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Review

Current Deficiencies In Schedule Y

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Abstract

To investigate "up-to-date" and "age-appropriate" indicators of preschool vaccination status and their implications for vaccination policy. The authors analyzed medical records data from the Baltimore Immunization Study for 525 2-year-olds born from August 1988 through March 1989 to mothers living in low-income Census tracts of the city of Baltimore.While only 54% of 24-month-old children were up-to-date for the primary series, indicators of up-to-date coverage were consistently higher, by 37 or more percentage points, than corresponding age-appropriate indicators. Almost 80% of children who failed to receive the first dose of DTP or OPV age-appropriately failed to be up-to-date by 24 months of age for the primary series.Age-appropriate immunization indicators more accurately reflect adequacy of protection for pre schoolers than up-to-date indicators at both the individual and population levels. Age-appropriate receipt of the first dose of DTP should be monitored to identify children likely to be under immunized. Age-appropriate indicators should also be incorporated as vaccination coverage estimators in population-based surveys and as quality of care indicators for managed care organizations. These changes would require accurate dates for each vaccination and support the need to develop population-based registries.

Keywords: Deficiencies

INTRODUCTION

The growing prevalence of obesity[1], combined with the absence of effective conservative treatment [2] and probably with the development of laparoscopic surgery, has led to a significant increase in the number of bariatric surgical procedures performed each year in most Western countries [3]. Bariatric surgery has been shown to produce effective and sustainable weight loss, which in turn results in improvement of obesity-related comorbidities, of quality of life, and of survival [4].

Gastric banding and Roux-en-Y gastric bypass (RYGBP) are currently the most commonly performed surgical procedures for morbid obesity [body mass index (BMI; in kg/m2) >40]. Laparoscopic gastric banding is a purely

restrictive procedure. It has a low operative morbidity but is associated with a substantial rate of late complications and failure[5,6]. Laparoscopic RYGBP is essentially restrictive, but in contrast with gastric banding, it is associated with nutritional deficiencies and has a higher operative morbidity[7]. However, it represents the procedure of choice for many surgeons[8,9] because it induces greater weight loss with better food tolerance.

After RYGBP, careful follow-up is needed to detect and correct nutritional deficiencies. Unfortunately, data about the type and the frequency of these postoperative deficiencies remain scarce[10,11].

The aims of this retrospective study were

- To assess the type, frequency, and pattern of development of nutritional deficiencies over the first 24 months after RYGBP,
- To determine the amount of supplements prescribed to each patient,
- To evaluate the cost of the substitutive treatment.

This information is important to standardize postoperative follow-up and to define which type of nutritional substitution has to be prescribed after RYGBP. It will allow a reduction of the frequency and the consequences of nutritional deficiencies and a decrease in health care–related costs.

Incorporating the patient experience into the clinical decision-making process is of increasing interest to the international regulatory and health policy community,[12] as these bodies increasingly recognize that patients are experts in terms of their preferences and have a unique knowledge of their own health. The patient experience can be captured in a number of different ways; an increasingly important approach is via patient preference (PP) studies.

PP studies generate rigorous data on patients' perception and preferences surrounding different aspects of existing or investigational health-related products, services, and interventions. The growing use of PP studies helps incorporate the patient perspective into clinical drug development, care management, and the broader healthcare decision-making of regulators and payers.[13-17] Over the last decade, benefit-risk methodologies have evolved substantially and are seen by regulators and industry stakeholders as a valuable tool in aiding transparency and communication in decision-making. Benefit-risk evaluation is both subjective and objective, and PP data can help regulatory and other stakeholders (eg, payers) evaluate and communicate value-based judgments.

Preference research allows estimation of the relative importance of different aspects of care, the trade-offs between these aspects, total satisfaction or utility that respondents derive from healthcare services and can help with decision making for some of the important issues in healthcare.

As summarized in the US Food and Drug Administration (FDA)'s "Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labelling" guidance, patient preference data may be collected through qualitative or quantitative approaches. There are several quantitative approaches to eliciting patient preference data; some use revealed-preference methods (whereby patient preferences are obtained from actual observed choices made by participants), while others use stated-preference methods (in which preferences are elicited by offering choices to participants). A discrete choice experiment (DCE) is a quantitative stated-preference method for eliciting preference data. DCEs are based on random utility theory (RUT), a long-standing theory of choice behaviour proposed by Thurstone in 1927.[18,19] The method involves presenting participants with a choice task that requires a force choice between hypothetical alternative products (or programs, or services). Participants are asked to state their preference from the alternative options. These data are used to evaluate how respondents' value selected attributes of a product (or program or service), whether preferences are influenced by the attributes, and the relative importance of the attributes.[20]

