11. Мечев ДС. (2012). Сучасний стан розвитку променевої терапії в Україні. Радіологічний вісник. 42 (1): 5–7.
12. Національний канцер-реєстр України. (2010). Аналіз виживаності хворих на рак в Україні. Бюлетень національного канцер-реєстру України. 11: 4–13.
13. Національний канцер-реєстр України. (2012). Виживаність хворих як індикатор якості організації онкологічної допомоги хворим на рак шийки матки. Бюлетень національного канцер-реєстру України. 13: 72–87.
14. Пилипенко МІ, Скалецький ЮМ, Стадник ЛЛ, Федько ОА. (2011). Стан та проблеми ядерних і радіаційних технологій в системі охорони здоров'я України. Ядерні та радіаційні технології в Україні: можливості, стан і проблеми впровадження. Зб. наук. статей за заг. ред. академіка НАН України, д. т.н., проф. В. П. Горбуліна. Київ: ДП «НВЦ «Пріоритети": 82–94.
15. Пилипенко МІ, Стадник ЛЛ, Корнєєва ВВ та ін. (2010). Стан дозиметричного забезпечення променевої терапії в медичних закладах України за результатами анкетування та ТЛД-аудиту МАГАТЕ/ВООЗ. Український радіологічний журнал. 4: 409–416: URL: http://medradiologia.kharkov.ua/assets/files/arch/2010/4/p409_416.pdf.
16. Шарабчиев ЮТ. (2007). Врачебные ошибки и дефекты оказания медицинской помощи: социально-экономические аспекты и потери общественного здоров'я. Медицинские новости. 3: 34. URL: http://www.mednovosti.by/journal.aspx?article=301.
17. ВОЗ. (2005). Восьмой форум по вопросам будущего: управление вопросами безопасности пациентов. Эрпфендорф, Австрия, 28–29 апреля 2005 года. Европейское региональное бюро ВОЗ: 38. URL: http://www.euro.who.int/__data/assets/pdf_file/0007/98287/E87770R.pdf.

M.I. Pylypenko[1], L.L. Stadnyk[2], M.M. Rygan[3], Ju.M. Skaleckyj[4], O. Ju. Shalyopa[2]

Medical and social consequences of the safety problems of oncological radiology

[1]Kharkiv National Medical University, Ukraine
[2]Grigoriev Institute for medical Radiology of the NAMS of Ukraine
[3]Medical Center «Clinic of modern orthopedics», Kyiv, Ukraine
[4]National Commission for Radiation Protection of Ukraine, Kyiv

The relevance of the problem of patient safety in oncoradiology in Ukraine and other countries has been substantiated.

The **purpose** – is to assess the safety of patients receiving radiation therapy and the magnitude of the health and social consequences of human error in this area.

Materials and methods. The material of the study was the results of international TLD audit (IAEA/WHO) of the dosimetry quality during procedures on cobalt telegram devices in Ukraine as well as the international and domestic regulatory framework on safety of the radiotherapy care, and scientific publications of domestic and foreign specialists on patient safety. The methods of the research: statistical, analytical, bibliographic, systems approach.

Results. By the example of radiotherapy using the results of the international IAEA/WHO program on the TLD audit of the quality of the dosimetric calibration of the remote gamma-therapy units in Ukraine in 1998–2014, an attempt has been made to estimate the scale of medico-social consequences of the underestimation of medical errors in oncoradiology. The problems of regulatory nature of medical errors in oncoradiology had been tentatively identified.

Conclusions. The problem of medical errors in the treatment of cancer patients with radiation oncology in Ukraine is extremely topical. Usually the problems of errors in oncoradiology are considered in the organizational, methodological, personnel and technical aspects, while the medico-social consequences of the problem are not covered. In the optimistic scenario, about 10,000 cancer patients for a year may suffer from dose-related errors alone, while in the pessimistic scenario the number may be as high as 15,000 over the same period. There are legal issues to be clarified in oncoradiology for patient safety reasons. The first priority for improving patient safety in oncoradiology is to record and analyze defects in radiotherapy and their consequences.

No conflict of interests was declared by the authors.

