The human factor and technical conditions in the process of shaping the safety of medical staff during the treatment of cancer diseases – an original concept of drug packaging using CAD software and 3D bioprinting

Людський фактор та технічні умови у процесі формування безпеки медичного персоналу під час лікування онкологічних захворювань – оригінальна концепція упаковки ліків за допомогою САПР та 3D біодруку

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Purpose: The use of 3D printers for printing tablets, CAD software for 3D modeling for medical purposes, as well as the impact of the human factor on the safety of medical staff during the care of a cancer patient were studied.

Method: concept based on statistical data from the National Cancer Registry and information on bioprinters and 3D printers. Concept using AutoCAD software as well as statistical data related to accidents at work of medical personnel.

Findings: The concept of packaging anticancer drugs for an individual patient with the use of AutoCAD software as well as bioprints and 3D printers and its impact on the safety of medical staff.

Value: Thanks to 3D bioprinting and packaging of anticancer drugs, it will be possible to conduct further research on the treatment of cancer patients around the world with drug packages, to develop new technologies for the production of anticancer drugs, to increase access to drugs. The concept may force the standardization of treatment of oncological patients, as well as changes in the procedures for drug approval. The presented concept is the basis for further research. The concept will also affect the protection of medical personnel against human errors as well as the improvement of occupational health and safety.

Paper type: practical.

Key words: cancer, anticancer drugs, AutoCAD, 3D bioprinting, pharmaceutical industry, medical staff, safety.

Мета роботи: дослідити використання 3D-принтерів для друку планшетів, САПР для 3D-моделювання в медичних цілях, а також вплив людського фактору на безпеку медперсоналу під час догляду за онкохворим.

Метод дослідження: Концепція, заснована на статистичних даних Національного канцер-реєстру та інформації про біопринтери та 3D-принтери. Концепція з використанням програмного забезпечення AutoCAD, а також статистичних даних щодо нещасних випадків на виробництві медичного персоналу.

Результати дослідження: Запропонована концепція упаковки протипухлинних препаратів для окремого пацієнта з використанням програмного забезпечення AutoCAD, а також біопринтів і 3D-принтерів та її вплив на безпеку медичного персоналу.

Цінність дослідження: Завдяки 3D біодруку та упаковці протипухлинних препаратів стане можливим проводити подальші дослідження лікування онкологічних хворих у всьому світі за допомогою упаковок ліків, розробляти нові технології виробництва протипухлинних препаратів, розширювати доступ до наркотиків. Концепція може змусити стандартизувати лікування онкологічних хворих, а також змінити процедури затвердження ліків. Представлена концепція є основою для подальших досліджень. Концепція також вплине на захист медичного персоналу від людських помилок, а також на покращення гігієни та безпеки праці.

Тип статті: практична.

Ключові слова: рак, протипухлинні препарати, AutoCAD, 3D біодрук, фармацевтична промисловість, медичний персонал, безпека.

1. Introduction

The National Cancer Register (KRN) is run by the National Institute of Oncology at the request of the Minister of Health in Poland, and the substantive supervision over the project is exercised by the

Scientific Council composed of recognized experts. According to data from the National Cancer Register, only in 2019, according to the published report, 171.2 thousand information about new cancer cases was received[i]. Malignant neoplasms are the second cause of death in Poland. The data collected only from 2015-2019 show how the statistics from individual voivodeships are shaping up – which are terrifying when it comes to the number of cases in both men and women.

Report: Map of Poland
Filters selected:
Total neoplasms
Standardization: Population of Europe
Year: from 2015 to 2019
Gender: Women
Type: Illnesses

