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# Systematic Development of National Guidelines for Obesity Care: The Swedish Approach

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#### **Keywords**

Adult · Bariatric surgery · Child · Disease management · GRADE approach · Guideline · Health care · Obesity · Policy · Quality indicators

# Abstract

**Introduction:** With the rapid development of treatment modalities for obesity management, there is an increasing demand for guidance to facilitate the prioritization of interventions. In 2020, the Swedish National Board of Health and Welfare started the process of producing the first national guidelines for obesity care directed to decision makers who allocate resources to the best knowledge-based care. The main aim of this paper was to describe the systematic development of these guidelines, designed to guarantee

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This article is licensed under the Creative Commons Attribution 4.0 International License (CC BY) (http://www.karger.com/Services/ OpenAccessLicense). Usage, derivative works and distribution are permitted provided that proper credit is given to the author and the original publisher. uniformly high standards of care throughout the whole country. Methods: The standardized procedures of the National Board of Health and Welfare were applied to construct guidelines in a systematic and transparent way, including priority setting of recommendations and quality indicators to evaluate the progress of implementation. The process involved independent expert committees including professionals and patient representatives, and the guidelines were reviewed through an open public consultation. Results: National guidelines were issued in 2023, encompassing a broad scope, from identification and diagnosis to multiple treatment modalities, embedded in a life-course perspective from pregnancy to the elderly, as well as highlighting the need for improved knowledge and competence of health care providers. Conclusions: National guidelines for improved standard care and evidence-based

Correspondence to: Ylva Trolle Lagerros, ylva.trolle@ki.se and efficient use of health care resources for obesity treatment can be developed in a systematic way with professionals and patient representatives.

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# Introduction

In Sweden, rates of obesity (BMI  $\geq$  30 kg/m<sup>2</sup>) and severe obesity (BMI  $\geq$  35 kg/m<sup>2</sup>) have increased by 86% and 153%, respectively, since 1995 [1]. Currently, 16% of the adult population and 7% of the children (6–9 years) have been classified with obesity according to the Public Health Agency of Sweden [2].

Obesity treatment primarily relies on a multicomponent approach, preferably including simultaneous implementation of dietary changes, leading to a lower energy intake, increased physical activity, and lifestyle or behavioral training. Treatment with pharmacotherapy for weight management and obesity surgery can add further weight loss and health benefits [3].

During the last couple of years, the field of obesity management has experienced a number of scientific breakthroughs in lifestyle interventions [4, 5], pharmacotherapy [6], and surgery [7]. At the same time, increased rates of obesity and obesity-related comorbidities, as well as the improved treatments, have increased the need for continuously updated evidence-based recommendations both among clinicians and decision makers. The first European guidelines on management of obesity in adults were published in 2004 [8] and subsequently updated [9-11]. Guidelines or medical care programs on obesity management are commonly issued by professional societies [12-15] and often aim to target the local context such as national models of obesity health care systems [16, 17]. Currently, a number of guidelines have been updated to reflect the state of the art for certain patient groups, for example, clinical practice guidelines for the treatment of children and adolescents with obesity [18, 19] and indications for metabolic and bariatric surgery [15].

Even though obesity is a major health concern, national Swedish guidelines for obesity care have been lacking. In 2018, health care practitioners, as well as patient representatives, approached the Swedish National Board of Health and Welfare (from here on referred to as "the Board"), requesting guidelines for obesity care. As a response, the Board conducted a needs-and-problem analysis to map and interpret the status of obesity care in Sweden. This standardized process encompasses six criteria (need for national knowledge support, regional treatment differences, unequal health care, high severity of the disease, high prevalence, and high costs) that must be met if a new national guideline should be initiated (online suppl. Table 1; for all online suppl. material, see https://doi.org/10.1159/000536320). All these criteria were met, and in 2020, the Board decided to develop Swedish national guidelines with recommendations for the health care system regarding publicly funded obesity care for both children and adults.

