, implementation of studies and presentation of research findings for commercial interest⁽⁷⁾. Scholars have challenged the conceptual basis and proposed a major overhaul to ensure societal value, credibility and conceptual relevance in the years to come⁽⁸⁾.

In 2014, an assessment of biomedical research described 'research waste' as any research that ignores the needs of any possible user (including patients, practitioners and policy makers) of the research output, as well as research that is conducted in isolation of current evidence (concurrent research and past)⁽⁹⁾. The series scrutinised underlying issues in biomedical research that lead to waste, including poor consideration of existing knowledge and priority of stakeholders, poorly designed and managed research, unethical conduct of research and incomplete or inaccessible research output⁽⁹⁻¹³⁾.

The current paper reviews progress to address waste in nutrition research to date.

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In doing so, it aims to define knowledge gaps and inform wider considerations about the quality of nutrition research. The review is organised according to the research cycle as proposed earlier by Chalmers *et al.*⁽¹⁴⁾ from priority setting to dissemination of research results. After summarising the challenges per research stage, we provide examples of relevant on-going initiatives in nutrition. Table 1 is a concise summary of efforts in nutrition research per research stage.

Stage one: research priority setting

Waste in research can be traced to the earliest stage in the cycle, when priorities on what to study are being set. For research to be relevant, it needs to address the interests of patients, consumers and the wider public. Priority setting is key to ensure research addresses the needs of stakeholders and adds societal value⁽⁹⁾. Amongst others, careful consideration of investment by funders, inclusion of stakeholders and consideration of prior existing knowledge are needed to justify new research efforts.

However, given the wide interest and isolated actors in nutritional epidemiological research, agenda setting is not a panacea⁽³¹⁾. Tools for priority setting exercises have been developed such as the Delphi rounds and the Child Health and Nutrition Research Initiative⁽³²⁾ and provide a structured approach to define priorities in nutrition research using online consultation rounds.

There are ample initiatives that have documented priorities for nutrition research or proposed a formal nutrition research agenda. A recent scoping review identified twenty-seven reported nutrition research priority setting exercises in 2018⁽¹⁸⁾. As an example, Haddad *et al.* proposed a global nutrition research agenda that focuses on creating food systems that foster nutrition rather than feeding populations within the context of Sustainable Development Goals⁽³³⁾.

Concerns have emerged about the transparency and ethics during the priority setting process, in particular related to food industry efforts to influence agenda setting in nutrition research. The processes through which private corporate funding have affected research focus have meanwhile been well described and understood⁽³⁴⁾. For example to direct research efforts towards energy balance and exercise, instead of the effects of sugar⁽³⁵⁾.

Much less focus has been given to transparency and accountability of non-private sector stakeholders that are involved in nutrition research. There is an apparent need for stakeholders, such as funders and researchers to be transparent to ensure accountability and monitoring of commitments. Most of the research priority setting efforts are led by researchers in high-income countries (18). Specific efforts are required to forge equitable relationships with researchers in low- and middle-income countries when setting nutrition research priorities. A review of nutrition research in Africa for instance indicated how research agendas are largely driven by donors or academia in high-income countries (36). In addition, African researchers perceive research findings to be poorly considered by local policy makers and integrated

in action⁽³⁷⁾. Although a partnership was established to support an African-led and evidence-driven research agenda in Africa, the initiative was underfunded and short-lived⁽¹⁵⁾.

Moreover, values that underpin decisions for specific priorities are poorly reported in nutrition priority setting efforts. In accordance with the development of the Research Fairness Initiative to foster fair and responsible actions within global joint research and advances in health⁽³⁸⁾, a tool was developed to ensure transparency and consideration of values when setting research priorities in nutrition⁽¹⁸⁾, which is required to be tested and monitored in the years to come.