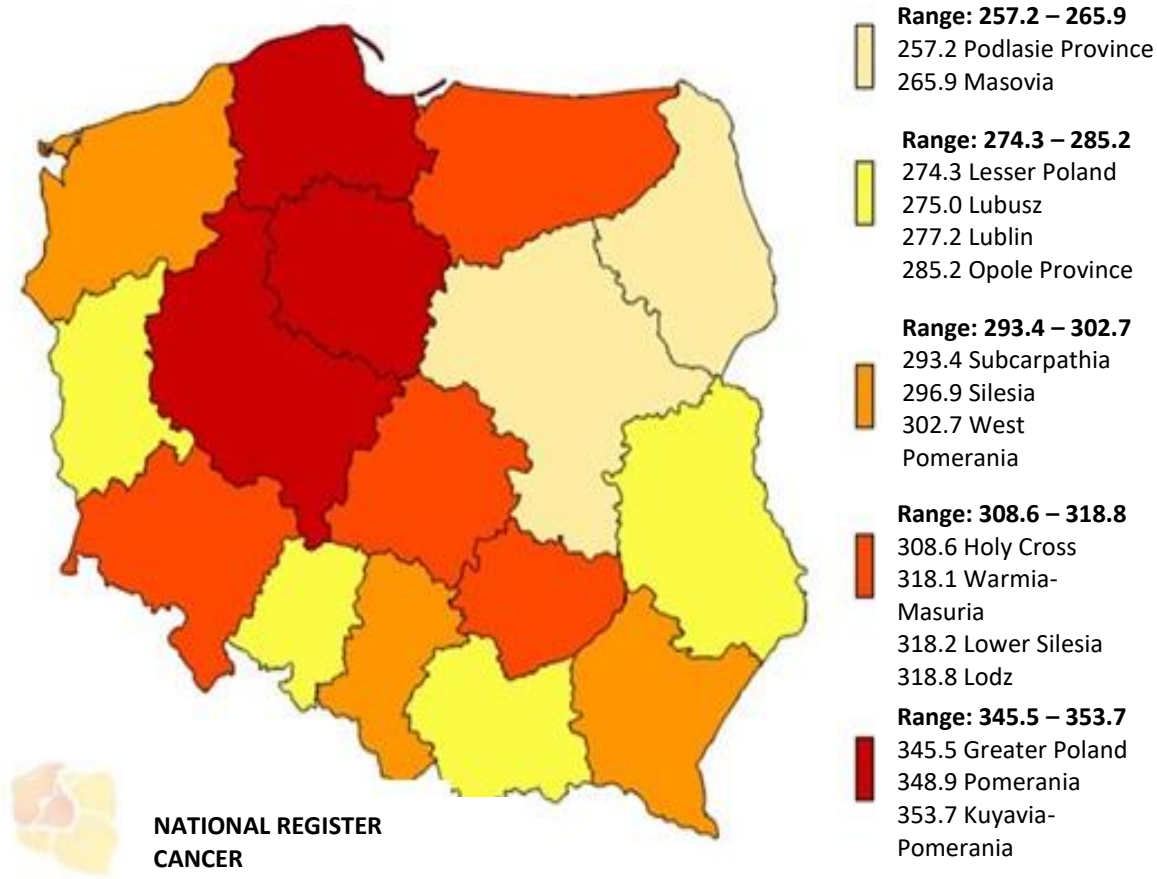

Figure 1 – Map of cancer incidence in women in individual voivodeships in 2015-2019
http://onkologia.org.pl/raporty/#wykres_kolowy [accessed 18.08.2023]

Report: Map of Poland
Filters selected:
Total neoplasms
Standardization: Population of Europe
Year: from 2015 to 2019

