Economic evaluation of the cost-utility of remote monitoring in children with obese in rural zone

Avaliação econômica da relação custo-utilidade do monitoramento remoto em crianças com obesidade na zona rural

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ABSTRACT
Background: Obesity is a risk factor that triggers other chronic diseases such as cardiovascular, respiratory and diabetes mellitus, among others. However, this scenario can be improved with the use of remote monitoring technologies bringing economic benefits, clinical effectiveness and a better follow-up of users. Objective: Conduct a cost-utility economic assessment of the impact of remote monitoring technology for biomedical signals in preventing obesity in children, within the scope of primary health care, in rural areas. Methods: The study was based on assistance with remote monitoring of 296 children. An economic evaluation was carried out based on health costs, clinical utilities and quality-adjusted life years (QALYs). The cost-utility analysis (CUA) was obtained from the direct costs divided by the QALYs. To check if there is a statistically significant difference in clinical utility between the conventional system and the use of Free Living Energy Expenditure Monitoring System® (FLEEM System®), the Kolmogorov-Smirnov normality test (p <0.05) and the Wilcoxon test were applied. Results: The direct annual cost to care for a child using remote monitoring was R$ 541.31 (US$ 137.25) against the conventional practice of R$ 801.96 (US$ 203.34). The average value of 0.06 for the utility and 3.72 QALYs gained from the intervention. CUA was R$ -70.07 (US$ -17.77) per QALY gained from the perspective of remote monitoring. Conclusions: Remote monitoring represents a 32.50% economic gain for the health system, the negative CUA result means that the FLEEM System® can save R$ 70.07 (US$ 17.77) per QALY gained.

Keywords: cost-utility analysis, economic evaluation in health, FLEEM System®, remote monitoring, obesity.

RESUMO  
Antecedentes: A obesidade é um fator de risco que desencadeia outras doenças crônicas, como a cardiovascular, respiratória e diabetes mellitus, entre outras. No entanto, este cenário pode ser melhorado com o uso de tecnologias de monitoramento remoto, trazendo benefícios econômicos, eficácia clínica e um melhor acompanhamento dos usuários. Objetivo: Realizar uma avaliação econômica custo-utilidade do impacto da tecnologia de
monitoramento remoto para sinais biomédicos na prevenção da obesidade em crianças, no âmbito da atenção primária à saúde, em áreas rurais. Métodos: O estudo foi baseado na assistência com monitoramento remoto de 296 crianças. Foi realizada uma avaliação econômica com base nos custos de saúde, serviços públicos clínicos e anos de vida com qualidade ajustada (QALYs). A análise de custo-utilidade (CUA) foi obtida a partir dos custos diretos divididos pelas QALYs. Para verificar se há uma diferença estaticamente significativa na utilidade clínica entre o sistema convencional e o uso do Sistema de Monitoramento de Despesa de Energia Livre em Vida (FLEEM System®), foram aplicados o teste de normalidade Kolmogorov-Smirnov (p <0,05) e o teste de Wilcoxon.

Resultados: O custo anual direto para cuidar de uma criança usando monitoramento remoto foi de R$ 541,31 contra a prática convencional de R$ 801,96 (US$ 203,34). O valor médio de 0,06 para a utilidade e 3,72 QALYs obtidos com a intervenção. O CUA foi de R$ -70,07 (US$ -17,77) por QALY obtido sob a perspectiva de monitoramento remoto. Conclusões: O monitoramento remoto representa um ganho econômico de 32,50% para o sistema de saúde, o resultado negativo do CUA significa que o FLEEM System® pode economizar R$ 70,07 (US$ 17,77) por QALY ganho.


1 INTRODUCTION

Obesity is a disease characterized by excess body fat, where 95% of these causes are multifactorial, such as eating habits, sedentary lifestyle, genetic, psychological, social, cultural and economic (Chaves et al., 2011). Besides being a risk factor triggering several other chronic diseases such as cardiovascular, respiratory, diabetes mellitus, among others (Bray, 2004; Choukem et al., 2020), obesity has been causing large consumption of economic resources of both public (Barbany; Foz, 2002; Finkelstein; Strombotne, 2010) and private health systems (Canella; Novaes; Levy, 2015). According to Dobbs et al. (2014), these costs were estimated at 2.8% (US$ 2.0 trillion) of the World Gross Domestic Product (GDP), roughly equivalent to the global impact of smoking or gun violence, war and terrorism in 2012. The years 2017, 2018, and 2019 represented rising costs of US$ 2.27 trillion, US$ 2.42 trillion, and US$ 2.45 trillion, respectively (World Bank, 2020).

