

ANALYSIS OF THE SPECIFICS OF FORECASTING THE NEED AND IMPLEMENTATION PUBLIC PROCUREMENT OF MEDICINE FOR ANESTHESIA

Nemchenko A.S., Nazarkina V.N., Kurylenko Yu. Ye.*, Koba T.N.
National University of Pharmacy, 53 Pushkinska str., 61002, Kharkiv, Ukraine
[*n1ka5@ukr.net](mailto:n1ka5@ukr.net)

Abstract

One of the main functions of the state is to meet public needs through the procurement of goods, works and services. The efficiency, accessibility and transparency of the procurement procedure determines the rationality and efficiency of the use of limited budget funds. This problem is especially relevant in the organization of public procurement in the health care system. At the same time, one of the key elements is the justification of the need for the necessary medicines and medical devices. In the field of anesthesiology and intensive care, the correctly selected anesthesia product, taking into account the individual characteristics of the patient, plays a very important role.

The purpose - analysis of the specifics of public procurement of medicine for anesthesia.

Materials and methods. Informational and analytical materials were used, namely: scientific works and publications on the organization of public procurement of drugs; regulations; statistics on the procurement of drugs for anesthesia; official sites of government bodies. Methods - analytical, generalization of information.

Results. Theoretical principles of the organization of the public procurement system in health care, normative-legal regulation is studied. Modern technologies of anesthesia care in accordance with current standards of safe anesthesia practice are studied. Peculiarities of forecasting the need and organization and implementation of public procurement of drugs for anesthesia.

Conclusions. The results of the research can be used to improve the mechanisms of state regulation of pharmaceutical activities, as well as to improve the system of public procurement in the health care system, in particular, drugs for anesthesia.

Keywords: anesthesia care, healthcare technologies, anesthetics, public procurement.

Introduction.

The key point in conducting effective procurement in the healthcare system is drawing up an annual procurement plan and justifying the need for the necessary drugs. The algorithm for calculating the need is spelled out in the Procedure approved by order of the Ministry of Health of Ukraine No. 782 dated July 11, 2017, according to which hospitals can independently calculate the need in accordance with the approved methodology: depending on morbidity or consumption[1,2].

To calculate the need for a medical institution, a working group is created consisting of: the head of the medical institution; Deputy Chief Physician for Economic Affairs; pharmacist, representatives of public organizations (if necessary).

The difficulty in predicting the need for anesthetic drugs lies in the uncertainty about the number of planned and unscheduled surgical interventions, therefore, in this case, it is advisable to determine the need for consumption (retrospectively), taking into account the correction factors.

In order to justify the need, we analyzed the consumption of drugs used for endotracheal and intravenous anesthesia in 2018-2019. Endotracheal (intubation) anesthesia is currently the main type of inhalation anesthesia for large, traumatic cavity operations requiring muscle relaxation. In this method, the drug mixture is fed directly into the tracheobronchial tree, bypassing the mouth and upper respiratory tract. Thus, for endotracheal anesthesia used Sevoran 100% 250 ml, Dithiline 5 ml, Thiopental sodium 1 g, for intravenous (IV) - propofol 10 mg.

The purpose - analysis of specific prediction of public procurement of medicines for anesthesia at the central hospital in the example of Ukraine.

Methods

Informational and analytical materials were used, namely: scientific works and publications on the organization of public procurement of drugs; regulations; statistics on the procurement of drugs for anesthesia; official sites of government bodies. Methods - analytical, generalization of information [3-6].

Results and Discussion.

As a result of the study, it was found that the use of anesthetics is uneven over the months, while no trends can be traced. So, in 2018, a total of 3,760 surgical interventions were performed, of which the leading positions are held by intravenous anesthesia using propofol (42.5% of the total number of anesthesia per year). Dilitin ranks second in frequency of use (35%), followed by sodium thiopental - 21.8% and Sevoran - 0.07%. In 2019, the situation has changed somewhat. A total of 1591 surgical interventions were performed, while the ratio of the use of various anesthetic agents was as follows: the largest amount was Propofol (40.4%). Dilitin and sodium thiopental - 22.6% each of the total amount of anesthesia, 14.5% were interventions using Sevoranu[7-9].