Gender: Men
Type: Illnesses

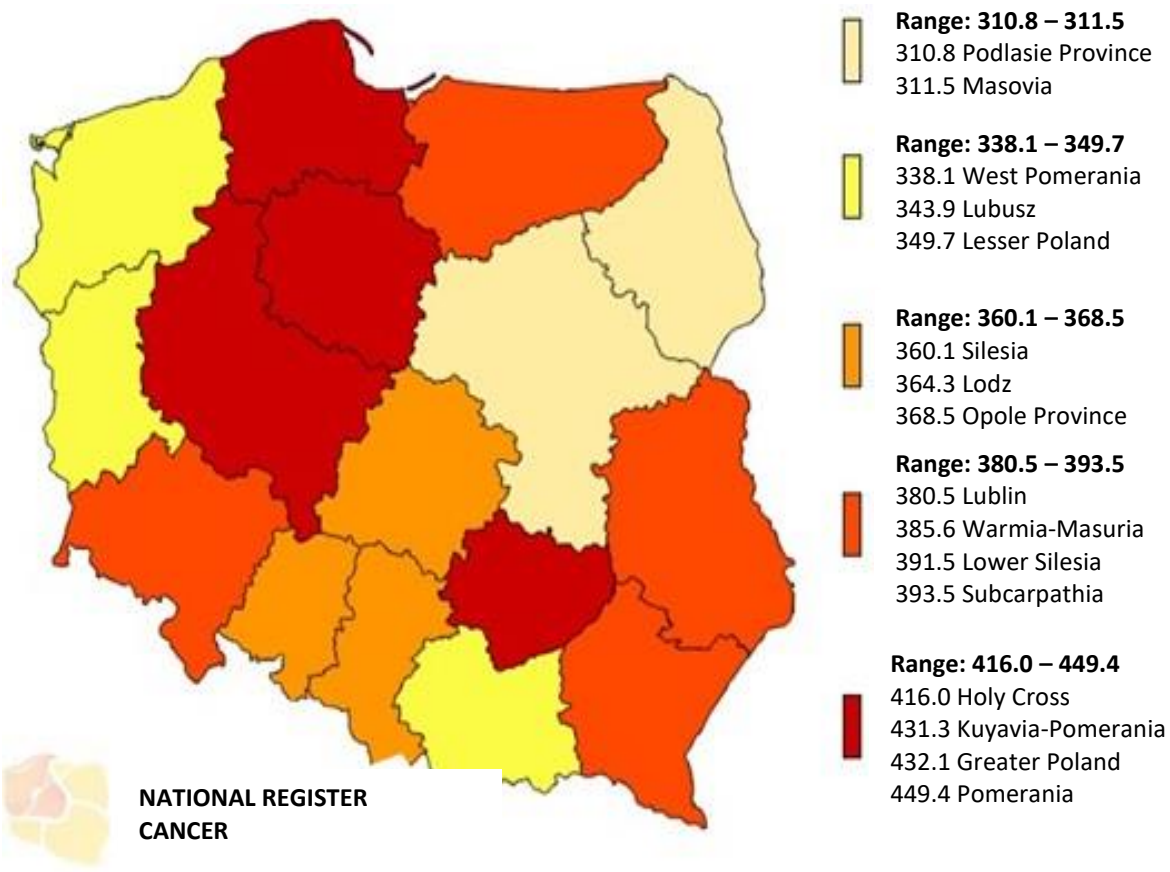

Figure 2 – Map of male cancer incidence in individual provinces in 2015-2019
http://onkologia.org.pl/raporty/#wykres_kolowy [accessed 18.08.2023]

Analyzing the above maps of Poland in terms of cancer incidence, it can be safely stated that the data are alarming and are constantly growing year by year. The time of recovery from cancer depends on the individual health predispositions of each patient as well as the advancement of the cancer. Not all cancers are also malignant, and the stories of oncology patients show that it is possible to overcome the disease through proper treatment and following the doctors' recommendations.

Engineers from around the world, ergonomists, try to design and improve everyday objects so that the disease can be easily overcome. Here you can present the example of electric beds, lifts, sliders for patients who are lying down, weakened by the disease. These are, of course, examples without which some people cannot imagine today's medical care. However, to a large extent, the issue of taking medications, which are to a large extent intended to relieve the patient's pain, still remains – and in this case, in Poland and in the world, we are traditional in this matter. Medical staff, if the patient is hospitalized, must carefully analyze the doctor's recommendations and provide the patient with the appropriate amount of medicine. Statistics show that in many industries, people are responsible for accidents at work. Therefore, in order to meet high expectations, I will present the concepts of drug packaging for an individual patient and thus exclude the human error of administering the wrong drug or in the wrong dose. Physicians working in oncology wards often hear from their patients that they are taking medications – while oncology

patients treated at home skip doses of the drug or do not take them, relatives caring for the sick person also have a problem with assessing the situation whether the patient has taken the right amount. The concept of individualization and packaging of drugs will improve work in hospital and home conditions and will allow doctors to properly assess the systematic treatment of oncological patients and protect medical staff against human errors. Errors in the pharmacotherapy process cause harm to patients, but also expose healthcare professionals to the resulting legal consequences, such as civil liability and even criminal proceedings. This situation reduces the comfort of performing daily professional activities. Specialized law firms make money from medical errors. Fear of disciplinary punishment means that reported errors are only a fraction of their actual number. The reasons for this state of affairs also include:

- not being aware that an error has occurred;
- lack of awareness of the need to report;
- the belief that if the patient has not been harmed by the error, then no it must be reported;
- lack of knowledge of reporting procedures;
- no time for reporting;
- no feedback on the sent report.[ii]

The pharmaceutical industry and 3D modeling and printing programs.

