How to become a high-performance dose excellence center: Current concepts and applications of modern dose management system in SBU Fatih Sultan Mehmet Training and Research Hospital

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Background/introduction

Computed tomography (CT) is considered as one of the greatest advancements in medicine. Although, it provides very valuable diagnostic information that considerably affect clinical management of many diseases, the relatively high level of ionizing radiation inherent to the technique, may cause adverse biological effects on human cells. In modern practice, the magnitude of patient exposure is much below the levels for acute deterministic effects -such as acute radiation sickness, to be observed. Late stochastic effects, on the other hand, are inevitable, as they have no dose threshold in individuals. Such effects are seen as malignancies, teratogenic disorders and mutations, and their incidences are known to be related to collective dose levels (1).

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) indicates that medical diagnostic and interventional radiology is the largest man-made source of radiation exposure. Between 1980 and 2006 the annual per-capita effective dose from radiologic and nuclear medicine procedures was increased by 600% (2). CT has the major share in that context, and, is now responsible of almost 24% of collective effective dose. This makes this modality an important causative for stochastic effects.

The ever-increasing role of CT in per-capita effective dose stems from the steady increase in the number of CT equipment and CT examinations in most countries (3). In Turkey, however, the number of CT scanners are still below OECD averages. On that context, the average number of CT scanners is 25.7 per million people in OECD, whereas it is only 14.3 per million people in Turkey. The difference between OECD countries and Turkey, become reversed when considering number of scans per capita. In Turkey 175 CT examinations were performed per thousand people during 2015. This number was only 142 in OECD on average (4). These facts points to the possibility that CT has higher impact regarding per capita medical radiation exposure to Turkish than average European population. To complicate the matter, the discordance between per capita number of scanners and examinations exerts a major pressure on CT scanners, resulting in nonstandardised imaging in many instances.

Typical dose levels during CT examinations may reach, for example, to »10 mSv in abdominal scans. This dose level is almost fifty times more than the average exposure caused by Chernobly accident, and is expected to result in an increased cancer risk of 1/2000 (5). There are also some reports on patients that were accidentally exposed to very high radiation, at the magnitude of 2.800-11.000 mSv (e.g. Arcata Medical Imaging Accident, USA, 2008). However -from the point of patient and population point of view, the most important aspect in radiation protection is not the detection of such exceptional accidents (so called strong signals) but the detection of frequent small anomalies (so called weak signals) in daily practice that may only be detected by the use of advanced...
analytics (Fig. 1 on page 4). In US, for example, more than 200 patients that were exposed to inappropriately high doses, were able to be detected long after the incidents. Many of these patients had shown signs of overexposure (e.g. epilation) but went unnoticed by relevant authorities for the next several months. Such unfortunate events are not exclusive to any hospital or to any country. In hospitals where hundreds to thousands CT scans are performed daily, low levels of overexposure may only be detected with the use automated of dose tracking systems that receive on-line demographical and dose data of large number of patients from several CT scanners and perform real-time analytics on them.

Although above-mentioned IT solutions are now indispensable in high-quality and value-based healthcare systems, they are only meaningful in the context of comprehensive quality improvement systems on dose management. Such systems encompasses whole imaging cycle (Fig. 2 on page 5) and incorporate leadership, technology and practices to lower patient doses according to ALARA principle.

In this presentation an overview of several aspects of dose management approach of Health Sciences University Istanbul Fatih Sultan Mehmet Education and Research Hospital (FSM) - a EuroSafe Imaging Star (*****) regional dose excellence center (Fig. 3 on page 5), was presented to show current concepts and applications of modern dose management.
Fig. 1: Figure 1. The concept of high performance healthcare delivery. In that model, healthcare services are synchronously modulated by the conventional delivery cycle and the innovative learning cycle. Majority of the incidents regarding patient safety are emerged as small anomalies that are not measured by conventional cycle. Many of these anomalies are very rare and ambiguous during their actual occurrence, and they therefore cannot be detected or stored without modern IT solutions (Adapted from Bohmer, 2009, p. 202. Ref. 12).

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**Fig. 2:** Figure 2. Continuous quality improvement list for dose excellence centers. Numbers are in order and correspond to infrastructure and processes that must be present in these institutions.

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Fig. 3: Figure 3. Eurosafe Imaging Stars initiative has been designed to identify and recognise imaging facilities that embody best practice in radiation protection and that are committed to putting the principles advocated and concepts developed by the ESR. Imaging departments participating in the EuroSafe Imaging Stars initiative are required to perform a self-assessment on their level of radiation protection. After successful evaluation, the participating imaging departments are listed on the 'Wall of Stars' according to the level attained.

