Available online on 15 Mar, 2024 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Research Article

Open Access

Quality of examination gloves in health facilities in Addis Ababa, Ethiopia

Yisihak Abraham Mehari*[,a] , Yemane Berhane[b], Heran Gerba Borta[c], Kidanemariam Gebre Michael[d]

[a,c,d] *Ethiopian Food and Drug Authority, Addis Ababa, Ethiopia.*

[b]*Addis Continental Institute of Public Health; Department of Epidemiology and Biostatistics, Addis Ababa, Ethiopia.*

Abstract

Background: Examination gloves are used in health facilities to protect health professionals and patients from the risk of infection and reduce opportunities for cross-transmission of infectious microorganisms. Poor-quality examination gloves can expose health professionals to infectious diseases such as Covid-19, Hepatitis, HIV/AIDS, and other contagious diseases. Hence, this study aimed to assess the quality of examination gloves in health facilities in Addis Ababa.

Methods: A cross-sectional study design was employed. The examination gloves were collected from randomly selected health facilities in Addis Ababa. The gloves were examined following standard procedure in the Ethiopian Food and Drug Authority. Holes in the examination gloves were detected using the watertight (leakage test) and geometrical dimensions such as thickness, width, and length were measured.

Results: A total of 2500 selected examination gloves were collected between Feb 10 and Feb 20, 2021. The gloves were sampled from health facilities in Addis Ababa. From the total samples collected, only 2280 examination gloves of five different brands were tested, which makes the response rate 91.2%. The proportion of gloves with holes detected ranged from 5.7% to 21.9%. Overall, only 0.17% and 3.2% of the gloves had width and length below standard, respectively. None of the gloves tested in this study had a thickness below the standard.

Conclusions: All brands of examination gloves tested had a higher hole (leakage) rate than the acceptable quality limit. This implies there is a substantial risk of infectious disease transmission to health professionals and patients in healthcare settings. Hence, regulatory enforcements need to be strengthened across the life cycle of the product.

Keywords: Examination glove, Rubber gloves, Addis Ababa, Ethiopian Food and Drug Authority (EFDA), US Food and Drug Administration, acceptance quality limit (AQL), Glove Visual Leak Tester (VLT), ISO 2859.

Article Info: Received 17 Feb 2024; Review Completed 14 Mar 2024; Accepted 15 Mar 2024

Cite this article as:
Mehari YA, Berhane Y, Borta HG, Gebre Michael K. Quality of examination gloves in health facilities in Addis Ababa, Ethiopia. Int J Drug Reg Affairs [Internet]. 2024 Mar 15 [cited 2024 Mar 15]; 12(1):48-53. Available from: http://ijdra.com/index.php/journal/article/view/652

DOI: 10.22270/ijdra.v12i1.652
*Corresponding author

1. Introduction

Rubber gloves have been used in healthcare settings since 1890 to limit the transmission of infectious diseases. (1) Gloves function as mechanical barriers to reduce the transmission of body fluids and pathogens from patients to health care providers and vice versa. (2)The integrity of gloves, including lack of perforation, is crucial to effectively reduce transmission of infectious pathogens. (2) Infectious pathogens can manage to escape even via small defects in gloves that may not be visible to naked eye. (3)

Hand gloves in healthcare are intended for single use to minimize cross-contamination. (4) Single-use practicesare recommended to avoid the burden of sterilization from health care contamination. However, even a single use may not guarantee safety of users unless the gloves meet minimum quality standards. The Ethiopian Food and Drug Authority (EFDA) requires that a batch of 500,001 and above gloves contain no more than 21 defective gloves, (5) which is similar to the US Food and Drug Administration standards. (6)

There are many causes for leakage of poor-quality examination gloves. The defect could happen during manufacturing, improper storage and transportation. The defects during manufacturing could be due to poor chemistry of the latex, unclean forms that contain oil or mechanical damage during packaging. (7, 8) Furthermore, studies on surgical glove perforation rates in developing countries such as Nigeria and Ethiopia revealed that low-cost and low-quality products were imported. Hence, manufacturing-related holes may be more common. (9, 10) In Ethiopia, it is observed that there is a more frequent failure of consignment samples of examination gloves

tested for acceptance quality limit (AQL) by the Ethiopian Food and Drug Authority (EFDA). Although there were anecdotal reports of substandard products and enforcement gaps, there was limited empirical evidence to corroborate the reports. In addition, it was imperative that the vulnerability of the local market to illegal distribution of medical supplies be considered. Therefore, this study was aimed at assessing the quality of examination gloves in the health facilities of Addis Ababa, Ethiopia.