Investment in new research should consider the extent to which this research adds value to the existing knowledge. To ensure added value of new studies, knowledge gaps need to be considered, preferably through a systematic review and quality appraisal of evidence⁽⁹⁾. Systematic and mapping reviews are increasingly being used in nutrition research (39). Yet, most systematic reviews have focused on nutrition specific interventions and supplements and curative approaches. The available methods to assess evidence in medicine might not be readily applicable to wider dietary and food system interventions (40). The multisectoral nature of nutrition research presents particular challenges to identify and retrieve relevant papers. To address this, a specific search syntax (or hedge) to retrieve food, diet and nutrition related manuscripts from PubMed is proposed⁽¹⁹⁾. In addition, Cochrane Nutrition was established in 2016 to summarise evidence in nutrition research⁽¹⁶⁾. It presents a collaborative effort for evidence synthesis in nutrition and seeks to develop specific tools and summarise knowledge.

Grading of Recommendations Assessment, Development and Evaluation (GRADE)⁽⁴¹⁾ guidelines, which is a tool to grade the quality of evidence and recommendations in healthcare, are relevant but present challenges for nutrition research. Recently NutriGrade⁽¹⁷⁾ has been proposed as a scoring system to grade the evidence of randomised controlled trial and cohort study nutrition-related meta-analysis. NutriGrade pays specific attention to certain methodological issues related to nutrition research when assessing the meta-evidence of diet-disease relations, i.e. dietary assessment methods, calibration of FFQ, the assessment of diet-associated biomarkers, the limitation of blinding participants and personnel in nutrition research.

Stage two: research design, conduct and analysis

Careful study design, conduct and analysis are cornerstones for sound research. Bias in amendable flaws at this stage, can induce implausible effects. Other issues during the implementation of research include arbitrary choice of methods, analyses and an overemphasis on reporting random extremes⁽¹²⁾.

Available methods to assess dietary exposure have inherent limitations. Food consumption and nutrient intake vary from day-to-day, between and within populations and over the different life cycle stages⁽⁴²⁾.



Table 1. Developed tools to improve the quality of nutritional epidemiological research

Research cycle stages	Developed tools
Stage one: research priority setting	EVIDENT network ⁽¹⁵⁾
	Cochrane Nutrition ⁽¹⁶⁾
	NutriGrade ⁽¹⁷⁾
	Guidance for Transparency When Setting Priorities in Nutrition Research:
	Consideration of Values ⁽¹⁸⁾
	PubMed hedge ⁽¹⁹⁾
Stage two: research design, conduct and analysis	Nutritools website ⁽²⁰⁾
Stage three: research regulation and management	The WHO e-Library of Evidence for Nutrition Actions (eLENA) ⁽²¹⁾
	The WHO Global database on the Implementation of Nutrition Action (GINA)(22)
	NOURISHING framework by the World Cancer Research Fund International (23)
	Conflict of Interest Decision Tool ⁽²⁴⁾
Stage four: addressing inaccessible research	FAO/WHO GIFT Global Individual Food consumption data Tool ⁽²⁵⁾
	Data quality descriptors and ONS ⁽²⁶⁻²⁸⁾
Stage five: reports of biomedical research	STrengthening the Reporting of OBservational studies in Epidemiology-Nutritiona Epidemiology (STROBE-nut) ^(29,30)

Establishing recommended intake and nutrient requirements is equally challenging and large variations prevail between countries⁽⁴³⁾. Most dietary assessment tools rely on memory of the study participants and are hence subject to substantial bias and error⁽³⁾. Furthermore, validated tools need to be carefully considered when assessing diet between specific populations i.e. minority ethnic groups⁽⁴⁴⁾.

The Nutritools website⁽²⁰⁾ hosts numerous existing dietary assessment instruments and tools regarding the strengths and limitations of dietary tools⁽⁴²⁾. The website has a built-in e-library that contains validated assessment tools and facilitates re-use of previous efforts. The best practice guidelines on the websites provide important guidance on crucial prerequisites for study designs, including careful consideration of the objectives and outcomes to be measured. With regard to validation studies for dietary assessment, Serra-Majem *et al.* have previously provided recommendations for dietary validation studies⁽⁴⁵⁾.

