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ORIGINAL ARTICLE

PRACTICALITY OF VALIDATED INDICATORS FOR PROCESSING HEALTH PRODUCTS

PRATICABILIDADE DE INDICADORES VALIDADOS PARA O PROCESSAMENTO DE PRODUTOS PARA SAÚDE

PRACTICABILIDAD DE INDICADORES VALIDADOS PARA EL PROCESAMIENTO DE PRODUCTOS DE SALUD

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ABSTRACT

***Objective*:** to evaluate the practicality of 7 validated indicators to check the quality of processing of health products in primary health care (PHC). ***Method*:** methodological study that measured the time required to fill out the indicators and registered the factors that make it more difficult to apply them to 10 health centers selected by convenience. ***Results*:** structural indicators were the most feasible, followed by those related to outcome and process. Indicators that require a sample are directly influenced by it in terms of application time; unavailability of records in the health centers and standardized information were factors that made it more difficult to apply the indicators. ***Conclusion*:** the indicators showed to be feasible, however, it is suggested to fill out their components according to the routine of service to optimize the time spent to do so. ***Descriptors*:** Primary Health Care; Sterilization; Indicators; Viability Studies.

RESUMO

***Objetivo*:** avaliar a praticabilidade de 7 indicadores validados para conferir a qualidade do processamento de produtos para saúde na atenção primária à saúde (APS). ***Método*:** estudo metodológico que mensurou o tempo demandado para preenchimento dos indicadores e registrou os fatores dificultadores de sua aplicação em 10 unidades de saúde selecionadas por conveniência. ***Resultados*:** os indicadores de estrutura foram os mais exequíveis, seguidos pelos de resultado e processo. Indicadores que demandam amostra são influenciados diretamente por esta no quesito tempo de aplicação; a indisponibilidade de registros nas unidades de saúde e informações padronizadas foram fatores que dificultaram a aplicação dos indicadores. ***Conclusão*:** os indicadores mostraram-se exequíveis, contudo, sugere-se preenchimento de seus componentes de acordo com a rotina do serviço para otimização do tempo dispendido para tal. ***Descritores*:** Atenção Primária à Saúde; Esterilização; Indicadores; Estudos de Viabilidade.

RESUMEN

***Objetivo*:** evaluar la practicabilidad de 7 indicadores validados para comprobar la calidad del procesamiento de productos de salud en la atención primaria de salud (APS). ***Método*:** estudio metodológico que midió el tiempo necesario para llenar los indicadores y registró los factores que hacen más difícil su aplicación en 10 centros de salud seleccionados por conveniencia. ***Resultados*:** los indicadores estructurales fueron los más viables, seguidos por los de resultado y proceso. Indicadores que requieren una muestra son influenciados directamente por ella en términos de tiempo de aplicación; la indisponibilidad de registros en los centros de salud e informaciones estandarizadas fueron factores que hicieron más difícil la aplicación de los indicadores. ***Conclusión*:** los indicadores demostraron ser viables, sin embargo, se sugiere llenar sus componentes de acuerdo con la rutina de servicio para optimizar el tiempo dedicado a hacerlo. ***Descriptores*:** Atención Primaria de Salud; Esterilización; Indicadores; Estudios de Viabilidad.

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INTRODUCTION

Health indicators are tools that aim to check the effectiveness, efficiency, reliability, and comprehensiveness of certain work procedures, in order to evaluate health services, identifying actual or potential problems, to deploy actions for quality standardization.[1] They may be organized into: structure indicators, which assess attributes related to human, material, and organizational resources of a service, process indicators, which assess how a given practice has occurred in a service, and outcome indicators, which assess the effects of a practice on a given population.

Among the activities that may be evaluated through health indicators, there is processing of health products. Its relevance derives from the conception as one of the measures that help preventing and controlling health care related infections (HCRIs), since it aims to avoid the risks arising from the use of health products, so, there is a need to maintain quality in health, by minimizing damage caused by the transmission of pathogens or the toxicity of substances used for cleaning or disinfection.[3,4]

It is well-known that the HCRIs in an out-of-hospital environment is a theme that is still poorly explored both in the national and international literature[5], however, their diagnosis, prevention, and control are key for promoting patient safety.[6,7]

The importance of knowing the practice performed in the Center for Sterilized Material (CSM), as well as the available resources, either material, organizational, or physical, has been found in the literature, so that the sense that situational diagnosis and compliance with current legislation are the early step for the quality of processing health products.[8,9]

Considering the increase in out-of-hospital care and the need for practices that help controlling HCRIs in this context, the quality indicators for processing of health products in primary health care (PHC)[10] were adapted and validated by content.