2. Methods and Materials

Materials and Instruments

Product information review: Each collected sample was subjected to a product information review. Product description, brand and generic names, manufacturer's name and address, batch or lot number, manufacturing and expiry date, registration status, availability of information on package, intended use, language, and physical appearance were the main product characteristics reviewed. Eligibility and correctness of the above information were checked against EFDA labeling and packaging requirements. The information was recorded on a standardized form.

Visual inspection test: Visual inspection was conducted by examining the collected samples for leakage, damage and adherence to national legislation requirements on labeling.

Water: we used degassed water during testing to avoid bubbling from the water.

Instruments and apparatus: The instruments used for quality control assessment of the examination glove were: Glove Visual Leak Tester (VLT) apparatus, Thickness Tester Apparatus, Beaker and Measuring Cylinder, Marker and Ruler.

Test parameters and test methods: the test parameter focused only on freedom from hole (FFH) by using water tight method and dimension parameters (Width, Length and Thickness). Test methods used was ASTM D5151 and ASTM D-3578 for FFH, and ASTM D 3767 for dimension parameters.

Sampled examination gloves: Five different brands of examination gloves were purchased from health facilities in Addis Ababa, Ethiopia. Each brand of examination gloves was randomly coded from A to E. All brands of examination gloves were purchased with their original packaging and were within their expiration dates (Table 1).

Table 1. Brands of examination gloves included in the study

Brand code	Sample size	Gloves size	Batch/lot No.
A	500 pieces of gloves	Medium	202009
B	500 pieces of gloves	Medium	041219
C	500 pieces of gloves	Medium	03782
D	500 pieces of gloves	Medium	0700112305
E	500 pieces of gloves	Small	2108

Study design and setting

A laboratory-based cross-sectional study was conducted in Addis Ababa from Feb 10-Mar 20, 2021 to assess the quality of examination gloves. Addis Ababa is the diplomatic capital of the African Union and the capital city of Ethiopia. It has ten sub-cities and 117 districts and the city has an estimated population of 3.4 million of which 52.6% are female. (11) During the study period, there were 36 hospitals, 98 functional government health centers, 597 pharmacies, 260 drug shops, and 458 of clinics in Addis Ababa. (12) The reason for selecting this study area was the availability of a large number of health institution including community pharmacies, drug stores and private and governmental health facilities (hospitals and health centers). Though examination gloves are packed locally, but a large portion of the gloves available in the market are imported from overseas. The EFDA regulates the manufacturing, importation, and distribution of pharmaceutical products in the country. The EFDA has a medical device quality testing laboratory that tests the quality of examination gloves. Hence, EFDA sets AQL standards depending on ISO 2859. (13) The standard for the batch is ASTM D3578. However, the EFDA's capacity to strictly and regularly control the market is quite limited, and some products that may not fulfill the requirements can be found in use in health facilities. Health facilities mainly obtain their medical supplies from government distributors, but at times of scarcity, health facilities can purchase medical supplies from private importers and/or distributors.

Source and study population

The source population was all examination gloves distributed to the market in Addis Ababa, and the study population was selected samples of examination gloves available in the selected health facilities.

Sample size determination

Statistically, the sample size was determined by using a single population proportion formula for the quality of examination gloves, assuming a 5% expected proportion of defects at a 95% confidence interval, a margin of error of 2%, and a 10% non-response rate. In addition, according to EFDA testing protocols and international sampling standards stated in ISO2859 standard, (13) for a batch of >500,000 examination gloves, a minimum of 500 gloves each needs to be tested as a sample. Accordingly, a sample size of 500 examination gloves for each of the five brands was taken, which makes a total of 2500 samples for the batches.

