Obesity

Caring for US Children: Barriers to Effective Treatment in Children with the Disease of Obesity

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In 2020, impediments to pediatric obesity (PO) treatment remain pervasive, even though these barriers are clearly documented in medical literature. Providers must invest considerable resources to overcome these barriers to care. Notable barriers include gaps in medical education, misperceptions of the disease, weight bias and stigma, exclusion of coverage in health plans, and thus an unsustainable financial framework. Hence, this review offers an updated social-ecological framework of accessibility to care, wherein each barrier to care or variable is interdependent on the other and each is critical to creating forward momentum. The sum of all these variables is instrumental to overall smooth function, configured as a wheel. To treat PO effectively, all variables must be adequately addressed by stakeholders throughout the health care system in order to holistically comprehend and appreciate undertakings to advance the burgeoning field of PO medicine.

Obesity (2021) **29**, 46-55.

Study Importance

What is already known?

- As demonstrated by the increasing prevalence of pediatric obesity (PO) and the resulting detrimental impact on organ systems, psychosocial issues, and overall health economics, the medical community has been unsuccessful in efforts to effectively treat PO.
- Barriers to PO treatment remain largely unchanged despite increasing medical literature citing these numerous barriers to obesity and calls to action for 15 years.
- Considerable time and resources are drained daily to overcome these barriers to care, resulting in poor patient care and loss of productivity.

What does this review add?

- Identified barriers to PO care include gaps in medical education, misperceptions of the disease, weight bias and stigma, exclusion of coverage in health plans, and an unsustainable financial framework for obesity care programs.
- This paper proposes an updated social-ecological framework of accessibility to PO care and treatment in which each barrier to care (variable) is interdependent on the other, and each is critical to creating forward momentum. All variables must be adequately addressed by stakeholders throughout the health care system in order to support effective PO treatment.

Introduction

There has been an incremental rise in severe obesity in US children (≥class 2 obesity; BMI ≥ 35 kg/m^2; ≥120% of the 95th BMI percentile) and associated obesity-related medical comorbidities and disability (1-3). Recommended pediatric evidence-based treatment options for obesity require the delivery of intensive, multicomponent behavioral interventions including family-based therapy with at least 26 hours of behavioral treatment, as supported by the latest US Preventive Services Task Force recommendations and the recent American Academy of Pediatrics policy statement (4,5). Treatment options might be all encompassing, be multimodal, and include monotherapy or a combination of intensive lifestyle interventions focused on nutritional and behavioral therapies, antiobesity pharmacotherapy (only two US Food and Drug Administration [FDA]-approved in adolescent patients [orlistat, ≥12 years of age; phentermine, >16 years of age]), medical devices (none approved in pediatrics), and metabolic and bariatric surgery (MBS) (6,7). Despite sufficient evidence to support behavioral therapy, MBS, and, most recently, pharmacotherapy (8), less than 1% of patients with severe childhood obesity receive treatment (5,9). Significant barriers to care are pervasive and they impact the clinical direction for patients with severe pediatric obesity (PO), resulting in frustration of PO care providers to deliver better health outcomes. Often, those efforts seem futile.

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 Received: 1 April 2020; **Accepted:** 24 June 2020; **Published online 21 December 2020. doi:10.1002/oby.22987**

For this review, a small group of PO medicine specialists (including academic, research, and rural-community specialists) in active clinical practice, individual patient and family advocates for childhood obesity, and specialists in weight stigma collectively felt the need and urgency to synthesize a fresh perspective on the present state of the field of PO for stakeholders to holistically comprehend and appreciate current efforts to advance the burgeoning field of PO. We purposely chose authors who are actively at the forefront of their fields to capture their views. This group convened together in a series of conference calls and phone meetings to create a refined list of top barriers to care faced in the field of PO. We define these barriers on the basis of a social-ecological framework, taking into consideration individual, interpersonal, institutional, societal, and policy-level impediments. Organized into five domains (clinical, education, insurance, policy, and research), 12 common impediments to obesity care are presented (Figure 1) with corresponding narrative explanations and suggested recommendations to overcome challenges (Tables 1 and 2). These barriers to PO care are interdependent, equally important, and directly or indirectly related, as in a "wheel" configuration. To create forward momentum, each impediment needs to be addressed.

