„Radiotherapy of pregnant patient – Procedures and their improvements to strenghten radiation safety culture in Maria Skłodowska-Curie Institute – Oncology Centre, Warsaw, Poland”

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A. Kuchcińska, E. Lampka, W. Bulski, M. Rubach, J. Lampka, D. Kiprian

14th International Conference&Workshop "Medical Physics in the Baltic States 2019"

IAEA competition „toward strong radiation safety culture”

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- Most of this presentation has been prepared as a digital project, submitted as part of the IAEA competition, aimed at strengthening radiation safety culture during the treatment of pregnant patients
- It was positively evaluated and got through the selection of the first stage
- During third stage only 3 over 106 has been choosen by IAEA as winner. We congratulate winners coming from Greece, Unites States and New Zealand.

Strong Radiation Safety Culture & IAEA/WHO BONN call for actions

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- To ensure safety of the medical procedure it is wise to support every safety trait and actions, as:

the chain is only as strong as its weakest link.

Strong Radiation Safety Culture & IAEA/WHO BONN call for actions

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- in our opinion the most important action in the scope of this project is:

  *establish **patient safety as strategic priority** in medical uses of ionizing radiation*

  &

  *Recognize **leadership as a critical element** of strengthening radiation safety culture*

of both:
mother & fetus

- strongly supported by the Director of our institute, by relevant involvement of the **Leader of Radiotherapy Team**

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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- Radiotherapy of pregnant patient is a very sensitive topic.
- Our Institution is one of the biggest in Poland.
- The Warsaw branch of the Institute has a long experience with successful therapy of pregnant patients (266 patients in period 1988-2018)
  - mostly with breast cancers, sarcomas and lymphomas, including the biggest group of 147 patients with Hodgkin Lymphoma (131 children delivered by this group of patients).
  - Patient treatments schemes included chemotherapy, radiotherpy, surgery performed either alone or combined according to type of cancer and clinical indication.
  - contribution to better understanding when radiation treatment of a pregnant patient is safe for fetus.

Source of fetus images: www.icrp.org

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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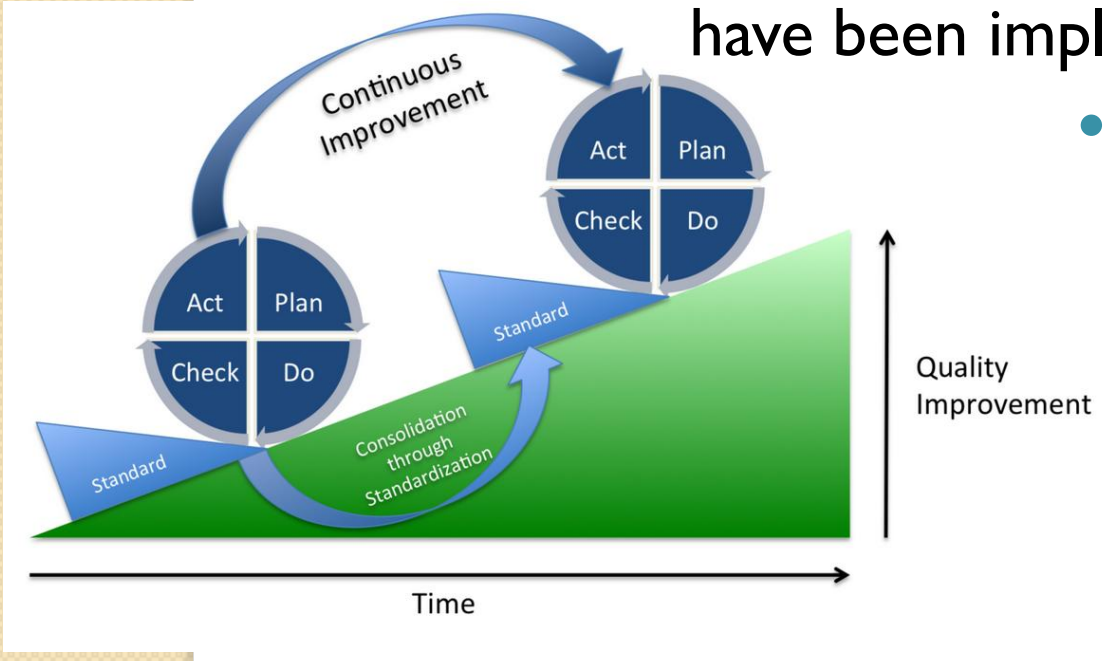
- All necessary radiation safety procedures have been implemented so far.



