

# Roundtable C

How are we fostering and improving the radiation benefit/risk dialogue?

# **FOSTERING PHYSICIAN PATIENT DIALOGUE TO UNDERSTAND PERCEPTIONS AND MYTHS CONCERNING RADIATION PROTECTION IN RADIOIODINE TREATMENT (RIT) FOR THYROID CANCER**

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## **Abstract**

**Objectives:** Report perceptions and myths concerning radiation protection in patients receiving RIT, identify people who stimulate myths and share these myths with medical community to achieve future educational strategies. **Material and Methods:** 2000 patients received RIT for thyroid cancer from 2007 to 2017 in the National Institute for Neoplastic Diseases. Each patient was evaluated by head and neck surgeon, nuclear medicine physicians, technologists, medical physicists and nurses. Patients interacted with other patients and non-medical staff before arriving to treatment rooms. Focus groups were performed with patients and interviews with nurses in order to acknowledge perceptions, fears and myths from patients before, during and after RIT. **Results:** Patients referred to have been told to burn their clothes or leave them in hospital; actually 15% leaved them in the room, considering RIT as contaminant. 25% of patients stayed in a hotel for a week after leaving hospital, to avoid radiation to others. Patients left cell phones out of the room for the same reason. Non medical staff and other patients were identified as information sources for these myths. **Conclusions:** Physicians should be aware of myths and enhance dialogue with patients and non-medical staff to avoid them through education.

## **1. INTRODUCTION**

Thyroid cancer is the second cause of cancer in patients from Lima, Peru (1). Patients accept RIT as a possibility for treatment, after having thyroid surgery (total thyroidectomy). In last years, after dialogue with patients and non-medical staff, some myths concerning radiation protection in RIT have been discovered, and persist in spite of efforts done to overcome them.

### **Objectives:**

- To report perceptions and myths of patients concerning radiation protection in patients receiving RIT for thyroid cancer treatment
- To identify groups of people who interact with patients and stimulate myths and attitudes in radiation protection in this area
- To share with the medical community these myths in order to try some future educational strategies to overcome myths

## 2. METHODS

2 000 patients have received radioiodine for thyroid cancer ablation or treatment in the last 10 years (2007-2017), in the Nuclear Medicine Centre of the Peruvian Nuclear Energy Institute and the National Institute for Neoplastic Diseases.

Each patient has been evaluated by a team consisting in two nuclear medicine physicians, one endocrinologist, head and neck surgeons and technologists. Additionally, each patient has been instructed by nurses from the hospitalisation board, technical nursing staff and two medical physicists. While waiting for treatment, they are confined in the first floor, and interact with other patients and non-medical staff. When they arrive to the treatment room they also have contact with security officers and cleaning personnel, as well as with nutritionists.

## 3. RESULTS

### (a). Contamination in clothes

Patients referred to the Nuclear Medicine Department for RIT have been told to burn their clothes or leave them in hospital; actually 15% leaved them in the room, considering RIT as contaminant. Most patients (80%) bring new clothes to the hospital, for receiving radioiodine.

### (b). Hotel accommodation after isolation for RIT in hospital, to minimize radiation to others

25% of patients stayed in a hotel for a week after leaving the hospital, to avoid radiation to others. This was suggested by other patients or non-medical staff. In some cases it was necessary for them to stay in Lima for whole body iodine 131 post therapy scan and, since they were from provinces, they chose to stay in a hotel, as suggested.

### (c). Cell phones may be contaminated

Patients left cell phones out of the room for considering saliva could be split to the phone and contaminate it. Others avoided carrying with them laptops for the same reason.

Non-medical staff and other patients were identified as information sources for these myths

## 4. DISCUSSIONS

“Myths are perceived realities with no empirical evidence” (2). They persist in time and are orally transmitted from one generation to another, in spite of several efforts to debunk them. “Where ignorance exists myths flourish” (3).

In the present study educational efforts have been performed year after year in pre-treatment interviews with the patient. They seem to understand, but prejudices or myths are profoundly installed in their minds, so as nurses say, they will behave as decided, in spite of your well prepared data for counselling and diminishing anguish or trying to debunk a myth.

Miller (4) stated: “Professional development is largely about deciding which medical narratives (patterns) to adopt, not about personal analysis of recent research. Evidence based medicine indicates what to do as radiation protection while administrating radioiodine, but there is a subjective perception of radioactivity (5-6) to be considered, and a lot of time and patience must be put in work with patients, in a personal communication, to assure ideas are being incorporated in their minds, fears are understood and nothing they say should be neglected to convey a high quality treatment. Patients can overestimate or underestimate risks, which can be confirmed with management of new clothes and cell phones.

Physicians are eager to explain radiation protection issues following RIT, sometimes so eager that, without wanting to, they can stimulate patients to be far from their family.

Many stories are told to patients, that in hotels they do not know who is coming, so they cannot be sure not to “contaminate” anyone, even children, but the idea is so inside the patient that preferences are to be completely isolated for one week more, even at a high cost for a poor patient. This practice is normal in patients coming from abroad the capital city. Their family in Lima usually live in small rooms and have children around, so in this particular case it cannot be considered a myth but a somehow logical decision.

It is time to think in solutions to debunk myths. There is some literature in shared decision making (6) and in follow-up of cancer survivors (7-9). All of them agree in educational efforts and identifying “future

opinion shapers” (6). Education comes from sides, the physician and the non-medical staff, the physician and the patient, each one has to learn from the other and improve patient care.

## 5. CONCLUSIONS

- Physicians should be aware of myths in radiation protection in patients receiving radioiodine for treatment in thyroid cancer and enhance dialogue with patients and non-medical staff to avoid them through education.
- Qualitative research would be a good tool to perform regional and interregional research in these topics.

