CLINICAL GUIDELINES: WHY, HOW AND FOR WHOM?

Pr. Guy FRIJA
Chair, EUROSAFE IMAGING
LAYING DOWN BASIC SAFETY STANDARDS FOR PROTECTION AGAINST THE DANGERS ARISING FROM EXPOSURE TO IONISING RADIATION.

MEMBER STATES HAD TO BRING INTO FORCE THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS BY FEB. 2018.
Article 55: Justification
Article 56: Optimisation
Article 57: Responsibilities
Article 58: Procedures
Article 59: Training and Recognition
Article 60: Equipment
Article 61: Special Procedures
Article 62: Special Protection during Pregnancy
Article 63: Accidental and Unintended Exposures
Article 64: Estimation of Population Doses
Article 9: Dose Limits for Occupational Exposure
Article 22: Practices involving the Deliberate Exposure for Non-medical Imaging Purposes
MEMBER STATES MUST HAVE GUIDELINES

- Article 55: Justification
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European BSS Directive 2013/59/EURATOM

MUST HAVE CIG

MUST USE CDS

SAFETY

COST CONTAINMENT

New Law Mandates Use of Imaging Appropriateness Criteria

2020
OVERUSE AND UNDERUSE OF HC SERVICES COEXIST WITHIN POPULATIONS, WITHIN SYSTEMS, AND EVEN WITHIN PATIENTS AROUND THE WORLD
DEVELOPED AND DEVELOPING COUNTRIES
Fig. 5.1: Over- and underutilization frequencies per 1000 of population for different countries. The relative contributions of the four main groups (plain radiography including dental, fluoroscopy, computed tomography and interventional radiology) are also shown. Plain radiography includes dental procedures.

**OVERUSE**

**UNDERUSE**

_Dose Datamed 2 - 2014_
AMONG 4 COUNTRIES AND 58 CLINICAL SITUATIONS, AN OVERUSE OF IMAGING IS MENTIONED 19 TIMES (32 %)

Lancet 390, 2017
MRI in mild traumatic brain injury patients

Upper-tract imaging for BPH

Imaging in low-risk prostate cancer patients

Imaging for skeletal metastases in low-risk prostate cancer patients

Contrast material use in thorax CT

Frequent DXA tests

Initial imaging for LBP

Syncope patients with non-indicated carotid ultrasound

Early stage breast cancer patients with preop advanced imaging

Contrast material use in abdomen CT

Early radiographs for LBP

Imaging for LBP

Low-risk surgery patients with chest x-ray

Lung cancer patients with combined BS and PCT

Repeated spine CTs

MRI imaging for LBP

Repeated chest CTs in 3 years
MRI in mild traumatic brain injury patients
Upper-tract imaging for BPH
Imaging in low-risk prostate cancer patients
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Repeated spine CTs
MRI imaging for LBP
CT SCANS IN THE ED: 1996-2007

VISITS: +11%

CT: +330%
USA: 30% OF INAPPROPRIATE TESTS

**Figure 4**

Heatmap of CT Utilization by Intensity
(Studies per 1000 beneficiaries)

Heatmap of MR Utilization by Intensity
(Studies per 1000 beneficiaries)
USA: 30% OF INAPPROPRIATE TESTS

- EVIDENCE OF IMAGING OVERUSE
- WORLDWIDE PHENOMENON
GUIDELINES

- BETTER USE OF MEDICAL SERVICES
- EVIDENCE BASED + EXPERT OPINION
- STARTED IN THE 1980’s
- MOSTLY EST. BY PROFESSIONAL BODIES
PRINCIPLES

- CLINICAL EFFECTIVENESS : CHOOSE THE MOST EFFECTIVE
- DOSE EXPOSURE AMOUNT : CHOOSE THE LOWEST
- COST-EFFECTIVENESS : CHOOSE THE CHEAPER
REFERRAL GUIDELINES