An analysis of the dynamics of anesthesia for 2018 and 2019 made it possible to establish that 26 anesthesia was performed using Sevoran in 2018 and two hundred and thirty-first in 2019 (almost 9 times more). Dilitin is used much more often - with 359 surgical interventions in 2018 and 1315 - in 2019 (consumption increased by 3.7 times). Sodium thiopental - 820 in 2018 and 359 in 2019. (Reduced by 2.3 times). The use of the drug for intravenous anesthesia Propofol is also uneven during the analyzed period - during 2018 it was used in 1599 surgical interventions, in 2019. - 642 (60% less).

In accordance with the order of the Ministry of Health of Ukraine dated February 14, 2012. No. 110 is provided for by anesthesiologist for a day before the appointed operational intervention of a preoperative inspection with the mandatory fill in the form of primary accounting documentation No. 003-3 / "Preoperative review of the anesthesiologist and a general anesthesia protocol" , containing information about the objective state of the patient (mapping the functions of all organs and systems of the patient, data of laboratory and additional research methods), as well as the data of the history of life, diseases, allergological history, the presence of bad habits, chronic reception of some medicines. The conclusion contains recommendations for the preparation of a patient to surgery, premedication, intended to anesthetic and the degree of operational risk. Given all the factors, general anesthesia can be appointed, in particular,

anesthesia (inhalation, with spontaneous breathing, with IVL), intravenous (with spontaneous breathing, with IVL) intramuscularly (analgesia, combined general anesthesia) or regional (local, conductive, stem, Plexus, Neuroaxial, Epidural, Subarachnoid, Combined Regional Anesthesia). Also, form No. 003-3 / contains a sheet of anesthetic and anesthetic protocol, including information on the course of anesthesia, features of the provision of anesthesiological assistance and the recommendation of the anesthesiologist for further intensive observation of the patient. This form is signed by anesthesiologist, inserted into a medical record of a stationary patient, where it is stored for 25 years[10-12].

In accordance with the safety standards and the organization of the provision of anesthetic care during anesthesia, the best drugs for surgical interventions are ketamine, diazepam or midazolam, morphine, local anesthetics (lidocaine or bupivacaine). Alternative drugs are thiopental or propofol, inhalation anesthetics (halothane, isoflurane), succinylcholine, non-depolarizing muscle relaxants (pancuronium or atracurium), neostigmine. The use of propofol, alternative inhalation anesthetics (sevoflurane), alternative non-depolarizing muscle relaxants (rocuronium or cisatracurium) is also proposed.

According to the current legislation, healthcare institutions and institutions can purchase medicines included in the National List of Essential Medicines, approved by the Cabinet of Ministers of Ukraine dated March 25, 2009 No. 333 (as amended by the Cabinet of Ministers of Ukraine dated December 13, 2017 No. 1081), while the prices for these drugs must be declared in the prescribed manner in the register of wholesale selling prices[13-15].

According to the results of the study, it was established that the following agents for general anesthesia are included in the National List of Essential Medicines, which are presented in Table 1.

Among the indicated inhalation drugs as of 09/01/2020, the following drugs are registered in the State Register under the international non-proprietary name:

- Isoflurane (N01AB06) Isoflurane, vial. 100 and 250 ml (Piramal Enterprises, India) Isoflurane, USP, fl. 100 ml, 250 ml (Halocarbon Products Corp., (USA));