In Brazil, the cost of obesity represents 8.05% of hospital costs (Coutinho; Lins, 2015), or 2.4% of the national GDP (Dobbs et al., 2014), representing R$ 175.2 billion
(US$ 44.42 billion) in 2019 (World Bank, 2020). This burden with obesity can reach a higher level, going beyond the expenses of the health service as loss of income or productivity at work such as presenteeism and absenteeism, difficulty relocating in the labor market, benefits paid by social security, monetary entailments by the low quality of life resulting from obesity among others (Goettler; Grosse; Sonntag, 2017). Consequently, these facts represent burdens to the global public coffers (Bahia; Araújo, 2014). On the other hand, the use of health information technology, such as telemedicine, has a great potential to reduce these costs, as they make healthcare more accessible while improving patients' clinical condition at a reduced cost (Flodgren et al., 2015). In the Netherlands, a study of economic evaluation on smoking abstinence was conducted with three groups of interventions: one group used the internet and nurses' guidance; another group made use of the internet only; the third group received traditional care with guidance from nurses (Smit et al., 2013). According to the authors, the groups using the internet were cost-effective, but the group that received traditional care showed greater clinical effectiveness.

Biomedical technologies are used successfully in a variety of situations that would not be possible to solve by conventional medicine therapies and their resources and surgical or pharmacological interventions. It is understood as a conventional practice the structure and services of public health adopted in the Line of Care adopted by the Brazilian Unified Health System (SUS) (Brasil, 2021).

It is currently possible to use robotic rehabilitation resources to increase the quality and life expectancy of a person after an accident (Rodgers et al., 2017). Similarly, the use of technologies for remote monitoring allows to enhance the nutritional medical monitoring of an obese person, and thus improving the results in weight control with increased quality and life expectancy of patients (Lopes et al., 2020a).

According to Schulz et al. (2014), the economic evaluation indicators are obtained by calculating the cost-utility comparing the conventional practice with the technology incorporated into the health system, both in relation to the quality of health of users (patients). For this research, the suggested technology is the incorporation of the FLEEM System® (Free Living Energy Expenditure Monitoring System®) as a remote patient
monitoring aid. This technology is a remote monitoring platform that captures, stores, and processes the user's biomedical data (Goroso et al., 2013; López, 2012; Silva et al., 2019).

Both conventional practice and remote monitoring aim to improve the quality of life of their users. The comparison between them was performed in two steps. The first step consists of quantifying the usefulness of health status measures on a scale from 0 to 1, where 0 represents death or worse health status and 1 refers to a person in perfect health (Khabibullina; Gerry, 2019). The second step was based on Quality-Adjusted Life Years (QALY), a measure that adds the gains in quantity of years of life with quality of life. The QALY calculation is the result of combining the utility of health status with survival years (Nuijten; Dubois, 2011; Schulz et al., 2014). The representation of these elements is fundamental in the economic analysis between the FLEEM System® and conventional practice by means of cost-utility.

Currently there is an increase in the number of cases of obesity and consequently an increase in the economic cost resulting from the disease (Xu et al., 2020), where the patient is usually followed only in the consultation scheduled by the doctor or nurse (Bogt et al., 2011; Lopes et al., 2020b). The municipality of Monteiro Lobato in the state of São Paulo, Brazil, currently adopts the conventional practice, being medical and nursing consultations the main health interventions of the SUS (Silva et al., 2020). On the other hand, in the studies conducted by Schulz et al. (2014) and Schulz and Hulsman (2009) it was verified health cost reduction and the effectiveness of intervention in health care and health promotion through the use of remote monitoring technology in health care. Therefore, this work aims to verify the economic gain in cost and better effectiveness of health status with the intervention of remote monitoring in the prevention and control of obesity in children in the rural area. To this end for that, this research was elaborated with quantitative and exploratory characteristics, which aimed to perform an economic evaluation of cost-utility of the impact of remote monitoring technology of biomedical signals to prevent obesity in children, in the context of primary health care in rural areas, through the interventions of the FLEEM System®, comparing it with the conventional practice. Considering the cost-utility analysis, expressed as the quality and quantity of years of life, based on the cost-effectiveness for each intervention, it was observed the
relevance of the remote monitoring intervention with favorable cost and effectiveness, economic and clinical gain.

2 METHODS
2.1 DESCRIPTION OF THE SEARCH FIELD

For this study, we measured the costs and cost-utility of remote monitoring of 296 children, aged 9 to 12 years, from four schools in the municipality of Monteiro Lobato, state of São Paulo, Brazil. The object of study were two health services, being: i) the FLEEM System® remote monitoring platform, an advanced health system for capturing, storing and processing biomedical data, with the accompaniment of a health team composed of a doctor, nurse, physical education professional and nutritionist, with real-time care. The Operations Center for this system is installed at the Technological Research Center (NPT) of the University of Mogi das Cruzes (UMC), in the Municipality of Mogi das Cruzes in the state of São Paulo, Brazil; ii) the conventional health practice by SUS is performed by two health professionals, in general by a doctor and nurse who accompany them according to the service schedule at the Basic Health Unit or SUS Family Health Strategy Unit linked to the Municipal Health Secretariat. Health of the municipality of Monteiro Lobato located in the Vale do Paraíba and Litoral Note region of the state of São Paulo, Brazil. Primary care with comprehensive care is part of a reference network composed with support from the municipality of São José dos Campos/SP, 35 km away, for assistance with specialists (Monteiro Lobato, 2020a), in particular, the medical professional endocrinologist.

