









Handcrafted face shields as a temporary response during COVID-19 pandemic: analyses of variables advocated in nº 356 Resolution by ANVISA

Face shields artesanais como solução temporária frente à pandemia da COVID-19: análise das variáveis contidas na Resolução nº 356 da Anvisa

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Summary Objective: The present research aimed to analyze the handcrafted face shields donated by the philanthropic group “Amor em Foco” to health professionals regarding the variables contained in ANVISA’s nº 356 resolution, which concern: comfort, not causing accidents, stability and adjustment. Furthermore, the present study also analyzed the variables cost, production time and quantity of facial protectors manufactured. **Methods:** Cross-sectional, descriptive and inferential study which included 45 health professionals. Data was obtained from establishments which are under custody of the Municipal Health Department of Belém, carried out between August and December 2020 through a survey containing 5 questions on a 5-point Likert scale. The internal consistency of the questionnaire was tested using Cronbach’s Alpha and McDonald’s Omega Coefficient. Data were analyzed using Jamovi software, with a significance level of 5%, with the exception of univariate analyzes of the regressions performed (conservative significance level of 20%). **Results:** A high level of satisfaction was obtained in the variables tested: 96% for “comfort”, 98% for “does not cause accidents”, 95% for “stability during use”, 89% for “ease of elastic adjustment” and 100% of “recommendation for other health professionals”. The homemade face shields proved to be more affordable and with less production time compared to other authorized models (19 times lower cost and 27 times lower production time than 3D printed models). **Conclusion:** The face shields donated by “Amor em foco” were able to provide a temporary solution during COVID-19 pandemic aligned with the variables advocated by ANVISA.

Keywords: personal protective equipment; Brazilian Health Surveillance Agency; coronavirus infections; pandemics; solidarity.

RESUMO Objetivo: Avaliar os protótipos de face shields artesanais doados pelo grupo “Amor em Foco” para profissionais da saúde quanto às variáveis contidas na resolução nº 356 da ANVISA: conforto, geração de acidentes, estabilidade e ajustabilidade. **Método:** Estudo transversal, descritivo e inferencial que contou com 45 participantes da área da saúde contemplados com as doações. A coleta de dados abarcou instituições sob custódia da SESMA de Belém-PA, realizada entre agosto e dezembro de 2020, por meio de um formulário estruturado em 5 assertivas em escala Likert de 5 pontos, cuja confiabilidade foi verificada por meio do Alfa de Cronbach e Ômega de McDonald. Os dados foram analisados com auxílio do software Jamovi, sendo o nível de significância estabelecido o de 5%, com exceção das análises univariadas das Regressões realizadas (nível de significância conservador de 20%). **Resultados:** As variáveis avaliadas apresentaram elevado grau de concordância pelos participantes do estudo: 96% para “conforto”, 98% para “não causar acidentes”, 95% para “estabilidade durante o uso”, 89% para “facilidade de ajuste do elástico” e 100% de “recomendação para outros profissionais”. Ademais, os protótipos demonstraram-se mais acessíveis financeiramente e com menor tempo de produção em comparação com outros modelos validados (custo 19 vezes menor e tempo de produção 27 vezes menor do que os modelos impressos em impressora 3D). **Conclusão:** As face shields artesanais doadas pelo “Amor em foco” foram capazes de fornecer solução temporária frente à escassez de EPIs durante a pandemia da COVID-19 em consonância com as variáveis da Resolução nº 356 da ANVISA.

Descritores: equipamento de proteção individual; Agência Nacional de Vigilância Sanitária; infecções por coronavírus; pandemias; solidariedade.

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INTRODUCTION

COVID-19, which is an infectious disease caused by the SARS-CoV-2 virus, was declared a pandemic by the World Health Organization in March 2020¹. Due to its high infectivity, added to the momentary shortage of Personal Protective Equipment (PPE) and occupational exposure, health professionals are responsible for a significant proportion of infections².

Thus, due to concerns about the health and well-being of professionals, who maintain the necessary workforce during the COVID-19 pandemic, actions were taken to assemble homemade PPE or “MacGyvered” solutions^{3,4}.

Angus “Mac” MacGyver is one of the most famous fictional characters in modern pop culture. In the original television series (that aired from 1985 to 1992), MacGyver routinely overcame seemingly insoluble problems under time pressure using only readily available items, common sense and scientific insight. There are many healthcare-related examples of “MacGyvering”, through which immediately available equipment are combined to substitute equipment that is either unavailable or non-functional⁴.