Keywords: *patient safety, malpractice, medical errors, cobalt telegrams, TLD audit, radiation accident.*

Introduction

With annual increase of early diagnostics indicator of cancer and decrease of the neglect of disease level the one-year and five-year survival rate of cancer patients that are considered as integrated indices of the efficiency of counter-cancer measures is still low. Survival rates of cancer patients in Ukraine are 1.5–2 times lower, and 5 times lower on specific cancer localization, then in the European states, the US, and Australia [12,13].

Besides different consideration on the reasons of this disparity (organizational, human resources, technology, methodology were mentioned) [11,14] we suggest that analysis of this situation in the aspects of medical care defects [2] and possibility of the medical and social consequences should be added. Considerable attention was paid for the issue of medical care defects by international and national institutions of the certain states [17].

There is no doubt regarding need for the increase of accessible radiological medical services for population because of huge value for human health treatment that medical use of radiation sources may provide. Radiological risks related to diagnostics procedures are generally low. Meanwhile as a result of radiotherapy faults the significant consequences may occur.

Even minor deviations of the planned doses caused by various reasons in oncological radiology effect on overvaluation of actual total local dose that cause radiation injuries (sometimes fatal injuries) of the patient, or on undervaluation of dose that leads to clinical treatment efficiency reduction and increase likelihood of relapse or occurrence of secondary malignancies.

The problem of bringing a dose to the tumor target is seen mainly as a technical and medical and social consequences of this problem were out of focus [1,15]. According to requirements on radiation treatment efficiency for malignant tumors and prevention of their recurrence and complication due to irradiation it is necessary to ensure that error of target tumor and adjacent tissue irradiation is not exceed ±5% [6]. Unfortunately in practice the scale of medical and social consequences of medical personnel in Ukraine faults particularly in oncological radiology was not researched yet. But this information could facilitate the increase of patients' safety [2,11,13].

The **aim** of research – taking into account mentioned above, the purpose of this research is to estimate the state of radiation therapy patients' safety and the scale of medical and social consequences of medical personnel faults in this area.

Materials and methods of research

The material of the research is results of TLD audit (IAEA/WHO) of dosometry quality of the procedures on cobalt telegamma-devices in Ukraine, international and domestic legal framework for radiotherapy care safety, as well as scientific publications domestic and foreign experts in the field of patient safety.

Research Methods are following: statistical, analytical, bibliographic, system approach.

Results of the research and discussion

Defects of medical treatment in oncological radiology. The reasons of the unwanted effects in medical practice are medical faults, offences and accidents [3]. When the negative consequences of medical care for the patient occurred due to negligence, inattention, excessive overconfidence or medical ignorance, we will talk about the offence. According the Criminal Code of Ukraine, chapter «Crimes against life and health» that has 15 «medical» articles (130–145), medical personnel may be subject to liability. These offences of professional medical personnel may be found in the annual reports of the Prosecutor General of Ukraine. Thus, nearly 600 cases of prosecuted for these offences were registered in 2014.

There are accidents in medicine, as in any field of human activity that related to the use of electricity, radiation sources, pressured gases, toxic or explosive substances in medical facilities, as well as traumatic falls, fires etc. Proper attention was given for these accidents in medical practice, which are mainly on responsibility of the state authorities for industrial, technological and labor safety [16]. These cases being investigated, recorded, analyzed, and appropriate measures to prevent them were taken.

Finally, the medical fault is considered as an accidental injury of patient, caused by faulty actions or inaction of the medical personnel, characterized by his/her misleading in good faith within respect to professional duties and the lack of signs of malice, negligence or carelessness [3]. Unfortunately, the less attention is given for medical faults despite they result more death tolls that transport incidents in developed countries [17]. Also medical faults receive less attention in the health care system that offences or accidents.

In 2013 IAEA have generalized the experience of radiation accidents response and presented a brief description of all accidents registered between 1945 and 2010 [8]. According to IAEA there were occurred 42 accidents related to ionizing radiation use in medical practice between 1967 and 2007, and 13 of which were in the cobalt-telegamma devices. There were severe radiation exposure injuries in 41 cases that led to death of the patient groups in some cases. Only in one of observed cases the radiation doses was 5–30% lower than planned that resulted local recurrence of cancer for 492 of 1,045 patients. In 18 cases the cause of accidents in ontological radiology was related to dose planning.