The research was developed based on health economic evaluation data, biomedical signals, and health costs of the two intervention modalities. The cost data were based on the values of 2019, where the average price of the dollar was R$ 3.944 (World Bank, 2020).

2.2 ETHICAL ASPECT

The research involving human beings was approved by the Research Ethics Committee of the University of Mogi das Cruzes under CAAE Registration No.
47883215.0.0000.5497 and by the Municipal Health Department of São Paulo under CAAE Registration No. 47883215.0.3001.0086, with favorable opinions for the research.

2.3 STUDY VARIABLES

In the economic evaluation of health, the costs of health professionals, consumption of input and service are classified as direct costs in the clinical care of the patient (Dee et al., 2014). For this study, the classified costs were of the FLEEM System® and conventional practice. The cost of the FLEEM System® was prepared considering the physician's care in the evaluation of clinical reports, nurses with procedures and nursing consultations, nutritionist with application of the questionnaire on food frequency, physical education professional in the execution of the anthropometric evaluation and inputs and services related to the consumption of different resources. Conventional practice was carried out mainly with medical, nursing and inputs and services related to the consumption of different resources.

Equation 1, developed by the authors, makes it possible to calculate the annual unit cost of health professionals in patient care for each intervention.

\[
CHP_{fs or cp} = \frac{\left[\left(W_n / T_n\right) \times T_n\right] + \left[\left(W_{pe} / T_{pe}\right) \times T_{pe}\right] + \left[\left(W_{nt} / T_{nt}\right) \times T_{nt}\right] + \left[\left(W_d / T_d\right) \times T_d\right]}{J \times F}
\] (1)

Where:

- \(CHP_{fs or cp}\): Annual unit cost of each service per health professional, \([CHP_{fs or cp}]=[R]\]=[USS];
- \(W_n\): Gross monthly salary (without discounts) of nursing, \([W_n]=[R]=[USS]\);
- \(W_{pe}\): Gross monthly salary (without discounts) of the physical education professional, \([W_{pe}]=[R]=[USS]\);
- \(W_{nt}\): Gross monthly salary (without discounts) of the nutritionist, \([W_{nt}]=[R]=[USS]\);
- \(W_d\): Gross monthly salary (without discounts) of the doctor, \([W_d]=[R]=[USS]\);
- \(J_n\): Nursing weekly working hours, 30 hours per week, \([J_n]=[hours]\);
- \(J_{pe}\): Weekly workday of the physical education professional, 40 hours per week, \([J_{pe}]=[hours]\);
- \(J_{nt}\): Professional nutritionist's weekly working day, 30 hours a week, \([J_{nt}]=[hours]\);
- \(J_d\): Doctor's weekly workday, 20 hours a week, \([J_d]=[hours]\);
- \(T_n\): Time spent per nursing care or procedure per patient, \([T_n]=[minutes]\);
- \(T_{pe}\): Time spent by the physical education professional's service or procedure per patient, \([T_{pe}]=[minutes]\);
- \(T_{nt}\): Time spent per care (procedure) of the nutritionist per patient, \([T_{nt}]=[minutes]\);
- \(T_d\): Time spent per doctor's care or procedure per patient, \([T_d]=[minutes]\);
- \(J\): Monthly working hours for legal purposes, 5 weeks, \((J=5)\), \([J]=[weeks]\);
- \(F\): Conversion Factor, turn hours into minutes, 1 hour corresponds to 60 minutes, \((F=60)\), \([F]=[minutes]\).
To measure the cost of inputs and services related to the consumption of different resources, Equation 2 was used, which represents the unit value for performing the annual remote monitoring procedure. This equation was also developed by the authors.

$$u_{c_{fs}} = \frac{(IS_{fs})}{T_{q_{fs}}}} \times T_{fs}$$

(2)

Where:

$U_{c_{fs}}$: Annual unit cost of inputs and services for FLEEM System $^\circledR$, $[U_{c_{fs}}]=[R]=[US]$; $IS_{fs}$: Total cost of inputs and services for the operation of the FLEEM System $^\circledR$, $[IS_{fs}]=[R]=[US]$; $T_{q_{fs}}$: Number of minutes month on a legal basis, (24 hours x 7 days x 5 weeks x 60 minutes [minutes conversion factor]), $T_{fs} = 50,400$ minutes, $[T_{q_{fs}}]=[minutes]$; $T_{ps}$: Total in annual minutes, time provided by health professionals in the care per patient, total of 1,440 minutes (considered one minute per day for each professional [physician, nurse, physical education professional and nutritionist]), $[T_{ps}]=[minutes]$.

Equation 3 represents the annual unit cost of supplies and services per service in conventional health care (Cortez et al., 2019).

$$u_{c_{cp}} = \frac{IS_{cp}}{Q}$$

(3)

Where:

$U_{c_{cp}}$: Unit cost of inputs and services per conventional health care service, $[U_{c_{cp}}]=[R]=[US]$; $IS_{cp}$: Total cost of supplies and services to operate in accordance with conventional health practice, $[IS_{cp}]=[R]= [US]$; $Q$: Number of visits by conventional health practice, total annual care of 296 patients, $[Q]=[quantities]$.