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Description of activity and work performed

Institution

As the largest provider of health services in Turkey, the Ministry of Health is segmented into multiple hospital associations including the 2nd Healthcare Region of Istanbul Province (a.k.a. Anatolia North, which consists of 13 hospitals and 6 dental hospitals/centers. In Anatolia North 3 million residents are being served; 11.1 millions outpatient admissions and 250 thousands surgical operations are being performed annually. The annual number of radiologic procedures in Anatolia North are more than 4 milion and roughly represents 1/1.000th of world radiological services.

FSM is a mid-size receiver hospital. Although it is serving to a core population of circa 400.000, many patients from oether hospitals and districs also prefer or are referred to this institutuion. FSM was determined as the pilot (model) site within the larger Anatolia North’s radiology organization, in which people can develop, practice and improve the components of the high-performance clinical, operational and financial radiology management models through outcome-based experiments. The facility is a center that has been acknowledged for its supreme operational efficiency. To give an example, FSM was performing much above international benchmarks on CT with 94% room utilization, 2x higher scan volumes, and 99.47% uptime performance rate. Annual number of CT examinations have exceeded 100.000 in 2008 (Fig. 4 on page 12)

Why to Establish a Dose Excellence Center?

FSM Hospital, on that context, was the first institution in Turkey, where a comprehensive dose management system was implemented, and modern dose surveillance IT applications were used. FSM was designed to comply with highest standards and provide a framework to assist other centers develop the required dose management infrastructures according to relevant IAEA guidelines (6).

Such center of competence (CoC) was required in order to be utilized as initial host institution for fellows that need to be trained within the Anatolia North, and to be a reference center that other hospitals in Turkey can duplicate in order to develop quality assurance practices. The compliance of the facility with the established criteria was verified through a process of systematic and critical analysis of the quality of radiological services to allow comparison of trainees/observers’ practices of service against established standards of good practice.
Basic Guidelines and Criteria for CoC

The facility fulfills all the guidelines and criteria set by IAEA to establish for regional Centers of Competence for QA/QC in diagnostic and interventional radiology (6). Accordingly, (1) **objective of the facility**; (2) **access to institutional/industry funds** for the sustainability; (3) infrastructure, i.e. technical (**equipment**) resources, inventory control (**asset management system**), number of examinations and procedures (**demand**) to correspond to the scope of the facility to be a centre of professional education and training regarding the establishment of quality assurance/quality control in radiology; (4) **human resources**, and (5) **quality processes** were set to support the duty explained above.

Key Elements of a Dose Excellence System

Lowering dose requires more than technology. An effective dose management approach requires a **wing to wing approach** from the **justification of the examination** (i.e. performing the appropriate procedure) to the **optimization of the exposure** (i.e. performing the procedure appropriately) (7) (Fig. 2 on page 12). In that context, basic steps and goals of a dose management strategy are as follows:

- **Transform** dose awareness from an act to a habit
- **Educate** personnel
- **Justify** high dose examinations
- **Standardize** protocols and practices
- **Optimize** protocols and practices
- **Communicate** message to stakeholders
- **Promote** best practices and be safe

To meet above mentioned goals FSM (or any CoC) has to have below mentioned infrastructure and processes (Fig. 2 on page 12):

1. **Access to prior exams**: FSM has access to patient's past radiological exams through national teleradiology system, connecting all Turkish hospitals, public and private.
2. **Appropriateness**: Electronic clinical decision support system, embedded in hospital information to assist referring physicians in selecting the most appropriate examination based on the patient's clinical presentation. This ensures that patients are referred for the "right" imaging study, prevent over-utilisation of imaging, and will prevent unnecessary exposures.
3. **Equipment quality**: All CT equipment should meet XR-29 lower dose criteria. Availability of modern dose reduction algorithms (i.e. statistical iterative reconstruction) is preferred.
4. **Standardization**: Mapping local imaging procedures with standard procedures to obtain uniform scanning and facilitate data analysis. This
step includes the assignment to site protocols a specific ID. (i.e. RadLex v.1.2). In FSM, 65 standartized protocols are currently used. The use of nonstandartized protocols are not permitted, unless clearly justified and only exceptionally. Standardization allows to compare protocols/technologies/ radiographers, and assists in tracking of examinations and in making comparisons between same protocols of same CT systems. Development and implementation of standardized imaging has also been shown to lead to better results by means of quality imaging and high patient throughput.

