

Legislative aspects related to the release of the nuclear medicine patient in Europe

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Why a release process?

- The release process aligns with the optimization of radiation protection
- The release process ensures that the radiation dose to individuals is minimized
- The release process allows the patient to return to normal life

Balancing

Beneficence

Medical benefits of the therapeutic or diagnostic procedure for the patient



Non-Maleficence

By controlling when and how a patient is released, the risk of harm to the patient, their family, and the public is minimized

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The level of restrictions

EURATOM BSSD

- Member States shall ensure that dose constraints are established
 - Occupational exposure
 - Public exposure
 - Medical exposure
 - protection carers/comforters/volunteers
- Dose constraints
 - Individual effective or equivalent doses
 - Defined appropriate time period



Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

EURATOM BSSD

- Related to the dose constraint for public exposure and exposure of comforters and carers
 - Need for adequate release criteria of patients from the hospital
 - Provision of instructions



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EURATOM BSSD

- “Member States shall ensure that in case of a patient undergoing **treatment or diagnosis with radionuclides**”
- Patient or representative should be provided with information on risks
 - Appropriate instructions to restrict doses to persons in contact (AFARA)
 - Written instructions for therapeutic procedures
 - Instructions shall be handed out before leaving the hospital

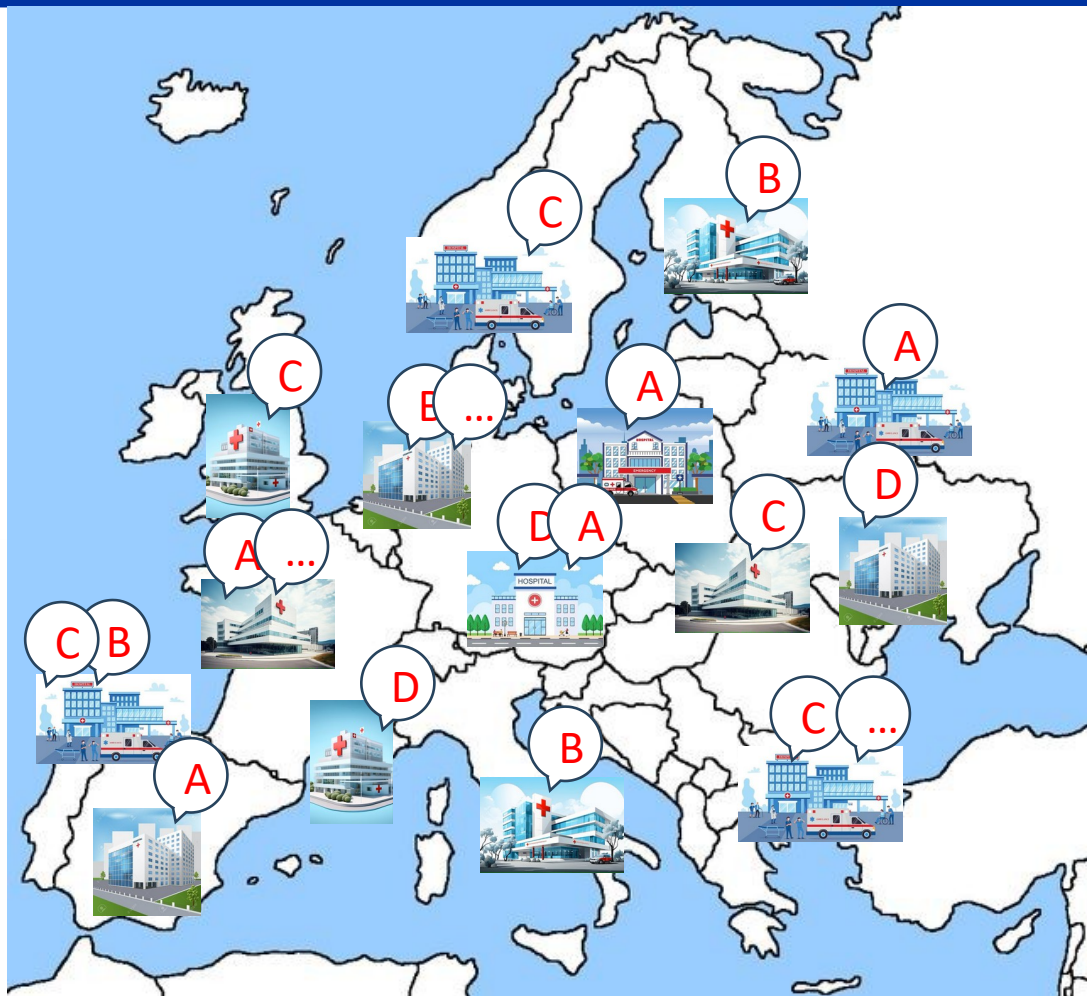


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Over the years...



Today...



Heterogeneity

Dose constraints

Release criteria

Release instructions

Regional differences within same country

Difference of non-written instructions
(diagnostic procedures) expected within the
same hospital

Heterogeneity confirmed during Simplerad

SAMIRA Study on the Implementation of the Euratom and EU Legal Bases with Respect to the Therapeutic Uses of Radiopharmaceuticals

S
Simplerad

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2022-2024

*The information and views set out in the SIMPLERAD report are those of the authors and do not necessarily reflect the official opinion of the EUROPEAN Commission

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Simplerad objectives