The absorption of these costs resulted in the direct total cost, or simply total cost, which aggregate all the expenses involved in the health service (Dee et al., 2014). For the study, costs by intervention modality of health professionals and consumption of input and service were included.

The relationship between cost and effectiveness is essential to measure the outcome of health quality (Nuijten; Dubois, 2011). For the authors, the effect on health should be measured in quality and years of life gained.
The quality of health is based on the so-called utility value, which represents the health status or result obtained with treatment. The measure is quantified by a scale ranging from 0 (zero) to 1 (one), where the approximate value of 0 represents death or worse health status and the increasing value means the search for full health or healthy state denoted by value 1 (Khabibullina; Gerry, 2019). In this study, the outcome was measured based on the health status of the biomedical data, which is described in the following subsection.

2.4 PREPARATION OF THE CLINICAL UTILITY SCALE

To transform biomedical data into a scale of clinical utility, the following considerations are made:

a. The clinical utility scale is divided into 4 intervals called: i) Critical: from 0 to 0.3; ii) Transition: from 0.4 to 0.5; iii) Precaution: from 0.6 to 0.7; and iv) Healthy: from 0.8 to 1.0.

b. The physiological intervals corresponding to each biomedical data are transformed into a scale from 0 to 1 according to the impairment of health status. E.g: the range of total cholesterol (TC), TC ≤ 20 mg/dl and ≥ 401 mg/dl is associated with a scale value of 0.0; since the value ≤ 20 mg/dl represents the lack of fat in the blood and the value ≥ 401 mg/dl represents the excess fat in the blood, both values harm the individual’s health (Subczynski et al., 2017). However, the range of 121 ≤ TC ≤ 180 mg/ml is assigned the value 1.0; considered healthy or ideal on the clinical utility scale. Other ranges have intermediate assignments. The same is true for other variables.

c. Biomedical data are classified according to the physiological ranges denoted by the clinical reference of each parameter. E.g.: the value of 85 mg/dl of glucose is classified as normal according to the range of 81 to 90 mg/dl, according to the classification of the Brazilian Society of Cardiology (SBC, 2017), this SBC reference is also for the other biochemical results.
Finally, once the biomedical data are classified, the value of the clinical utility scale is assigned. E.g.: the Glucose value of 85 mg/dl corresponds to the value of 1.0 of the healthy range.

Table 1 shows the 0-1 clinical utility scale and its respective intervals in relation to the physiological classification of each parameter.

### Table 1 - Utility scale and classification of biomedical data

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>CRITICS</th>
<th>TRANSITION</th>
<th>PRECAUTION</th>
<th>HEALTHY</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC</td>
<td>13.0 ≤ TC &lt; 180</td>
<td>21.0 ≤ TC &lt; 240</td>
<td>31.0 ≤ TC &lt; 360</td>
<td>41.0 ≤ TC &lt; 480</td>
</tr>
<tr>
<td>LDL</td>
<td>LDL ( Low)</td>
<td>4.0 ≤ LDL &lt; 160</td>
<td>7.0 ≤ LDL &lt; 260</td>
<td>11.0 ≤ LDL &lt; 350</td>
</tr>
<tr>
<td>HDL</td>
<td>HDL ( High)</td>
<td>69.0 ≤ HDL &lt; 160</td>
<td>28.0 ≤ HDL &lt; 260</td>
<td>41.0 ≤ HDL &lt; 350</td>
</tr>
<tr>
<td>TC/HDL</td>
<td>TC/HDL ( Low)</td>
<td>91.0 ≤ TC/HDL &lt; 180</td>
<td>121.0 ≤ TC/HDL &lt; 260</td>
<td>169.0 ≤ TC/HDL &lt; 350</td>
</tr>
<tr>
<td>HDL</td>
<td>3.0 ≤ HDL &lt; 5.0</td>
<td>3.0 ≤ HDL &lt; 5.0</td>
<td>5.0 ≤ HDL &lt; 7.0</td>
<td>7.0 ≤ HDL &lt; 9.0</td>
</tr>
<tr>
<td>HDL</td>
<td>1.0 ≤ HDL &lt; 3.0</td>
<td>3.0 ≤ HDL &lt; 5.0</td>
<td>5.0 ≤ HDL &lt; 7.0</td>
<td>7.0 ≤ HDL &lt; 9.0</td>
</tr>
<tr>
<td>LMW</td>
<td>0.30 ≤ LMW ≤ 0.50</td>
<td>0.30 ≤ LMW ≤ 0.50</td>
<td>0.50 ≤ LMW ≤ 0.70</td>
<td>0.70 ≤ LMW ≤ 0.90</td>
</tr>
<tr>
<td>HDL</td>
<td>0.30 ≤ HDL ≤ 0.50</td>
<td>0.30 ≤ HDL ≤ 0.50</td>
<td>0.50 ≤ HDL ≤ 0.70</td>
<td>0.70 ≤ HDL ≤ 0.90</td>
</tr>
</tbody>
</table>
| TABLE 1 - Utility scale and classification of biomedical data