5. **Continuous education:** (1) Technologists orientation training programs to deliver imaging quality training solutions to contribute the transformation in radiology department to shift technicians autonomy from the individual to the professional level. (2) Technical conferences and workshops to apply advanced capabilities of devices into practice making the full use of the systems.

6. **Centrally managing and tracking compliance to standartized imaging protocols:** An essential component of protocol management, a feature embedded dose tracking software.

7. **Availability of diagnostic reference levels (DRLs):** These are values which are usually easy to measure and have a direct link with patient doses. They are therefore established to aid efficient dose management and to optimize patient doses. DRLs should not to be exceeded for standard procedures when good and normal practice is performed. If patient doses are found to exceed consistently the corresponding reference level, investigation and appropriate corrective action should be taken, unless the unusually high doses could be clinically or technically justified. As a part of proper radiation protection program, and according to Radiation Protection 109 (EC 1999), Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures (8), these levels should be established, have to be revised periodically, and be specific to a country or to a region because published DRLs values from other countries (with potentially different imaging practices and technology) may not be relevant to other countries’ particular circumstances. For Turkey, these levels were not established, and Anatolia North’s median DRLs are generally used to fulfill the gap. For Anatolia North itself, and for FSM in particular **unified pan-European DRLs** of our CT service provider, Affidea was initially used. These were determined after median DRLs published from several European countries (Switzerland, Belgium, Finland, Norway, France, Germany, Poland, UK) from 2010 onwards (9).

8. **Dose data acquisition, registry and analysis system:** In FSM a commercial software *(Dosewatch, GEHC)* is being used. This web-based vendor-neutral solution captures, tracks and reports radiation dose directly from the medical devices. It monitors and analyzes high dose alerts and patient cumulative dose, includes quality metrics to assess the technical factors, has data consolidation and statistical analysis tools for protocol optimization and dose reduction by optimizing dose levels. In that system if the DLP or CTDIvol for a scan is equal or more than [median x 2], an alert is
triggered. Alert thresholds are moving targets; so as technicians got better, dose thresholds become tighter.

9. **Justification**: Cases for whom overdose alert is triggered had to be justified on the dose tracking software by responsible technician to assist finding root causes of overdoses. These justifications might point to patient-related (e.g. obesity, incooperative movements), technician related (e.g. choosing wrong protocol, por iso-centering), or procedure related (e.g. difficult procedure, over-length scanning) factors.

10. **Systematic image quality assessment**: FSM has an embedded module in its teleradiology system, allowing radiologists to evaluate the image quality. Quality scores are tracked on-line to maintain balance between low doses and clinically useful image quality.

11. **Periodical assessments**: Meetings to assess the standartization, justification and optimization goals. These meetings also permit detection and retrospective evaluation of severe over-exposures to be analysed by experts in the presence of responsible technologists.

12. **Optimization**: Distances of hospital DLPs to the initial DRLs (**unified pan-European DRLs**) that were determined after published data from several European countries (Switzerland, Belgium, Finland, Norway, France, Germany, Poland, UK) from 2010 onwards (9).

13. **Patient education**: Posters, banners, booklets and audiovisual materials on dose-awareness to be disseminated at imaging facilities.

14. **Creating public awareness**: Generated a lot of interest across the Anatolia North, nationally broadcasted through TVs, and found place in social media and national press. This interest has created a dose awareness throughout the country.

15. **Internal/independent audits**: To measure current state, identify process gaps and areas to bring more optimization.

**Dose Optimization Achievements**

For current dose levels, data set was from **01.01.2018 to 17.12.2018**. In that period, **102.160 individual standartized sequences for adults** covering wide range of clinical indications were available to analysis. The sequences were acquired with a 128-slices scanner that had statistical iterative reconstruction algorithms, and we have calculated DRLs for this scanner before successful implementation of dose management system and after subsequent dose optimization.

All patients were measured for length and weight before the study. For pediatric patients Broselow-Luten System for color coded protocols was used where appropriate (10). This procedure was necessary to calculate **size specific dose estimates** (SSDE) and to perform size-based CT dose optimization (11). Conventional dose data (CTDInvol and Dose Length Product) were recorded or calculated. Basic dose statistics based on protocol (DLP, minimum, P25, mean, P75, maximum), were automatically determined.
using all available patients. Detailed dose information such as SSDE, effective dose, and detailed protocol parameters were also recorded or calculated. Off isocenter shift to identify how the patient was positioned in the bore of the CT and mA modulation to visually observe how dose was optimized along the patient scan length were also presented graphically and observed to determine the optimality of technical parameters.