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# EVALUATION OF BACKGROUND IONIZING RADIATION LEVEL AND ITS RADIOLOGICAL IMPLICATIONS IN SELECTED QUARRIES IN ABUJA, NORTH CENTRAL NIGERIA

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## Abstract

An evaluation of ionizing radiation level and its radiological implications in selected quarries in Abuja, North Central Nigeria was carried out in quarries in three area councils of the Federal Capital Territory, Abuja using 2 calibrated survey meters. The highest average annual effective dose of  $0.41 \pm 0.13$  mSv/y was recorded in Stud quarry in Kwali Area council while the lowest average annual effective dose of  $0.27 \pm 0.04$  mSv/y was recorded in Arab Quarry in Municipal Area Council. It was observed from the study that all the values of the annual effective dose rate are below the dose limit of 1 mSv/y set by International Commission for Radiological Protection (ICRP) for members of the public. However, the highest average values of fatality cancer risk, severe hereditary effect and estimated total detriment of  $168.10 \times 10^{-7} \text{ Sv}^{-1}$ ,  $8.20 \times 10^{-7} \text{ Sv}^{-1}$  and  $176.30 \times 10^{-7} \text{ Sv}^{-1}$  respectively were recorded in Stud Quarry. This is so because the higher the dose the higher the risk. These values imply that workers and dwellers in and around these quarries as at the time of this study may not face any serious health risk though farther work is recommended

## 1. INTRODUCTION

Ionizing radiation is any type of particle or electromagnetic wave that carries enough energy to ionize or remove electrons from an atom (Pattison *et al.*, 1996). There are two types of electromagnetic waves that can ionize atoms: X-rays and gamma-rays, and sometimes they have the same energy. Gamma rays are produced by interactions within the nucleus while X-rays are produced outside of the nucleus by electrons. Others include alpha particles, beta particles and neutron radiations. The alpha particle is composed of two protons and two neutrons, or a helium nucleus. The beta particle is either a positron or an electron. Neutrons emitted during some nuclear decay processes are often included as ionizing particles though they do not actually ionize atom directly [1]. Neutrons interact with another nucleus, which may result in a secondary process involving ionizing radiation. All these radiations can be classified into different sources. However, any benefit of radiation comes with associated risk if proper radiation techniques are not being applied [2].

Background radiation is that which is naturally and inevitably present in our environment. Human beings are exposed to background radiation that stems both from natural and man-made sources. In general, approximately 85% of the annual total radiation dose of any person comes from natural radionuclides of both terrestrial and Cosmo genic origin [3]; [4].

Risks of exposure to radiation from radioactive elements is at times ignored with their great health effects while major attention is always paid to the health effects of atomic and nuclear power plants [5].

Monitoring radiation levels involve both in situ and laboratory methods. The particular method to be used depends on several factors. In achieving fast estimate the in-situ method is a better way as it gives quick results [6].  $^{222}\text{Rn}$  results from the radioactivity of  $^{238}\text{U}$  and itself decays with a half-life of 3.82 days. When it is inhaled it penetrates into the lung. It's most dangerous daughters are  $\alpha$ -emitters  $^{218}\text{Po}$  and  $^{214}\text{Po}$  which emit  $\alpha$ -particles with energy of 6.0 MeV respectively. The continuous deposition and interaction of such high energy particles with the lung lead to its damage and the incidence of lung cancer [7]. Excessive and prolonged exposure to radioactive elements has general deteriorating side effects on human health [8]. The most important way of

preserving the human cell is to protect it from ionizing radiation. This is why radioactivity measurement and evaluation are very important in our environment [9].

It has been established that chronic exposure to a low dose rate of nuclear radiations from the environment has the potential to induce cytogenetic damage to human beings [10]. This induced cytogenetic damage can cause leukaemia, chromosomal breakage, bone necrosis, bone cancer; mutation of genes, cataracts of the eye lens etc. The great interest expressed worldwide for the study of naturally occurring radiation and environmental radioactivity has led to the performance of extensive research in many countries of the world. Such investigations can be useful for assessment of public dose. Furthermore performance of epidemiological studies, as well as keeping reference data records, to ascertain possible changes in the environmental radioactivity due to nuclear, industrial and other human activities. The total amount of radioactivity in an environment should be accurately known and kept to As level as Low AS Reasonably Achievable (ALARA).

## 2. METHOD

The two survey meters (calibrated by the Nigeria Institute of radiation Protection) described in figures 3.2 and 3.3 was deployed for the background ionizing radiation measurement in the selected quarry sites. The measurement was conducted between 1200 and 1600hours since the exposure rate meter has a maximum exposure to environmental radiation within these hours [11]. An in-situ approach was adopted and preferred to allow samples maintain their original characteristics.

Following standard procedure, the window of the radiation instrument was held at a distance of 1.0 meter above ground level. Each measurement was taken for five minutes, five measurements were taken and the average recorded as a single reading. More so, 3 area councils namely Kwali, Bwari and Municipal were covered with 2 quarry sites per area council. The choice of these quarries was based on their strategic locations and volume of activities at the time of this study. A total of 20 measurements were taken per site in the following order; 5 measurements inside the mined pit, 5 measurements outside the pits, 5 measurements 100 meters away from the pit and another 5 measurements 200 meters away from the pit thus making a total of 60 readings.

### 2.1 Method of dose and radiological consequences estimations

The data generated from this measurement was used to compute the annual effective dose rate, estimate the cancer risk a (radiological consequences) for both the occupationally exposed and members of the public. Annual Effective Dose helps us to determine the absorbed dose in micro Sievert per year ( $\mu\text{Sv/y}$ ). Equation (1) was used to calculate the annual effective dose rate as shown;

$$E (\text{mSvy}^{-1}) = D (\text{nGh}^{-1}) \times 8760 (\text{h}) \times 0.2 \times 0.7 (\text{mSvy}^{-1}) \times 10^{-6} \quad (1)$$

Where ( $\text{mSvy}^{-1}$ ) = Annual Effective Dose Rate in milli Sievert per year,  $D (\text{nGh}^{-1})$  = Dose rate in nanoGray per hour, 0.2 is the outdoor occupancy factor, 8670 (h) is the total time spent by workers at the site, while 0.7 is the conversion coefficient.