Such a validation was needed due to the particularities of the health product processing in the PHC environment, among which it is mentioned that, unlike the in-hospital area, its CSM may be classified as class I, according to the RDC no. 15.[10] In the same vein, having in mind the increased use of questionnaires and scales in health research, scholars are advised to seek a careful evaluation of their psychometric properties.[11] Among the attributes that can be evaluated, there is practicality, defined as the practical aspects of using an instrument. To do this, one can observe factors such as the time required and eases and difficulties of filling out the instrument.[11,12]

This study aimed to evaluate the practicality of 7 indicators validated to check the quality of processing of health products in PHC.

METHOD

This is a methodological study[13], which took place in the municipality of São Carlos, São Paulo, Brazil, where a Family Health center (FHC) and a primary health care center (PHCC) from each of the 5 reginal health management offices of the municipality were selected by convenience to enter the sample. The choice of a health facility was due to random selection through the software *Microsoft Excel*, version 2010, totaling 10 health facilities.

The inclusion criteria were: a drawn facility and the professional in charge of processing health products who accepted to participate in the study.

The practicality of indicators was evaluated through the time required to apply them (timing at the beginning of filling out the component/indicator to be observed and end as soon as the component/indicator was completed) and direct observation of the factors that made this filling out more difficult.

These indicators were evaluated for practicality: Indicator of evaluation of the technical-operational resources for cleaning health products (L.1), Indicator of evaluation of the process for cleaning health products (L.2), outcome indicator of cleaning health products (L.3), Indicator of evaluation of occupational accidents with cleaning of health products (L.4), Indicator of evaluation of technical and operational resources for preparation, packaging, disinfection/sterilization, custody, and distribution of health products (PE.5), Indicator of evaluation of the process of preparation, packaging, disinfection/sterilization, storage, and distribution of health products (PE.6), and Indicator of evaluation of the conservation of packaging of sterilized health products (PE.9).

The number of components for each of the aforementioned indicators is shown in Figure 1

Indicator	Type of indicator	Number of components
L.1	Structure	22
L.2	Process	13
L.3	Outcome	*
L.4	Outcome	*
PE.5	Structure	21
PE.6	Process	36
PE.9	Outcome	*

Figure 1. Indicators for conformity diagnosis of the processing of products for primary health care according to type of indicator and number of components. São Carlos, 2013.
*Do not have components, they require a sample through direct inspection of health products to make the conformity index.

To fill out the components that require a mid-sized sample, the software *OpenEpi* was used (Figure 2).

Processing step	Indicator	Facility	Sample
Pre-cleaning	L.2	PHCC	202
		FHC	200
Post-cleaning	L.3	PHCC	214
		FHC	222
Predisinfection	PE.6	PHCC	199
		FHC	209

Figure 2. Sample of health products used according to the second step of the cleaning process of health products and indicator. São Carlos, 2013.

Processing step	Indicator	Facility	Sample
Immersion in disinfectant	PE.6	PHCC	305
		FHC	252
Rinse after disinfection	PE.6	PHCC	264
		FHC	210
Drying/storage of disinfected products	PE.6	PHCC	293
		FHC	275
Pre-sterilization	PE.6	PHCC	249
		FHC	185
Packaging integrity of sterilized products	PE.9	PHCC	237
		FHC	215

Figure 3. Sample of health products used according to the second step of the cleaning process of health products and indicator. São Carlos, 2013.

In order to fill out the indicator L.4, those in charge of processing health products from each health center participating in the study were interviewed.

The study was approved by the Research Ethics Committee of the Federal University of São Carlos (REC/UFSCar), under the Opinion no. 112,528 and the Brazilian Certificate of Submission for Ethical Assessment (CAAE) no. 06815412.7.0000.5504 and it complied with all ethical recommendations of the Resolution no. 196/96, from the Brazilian National Health Council (CNS), in force during the data collection period.