- Understanding of the links and interdependencies between the European pharma legislation and Euratom RP requirements
- Propose practical guidance and explore quality and radiation safety issues
 - Current use and introduction of novel therapeutic radiopharmaceuticals
 - Implementation of patient dosimetry
 - Role of MPEs
 - Release of patients from hospitals
 - Management of radioactive waste

Simplerad methodology

- WP1: analysis of the interrelations between EU pharma legislation and Euratom BSSD requirements for therapeutic nuclear medicine
- WP2: survey on the implementation of the relevant European legal requirements
- WP3: recommended actions to advance the coherent implementation of the European legal requirements
- WP4: project workshop

Survey dose constraints / release criteria

As part of WP2: survey among stakeholders

Health professionals

Competent authorities

National societies

National training bodies

Industry

193 valid responses

Survey dose constraints / release criteria

Are you familiar with the concept of dose constraints for comforters/carers/public?



Yes! ~ 70% respondents

Survey dose constraints / release criteria

**Can you provide further information
regarding these constraints ?**



Variety of answers

- Numerical effective dose value of a constraint
- Numerical effective dose value of the public dose limit
- Decision of practitioner
- Release criterion or dose rate
- Reference to national regulations

Survey dose constraints / release criteria

Numerical effective dose value of the dose constraint?



Variety of answers

- No specific numerical value
- Specific numerical value and difference between public and comforters/carers (age-dependent)
- “Appropriate time period” translated into “per y”/ “per treatment cycle” / “per single procedure”

Survey dose constraints / release criteria

Guidance provided concerning patient instructions and release criteria?



Yes ~ 50% respondents

Survey dose constraints / release criteria

Specific release criteria (^{177}Lu)

- Time post administration
- Measured dose rate @ 1 m
- Time post administration and measured dose rate @ 1 m

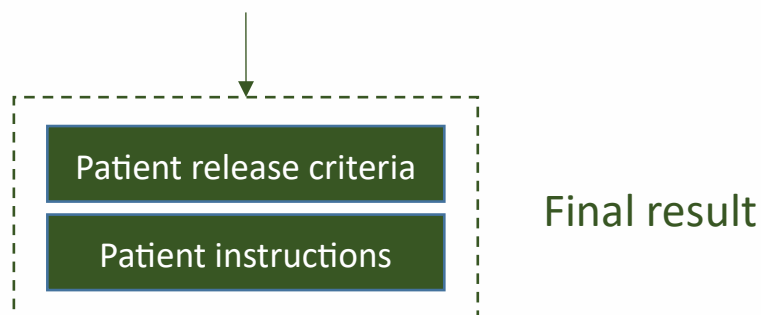
Country	^{177}Lu -DOTATATE	^{177}Lu -PSMA
A	48h	48h
B	None	None
C	< 20 $\mu\text{Sv/h}$ @ 1 m	< 20 $\mu\text{Sv/h}$ @ 1 m
D	24h	< 25 $\mu\text{Sv/h}$ @ 1 m
E	< 30 $\mu\text{Sv/h}$ @ 1 m	< 30 $\mu\text{Sv/h}$ @ 1 m
F	24h and < 20 $\mu\text{Sv/h}$ @1 m	24h and < 20 $\mu\text{Sv/h}$ @1 m
G	< 20 $\mu\text{Sv/h}$ @ 1 m	6 h