MANDATORY IN 97-43 DIRECTIVE

- EUROPEAN SURVEY BY THE ESR in 2014.
- AVAILABILITY OF REFERRAL GUIDELINES (~70%).
- PRODUCTION: UK AND FRANCE.
- ADOPTED AND ADAPTED: OTHERS
“In Belgium we have referral guidelines; in fact, nobody really takes them into account” …
“Referral guidelines for diagnostic imaging in general are not in use in Hungary” …
“They are not used in the Netherlands” …
“Although we have several official referral guidelines published (in Spain), they are not used generally speaking” …
“In Italy the referral guidelines were published in 2004 by the Ministry of Health. Unfortunately they are not always followed in clinical practice” …
“There is no official guide line enforcement in the State service in Ireland” …
“In Germany, the guidelines are note routinely used
“In France, there are guidelines, but they are not used” …
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MEDICARE AND PRIVATE INSURERS PRESSURES IN THE USA

PRE AUTHORISATION
RADIOLOGY BENEFIT MANAGER
LACK OF TRANSPARENCY
Preauthorization of CT and MRI Examinations
A. Blachar et al Am Coll Radiol 2006;3:851-859

Fig 1. Evaluation of the quarterly computed tomography (CT) performance rate per 1,000 standardized capita from 2000 to 2003.

Fig 2. Evaluation of the quarterly magnetic resonance imaging (MRI) performance rate per 1,000 standardized capita from 2000 to 2003.
EFFECTIVENESS OF ORDER CHECKING

- RETROSPECTIVE STUDY IN MY INSTITUTION HEGP LOOKING AT APPROPRIATENESS.
- 2 BLINDED SENIORS REVIEWED 100 CT SCANs OF HEAD, CHEST-ABDOMEN, MUSCULOSKELETAL EACH

**APPROPRIATENESS**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Appropriateness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>87%</td>
</tr>
<tr>
<td>Chest-Abdomen</td>
<td>85%</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>98%</td>
</tr>
</tbody>
</table>
RETROSPECTIVE STUDY IN MY INSTITUTION HEGP LOOKING AT APPROPRIATENESS.

2 BLINDED SENIORS REVIEWED 100 CT SCANS OF HEAD, CHEST-ABDOMEN, MUSCULOSKELETAL EACH

APPROPRIATENESS

HEAD 87% NO CHECKING
CHEST-ABDOMEN 85% NO CHECKING
MUSCULOSKELETAL 98% CHECKING
LESSONS

- BEYOND REGULATION
- PRE AUTHORIZATION IS EFFECTIVE
- INTERNAL CHECKING IS EFFECTIVE
GUIDELINES’ LIMITATIONS

- GENERIC, RIGID: POPULATION-BASED AND NOT PATIENT-CENTRIC
- MOSTLY BASED ON CONSENSUS APPROACH RATHER THAN ON EVIDENCE: LACK OF RELEVANT PUBLICATIONS
- NOT INTEGRATED INTO THE WORKFLOW AND NOT AT THE POINT OF CARE
- COST CONTAINMENT ORIENTED
- NOT SUPPORTED BY OTHER SPECIALTIES
- NOT SUPPORTED BY A GLOBAL POLICY
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Better Use

Regulation

Guidelines

WF INTEGRATION

PATIENT CENTRIC

CDS
CONCEPT OF CDS

- **Answer to a Clinical Question**
- **Provide Guidance Based on Appropriateness Criteria**
- **Integrated in the Physician Workflow**
HAS THE TEST ALREADY BEEN DONE?
CDS can check for prior exams for the same patient

IS THE NECESSARY INFORMATION PROVIDED?
CDS requires referrers to submit a clear reason for the exam

WHAT IS THE RIGHT TEST?
CDS provides feedback on the appropriateness of different modalities for a clinical indication

IS IMAGING NEEDED?
CDS provides feedback whether imaging is the best answer
CDS ADVANTAGES

- Access to guidelines
- Adaptable and scalable
- Proven efficiency in the literature
FROM PAPER TO SOFTWARE

