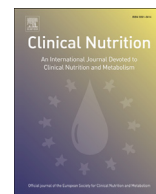




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Original article

Patient needs and research priorities in the enteral nutrition market – A quantitative prioritization analysis

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SUMMARY

Background & aims: A quantitative systematic identification and prioritization of unmet needs and research opportunities in relation to enteral nutrition was conducted by means of a tailor-made health research prioritization process.

Methods: The research objectives were reached by conducting qualitative interviews followed by quantitative questionnaires targeting enteral nutrition key opinion leaders (KOLs). (1) Define disease areas that deserve more research attention; (2) Rank importance of product characteristics of tube feeding (TF) and oral nutritional supplements (ONS); (3) Assess involvement of KOLs in enteral nutrition R&D process. KOLs ranked three product characteristics and three disease areas that deserve additional research attention. From these, overall priority scores were calculated by multiplying ranks for both product characteristics and disease areas.

Results: 17 qualitative interviews were conducted and 77 questionnaires (response rate 35%) were completed and returned. (1) Disease areas in ONS and TF with highest priorities are: ONS: *general malnutrition & geriatrics*, TF: *intensive care*. (2) TF product characteristics with highest priorities are: composition and clinical evidence from a KOL perspective; tolerance and ease of use from a patient perspective. ONS product characteristics with highest priorities are: composition, clinical evidence and taste from a KOL perspective; taste from a patient perspective. We find a high discrepancy between product characteristic prioritization from a KOL and patient perspective. (3) Although 62% of all KOLs give advice to enteral nutrition companies on patient needs, they under-influence the setting of research priorities by enteral nutrition companies.

Conclusions: This study provides a systematic approach to achieve research prioritization in enteral nutrition. In addition to providing new directions for enteral nutrition research and development, this study highlights the relevance of involving KOLs in the identification of research priorities as they have the ability to provide a balanced view of the unmet patient needs.

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1. Introduction

The health and life science industry, which is an important driver of the health care sector, revolves around addressing unmet medical needs. A medical need is defined as the fundamentals required to sustain a healthy individual.¹ To achieve optimal health services, policies and strategies from a public health perspective but also from a health care industry perspective, it is necessary to

Non-standard abbreviations: EN, enteral nutrition; ENHA, European Nutrition for Health Alliance; ESPEN, European Society for Clinical Nutrition; HRP, Health Research Prioritization; KOLs, key opinion leaders; MD, medical doctor; MNI, medical nutrition industry; ONS, oral nutritional supplements; TF, tube feeding.

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identify and prioritize medical needs, thereby functioning as the basis for research priorities. Unfortunately, there is limited knowledge of patient needs and priorities. As a result, there is often a mismatch between research driven by the interests of scientists, funders and powerful interest groups and the health needs of the population.

The enteral nutrition (EN) market targets patients that require nutritional support to prevent or treat malnutrition or alleviate and manage symptoms of specific medical conditions. Through advancements in the fundamental knowledge of human bodily functions, a wide range of EN products are now available for several (previously unmet) medical needs/conditions. These products are prescribed by medical professionals for the nutritional support of patients in the dietary management of diseases. With 33 million people at risk of malnutrition throughout Europe, the development of specific and targeted EN products is crucial.² Although awareness concerning the importance and effectiveness of EN is growing,³ there are still numerous unmet medical needs that need to be addressed, at the interface between pharma and food, by the EN industry.

Unmet medical needs can be fulfilled through 'market pull' strategy, where the unmet medical need functions as the innovation opportunity input. The first step is to assess these unmet medical needs by means of a so-called needs assessment. This allows for the accurate evaluation of health related patient needs and may eventually function as innovation opportunity input for the EN industry.^{4,5} The assessment of patient needs leads to the understanding of patient experiences and addresses which needs should be prioritized to improve the quality of care.^{6,7} The identification of patient needs is an essential success factor in the complex process of product development and innovation.^{8–10} Products are more likely to be successful when built around customer needs as opposed to only addressing technological opportunities.⁸ Need assessment can be performed by means of health research prioritization (HRP) and may provide directions for future resource allocation and strategic planning at institutional, regional, national as well as international level.¹¹