Simplerad survey

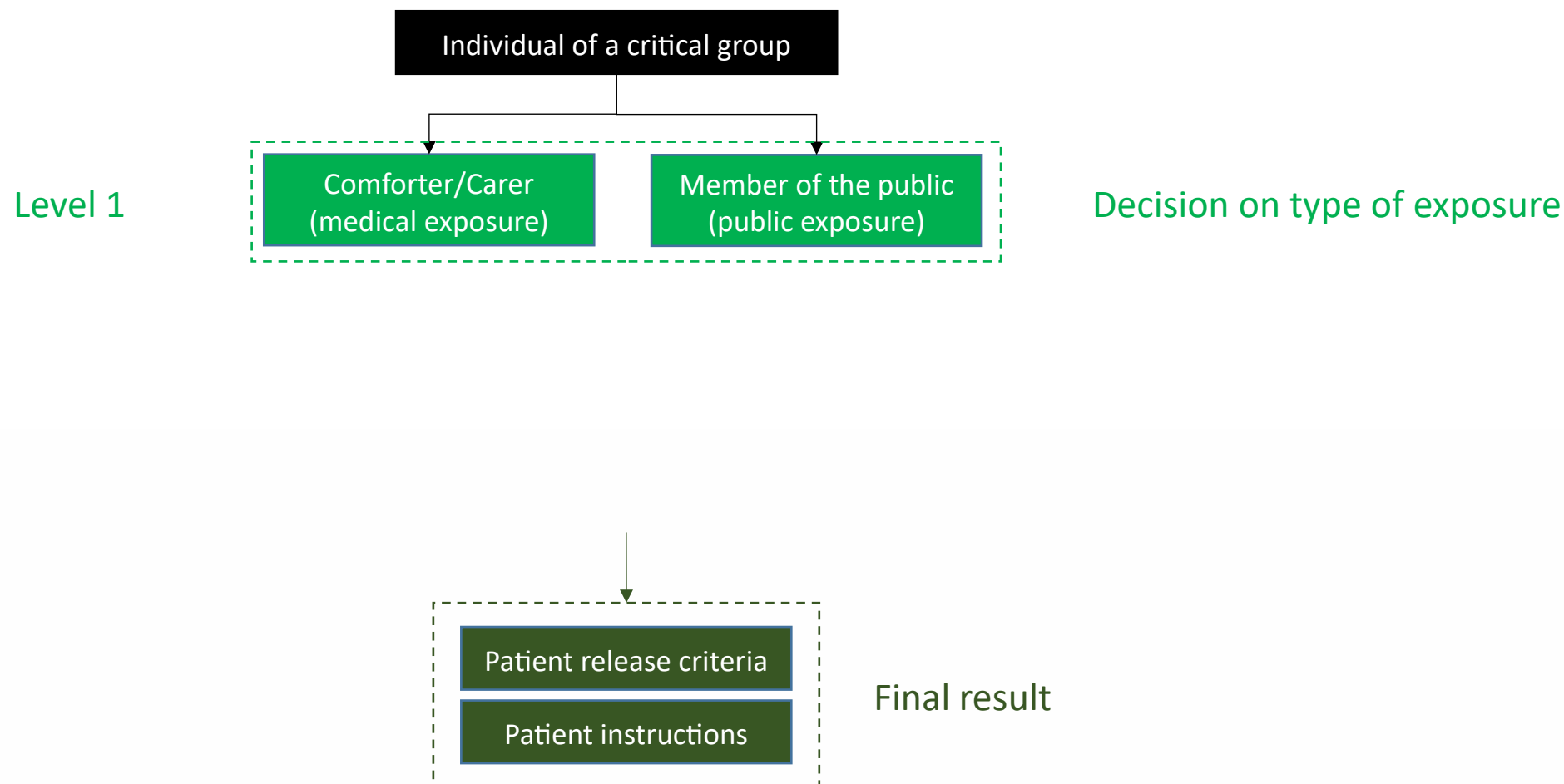
- Highlighted once more the heterogeneity
 - Dose constraints
 - Release criteria
- Responsibility for setting dose constraints and release criteria varies across member states and were either established by
 - Competent authorities
 - Professional bodies /societies
 - Treating centres
- Different criteria and decision levels can influence this setting...