From James Brink, MGH
FROM PDF TO ALGORITHM
1. SELECT TEST

- **BASIC TRANSACTIONAL WORKFLOW**

2. ENTER REASON FOR EXAM

3. FEEDBACK

**Modalities**
- CT
- DXA
- END
- FLUOR
- INV
- MAM
- MEG
- MR
- NUC
- PEM
- PET
- PET-CT
- US
- US-XRAY
- XRAY

**Body Areas**
- abdomen
- abdominal aorta
- chest
- heart
- lower extremity
- neck
- pelvis
- spine
- upper extremity

**Clinical Indications**
- Abnormal gait (ataxia)
- Abnormal gait, progressive, or long duration
- Ataxia, acute or sub-acute, infection suspected
- Ataxia, after head trauma (24+ hours)
- Ataxia, after head trauma (24-19 hours)
- Ataxia, 24 hours
MR imaging of the lumbar spine with symptom of “back pain improved with exercise” and abnormal x-ray e.g. degenerative joint disease.
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MASSACHUSETTS GENERAL HOSPITAL
HIGH COST IMAGING

EFFECTS OF CDS 2000 - 2007

= TOTAL EXAMS

= ORDERED WITH CDS

Quarters 2000-2007

From Keith Dreyer MGH
Radiology Utilization in the Emergency Department Ali S. Raja et al., DOI:10.2214/AJR.13.11892
HOW

REGULATION

CENTIVES

CDS: EFFECTIVE

VOLUME

APPROPRIATENESS

WF INTEGRATION

PATIENT CENTRIC
- **American College of Radiology (ACR)**
  - The Content
- **National Decision Support Company (NDSC)**
  - The Platform
- **Introduced in the United States in 2012**
  - “ACR Select”
TRANSATLANTIC PARTNERSHIP

AMERICAN COLLEGE OF RADIOLOGY (ACR), i.e.

“THE CONTENT

NATIONAL DECISION SUPPORT COMPANY (NDSC), i.e.

INTRODUCED IN THE UNITED STATES IN 2012

“ACR SELECT”
TRANSATLANTIC PARTNERSHIP

ESRF + NDSC Licensing, Platform and Support = ESRF iGUIDE
EUROPEANISATION

- Adaptation of ACR AC to European standards of practice, incorporating evidence from the latest studies.
- Scientific review by ESR experts started in November 2014.
- Overseen by dedicated methodologist.

1,600 indications with associated exams incl. appropriateness ratings for defined patient groups.
DISCREPANCIES: 9%

Breast: 2%
Urinary: 0%
MSK: 4%
Brain: 7%
Cardiac: 28%
Vascular: 7%
Chest: 1%
Women’s: 0%
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RESULTS FROM 4 IMPLEMENTATIONS IN CROATIA

TOTAL CROATIA

- Integrated with local HIS system
- In-house doctors only
- Advisory feedback not shown
- All modalities included
- Structured indications compulsory

LARGE HOSPITAL

MEDIUM-SIZED

SMALL

UNIVERSITY

BASELINE
Appropriateness of referrals with ESR iGuide
Example from hospital implementation in Croatia
November 2016-September 2017, 55,000 DS sessions
### ESR iGUIDE PILOT PROJECT SWEDEN RESULTS

- **URL integration with optional CDS workflow (technically limited integration)**
- **Users can “jump out” of the CDS workflow at multiple points**

Based on results, a full integration of ESR iGuide was approved to improve the user experience.

**Non-CDS referrals**
- Inappropriateness rate 10%

**CDS referrals**
- Inappropriateness rate 1%
BARCELONA PILOT

- Preparation and adaptation of the solution
- Strategy definition
- Installation and deployment of the solution
- Follow up and analysis of data

Month 1
- Kick-off
- Strategy validation
- Adaptation of the solution

Month 2

Month 3

Month 4

Month 5
- Service startup

Month 6
GLOBAL PLAN SUPPORTED BY THE INSTITUTION
CHANGE MANAGEMENT
TRAINING OF PHYSICIANS
TRAINING OF IMAGING TEAM
HAND IN HAND WITH IT DEPARTMENT
- **HUNGARY**: Negotiations over country-wide portal licence
- **BELGIUM**: Ministry of Health has decided to start 9 pilot projects as part of a national programme
- **TURKEY**: ESR letter to Ministry of Health sent to facilitate coordinated pilot projects
- **DOHA**: Health Authority has confirmed intent to start a pilot implementation
- Request from **AFROSAFE** to adopt ESR IGuide and to pilot them in 3 English speaking countries with the support of IAEA
- **ONGOING PILOTS**: CAIRO (D.HUSSEINY), UGANDA (M.KAYOWA)
ESR iGUIDE ARCHITECTURE