- Sevoflurane (N01AB08) Sevoflurane, vial. 250 ml, Piramal Critical Ker Inc., USA; Sevoflurane, YUSP, fl. 250 ml, Halocarbon Products Corp., USA; Seva-Anesteran, fl. 100 ml or 250 ml, Rompharm Company, Romania; Sevoran, fl. 250 ml, Aesica Queenborough Ltd, UK;
- Nitrous oxide (N01AX13) contains 2 names of Nitrous oxide (Nitrous oxide) produced by Messer Technogaz (Czech Republic), DIPI Air Gas LLC, Ukraine and Trading House Medical Gas Service LLC, Russia.
- Ketamine (N01AX03) in the form of a solution for injection, 50 mg / ml registered 2 trade names: Castor oil-ZN, amp. 2 ml No. 10 (People's health, Ukraine), Ketamine amp. 2 ml No. 10; fl. 10 ml No. 5 (Farmak, Ukraine);
- Propofol (N01AX10) in the form of an emulsion for injection. or d / inf.

According to the INN Thiopental (N01AF03), only 2 names of domestic production are registered - Thiopental, a lyophilisate for the district of d / in. 0.5 g, 1.0 g in a vial (Kievmedpreparat, Ukraine).

The state register contains the following trade names: Diprivan, 1% amp. 20 ml No. 5; fl. 50 ml (Corden Pharma, Italy AstraZeneca, UK); Diprofol® 1% and 2% amp. 20 ml No. 5; fl. 50 ml No. 10 (Synthon Hispania, Spain, Fresenius Kabi, Austria) as an FPP and in bulk; Propofol Kabi 1% amp. 20 ml No. 5; fl. 50 ml No. 10 (Fresenius Kabi, Austria / Germany) Propofol Kabi 2% fl. 50 ml No. 1, No. 10 (Fresenius Kabi, Austria / Germany) Diprofol® EDTA 1% amp. 20 ml No. 5, fl. 20 ml No. 1, No. 5, or No. 10, fl. 50 ml No. 1 (Farmak, Ukraine); Diprofol® EDTA 2% amp. 20 ml No. 5, fl. 20 ml No. 1, No. 5, or No. 10 fl. 50 ml No. 1 (Farmak, Ukraine); Propofol 1% in vial 10 ml, 20 ml, 50 ml, 100 ml (Baxter Pharm. India Private, India) Propofol Fresenius 1% amp. 20 ml No. 5; fl. 50 ml No. 1 (Fresenius Kabi, Austria / Germany) Propofol PharmUnion 1% amp. 20 ml No. 5 (Dong Kuk Pharm. Co., Korea) Propofol-Lipuro 1% 10 mg / ml amp. 20 ml No. 5; fl. 50 ml, 100 ml No. 10 (B. Braun Melsungen AG, Germany); Propofol-Novo 1% in a bottle of 10 ml, 20 ml No. 5; 50 ml, 100 ml No. 1 (Novopharm-Biosynthesis, Ukraine).

The cost of drugs registered in the register of wholesale prices is presented in table 2.

So, according to the ATX classification, Ditolin belongs to the M03A group of muscle relaxants with a peripheral mechanism of action, INN suxamethonium (M03AB01). It should be noted that only Ditolin r d / in are included in the State Form (XII issue) of all the above. 20 mg / ml amp. 5 ml of domestic production under the following trade names: Ditolin-Biolek, Pharmstandardbiolik (declared per 1 ampoule - UAH 12.35), Ditolin-Darnitsa, (8.65 UAH), Ditolin-N LLC "Niko" (7.50 UAH). In the register of the OVTs, prices are declared for 2 domestic drugs in the form of a d / in solution. 20 mg / ml, 5 ml in ampoule No. 10, namely: Ditolin-Darnitsa (Darnitsa) - 103.05 UAH. and Ditolin-Biolek (Pharmstandard-Biolek) - UAH 61.74. The price discrepancy is 67%.