Source: Prepared by the author, based on the conducted research. TC: Total cholesterol; LDL: Low Density Lipoproteins; HDL: High Density Lipoproteins; VLDL: Very low-density lipoprotein; TG: Triglyceride; UA: Uric acid; GC: Glucose; TSH: Thyroid-stimulating hormone; IS: Insulin; BMI: Body mass index; SZ: Score-Z; HomaIR: Homeostasis Model Assessment of Insulin Resistance; %Fm: %Fat (male); %Ff: %Fat (female); WHRm: Waist-hip ratio (male); WHRf: Waist-hip ratio (female); %Fm: %Fat (male); %Ff: %Fat (female); WHRm: Waist-hip ratio (male); WHRf: Waist-hip ratio (female); SBP: Systolic blood pressure; DBP: Diastolic blood pressure.
Biomedical data related to conventional health practice and the experimental protocol of remote monitoring with the FLEEM System\textsuperscript{®} were transformed into clinical utility measures, as shown in Table 2.

Table 2 - Attributed utility of biomedical data

<table>
<thead>
<tr>
<th>Variables</th>
<th>Conventional health practice</th>
<th>FLEEM System\textsuperscript{®}</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol</td>
<td>0.86 ± 0.19</td>
<td>0.93 ± 0.09</td>
<td>0.0436</td>
</tr>
<tr>
<td>Low Density Lipoproteins</td>
<td>0.82 ± 0.21</td>
<td>0.94 ± 0.08</td>
<td>0.0001</td>
</tr>
<tr>
<td>High Density Lipoproteins</td>
<td>0.89 ± 0.17</td>
<td>0.91 ± 0.12</td>
<td>0.4651</td>
</tr>
<tr>
<td>Very low-density lipoprotein</td>
<td>0.96 ± 0.10</td>
<td>1.0 ± 0.10</td>
<td>0.0300</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>0.89 ± 0.17</td>
<td>0.95 ± 0.09</td>
<td>0.0178</td>
</tr>
<tr>
<td>Uric acid</td>
<td>0.95 ± 0.12</td>
<td>0.99 ± 0.04</td>
<td>0.0454</td>
</tr>
<tr>
<td>Glucose</td>
<td>0.89 ± 0.11</td>
<td>0.94 ± 0.09</td>
<td>0.0058</td>
</tr>
<tr>
<td>Thyroid-stimulating hormone</td>
<td>0.97 ± 0.10</td>
<td>0.99 ± 0.02</td>
<td>0.2489</td>
</tr>
<tr>
<td>Insulin</td>
<td>0.93 ± 0.17</td>
<td>0.98 ± 0.05</td>
<td>0.0464</td>
</tr>
<tr>
<td>Body mass index</td>
<td>0.74 ± 0.13</td>
<td>0.79 ± 0.13</td>
<td>0.0002</td>
</tr>
<tr>
<td>Score-Z</td>
<td>0.85 ± 0.17</td>
<td>0.90 ± 0.13</td>
<td>0.0003</td>
</tr>
<tr>
<td>Homa-IR</td>
<td>0.71 ± 0.27</td>
<td>0.82 ± 0.21</td>
<td>0.0655</td>
</tr>
<tr>
<td>%Fat (male)</td>
<td>0.81 ± 0.16</td>
<td>0.86 ± 0.10</td>
<td>0.0289</td>
</tr>
<tr>
<td>%Fat (female)</td>
<td>0.78 ± 0.17</td>
<td>0.85 ± 0.17</td>
<td>0.0010</td>
</tr>
<tr>
<td>Waist-hip ratio (male)</td>
<td>0.87 ± 0.14</td>
<td>0.92 ± 0.06</td>
<td>0.1574</td>
</tr>
<tr>
<td>Waist-hip ratio (female)</td>
<td>0.94 ± 0.09</td>
<td>0.98 ± 0.05</td>
<td>0.0025</td>
</tr>
<tr>
<td>Waist-to-height ratio</td>
<td>0.89 ± 0.12</td>
<td>0.92 ± 0.07</td>
<td>0.0703</td>
</tr>
<tr>
<td>Localized adiposity index (male)</td>
<td>0.72 ± 0.40</td>
<td>0.82 ± 0.37</td>
<td>0.0529</td>
</tr>
<tr>
<td>Localized adiposity index (female)</td>
<td>0.59 ± 0.41</td>
<td>0.62 ± 0.42</td>
<td>0.4290</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>0.97 ± 0.11</td>
<td>1.00 ± 0.04</td>
<td>0.0262</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>0.93 ± 0.17</td>
<td>0.96 ± 0.11</td>
<td>0.0078</td>
</tr>
</tbody>
</table>

Source: Prepared by the author, based on the conducted research.

