Mobile PET Center Project

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Abstract. Positron emission tomography is the most promising technology to monitor cancer and heart disease treatment. Stationary PET center requires substantial financial resources and time for construction and equipping. The developed mobile solution will allow introducing PET technology quickly without major investments.

1. Introduction

Cancers incidence rate in the last decades has continued to grow slowly (1.2 % per annum). Cancers still come second after cardiovascular diseases in the list of causes of death. In the Russian Federation, 2.5 million people are registered as cancer patients in medical institutions. About 450 thousand new cancer cases are registered annually, and the annual mortality rate from cancer is 300 thousand people.

Skin, mammary gland, cervical, gastric, pulmonary and intestinal malignant tumors are the most frequent causes of mortality. Due to modernization programs and the oncology program of the Ministry of Healthcare, mortality rate has been slowed down by 3%, treatment efficiency has been increased and diagnostic procedures improved. However, the mortality rate here is still very high, as not in all regions patients have sufficient access to modern equipment and highly qualified professional medical staff to diagnose and treat oncology diseases, which could help to identify when the disease started and its stage early, evaluate the effect of radiation treatment, radionuclide therapy and chemotherapy.

Compared to advanced European countries and USA, Russia has the lowest five-year survival rate, less than 45%. This level is due to late diagnostics, lack of necessary treatment with lack of qualified professional staff and using outdated equipment for treatment, which has a margin of treatment efficiency as broad as 35%, when the global standard is about 3%. The most frequent male patient cancers are pulmonary, gastric, skin, prostatic gland, large intestine and rectum cancers. The most frequent female cancers are malignant tumors of mammary gland, uterine body and cervix, skin, stomach and large intestine [1].

Due to the level of urgency of this problem, particular attention is paid to such factors as early diagnostics, diagnosis verification and treatment monitoring. One of the methods to act on these incentives is positron emission tomography (PET/CT).

2. Positron emission tomography

Positron emission tomography is a group of radiological diagnostic methods that involves using ultra-short-lived radionuclides to visualize structural and functional condition of organs and systems of the body at cellular level.

Introduction of PET methods in clinical practice has determined the role and importance of non-invasive pathology diagnostics at early stage in treatment of disease entities in oncology, cardiology, neurology and other fields.

Presently there are about 60 PET centers in the Russian Federation. All the centers are at different stages of operation, some of them are only being launched and some are in construction. 34 centers actually work.

Current population of Russia is 146 million people. According to the WHO, 1 PET/CT scanner's operation capacity is 1 million people, so the demand is about 112 PET scanners/centers.

A PET center consists of three units: a cyclotron for generating the USL radionuclides, a radiochemical laboratory for receiving and dispensing a particular radiopharmaceutical, and a PET/CT or a PET/MRI scanner [2]. PET centers may be structurally organized in different ways depending on the location, local population and incidence rate:

1. Research PET centers. These are created as parts of a federal medical science center and may be used to conduct medical studies, as well as to develop new radiopharmaceuticals and pursue following experimental and preclinical research to register new pharmaceuticals, and also for radiopharmaceuticals sales.

2. Clinical PET centers. Creation of such center may be recommended in the regional clinical hospital or a large oncology treatment center, in oncologic dispensaries, territorial and district hospitals. Such PET center consists of a 16-19 MeV cyclotron. It can produce a standard selection of radiopharmaceuticals for PET examinations (fludeoxyglucose, carbon, ammonium, oxygen); equipment: 2 PET/CT scanners.

3. Clinical mini PET centers. These are installed in oncologic dispensaries, in communities of about 500-900 thousand people, or in a remote area with high incidence rate. The center includes a 7.5-10 MeV cyclotron, mini-laboratory and 1 PET/CT scanner.

4. Individual PET scanners installed in hospitals require radiopharmaceuticals supplies. Today the only radiopharmaceutical that can be supplied is [18F]fludeoxyglucose (half-life 120 min).

5. The newest solution for remote areas with high incidence rates is a mobile PET center, which may consist of a complete unit: a cyclotron up to 8 MeV, a mini-laboratory and a PET/CT scanner, or just of a PET/CT scanner.

3. Project: Mobile PET center

This solution is developed by Unix Medical Company together with NGO Mobile Clinic, under supervision of Federal State Budget Institution Russian Cardiology Research and Production Complex of the Ministry of Health of the Russian Federation, Federal State Budget Institution N. N. Petrov Research Institute of Oncology of the Ministry of Health of the Russian Federation and the Association of Medical Physicists in Russia (AMPR).

The project includes 4 mobile modules. Figure 1 shows equipment location diagram in mobile modules. Module 1 – is a reception section, the "cold" waiting area and a doctors room (to prepare reports). Module 2 – is a PET/CT scanner. Module 3 – for radiopharmaceuticals dispensing, "hot" patient waiting area. Module 4 – is a cyclotron with a radiochemical laboratory.