According to the results of the analysis of reliable data obtained according to the registration logs of the Department of Anesthesiology and Intensive Care of the Vyshgorod Central Regional Hospital, we observe the dynamics of increasing the number of anesthesia. According to forecast calculations, the number of endotracheal anesthetics in 2020 will increase by an average of 177 anesthetics; intravenous - by 64. Based on this, the purchase of drugs for anesthesia will increase, we take into account this factor in the formation of the budget and procurement. When substantiating the choice of the most optimal drugs by price and form of release, we consider the following: for INN Sevoflurane - Sevoflurane 250 ml at a price of UAH 3,566.49; for INN Propofol - Diprofol 2% 50 ml in a bottle - UAH 284.35. ampoule solution is not used due to irrationality, as during anesthesia there are residues; from muscle relaxants - for INN Suxamethonium - Dithylin-Biolik 5 ml № 10 - 64.18 UAH; for INN Thiopental - Sodium Thiopental 1.0 - 77.75 UAH.

According to the public module of BI analytics, an analysis of the state of procurement of drugs for anesthesia (table 3), [16-21].

Conclusion

The analysis of the features of the organization of public procurement in the health care of Ukraine is carried out on the example of one of the central regional hospitals. The features of forecasting needs

and analysis of purchases for 2017-2020 have been investigated. According to statistics, annual procurement plans and the analytical module of the Prozorro system.

In accordance with the safety standards and the organization of the provision of anesthetic care during anesthesia, the best for surgical interventions are: ketamine, diazepam or midazolam, morphine, local anesthetics (lidocaine or bupivacaine).

Alternative drugs are thiopental or propofol, inhalation anesthetics (halothane, isoflurane), succinylcholine, muscle relaxants (pancuronium or atracurium), neostigmine. The use of propofol, alternative inhalation anesthetics (sevoflurane), alternative non-depolarizing muscle relaxants (rocuronium or cisatracurium) is also proposed.

According to the results of the study, it was established that the following agents for general anesthesia are included in the National List of Essential Medicines: inhalation drugs: Isoflurane, Sevoflurane, Nitrous oxide, Halothane, injection drugs Ketamine, Propofol Thiopental.

The analysis of anesthesia for 2018 and 2019 made it possible to establish that 26 anesthesia was performed using Sevoran in 2018 and 231 in 2019 (almost 9 times more). Ditolin is used much more often - with 359 surgical interventions in 2018 and 1315 - in 2019 (consumption increased by 3.7 times). Sodium thiopental - 820 in 2018 and 359 in 2019. (decrease by 2.3 times). The use of the drug for intravenous anesthesia Propofol is also uneven during the analyzed period - during 2018 it was used in 1599 surgical interventions, in 2019. - 642 (60% less).

References

1. Adapted clinical guidelines based on evidence "Control of perioperative pain". PainMedicine Journal / Pain Medicine Clinical guidelines. 2017. Volume 2, №4. 48 p. <https://painmedicine.org.ua/index.php/pnmdcn/article/download/70/67/>
2. Nazarkina V.N, Kozhan L.S. Analysis of the features of forecasting the need and implementation of public procurement of drugs for anesthesia. Actual problems of development of branch economy and logistics: mater. VIII