Healthcare professionals create and modify devices not only because an equipment does not exist, but more commonly because there is lack of access to commercially available resource⁴. Therefore, due to the sporadic unavailability of facial protectors in March and April 2020 in the state of Pará (Brazil), academics who had their classes suspended during pandemic and other volunteers from a philanthropic group called “Amor em Foco” developed a low-cost face shield model that could be largely donated to health services, destined for professionals who were part of the task force (Figure 1). The face shields were handed with extra foams and elastic bands that could be changed after hygiene of the product.

It is important to point out that products must meet standards required by regulatory authorities in order to be dispersed⁴. However, due to scarcity of PPE during the pandemic, such equipment was momentarily exempted from authorization to operate and from notification to ANVISA (National Health Surveillance Agency), as well as from other health authorizations usually implied. Apart from that, requirements and recommendations were still advocated in No. 356 Resolution by ANVISA containing minimum conditions for manufacturing equipment in the health sector.



Figure 1. *Amor em foco's* handcrafted face shield being worn by a healthcare professional in Breves, Marajó island, state of Pará.

Moreover, a “MacGyvered” device can effectively provide a temporary solution to a problem⁴. In spite of that, even with the possible help already achieved with these PPE — which followed the resolution’s recommendations — they had not yet been sufficiently evaluated for their effectiveness regarding the variables disposed by ANVISA.

Therefore, our research aimed to analyze the handcrafted face shields donated by the philanthropic group “Amor em Foco” to health professionals regarding the variables contained in ANVISA’s resolution: comfort, not causing accidents, stability and adjustment⁵. Furthermore, the present study also analyzed the variables cost, production time and quantity of facial protectors manufactured. We also compared our model with other studies in the literature.

METHODS

This cross-sectional study was conducted in the city of Belém, in Pará state, Brazil (protocol number: 4.435.977). A number of 45 healthcare workers who received the donation of handmade face shields by the philanthropic group “Amor em foco” during the months of March and April 2020 participated in this study (including doctors, physiotherapists, nurses, nursing technicians, dentists, pharmacists, physiotherapy students and medicine students).

Data collection was carried out between August to December 2020. An online semi-structured survey was created organized on a 5-point Likert scale with questions concerning the ANVISA variables being evaluated on the handmade face shields donated by “Amor em Foco”, which was conducted after acceptance of the Consent Term by the participants. The questionnaire was prepared by the project researchers and its internal consistency was verified using the Cronbach’s Alpha and McDonald’s Omega Coefficient.

Descriptive and Inferential analyzes were performed using the Jamovi software (version 2.3.2.0, Sydney, Australia). The level of significance established was 5% with the exception of univariate analyzes of the regressions performed (conservative significance level established at 20%). The association between the variables “Comfort”, “Does not cause accidents”, “Stability during use”, “Ease of Adjustment of the elastic band” and “Recommendation to other health professionals” was performed using Spearman’s Correlation Coefficient. Multivariate Ordinal Logistic Regressions were developed to evaluate the relationship between the independent variables “sex” and “age” with the dependent variables “Comfort”, “Does not cause accidents”, “Stability during use”, “Ease of adjustment of the elastic band” and “Recommendation to other health professionals”. Since it was not possible to aggregate the variable “Professional Activity” to the regression model due to the excess of professional categories, the Kruskal-Wallis Anova Test was performed to compare the different healthcare professionals’ specialties vs. variables referring to the statements of the questionnaire.

RESULTS

A total of 45 healthcare workers answered the research’s questionnaire. Most patients were female, corresponding to a number of 27, and 18 were male. Regarding professional practice, data collected included those of 13 physicians, 10 physiotherapists, 7 nurses, 7 medicine students, 3 dental surgeons, 3 nursing technicians, 1 physiotherapy student and 1 pharmacist. The mean age was 31.4±9.54 years (30.3±9.09 for females and 33.1±10.2 for males). The Mode among all questionnaire items/questions was score 5 (strongly agree). For the variables “Comfort”, “Does not cause accidents” and “Recommendation to other health professionals”, the Median±Interquartile Range was 5.0±0.0. For the variables “Stability during use” and “Ease of Adjustment of the elastic band”, the Median±Interquartile Range was 5.0±1.0. The item “strongly disagree” was not selected by the participants in all questions. The most selected item was “strongly agree”, which was chosen by 75.6% of the participants for the “comfort” variable, 91.1% for the “does not cause accidents” variable, 62.2% for “stability during use”, 73.3 % for “ease of adjustment of the elastic band” and 97.8% for the variable “recommendation to other health professionals”. Table 1 clarifies all absolute and relative frequencies (shown in percentage) for each variable. For a clearer percentage interpretation, see the clustered Likert chart (Figure 2).