The development of new technologies in the development of programs for modeling and 3D printing is a big breakthrough in various areas of our lives. The development of these technologies has resulted in the creation of huge amounts of 3D printed products and prototypes, which are present in the industry on a large scale. Modeling in 3D programs and printing these models is also very popular in the medical industry, we can model implants, human organs in 3D programs, we can also visualize the development of a disease or the course of a surgical operation. These are, of course, only selected examples of the use of 3D modeling programs. The next step in 3D modeling is 3D printing, which in the medical industry allows you to assess the severity of the disease, plan operations, try on prostheses, etc. 3D modeling and printing is equally popular in the pharmaceutical industry. Manual tablet presses have been replaced over time by automatic ones and in recent years by 3D printers. 3D printing is based on a model created in a CAD program (Computer Aided Design) or a spatially scanned object. In order to print a model designed in a CAD program or scanned on a 3D printer, it must be saved to an STL file. The model is then 3D printed and post-processed In order to print a model designed in a CAD program or scanned on a 3D printer, it must be saved to an STL file. The model is then 3D printed and post-processed In order to print a model designed in a CAD program or scanned on a 3D printer, it must be saved to an STL file. The model is then 3D printed and post-processed[iii]. Thanks to such methods, the US Food and Drug Administration (FDA) 3D printed the world's first tablet. A tablet called Spritam by Aprecia Pharmaceuticals was printed with epileptics in mind[iv]. In addition, the tablet dissolves faster and will be easier to swallow. Bioprinting will play a major role in drug production. Research on bioprinting of human organs cooperating with the human body is ongoing. Natural polymers are introduced to the market, i.e. alginate, gelatin, gelatin, chitosan, fiber or hyaluronic acid, which can contribute to the development of the pharmaceutical industry and anti-cancer drugs[v]. Heart tissue, ear structure, kidney and bone were printed using bioprinting. Scientific work on the printed bioprint is also intended to support research on testing drugs for various diseases, including cancer.

2. Materials and Methods

Materials on cancer were obtained from the online statistics of the National Cancer Registry and available literature on bioprints and 3D printers. The very concept of packaging drugs for an individual patient developed in AutoCAD is an original development.

3. Results

The concept of drug packaging for an individual patient.

Bearing in mind the above considerations on modeling in CAD programs and 3D bioprinting, the concept of drug packaging for an individual patient was developed. According to the National Cancer Registry, anticancer drugs can be divided into:

- classic drugs that are toxic to cells (cytotoxic – chemotherapy),
- medicines that work by inhibiting or enhancing the action of certain hormones (hormone therapy),
- molecularly targeted drugs (targeted),
- medicines that stimulate the immune system (immunotherapy)[vi].

Drugs are most commonly administered orally or intravenously. The concept of packaging anticancer drugs was based on oral tablets. Conceptual models of drug packaging for an individual patient were designed in AutoCAD. AutoCAD is a program distributed by Autodesk, used for 2D and 3D computer-aided design (AutoCAD 2D and 3D).

Assumptions for the drug packaging concept:

1. Drugs were packaged for an individual patient in accordance with the division of drugs in the NCR due to the mechanism of action (chemotherapy, hormonal therapy, targeted, immunotherapy). Each package will include one type of medication | depending on the stage and type of cancer.
2. Drug models based on oral tablets.
3. Packages based on the individual needs of the doctor and oncological patient.
4. Models of anti-cancer drugs and packages designed in AutoCAD.
5. Concepts for different tablets of one dose, combining different tablets of two doses, combining different doses of tablets of the same type, combining different doses of tablets of different types. The Concepts of A B C D are presented accordingly.

CONCEPT A ONE DOSAGE OF DIFFERENT TABLETS

Models of tablets with dimensions were designed:

- diameter 10 [mm],
- thickness 2 [mm]