- International. scientific-practical internet-conference on international participation, Kharkiv, November 12, 2020. Kharkiv: NUPh, 2020. P. 240-242.
3. Nemchenko AS, Nazarkina VN, Kurylenko Yu.Ye Harmonization of public procurement in Ukraine with EU standards: textbook. manual Kharkiv: NUPh, 2018. 370 p.
4. On public procurement: Law of Ukraine of 25.12.2015 №922-VIII. Edited from 15.08.2020. URL: <https://zakon.rada.gov.ua/laws/show/922-19#Text>
5. Public module of VI ProZorro analytics <https://bi.prozorro.org>
6. Public procurement <https://prozorro.gov.ua/>
7. Dion P. The cost of anesthetic vapors. *Canada Journal of Anesthesia*. 1992; 39 (6): 633.
8. Grocott MP, Mythen MG. Perioperative Medicine: The Value Proposition for Anesthesia?: A UK Perspective on Delivering Value from Anesthesiology. *Anesthesiol Clin*. 2015 Dec;33(4):617-28.
9. Eichhorn JH. Review article: practical current issues in perioperative patient safety. *Can J Anaesth*. 2013 Feb;60(2):111-8. doi: 10.1007/s12630-012-9852-z. Epub 2012 Dec 20. PMID: 23263979.
10. Odin I, Feiss P. Low flow and economics of inhalation anesthesia. *Balliere's Best Practice in Clinical Anesthesiology*. 2005; 19: 399-413.
11. The Pharmacology of Inhaled Anesthetics / Talmage D. Egan, M.D .; David O. Warner, M.D. *Anesthesiology*. 2004, Vol. 101, 563-564.
- Nemchenko, A.S., Titko, I.A., Podgaina, M.V., Korzh, 12.Y.V., Zaytzeva, Y.L. Legal and organizational economic aspects of the functioning of the main models of health-care systems. *Asian Journal of Pharmaceutics* this link is disabled, 2018, 12, S937-S945
13. Mishchenko, V., Nazarkina, V., Vynnyk, O., Kurylenko, Y., Breusova, S. An analysis of approaches regarding the regulation of parapharmaceutical products sales through the network marketing system in Ukraine. *Research Journal of Pharmacy and Technology* this link is disabled, 2020, 13(3), 1204-1210
14. Lebed, S., Nemchenko, A., Nazarkina, V. Actuality of the implementation of international practice in proliferation of counterfeit medicines involving Interpol. *Journal of Advanced Pharmacy Education and Research* this link is disabled, 2020, 10(2), 52-59
15. Pharmaceutical Expenditure Tracking, Budgeting and Forecasting in 23 OECD and EU countries <https://www.oecd.org/health/health-systems/Pharmaceutical-Expenditure-Tracking-Budgeting-Forecasting-Country-Notes.pdf>
16. Quality of Public Administration A Toolbox for Practitioners file:///C:/Users/%Do%AE%Do%BB%D1%8F/Ddownloads/10%20T2017%20Theme%208%20Public%20funds_web.pdf
17. Consolidation in the Anesthesiology Services Market Continues with New Partnership Option https://www.anesthesiologynews.com/PRN-Article/10-19/Consolidation-in-the-Anesthesiology-Service-Market-Continues-with-New-Partnership-Options/56101?sub=53ABFC48963F2CB94EBDE98F96D10979CDA7733331E3E9CF48FoDF2D8CC9&enl=true&dgid=X3659420&utm_source=enl&utm_content=3&utm_campaign=20191023&utm_medium=button
18. Kalmoe MC, Janski AM, Zorumski CF, Nagele P, Palanca BJ, Conway CR. Ketamine and nitrous oxide: The evolution of NMDA receptor antagonists as antidepressant agents. *J Neurol Sci*. 2020 May 15;412:116778. doi: 10.1016/j.jns.2020.116778. Epub 2020 Mar 19. PMID: 32240970.
19. Fleisher LA. Quality Anesthesia: Medicine Measures, Patients Decide. *Anesthesiology*. 2018 Dec;129(6):1063-1069. doi: 10.1097/ALN.0000000000002455. PMID: 30273268.
20. Gelb AW, Morriss WW, Johnson W, Merry AF; International Standards for a Safe Practice of Anesthesia Workgroup. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. *Can J Anaesth*. 2018 Jun;65(6):698-708. English. doi: 10.1007/s12630-018-1111-5. Epub 2018 May 7. PMID: 29736769.
21. Das J. Repurposing of Drugs-The Ketamine Story. *J Med Chem*. 2020 Nov 25;63(22):13514-13525. doi: 10.1021/acs.jmedchem.0c01193. Epub 2020 Sep 22. PMID: 32915563.