One on the latest cases of massive overexposure of patients due to medical personnel and engineer-radiologist fault of

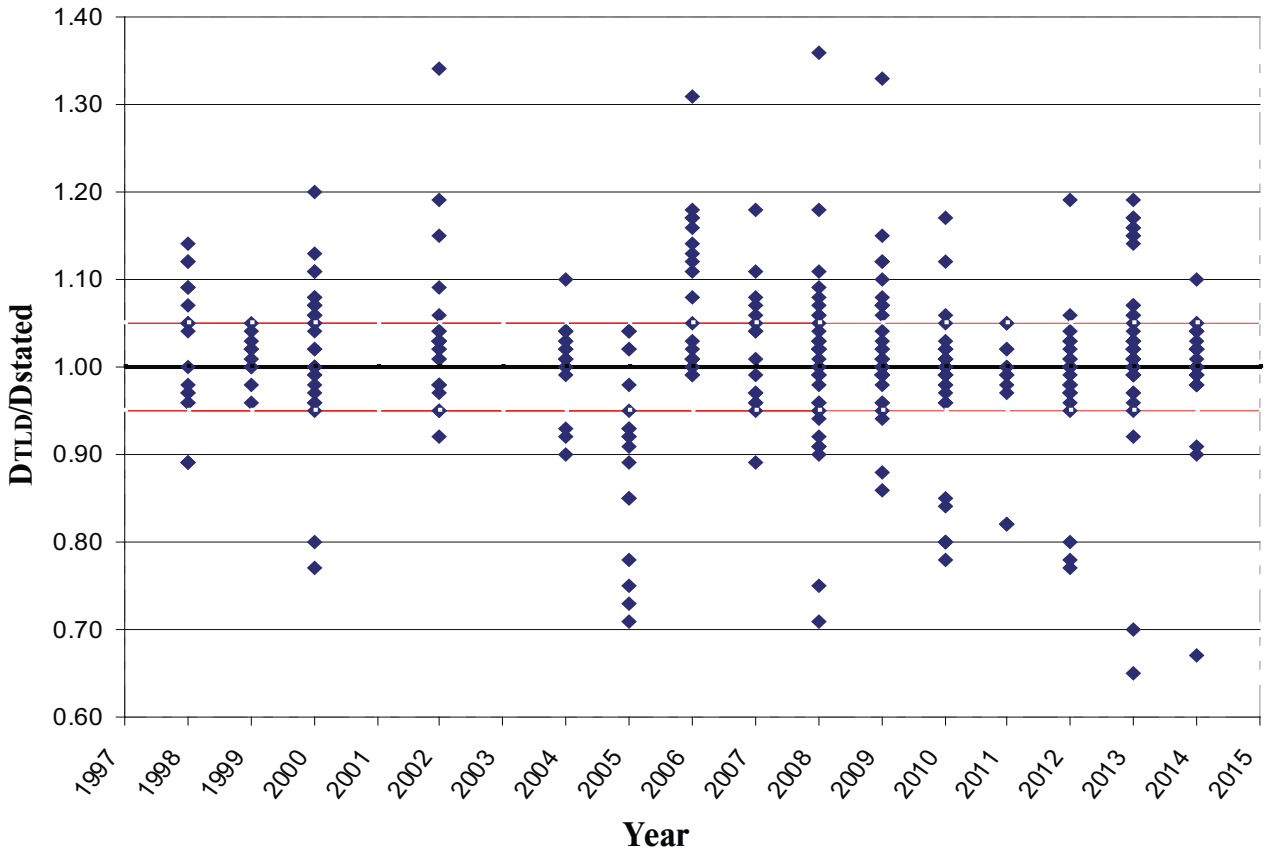

Figure. TLD audit results for ray radiotherapy devices in Ukraine in 1998–2014

dose calculation (overexposure of 7 to 34% of planned dose during period of May 2004 to May 2005) occurred in Jean Monnet Hospital in Epinal (France). As a result at least 12 persons died and tens of patients were seriously injured. Deviations from the planned doses in described accidents predominantly varied in the range of +75% to −30%. This generalization of radiation accidents confirmed again that the most serious consequences of radiation accidents are related to errors of dosimetric planning and implementation of all technological stages of radiotherapy [9].