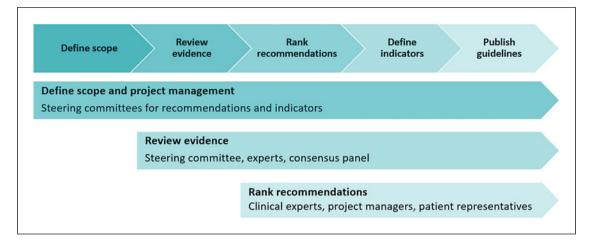
The overall aim with national guidelines is to ensure equal high standard care across the country, by supporting decision makers to allocate resources to the best knowledge-based care and to develop and evaluate health care as well as social services. Health care in Sweden is mainly publicly funded. Both primary and hospital health care is free of charge for children, while adults pay a fee of maximum ~200 EUR/year. Since the health care system is largely decentralized, each region (21 in total) has far-reaching freedom to shape delivery of their health care. This may result in unequal distribution of care. Thus, the main target audiences for guidelines are decision makers such as politicians, civil servants, health care managers, and social services, who oversee their regional resources. Therefore, only treatments that are publicly funded can be prioritized in national guidelines. The national guidelines also serve as a basis for the development of clinical practise guidelines with practical and detailed recommendations for clinicians about evidence-based treatment, regardless of funding source. In this paper, we describe how the first Swedish national guidelines for obesity care for both children and adults, based on scientific evidence and best clinical practice, were developed.

#### **Materials and Methods**

The Board has a standardized process for developing national guidelines. Figure 1 and online supplementary Figure 1 shows an overview of the process which typically takes 2–3 years. Since it was deemed that the need for obesity guidelines was urgent, the Board decided that the first obesity guidelines should be finalized within 1 year. Thus, only the most important questions, where the need for guidance was considered the greatest, were to be included.

Steering Committees

As a first step, two steering committees were formed. One was in charge of the development of the guidelines with recommendations. The other one, of the development of specific quality indicators, with which it would be possible to evaluate quality of care and whether the different regions follow the guidelines or not. The committees consisted of internal scientific experts from



**Fig. 1.** A schematic overview of the process to develop national guidelines from start to first publication, and the experts involved according to the Swedish National Board of Health and Welfare's government documents.

the Board and five independent external experts from different clinical and professional specializations within obesity management (paediatrics, internal medicine, obesity surgery, psychology, and dietetics). The external experts contributed to the entire guideline process, for example, by reviewing the knowledge base and leading the Ranking panel. All members of the Steering Committee were free from conflict of interest, i.e., they did not have any ongoing affiliations with the pharmaceutical industry, neither financial interests, nor business in the field of obesity management.

#### Population and Intervention Pairs

To structure recommendations, we defined populations that should be covered by the guidelines, such as children of different ages and adults with different BMIs, ages, or specific needs. Next, we defined clinically relevant interventions, such as combined lifestyle treatment, pharmacological treatment, and obesity surgery. Populations and interventions were paired together, and from here on, called *Population and intervention pairs* (online suppl. Table 2). An example of a Population and intervention pair was *Adults with obesity* (population) and *Combined lifestyle treatment* (intervention).

#### The PICOS Model to Frame the Question

The next step was to construct a question for each population and intervention pair, and for this purpose, the PICOS model was used. PICOS is an abbreviation for Population, Intervention, Comparison, Outcomes, and Study Design, and is a standardized way to construct questions before scientific evidence is gathered. An example of a PICOS is P: adults with obesity, I: combined lifestyle treatment, C: other or no intervention, O: change in weight related measures or health-related quality of life, leading to the question: "What effect does combined lifestyle treatment have on outcomes related to weight and health related quality of life in adults with obesity, compared to other or no treatment?". The search strategy for this example can be found in online supplementary Table 3.

#### Compiling Scientific Evidence and Best Clinical Practice for Population and Intervention Pairs

In total, 22 PICOS were constructed. A national hearing was held, giving health care professionals, the public, and patient advocacy groups the possibility to comment on or ask for changes concerning the areas that were chosen. As a next step, a literature search was conducted for each PICOS by information specialists. Several databases, such as PubMed, APA PsycInfo, CINAHL, and the Cochrane Library were searched for relevant publications using MeSH terms and free text. All literature searches are published on the Board's website.

Scientific authors were recruited specifically for the review of the identified literature. They were all obesity experts, had a PhD degree and had no conflict of interest. The scientific author assessed the title and the abstract, removed those not matching the PICOS, and read the remaining articles in full text.

Systematic reviews of randomized controlled trials were prioritized, then randomized controlled trials, and if those were not available, non-randomized controlled studies and observational studies were included. Studies without control group were excluded.

The next step involved an assessment of risk of bias following a standardized protocol as described by Cochrane [20]. For systematic reviews, the assessment included an evaluation of the aim, criteria for study selection, data extraction, analysis, and synthesis. For primary studies, it included an evaluation of the randomization, protocol adjustments, attrition, and outcome assessment. For both systematic reviews and primary studies, an assessment of conflict of interest was also made. Studies with very high risk of bias were excluded.