Growth hormone deficiency (GHD) in adults and children has been treated over the last several decades with recombinant human growth hormone (r-hGH) administered as a daily injection. Whilst this treatment has, on the whole, been successful, evidence indicates that adherence with daily treatment is less than optimal[21] and presents a particular challenge in children for a variety of reasons (including discomfort or pain with daily injections, the required length of treatment, and the patients and parents understanding of treatment benefit and consequences of non-compliance).[22,23] The psychological impact on the family, and in particular the impact on the caregiver who primarily administers the daily injections to young children, can be emotionally distressing.

It has been hypothesized that a less frequent injection schedule (for example, a weekly or monthly injection schedule) could improve patient adherence.[24] In children, this would obviously result in improved long-term height outcomes and improved quality of life (QoL). Injection frequency for administration of r-hGH injections may be an important factor for patients and clinicians when initiating therapy for GHD and making subsequent treatment choices for this chronic condition. Various delivery and device attributes (ie, product features such as safety, effectiveness, or mode of administration) may factor into patient preferences about r-hGH injections, such as frequency, device, and storage options. Little research regarding r-hGH injection frequency preferences has been done to date, since the development work on these newer "less frequent" products is still ongoing, and they are not currently available for

routine prescribing. The goal of this study was to ascertain relative patient preferences associated with the r-hGH injections and injection devices using DCE methods.

Screening of medical records and patient selection

This study was a retrospective analysis of medical records of obese patients who underwent bariatric surgery by RYGBP at our centre. Only patients who complied with our follow-up schedule (see below) during the first 2 y after surgery were included. We excluded from our analysis

1) Patients who underwent RYGBP secondarily after having previously undergone another bariatric procedure,
2) Patients who were lost to follow-up or who attended <4 of the planned medical visits during the first 2 y after RYGBP,
3) Patients whose blood analyses were performed in outside laboratories,
4) Patients who became pregnant during the first 2 y after RYGBP
5) Patients who were treated with nutritional supplements before RYGBP.

Surgical technique

The surgical technique was described in detail elsewhere. The length of the Roux-en-Y limb was determined by the patient's BMI; it was 100 cm for those with BMI ≤ 48.0 and 150 cm for those with BMI > 48.0. Cholecystectomy was performed if gallstones were present and in many of the remaining patients as prophylaxis against the occurrence of gallstones during rapid weight loss. All patients included in the analysis were operated on between November 1999 and June 2004.

Clinical and biologic follow-up

Every patient met a physician of our team at least once before surgery; after surgery, they were seen every 3 Mo during the first postoperative year and at 6-mo intervals during the second year. Height was measured at the preoperative consultation with the use of a studio meter. At each consultation, body weight was measured using a Detector scale (Detector, Webb City, MO), and BMI was calculated. The percentage of excess body weight was calculated according to the ideal body weight.

At each postoperative consultation, a non fasting blood sample was drawn. Measurements included total and corrected calcium, albumin, parathyroid hormone, 25-hydroxyvitamin D, iron, ferritin, folic acid, erythrocyte magnesium, zinc, and vitamin B-1, B-6, and B-12 concentrations and a complete blood count. All biochemical analyses were performed by certified laboratories (ISO CEI 17025) and run in duplicate or triplicate samples. Normal reference ranges and techniques used by our laboratory for the measurement of several vitamins and micronutrients.

Substitutive treatment

A standardized multivitamin preparation was prescribed for all patients between the first and the sixth postoperative months. It contained the following daily amounts of vitamins and minerals: 800 μg vitamin A, 4.2 mg vitamin B-1, 4.8 mg vitamin B-2, 6 mg vitamin B-6, 3 μg vitamin B-12, 180 mg vitamin C, 5 μg vitamin D-3, 10 mg vitamin E, 30 μg vitamin K, 0.45 mg vitamin H, 0.6 mg folic acid, 54 mg nicotinamide, 18 mg pantothenic acid, 120 mg Ca, 25 μg Cr, 8 mg Fe, 1.5 mg F, 75 μg I, 0.9 mg Cu, 45 mg, 1.8 mg Mn, 45 μg Mo, 126 mg P, 55 μg Se, and 8 mg Zn.