Spin i.e. modifications in reported findings that affect and mislead interpretation are unfortunately not uncommon in nutrition research⁽⁴⁶⁾. Thus, careful consideration of the methodological limitations, cost and participant burden, as well as defining and pre-registering of outcomes and exposures are required when establishing nutrition and health associations. Kirkpatrick *et al.* provide an overview of methodological challenges to define dietary outcomes of intervention studies, including application of biomarkers⁽⁴⁷⁾. The Core Outcome Measures in Effectiveness Trials fosters the development of outcomes for trials⁽⁴⁸⁾. To date (November 12, 2018) however, the database contains just a handful of outcomes for diet and nutrition, i.e. on the prevention of obesity and assessment of iron deficiency.

Stage three: research regulation and management

Research regulation and management entails careful consideration regarding the following: the adherence to the choice of an appropriate study design, the rigorous approaches to recruitment and retention of participants, data collection and monitoring, participants' engagement and conflict of interest⁽¹⁰⁾.

Complexity in nutrition research is not limited to the measurement tools and outcome measures. Nutrition research cannot be isolated from its context, i.e. political, religious, cultural, product marketing connotation and laws. Therefore, appropriate regulation and management of nutrition research, should consider this context and any conflicts of interest⁽⁴⁹⁾.

To assess prevailing rules and context, a few resources are available. For instance, the WHO e-Library of Evidence for Nutrition Actions (eLENA)⁽²¹⁾ and the WHO Global database on the Implementation of Nutrition Action (GINA)⁽²²⁾ provide recommendations, policies and legislations on national, regional and international levels. For instance, legislation on food fortification and breast-feeding substitutes in GINA, together with an overview of current evidence on the eLENA platform, provide context and guidance for new research regarding the promotion of appropriate breast-feeding and regulation of breast-milk substitutes.

The World Cancer Research Fund International has recently developed the NOURISHING policy framework, to encourage actions within three essential domains: the food environment (NOURIS), food system (H) and behavioural change communication (ING)⁽²³⁾. The framework is built to support action and research that focus on unhealthy eating.

When it comes to research management and regulation during the data collection, handling and analysis phase, there are specific training guides, procedures manuals and standard operation procedures to harmonise procedures and increase transparency. In clinical studies, institutional review boards request monitoring of data collection and reporting of safety issues⁽⁵⁰⁾.

Appropriate declaration of conflicts of interest (e.g. financial⁽⁵¹⁾ or dietary^(52,53)) is a clear issue in nutrition research and further guidance on how to disclose competing interests is apparent. The WHO has developed a decision-making process as part of an approach for the prevention and management of conflicts of interest in

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the policy development and implementation of nutrition programmes at the country level⁽²⁴⁾.

The need to protect participants involved in nutritional research and to understand the rules concerning the use of data collected during studies has been looked at within the European Nutritional Phenotype Assessment and Data Sharing Initiative project. A set of policies has been centralised for data protection, sharing and re-use as well as ethics and intellectual property according to the legal and ethical aspect of EU countries⁽⁵⁴⁾.

Stage four: addressing inaccessible research

Inaccessibility of research findings can lead to redundant. misguided or potentially harmful decisions. Inaccessibility has different dimensions including language barriers, manuscripts locked behind journals pay walls, inaccessible study data, published in local, non-indexed, journals or grey literature making it irretrievable⁽¹⁵⁾.

Similar to other types of biomedical research, open access publishing has gained popularity in nutrition. Within the Nutrition and Dietetics subject category of the Web of Science for instance, eleven of the eightythree journals publish only open access papers. Most other journals provide options to publish manuscripts under an open access license. Popular repositories for trials such as Clinical Trials⁽⁵⁵⁾, WHO's International Clinical Trials Registry Platform⁽⁵⁶⁾ or systematic reviews such as PROSPERO⁽⁵⁷⁾ include nutrition-related studies.

Capitalising on the existing research data is a promising way to add value to research e.g. through metaanalysis, re-analysis or pooling of data to increase power of (subgroup) analysis. The Global Burden of Disease study⁽⁵⁸⁾, Non-Communicable Disease Risk Factor Collaboration⁽⁵⁹⁾ and the Global Dietary Database⁽⁶⁰⁾, are a few examples that demonstrate how the re-analysis of the existing data can generate new insights into diet, nutrition and human health.