How might these results change the direction of research or the focus of clinical practice?

- Silos between disciplines need to be eliminated so that research on each variable is interwoven with the others to provide comprehensive knowledge across disciplines and research arenas.
- Creative education and advocacy endeavors such as adaptation of film media to reach masses, coalitions of regional and/or local obesity societies to mandate coverage for obesity services, or use of the telemedicine platform for rural areas may enhance efforts to eliminate barriers to PO care.

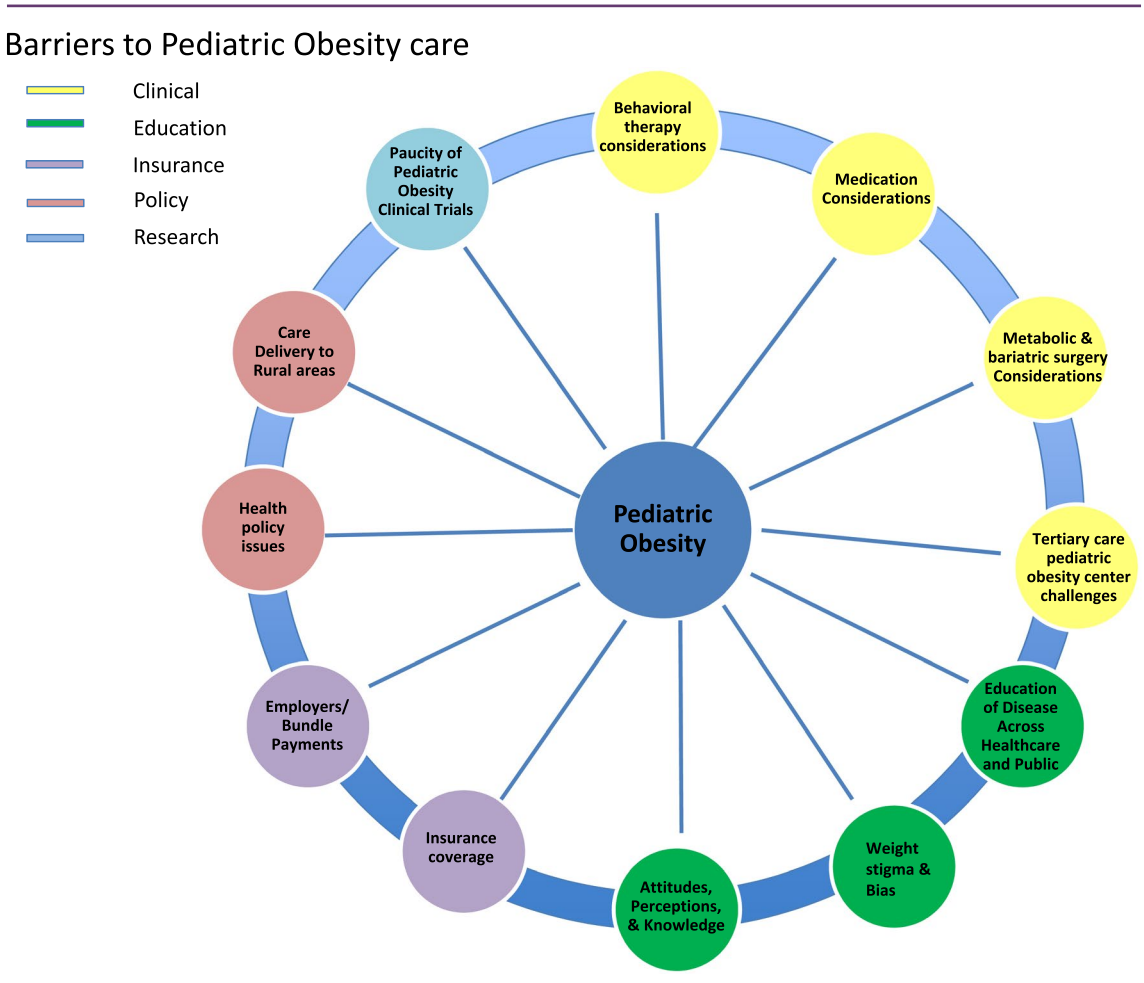

Figure 1 Depiction of 12 barriers to care (not inclusive) in pediatric obesity that incur key challenges for both patients and providers. These barriers are interrelated directly or indirectly, and all need to be adequately addressed in order to create forward momentum. Continued impediment slows progress and creates friction, in a manner similar to those of the rusted moving parts of a wheel, preventing acceleration. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Barriers to PO care with suggested recommendations to overcome these challenges