The risk of workers in the quarries under study is estimated using the 2007 ICRP recommendations based on assumed 70 years lifetime of continuous exposure of the population to low level radiation. According to the ICRP methodology,

$$\text{Cancer risk} = \text{TAED (Sv)} \times \text{Cancer risk factor} \quad (2)$$

$$\text{Heritable effects} = \text{TAED (Sv)} \times \text{Heritable effect factor} \quad (3)$$

$$\text{Total detriment} = \text{Cancer risk} + \text{Heritable effects} \quad (4)$$

Where;

TAED is the Total Annual Effective Dose in Sievert.

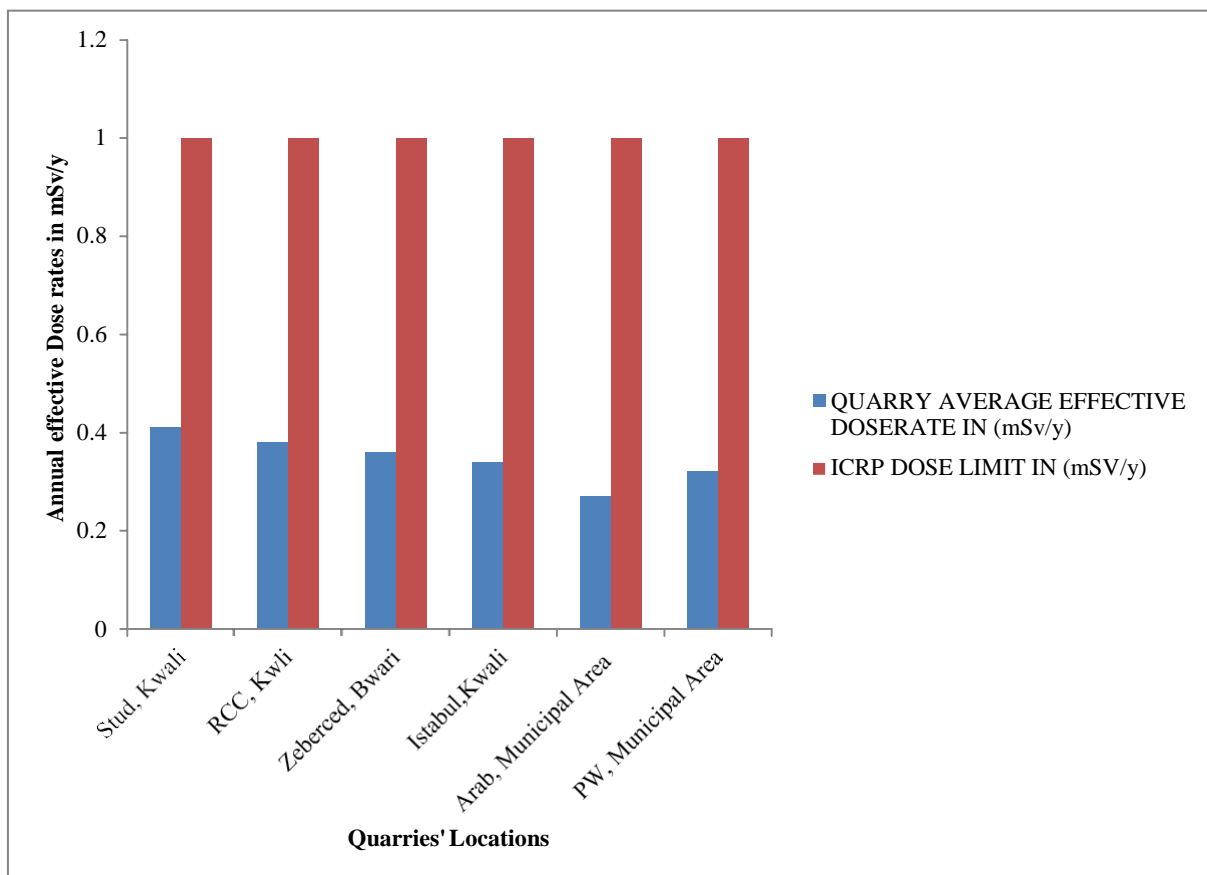
## 3. RESULTS

The gamma dose rate measurement was done in micro Sievert per hour and converted to milli Sievert per year using equation (1). The average annual effective dose rate was also computed per quarry site with the corresponding cancer risk, hereditary effect and total detriments calculated using equations (2), (3) and (4) above). The results are shown in table 1 below.

**Table 1: Quarry Annual Effective Dose rate, Associated Cancer Risk, Hereditary Effect and Total Detriment**

Site Location	Annual Effective Rate in mSv/y	Cancer Risk ( $10^{-7}$ )	Hereditary Effect ( $10^{-7}$ )	Total Detriment ( $10^{-7}$ )
Stud quarry, Kwali	0.41±0.13	168.10	8.20	176.30
RCC Quarry, Kwali	0.38±0.15	155.80	7.60	163.41
Zeberced Quarry, Bwari	0.34±0.11	147.60	7.20	154.80
Instanbul Quarry, Bwari	0.34±0.07	139.40	6.80	146.20
Arab Quarry, Municipal	0.27±0.04	110.70	5.40	116.10
PW Quarry, Municipal	0.32±0.12	135.30	6.60	141.90

The average annual effective dose per year in all the quarries studied is compared with the ICRP dose limit of 1 mSv/y for member of the public as shown in Fig. 1 in page 4



**Figure 1: Quarry annual effective dose compared with ICRP dose limit of 1mSv/y**

#### 4. DISCUSSIONS

Considering spatial variations on all the 6 quarries, changes were noted among values at different locations. Moreover a decrease trend was seen as measurements were taken away from the Stud, RCC, Zerbeced, Istanbul and Arab Quarries. At PW quarries in Municipal, there was a shoot up as observed in both table 1 and figure 1 above though all values are below the ICRP limits. It is also observed that radiation exposures doses were comparatively lower at 200 meters away from the mined pit than at the mined pit suggesting probably a significant contribution from the parental rocks in the mined pits. It is to be noted that all measure and calculated values are lower than 1mSv/y for members of the public, 20mSv/y for occupational exposed and the world average of 2.4mSv/y.