Decision levels in setting release criteria

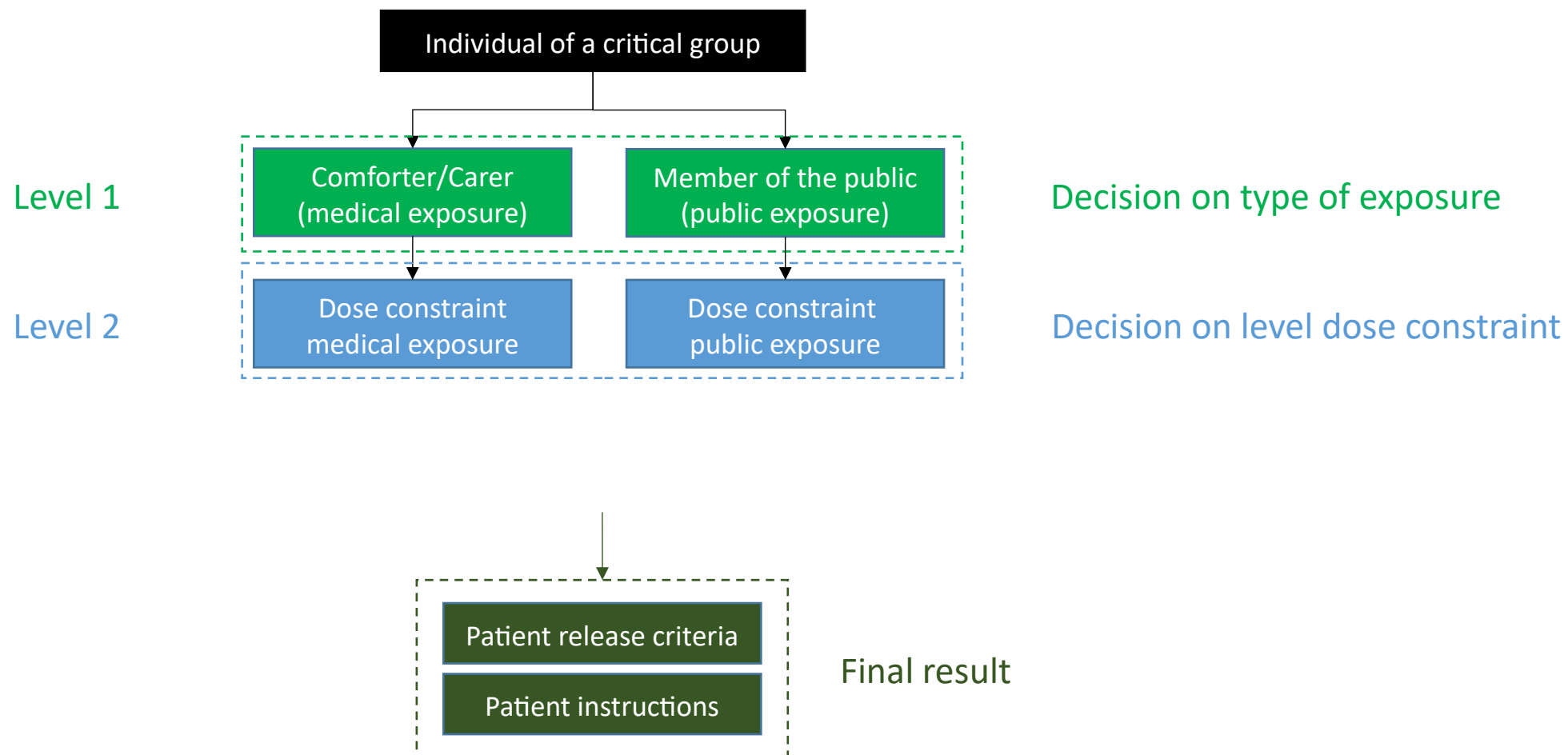
Individual of a