Barrier	Specific challenge	Interventions	Limitations	Creative ideas for improvement
Behavioral therapy considerations	Poor rate of reimbursement for behavioral therapy and intensive lifestyle interventions, which are foundational for more intensive obesity therapies	Reimbursement for behavioral therapy and intensive lifestyle interventions, which are foundational for more intensive obesity therapies	Mass efforts may be required to obtain state Medicaid coverage	Appoint national PO treatment task force committee to institute mandated coverage; coalition of state obesity societies to advocate state-level PO coverage
Medication considerations	Financial sustainability, high attrition rates in high-risk pediatric population	Reimbursements for all types of obesity treatment services: intensive lifestyle therapy, behavioral, pharmacotherapy, surgery, or combination	Because of limited large-scale pediatric clinical trials, a large portion of pediatric care is delivered off-label; reimbursement is usually for FDA-approved treatment modalities	Government-based incentives for establishment of tertiary care PO centers
Metabolic and bariatric surgery considerations (including medical devices)	Patient and provider understanding of disease process and/or unfamiliarity with adolescent bariatric surgery indications, poor rate of insurance coverage	Reimbursements for all types of obesity treatment services: intensive lifestyle therapy, behavioral, pharmacotherapy, surgery, or combination; continued education efforts for health care industry and public	Mass efforts may be required to obtain state Medicaid coverage	Appoint national PO treatment task force committee to institute mandated coverage; coalition of state obesity societies to advocate state-level PO coverage and mandate obesity education at local and regional levels
Tertiary care PO center challenges	Financial sustainability, high attrition rates in high-risk pediatric population	Reimbursements for all types of obesity treatment services: intensive lifestyle therapy, behavioral, pharmacotherapy, surgery, or combination	Because of limited large-scale pediatric clinical trials, a large portion of pediatric care is delivered off-label; reimbursement is usually for FDA-approved treatment modalities	Government-based incentives for establishment of tertiary care PO centers
Education	Misinterpretation and misunderstanding of underlying pathophysiology of obesity	Establishment of obesity medicine fellowship program; mandated obesity curriculum in undergraduate and graduate medical education	Long-term funding to sustain obesity fellowship programs; mass efforts from collective educational societies may be needed to mandate curriculum change	Obesity medicine preceptorship programs offered by various academic institutions to support continuing medical education of MDs and ancillary providers; obesity medicine leadership programs for hospital executives and nonmedical C suite–level positions, including economic impact to health care system and potential savings with BMI reduction with populations
Weight stigma and bias	Misinterpretation and misunderstanding of underlying pathophysiology of obesity leading to patient blame, negative stigmatization within health care, obesity stereotypes, communication barriers, and disrespect	Education throughout health care system and public	Mass efforts may be required to affect large-scale population	Creative endeavors such as use of film and photography media to relay positive messages about people affected by obesity; continued establishment of obesity education pathways across health care industry and public

TABLE 1 (continued).