RESULTS

Figure 4 displays, respectively, the time required by each indicator and the difficulties to obtain them.

Indicator	Average time		Maximum time		Minimum time	
	PHCC	FHC	PHCC	FHC	PHCC	FHC
L.1	02’59’’	03’25’’	04’21”	06’28”	01’48”	01’48”
L.2	11’24’’	12’24’’	16’12”	16’19”	07’18”	05’43”
L.3	04’23’’	04’12’’	07’18”	02’54”	05’47”	02’59”
L.4	06’01’’	02’55’’	09’21”	05’07”	02’30”	01’32”
PE.5	02’04’’	03’24’’	02’58”	05’10”	01’26”	02’18”
PE.6	43’15’’	46’27’’	1h11’17”	51’12”	22’01”	34’44”
PE.9	05’28’’	3’58’’	08’59”	05’40”	03’21”	00’51”

Figure 4. Practicality of health product processing indicators according to the average, maximum, and minimum time required to obtain them, by type of facility. São Carlos, 2013.

Regarding the difficulties observed during the filling out of the indicator components, 7 components (L.2.2, L.2.4, L.2.5, L.2.6, L.2.7, L.2.9, L.2.11) established as an evaluation criterion a single observation, but the number of professionals who performed this activity was large, requiring more than one observation. Therefore, when one of the components was not addressed during observation by one of these, it was considered as 'no answer.'

In addition, it was not possible to conduct an interview with all professionals who were in the purge of the facilities in the last year, as required by indicator L.4, since there is turnover of professionals in the network and some of these were not found on the day this indicator was evaluated.

The indicator PE.6 (with greater number of components) was the one that showed greater number of limitations to be filled out.

Regarding PE.6.2, as the manufacturer did not provide instructions for disinfectant dilution to use with health products and there was no standardization in the recommendations found in the literature, this component had limitations to be filled out, too.

For PE.6.5 it was not possible to observe the same number of times established for the others that required a sample, since its occurrence depended on other activities and, consequently, it occurred in a smaller number.

In four components of PE.6 (PE.6.6, PE.6.7, PE.6.8, PE.6.9), although the original indicators suggested observing health products, we chose to observe the constituent parts, since it is understood that the products must be disassembled and the parts filled by the solution. There were no cases where products were placed in a disinfectant solution, without being disassembled, and considered as a 'product.'

The component PE.6.22, which required verification of autoclave registration from the Brazilian National Sanitary Surveillance Agency (ANVISA), was also not addressed, as no documentation regarding this was found in situ.

For PE.6.23, the evaluation criterion required a single observation, however, the number of professionals who performed this activity was large. Therefore, when one of the components was not addressed when observing one of these components, it component was considered as 'no answer.'

For four components (PE.6.24,PE.6.25, PE.6.26, PE.6.27), the original indicators suggest the need for evaluation in all periods at which the processing of health products occurs, so that the activity developed by all the professionals can be inspected, however, it was not possible to observe all professionals that perform such practice.

The use of cap by professionals for processing health products (PE.6.35) also evidenced difficulties to be addressed according to the indicator, since the evaluation criterion required a single observation, however, the number of professionals who performed this activity was large. Hence, when one of the components was not addressed during the observation by one of these, it was considered as 'no answer.'

Regarding the indicator PE.7, concerning the sealing of packages allowed according to the current legislation, only one health facility had some surgical grade paper packaging, so it was not possible to apply this indicator.

The indicator referring to the packaging of disinfected health products for (PE.8) was not observable, so there is no individual packaging for disinfected health products.

The preservation of sterilized health products (PE.9) also had a filling limitation, since it was not possible to select the packages whose sterilization dates were older, because, besides there was few material available, leading to intense material turnover, in most facilities there is no identification routine on the packaging as for the date of sterilization of health products.

DISCUSSION

The knowledge on the practicality of instruments used in the health field has been deployed in papers available in the scientific literature[14-16], demonstrating the relevance of this evaluation by obtaining the efficiency of indicators for its application in the clinical routine, in various contexts.