Specific substitutive treatments were prescribed as soon as the value measured in a given patient was below the lower value of the reference range for folic acid, magnesium, vitamin B-1, vitamin B-6, vitamin B-12, and zinc. Calcium and vitamin D-3 were prescribed when corrected calcium or 25-hydroxyvitamin D concentrations were below the lower value of the reference range or when the parathyroid hormone concentration was higher than the higher value of the reference range. Iron was prescribed when either the iron or ferritin concentration was below the lower normal reference value. If a specific substitution was started, the patient was considered deficient in that particular nutriment/hormone for the rest of the follow-up, because discontinuation of the treatment generally leads to reemergence of the deficit.

Nutritional supplements usually were prescribed orally at the following doses: vitamin B-12, 1 mg/mo; iron, 80 mg/d; calcium, 1000 mg/d; vitamin D-3, 0.02 mg/d; folic acid, 1 mg/d; zinc, 5 mg/d; vitamin B-1, 100 mg/d; vitamin B-6, 40 mg/d; and magnesium, 100 mg/d. These doses were then adapted individually according to routine laboratory checks. When no satisfactory response (assessed by laboratory analyses) was obtained, the doses were increased. Vitamin B-12 was always administered intramuscularly, and iron was given intravenously when a satisfactory response to the oral treatment could not be obtained.

Cost of substitutive treatments

Swiss prices as published on the Swiss Compendium website[25] were used to calculate treatment costs, and then converted to US dollars[26]. Of note, the cost of intramuscular or intravenous administration was not included in our evaluation.

Statistical analyses

Data are shown as means ± SD. Paired t tests were used for intragroup comparisons, and nonpaired t tests were used for intergroup comparisons. A two-tailed Fisher's exact test was used for comparison of proportions. Simple bivariate analysis was performed by use of the 2-tailed Pearson correlation coefficient test. The significance level was defined as $P < 0.05$. SPSS version 15.0 (SSPS, Inc, Chicago, IL) was used for all statistical analyses.

Distress and suffering are an existential cornerstone of the human condition, yet how we reflect upon and describe the extremes of our mental duress has varied enormously across history. For more than 100 years, certainly in the West, the predominant means of conceptualizing mental health struggles has been to categorize them within formal taxonomic systems, organized according to hypothetical distinctions between different sets of signs and symptoms, and compiled into comprehensive compendia of psychiatric diagnoses. The current leading such taxonomies—the Diagnostic and Statistical Manual of Mental Disorders (DSM; now in its 5th edition) and the International Classification of Diseases (ICD; now in its 11th edition)—are long-established, have global reach, and exert a profound influence over the ways in which we understand, assess, and manage mental ill health.

Despite the historical momentum and widespread influence of the diagnostic rubric, there is an emerging and growing consensus that such psychiatric nosologies may be reaching the limits of their research and clinical utility. In their place, there is gathering support for a "transdiagnostic" approach that cuts across the traditional diagnostic boundaries or, more radically, sets them aside altogether, to provide novel insights into how we might understand mental health difficulties. This transdiagnostic approach extends beyond issues of taxonomy. Removing the distinctions between proposed psychiatric taxa at the level of classification opens up new ways of conceptualizing the underlying theories and processes implicated in mental ill health and provides a platform for novel ways of thinking about onset, maintenance, and clinical treatment and recovery from experiences of disabling mental distress.

The transdiagnostic field is nascent yet fast-developing. This Special Section of the Journal of Consulting and Clinical Psychology provides a timely opportunity to take stock of the current state of transdiagnostic science. In this introduction we review where the field has come from and where it is heading, highlighting issues that require some resolution and offering recommendations for progress.

Diagnostic and Transdiagnostic Approaches

Although attempts to classify mental health difficulties date back several thousand years, formalized diagnostic models only emerged properly from the biological and Linnaen botanical classification systems of the 19th century. Most prominently, Kraepelin's Compendium der Psychiatrie in 1883 exerted a profound influence on the development of the emerging field of clinical psychiatry especially in the United States, laying the foundation for the publication of the first edition of the DSM in 1952 (DSM-I, American Psychiatric Association, 1952). In 1980, the publication of the DSM–III outlined for the first time a thorough multiaxial diagnostic system with carefully operationalized criteria for a wide range of disorders, with no allegiance to any theoretical approach aside from a broad biomedical model. The DSM–III was hailed as a "paradigm shift" (Blashfield, Keeley, Flanagan, & Miles, 201) for diagnostic psychiatry, rescuing the profession ". . . from unreliability and the oblivion of irrelevancy" (Frances, 2009, p. 2). The current instantiation of the DSM—the DSM–5 – appeared in 2013 after a 14 year gestation and runs to 947 pages covering some 541 diagnostic categories (up from 106 in the DSM-I; American Psychiatric Association, 2013).