Specific initiatives have emerged to consolidate and share data in diet and nutrition. The FAO/WHO Global Individual Food consumption data Tool (GIFT)⁽²⁵⁾ integrates large and small-scale surveys from countries worldwide and provides a unified database to share the existing food consumption data. Apart from merging food intake data, GIFT shares individual level data where allowed by the data provider. National Information Platforms for Nutrition, piloted in Bangladesh, Ethiopia, Kenya, Laos, Niger and Uganda, are created to collect the existing data and leverage knowledge for nutrition interventions and policies⁽⁶¹⁾. Other options to share both meta and individual study level data, including intervention and mechanistic studies, are provided through the DASH-IN database (62). This database contains study data with a harmonised set of data descriptors.

In addition to more centralised approaches for data sharing. BioSHaRE-EU developed additional applications to share and access epidemiological data in a federated configuration. In this regard, DATASHIELD

provides useful tools to analyse data stored at different locations within ethical and privacy boundaries that apply to the re-use of human data (63)

However, sharing data with several initiatives involves substantial preparations to fit the desired data requirements and templates. Given the variety of developed initiatives, streamlining data preparation would be helpful, in particular the development of a uniform standard for food intake (meta) data.

Standardised approaches to collect, analyse and harmonise dietary intake data are available from the European Food Standard Agency (EFSA)⁽⁶⁴⁾. FoodEx2 provides a vocabulary for disambiguation and correct description of food and its properties⁽⁶⁴⁾. An EFSA data transmission schema has been made available which provides a template to standardise food intake data collected using the EFSA recommendations. However, to identify studies and research data effectively, meta-data should also be accessible, preferably in a harmonised manner to facilitate searches. Many efforts have been made to establish a common set of (meta) data descriptive and facilitate identification, re-use and interpretation. Essential study descriptors were developed earlier that assist researchers to define key study characteristics⁽⁶⁵⁾. In addition, data quality descriptors for nutritional epidemiological research have been recently developed as metadata of nutrition and will support researchers when using the existing data for pooled or secondary analyses⁽²⁶⁾.

Nonetheless, leveraging the power of information science to nutrition research will require further development and applications of ontologies. Ontology is a representation of knowledge networks arranged in a taxonomic hierarchy, where a machine-readable identifier is set for each term in the knowledge network (66). Use of ontologies enables linking and processing of heterogeneous data⁽⁶⁷⁾. Although some progress has been made to represent the systematic classification of diet, food and nutrients⁽²⁷⁾ further efforts are needed to link diet and foods with the corresponding nutritional values.

Stage five: research reporting and publishing

Consequences of incomplete studies or misreporting include reaching erroneous conclusions, failure to include evidence in systematic reviews and inappropriate implementation of interventions⁽¹³⁾. Specific incentives, capacity building efforts and applications are needed to ensure research reports contain all necessary detail for readers to understand what was done and found⁽⁶⁸⁾. Reporting guidelines such as Consolidated Standards Of Reporting Trials for randomised controlled trials (CONSORT)⁽⁶⁹⁾, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)⁽⁷⁰⁾ and Strengthening the Reporting of Observational Studies in Epidemiology for observational studies (STROBE)⁽⁷¹⁾ have been developed as authoritative recommendations to increase reporting completeness. Reporting guidelines are typically applied during the write-up of manuscripts and provide useful tools for





editors and reviewers during the peer review process. The Equator Network centralises reporting guidelines⁽⁷²⁾.

Different systematic reviews have indicated how reporting completeness is also an issue in nutrition research (73–75). As a response, Strengthening the Reporting of Observational studies in Epidemiology-Nutritional Epidemiology (STROBE-nut) (29) was developed for use in nutritional epidemiology and dietary assessment. STROBE-nut aims to incorporate previous guidelines for nutrition research and dietary assessment (74,76–78). The STROBE-nut checklist comprises a set of twenty-four items, organised as a checklist. An explanation and elaboration document was developed and describes good practices with examples (79). To date, most nutrition journals recommend the use of reporting guidelines and those of the BMC Springer Nature group, refer to STROBE-nut in their instructions for authors (80).