To assess the radiological consequences; the fatality cancer risk, severe hereditary effect and the total detriment were calculated from the annual effective dose values as shown in table 1. These values are the total average of annual effective doses in both the rainy and dry seasons and in all the locations. From these values, it was found that the fatality cancer risk range from  $168.10 \times 10^{-7} \text{ Sv}^{-1}$  recorded at Stud quarry to  $110.70 \times 10^{-7} \text{ Sv}^{-1}$  recorded at Arab Contractors quarry. The severe heritably effects also range from  $8.20 \times 10^{-1} \text{ Sv}^{-1}$  at Stud quarry to  $5.40 \times 10^{-7} \text{ Sv}^{-1}$  at Arab Contractors quarry. From the values also, it can be deduced that the higher the absorbed dose, the higher the detriment. The concept of cancer risk as a result of low doses of radiation remains a probability. From the above analysis, the highest recorded value of cancer risk is less than the world average of  $0.29 \times 10^{-3}$  which requires further studies. As it stands, it can be deduced that Stud quarry recorded the highest level of risk to its workers and could be inferred that the probability of a worker expiring from a radiation induced cancer and passing on radiation induced heritable effect to their offspring is high. From this study, approximately 16 persons out 1,000, 000 workers in 70 years are likely to suffer related disease from irradiation due the stochastic effect. In case of lifetime hereditary effect, approximately 8 people out of 10,000, 000 workers are likely to pass on radiation hereditary diseases to their offspring. This of course remains a probability.

#### 5. CONCLUSIONS

The mean absorbed dose rate values measured in each of the study area were comparable to those for the environs in Nigeria and the entire world. Significantly, the average annual effective dose rate was found to be less than the dose limit set by ICRP for members of the public. However, no matter how low the dose rate is, all levels of radiation are hazardous to human health. Even though there are no zero values for cancer risk or hereditary effect in this study, there should be no fear of extreme radiological consequences from radiation exposure or dose emanating from any of the study areas as at the time of this study.

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## **HARNESSING BIODOSIMETRY FOR PERSONALIZED MEDICINE**

### *Identify Radiation-Sensitive Population Using Biological Dosimetry Methods*

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#### **Abstract**

In Israel a new idea emerged in the field of personalized medicine: modifying the use of biodosimetry for clinical practice to identify a marker for radiation response and radiation sensitive individuals. The aim is to develop a risk index, calculated by an individual's chromosomal damage combined with his medical considerations. This index will help to better manage the medical treatment, including fitting the optimal radiation dose for each medical problem without increasing the risk for side effects and late malignancy. The objectives of the project are to explore a biomarker of radiation sensitivity based upon chromosomal abnormalities induced by X ray exposure. Followed by developing a mathematical predictive formula to risk-stratify individuals, which calculates the number of chromosomal aberrations, the level of radiation exposure and potential harm. Data will be collected in order to create an epidemiological model that strives to uncover the direct relationship between chromosomal aberration and cancer. Israel is pioneer in its perspective on biodosimetry and its potential as predictive value tool to be used in personalized medicine. The new lab combines Israel strengths in cancer research, genetic analysis and radiation biology.

#### 1. INTRODUCTION

During the last decades there has been a significant increase in the number of medical procedures involving the use of ionizing radiation, both for diagnosis and for treatment. Radiation protection became a concern of governments, international organizations and professional societies on three main fields: occupational, medical and public exposures. Occupational exposure is limited and monitored under labor regulation, according to International Basic Safety Standards (BSS). Since no exposure limits are set for medical exposure of patients there are two fundamental principles guiding in performing the procedure: Justification and Optimization..

Despite the many precautions taken and improvements in radiation therapy techniques, the literature points out on cases of patients experience moderate to severe radiotoxicity that can affect their quality of life. Normal tissue damage might present as acute (early responding), chronic (late responding malignancies), or both [1][2]. Current standards of radiation protection are based on the stochastic assumption that all people have a uniform radiosensitivity, means that radiation-induced cancers are statistically and randomly distributed in all radiation exposed population.

There is new theme that conflict with this paradigm. The interpatient variability in the incidence of late side effects could be partially due to difference in an individual's radio sensitivity [3]. The need for a better understanding of the variations in radiosensitivity between individuals and to personalize patient's protocols has led to several studies aimed to identify biomarkers as predictors of an individual's radiosensitivity.

#### 2. EPIDEMIOLOGICAL AND CLINICAL RADIOSENSITIVITY

In most cancer studies, tumor genesis is thought to occur after exposure to certain carcinogenic environmental agents (including exposure to ionizing radiation), and that some inherited genetic component can increases the individual's sensitivity to this environmental risk factor. Known as the gene-environmental paradigm.

One source of evidence for this association is an Israeli follow-up study [4] of thousands of children, mostly of North African and Middle Eastern origin, who underwent radiation to treat tinea capitis (a fungal infection of the scalp) during the mass migration to Israel in the 1950s. This dataset of families, which included irradiated and unirradiated, and also affected and unaffected family members, created a natural experiment, which enabled the assessment of the effect of exposure and familial aggregation of meningioma. The findings, of a high frequency of meningioma and other radiation-related cancers in irradiated relatives of radiation associated meningioma cases compared with irradiated controls, support the idea that genetic susceptibility increases the risk of developing meningioma after exposure to radiation.