The practicality of an instrument, either developed, adapted, or even tested in a population different from the one for which it was developed, is one of the major aspects to be evaluated, since it allows the verification of instrument viability at the new context where it will be used.[17] When evaluating the time spent in the application of indicators, those of structure (L.1 and PE.5) were the ones requiring less time, followed by the outcome indicators (L.3, L.4, and PE.5) and the process indicators (L.2 and PE.9), which took more than 40 minutes to be obtained.

When measuring the time needed to fill out the indicators mentioned above, it corroborates a study[14] that brings practicality by measuring the time to apply the instrument, as well as the method's cost and occasional specificities related to the place and situations to which the questionnaire may be applied.

The practicality of process indicators, considering the methodology employed, where the sampling plan required for some components was established by the average processing production in the 10-facility set, needed too much time for its evaluation, tending to make it unfeasible under those conditions. Sampling should be calculated by considering the processing of health products in each facility.

When evaluating the ease of completion of indicators for practicality[14], however, based on the fact that it was applied by a single researcher, it was not possible to evaluate their acceptability by the nursing team, and the factors that make it easier or more difficult found through access to the source of information.

The components, L.1 and PE.5 were those that showed the best practicality when considering these factors, because no difficulty-driven factors were identified. On the other hand, L.2 (referring to the cleaning process) had the highest percentage of difficulty-driven factors, where 7 out of 18 components (53.84%) were affected by the need to observe only one of their occurrences. In the facilities participating in the research, the activity was a duty of various professionals, something which generated inconsistencies in this evaluation.

L.4, an outcome indicator, suggested that all professionals who had been in the purge the last year were interviewed[8], and because of the significant turnover of professionals in such facilities, they could not be located.

The process indicator PE.6 evidenced difficult factors in 13 components (36.11%). Among these, there are: unavailability of dilution instructions by the manufacturer or a standard model for disinfectant dilution to process health products; professional turnover to carry out product processing, associated with professional work schedule and daily work demand; impossibility of observing assembled health products (for disinfection components); and absence of the information needed by the component in registers or easily accessible places.

In turn, when evaluating the indicator PE.9 (outcome indicator), there was no way to recognize packages that had been sterilized for more time, since there was few material available, with a significant turnover; and there is no record in the packages of the date and name of the professional in charge for sterilization. Based on the evaluation of practicality of the instrument concerned, some changes are suggested to allow improving these instruments, making it easier to handle and apply them to the PHC.

The first suggestion is establishing 80% of compliance for L.2.2, L.2.4, L.2.6, L.2.7, L.2.9, L.2.11, PE.6.23, since they originally require more than one evaluation and there is no percentage to address these components, and they should be evaluated having a sample calculated according to the particularities of the service as a basis.

It is proposed to interview all professionals who are working in the health facility and carry out activities in the purge for L.4 and not only a professional from the facility, as such activities are shared among several professionals and that there are no protocols for this activity, i.e. the practice does not take place in a standardized way.

Regarding disinfection, it is also recommended to consider the immersion time of health products in disinfectant solution for PE.6.2, as well as the disassembled products (parts) for PE.6.5, PE.6.6, PE.6.7, PE.6.9.

Non-establishment of a sampling plan and observation of health product processing over a period of time for evaluating the indicators is something to consider, since it provides knowledge on the modus operandi of this activity and minimizes the time spent to do this, the aspect that most negatively affected indicator practicality, especially those related to the process.

It is worth noticing that the best practicality of structure indicators (L.1 and PE.5) may also be related to the fact that, unlike the components of process indicators (L.2 and PE.6) and outcome indicators (L.3, PE.7 e PE.9) do not require a sample for this, something which directly influences the time of its application.

CONCLUSION

It is understood that the structure indicators are the most feasible, followed by the outcome and process indicators, considering the factors time and ease of filling out. The least feasible were PE.6, regarding the time spent, and L.2, as for the difficulty of filling out.

For the implementation of process evaluation, the use of standardized, practical,

and feasible instruments is key. Based on the fact that the processing of health products is one of the measures that help preventing and controlling HCRIs, this theme becomes even more significant, because it contributes to the qualification of these procedures in PHC and, to do this, suggestions are made for completing the indicators, respecting service particularities in order to optimize the time spent to do this.

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