Table 1. Frequencies and measures of central tendency of the analyzed variables.

	N	Absolute and relative frequencies					Mo	Md±IQR
		1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly agree		
Comfort	45	0 (0,0%)	1 (2,2%)	1 (2,2%)	9 (20,0%)	34 (75,6%)	5	5,0±0,0
Does not cause accidents	45	0 (0,0%)	0 (0,0%)	1 (2,2%)	3 (6,7%)	41 (91,1%)	5	5,0±0,0
Stability during use	45	0 (0,0%)	1 (2,2%)	1 (2,2%)	15 (33,3%)	28 (62,2%)	5	5,0±1,0
Ease of adjustment of the elastic band	45	0 (0,0%)	0 (0,0%)	5 (11,1%)	7 (15,6%)	33 (73,3%)	5	5,0±1,0
Recommendation to other health professionals	45	0 (0,0%)	0 (0,0%)	0 (0,0%)	1 (2,2%)	44 (97,8%)	5	5,0±0,0

Mo: mode; Md: median; IQR: Interquartile Range.

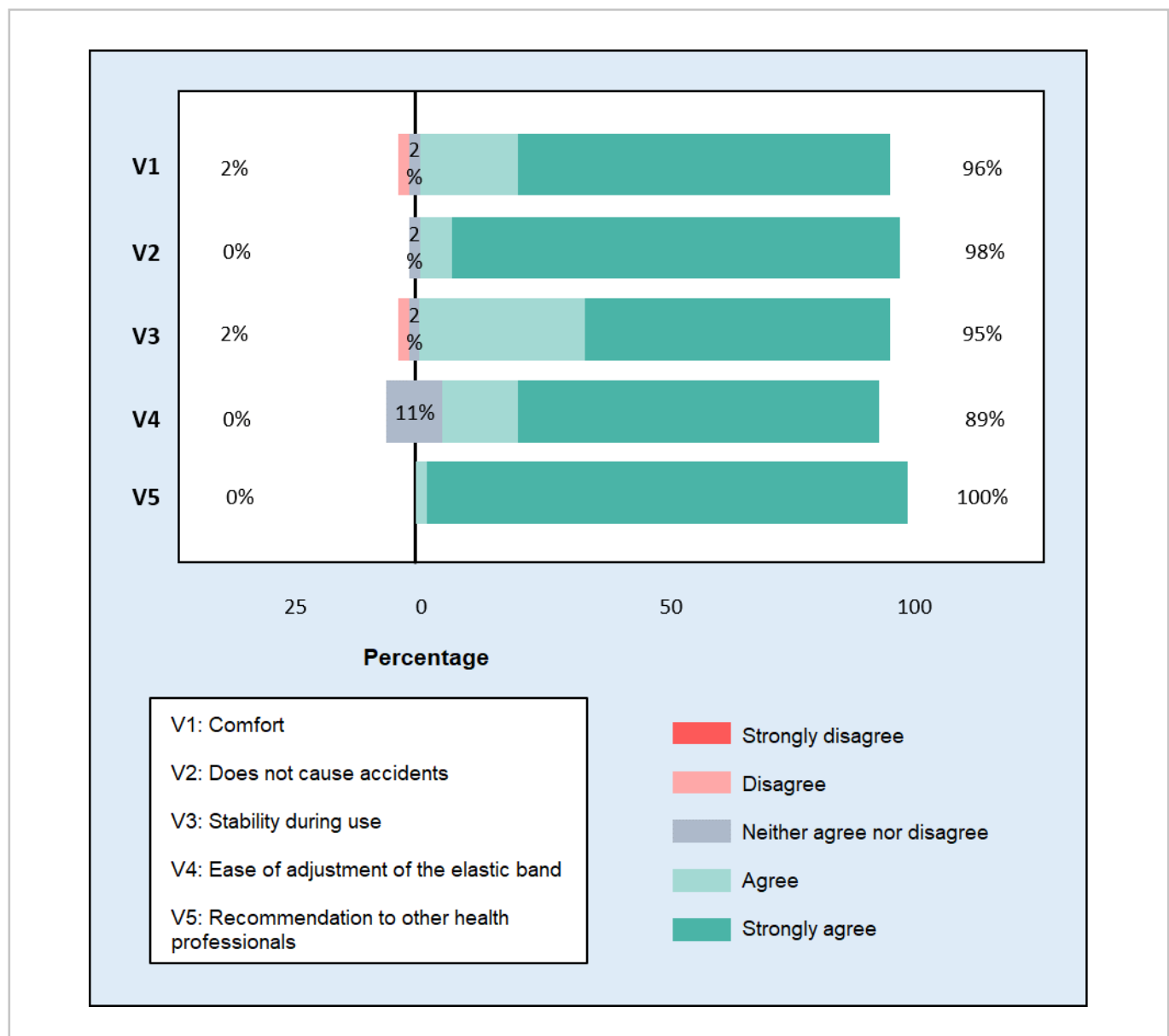


Figure 2. Frequencies clustered in percentage according to the answers chosen by the participants of the study.

Nine out of forty-five participants left a comment for the authors in the “additional comments” section, which was the last item of the survey. Five of those were comments with thankful notes regarding the donations made by the philanthropic group and 1 reported difficulty in the use of the face shield with a complaint that the equipment sometimes blurred and made vision a little tough.

The internal consistency of the Likert questionnaire in this study was tested using Cronbach’s Alpha and McDonald’s Omega Coefficients. There was a variation from 0.391 to 0.602 for the Alpha and 0.497 to 0.652 for the Omega (Table 2). Considering all 5 statements in the questionnaire, the general coefficients’ results were 0.591 for Alpha and 0.634 for Omega, suggesting that the items have moderate internal consistency. If item 5 (which relates to the face shield recommendation for other health professionals) is excluded, the coefficients would rise to 0.602 for Alpha and 0.652 for Omega, with internal consistency still moderate, but closer to substantial.

Table 2. Internal consistency coefficients for this study’s Likert questionnaire.

Internal consistency for all items		Item	Internal consistency if a questionnaire item is excluded	