In addition to completeness of reporting, clear communication of research findings to non-researchers is essential. Cainzos-Achirica *et al.*⁽⁸¹⁾ have reviewed communication issues and related challenges for nutrition research. Specific recommendations for diverse stakeholders such as authors, journals, press and the general audience are provided. Critical communication of research findings and acknowledgement of limitations is essential, as popular misbeliefs are prevalent⁽⁸²⁾. Unscientific beliefs about nutrition are widely present and more needs to be done to address these in order to restore trust in nutrition science⁽⁸²⁾.

Moving forward and perspectives

The present paper summarises past and on-going efforts to improve the quality and added value of nutrition research. To our knowledge, this is the first attempt to address efforts across the entire research cycle. Several priorities emerged from the present review.

First, despite some useful initiatives, the magnitude of research waste in nutrition has not yet been assessed. Establishing a clear and integrated vision on how to address challenges in nutrition research is required first. Similar to the Lancet series on research waste⁽⁹⁾, a review to quantify the magnitude and prevalence of practices that lead to waste in nutrition research would be useful to guide further action. Meta research or 'research on research' has attracted considerable interest in biomedical sciences⁽⁸³⁾. Although research on nutrition research has been limited, it has the potential to provide useful insights to guide interventions and develop new tools and instruments.

Secondly, reflection on what can be done, and what tools can be used at each stage for different research designs is key. Although several initiatives that can enhance added value of nutrition research have been undertaken, they are focused at single stages of the research cycle without a comprehensive vision on the research system. To address research waste, the intricate linkages between the stages of the research cycle defined earlier, should be acknowledged (Fig. 1). For example, efforts to increase data quality and accessibility cannot

be seen separately from reporting guidelines of manuscripts or considerations about study designs and dietary assessment methods.

Thirdly, the research community at large would eventually need to have open discussions regarding how to implement these tools, and the added value of their implementation. These discussions could drive the intention of further use and govern efforts to enhance nutrition research. The nutrition societies and in particular the International Union of Nutrition Societies would be well placed to drive this process, to establish consensus and coordinate action. Given the vast needs, prioritisation of efforts and agreement on what should be tackled first would be a useful first step. Events organised by the International Congress of Nutrition or national nutrition societies could serve as fora for dissemination and consensus building across the research community.

Fourthly, the activities listed to tackle research waste essentially address the research community. Although this is a useful start, stakeholders such as research funders, journalists, consumer societies, policymakers and publishers ideally need to be involved in this process from the onset. Involving these stakeholders would hopefully set realistic expectations for nutrition research findings. It could potentially improve important drivers of research practices such as resource allocation, and reward systems of staff and students. While we acknowledge that the whole reward system is institutionalised and internationally fixed, which can hinder potential change; the mere recognition of sound and reproducible research instead of quantity of publications and journal impact factor would be a valuable step forward.

Sound knowledge as well as a critical attitude towards dietary assessment methods and nutrition study designs are needed to foster credible findings. Specific training efforts can support the development of essential competencies for nutrition action in different professions, i.e. nutritionist, dietitians, medical doctors, food safety and technology experts, etc. To date however, it remains unclear to what extent training in research integrity and waste is incorporated and discussed in training programmes and curricula in nutrition. Additional efforts will be required to integrate critical reflection about quality and limitations of nutrition research in curricula at BSc, MSc and PhD level. In service training or online guidance would be useful for other professionals dealing with nutrition research such as journalists, dietitians and medical doctors.