Clinical radiosensitivity is related as a patient radiosensitivity is measured in terms of radiotoxicity after radiation therapy. There is evidence for variation in clinical radiosensitivity between patients and even in an individual patient, some studies suggested that the genetic factor could be highly significant, after accounting for known risk factors as age, smoking, previous treatment and physics of treatment [5] [6]. Clinical radiosensitivity is site-dependent and relate to a range of effects from weeks, classified as acute toxicity, to years, which are classified as late toxicity and second cancers [7]. Moreover, the radiosensitivity of a tumor will be expressed in the clinical results of the radiation therapy - whether and to what extent the radiotherapy affected the current malignancy. Patients receiving similar treatments regimen show a variety of toxicity as well as clinical benefit from the therapy. Although the clinicians are keen for additional information to assist them in the planning of the radiation therapy, most of the existing studies are limited by the lack of systematic recording of toxicity and the heterogeneity of recording toxicity. While the impact of dose is well known and reported in studies, multivariate analyses involving genetic information can support clinicians' decision in prescribing dose for therapy.

### 3. BIODOSIMETRY METHODS

- (a) For several decades, during an emergency, the level of exposure of individuals to carcinogen source is being assessed retrospectively using Biological Dosimetry methods. In these methods chromosomal aberration are being analysed and counted for Dose Assessment. The tests are based on numerous studies dealing with the relationship between ionizing radiation and chromosomal change, and a significant increase in the incidence of cancer in people with a high percentage of changes. There are several ways to test the effect of irradiation on humans, among them we can focus on two levels: At the chromosome level, using cytogenetic methods from the well established Biological Dosimetry methods: Dicentric chromosomes, Micronuclei, FISH. Although cytogenetic has been used as a marker of radiation exposure for many years, to date its use as a marker of radiation sensitivity is limited. The assumption that cytogenetic analysis may be useful for predictors of radio sensitivity was tested and validated by several groups such as Beaton, L.A et al. (2013) [9] working with prostate cancer patients, which further validate the results found by Borgmann et al (2008) [10] and Chua et al (2011) [11] working with breast cancer patients.
- (b) At the gene level, using molecular methods. There are currently no established mechanistic methods for identifying radio sensitivity. Future studies should aim to identify the specific genetic components that modify the individual's ability to tolerate or accurately repair and manage radiation-induced DNA damage. Candidate genes for analysis should be DNA repair genes and genes associated with cell-cycle control. As more mechanistic information on genetic susceptibility becomes available, the practice of risk assessment and primary and secondary prevention will be improved for many kinds of cancers.

### 4. PURPOSE OF THE PROJECT: IMAG(IN)E A BETTER FUTURE

Today there is no established biological dosimetry laboratory in Israel, neither for clinical use nor for emergency purposes. In the past, several stakeholders carefully considered to establish an independent biodosimetry laboratory, yet without adequate resources and experts available, the proposal returned to the drawer. Until three years ago, the Medical Technology, Health Information and Research Directorate (MTIR) in the Israeli Ministry of Health (MOH) took a leadership role on the initiative and moved it forward to actualize the vision of using biological dosimetry for clinical applications.

MTIR is a directorate in the Israeli MOH that is responsible for regulating drugs, medical devices, cosmetics, radiation-emitting products and clinical trials; licensing of health care infrastructure as hospitals and clinics; setting national policy regarding medical technologies, including annual update of reimbursement criteria; collecting and processing health information and managing the Israeli Center for Disease Control (ICDC) with its national cancer registry. In its wide view perspective, the MTIR is operating national programs that aim to improve clinical service in various fields, some as radiation therapy and other radiation-related topics, are with the support of the Technical Cooperation (TC) mechanism in the International Atomic Energy Agency (IAEA).

The MTIR Directorate, led by Dr. Osnat Luxenburg, identified the clinical need for a biomarker to personalize the radiation therapy regimen of cancer patients. Israel has a vast knowledge in the field of cytogenetics and advanced cancer research, collaboration between researchers, clinicians and radiation experts, together with a dominant leadership that is leading toward the desired breakthrough in clinical biodosimetry research and application, with the following partners:

- Sheba Medical Center is a government-owned public hospital and as a tertiary referral center, the Sheba Medical Center combines Israel's largest Acute Care Hospital with its national Rehabilitation Hospital, with more than 1400 beds. Sheba MC is the main counterpart in this project, and the biodosimetry laboratory will be installed in its campus.
- The Cancer Research Center, within Sheba MC, led by Prof. Gideon Rechavi and Prof. Ninette Amariglio, perform clinical and pre-clinical research that brings to cancer patients advanced diagnostic and treatment modalities. In the center clinical studies are aimed to develop new drugs, using advanced techniques as Gene Sequencing, Microarrays, Bioinformatics, Molecular Cytogenetics, Stem Cells, and others. The Cancer Research Center support this project with its capabilities in cytogenetics and bioinformatics.
- The Radiation Therapy center in Sheba MC, led by Prof. Zvi Symon. The radiotherapy center is treating 250 new cancer patients monthly, teaching and supporting a satellite center in the north of Israel, operating the National Training Center for Radiotherapy Professions and conducting research in the field of radiobiology in a laboratory led by Dr. Yaacov Lawrence. The radiobiology laboratory is part of the IAEA Coordinated Research Project (CRP) titled “Applications of Biological Dosimetry Methods in Radiation Oncology, Nuclear Medicine, Diagnostic and Interventional Radiology”.
- Cancer and Radiation Epidemiology Unit, The Gertner Institute, led by Prof. Siegal Sadetzki. Among its vast epidemiological research, Prof. Sadetzki is leading a follow up study on more than 10,000 individuals who were treated for tinea capitis with X rays in the 1950s in Israel.
- The Israel Cancer Registry within the Israeli Center for Disease Control (ICDC), led by Prof. Tamar Shohat and Prof. Lital Boker-Keinan. Israel has a cancer registry since 1960, and reporting of newly diagnosed cancer cases has been mandatory by law since 1982.