The current paper simplifies the study, and aims to provide the existing CT dose levels for five basic and most used protocols (i.e. *Abdomen/pelvis* follow up max 1 phase, RPID 860; *General head* helical, RPID 213; *Lumbar spine* herniation helical, RPID 1527; *Renal stone*, RPID 343; *Chest* follow-up, RPID 16).

Dose levels before (01.05.2015 to 01.08.2015, N=5.283 exams) and after optimization (01.01.2018 to 17.12.2018, N=89.587 exams) were presented. Before and after optimization comparisons with unified pan-European DRLs were made.

During preoptimization period, all doses were significantly higher than pan-European unified DRLs. Same protocol was used for different purposes; hence unoptimised dose levels (i.e. high median doses with large variability) and inconsistent image quality (as reported by radiologist from IQ feedback module of teleradiology system) were common to observe.

After appropriate trainings and technical optimizations by vendors, physicists and radiologists median and standard deviations improved significantly. For five basic protocols median dose levels decreased significantly below unified DRLs and standard deviations dropped 2 to 6 fold (Fig. 5 on page 13).

To give an example, median DLP (mGy.cm) for head protocol was 1246±337 during preoptimization, and improved to 724±158 after the optimization. These values represent an improvement of 42% in median dose level and an improvement of 53% in standard deviation (Fig. 6 on page 14).

Similar improvements were observed for all remaining protocols. For example, median DLP (mGy.cm) for thorax protocol was 291±647 during preoptimization, and improved to 168±82 after the optimization. These values represent an improvement of 42% in median dose level and an improvement of 87% in standard deviation (Fig. 7 on page 15). The most important observation was the sustainability of the improvements over three years.
**Fig. 2:** Figure 2. Continuous quality improvement list for dose excellence centers. Numbers are in order and correspond to infrastructure and processes that must be present in these institutions.

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Fig. 4: Figure 4. Geolocation of FSM Hospital. The institution (star) is situated at the heart of Anatolian side of Istanbul province. At the bottom right, is the CT scanner from which the dose data were obtained. One may also notice the dose monitoring system, an indispensable element in modern CT facilities.

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Fig. 5: Figure 5. The comparison of FSM's DLPs to unified pan-European DRLs before and after dose optimizations.

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Fig. 6: Figure 6. Three year dose data for head protocol. The sustained course of optimized dose levels is remarkable.

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Fig. 7: Figure 7. Three year dose data for thorax protocol. A remarkable and sustained reduction in median dose level and standard deviation is seen.

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Conclusion and recommendations

The concept of DRL is beginning to be a well-defined tool in many countries and is used to reduce patient dose during medical interventions and examinations. All countries should therefore try to develop concepts in order to implement and use diagnostic reference level to ensure patient doses are reduced as much as possible.

Results shown in FSM are quite promising regarding patient and population health. Our key success factor was the adoption of a wing to wing approach in dose management encompassing the whole imaging cycle. Standardization of protocols, strict adherence to and uniformity of scanning technique powered by intensive training courses and regular dose meetings, engagement at every level and awareness through data by the use of advanced IT solutions, and strong leadership are among our established standards of good practice.

FSM was used as initial host institution and a reference center for other hospitals in Anatolia North for quality assurance practices to be duplicated. It is still used by other hospitals to compare their dose management practices against established standards of good practice.
Personal/organisational information

About the primary author: Prof. Hakki Muammer Karakas, MD., is the Chief Officer and Chairman of Istanbul Provincial Public Imaging Services where 1/200 of world's radiological services are conducted. He is also the Chairman of Radiology at FSM Research and Training Hospital, Istanbul, and professor of radiology at Health Sciences University of Turkey.

About the institutions: The presentation include data from FSM Hospital. The institution belongs to and is the administrative center of 2nd Healthcare Region of Istanbul Province (a.k.a. Anatolia North). Radiology clinics of these hospitals are currently functioning as units of greater Anatolia North Radiology (ANR). The annual number of radiologic procedures in ANR are more than 4 milion and roughly represents 1/1,000th of world radiological services.

About the service provider: Advanced radiological services (CT, MRI and mammography) are being provided in many Anatolia North locations by Affidea under public private partnership. Affidea is the largest pan-European medical service provider in diagnostic radiology. According to the partnership the administrative, clinical and scientific integrity of the service is under the responsibility of the public authority, whereas the private body supplies the before-mentioned radiological equipment and technicians.

About the analyst: Analyses shown in this presentation were performed by Mr. Selim Sanje. He is a process excellence and change management expert, and is a senior project manager - lean master black belt for GEHC.
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