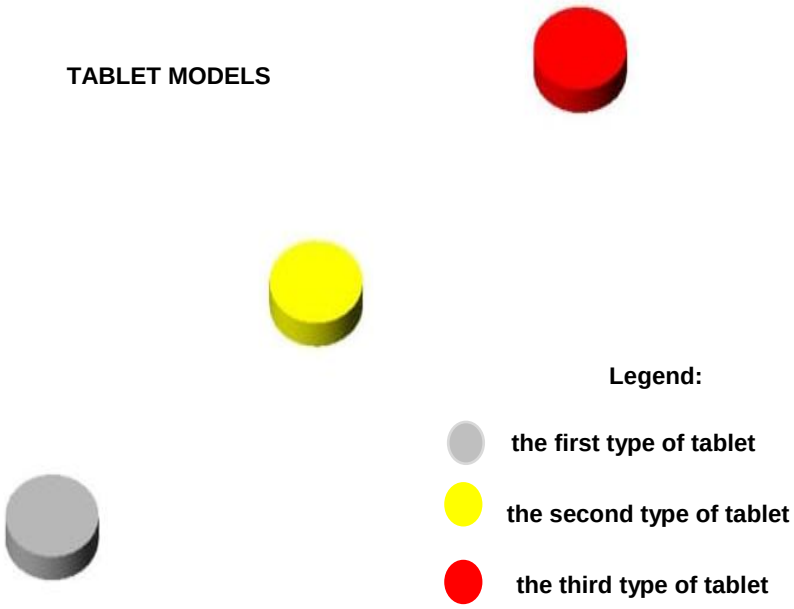

Figure 1 – Oral tablet models designed in AutoCAD – Concept A

CONCEPT A COMBINING DIFFERENT TABLETS AFTER ONE DOSE | IN THE PACKAGE

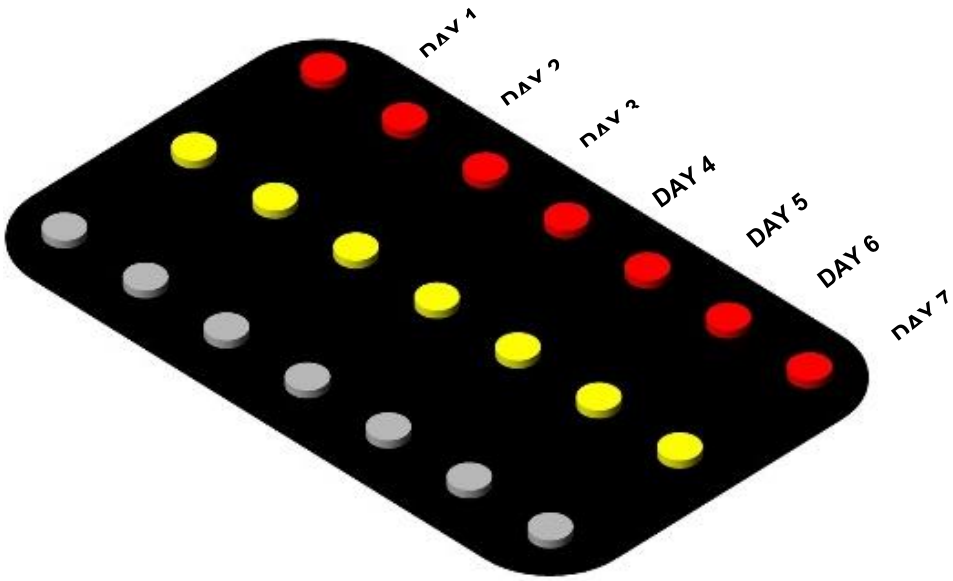

Figure 2 – Oral tablet models in a bundle designed in AutoCAD for Concept A.

CONCEPT B_COMBINING TABLETS OF DIFFERENT TYPES IN DOUBLE DOSE

Models of tablets with dimensions were designed:
- diameter 10 [mm],
- thickness 2 [mm]