critical group



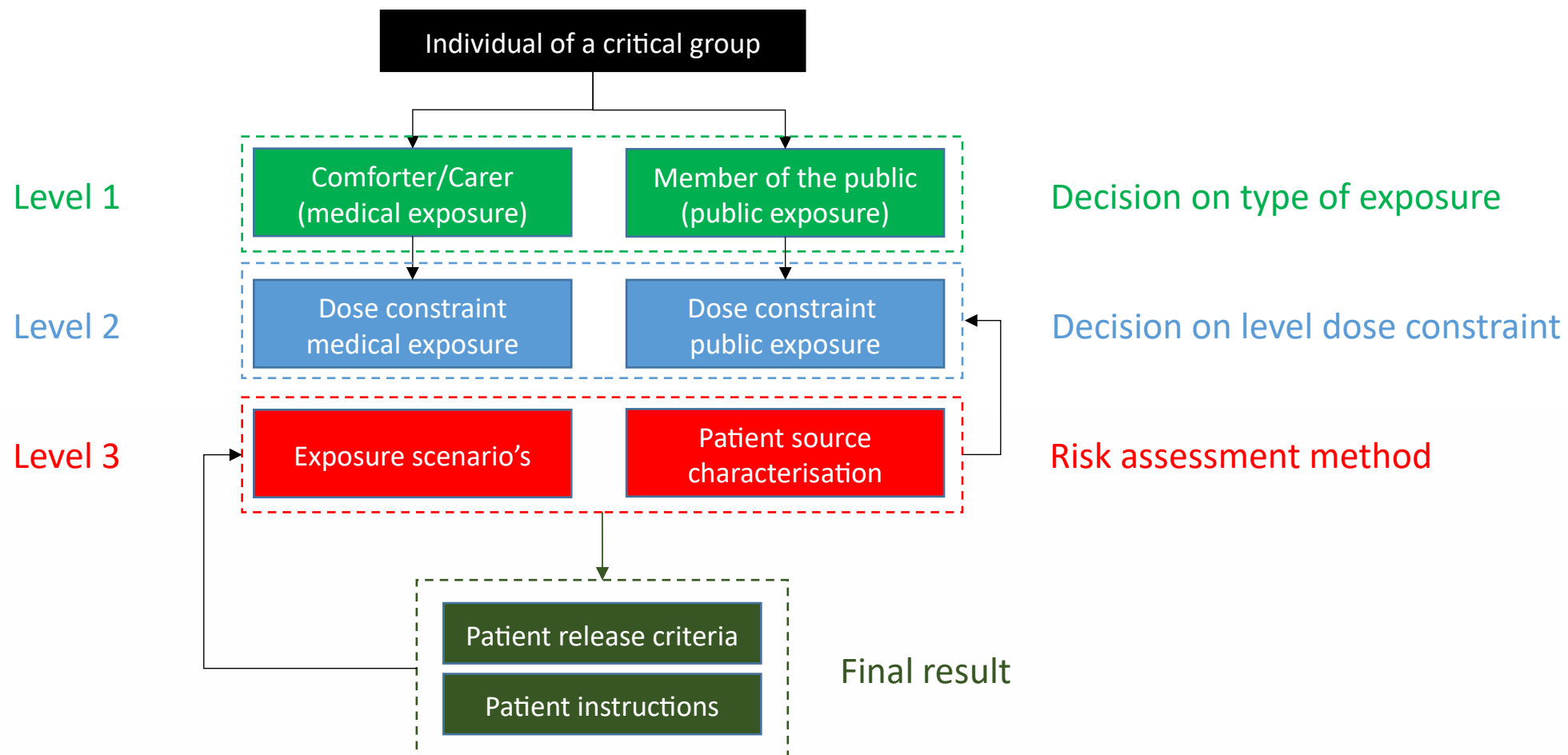
Decision levels in setting release criteria