The DSM and ICD have evolved into self-perpetuating systems that now govern and define all aspects of how we conceptualize mental health. They provide an organizing framework for virtually all core texts in psychiatry, clinical psychology, and abnormal psychology (Cosgrove, Krimsky, Vijayaraghavan, & Schneider, 2006; Marecek & Hare-Mustin, 2009), they guide mental health training across the helping professions, and they define how we assess, manage and treat mental health problems worldwide. The diagnostic systems that they enshrine have created a form of "epistemic prison" (Hyman, 2010) that constrains health insurance and pharmaceutical industry practices, is sanctioned and supported by government and legal policies, and dominates social and public discourse about mental health and illness, as reflected in art, literature and the visual media (Ussher, 2010).

There are many factors underscoring this rise to dominance. Some are certainly sociopolitical (Kawa & Giordano, 2012; Khoury, Langer, & Pagnini, 2014) with diagnoses offering a biomedical legitimacy to discourse about mental ill health that has a broad academic, professional, and social appeal. Others are more pragmatic as, without doubt, the diagnostic paradigm offers some clear benefits to clinical and research practice: It provides a lingua franca for describing clusters of symptoms that facilitates communication between users of services, clinicians and

researchers; it sets out a common metric for research programs; and it provides an organizing principle for the development and evaluation of diagnosis-led assessment and treatment approaches (Hayes & Hofmann, 2018). Finally, for some, the biomedical model at the heart of the diagnostic approach also brings a legitimacy to the suffering that is experienced, reducing stigma and deflecting pejorative judgments that mental ill health reflects some form of personal weakness on the part of the diagnosed.

Despite these advantages of the diagnostic paradigm, there is a gathering apprehension that the taxonomic approach instantiated in the DSM and ICD runs counter to the available clinical and research evidence and may hamper our understanding of mental ill health and consequently how we manage and treat mental distress (Insel, 2014; Kotov et al., 2017). Here we touch briefly on seven areas of concern that have currency within this debate. We focus predominantly on so-called common mental health problems (Craig & Boardman, 1997), captured by the various diagnoses of mood disorder, anxiety disorder, stressor related disorders, and obsessive–compulsive disorders within the diagnostic manuals, but the arguments of course extend beyond these presentations.

The Underlying Biopsychosocial Processes are Transdiagnostic

A perhaps unintended consequence of the psychiatric diagnostic paradigm is the notion that diagnoses somehow capture or reflect the underlying reality of the world, carving nature at its joints and identifying natural kinds of "mental disorder." This idea stems from general medicine, where the majority of physical illnesses and diseases reflect qualitatively different states of health with one or a small number of identifiable and discrete causes. This is not the case for mental health problems where it is generally accepted that causes are not only complex, multiple and interactive but as yet poorly understood. What we know is that mental ill health prototypically emerges from an inter play between myriad biological, behavioral, psychosocial, and cultural processes that do not respect established diagnostic boundaries, where the interactions are multifarious, and modulated by an individual's lifelong experiences of the world.

The Symptom Space is Dimensional

Within the diagnostic manuals, symptoms are thresh-holded, imposing binary notions of "present" versus "absent". Groupings of symptoms deemed to be present then comprise the different diagnoses albeit with guidance on severity qualifiers for "mild," "moderate," and "severe" manifestations of individual diagnoses. However, evidence overwhelmingly suggests that mental health symptoms are not all-or-none phenomena, but are better conceptualized along continuous dimensions within the population as opposed to these distinct categorical entities. Indeed, there is a lack of compelling evidence for even a single symptom or disorder being a distinct category.

This imposition of artificial categories onto a multidimensional space inevitably sacrifices much of the richness of the available clinical information, contributing to diagnostic instability with symptoms falling above or below imposed thresholds over time, as well as reduced interpreter reliability as assessors struggle to elucidate whether marginal symptoms cross the designated thresholds. Most importantly, many individuals experiencing psychological distress fall short of the criteria for any diagnosis, despite a manifest need for care.

The unfavourable metabolic milieu associated with obesity is a worldwide concern and was recently highlighted by the Coronavirus Infectious Disease 2019 (COVID-19) pandemic[27-30]. Epidemiological studies from around the globe have conclusively demonstrated a linear association between obesity and all-cause mortality, with mortality pre-dominantly attributable to cardiovascular disease[31-32]. A recent meta-analysis suggests a rise in death rate as body mass index (BMI) increases above 25 kg/m2[33].