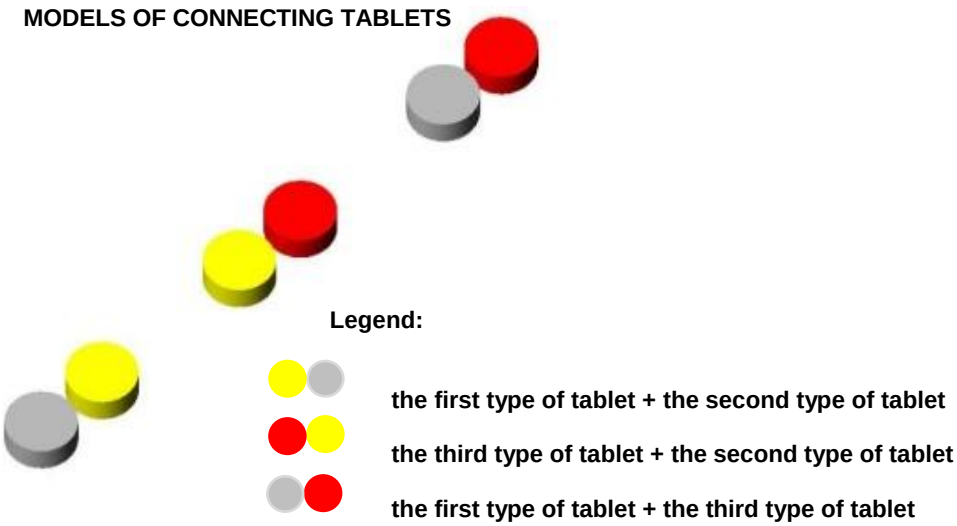

Figure 3 – Oral tablet blending models designed in AutoCAD for Concept B

CONCEPT B COMBINING TABLETS OF DIFFERENT TYPES IN DOUBLE DOSE IN A PACKAGE

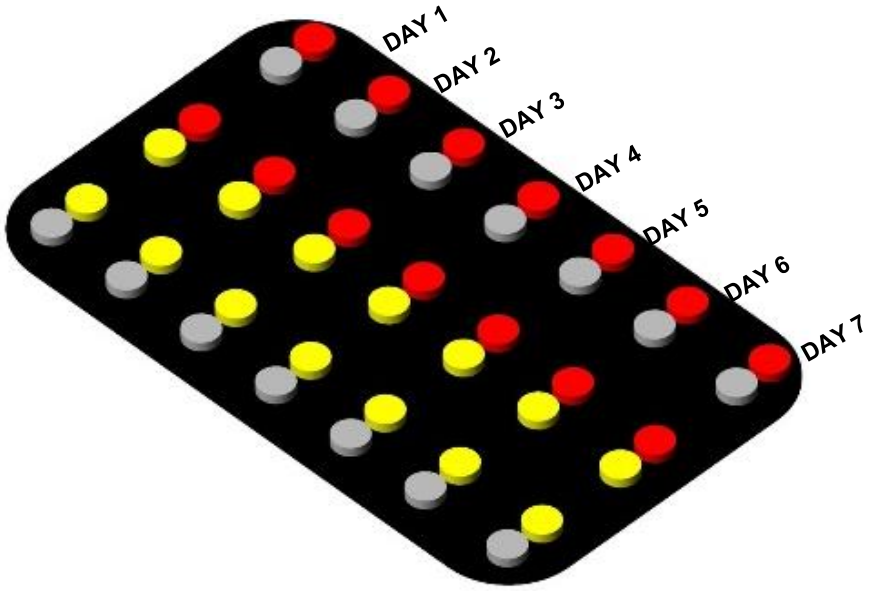

Figure 4 – Oral pill combination models bundled designed in AutoCAD for Concept B

CONCEPT C COMBINING THE SAME TYPE OF TABLETS IN DIFFERENT DOSAGES

Models of tablets with dimensions were designed:
- diameter 10 [mm],
- thickness 2 [mm]

and tablets with dimensions:
- diameter 5 [mm],
- thickness 2 [mm]