Barrier	Specific challenge	Interventions	Limitations	Creative ideas for improvement
Attitudes, perceptions & knowledge	Challenges in maintaining weight loss, reluctance to seek help, inadequate diagnosis, insufficient dialogue and follow-up	Education throughout health care system and public	Mass efforts may be required to affect large-scale population	Continued establishment of obesity education pathways across health care industry and public
Insurance coverage	Poor rate of reimbursement for behavioral therapy, antiobesity medications, and metabolic and bariatric surgery, even when all components of clinic are covered	Coverage for all obesity treatment modalities	Mass efforts may be required to obtain state Medicaid coverage	Appoint national PO treatment task force committee to institute mandated coverage; coalition of state obesity societies to advocate state-level PO coverage
Employers/bundle payments	Misinterpretation and misunderstanding of underlying pathophysiology of obesity, support of wellness or prevention programs while excluding much-needed specialty services for those who need treatment	Establishment of robust obesity bundle payment services for large regional and/or local employers	Many employers require evidence-based data generated from regional and/or local hospital affiliations to support services	Similar to accreditation of metabolic and bariatric surgery centers that are required to track outcomes, continue support for national registry to track PO medicine outcomes; coalition of state obesity societies to advocate state-level PO coverage and mandate obesity education at local and regional levels
Health policy issues	Monetary investment for policies that may have indirect links or association to PO but may not show evidence for BMI reduction	Establishment of sound health policies that show evidence-based BMI reduction and improvement in obesity-related comorbidities	Policies are often geared toward positive healthy behavioral changes that are equally important for preventive efforts to combat obesity; although those are important, policies targeting direct change in BMI reduction may be more difficult to implement	Establishment of school-based reform targeting positive behavioral change with an integrated PO center referral base for those identified as high risk; obesity education efforts for policy makers
Care delivery to rural areas	See Table 2	See Table 2	See Table 2	See Table 2
Paucity of PO clinical trials	Difficulty in recruitment, adult data may be required prior to pediatric clinical trial, pharmacokinetic information in pediatrics may be required prior to phase 3, may take 15-20 years for drug or medical device discovery to FDA approval	Financial incentives to launch PO clinical trials and advocate for more PO research	Low adoption of PO treatment by health care providers because of current challenges	Creation of national PO treatment task force to advise off-label and FDA-approved guidance on available treatment modalities; expedite publishing retrospective or prospective real-time clinical data evaluating effectiveness of therapeutic options used in combination with intensive lifestyle interventions

These barriers are interconnected with each other; successful intervention strategies might affect some or all of these barriers.
MD, medical doctor; PO, pediatric obesity; FDA, US Food and Drug Administration.

TABLE 2 PO care delivery barriers in rural areas

Barrier	Specific challenge	Interventions	Limitations	Creative ideas for improvement
Geographic distance	Travel, time out of school and work	Telemedicine from distant (specialist) to PCP office in rural area to receive telemedicine services	PCP office impact: space, staff to room patient, possible colocation compliance issues; even travel to PCP can be challenging in very rural/remote areas of country	Expansion of definition of *originating site* to include patients' homes and schools, in addition to PCP office assistance to improve access
Community resources	Small and rural towns without YMCA, fitness centers, etc., family finances to access some activity resources limited	Physical activity component as part of PO treatment, vitally important via PT/OT/personal or athletic trainers	Not all small and rural towns have access; currently difficult to obtain coverage for this component; for those that are covered, families billed for significant copays	Use local community colleges when available; build on telemedicine to provide access to one-on-one PA assistance; improve coverage (i.e., bundling) for episodes of care
Technology	Broadband variability, patient demographic with limited finances to afford Wi-Fi	Connecting within PCP office as originating site where Wi-Fi is available without cost to family	Travel to PCP; possible complications due to CMS colocation policy	Incorporating combinations of telemedicine sites: PCP, home, and school; funding for Wi-Fi access directly to families who need this level of medical services
Payment model	Particularly in rural areas, high percentage of PO clinic demographic relies on state Medicaid: poor rate of reimbursement even when all components of clinic are covered	PO telemedicine service to rural areas using standard professional fees only for individual components of PO clinic (medical, medical nutrition therapy, behavioral therapy, and physical activity prescription)	Provider needs to travel to PCP originating site for initial evaluation; challenges with credentialing, colocation, or family travel; reimbursement variance for in person at hospital-based clinic vs. professional fees only when using telemedicine	Reassess payment model and bundling; more effective use of modifier 33 for PO clinic meeting USPSTF grade B requirements; universal workflow to access EPSDT for all states

CMS, Centers for Medicare and Medicaid Services; EPSDT, Early and Periodic Screening, Diagnostic and Treatment; OT, occupational therapy; PA, physical activity; PCP, primary care physician; PO, pediatric obesity; PT, physical therapy; USPSTF, US Preventive Services Task Force.