- Nevertheless, due to constant improvement of radiation safety culture, better procedures are under investigation within new PhD track currently opened.

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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Basic Rules

- Avoiding accidental irradiation
- PLANNED EXPOSURE : Risk assessment, Benefits analysis (**for both: mother & fetus**)

Safety of the prcedure => '3A' rule

- **Awareness** (of all key personnel involved in the treatment process)
- **Appriopriateness** (justification & optimisation)
- **Audit** (full process of treatment & health outcomes, multidisciplinary team)

Safety of the PLANNED Procedure – esspecially Pregnant patient undergoing Radiotherapy

- **Justification** [eg. Choose: relevant treatment scheme (chemotherapy / Radiotherapy / combined); if possible choose relevant stage of gestation when treatment cause less potential risk to fetus]
- **Comunication** (all neceissary information concerning recommended treatment scheme including radiation risk-benefits dialogue (concerning impact of the therapy on both mother & fetus)
- **Optimization** [eg. Choose: relevant Energy; irradiation method IMRT/VMAT, 3D(?), dosimetry method (both pre-procedure & in vivo); treatment mashine to reduce fetus dose...]

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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- Radiation Oncology,
- Clinical Oncology.
- Gynecology,
- Conducting clinical trials,
- Radiobiology,
- Epidemiology,
- Medical Physics,
- Radiation Protection,
- RTT's KSC,
- Risk analysis,
- Auditing,
- Health Technology Assessment,

- Leader to oversee and accept all standard medical procedure.

- Radiotherapy Team's field of Knowledge &Skills &Competences needed to perform procedure in safy way (can be gained by E&T and/or research)

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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- Leader to oversee and accept all standard medical procedure.

- Radiotherapy Team's field of Knowledge &Skills &Competences needed to perform procedure in safy way (can be gained by E&T and/or research)

- Communication skills to inform Pregnant Patient & her family
- Psychology to support Pregnant Patient & her Family.
- Legal requirements
- International/ proffestional societies/bodies reccomendations
- Ethics aspects

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

CENTRUM ONKOLOGII – INSTYTUT
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- In diagnostic radiology the use of ionizing radiation is better established and better known.
- in Radiotherapy – experience & networking is crucial

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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- Please for more details look at the attached file 'INCIP_19-01-2018.pdf': materials that has been published due to INCIP (*International Network on Cancer Infertility and Pregnancy*) meeting in Warsaw.

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- in Radiotherapy – experience & networking is crucial

Radiotherapy of pregnant patient @ MSC Institute – Oncology Centre, Warsaw Poland

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- On the previously mentioned attached file (slide no 4) we also show how we are cooperating with patients organizations, and how the safety of RT of pregnant patients is promoted among the public in Poland.

pol. RAK
ang. Cancer

Rak'n'Roll Cancer Foundation was founded in 2009 by the initiative of Magda Prokopowicz after her own experience of pregnancy during cancer disease.

Our priority is to create programs of complex care that go outside the system and address problems that the medical community in Poland does not addressed. The key goal of the Foundation is to create a new way of communicating about cancer disease in Poland, to break down the stereotypes surrounding this illness and to improve the quality of life of those struggling with cancer.

Everything that we do is designed to inspire others to a positive way of thinking, deliver proper solutions and to change the perception of cancer in people's minds.

One of the initiatives of the Rak'n'Roll Cancer Foundation is the Divine Mothers programme, which allows pregnant women with cancer to receive complex and free care; oncological, gynecological, psychological, dietary, as well as beauty and rehabilitation care. This is the missionary program of the Foundation, initiated by Magda Prokopowicz in 2011 and implemented by the Foundation in 2015 as a fulfillment of the founder's will. Magda was the first to speak out loud that one can, not only live with cancer but even give live. Till today we were able to take care of 108 Divine Mothers and we welcomed 102 children into the World – we are waiting for the others to arrive. As our initiative, together with 25 expert oncologists and gynecologists, we created „Standards of diagnostic and therapeutic procedures in pregnant women with oncological diseases".

ABOUT RAK'n'ROLL

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BOSKIE MATKI

Personal Accountability:

IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
All individuals take personal responsibility for safety. Responsibility and authority for safety are well defined and clearly understood. Reporting relationships, positional authority, and team responsibilities emphasize the overriding importance of safety.	***patient safety as strategic priority*** *(both mother and fetus)* • All medical staff contributing in the process of radiotherapy of pregnant patient are notified about pregnancy of patients, and they know their responsibility which is relevant at each step of the procedure (eg. RTTs performing CT for treatment planning purposes, used lead apron on the fetus due to national law regulation; medical physicist responsible for assessment of fetus dose; medical doctor who is helping to determine precise distance between targets and fetus etc.)