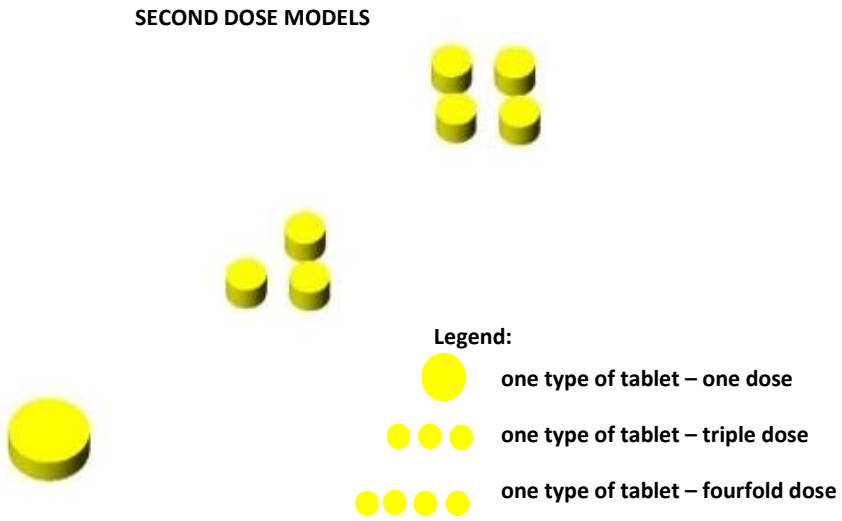

Figure 5 – Oral drug dose combination models designed in AutoCAD for Concept C

CONCEPT C TO COMBINE THE SAME TYPE OF TABLETS IN DIFFERENT DOSAGES IN A PACKAGE

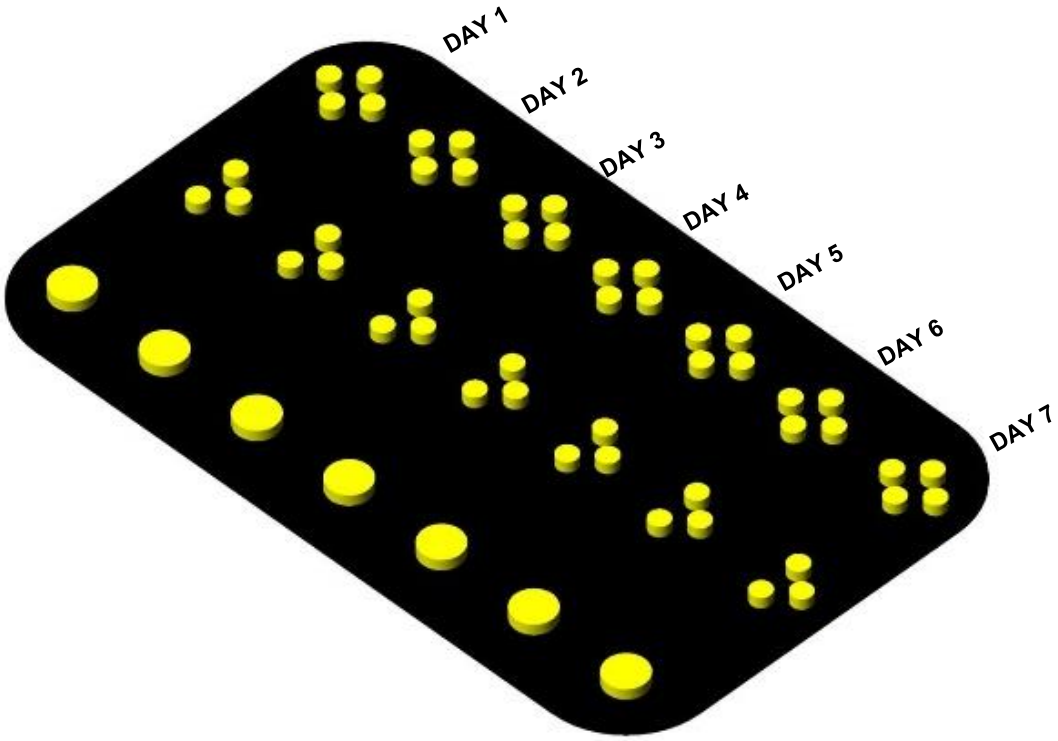

Figure 6 – Oral Drug Packet Combination Models Designed in AutoCAD for Concept C

D CONCEPT OF COMBINING A CLICK OF TYPES OF TABLETS IN DIFFERENT DOSAGES

Models of tablets with dimensions were designed:
- diameter 10 [mm],
- thickness 2 [mm]

and tablets with dimensions:

- diameter 5 [mm],
- thickness 2 [mm]

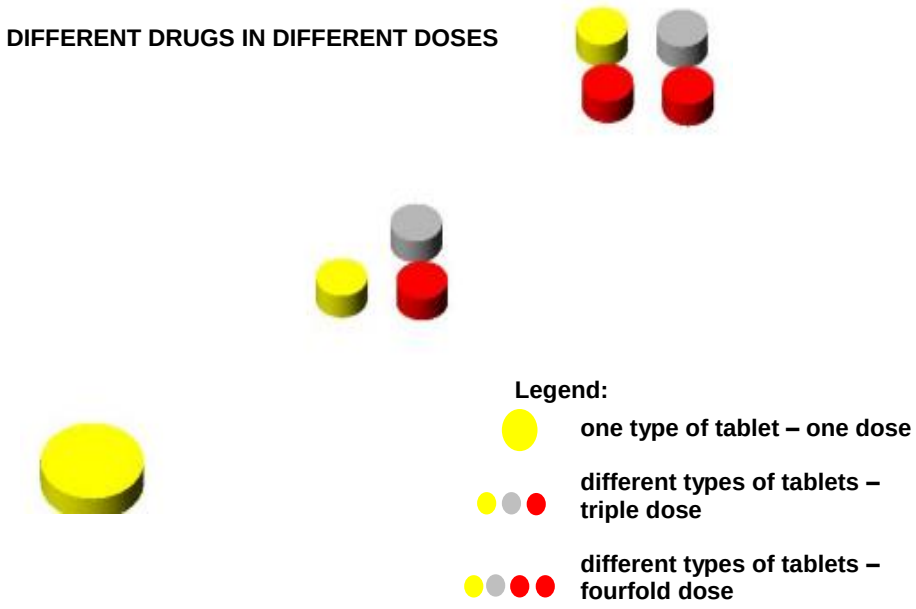

Figure 7 – Oral drug and different tablet dose combination models designed in AutoCAD for Concept D