Key Challenges

Clinical domain

Behavioral therapy considerations. Obesity requires an interdisciplinary approach including access to obesity medicine-trained PO specialists, mental health providers, physical activity experts, and dietitians. Required PO multidisciplinary components and expertise training are well defined (6), but coverage for these ancillary resources typically has been minimal or nonexistent. Some hospital organizations support pediatric weight-management programs by subsidizing ancillary costs; others find internal or external grants. Although neither of these solutions is a long-term fiscal strategy, a case can be made that obesity care should be viewed as necessary infrastructure for a pediatric medical facility. As such, subsidization by the hospital could be a justifiable and sustainable approach.

In July 2015, 43 cross-sector stakeholders came together for a consensus conference to generate recommendations for childhood obesity treatment (10). Family-based multicomponent behavioral therapy (treatment at or above the minimum dose of 25 hours), a well-trained multidisciplinary team using an integrated care model, and evidence-based protocols were deemed necessary to achieve clinically meaningful weight loss and deliver high-quality care. Improving access for evidence-based obesity care delivery with reimbursable payment models was emphasized (10).

Medication considerations. Recent advances include FDA approval for medications in the treatment of type 2 diabetes in adolescents as young as 10 years of age (11). Similar advances are needed in the field of PO. Pediatric subspecialists frequently administer medications with off-label indications, given the high benefit/risk ratio and urgency to treat (12). Antiobesity medication use in pediatrics is recommended for BMI ≥ 95th percentile with obesity-related comorbidity or for BMI ≥ 120% of the 95th percentile (6).

PO pharmacotherapy treatment suffers from insurance-coverage issues (13), a paucity of clinical trials, and culturally derived bias against children with obesity and their families (14). Limited evidence and parental anxiety may discourage pediatric care providers from advocating use, even in adolescents with severe forms of obesity causing disability and debilitation. Advanced PO training and education in antiobesity medication prescribing are warranted. Education to empower families and patients to reduce self-blame and internalized bias that may prevent them from seeking care for obesity is needed.

MBS (including medical device) considerations. Medical devices and MBS are powerful adjuncts to intensive lifestyle and medication therapy. These advanced tools should be used within tertiary care PO centers; however, their place in the overall treatment regimen needs to be understood by health care colleagues (especially primary care providers), policy makers, insurance-coverage entities, and the general public.

Medical devices exist, have a large usage rate outside the United States, and can serve as a bridge between medications and MBS. Recent medical device technology includes an easily swallowed capsule; one such capsule (cleared by the FDA) releases a biodegradable supra-absorbent cellulose hydrogel in the stomach, resulting in satiety and fullness (15).

Medical devices may have robust implications in clinical PO. Although no medical devices are currently FDA-approved for PO treatment, PO product development pipelines should consider innovative medical devices for prospective clinical trials. Device treatment of obesity in adolescents in other countries demonstrates safety and effectiveness with short-term meaningful weight loss, thus warranting further studies in the United States (16-18).

In contrast to antiobesity medications and medical devices, the use of MBS has sound evidence in adolescent patients who meet clinical criteria (BMI ≥ 120% of the 95th percentile plus obesity-related comorbidity or ≥140% of the 95th percentile) (7,19,20). The majority of adolescent patients with severe obesity present with multiple obesity-related complications and comorbidities. Early intervention with MBS therapy within an ongoing comprehensive multidisciplinary program can sustainably improve and reverse many of these medical and psychological conditions, as demonstrated by the Teen Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study (19) and many others, substantiating appropriateness of the procedure in adolescents with severe obesity (21-24).

Despite growing evidence of the usefulness of MBS therapy in conjunction with an ongoing weight-management program, less than 1% of patients who meet criteria for adolescent MBS undergo the procedure (5,9). The remainder lack insurance coverage, may not have adequate family or psychosocial support, or may not be aware of the operation as a potential treatment option (25). The insurance approval process can be lengthy, involving multiple appeals despite the adolescent meeting MBS criteria. Less than 49% of adolescents receive insurance approval for MBS on their first application, with the most common reason for denial being age less than 18 years (25).

Primary care providers may be unfamiliar with current recommendations, the current safety and effectiveness of MBS for treating obesity-related complications, and the sound scientific underpinnings of energy metabolism, which have moved the understanding of obesity etiology beyond personal responsibility for the disease. The American Academy of Pediatrics' recent policy statement on adolescent MBS encourages primary care providers to follow these best-practice guidelines (5).