2.5 CALCULATION OF ECONOMIC MEASURES

The incorporation of measures of quantity and quality of life in economic health assessment can measure the cost-effectiveness of interventions in health prevention and control (Lancsar et al., 2020). Utility is associated with the years of survival, according to the authors, thus obtaining the Quality-Adjusted Life Years (QALY), which represents years of life gained (Equation 4). QALY is an outcome measure for cost-utility analysis (CUA). For this study, life expectancy was 72 years for the municipality of Monteiro Lobato (Monteiro Lobato, 2020b).
$$\text{QALY} = U.T$$

Where:

QALY: Value of years gained [QALY]=[years]; U: Measure of quality of life in utility, factor from 0 to 1, [U] = [unitless]; T: Number of years of survival, [T] = [years].

The CUA is a form of economic evaluation, which allows comparing interventions with the outcomes of quality and quantity of life (Savitz; Savitz, 2016). The CUA estimates not only the outcome of the economic cost of the years of life lived, but also the cost of a healthy quality of life, with the lowest cost per QALY gained (Schulz et al., 2014). According to the authors, the formula to calculate the CUA is applied to Equation 5.

$$\text{CUA} = \frac{\text{Cost}_{FS} - \text{Cost}_{CHP}}{\text{QALY}_{FS} - \text{QALY}_{CHP}} \quad (5)$$

Where:

CUA: Cost-utility analysis in relation to QALYs, [CUA] = [R$] or [US$]; Cost$_{FS}$: Cost of Fleem System® intervention, [Cost$_{FS}$] = [R$] or [US$]; Cost$_{CHP}$: Intervention cost of conventional practice, [Cost$_{CHP}$] = [R$] or [US$]; QALY$_{FS}$: Represents years gained from Fleem System®, [QALY$_{FS}$] = year; QALY$_{CHP}$: Represents years gained from conventional practice, [QALY$_{CHP}$] = [years].

2.6 STATISTICS

The realization of the normality of the distribution of variables was tested using the Kolmogorov-Smirnov test. The normality test confirmed the variables with non-parametric results (Kitamura; Stoye, 2018; Mishra et al., 2019). The Wilcoxon test was applied to compare both results of each intervention with a statistical significance level of $p < 0.05$ (Verma; Abdel-Salam, 2019). The following hypotheses were formulated:

H0: There is no difference between the utilities generated by the biomedical data by interventions.
H1: There is a difference between the utilities generated by biomedical data by interventions. Statistical tests were performed using BioStat 5.3.
3 RESULTS

The costs considered were from the FLEEM System® platform and the conventional health practice, with health professionals and consumption of supplies and services, in the prevention and control of obesity in children.

For the FLEEM System®, the cost related to health professionals, such as salary, weekly working hours and time to perform the procedures per professional were as follows: i) Doctor - salary of R$ 9,173.33 (US$ 2,325.89) based on the 20-hour workweek and the average time in the evaluation of clinical reports is 60 minutes/year; ii) Nurse - salary of R$ 5,351.11 (US$ 1,356.77) based on a 30-hour workweek and the average time to carry out the nursing procedures is 135 minutes/year; iii) Nutritionist - salary of R$ 4,128.00 (US$ 1,046.65) based on a 30-hour workweek and the average time in food frequency assessments is 100 minutes/year; iv) Physical Education Professional - salary of R$ 3,822.22 (US$ 969.12) based on a 40-hour workweek and the average time for anthropometric assessments is 140 minutes/year. Total costs with inputs and services added to the amount of R$ 9,759.44 (US$ 2,474.51), based on 1,440 minutes/year of services.

For the conventional health practice, the cost related to health professionals (doctor and nurse), for the monthly salary and working hours are equal to the FLEEM System®, the average time for medical consultations is 180 minutes/year and nursing procedures and consultations on average are 240 minutes/year. The total costs with inputs and services were R$ 113,699.52 (US$ 28,828.48) per year. The total direct cost of the FLEEM System® was R$ 541.31 (US$ 137.25) and conventional healthcare was R$ 801.96 (US$ 203.34), both values representing the annual costs, per child (user) of each mode. In Table 3, the details of each element of the accumulated cost for prevention and control of obesity in children, over a period of one year, Equations 1 to 3.
The effectiveness of the usefulness of children's health status in monitoring by conventional health practice and remote monitoring by the FLEEM System®️, based on coefficients based on the values of the clinical picture of biomedical data. Table 4 shows the values obtained related to the health status by intervention and the clinical utility attributed to the biomedical data. To calculate the QALY the clinical utility and the remaining years must be taken into account. Therefore, the years of healthy lives that each intervention will provide, through clinical utility, will transform years into quantity and quality of life. Table 4 presents the healthy years of life (Table 2) based on the QALY (Equation 4).