Obesity is often mistakenly assumed to be synonymous with a state of nutritional excess. The excess, however, only applies to the energy balance. As such obesity can paradoxically represent a state of nutritional deficiency. Obesity is often compounded by a change in diet to low-cost, readily available, high sugar, high carbohydrate, and nutrient-deficient meals. Therefore, excess weight can co-occur with malnutrition, known as the 'overfed but undernourished' phenomenon[34,35].

Metabolic surgery effectively addresses the harmful effects of excess weight and has decreased morbidity and mortality associated with excess adiposity[36-39]. The benefits of metabolic surgery performed in high volume centers outweigh the associated potential harm, provided that precautionary measures are taken to prevent long-term adversities[40-43].

In recent years reports of pre-existing micronutrient deficiency in patients scheduled for metabolic surgery have increased[44,45] demonstrated a high prevalence of micronutrient deficiencies preoperatively in Austria, with 25-hydroxy vitamin D (25(OH)D) deficiency significantly associated with higher BMI. Flancbaum reported preoperative deficiencies of 43.9% for iron, 8.4% for ferritin, and 68.1% for 25(OH)D in a cohort from New York. Geographical, socio-economical, and ethnic variables limit extrapolation of these findings to the South-African population undergoing surgery for obesity.

Since metabolic surgical procedures may further impact micronutrient status, correcting pre-existing deficiencies is standard care. It is thus recommended to evaluate and optimize the micronutrient status of all patients scheduled to undergo metabolic surgery preoperatively[46-48]. In resource-limited environments, the cost of a comprehensive preoperative micronutrient assessment needs to be weighed against both the prevalence of deficiencies and the potential harm if these deficiencies remain undetected. Recommendations on preoperative testing should ideally be contextualized. The primary objective of this study was to determine the prevalence of micronutrient and vitamin deficiencies in obese patients scheduled to undergo metabolic surgery at a tertiary referral centre from a low-middle income country.

Iron deficiency is present in ~50% of patients with severe aortic stenosis.[49,50] Iron is an essential micronutrient, and while its fundamental role in oxygen transport through erythropoiesis is well recognised, it is equally critical for energy production and efficient functioning of all of the body's organs.[51,52] Iron deficiency is a condition in which there is insufficient available iron to meet the body's needs.

Patients who are scheduled for transcatheter aortic valve implantation (TAVI) are often elderly and have multiple comorbidities that may affect clinical outcomes after valve implantation. Approximately one third of patients undergoing TAVI do not experience an improvement in physical capacity and symptom burden – despite successful valve implantation.[53,54] It is therefore relevant to address the comorbidities of these patients and to investigate whether we can identify therapeutic targets to optimise the effect of the TAVI procedure. In patients with heart failure, intravenous iron improves exercise capacity, quality of life, myocardial function, and reduce the risk of heart failure hospitalisations.[55-60] In patients with severe aortic stenosis, observational data suggest that iron deficiency is associated with an unfavourable clinical profile and adverse outcomes. Furthermore, the symptoms of iron deficiency, such as fatigue, dyspnoea, and reduced exercise capacity, are similar to the cardinal symptoms of symptomatic aortic stenosis.[61,62] Iron deficiency may therefore contribute to a lack of improvement in symptoms after TAVI, and may thus represent a potential cost-effective treatment to improve outcomes after TAVI.

The Intravenous Iron supplement for Iron deficiency in Severe Aortic Stenosis (IIISAS) trial is the first randomised, clinical trial to assess the efficacy and safety of intravenous iron in patients with severe aortic stenosis. We hypothesised that in iron-deficient patients with severe aortic stenosis, intravenous iron would improve physical performance, New York Heart Association (NYHA) functional class, muscle strength, and health-related quality of life beyond the effect of TAVI.

Aim and objectives

The aims of this retrospective study were

1) to assess the type, frequency, and pattern of development of nutritional deficiencies over the first 24 mo after RYGBP,
2) to determine the amount of supplements prescribed to each patient,
3) to evaluate the cost of the substitutive treatment.

CONCLUSION

In conclusion, the study documented micronutrient deficiencies and a concerning prevalence of abnormal glucose status in obese individuals scheduled for metabolic surgery. The appropriate detection and management of these nutritional deficiencies need to be moderated by the judicial use of resources and should include, at a minimum, the measurement of 25(OH)D and folate level and evaluation of iron status. Future efforts should seek to collate patient data on a national scale, to provide a more holistic, longitudinal picture of the relationship between obesity, metabolic surgery, and micronutrient status in the developing world, which may optimize evidence-based care.

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