Tertiary care PO center challenges. Because of financial nonsustainability resulting from poor insurance reimbursements (commercial and government-based), notable other challenges, and serving high-risk pediatric populations, many tertiary care PO centers have disintegrated or conceptualized novel methods of incorporating pediatric weight management within routine practice, as reported by many colleagues. Although this alternative might not be a substitute for robust in-practice management, cost-sharing can offset routine expenses to support the program. Other programs unable to exist independently are embedded in subspecialty clinics, such as gastroenterological, hypertension, and polycystic ovarian syndrome programs. In contrast to direct nonreimbursable obesity coverage, pediatric providers often code reimbursable obesity-related complications to cover weight-management services indirectly. The caveat is that to be eligible for treatment, the pediatric patient must present with more advanced obesity disease staging (Edmonton Obesity Staging System for Pediatrics Stage 2 or higher, wherein patients may present with moderate metabolic, mechanical, mental, and social-milieu complications) to qualify for these weight-management services (26,27). Without the presence of an obesity-related complication, obesity-treatment reimbursement is problematic. As a result, many children wait for worsening

disease progression and the onset of an obesity-related comorbidity development before seeking intervention.

Another barrier to tertiary weight-management viability is a high attrition rate. Factors increasing attrition include insurance status, race and ethnicity, perceived quality of care, and misalignment between parental expectations and program goals (28). Although viable PO care centers are often funded through internal or external research grants; sustainable reimbursement models for intensive interdisciplinary pediatric weight-management programs should be a priority. Bias and lack of understanding of obesity as a disease slows this process.

Recent studies have shown promise in overcoming some of these challenges. One PO study indicated successful sustainability methodology for a tertiary care center, although at a low level of profitability, encompassed by improved charge capture for all billable services, including biometric measurements, quality efforts such as use of nurse practitioners to increase revenue at lower costs, and evaluation/management coding (29). Another recent randomized controlled pediatric weight-management trial leveraging high-quality obesity clinical care with community resources demonstrated improved family-centered outcomes and reduction in childhood BMI (30), therefore leading to lower attrition rates.

Education domain

Education on disease across health care and public. Unlike other diseases, obesity education often lacks training around disease pathophysiology, treatment, and management (31). That obesity results from the body being unable to defend a healthy body mass, and is a breakdown of the energy regulatory system, is poorly comprehended across health care training, health policy makers, and health care executives (32). This lack of knowledge continues to permeate throughout the health care system. Across the United States, the old tenet "calories in equals calories out" still predominates, indicating a clear need for education about the physiological contributors to obesity.

Nutrition and obesity education are rarely taught (<1% of curriculum) in medical or nursing education, and they are not prioritized compared with chronic diseases such as diabetes and cardiovascular disease (33). Providers-in-training are ill equipped to treat patients with obesity after completing their education and transition to clinical practice (31). To date, there are now13 established obesity medicine fellowships in the United States (4 are PO medicine fellowships and 7 incorporate pediatric experience), of which 8 have most recently been established in the past 1 to 3 years (34).

Weight stigma and bias. Assumptions that obesity is a character flaw and completely within volitional control persist in our society, contributing to stigmatization of individuals with overweight or obesity. The health care setting is not immune to this stigma, and negative weight-based stereotypes and biases have been documented among health care providers (35,36); this bias can translate into suboptimal patient care for patients with obesity, including less time spent in appointments, stigmatizing communication, disrespectful treatment, parents blamed for their child's weight, and avoidance of future medical appointments (37-39).

Youth with obesity face high rates of weight-based teasing and bullying (e.g., verbal teasing, relational victimization, cyberbullying, and/or physical aggression) compared with lower-weight peers (40,41). These experiences incur a range of adverse health outcomes, including psychological distress (e.g., depression, anxiety, and/or low self-esteem) and physical health consequences, including maladaptive eating behaviors, binge eating, decreased physical activity, and weight gain (42,43).

Evidence of the harms of weight stigma for children prompted a policy statement published by the American Academy of Pediatrics in 2017, calling on pediatric providers to take steps to reduce weight stigma in clinical practice. Recommendations include increasing use of supportive language and communication about weight with youth and families, creating a nonstigmatizing clinical environment, and assessing youth for emotional comorbidities associated with obesity (e.g., weight-based bullying) in behavioral health screenings (42).