ESR GUIDELINES ARE CONTINUOUSLY UPDATED

CLOUD PLATFORM AVAILABLE AT THE POINT OF PATIENT CARE
ESR iGUIDE ARCHITECTURE

ESR GUIDELINES ARE CONTINUOUSLY UPDATED
ORDER CHANGE
DUPLICATION
« RED ORDER »
WEB PORTAL

ESR iGUIDE PLATFORM

CDS/CPOE

EHR/HIS/RIS

INTEGRATION
FREE ACCESS FOR
RADIOLOGISTS ESR GOOD
STANDING MEMBERS

WEB PORTAL

INTEGRATION

ESR iGUIDE PLATFORM

CDS/CPOE

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WEB PORTAL

ESR iGUIDE PLATFORM

STEP 1

STEP 2

INTEGRATION

EHR/HIS/RIS

CDS/CPOE
FREE ACCESS FOR RADIOLOGISTS ESR GOOD STANDING MEMBERS

WEB PORTAL

CDS

EHR/HIS/RIS

INTEGRATION

CDS/CPOE

STEP 3
FOR WHOM

- PHYSICIAN REQUESTER
- IMAGING TEAM
- REGULATORY BODY
- HEALTH AUTHORITY
FOR WHOM

- GLOBAL PLAN WITH PHYSICIANS
- CLEAR IDENTIFICATION OF RESPONSIBILITIES
- POLITICAL SUPPORT FROM HEALTH AUTHORITIES
EUROSAFE IMAGING CALL FOR ACTION 2018

**ACTION 1**
Disseminate guidelines and develop implementation policies for a clinical decision support system (ESR iGuide) in Europe

**ACTION 2**
Develop clinical diagnostic reference levels (DRLs) for adults and children

**ACTION 3**
Develop image quality assessment based on clinical indications

**ACTION 4**
Promote dose management systems to establish local, national, and European DRLs

**ACTION 5**
Develop performance indicators for radiation protection management

**ACTION 6**
Implement a clinical audit tool for imaging to improve the quality of patient care

**ACTION 7**
Radiation protection of children; develop guidance for good and safe use of imaging, and for effective communication

**ACTION 8**
Organise radiation protection training courses and develop e-learning material to promote safety culture and raise awareness on radiation protection

**ACTION 9**
Support research in advanced topics of radiation protection, e.g. artificial intelligence, as well as facilitate the dissemination and facilitate the dissemination and translation into clinical practice of this research

**ACTION 10**
Strengthen the EuroSafe Imaging Stars network of imaging centres that embody best practice in radiation protection

**ACTION 11**
Establish a dialogue with industry regarding improvement of radiological equipment, the use of up-to-date equipment (e.g., dose management systems) and the harmonisation of exposure indicators

**ACTION 12**
Improve information for and communication with patients about radiological procedures, related benefits and possible risks

**ACTION 13**
Engage with stakeholders and collaborate with related initiatives and regulatory authorities in Europe and beyond to contribute to a global safety culture in medical imaging
EUROSAFE IMAGING CALL FOR ACTION 2018

DISSEMINATE GUIDELINES AND DEVELOP IMPLEMENTATION POLICIES FOR ESR iGUIDE, THE ESR CDS
PROFESSIONAL SOCIETIES

- TOOLS
- AWARENESS: HCP, PATIENTS
- INTERFACE WITH AUTHORITIES
- INTERFACE WITH OTHER SPECIALTIES
- CAMPAIGNS: AFROSAFE - ARABSsafe
A HOLISTIC APPROACH

- Justification is only a part of the safety and quality concept.
- A holistic approach rather than a focused one on imaging justification.
- Expand to lab tests, drug prescription.
- Liaise with health policy makers.
NATIONAL HEALTH POLICY

- MULTI-APPROACH
- REGULATION
- INCENTIVES
- CONSTRAINTS
CHANGE IN PARADIGM

PRODUCING GUIDELINES → USING GUIDELINES
MERCI  !!!!!!!