Israel has advantages in the field of digital health that can contribute to this project. Israeli citizens have electronic health records (EHR) for 20 years already, providing long term retrospective information. Israel is leading in the field of bioinformatics research, together with increased number of start-ups operating in Israel in the field of digital health. The population in Israel has some unique genetic characteristics, on one hand as country of immigrants from all over the world one can find diversity, on the other hand there are groups in the population that show distinct and unique genes, with long history of introversion.

The unique combination of advanced cytogenetics capabilities, radiobiology laboratory, state of the art radiotherapy department, leading cancer epidemiology research center, national cancer registry, digital health and bioinformatics, under the leadership of the MTIR directorate, is a rare opportunity to design and deliver a research that can make a difference, to answer on some of the problems raised in previous studies, and learn the effect of multivariate in large scale studies done in the clinical sphere.

The leadership of the MTIR is a critical factor to the successful implementation of this project: a governmental organization that can ensure sustainability of resources, where its objective is to advance public health, in a field that the pharma or biotech industry will not have financial incentive to support research in. On top of that, the wide virtual umbrella of the MTIR on this project will break the silos between the research and clinical entities, as the MTIR is regularly coordinate with all the stakeholders.

## 5. PLAN OF ACTION

The goal of the project is to explore biological markers for radiation sensitivity that in turn will enable the prediction of an individual response to ionizing radiation. In the first phase, after establishing the classical biodosimetry methods, a calibration curve will be created for the Israeli population to demonstrate the blood response to ionizing radiation. Once a method will be set, it can be valuable to study the following sub-populations:

- Individuals exposed to high radiation doses, i.e. cancer patients who undergo radiation therapy. The goal is to create a designated calibration curve for the cancer population of various types, and to look for a pattern that link cancer to the body's response to radiation.  
The cancer population will be sampled twice: First, before the beginning of a radiation therapy. A systematic recording of the cancer type, stage of the disease and the number of chromosomal changes will be conducted. Second, patients blood will be irradiated ex-vivo at the conventional doses. The number of chromosomal changes will be counted and compared to the first test. A patient who has unusual number of changes compared with his initial condition and the calibration curve, will be considered as a person sensitive to radiation. This information will support the physician decision in the treatment regimen planning.
- Individuals exposed to medium radiation doses, i.e. tinea capitis group. Since this group is under long-term follow-up, we can conduct clinical and epidemiological trial simultaneously. A search for differences in the number of genetic changes among family members who have and have not had meningioma to indicate a difference in sensitivity to radiation. A complete genome mapping for a sample from this population is currently being carried out. This data can expand the genetic observation and comparison among relatives who reacted differently to ionizing radiation.
- Individuals exposed chronically to low radiation dose, i.e. occupational exposure. The population of radiation workers, who have been exposed over the years to low doses of radiation. The goal is to identify radiation sensitive workers and adjust their optimal radiation threshold doses ("tailor made employment"). In this population several questions are being asked about the effect of radiation on them: Is there permanent damage? How did chronic low doses radiation affect them? Do they have a different number of chromosomal changes compared to the general population? How they react to ionizing radiation? Are they more or less sensitive to radiation?

Israel act in two dimensions simultaneously: One, establishing the classic cytogenetic dosimetry biology methods to identify radiation damages, developing a national calibration curve and learning the impact on different groups who exposed to radiation, as described above. Second, develop advanced molecular techniques to understand the impact of radiation on the cell cycle and its corrective actions in vitro and in vivo. As the incentive for this project came from the clinical field, the focus is on identifying the radiosensitivity individuals in order to make precise and personalize medicine and follow-up, even in the cost of longer periods of time in performing the tests. This is different from the traditional biodosimetry, where the goal is a fast estimation of the dose individual was exposed to.

## 6. SUMMARY

The MTIR initiate the project of developing clinical applications of biodosimetry as a tool for personalized medicine, with the support of the IAEA TC on national projects. The IAEA TC support the establishment of the laboratory in procurement of advanced laboratory equipment, expert missions to teach and consult locally, scientific visits of local teams to learn from the experience of other labs worldwide and more. The collaboration between government, international organization, research centers and clinicians is unusual and can serve as an example of integrating variety of capabilities and breaking silos between entities, to make a breakthrough in research. As the study is in its first phase, it is impossible to predict its results, yet the starting point is infinitely better and will answer the challenges raised by previous studies in this field. The implementation of the project is complex, from procurement done by different organizations to signing contract related to future intellectual property between the different stakeholders, with the constant challenge to secure resources for long term.

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## AN ARGUMENT AGAINST THE USE OF THE TERM “DOSE REDUCTION”.

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### Abstract

Radiation Safety protection culture focuses on mitigating the risk to patients, workers or members of the public from potentially harmful exposure to ionizing radiation. Arguably, too little attention is paid to the danger of a disproportional emphasis being placed on radiation risk. Overestimating as well as underestimating risks can lead to poor, misinformed decisions. This paper argues that the term Dose Reduction, which is increasingly being used in place of Dose Optimization, can lead to practices where an imbalanced assessment of risk develops, with potential negative consequences for patient care.