Questioning Attitude:

IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Individuals avoid complacency and continuously challenge existing conditions and activities to identify discrepancies that might result in error or inappropriate action. All employees are watchful for assumptions, anomalies, values, conditions, or activities that can have an undesirable effect on facility safety.	***patient safety as strategic priority*** *(both mother and fetus)* • over the years we noticed huge change in the health technology which constantly contributed to better patients safety by possibility of tumor and OAR delineation, using adaptive therapy during treatment, IGRT, respiratory gating or finally very precise SBRT. All modern techniques are used in clinical practice in MSC-Institute Oncology Centre, and they are tailored to specific types of tumors but as well to possible cooperation with the patient (eg. Respiratory gating used in treatment left breast cancer possible if patient is able to learn proper inhalation). • All medical staff is involved in constant development and implementation of new technology if this might pave the way to either better tumor control or to lowering treatment toxicity.

Effective Safety Communication:

IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Communications maintain a focus on safety. Safety communication is broad and includes facility level communication, job-related communication, worker-level communication, equipment labelling, operating experience, and documentation. Leaders use formal and informal communication to convey the importance of safety. The flow of information up the organization is seen as being just as important as the flow of information down the organization.	***patient safety as strategic priority*** *(both mother and fetus)* • The leader of Radiotherapy Team appreciates every information coming via any available channels eg. personal meeting, e-mails to evaluate any of the reported issues and is open for further analysing. • There are established regular high-level multidisciplinary meetings with leaders of each department and working groups. • Consequently each working group has established meetings with employees eg. Dosimetry in Radiotherapy group, Treatment Planning Group which are part of the Medical Physics department.

Leadership Safety Values & Actions:

IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Leaders demonstrate a commitment to safety in their decisions and behaviors. Executive and senior managers are the leading advocates of nuclear safety and demonstrate their commitment both in word and action. The nuclear safety message is communicated frequently and consistently, occasionally as a stand- alone theme. Leaders throughout the nuclear organization set an example for safety. Corporate policies emphasize the overriding importance of nuclear safety.	***patient safety as strategic priority*** *(both mother and fetus)* • The leader of Radiotherapy Team is involved in actions that might improve patient safety and supports teams working on each task eg. more precise patient positioning by applying IGRT, optimising procedures – treatments plan that might reduce toxicity of procedure while maintaining tumor control, the teams conducting clinical trials, evaluating health outcomes, etc. • Employees are aware that the managers of each team (RTTs, MDs, MPEs) are advocates of nuclear safety (eg. Overseeing commitments with national regulation as using lead aprons on pregnant patient undergoing CT examination, including one for RT treatment plan purpose)

Decision Making:

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IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Decisions that support or affect nuclear safety are systematic, rigorous, and thorough. Operators are vested with the authority and understand the expectation, when faced with unexpected or uncertain conditions, to place the facility in a safe condition. Senior leaders support and reinforce conservative decisions.	***patient safety as strategic priority*** *(both mother and fetus)* • conservative decision with respect of radiation protection safety are supported. This concern as well safety of medical staff eg. in case of insure status or broken ventilation system in the radiotherapy bunker, treatment of the patients is stopped and other facility is used unless relevant working conditions are confirmed. • all dynamic treatment plans (IMRT/VMAT) are verified before patient start irradiation to minimize situation when practical realization of treatment plan or specific LINAC do impossible or do not meet requirements.

Respectful Work Environment:

IAEA Description	one of the examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Trust and respect permeate the organization. A high level of trust is established in the organization, fostered, in part, through timely and accurate communication. Differing professional opinions are encouraged, discussed, and resolved in a timely manner. Employees are informed of steps taken in response to their concerns.	***patient safety as strategic priority*** *(both mother and fetus)* Leader of Radiotherapy Team analyse issues raised by employees, and if necessary there are relevant working groups established to deal with the issue, their findings are evaluated and implemented in clinical practice. Topics might be as follow: • Improvement of in vivo out-field dosimetry which is crucial for monitoring and confirming fetus dose during radiotherapy, • choosing best treatment plan strategy to optimize toxicity of the procedure for the mother (reducing dose for mother's OAR) while maintaining at the same time the doses to the fetus as low as possible (minimizing interactions of photons with collimators and beam modifiers rising scattered dose to fetus being out-main-field).