Sampling procedure

Information was gathered on available brands of examination gloves from health facilities. A total of five brands of examination gloves were identified in the market during the study period. A simple random sampling technique was employed to select the study population.A

list of health facilities was obtained from the Ministry of Health and Addis Ababa Health Bureau. All health facilities were listed, sorted alphabetically, numbered, and coded. A random sampling technique using lottery method was employed to randomly draw the number of health facilities where the study population was taken. Accordingly, five health facilities were selected using simple random sampling techniqueequal numbers of examination gloves were collected from each health facility. Then, a total of 2500 examination gloves from the selected health facilities were collected.

Data collection procedures and quality assurance

At the time of the study, there were five brands of examination gloves that were widely available in Addis Ababa. The data collectors collected five brands of unused latex examination gloves (four brands medium in size and one brand small in size) from the randomly selected health facilities. A data extraction spreadsheet was used to collect the data. The collected examination gloves belonged to the same lot/batch number and all were made of rubber latex and ambidextrous. A total of 2500 examination gloves were collected from the selected health facilities in Addis Ababa, Ethiopia.

The sample collectors were trained drug inspectors who executed the work according to the pre-prepared sampling plan and EFDA standard operating procedures. At each health facility, the targeted products were collected. The collected data were checked for completeness and consistency. The quality of testing results was assured by performing system suitability tests and strictly applying the procedures as described in the EFDA's standard operating procedures. The EFDA uses the gold standards from the American Standards of Test Methods (ASTM).

Data management and analysis

After sample collection using the data extraction spreadsheet, the gloves were taken from the original package for testing. Standardized visual and water-tight techniques were used to test the gloves for pinholes. (13,4) Laboratory testing was done after visual inspection and a water-tight test was conducted to check the existence of holes. Each glove was tested by a standardized water-leak test. Gloves were filled with 1000 ml of water followed by manual compression on the wrist of the glove for 2 min to check the availability of holes where leakage of water indicates a hole. (5,14)

Dimensions of gloves were also measured. The length as expressed in millimeters was measured from the tip of the middle finger to the outside edge of the cuff. The width of the palm as expressed in millimeters was measured at a level between the base of the index finger and the base of the thumb. The thickness was also measured. Using a dial micrometer and cutting the glove is necessary to obtain single-thickness. (15, 16)

Data inconsistencies were checked for all collected samples and then transferred to SPSS version 24 for cleaning and analysis. The data was presented based on categorized brands and testing parameters. The proportion of gloves with holes was calculated by dividing gloves with holes by the total number of tested gloves for each brand. In addition, the measurement of dimension and acceptable limits of dimension tests for the gloves were identified by using ASTM D-3578. (5)

Descriptive statistics were used to analyze continuous variables in terms of frequencies and percentages. The descriptive data were presented using tables and Figures.

Ethical considerations

Ethical approval was obtained from Addis Continental Public Health Institute (ACIPH) ethical clearance committee (ACIPH-MPH/035/13). In addition, a permission letter was sought from EFDA to collect samples and test the samples in EFDA medical device laboratory testing. To ensure confidentiality, each tested brand of examination gloves was coded and the testing result was kept in a secure area and only accessible to the research team.

3. Results

All five brands of examination gloves were included in the study and were imported from overseas. Out of the total 2500 samples collected, 2280 examination gloves were tested (456 gloves for each brand). Three of the five brands of examination gloves (Brand B, Brand C, and Brand E) tested had the proper size for the length dimension. But, glove brand A and glove brand D had 4.2% and 11.2%, respectively, which is out of the standard specification **(Table 1)**.

Table 1. Proportion of gloves tested for width, length, thickness and holes

Parameters	Brands				
	A, n (%)	B, n (%)	C, n (%)	D, n (%)	E, n (%)
Gloves below Standard width (mm)	0	0	2 (0.4)	2 (0.4)	0
Gloves below Standard length (mm)	19 (4.2)	3 (0.7)	0	51 (11.2)	0
Gloves below Standard thickness (mm)	0	0	0	0	0
Gloves with Holes	67 (14.7)	26 (5.7)	100 (21.9)	76 (16.7)	66 (14.5)