### 1. INTRODUCTION

Dose reductions achieved by engineering and software advances can be very beneficial, but there is a danger that the term is being used in a wider sense, which is inappropriate. Increasingly, the term ‘Dose Reduction’ is being used to describe processes which would previously have been described as ‘Dose Optimization’. When considering a dose adjustment process, Dose Reduction and Dose Optimization are different philosophies. Optimization keeps a focus on both radiation exposure and image quality. Dose Reduction concentrates on radiation exposures, and while it is not intended that image quality is neglected, in placing the emphasis on dose alone, it risks losing sight of it. This is made all the more likely because image quality is more difficult to define and measure than dose. This paper advocates that image quality must be kept firmly in view when dose is being adjusted, even if this means achieving less ambitious dose reduction.

### 2. DOSE REDUCTION

X-ray supplier product literature is replete with examples of claims of Dose Reduction. A review of Internet sites shows Dose Reduction included in a prominent manner in three of the major CT manufactures [1-3]. Product brochures may also advertise the degree of Dose Reduction achieved. Increasingly Guidelines and Standards are using the term. For example, Image Gently has been described as dose reduction campaign for paediatric imaging [4]. The term has been adopted in the scientific literature. A large number of papers and presentations, easily accessed by an internet search, have dose reduction as the theme. The degree to which image quality is also considered in these publications varies, but the main point for the purposes of this argument is that the term Dose Reduction has become so prevalent, there is a danger that Dose Reduction, not Dose Optimisation, is driving the agenda for change and improvement.

Ostensibly, publications advocating dose reduction make a valuable contribution to radiation safety. Reducing dose reduces risk. This is true as far as it goes. Steps which reduce dose can and often are beneficial, but promotion of those measures separately from image quality is always a cause for concern. It diverts our attention from a key problem in medical imaging which is that we can neither easily measure image quality, nor set a precise threshold or lower limit for image quality. The difficulty in producing quantitative metrics that adequately represent clinical image quality continues to be a problem for engineering solutions with set reference parameters for automatic dose control systems. Routine image quality tests performed by operators and physicists tend to be conducted under standard conditions which don’t replicate clinical doses used in practice. Non-anthropomorphic test phantoms provide only a weak representation of clinical image quality. Nor

can we expect experts in reading images to provide a calibration point for dose which protects image quality. Inter and intra subjective variability, together with complexities in image quality processing and post processing make reliable and reproducible visual assessment of image quality very difficult.

While image quality isn't being intentionally neglected, encouraging Dose Reduction may prompt an imbalanced approach. Simply by virtue of using terminology which isolates Dose and emphasizes its Reduction, we supply a prompt for the development of strategies which focus on the comparatively easy measurement of dose, while paying less or cursory attention to image quality, which is much more difficult to assess. In the following section three examples are discussed where attempting dose reduction, on the assumption that significant loss of image quality will be noticed, could be problematic.

## **2.1 Competing on the basis of Dose Reduction**

Dose reduction is often claimed of engineering advances which produce superior imaging capability, and allow diagnostic images to be acquired at lower doses. Dose reductions can be expressed numerically, making it easy to highlight impressive dose savings in a manner which is defined and tangible. Image quality on the other hand has to be described subjectively. It can be claimed that dose has been halved, but not that image quality has been doubled. Good image quality is not only subjective, but hard to reproduce reliably in all circumstances. It is relatively easy to get a good image at low dose in a given circumstance: it is much more difficult to achieve a setting that produces good image quality across the full range of clinical use. The lack of sophistication in image reference parameters in automatic dose control can mean having to set dose higher than we need it to be in some circumstances if we want to be confident of achieving good image quality in all circumstances. A dose reduction strategy can push in the opposite direction to this.

Again it is emphasized that this is not to criticize the important engineering advances that produce more efficient imaging systems, and enable acquisition of diagnostic images at lower dose, but to raise a concern about the terminology which promotes such advances as 'Dose Reduction'.

## **2.2 Thinking 'Dose Reduction'**

With so much of the literature adopting dose reduction as standard terminology there is a danger that instead of having a process where dose is balanced with image quality, dose control alone may become the priority. Consider a scenario where this thinking prompts an approach where doses are gradually brought down so long as there are no complaints about image quality.

In this scenario a team approach is not being taken. For example, it may be that dose is being reduced unilaterally by one group, with the expectation that a significant change to image quality will be noticed (by another group). This might seem a useful way of implementing dose reduction, but it is likely to be a poor strategy for a number of reasons. First, as noted above, there is no agreed opinion on what constitutes a good image. There will be a large grey area where imaging seems adequate in some circumstances, or is less satisfactory to some readers than others. The situation is further complicated in modalities such as CT, where recent changes to image processing have changed the appearance of the image. Newly implemented image processing and a newly implemented dose reduction policy could both be affecting images at the same time. Finally if dose reduction is being introduced gradually with the intention of being cautious, this might have the unintended consequence of making negative changes in image quality more difficult to detect. Image quality assessment is difficult and complex: unless it is central to the design of the dose adjustment process there is insufficient safeguard against a loss of diagnostic image quality.

## **2.3 Dose Reduction in Clinical Audits of DRLs**

Diagnostic Reference Levels [DRLs] are commonly used in dose audits [4]. Consider a situation where an audit reveals that the median dose for an x-ray exam is half the DRL. If the audit is being approached with a view to optimisation, this merits urgent investigation. It may be prove that diagnostic image quality is being maintained, but the low dose level should flag the need to verify this. However, if the audit is approached with Dose Reduction firmly in mind, there is a possibility that this low value will be seen as meeting expectations and requirements, and a potential quality risk might not receive due attention.