On the one hand the problems of dose calculation and exposing of malignant formation should be attributed to medical errors based on their previous definition [16], but if this error led to the rejection of proven doses by more than 5% of the planned dose, such exposure is considered an emergency [6], that may be classified as an accident or offence.

The already mentioned case of Jean Monnet Hospital in Epinal has been qualified as offence, and two doctors and a radiologist of the clinic were sentenced to 18 months in prison.

Generally the emergency exposure in the medicine practice according to International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources is «any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute or secondary effects» [7]. The interpretation of reasons for such emergency exposure as an accident, mistake or offense is under competence of the authorities, and it is based on the national legislation norms that are mostly imperfect in this field. Thus there are problems of legal nature regarding safety of patients in radiology that require clarification.

The situation in Ukraine. Providing required accuracy of the release of absorbed dose in radiation therapy is possible due regular monitoring of the radiation output of therapeutic devices, ie dosimetric calibration of therapeutic beams both in the radiology department and when calibration of the radiation fields of radiotherapy apparatus conducted, as well as the independent external audit.

Since 1998 IAEA and WHO being conducted regular independent audit of dosimetric calibration of gamma-therapeutic beams using termolumeniscent dosometry method («dose by post») in Ukraine (TLD-audit). Participation in this procedure is voluntary and confidential for medical institutions.

The results of TLD audit for external ray radiotherapy devices in Ukraine in 1998−2014 are shown on the figure. On the vertical axis of this figure the ratio between measured dose by dosimeter and dose conditions by audit is shown. On the horizontal axis the year of research is shown.

Table

Analysis of TLD audit results for ray radiotherapy devices in Ukraine in 1999–2014

Year	Total number of devices, that were in TLD audit	Range of the error of dose release after I stage, ±%					Unsatis-factory results after I stage,%	Range of the error of dose release after II stages, ±%					Unsatisfactory results after two stages,%
		<5	5–10	10–20	20–30	>30		<5	5–10	10–20	20–30	>30	
1998	13	7	3	3	-	-	46,2	3	-	3	-	-	23,1
1999	10	10	-	-	-	-	-	-	-	-	-	-	0,0
2000	23	13	8	1	1	-	43,5	3	2	1	1	-	17,4
2002	19	13	3	2	-	1	31,6	4	-	-	1	-	5,3
2004	18	14	3	1	-	-	22,2	**2nd stage was not conducted**					22,2
2005	15	7	2	2	1	3	53,3	-	2	1	1	-	26,7
2006	14	7	-	6	1	-	50,0	4	1	1	-	-	14,3
2007	12	8	2	2	-	-	33,3	2	1	1	-	-	16,7
2008	28	19	4	1	1	3	32,1	4	3	2	-	-	17,9
2009	35	23	5	5	2	-	34,3	8	4	-	-	-	11,4
2010	24	18	1	2	3	-	25,0	3	-	2	1	-	12,5
2011	13	9	-	3	1	-	30,8	3	-	-	-	-	0,0
2012	25	19	1	1	3	1	24,0	5	-	-	-	-	0,0
2013	38	26	4	5	-	3	31,6	8	1	3	-	-	10,5
2014	33	29	2	1	-	1	12,1	4	-	-	-	-	0,0
Average values	21,3						32,6						11,9

Range limited by dotted lines on the figure corresponds to the ratio between the dosimeter measured dose and dose conditions by audit within ±5% variation [6] that is considered to be acceptable.

Attention is drawn to the fact that almost annually there have been cases of conditions caused by excess auditing dose by 20% or more, which can lead not only to radiation complications, but also to the deaths [8].

More detailed information on TLD audit results of the external ray radiotherapy devices in Ukraine in 1998–2014 presented in the Table.

According to the data from Table it can be seen, that in 1998, 2000, 2002, 2007, 2008, 2009, 2011 and 2013 for more than 30% of external ray radiotherapy devices that were TLD audited the accuracy of the release of absorbed dose exceeded ±5%, and in 2005 and 2006 these variation was in more than half of devices.