Alfa de Cronbach	Ômega de McDonald		Alfa de Cronbach	Ômega de McDonald
0,591	0,634	Comfort	0,585	0,616
		Does not cause accidents	0,505	0,586
		Stability during use	0,391	0,497
		Ease of adjustment of the elastic band	0,542	0,579
		Recommendation to other health professionals	0,602	0,652

The analysis of Spearman’s Correlation Coefficient (r_s) using the variables “Comfort vs. Does not cause accidents” ($r_s=0.388$, p -value=0.009), “Does not cause accidents vs. Stability during use” ($r_s=0.428$, p -value=0.003), “Stability during use vs. Ease of elastic adjustment” ($r_s=0.496$, p -value<0.001) and “Ease of elastic adjustment vs. Recommendation to other health professionals” ($r_s=0.300$, p -value=0.046) were significant and positively correlated. Other associations tested were not significant (p -value>0.05).

Due to the dependent variables’ ordinal nature, Ordinal Logistic Regression was used to measure the association between the dependent and independent variables. The associations between the independent categorical variable “sex” and the dependent variables were tested with chi-square tests, followed by a univariate ordinal regression model. The continuous variable “age” was also tested using a univariate ordinal regression model. In the chi-square analysis, the variable “sex” resulted in a statistically non-significant association (p -value>0.05) for all dependent variables. Considering the odds ratio and p -value of the univariate time series modeling, “gender” and “age” showed a significant association (p <0.20) only for the dependent variable “comfort” (Gender: OR=4.14; 95%CI 0.904–29.8); p -value=0.095 / Age: OR=1.12; 95%CI (1.01–1.29); p -value=0.054). Thus, the multivariate modeling occurred only for the Likert item “comfort” and was described as not very explanatory ($R^2=0.119$). Both predictor variables showed statistically non-significant multivariate causal association (p -value >0.05) for the dependent variables evaluated (Gender: OR=3.45; 95%CI 0.698–25.66; adjusted p -value=0.159 / Age: OR = 1.11; 95%CI 1.004 – 1.26; adjusted p -value = 0.076).