### 3. DOSE IS MORE EASILY QUANTIFIED THAN IMAGE QUALITY

The main objection to a dose reduction strategy (which proceeds without careful assessment of image quality) is that it cannot be assumed that loss of diagnostic image quality will be readily noticed. Unless there is a sudden and large drop in image quality, the change will be difficult to detect reliably. A wide range of dose settings might produce images which are regarded as diagnostic, and as dose reduces it can be difficult to pin down a point where images become non-diagnostic. An increase in dissatisfaction with some images among some radiologists would be noticed before we reach a point where imaging is clearly non-diagnostic in all cases for all readers. In this environment a dose reduction approach can easily fail. Optimisation on the other hand, is far more cautious about bringing down dose. It also accepts that dose may need to come up as well as down. Such caution may mean achieving less dose saving, but has the benefit of keeping diagnostic image quality more firmly in focus.

We lack the tools to adequately pursue image quality optimization, but that doesn't mean we can ignore it. Medical Physicists in particular have a responsibility to lead development of improved imaging assessment methods that have clinical relevance and are easily adapted to optimization. The BSS 2014 offers a degree of support to increased effort in optimization at least for higher dose systems [5]. The challenge for the next ten years is to ensure we can assess clinical images alongside the doses patients actually receive, and incorporate these in quality control and optimization programmes.

### 4. IS IT WORSE TO HAVE A DOSE THAT'S TOO HIGH, OR IMAGE QUALITY THAT'S TOO LOW?

The emphasis on Dose Reduction the literature may prompt a way of thinking which places a greater priority on reducing dose than on preserving image quality. But which is worse: too high a radiation dose, or too low image quality? Consider the scenario summarised in Table 1. If the dose is too high there is an increased risk of cancer. Images will also be improved, but the additional clarity might not add to diagnostic quality. If we give too low a dose, risk of cancer will be reduced, but diagnostic image quality has also been reduced with the attendant risks of misdiagnosis and/or the potential need to repeat the scan.

The final column takes an example of a CT scan to illustrate the point. Effective Dose and the Linear No Threshold model (LNT) are not suited to producing reliable predictions of numbers of cancers caused by low dose of radiation [6]; the purposes of the calculations made here are for estimating and comparing potential risk only.

Assume the ideal dose for this scan is 10mSv (and for the purposes of this example and ease of calculation allow that this is an ideal value for 20,000 such scans). Also assume that the potential risk of 1 in 2,000 of fatal cancer associated with this exposure has been justified. If the dose is set 3mSv too high, a further three or so out of 20,000 patients scanned, may get cancer as a consequence. Image clarity is also improved, but to no diagnostic benefit. If the dose is set too low - a 7mSv scan in this example - approximately three fewer cancers in the 20,000 population are caused, but each of the 20,000 scans has reduced image quality, which results in a higher risk of misdiagnosis.

For the purposes of risk comparisons, if we go too high in dose, there is a risk of three additional cancers caused in the 20,000 scans; if we go too low, three fewer cancers may be caused, but image quality is too low in each of the 20,000 scans.

The above example is artificial; we are assuming an ideal dose has been identified. This is almost impossible to do for every routine scan. In the absence of a precise means of measuring image quality, an approach which is cautious about image quality may err on the higher side of the correct dose. An imaging strategy that puts dose reduction to the fore is more likely to go the low side of the ideal dose, and negatively affect diagnosis.

The paper makes a case against use of the term 'Dose Reduction'. It is argued that the potential to reduce the number of cancers by three may not be justified by a step which leads to loss of diagnostic image quality in 20,000 scans. It is important to note that this argument does not support the opposite of dose reduction. The table clearly identifies problems with giving too high an exposure. Within the limits of our ability to measure image quality we should aim to set dose at a point where images are diagnostic, and no more. Even though this cannot be done perfectly, it should remain the focus of our efforts. Dose Optimisation strategies are more



cautious about reducing dose, are slower because they incorporate image measurement, but by keeping the goal of reaching an ideal dose in view, they are worth the additional effort.

TABLE 1. CONSEQUENCES OF OVER AND UNDER EXPOSING A PATIENT IN A CT EXAM. HERE WE ASSUME THE CORRECT DOSE FOR THE PATIENT TO RECEIVE IS 10MSV. IT IS AN IMPORTANT LIMITATION OF IMAGING THAT IT IS VERY DIFFICULT TO DETERMINE THE IDEAL IMAGE QUALITY AND A CORRESPONDING IDEAL EXPOSURE VALUE.

<b>Radiation Dose</b>	<b>Radiation Risk</b>	<b>Imaging</b>	<b>Example (20,000 CT Scans where 10mSv is the ideal dose)</b>
<i>Dose Set too High</i>	Increased risk of cancer	Improved clarity in images	Dose Set at 13mSv instead of 10mSv. Additional 3mSv may lead to additional cancers
<i>Optimum Dose</i>	Accepted (justified) Risk	Diagnostic Image	Potential risk of ~ 1 in 2,000 of fatal cancer has been justified. 10 cancer may be caused
<i>Dose Set too low</i>	Reduced cancer risk from current exposure. However, a further exposure may be needed to obtain a diagnostic image.	Image too noisy and may be non-diagnostic, or more difficult to interpret. Risk of misdiagnosis increased	Patient dose of 7mSv. May cause less cancers. 20,000 scans taken with image quality too low. Potential for misdiagnosis, or requirement for repeat image at the correct dose with further potential risk of 1 in 2,000 of fatal cancer

## 5. CONCLUSIONS

This paper argues that the ubiquity of term ‘Dose Reduction’ is potentially problematic. There is a danger that it will prompt measures which focus on the more easily assessed quantity of dose, while not paying sufficient attention to the complexity of maintaining diagnostic image quality across the range of clinical imaging requirements. The argument raises the concern that while a Dose Reduction strategy is more likely to produce greater dose savings than Dose Optimisation, it may also bring a greater risk of obtaining non-diagnostic images.

The argument does not criticise dose reduction actions per se: advances in technology which have enabled acquisition of diagnostic images at reduced dose are of great benefit to diagnostic imaging. The intention is to promote balance by identifying a potential area where one type of risk, rather than risk-benefit analysis, might drive the agenda.

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