Table 3 - Total cost of FLEEM System®️ and conventional health practice

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Resources</th>
<th>Cost (R$)</th>
<th>Cost (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEEM System®️</td>
<td>Inputs or services</td>
<td>278.88</td>
<td>70.70</td>
</tr>
<tr>
<td></td>
<td>Doctor</td>
<td>91.72</td>
<td>23.26</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>80.28</td>
<td>20.35</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>45.87</td>
<td>11.63</td>
</tr>
<tr>
<td></td>
<td>Physical Education</td>
<td>44.60</td>
<td>11.31</td>
</tr>
<tr>
<td><strong>Total cost</strong></td>
<td></td>
<td><strong>541.31</strong></td>
<td><strong>137.25</strong></td>
</tr>
<tr>
<td>Conventional Health Practice</td>
<td>Inputs or services</td>
<td>384.12</td>
<td>97.39</td>
</tr>
<tr>
<td></td>
<td>Doctor</td>
<td>275.16</td>
<td>69.77</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>142.68</td>
<td>36.18</td>
</tr>
<tr>
<td><strong>Total cost</strong></td>
<td></td>
<td><strong>801.96</strong></td>
<td><strong>203.34</strong></td>
</tr>
</tbody>
</table>

Source: Prepared by the author, based on the conducted research. (a) Physical Education Professional.

By using the FLEEM System®️️ to replace conventional health practice in preventing and controlling obesity in children, an effectiveness of 0.06 extra clinical utility and 3.10 QALYs gained in years of extra healthy lives was achieved. The incremental cost and incremental cost-utility analysis obtained with Equation 5 per QALY gained are the values represented in Table 5.

Table 4 - Clinical utility and QALY value

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Clinical utility</th>
<th>QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean utility</td>
<td>p-value</td>
</tr>
<tr>
<td>FLEEM System®️</td>
<td>0.91</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Conventional health practice</td>
<td>0.85</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

Source: Prepared by the author, based on the conducted research.
Table 5 - Outcome of the FLEEM System® cost-utility analysis with conventional healthcare practice

<table>
<thead>
<tr>
<th>Elements</th>
<th>FLEEM System®</th>
<th>Conventional health practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>R$ 541.31</td>
<td>US$ 137.25</td>
</tr>
<tr>
<td>Incremental cost</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Utility</td>
<td>0.91</td>
<td>0.85</td>
</tr>
<tr>
<td>Incremental utility</td>
<td>-</td>
<td>-0.06</td>
</tr>
<tr>
<td>QALY</td>
<td>56.42</td>
<td>52.70</td>
</tr>
<tr>
<td>Incremental QALY</td>
<td>-</td>
<td>-3.72</td>
</tr>
<tr>
<td>Incremental cost-utility</td>
<td>-</td>
<td>R$ -70.07</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US$ -17.77</td>
</tr>
</tbody>
</table>

Source: Prepared by the author, based on the conducted research.

By incorporating the FLEEM System® in relation to the conventional health practice, as shown in Table 5, the incremental cost was R$ -260.65 (US$ -66.09) which represents an economic gain of 32.50% and AUC of R$ -70.07 (US$ -17.77) per QALY gained.

4 DISCUSSION

The study on the cost of health care for a sample of children in the city of Monteiro Lobato/SP, which sought to assess the economic impact of the cost-utility analysis with health interventions, comparing the FLEEM System® and conventional practice of health in the prevention and control of obesity in children, identified the cost-effective effectiveness of health information technology intervention.

The FLEEM System® encompasses multidisciplinary health professionals, monitoring with remote monitoring in real time, with an application that also works offline, storage of biomedical data in cell phone memory and sent to a central when connecting to the internet, and with all these factors available for care, it showed greater effectiveness compared to conventional health practice; because it only provides consultations with a doctor and nurse with follow-up at scheduled times and to be carried out in person.

Under these circumstances, the use of remote monitoring with the FLEEM System® had an incremental cost gain, clinical utility effectiveness and incremental QALYs. This intervention was considered effective as it showed lower dominant cost and better effectiveness in the clinical picture. The results found in the study can be confirmed by a systematic review study on eHealth interventions, which aims to enhance the quality
of health care and reduce costs with online care (Elbert et al., 2014). In the economic evaluation of cost-minimization, it represented a savings of 32.50%, with a direct cost of R$ 541.31 (US$ 137.25) for the FLEEM System® against R$ 801.96 (US$ 203.34) for the conventional health practice, with an incremental cost gain of R$ -260.65 (US$ -66.09) per child per year with remote monitoring and resulting in a gain of R$ 77,152.28 (US$ 19,561.97) for one year in the care of 296 children. A study in Spain of telemonitoring obtained savings of 57.64% or € 63.28 per patient in 12 months, compared to conventional follow-up (Lopez-Villegas et al., 2019).

The gains in health quality effectiveness: with 0.06 clinical utility and 3.72 QALYs. The usefulness was clearly visible in Figure 1A, where the FLEEM System® contributed to improvements in the patients’ clinical status.