An average for 15 years period of 1998–2014 the discrepancy of the radiation output of external beam radiotherapy devices and specified parameters was observed in 32.6% of the results on the 1st stage of audit, and in almost 12% of cases for re-audit. These data is close to earlier estimations [15] that discuss the problems of the calculation of dose on 28% external gamma-therapeutic devices that were subject to TLD audit in Ukraine. In this paper it is also noted that according IAEA/WHO TLD audit results for developing countries there are only 5–15% of devices has an error of the calculation of radiation beam more than 5%.

Thus in practice every third devise that was subject of TLD audit in Ukraine there were problems with dose calculation.

Before we proceed to the assessment of the number of cancer patients which effectiveness of treatment could negatively be impacted by above-mentioned problems with external radiation devises, you should also note the following:

– Dose calculation is one of many stages of ray therapy, and error could be made on any stage [2,7];

– Lack of simulators, planning systems, devices for fixation of patients during irradiation, devices of individual protection of healthy tissues, and outdated models of clinical dosimeters in oncological radiology departments [14];

– Low qualification level of engineers, radiologists, and absence of certain professions in the national classification, and therefore absence of radiotherapy positions and specialists in «Medical Physics» in the medical departments [10];

– Lack of targeted activities in accounting and analysis of medical errors in Ukraine particularly in oncology [4,5].

Taking into account the aforementioned problems of oncological radiology it can be argued that a deviation of calculation and release of absorbed dose to the tumor target with accuracy above or below 5% took place for a half of gamma-therapy devices in Ukraine. At least it can be considered as a pessimistic option of the assessment of situation.

In order to estimate medical and social consequences of the dose miss-calculation problems, we may suggest that there are about 100 tele-gamma therapy cobalt devices in Ukraine (even larger number of these devices is expected for the near future) [11], and the annual load on each device is about 300 cancer patients. Therefore, we obtain an annual contingent of treated on these devices people that is about 30,000 people. Using this information it is quite easy to estimate the number of patients in whom radiotherapy is inefficient (absorbed dose is higher or lower than planned).

While according our optimistic option (32.6% of tele-gamma devices with unsatisfactory TLD audit results) we receive about 10,000 cancer patients, and the pessimistic option (50.0% of tele-gamma devices with unsatisfactory TLD audit results) we received 15,000 cancer patients respectively, for those who will receive ineffective radiological therapy or will obtain maligned complications or even fatal consequences.

Generally it confirms the significance of medical faults and patient safety issues in Ukraine that should be fundamentally investigated.

Conclusions

The problem of the medical faults of cancer patient treatment by radiological methods is extremely important in Ukraine.

Usually studies of medical faults in oncologic radiology consider organizational, thematic, personnel and technical aspects. Meanwhile known studies do not cover medical and social consequences of this unresolved problem.

According optimistic option there is about 10 thousand cancer patients annually who may suffer due dose calculation errors, and by pessimistic option such number may reach 15 thousand patients.

There are legal problems regarding patient safety in oncological radiology. These problems require clarification.

The primary task of improving the patient safety in oncologic radiology is the accounting and analysis of radiation therapy defects and their consequences.

No conflict of interests was declared by the authors.