Table 1. General anesthetics listed on the National Essential Medicines List

inhalation drugs	Halogenated hydrocarbons N01AB06 Isoflurane (Isoflurane), N01AB08 Sevoflurane (Sevoflurane)	N01A X Other means of general anesthesia: Nitrous oxide, Halothane, and Oxygen
Injectable drugs:	N01A X Other general anesthetics: Ketamine 50 mg / ml 2 ml, 10 ml, Propofol 10 mg / ml; 20 mg / ml, preparation of group	N01A F Barbiturates, monopreparations Thiopental (can be used as an alternative to propofol) injection of 0.5 g; 1 year

Table 2. Analysis of price indicators for the drugs under study

INN	Price	Note
Sevoflurane	In a bottle of 250 ml Sevoflurane, Pyramal Critical Ker Inc., USA - 4451.25 UAH, Sevoflurane, USP, Halocarbon Products Corp., USA - 4641.00 UAH, Sevo-Anesteran, K.T. Rompharm Company SRL, Romania - 2,516.48 UAH, Sevoran, Aesica Quinborough, Great Britain Abby Italy - 2,960.16 UAH.	Thus, the most expensive is Sevoflurane, USP (USA), the cheapest - Sevo-Anesteran (Romania), with a price difference of 85%.
Isoflurane	In the form of bottles of 250 ml Isoflurane (India) - 2,953.33 UAH, Isoflurane, USP (USA) - 1920.00 UAH; in the form of bottles of 100 ml - Isoflurane (India) - 1919.67 UAH, Isoflurane, USP (USA) - 1,300.00 UAH.	-
Propofol	In the form of an emulsion d / inf. 1% in a bottle of 50 ml: Propofol-Novo (Novopharm-Biosynthesis, Ukraine) - 126.00 UAH; Diprofol® (Farmak, bulk packaging, Ukraine) - 170.00 UAH, Propofol-Lipuro (B. Brown Melsungen AG, Germany) - 148.36 UAH; Diprofol® EDTA (Farmak, Ukraine) - 200.00 UAH.	The difference in prices for these drugs is 58.7%.
	Propofol in the form of an emulsion d / inf. 1% in the form of ampoules of 20 ml № 5 cheapest prices are declared for domestic drugs produced by PJSC "Farmak", namely: Diprofol® (packaging from the form in bulk) - 221.50 UAH and Diprofol® EDTA - 221.50 UAH; Propofol-Novo (Novopharm-Biosynthesis, Ukraine) - 255.84 UAH; imported drugs are more expensive - Propofol Farmunion (Korea) - 265.02 UAH, Propofol-Lipuro (Germany) - 300.00 UAH, Diprivan (Italy / Great Britain) - 313.27 UAH.	Thus, the price difference is 41.3%.

Propofol in the form of an emulsion d / inf. 2% in a bottle of 50 ml	Diprofol® (Farmak, packaging from the form in bulk) - 335.00UAH , Diprofol® EDTA (Farmak) - 390.00UAH .	The calculated price difference is 16.4%.
Thiopental	In the register the prices for 2 drugs of domestic production ("Kyivmedpreparat") under the trade name Thiopental yophilisate for the district are declared. in a bottle, with the price of 1.0 g - 67.00UAH , 0.5 g - 52.00UAH .	-

Table 3. Analytics of procurement of drugs for anesthesia

INN	Lots
Isoflurane	35 lots (921 units), 23 participants, 9 suppliers. 68.6% of procurement procedures were successfully completed. Main organizers: SI "Scientific and Practical Medical Center of Pediatric Cardiology and Cardiac Surgery of the Ministry of Health of Ukraine", SI "National Cancer Institute", SI "National Institute of Surgery and Transplantology named after OO Shalimov" of the National Academy of Medical Sciences of Ukraine
Tiopental	3.44 thousand lots (1,554,578 units) were registered in the system, the number of participants was 214, the number of organizers was 891
Propofol	3.2 thousand lots (1,210,407.40 units of the subject of procurement), 67.7% of lots were successfully completed. Tenders are organized by 819 organizers with the participation of 192 suppliers
Sevoflurane	674 lots (34,814 units of the subject of procurement), 71.2% of lots were successfully completed. Tenders were conducted by 246 organizers with the participation of 88 suppliers
Suxamethonium	3047 lots (34 814 units of the subject of procurement), 63.4% of lots were successfully completed. Tenders are organized by 825 organizers with the participation of 208 participants, 158 suppliers