D CONCEPT OF COMBINING A CLICK OF TYPES OF TABLETS IN DIFFERENT DOSAGES IN A PACKAGE

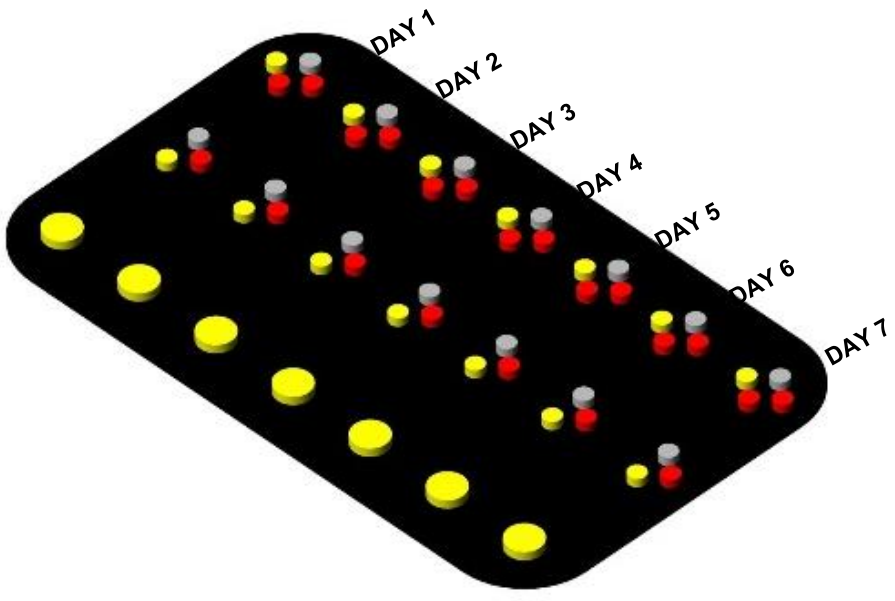

Figure 8 – Models for dose combinings of an oral drug and different tablets in a package designed in AutoCAD for Concept D

Advantages and disadvantages of drug packaging for an individual patient.

The concept of drug packaging for an individual patient has advantages and disadvantages, which are presented in the table below:

Advantages of the concept of packaged anticancer drugs for the individual patient	Disadvantages/doubtful points of the concept of packaged anti-cancer drugs for the individual patient
– systematic use of anticancer drugs, – it is not possible to divide one tablet into two portions, e.g. the doctor prescribes a dose of the drug twice as strong, which is a cheaper option for the patient and the patient should take half of it in treatment, this is a deliberate exclusion from the concept so that there are no human errors, – ease of controlling the use of anticancer drugs, – exclusion of errors in medication dosing, – when hospitalizing patients, it is easy to organize, reducing the time for distribution of medicines – the patient has only a package assigned to him in the card, – increasing access to anticancer drugs, – reducing the patient's time to look for anticancer drugs when a given type of drug is not available in a particular pharmacy, – economic advantages – the patient does not buy several types of drugs, – logistic advantages – the space for storing various types of drugs will decrease, – the package may include only days/months of treatment, so no unused drugs are wasted, – reliable assessment of treatment during the systematic use of appropriate drugs in the correct doses.	– it may be necessary for individual reasons the possibility of replacing anticancer drugs due to the individual predisposition of the patient, – the reasons for printing drugs on a 3D printer may be questioned, – the need to approve whole packages by the US Food and Drug Administration (FDA) and thus change the procedure of admitting whole packages to the market, – the need to standardize cancer treatment in Europe and in the world due to the approval of drugs in a specific country.

The presented disadvantages and doubts regarding the concept of drug packaging for an individual patient are also issues to master and skip procedures. Drug packaging may be a breakthrough in the field of pharmacy and constitute the basis for the development of standardization of drugs and procedures for the approval of anticancer drugs in Europe and in the world.

4. Discussion

Forecasts of new applications

It is predicted that the application of the concept of anti-cancer drug packages may change the existing procedures for admitting anti-cancer drugs to the market, but not only this concept may refer to other types of drugs for various diseases, the concept may also be used in widely available supplementation.

Comparison with other possibilities on the market

The concept of packaging anti-cancer drugs currently seems to be unrivaled because entire drug production lines or automatic tablet presses would have to be modified. Currently, only the use of 3D printing makes it possible to create a concept in the production of packaging of pharmaceutical drugs. It is worth mentioning here the Model of Systems Engineering for Patient

Safety, in which it is possible to redesign the work system that affects patient safety as well as the safety of healthcare workers. Thanks to the Model of Systems Engineering for Patient Safety, it is possible to design the work process (tools and technologies, organizations, people, tasks, internal environment).

5. Conclusions

The concept of drug packaging for an individual patient has advantages and disadvantages that are presented in the article. Thanks to 3D bioprinting and the packaging of anticancer drugs, it will be possible to conduct further research on the treatment of cancer patients around the world with drug packages, to develop new technologies for the production of anticancer drugs, and to increase access to drugs. The concept may force the standardization of treatment of oncological patients, as well as changes in the procedures for drug approval. The presented concept is the basis for further research. Progress in the field of bioprinting requires work and commitment from both the engineering and medical side. The literature often uses terms for medical error and adverse reaction. Not only patients can be victims of medical errors, but also their families or other medical personnel. Mental problems resulting from these medical errors in medical staff will affect work efficiency, the level of patient care and thus their own safety at work. The presented concept of drug packaging will allow to avoid medical errors and side effects, which will increase the level of safety of medical staff.

6. Financing

This study received no specific financial support.

7. Competing interests

The authors declare that they have no competing interests.

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