Figure 1 - Utility gain with FLEEM System®

Source: Prepared by the author, based on the conducted research. TC: Total cholesterol; LDL: Low Density Lipoproteins; HDL: High Density Lipoproteins; VLDL: Very low-density lipoprotein; TG: Triglyceride; UA: Uric acid; GC: Glucose; TSH: Thyroid-stimulating hormone; IS: Insulin; BMI: Body mass index; SZ: Score-Z; HomaIR: Homeostasis Model Assessment of Insulin Resistance; %Fm: %Fat (male); %Ff: %Fat (female); WHRm: Waist-hip ratio (male); WHRf: Waist-hip ratio (female); WHTR: Waist-to-height ratio; LAIm: Localized adiposity index (male); LAIf: Localized adiposity index (female); SBP: Systolic blood pressure; DBP: Diastolic blood pressure.
In Figure 1B a group of children who reached 0.31 point of gain utility, moving from the precautionary to healthy range, this represents an increase in QALYs gained and a reduction in costs. In this sense, Figure 1D shows a group of children in the healthy range and maintained clinical status. In this study period, Figure 1C represents children who did not have a good result with the FLEEM System®, where it was taken into account that these children did not follow the protocol as instructed.

The QALY gained, with the period analyzed, was 0.31 QALY per month, while a study using online monitoring technology was 0.09 QALY in relation to conventional monitoring (Lopez-Villegas et al., 2019). Studies show that after 30 years of age, people start the manifestations of diseases (Brasil, 2020; Moura; Carvalho; Silva, 2007), at that moment the clinical usefulness drops and, consequently, the reduction of the QALY. These children, at the time of the research, did not appear to have any diagnosis of disease, but laboratory analyses, anthropometric assessments, vital signs and the comparison of results generated other indicators, so it was possible to identify the usefulness associated with the clinical status of each child, as shown in Table two. The AUC of clinical care with remote monitoring by the FLEEM System® was R$ -70.07 (US$ -17.77) per QALY gained, which means that the remote monitoring technology is more economically viable and better in health gain. In summary, it saved R$ 70.07 (US$ 17.77) for each QALY gained and 0.06 in health utility, that is, with a better dominant cost outcome and with effectiveness in preventing and controlling obesity in children.

4.1 LIMITATION AND FUTURE RESEARCH

Several strengths were raised in the study, highlighted as follows: i) FLEEM System® showed better health effectiveness with lower cost to healthcare system compared to conventional healthcare practice; ii) The remote monitoring system works offline with the biomedical data being stored in the smartphone memory and transmitted to the server when connecting to the internet; iii) With FLEEM System® the follow-up of each patient's clinical picture is done 24/7, by four healthcare professionals, which does not normally happen in conventional healthcare practice; iv) With the remote monitoring the children maintained their social interaction and the parents had no costs or loss of
productivity to monitor their children; v) The biomedical data generated by the FLEEM System® are processed by intelligent tools and notify health professionals of changes in clinical status; vi) Through the platform health professionals, especially the physician, can give feedback to the patient.

These strengths highlighted the main contributions of the study to health professionals and health managers with the FLEEM System® intervention. To health professionals because it is an interactive tool that allows direct clinical care based on biomedical data of the clinical picture of each patient, in the process of prevention and control of obesity. In the practice of health management, due to the efficiency (cost-effective) and operation in full time online and offline, being the technological resources of remote monitoring a strategic health management in the prevention and control of obesity in children with reduced cost to the health system. Thus, managers are promoting the health system with low-cost health care (Lopes et al., 2020b), which represents economic gain, social welfare (quality of life) and potentiate productivity.

The main limitations of this study. i) Study was exclusive as the direct costs in health, as it did not cover the indirect and intangible costs in health; ii) During remote monitoring it is necessary that each child had his smartphone to install the remote monitoring application, FLEEM System®; iii) Uninstallation of the application by the user (child); iv) Not properly maintain the smartphone, in the pocket as directed and on for 24 hours a day; v) Resistance of the municipality of Monteiro Lobato in providing the conventional health practice accounting data.

With these limitations, opportunities for future studies have increased, such as: i) Economic impact of the total costs of the interventions analyzed; ii) Social impact of remote monitoring; iii) Predictive model of biomedical data for disease identification, especially in the adult phase; iv) Projection of economic costs for the predictive model; v) Future costs, if there is no intervention for obesity in the current phase (child), to determine the projection of costs in the adult phase.
5 CONCLUSION

Remote monitoring with the FLEEM System® showed better economic and clinical outcomes compared to conventional health care practice, and the system works offline in rural areas without loss of biomedical data quality.

In this context, the FLEEM System® in online health monitoring assistance is an alternative for the health care system, as it has an impact on increasing access to health care, especially in isolated geographic locations. The monitoring system has presented quality health care at a low cost to the system.

In view of this reality, the FLEEM System® allows association with protocols based on scientific evidence and actions of education and health promotion for children, youth and families, because it is a tool that provides benefits and clinical quality and, consequently, better cost in health care. The use of remote monitoring provided, without interrupting the children's school routine and without parents’ absenteeism from work, by enabling with online technology in health, the evolution of markers and indicators for decision making by health managers.

The economic gain for the health system was 32.50% in care with remote monitoring, but this value can be even higher when measuring the reduction in medication, hospital admissions, medical specialists, and tests, among other health complications that can result.

The QALY obtained represents an estimate in years that the children will live healthily. This means a reduction in the cost of social security benefits and autonomy to generate their own income, besides promoting a reduction in spending in the public coffers and contributing to the economic movement of the municipality.

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