Continuous Learning:

IAEA Description	one of examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Opportunities to learn about ways to ensure safety are sought out and implemented. Operating experience is highly valued, and the capacity to learn from experience is well developed. Training, self-assessments, and benchmarking are used to stimulate learning and improve performance. Safety is kept under constant scrutiny through a variety of monitoring techniques, some of which provide an independent "fresh look."	***patient safety as strategic priority*** *(both mother and fetus)* • All staff involved in the process of Radiotherapy Treatment of pregnant patients are supported in their initiatives to seek constant networking and benchmarking. • Our medical doctor, who has biggest experience with pregnant patients, belongs to the INCIP (International Network on Cancer, Infertility and Pregnancy), which allows her to gain relevant experience concerning treatment of Pregnant Patients. She was able to compare her approach and results with other groups around Europe, and therefore perform treatments based on best available knowledge. • Medical staff in regular way take part in many congresses & conferences & workshops to update their knowledge, skills and competences

Problem Identification & Resolution:

IAEA Description	one of examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance. Identification and resolution of a broad spectrum of problems, including organizational issues, are used to strengthen safety and improve performance.	***patient safety as strategic priority*** *(both mother and fetus)* Imporving performance of cancer treatments, delivered to pregnant patients not only in our clinic, might be done due to sharing experience gained by a team who has been working for more than 30 years: • Schemes of conduct with attention to the use of irradiation therapy in particular types of lymphomas, especially Hodgkin's lymphoma, are presented. In cases of irradiation during pregnancy, a specialized team used all methods developed in 1986-2002, international recommendations and own treatment standards modified in subsequent years to maximize fetal protection. •The only Polish original material for the treatment of lymphomas in pregnancy based on the experience and material of one center. The authors' experience is unique, even on a European scale due to the number of patients, because the current reports are based on a maximum of 50 patients treated

Environment for Raising Concerns:

IAEA Description	one of examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
A safety-conscious work environment (SCWE) is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination. The facility creates, maintains, and evaluates policies and processes that allow personnel to freely raise concerns.	***patient safety as strategic priority*** *(both mother and fetus)* • effectiveness (healthcare outcome) of treatment in the analyzed group of patients confirmed the correct approach of treatment team and cooperating team while maintaining the rules developed by expert teams & recommendations of scientific societies. • There were no significant complications related to treatment in both patients and offspring and the causes of single fatal complications in the given diagnosis were discussed. • The safety of the procedure was confirmed by the examination of the bearings (placenta) for the presence of toxic substances and cancer cells • there are no cases of retaliation, intimidation, harassment, or discrimination of any medical staff who treated pregnant patients, neither of those who rise their concern due to pregnant patient treatment.

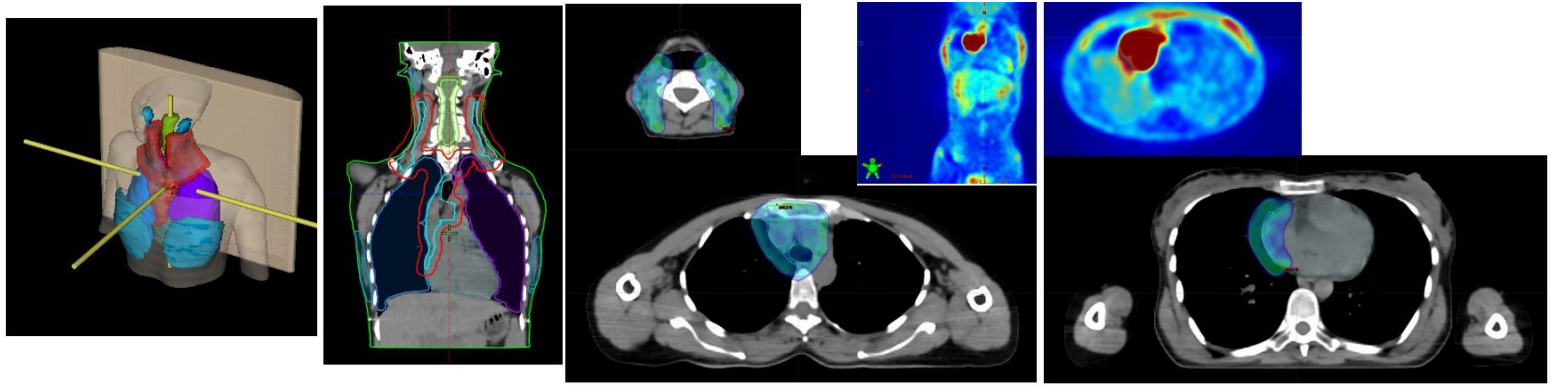
Work Processes:

IAEA Description	one of examples for demonstrating identified safety trait @MSC-Institute Oncology Centre, Warsaw, Poland
The process of planning and controlling work activities is implemented so that safety is maintained. Work management is a deliberate process in which work is identified, selected, planned, scheduled, executed, closed, and critiqued. The entire organization is involved in and fully supports the process.	***patient safety as strategic priority*** *(both mother and fetus)* The treatment of pregnant patient has been implemented • Depending on the trimester of pregnancy, • histopathological diagnosis, • stage of the disease, • taking into account religious, social, cultural and ethical beliefs, • the fetus's position, • the patient / father of the child / family wish and will, • treatment benefits, maximum protection of the fetus, danger for the mother and child, and the reproductive capacity of the patient (fertility).

One of Most Important Result:

- Over time treatment approach has developed due to technological and clinical changes.
- One of the biggest change is that now a days the ISRT (Involved site radiation therapy) has replaced MANTEL fields approach, which has significantly contribute to lower radiation treatment long term toxicity.

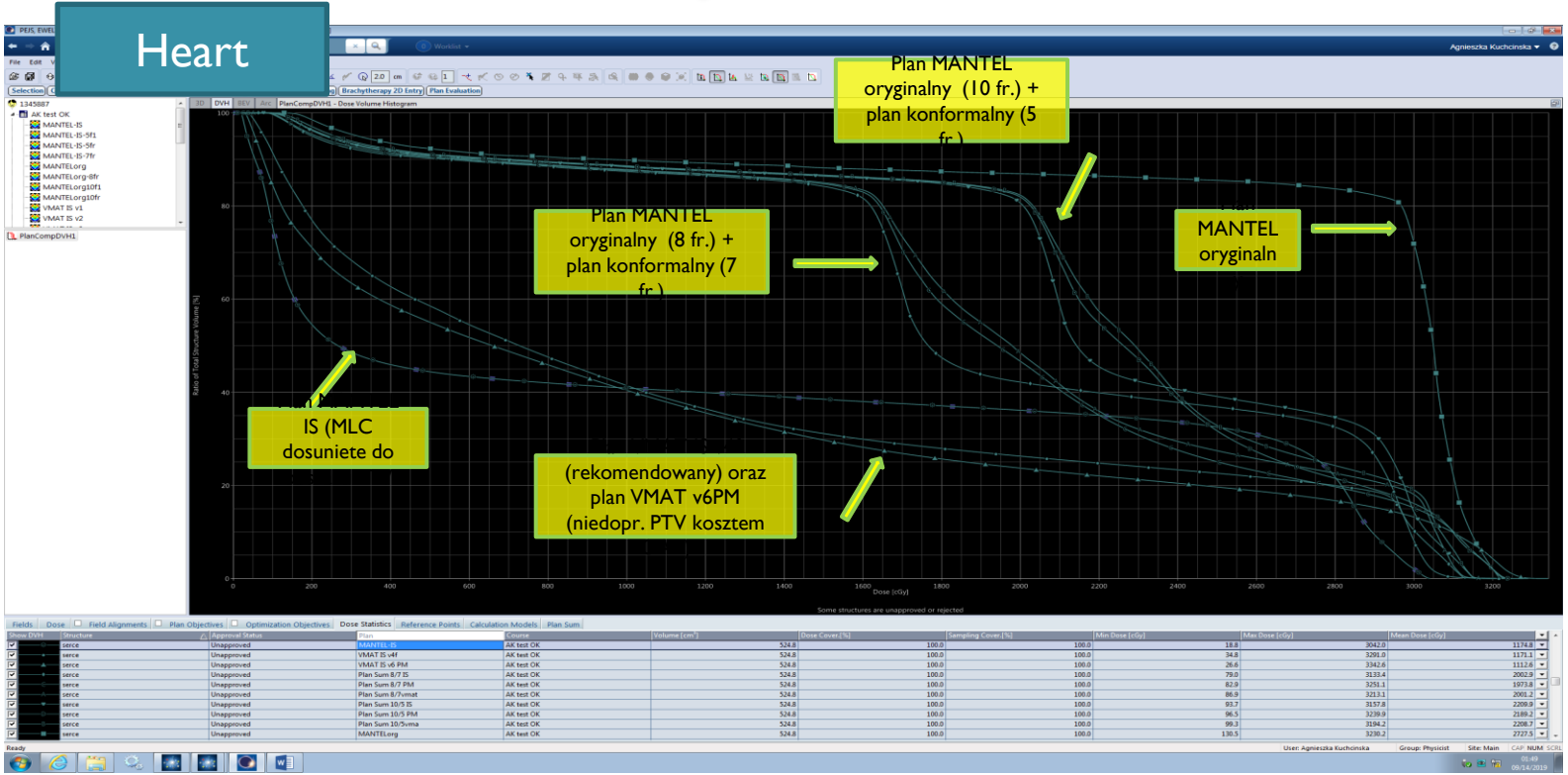
One of Most Important Result:



One of Most Important Result:

OAR	MANTEL fields	ISRT VMAT
Heart	V25 = 85,5 %, V30 =71,9%, Dmean= 27,28 Gy	V25 = 22,6 %, V30 =8,1%, Dmean= 11,71 Gy
Lungs	V20 = 51,9 %, V30 =36,6%, Dmean= 18,34 Gy	V20 = 10,1 %, V30 =1,6%, Dmean= 9,60 Gy
Left Lung	V20 = 48,7 %, V30 =33,2%, Dmean= 17,21 Gy	V20 = 3,5 %, V30 =0,2%, Dmean= 6,54 Gy
Right Lung	V20 = 54,4 %, V30 =39,4%, Dmean= 19,24 Gy	V20 = 16,4 %, V30 =2,7%, Dmean= 12,01 Gy
Salivary gland	Dmean(L)= 31,38 Gy, Dmean(R)= 31,14 Gy	Dmean(L)= 5,00 Gy, Dmean(R)= 4,63 Gy
Esophagus	Dmean=30,40 Gy, over 25 cm irradiation	Dmean=20,00 Gy, over 15 cm irradiation
Spinal cord	Dmax=35,11 Gy, V30=80,62%	Dmax=20,3 Gy, (Dmax@+5mm =27,6 Gy)
Left Breast	Dmax=31,29 Gy, Dmean= 6,00 Gy	Dmax=18,27 Gy, Dmean= 3,71 Gy
Right Breast	Dmax=30,25 Gy, Dmean= 5,31 Gy	Dmax=14,88 Gy, Dmean= 2,70 Gy

One of Most Important Result:



One of Most Important Result:

- In some countries MANTEL fields still might be choose to treat patient due to many reason as MANTEL fields treatment is quite easy to be prepared by medical staff (RTT, MD, MPE) or due to local condition like different type of insurance, which do not allow to propose complex treatment.
- This approach contraindicate ethics principle, as ISRT conformal treatment maintain benefits of radiation therapy while significantly reduce toxicity to patient, therefore no matter of the insurance policy ISRT should be performed.
- If the local technical capacity do not allow to propose ISRT instead of MANTEL fields, according to **ethics principle**, medical staff at least should inform patient where it is possible to try to undergo much less toxic treatment.
- Medical staff might show to patient comparison of OAR's doses and radiation fields, in order to explain this issue.

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Conclusion:

- Our approach supports all 10 BONN's calls for actions:
  - 01 (justification),
  - 02 (optimisation of protection and safety),
  - 04 (RP E&T of health professionals),
  - 05 (research),
  - 07 (prevention of incidents & accidents),
  - 08 (strengthen Radiation Safety Culture),
  - 09 (radiation benefit-risk dialogue),
  - 10 (implementation of safety requirements).

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Conclusion:

- Our experience might contribute to BONN's action 06 (global information about medical exposure) by releasing relevant data.
- Our institute closely collaborates with manufacturers, eg. our Institute has been one of the first in Poland equipped a with Varian EDGE Linear Accelerator dedicated for SBRT, which is in line with BONN's action 03 (manufacturers involvement).

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Closing Remarks:

- Radiotherapy of pregnant patient is a very complex process and urges multidisciplinary team approach as well as very close collaboration between medical staff and pregnant patient and her family.
- For each single multidisciplinary task a large amount of detailed E&T materials can be developed and shared, based on relevant research and clinical experience.
- We do believe that this simple presentation can pave the way for a further frutiful collaboration in this area.

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THANK YOU FOR YOUR ATTENTION

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