Attitude, knowledge, and perception barriers. Attitudes, knowledge, and perceptions about obesity from the perspective of patients with obesity, health care professionals, and employers have been attributed to challenges in maintaining weight loss, reluctance to seek help, inadequate diagnosis, insufficient dialogue and follow-up, and misaligned perceptions of wellness offerings (32). The Awareness, Care, and Treatment in Obesity Management (ACTION) study (8) noted that health care professional and patients with obesity often underrecognize the seriousness of obesity health consequences. In this study, only 50% of patients felt that excess weight would impair future health status. Education in obesity biology and treatment modalities throughout the stakeholder spectrum, engaging health care professionals in productive weight-management conversations, encouraging regular follow-up visits, and promoting the effectiveness of employer-based plans for patients aid in the collaborative development of an evidence-based understanding and viewpoint of obesity.

Insurance domain

Insurance coverage. Many insurance plans have a benefit exclusion for weight management, lifestyle intervention, antiobesity medications, and/or MBS coverage (44), as obesity treatment is erroneously considered "cosmetic." This benefit exclusion may be specific to both the adult and pediatric population. For most pediatric patients on governmental insurance plans, obesity treatment coverage is scarce. Programs that do offer coverage for PO services often reimburse at very low rates, creating a significant financial burden not compensated by volume or reduction in no-show rates and further creating financial bias according to socioeconomic status. The creation of an improved reimbursement model for high-level evidence-based care (US Preventive Services Task Force grade B guidelines: high intensity and high frequency within a comprehensive, interdisciplinary obesity team) (4) would improve coverage by private payers under existing Affordable Care Act section 2713. Of note, commercial insurance payers can be more restrictive in coverage and operate differently from Medicaid, often following principles of risk avoidance with respect to standard deviation from the norm and focusing on a healthy population (45). In contrast, Medicaid's Early and Periodic Screening, Diagnostic and Treatment program entitles low-income children under the age of 21 years to receive a broad array of preventive, treatment, and special-needs benefits.

Employers/bundle payments. Many employers do not recognize obesity as a disease and consider obesity treatment as nonmedical, unnecessary expenses (32). Benefit exclusions may apply. Employers may support wellness programs in the form of bundle payment for services, but these are often vested interests in commercial resources,

have high attrition, and are not evidence-based (46). Community or employer-based "treatments" often employ wellness or prevention measures rather than appropriate obesity referral pathways with advanced clinical tools and resources of weight management. Hospital organizations may need to contemplate creative endeavors to incentivize large employers to bundle pediatric weight-management services for their employees and their children.

Policy domain

Health policy issues. A recent study evaluated state and locally enacted policies in four US communities where childhood obesity declined in a span from 2003 to 2011 (47). All four states created and funded legislation supporting environment improvements, school nutrition, safe physical activity for families, and creation of obesity task forces. The authors called for ongoing research to further understand which policies (or which combination of policies) had the greatest impact and whether this trend was sustainable. A meta-analysis of childhood obesity-prevention programs also found moderate evidence to support school-based programs, accessibility to activity facilities, and healthy food choices (48).

Importantly, the literature is often unclear when describing interventions that prevent weight gain (prevention in susceptible children) and those that reduce weight (treatment in children with established disease). Interventions that probably do both only add to the confusion. Although successful preventive interventions for obesity may be helpful or neutral for children already suffering from the disease of obesity, policy makers need to understand that for children with the disease of obesity, many need additional intensity and frequency of currently available interventions, including intensive lifestyle interventions, medications, devices, and surgery.

In addition, school-based reforms, such as physical activity mandates, school lunch requirements (49), and reduction of sugar-sweetened beverages with direct links to childhood obesity (50-52) have been influential in the past from a policy perspective. Marketing of child-targeted nutrient-poor products is another area where public policy could positively influence family food choices using the concept of making the right choice the easy choice (53). However, in patients for whom genetic and biological phenomena are strong determinants of the obesity phenotype, other contributing variables need to be taken into consideration. Policy experts should be aware that prevention is not likely once an obesity diagnosis is already established, and focus should be shifted to treatment. Monetary investment for cost-effective obesity policies should be evidence-based, with clear effects for BMI reduction when feasible (54).