Comparison between the 8 types of healthcare professionals who answered the survey (doctors, physiotherapists, nurses, medicine students, dental surgeons, nursing technicians, physiotherapy student and pharmacist) and the dependent variables was performed using the Kruskal-Wallis Anova test. Healthcare area subdivision is not statistically significant (p >0.05) for all 5 statements observed in the Likert questionnaire.

Cost analysis vs. manufacturing time

The philanthropic group “Amor em Foco” produced 2,000 handcrafted face shields samples in 7 days with the support of 20 volunteers and an estimated time of production of 5 minutes per equipment. The products were handed to health establishments, with an estimated cost per unit of R\$ 2.00. Factors that contribute to the handling efficiency of the visors are shown in Table 3.

Table 3. Evaluation of cost and time of production of the handmade face shields manufactured by “Amor em foco”.

Production time	Number of prototypes	Cost
5 minutes	1	R\$ 2,00
1 day	285	R\$ 570,00
7 days	2000	R\$ 4.000,00

It's worth noting that from the total amount produced by the volunteers, only 300 face shields were destined to Belém, which is the city where the research was conducted.

DISCUSSION

According to a technical note issued by ANVISA entitled “Guidelines for health services: Prevention and control measures that should be adopted during assistance to suspected or confirmed cases of infection with the new coronavirus (SARS-CoV-2)”⁶, there are recommendations for the healthcare workers to wear surgical masks and extra equipment, such as goggles or a face shield. The fact is that the pandemic context involves periods of restrictions in all governments worldwide, which goes through financial limitations, scarcity in production and difficulties in the distribution of resources, when, at the same time, there is an important increase in demand.

Thus, in view of the situation faced, new PPE manufacturing techniques emerge, and those new techniques are extremely important in ensuring access to such materials to medical services, guaranteeing the safety of professionals in the field, in addition to providing safe and effective health assistance⁷. In order for this to be possible, the equipments produced must be aligned with the needs of the healthcare professionals, regarding the ease and suitability of use, being cost-effective in relation to production time and allowing efficient cleaning without equipment wear. Those characteristics allow reutilization of the equipment, providing an affordable resource with good durability for use in daily practice.

According to what was evaluated by the present study, the handmade face shields of “Amor em Foco” were able to meet the demands of healthcare professionals according to the variables recommended by ANVISA in Resolution No. 356. The level of agreement was 96% for the variable “comfort”, 98% for “not causing accidents”, 95% for “stability during use”, 89% for “ease of adjustment of the elastic band” and 100% for “recommendation for other professionals”. In addition, with the model made, it was also possible to develop a simple, low-cost equipment that could be produced in a short time.

When comparing the prototype produced by the philanthropic group with other models printed on a 3D printer, the study by Novak and Loy⁸ compared the production time of 37 designs and versions of face shields available and approved for use according to the protection rate presented by such models, including the analysis of the mold from the company “Prusa Research”, which is the most used nationally for the 3D manufacturing method. An average time of 2 hours and 15 minutes per printed PPE was evaluated, whereas the prototype with the fastest preparation was assembled in 46 minutes by the company “MSD Robotics Lab.” In addition, the cost variable is also extremely important for the magnitude of distribution and production of the equipment, with an approximate cost of \$7.30 (conversion to real July/2020 quotation: R\$ 38.60) for the manufacturing a face shield with the “Prusa

Research” technology⁹. That said, the handmade mold proposed by “Amor em foco” is a safe, cost-effective alternative with an adequate production time to meet the urgent demands that have been imposed in the context of a pandemic. The production time of the face shield distributed by the philanthropic group was 5 minutes per prototype – 27 times less than the average time in a 3D printer –, in addition to an individual cost of R\$ 2.00 – about 19 times less than the models printed –, which demonstrates the applicability of its use.

Regarding the topics comfort and non-occurrence of accidents during use – variables that showed high degrees of agreement in this study – when they are again compared with prototypes made in printers, studies reveal that the appearance of imperfections is recurrent during the 3D printing process, mainly caused by mechanical failures in the printers and by other external factors, such as ambient temperature variation, affecting the deposition of the material, causing accidents on the production path of the printer. In some pieces, it is possible to remove the imperfections generated, with simple touches and finishes, in order to restore their functionality, promoting the safety of use. However, when imperfections affect user comfort, to the point of making the use of the equipment uncomfortable or even causing accidents, the mold will often be discarded, affecting production¹⁰. It is noteworthy that in the present study there were no reports of accidents during use.