If deemed necessary, a meta-analysis was performed. We used the software RevMan 5.4. Depending on the outcome, different settings were used, according to the principles of Cochranes. The certainty of the evidence was graded for each outcome using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system. GRADE has four levels of certainty. Very low, low, moderate, and high. A very low GRADE rating indicates uncertainty about the true effect; the effect is probably very different from the estimated effect. A low GRADE rating indicates that the true effect might be very different from the estimated effect. A moderate GRADE rating indicates that the true effect is believed to probably be close to the estimated effect, while a high GRADE rating indicates that the authors are confident that the true effect probably is similar to the estimated effect [21].

The scientific author worked in collaboration with one of the internal scientific experts from the Board. As a final step, one of the external experts from the Steering Committee reviewed and approved all the steps and the final report on the scientific evidences, including the search strategy, the selected publications, and the data selected from each publication.

## The Consensus Procedure

The consensus procedure was applied for three reasons: (1) if the intervention was not ethically suitable to study, or (2) there was limited scientific evidence (no relevant studies were found, or they had very low GRADE on all primary outcomes), or (3) when it was deemed that there was common professional agreement and lack of debate.

The consensus panel consisted of 129 clinicians in the field of obesity, diverse in gender, geography, and profession. They received a web survey with statements to agree or disagree on and responded anonymously. According to the process, a statement was to be accepted if more than 75% of the consensus panel voted yes and if at least 30 panelists voted. There was a high assent (92–99%) for all statements and no statement had to go for a second round.

# Severity Scoring if no Intervention Is Given

Each population and intervention pair was assigned a severity score from minor severity, moderate severity, large severity to great severity. The severity score refers to how difficult the condition would be for affected individuals if no intervention was given. The level of severity was obtained using a tool for capturing how life expectancy, physical and mental health, and autonomy of patients, on a group level, impacted the specific population [22]. The ranking and the following recommendation were based on a standardized model following three ethical principles outlined in the Swedish Health and Medical Services Act [23].

- Human dignity: health care should be offered to anyone independent of personal traits, area of residence, age, gender, religion, etc.
- Needs and solidarity: those most in need of health care should be prioritized, i.e., the patients with the greatest level of severity of the disease and the most impaired quality of life.
- Cost-effectiveness: there must be a reasonable relationship between the cost and the effect of a treatment. If two treatments have the same effect, the one with lowest cost should be chosen. In addition, experts at the Swedish Institute for Health Economics evaluated the cost-effectiveness for interventions with presumably high costs.

The severity score is important since it affects what ranking a recommendation can be given. For example, only an intervention directed at a population that has a great severity should be given the highest priority, a ranking of 1, i.e., 1 corresponds to the highest priority and 10 to the least (online suppl. Table 4).

#### Prioritization of Recommendations by the Ranking Panel

Each county council nominated clinicians and the patient organization nominated patient representatives from their region to the Ranking panel. The panel members should have no conflict of interest. See online supplementary Table 5 for professional composition of the group.

The compiled evidence, with the final reports on the scientific evidences, was sent out to the panel beforehand. First, every member ranked the recommendation anonymously through a digital system. Next, the Ranking panel met for discussions. Based on the evidence, the cost-effectiveness, the ethical principles and the severity score, all participants had to agree to a ranking for each Population and intervention pair. See online supplementary Figure 2 for an overview of the work process in the Ranking panel.

#### Quality Indicators for Follow-Up and National Evaluations

To enable follow-up and national evaluations of how the recommendations are used and influence clinical practice, quality indicators were developed by the Steering Committee for the indicators. When creating indicators, there are some criteria that must be fulfilled e.g., that the indicator is relevant, valid, specific, measurable, established and built on knowledge. Following these criteria, new indicators can be designed more uniformly and in a systematic way. The quality indicators are essential to evaluate the development of health-care structures and to compare the progress over time. Only recommendations with high priority were selected to be followed up with quality indicators. The quality indicators are presented in online supplementary Table 6.

To define quality indicators, the existing national quality registries at the Board of Health and Social Welfare e.g., the National Patient Register, the Prescribed Drug Register, the Cause of Death Register, the Child Obesity Register in Sweden (BORIS) and the Scandinavian Obesity Surgery Registry (SOReg) were examined to find suitable indicators, i.e., data which are already collected on a regular basis in the registries. However, if codes and variables did not exist, contact was taken with national quality registers to discuss the possibilities to create new variables of relevance.

Other indicators for recommendations with high priority, such as competence development for health professionals, or the number of regions offering measuring of weight when visiting health care, will be assessed by questionnaires distributed among health care professionals. Finally, a mathematical base for calculating each indicator was specified. Based on the selected quality indicators, an overall national evaluation of obesity care will be done within a few years after publication of the guidelines.