Care delivery to rural areas. Obesity care requires complex multidisciplinary support with advanced training in obesity medicine, including nutritional components, behavioral health, and physical activity experts, not solely medical providers. The majority of primary pediatric patients reside in suburban and rural areas where resources and health care are scarce (Table 2). Patients in rural regions often travel several hours to a local health care facility; many are covered by Medicaid plans with limited obesity-care coverage. Rural tertiary care PO centers are challenged by financial sustainability. Efforts to strategically use innovative technology such as telemedicine and virtual health care platforms are needed to deliver necessary pediatric weight-management expertise to a large proportion of US children (55,56). The issue of low reimbursement rates for telemedicine impacts finances adversely in the same way as the face-to-face encounters. Recent Centers for Medicare and Medicaid Services telemedicine waivers due to coronavirus disease 2019 have reduced some of these challenges. If these modifications are allowed to remain after the pandemic, improvements in access to care, particularly for rural children, may occur.

Research domain

Paucity of clinical trials (specifically medications and devices). The time from drug discovery from the bench to FDA approval requires at least 12 to 15 years. In 2020, six FDA-approved medications (phentermine, diethylpropion, orlistat, phentermine-topiramate, naltrexone/bupropion, and liraglutide; lorcaserin is not included because it is now off the market) are available for the treatment of obesity in adults; two are approved in adolescents (orlistat, ≥12 years; phentermine, >16 years) (14,57). Most antiobesity medications have been tested in adult patients; pediatric clinical trials are lacking, despite the Pediatric Research Equity Act (section 505B of the Federal Food, Drug, and Cosmetic Act passed in 2003), which *requires* pharmaceutical companies to assess safety and effectiveness of new drugs likely benefiting pediatric patients. Prior to Pediatric Research Equity Act, the Best Pharmaceuticals for Children Act provided an incentive to *voluntarily* conduct pediatric studies (58). Pediatric product development is held to the same evidentiary standard as adult product development and must demonstrate substantial evidence of effectiveness and clinical benefit. In addition, before pediatric clinical trials can be conducted, adult pharmacological data are often needed. Safety and efficacy data for many medications in children are scarce, and adult data cannot be extrapolated to children because of variation in metabolism, absorption, and therapeutic response. Pharmacokinetic and pharmacodynamic modeling is required prior to pivotal phase 3 pediatric trials. Historically, choices for pediatric practitioners were either (1) to not treat children with potentially beneficial medications because of lack of FDA approval or (2) to treat with medications on the basis of the adult evidence, with limited or anecdotal pediatric experience (off-label use). In 2014, the American Academy of Pediatrics issued an updated policy statement reaffirming that pediatric medical providers prescribe medications off-label out of necessity because an overwhelming number of critical drugs still have no information on the label for use in children, especially for those with chronic or rare diseases (12).

Summary

We summarized 12 barriers to PO care adversely affecting the field. These obstacles feed forward a perpetuating cycle of ineffective PO treatment and management. Although significant progress has been made despite these barriers, strong, coordinated endeavors and advocacy are necessary to advance the wheel of PO care. Furthermore, we have made recommendations to create forward momentum of this wheel.

The prevalence of overweight and obesity approaches 35% of children and adolescents in the United States (1). Children with obesity of any classification have metabolic disease and psychosocial challenges at early ages (59,60). Delaying potential treatment until adulthood dooms these children to progressive disability and premature death (61-63). This is the reality of 13.7 million US children currently affected by obesity.

The future of our children living with obesity is in grave jeopardy; eliminating barriers to PO treatment is our only economically sound and

humane option. As current PO care providers, we will continue to do what we do best: provide the best evidence-based care to all who are in need. Evidence-based care mandates that we take action on every spoke of the wheel (Figure 1).**O**

Disclosure: GS reports advisory/consultant fees from Novo Nordisk and Rhythm, outside the submitted work. TKK reports advisory/consultant fees from Novo Nordisk, Nutrisystem, and Gelesis. NB, VO'H, AB, TN, and RP declared no conflict of interest.

Author contributions: GS conceptualized the manuscript. All authors wrote and edited the manuscript.

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