In 2011, the World Public Health Nutrition Association for Public Health Nutrition has developed the competency standards of workforce⁽⁸⁴⁾, which contains considerations about the use and appraisal of nutrition research findings. This framework deserves renewed attention and enforcement within the context of the Sustainable Development Goals and the Decade of Action on Nutrition. Geographic areas with the highest burden are unfortunately those with the weakest capacity (i.e. institutional capability and geographic coverage of workforce) to act⁽⁸⁵⁾. Progress about curricula, capacity development and competency standards however, has been overall limited⁽⁸⁶⁾.

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Although several countries including African countries have developed nutrition-training programmes worldwide, it remains unclear which competencies are taken up and where gaps remain. A review of how current nutrition training programmes contain considerations about ethics and research integrity would be useful to guide further action. In addition, a consultative process is needed to guide discussion on the required competencies for nutrition professionals with regard to the conduct and interpretation of nutrition research findings.

Discussions on how to add value to nutrition research are timely with regard to the renewed commitment by the African Union Commission to end hunger by 2025⁽⁸⁷⁾ and the commitment of various African countries to scale up nutrition action⁽⁸⁸⁾. Well-targeted programmes to improve nutrition demand context-specific and high-quality evidence. Against a backdrop of increasing research output of nutrition research, the growing African nutrition research community would be well placed to develop an African nutrition research agenda and define priorities for cost-effective research and interventions in the decades to come.

Furthermore, and in line with the recommendations proposed by Al-Shahi Salman *et al.*⁽¹⁰⁾ research is still needed to look into, participants' protection when nutritional epidemiological studies are conducted and consumers' ability of understanding the provided scientific evidence, and engaging in the transition of science into public policy.

Overall, monitoring activities on the effectiveness of approaches will be needed, and collecting more feedback from researchers is key to understand how useful these tools are. It is not unimaginable that efforts to improve quality of nutrition research will result in an additional burden for researchers potentially affecting those already engaged with good research practices, and possibly leaving the problem unsolved. Care should be taken to minimise the burden on the user. A good example in this regard is the additional efforts imposed on authors to fill in reporting guidelines⁽⁸⁹⁾. The potential of applying new technology to increase the efficiency of a search and the quality of the output is substantial⁽⁹⁾. Ultimately, long-term success and adherence to the use of reporting guidelines and tools for better research will depend on how well they are integrated into the digital ecosystem of software and day-to-day practices of researchers⁽⁸⁹⁾. For example, ontologies for nutrition could be used to connect data collection and sharing tools. Efforts related to fair data sharing need to be incorporated at multiple stages of the cycle to increase efficiency of information sharing, retrieval and integration. Links with other ontologies such as the Cochrane PICO ontology⁽⁹⁰⁾ need to be fostered for this purpose.

The present review relied on published work only. We were unable to collect potentially interesting experiences from research groups and institutions that promote integrity and good research practices. Sharing those lessons learned and documenting good practices would be a useful step forward. This review did not attempt to be exhaustive and we cannot rule out missing some initiatives or manuscripts. In addition, the present review

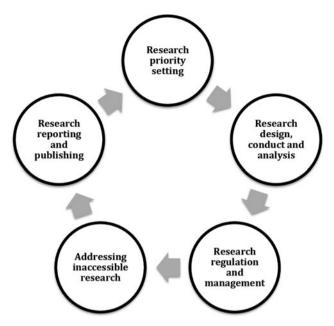


Fig. 1. Integrated view of tackling waste in nutritional epidemiological research.

mainly considered nutritional epidemiological research. Although there are potentially similar issues in clinical nutrition and more food science-oriented research, the present focus aims to present a timely contribution to the discussion and criticisms about nutritional epidemiology.

We consider the comprehensive approach proposed in this review a useful first attempt to map existing efforts. Within the next months, we will establish a portal on initiatives to add value to nutrition research. A specific website (www.betternutritionresearch.ugent.be) will be created for this purpose and act as a portal for researchers and other stakeholders of nutrition research looking for instruments to improve quality for nutrition research and a resource for educational purposes. We welcome contributions, new efforts and other additions to complete our assessment.

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Conflict of Interest

The authors have led work for nutritional epidemiology cited in this manuscript.

Authorship

The authors had joint responsibility for all aspects of preparation of this paper.

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