## Results

The first version of the Swedish national guidelines with recommendations and indicators was published in April 2022 on the website of the Board, as well as printed and distributed to key stakeholders (Table 1). The guidelines were open for consultation until the end of July 2022. In addition, six regional hearings across Sweden were organized to facilitate structured feedback and discuss implementation from health care providers and decision makers in each region. In total, 570 comments were submitted from 30

Number of the recommendation	Recommendation	Ranking
1	Offer weighing and measuring to children and adults who visit health care, in order to identify persons with obesity and offer them medical examination and assessment	2
2	Offer examination and assessment to children and adults with obesity, to be able to offer the right treatment	2
3 4	Follow-up children and adults treated for obesity in a structured, regular and long-term manner Offer structured care throughout the health care system for children and adults with obesity	
5	Offer competence development in obesity for health care professionals	2
Offer combined lifestyle	treatment for persons with obesity who are	
10 6, 7, 8	<ul> <li>Children and adults with need for special support</li> <li>Children, age 2–17</li> </ul>	2 3
9, 11	<ul> <li>Adults, below the age of 70, including pregnant women</li> </ul>	4
12 13	• Adults, 70 years and older Offer pharmacological treatment with orlistat, in addition to lifestyle treatment, to adults who are eligible for pharmacological treatment	6 4
Offer gastric bypass surg	ery for persons with obesity who are eligible for obesity surgery and	
18	Are adults • and have a BMI ≥35	2
16	Are adults • and have a BMI of 30-35 • and have severe obesity-related disease	3
14	Are children aged 15–17 years • and have a BMI ≥35 • and are eligible for obesity surgery after assessment at a specialist unit	3
Offer sleeve gastrectomy	surgery for persons with obesity who are eligible for obesity surgery and	
19	Are adults • and have a BMI ≥35	3
17	Are adults • and have a BMI of 30-35 • and have severe obesity-related disease	5
15	Are children aged 15–17 years • and have a BMI ≥35 • and are eligible for obesity surgery after assessment at a specialist unit	6
Offer BPD/DS (biliopancre	eatic diversion with duodenal switch) surgery for persons with obesity who are eligible for obesity su	rgery and
20	Are adults • and have a BMI ≥50 • and are eligible for extensive obesity surgery	5

# Table 1. The Swedish national guidelines for obesity treatment

stakeholders and 80 individuals. In response to the comments, a review took place, and an updated version of the national guideline was published in April 2023 [24].

# *Continued Management and Planned Updates of the National Guidelines*

The obesity national guidelines will be reviewed every second year to analyze if there is a need for update according to standard procedures at the Board. In order to promote evidence-based and equal care, a minor revision of

Development of the Swedish National Guidelines for Obesity Care the national guidelines for obesity care will also take place if pharmaceutical products that are not currently approved by the Dental and Pharmaceutical Benefits Agency, become approved for the nationwide state benefit program.

# Discussion

Herein we summarize and describe the development of the first evidence-based national guidelines with recommendations to the health care system in order to improve obesity care in Sweden and make it more equal across the country. The systematic development was directed by the Board and developed by independent expert committees including professionals and patient representatives and reviewed through an open public consultation. The national guidelines act as a starting point for decision makers when making decisions regarding operational planning, organization, and development of regional or local medical care programs. The guidelines provide ranked recommendations for obesity identification and management of obesity care in both children and adults, with strong focus on treatment modalities in need of special guidance for resource allocation, to ensure good and equal health care all over the country.

The standardized process of constructing national guidelines does not only bring the profession in a country together, but it also brings treatment controversies to the surface making them open for discussion. The standardization is both strength and weakness, as it is less flexible. For example, no qualitative studies could be included in the literature search. Nevertheless, it is the first step towards a consolidating framework for continuous care for diseases like obesity – chronic and involving many different professions over the course of life.

When compared to international endeavors of similar character, the Swedish guidelines are most similar to the National Institute for Health and Care Excellence (NICE) guidelines in terms of the governmental involvement in the process, as well as the way the evidence was examined and turned into policy recommendations. However, while the process described here targets decision makers, the NICE guidelines also include evidence-based recommendations for health and care in clinical practice [25]. In Sweden, the development of medical care programs is delegated to the health care regions. The Swedish Association of Local Authorities and Regions published the clinical practice guidelines for the treatment of obesity in children and adolescents in May 2023, and similar clinical practice guidelines for adults are currently being developed and will be aligned with these guidelines that are targeting the health care system.