All the brands fail only by one of the standards. For glove A, 67 gloves failed for hole detection and 17 gloves failed for length measurements, and only 2 gloves failed by both hole detection and length measurements. For glove B, 26 of the same gloves failed for hole detection and 3 gloves failed for length measurements. For glove C, 102 gloves failed where 100 gloves failed for hole detection and 2 gloves failed by width measurements. For glove D, 109 gloves failed, where 66 of them failed for hole detection, 2 gloves failed for width and the remaining 41 gloves failed for length. Moreover, 10 of 109 gloves failed for both hole detection and length measurements. Lastly, for glove E, all 66 gloves failed only for holes detection. Therefore, only glove A and glove D failed by two of the standards. None of the brands failed for more than three of the standards **(Table 2).**

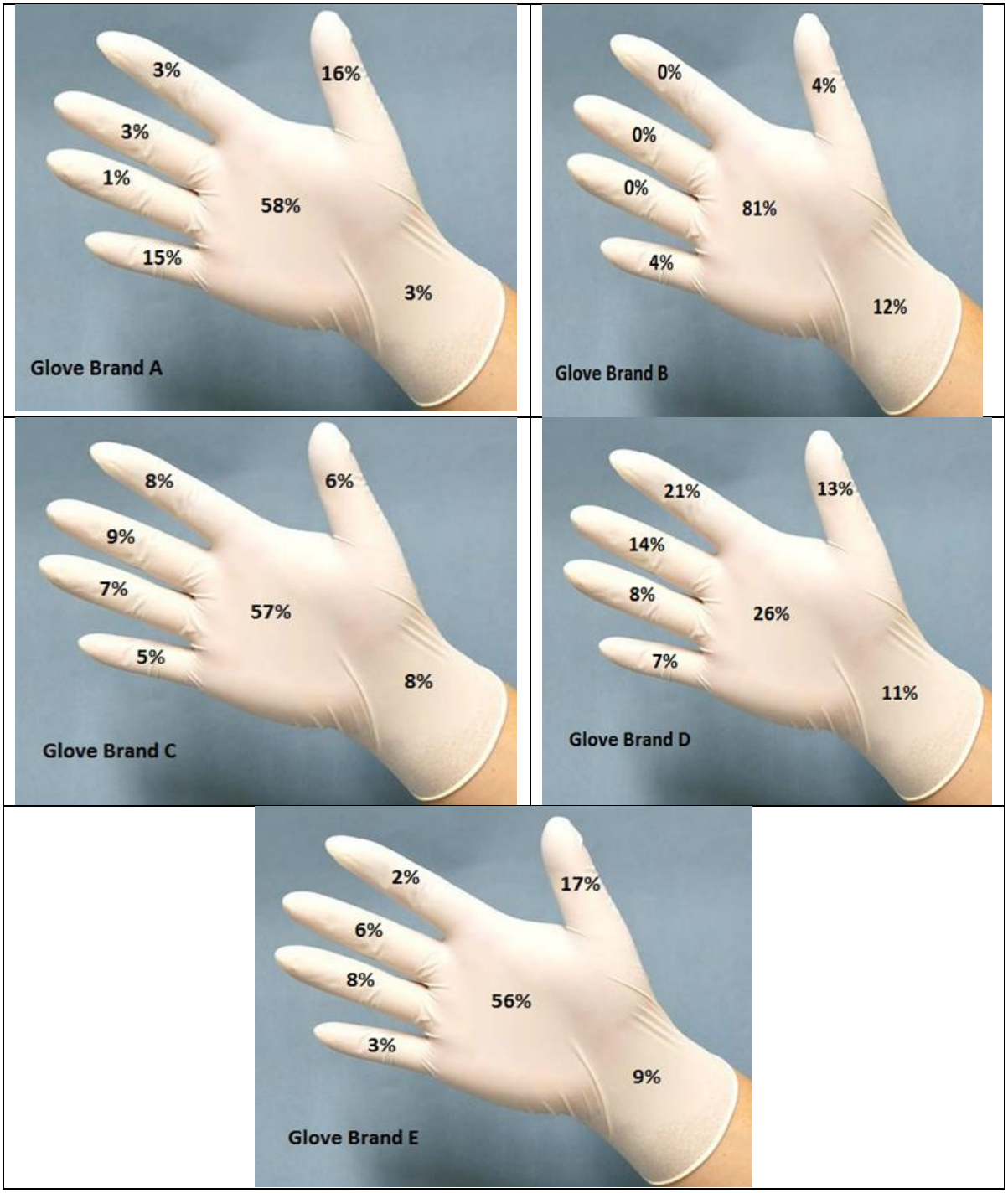

Figure 1. Positions of the holes of the gloves

Figure1 indicated the numbers and location of holes on the gloves for each brand and the result showed that most of the holes were found around the palm and fingers rather than cuff area where this indicated higher risk and the degree of contamination for health workers and patients.