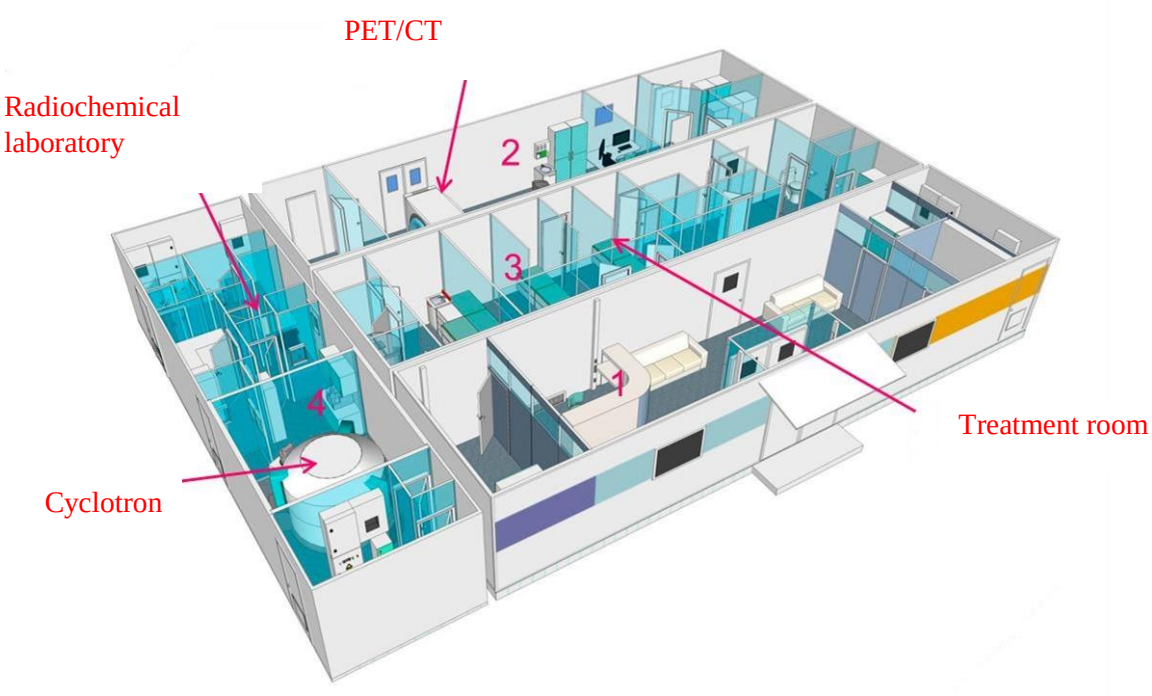

Figure 1. Mobile PET station diagram.

Module 4 radiopharmaceuticals generation technology includes following steps:

- target preparation (raw material for the target for ^{18}F radionuclide production is water of appropriate stable radionuclide composition);
- target matter radiation;
- transportation of radiated target matter to the synthesis module of the safe extraction hood of the synthesis and quality control laboratory;
- radiopharmaceutical synthesis from the generated radionuclide;
- radiopharmaceutical quality control (measuring the pharmaceutical potency, specific potency, chemical and radiochemical purity);
- filling a syringe with a diagnostic volume (dose) of radiopharmaceuticals, dose for each patient is specified individually;
- transferring radiopharmaceuticals to module 2 for radionuclide diagnostics.

Radiopharmaceutical production is performed in clean rooms (areas) with air-locks to provide access for personnel and/or equipment and materials transportation. In the clean rooms (areas), the cleanliness level compliant with the relevant standard is maintained, and the air is supplied through filters of required efficiency.

Each production operation requires measuring the purity of environment in operation condition. In order to ensure compliance with the requirements for clean rooms it is necessary that:

- the concept of air passing from cleaner to "dirtier" rooms is observed in the clean rooms area.
- raw materials enter the area and finished radiopharmaceuticals leave the area through sluice pass-through windows.
- personnel working in clean rooms must arrive at workplace through air-locks.

All the clean rooms of the station are class D purity rooms, since in this module the radiopharmaceuticals are produced in a closed system, radiopharmaceutical dispensing is performed in the closed module and a sterile syringe filling and sterilizing filtration of the finished product are performed on the line.

Radioactive exposure and contamination protection is ensured with barrier technology and air-locks operating by pressure spool principle.

Radiopharmaceutical synthesis, dispensing and quality control take place in one safety box. Linear and cross contamination do not take place, because it is a closed loop automated system.

Main factors stipulating harmful exposure when using sources of ionizing radiation are:

- photon and neutron radiation of cyclotron;
- gamma radiation from radiated targets, solutions, radiopharmaceuticals, waste;
- air contamination with radionuclides during work with bare radioactive sources;
- superficial contamination of equipment and rooms with beta radionuclides;
- radioactive waste;
- radionuclide emissions with vented air into atmosphere.

Radiological safety as a whole is based on the following technical and organizational measures:

- room zoning by level of radiological hazard, personnel access limitation;
- arrangements for radiological and ionizing radiation protection of personnel;
- arrangements for special ventilation in rooms with sources of ionizing radiation;
- arranging an interlock and alarm system that will not allow personnel to enter the cyclotron room when it's working;
- arranging a radiation control system, including an automated radiation control system.

4. Conclusion

Radiopharmaceutical production with an installation at a clinical institution allows solving many problems and offers numerous benefits:

1. There will be possibility to do positron emission tomography more frequently, so-called "dose on demand". As a result, planning will be optimized, and more patients will be served.
2. Financial expenses and time spent on PET/CT technology introduction at the regional level will be reduced as no special bunkers and rooms for radiochemical laboratory are needed, and as a result the number or PET/CT scanning procedures can be increased with no expense increase.
3. This mobile PET center solution produces fluorine-based radiopharmaceuticals, such as fludeoxyglucose, NAF, FMISO, carbon-based pharmaceuticals production is under development.

References

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