References

1. *Baba MH, Mohib-ul-Haq M, Khan AA. (2013, Jan). Dosimetric Consistency of Co-60 Teletherapy Unit- a ten years Study. Int. J. Health Sci (Qassim). 7 (1): 15–21. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612411.*
2. *Bilynskyj BT. (2013). Medical errors in oncology: monograph. Gen. editorship Ja.V.Shparyk. Lviv: Afisha: 234.*
3. *Fedorenko M. (2014). Features inspections of health facilities by OSH. Dovidnyk specialista z ohorony praci. 7: 46–51.*
4. *Grando OA. (2000). Problems of medical ethics and deontology. Socialna medycyna ta organizacija ohorony zdorovja. Under the gen. editorship Ju.V. Voronenko, V. F. Moskalenko. Ternopil: Ukrmedknyga: 645–668.*
5. *Green Paper. (2012). Green Paper of the National Plan of Action on Patient Safety Materials First National Congress on patient safety. Project 1.4.1. Council of Europe Action Plan for Ukraine in 2011–214 years. K.: Morion: 133.*
6. *IAEA. (2000). Absorbed Dose Determination in External Beam Radiotherapy An International Code of Practice for Dosimetry Based on Standards of Absorbed Dose to Water. Technical reports series No. 398. International Atomic Energy Agency, Viena: 229. URL: http://www-pub.iaea.org/mtcd/publications/pdf/trs398_scr.pdf.*
7. *IAEA. (2001). Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy Proceedings of an international conference held in Mбlaga, Spain, 26–30 March 2001, organized by the International Atomic Energy Agency and co-sponsored by the European Commission, the Pan American Health Organization and the World Health Organization. Vienna: 165. URL: http://www-pub.iaea.org/ mtcd/publications/pdf/pub1113_scr/pub1113_ scr1.pdf.*
8. *IAEA. (2014). Lessons Learned from the Response to Radiation Emergencies. August 2012. Venna: 136–142. [МАГАТЭ. (2014). Уроки реагирования на радиационные аварийные ситуации (1945–2010 годы). Вена: 136–142. URL: http://www-pub.iaea.org/MTCD/publications/PDF/EPR\Lessons%20learned% 202012r_web.pdf.*
9. *Kostylev BJa, Tarkevich VA. (2014). Radiation safety in medicine. Tutorial. Москва: 202.*
10. *Makarovska OA, Aslamova LI, Kulich JeV, Malenevska JeV. (2014). Training medical physicists as one of the main activities of professional associations of medical physicists. Medical physics – the current status, problems, the way of development. Innovation technologies. Abstracts of 4th International Conference, October 23–24, 2014, Kyiv, Taras Shevchenko National University of Kyiv. Kyiv: Morion: 1–2.*
11. *Mechev DS. (2012). The current state of development of radiotherapy in Ukraine. Radiologichnyj visnyk. 42 (1): 5–7.*
12. *Natsionalnyi kantser-reiestr Ukrainy. (2010). Analysis of survival of cancer patients in Ukraine. Bjuleten nacionalnogo kancer-rejestru Ukrainy. 11: 4–13.*
13. *Natsionalnyi kantser-reiestr Ukrainy. (2012). The survival rate of patients as an indicator of the quality of the organization of cancer care for patients with cervical cancer. Bjuleten nacionalnogo kancer-rejestru Ukrainy. 13: 72–87.*

14. *Pylypenko MI, Skaleckyj JuM, Stadnyk LL, Fedko OA. (2011). State and problems of nuclear and radiation technologies in the health system Ukraine. Nuclear and Radiation Technology in Ukraine: capabilities, status and problems of implementation: Scientific articles / under the gen. editorship academ. NAS of Ukraine, d. t.s., prof. V. P. Gorbulina. Kyiv: SI «RPC «Priorytety» 82–94.*
15. *Pylypenko MI, Stadnyk LL, Kornjejeva VV et al. (2010). State provision of radiotherapy dosimetry in medical institutions of Ukraine on the results of the survey and TLD-audit IAEA/WHO. Ukrainskyj radiologichnyj zhurnal. 4: 409–416. URL: http://medradiologia.kharkov.ua/assets/files/arch/2010/4/p409_416.pdf.*
16. *Sharabchiev JuT. (2007). Medical errors and defects of medical care: the social and economic aspects of public health and the loss of. Medicinskie novosti. 3: 34. URL: http://www.mednovosti.by/journal.aspx?article=301.*
17. *WHO. (2005). Eighth futures forum on governance of patients safety. Erpfendor, Austria, 28–29 April, 2005. WHO Regional office for Europe: 38. URL: http://www.euro.who.int/__data/assets/pdf_file/0007/98287/E87770R.pdf.*

Відомості про авторів:

Скалецький Юрій Миколайович *– Національна комісія з радіаційного захисту населення України. Адреса та контактна інформація для переписки: м. Київ, вул. Бастіонна, 15; тел.: +38 (044) 574–55–15.*

Пилипенко Микола Іванович *– д.мед.н., проф., проф. каф. радіології та радіаційної медицини Харківського НМУ, чл. – кор. НАМН України.*

Стадник Лариса Львівна *– ДУ «Інститут медичної радіології ім. С. П. Григор'єва НАМН України», центральна лабораторія радіаційної гігієни медичного персоналу і пацієнтів.*

Стаття надійшла до редакції 08.09.2021 р., прийнята до друку 07.12.2021 р.