All five brands of examination gloves included in the study exceeded the allowable hole limit with a failure rate of 2.5%. Glove brand B had a failure rate of 5.7% and glove brand C had a failure rate of 21.9%

Table 2. Proportion gloves below the recommended for quality standards, Addis Ababa March 2021

Brands	Only one of Standard, n(%)	Below two of the Standards, n (%)	Below three of the Standards, n (%)	Below all four Standards, n (%)
A	84 (18.4)	2 (0.4)	0	0
B	29 (6.4)	0	0	0
C	102 (22.4)	0	0	0
D	109 (23.9)	10 (2.2)	0	0
E	66 (14.5)	0	0	0

4. Discussion

The present study assessed the quality of examination gloves in health facilities in Addis Ababa, Ethiopia. This study found out that all brands of the collected examination gloves had leakage that exceeds the level of acceptable quality. In some brands, the deviation is almost tenfold. In addition, the dimension measurements (width, length, and thickness) showed little deviation from the required standards. These findings were almost similar compared to study conducted in theIndonesia. (17)

The study revealed that the leakage rate of the gloves ranged from 14.7% to 21.9% as compared to the level of acceptable quality stipulated in EFDA and ASTM 3578. (5) The leakage rate was obtained when testing the examination gloves straight out of the package. This could have been higher, and the size bigger, if tested after use. This is critical because of the high risk of infection for both healthcare providers and patients. Double gloving is used by professionals because they do not believe it, and it causes economic loss or raises political concerns. This is also one of the big threats to infection control in health facilities. The availability of an unacceptable hole rate might be due to the importation of low-cost, low-quality products with manufacturing flaws, the use of low-quality raw materials, damage during packaging and transportation, temperature handling issues during transportation, poor storage conditions at warehouses and health facilities, and insects biting. (7,18) These findings were almost similar compared to studies conducted in Ethiopia (9) Saudi Arabia, (8) and Nigeria. (10)

With regard to dimensions, width and thickness were not problems in our study. Both meet the necessary acceptable standards. However, there was a failure in the length of the gloves (4.2% for glove brand A and 11.2% for glove brand D). The size of gloves to be used in Ethiopia is from extra small to extra-large. (19) If gloves do not fit to the standards, breakage of gloves and convenience for use will be an issue. A possible explanation for this might be that most holes occur due to poor quality and manufacturing size specification problems. (7) Furthermore, the location of the holes in the gloves was in the fingers and palm areas. This is a favorable condition for infection and contamination. This finding is similar to a study conducted in USA. (20)

Healthcare providers should not only be cautious about gloves; they should also be cautious about their vaccinations. Most of the health workers in Ethiopia are not fully vaccinated against hepatitis B (21) and the working conditions and standards are not comfortable. The working environment should not be acceptable by any standards. In addition, the regulatory body should ensure the safety and quality of gloves before distribution, and the government should also envision economic, social, and political interests. As a result, manufacturers should be well aware of the Ethiopian market in terms of glove hand size and environmental conditions during transportation and storage.

Strengths and limitations of the study

Testing was conducted using gold standards (ASTM) which are used by EFDA and other international organizations. The total samples tested were also as per the ASTM standards, testing 500 gloves for a large consignment (>500,000 gloves). However, the study has limitations as well. The quality testing of the examination gloves only focused on two parameters: hole detection and dimension testing. Other parameters such as tensile strength were not considered. In addition, lot-to-lot (batch-to-batch) variations within individual brands were not considered.

5. Conclusion

The study found that all brands of examination gloves tested had a higher leakage or hole rate as compared to the allowable level of acceptable quality. This poses a significant risk of infection transmission in healthcare settings. Therefore, it is important for the regulatory body to strengthen inspection activities considering the life cycle of medical devices, including manufacturing and post-marketing surveillance. We recommend more research to determine the cause of the examination gloves' high leakage rate, tensile strength, compatibility with the users, force at break, and elongation at break.