As for variable “stability”, in the “Prusa Research” technology, a lower structure was added to increase the stability of the visor and maintain the curvature of the display. However, one of the main complaints concerns the economy of material and, consequently, the time spent manufacturing a single piece¹¹. As it was a situation of sanitary urgency and a philanthropic initiative, the prototype by “Amor em Foco” did not have an additional piece, but this option brought no compromise to stability, since it still showed a high level of agreement during the expected time of use.

Regarding the ease of adjustment of the elastic band, there was a lower degree of agreement when compared to the other variables of the study: comfort, not causing accidents and stability. However, the items “totally disagree” and “partially disagree” were not selected by any participant, and more than half (73.3%) chose “totally agree”. The elastic bands, used to hold the face shield properly around the head, were adjusted manually by whoever was carrying the prototype, being considered a variable inherent to the mode of operation deployed by the user himself, which provides greater versatility in the assessment of the assertion by the study participants.

Finally, the last variable evaluated by the questionnaire included the recommendation of the PPE provided to other professionals, in which a grade 5 on the Likert Scale (totally agree) was obtained by approximately 98% of the users. This statement, analyzed subjectively by the study participants, demonstrates a high level of satisfaction and suitability for the use of the face shield provided, which supports the effectiveness of the PPE tested in accordance with the elements proposed by the national regulatory agency.

As for the possibility of cleaning and reusing the prototype, studies show that common household disinfectants, including soap and water or a diluted solution of bleach, can deactivate the new coronavirus on surfaces. Coronaviruses are enveloped in a protective layer of lipid, vulnerable to disinfectants, which destroy this layer and easily attack the viruses⁶. As for the acetate used in assembling the prototype, it was recommended to always clean it after using the face shield with soap and water or a solution with bleach, in addition to 70% alcohol. As for the foam and elastics, which were distributed in extra quantity to be changed after use, these could also be placed for cleaning.

For the volunteers, the enrichment of knowledge about biosafety was evident, as well as an extensive personal and professional growth, since most of them were health professionals and academics. With classes and activities suspended, but with the purpose of helping and redefining the role of their actions, being able to innovate in the health sector, many volunteers were willing to help manufacture the prototypes during a period of scarcity of resources experienced in the initial times of the pandemic. The role of caring was re-signified in the face of adversity, which shows the great and fundamental ability of the new generation to adapt in the globalized world¹².

Professionals, on the other hand, were able to obtain a PPE that reduces the risk of infection, due to mechanical protection of the eyes and skin, in addition to avoiding touching the face, which prevents self-contamination¹³. The fact of feeling more protected in a contaminated environment significantly influenced the psychological aspect and the mood at work, as reported by numerous professionals who received the donation.

Regarding the difficulties encountered in the present study, the low adherence of health professionals was considered an obstacle by the researchers. This research emerged after the donations were finalized, which means that the present study was not the motivation for the voluntary work, but only after the voluntary work was finished that it was put into thought. That being said, the researchers contacted only the contact of a single representative of the health service who received several donation prototypes and not the contact of all professionals individually. It is believed, therefore, that the transfer of the electronic form did not reach all professionals in the areas and health services supported by the Municipal Department.

Even so, it is clear that the face shield prototypes donated by the philanthropic group "Amor em Foco" to health professionals could provide a temporary solution during a period of shortage of personal protective equipment.

The production of face shields in a quick response to momentary unavailability, which collaboratively assembled them for health professionals at no cost, demonstrates the genuine concern of several actors from different specialties, including volunteers and students, with the health of those who act directly in the task force of the coronavirus pandemic, being those professionals essential for maintaining the lives of those infected and for the mental and emotional health of their family and friends.

It is also expected, as a result of this initiative, as well as many others around the world, to strengthen unity and solidarity among citizens.

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Authors' contributions

ACMA: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. ICSA: Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. APMA: Conceptualization, Data curation, Methodology, Project administration, Supervision, Writing – review & editing. FMC: Conceptualization, Project administration, Writing – original draft, Writing – review & editing. SFSC: Data curation, Methodology, Writing – original draft. LMBA: Conceptualization, Project administration, Writing – original draft, Writing – review & editing. NACP: Data curation, Methodology, Writing – original draft. MSP: Methodology, Supervision, Writing – review & editing. All authors read and approved the final version submitted to the Pará Research Medical Journal.