With regards to the Nordic countries, only Finland has so far issued guidelines for treatment of obesity, which were released in 2021 [16]. Contrary to the Swedish government led guidelines, the Finnish guidelines come from the professional societies: Finish Medical Society Duodecim, the Finnish Association for the Study of Obesity and the Finnish Paediatric Society. The Finish guidelines are aligned with the Swedish guidelines and provide in essence the same recommendations, although more detailed with for example suggested blood samples to take, details that instead will be found in clinical practice guidelines in Sweden.

Guidelines reflect the state of the art and are most commonly developed by the professional organizations unlike the process described here. One such example is the American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): indications for Metabolic and Bariatric Surgery [15]. The ASMBS/IFSO document is a consensus statement based on a literature review, in comparison to the evidence graded and ranked recommendations developed through a process such as the one described above.

Similar to many other guidelines, the Swedish guidelines have chosen to focus on weight and BMI, which differs from the Canadian clinical practice guidelines that focus on a broader concept [14]. The Canadian guidelines emphasize improvement of patientcentered health outcomes. However, in the Swedish guidelines, quality of life has been included as an equally important outcome in all the assessed interventions.

The Swedish national guidelines are primarily developed for decision makers, but include involvement from the professionals and individuals living with obesity in several steps of the process. The Canadian guidelines on the other hand, have been written for, and together with, not only the profession, but also individuals with obesity, indigenous communities, stakeholders, and policy makers.

Key strengths are the broad engagement in the development of the Swedish guidelines, together with the standardized procedures of the Board to provide a systematic and transparent priority setting. Another strength is that we have a life course perspective, from pregnancy to the elderly, while others primarily focus on the adult population [12]. The ambitious scope (from identification and diagnosis to multiple treatment modalities, in all ages) is a potential limitation, given the time constraint. At the same time, during the development of the guidelines, a broad number of obesity experts were involved in the many different parts of the process. Still, the working process has been impeded by the fact that the first version of the guidelines was to be completed in only 1 year, initially during digital meetings due to the COVID-19 pandemic, and with a restricted number of Populations and intervention pairs. The latter resulted in difficult prioritizations, as several important areas needed to be left out.

Moreover, the standardized process assigning severity ranking has a limitation in that children may get a lower ranking score than adults. This is due to the needs and solidarity principle that has guided the work, i.e., prioritizing interventions for those with the greatest needs and most impaired quality of life at a given moment. This can automatically lead to allocation of lower scores for the young and currently less affected population – the children. For example, one of the key parameters is the time to death if no intervention is provided. The severity in children does not have the same immediate consequences on their physical and psychosocial health compared to for example an adult with a BMI >50 in need of surgery.

The guidelines initially included the second-generation anti-obesity medications (liraglutide, naltrexon/bupropion and semaglutide). Evidence was compiled using the PICOS model, the scientific authors wrote reports on the scientific evidence and the Ranking panel prioritized the anti-obesity medications. However, since the second-generation antiobesity medications are not yet approved by the Dental and Pharmaceutical Benefits Agency, i.e., so far, patients treated with these medications pay out of pocket, and since the guidelines issued by the Board primarily are directed to decision makers who allocate health care resources, the prioritization of the second-generation anti-obesity medications was not possible to include at this stage. These medications will be prioritized again, if reimbursement is implemented. They will nevertheless be included in the clinical practice guidelines that are now being developed. The rapid scientific and clinical progress in the field of pharmacotherapy for weight loss in both adolescents and adults emphasizes a need for regular updates of guidelines.

The development of the guidelines and the national attention it has reached has benefited the field of obesity in Sweden. Finally, the developed set of quality indicators is key to ensure whether the guidelines are implemented and are appropriate and effective. At the same time, efforts need to be made to improve knowledge and competence of health care providers, so that they can deliver interventions according to current guidelines. Overall, the result of this joint action will hopefully lead to improved health of people living with obesity and evidence based, as well as efficient, use of health care resources.

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# Conclusion

National guidelines for improved and evidence-based standard care of obesity in children and adults and efficient use of health care resources can be developed in a systematic and transparent way with professionals and patient representatives.

## Statement of Ethics

Ethical approval and consent were not required as this study was based on publicly available data.

#### **Conflict of Interest Statement**

The authors declare no conflict of interest.

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#### **Author Contributions**

P.N. and Y.T.L. have drafted the manuscript. L.S., A.-S.B., K.J., F.S., M.S., and L.T. have contributed to the manuscript writing and approved the final version. Y.T.L. have supervised the process.

#### **Data Availability Statement**

Documentation of the electronic search for publications, included and excluded studies, are published as an appendix to the Swedish national guidelines. Further inquiries can be directed to the corresponding author.

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