Although, during the past decades, an unprecedented number of innovations have had great clinical impact on the prevalence and treatment of disease-related malnutrition, an overview of unmet patient needs with priorities is lacking within the EN market. Considering the widespread prevalence and adverse consequences of malnutrition and the effectiveness of EN, such an overview would contribute to both fulfilling the unmet patient needs as well as the exploitation of commercial innovation opportunities.¹² Therefore, the aim of this research was to assess unmet patient needs and research priorities in the EN market by means of quantitative questionnaires targeting EN key opinion leaders (KOLs).

1.1. Health research prioritization

HRP processes assist researchers, policymakers and industry in effectively targeting research that is needed most.¹³ In addition, HRP stimulates to evaluate health research and to identify its strengths, weaknesses, gaps and opportunities.¹⁴ Setting successful research priorities is complex, because choosing between priorities creates ethical equipoise.¹⁵ Nevertheless, the efficacy of setting prioritization has previously been demonstrated by various research groups.^{14,16,17} The aim of prioritization is to develop a relative ranking list rather than to define an absolute cut-off beyond which diseases are not considered important.¹⁸

Several extensively tested and comprehensive approaches to HRP are available to guide researchers in setting their research priorities.^{13,19} Nevertheless, it has proven impossible to set a golden standard/best practice in HRP since the context of priority setting

varies per case.¹³ Therefore, researchers develop their own unique research prioritization method based on an existing HRP method but adapted to their subject and research goal. A tailored prioritization was developed for this research to rank patient needs in the EN market in order to uncover research priority insights and innovation opportunities. EN patient needs exist at different levels. Our focus lies on assessing which disease areas require research attention but also which product characteristics require improvement. The research methodology was predominantly based on a prioritization research described by Balabanova et al. who developed a prioritization method to establish strategic priorities for the German national public health institute concerning infectious pathogens.¹¹ Their research solely focused on the prioritization of infectious diseases in Germany. In our research, this method was extended by prioritizing both EN related disease areas but also the EN product characteristics. The aim of the research described here was to identify and prioritize unmet patient needs (disease areas and product characteristics) and research opportunities in the EN market by means of quantitative questionnaires targeting EN KOLs. This research also aimed to evaluate the opinions of the KOLs on their current involvement in EN research and research prioritization efforts. The objectives of this research are as follows:

1. To determine the unmet needs and research priorities in the EN market by means of health research prioritization:
 - 1.1. To assess the disease areas that require more research attention in the EN market;
 - 1.2. To assess which product characteristics have the highest priority in EN development.
2. To evaluate the degree of involvement of KOLs in the EN R&D process from a KOL perspective.

2. Methodology

The prioritization process was based on previously used prioritization methods^{11,13} and adapted to assess EN unmet patient needs and research priorities. The multi-staged prioritization process started with the compilation of a list of disease areas and product characteristics of EN by means of qualitative exploratory interviews. This was followed by the development of evaluation criteria, weighting of the criteria and ranking of the disease areas and product characteristics by means of an online questionnaire.¹¹ This research also aimed to evaluate the opinions of the KOLs on their current involvement in EN research and research prioritization efforts.

2.1. Study subject

Since patients do not have direct experience with more than a subset of innovations and generally only one disease area, KOLs were approached. Two-hundred-twenty KOLs with extensive EN knowledge (practicing MD, dieticians, nurses, researchers, professors, lecturers, and consultants) of the European Society for Clinical Nutrition (ESPEN) faculty were invited to participate in an email-survey. The aim of the survey was to investigate patient needs in the EN market. The anonymous online survey was created and distributed through the online web survey program Survey-Monkey. KOLs that did not respond to the initial survey received a follow up reminder e-mail 1.5 weeks later to increase response rates.

2.2. Exploratory interviews

A set of questions was pretested by means of 17 exploratory pilot interviews with KOLs, in order to validate the survey tool as

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