Acknowledgments

The authors would like to thank the Ethiopian Food and Drug Authority, the Addis Continental Institute of Public Health, data collectors and managers of the health facilities for their cooperation and facilitation of the study.

Authors' contributions

All authors meet the ICMJE criteria for co-authorship, providing substantial intellectual contributions for the manuscript. YA conceived the idea, wrote the proposal, participated in the data collection process, conducted laboratory analysis, analyzed the data and wrote the manuscript. YB approved the proposal with revision, participated in the data analysis and interpretation, and reviewed the final manuscript. KG participated in data analysis and interpretation, and manuscript preparation. HG reviewed the final manuscript. All authors approved the final manuscript and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Financial Disclosure statement

The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. Halsted LSCH. The first to use rubber gloves in the operating room. Proc Bayl Univ Med Cent. 2010 Oct;23(4):389-92.
2. Hübner N-O GoerdtA-M, Mannerow A, Pohrt U, Heidecke C-D, Kramer A. The durability of examination gloves used on intensive care units. BMC Infect Dis. 2013 May 20;13(1):226.
3. World Health Organization. Glove Use Information Leaflet. Geneve, SwitzerlandAugust; 2009.
4. European Committee for Standardization. ECF. EN 455-1 Medical gloves for single use Part 1. Belgium:

Requirements and testing for freedom from holes. Brussels; 2020 May.
5. American Standards Testing Method; Standard Specification for Rubber Examination Gloves. ASTM: D3578-2015. West Conshohocken. United States; 2015.
6. U.S. Food and DrugAdministration. CFR - Code of Federal Regulations. Title 21. Silver Spring, USA; 2020 Oct 11
7. Jose Paul Meleth. An Introduction to Latex Glove. Lambert academic publishing, Germany. September 16, 2015.
8. Al-Swuailem AS. Prevalence of manufacturing defects in latex examination gloves used in selected dental practices in central Saudi Arabia. Pubmed. Jul, 2014;35(7):729-33.
9. Bekele A Makonnen N, Tesfaye L, Taye M. Incidence and patterns of surgical glove perforations: experience from Addis Ababa, Ethiopia. BMC Surgical. 2017 Mar 20;17(1):26.
10. Makama JG, Okeme IM, Makama EJ, Ameh EA. Glove Perforation Rate in Surgery: A Randomized, Controlled Study- To Evaluate the Efficacy of Double Gloving. Pubmed. 2016 Aug; 17:436-42
11. Ethiopia. CSAin Addis Ababa, Population projection of Ethiopia for Addis Ababa; 2017 Jul.
12. Addis Ababa Food Medicine Healthcare And Control Authority annual reports; 2019.
13. International Organization for Standardization (en). ISO 2859: Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection Geneva Switzerland; 2020 Nov 13.
14. American Standards Testing Method for Detection of Holes in Medical Gloves. ASTM: D5151. West Conshohocken, United States: ASTM; 2015.
15. American Standards Testing Method, for Rubber-Measurement of Dimensions. ASTM D3767: West Conshohocken, United States. ASTM; 2014.
16. European Committee for Standardization. EN 455-2 Medical gloves for single use. Part 2: Requirements and testing for physical properties. Brussels, Belgium; 2020 May.
17. Yani Pertiwi, Teguh Martianto, Ageng Priatni. Comparative study of rubber household gloves standards in Indonesia. 2020 Nov; 231-40.
18. Food and Drug Administration (FDA). Guidance for Industry and FDA Staff : Medical Glove Guidance Manual. West Conshohocken, USA; 2008 Jan 22.
19. International Organization for Standardization. ISO 11193-1. Single use medical examination gloves. Part 1: Specification for gloves made from rubber latex or rubber solution. Second edition; 2008 Apr.
20. Phalen RN, Wong WK. Integrity of Disposable Nitrile Exam Gloves Exposed to Simulated Movement. Pubmed. 2011 May;8(5):289-99.
21. Bekele A, Tadesse A.Status of hepatitis B vaccination among surgeons practicing in Ethiopia. 2014 Jul;52(3):107-12.