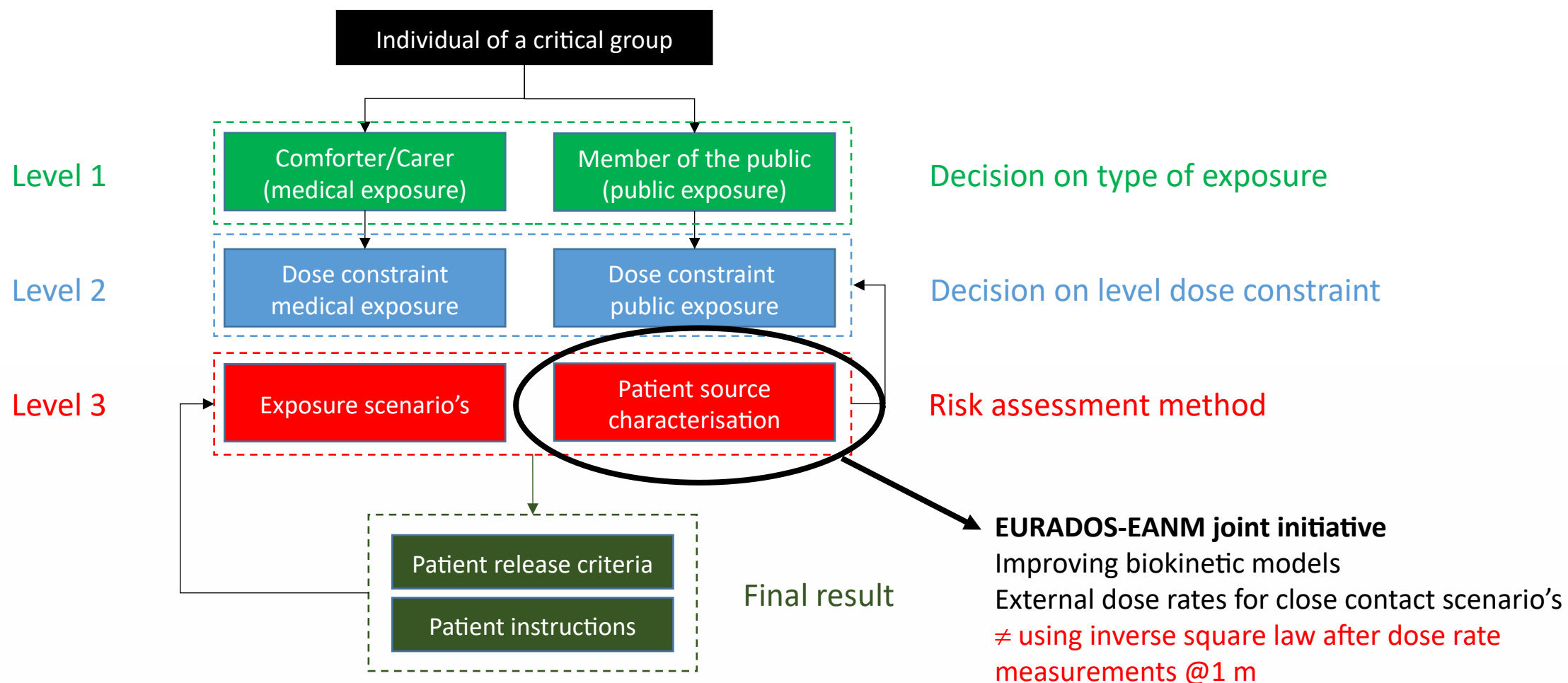
Decision levels in setting release criteria



Decision levels in setting release criteria



Decision levels in setting release criteria



Some of Simplerad proposed potential remedies...

➤ Generation of data

- EU-database of measured doses to family members and comforters and carers
- EU-database for dose rates and excretion factors, including biokinetic data

➤ Guidance documents

- Helping in the decision of which individuals and in which situations they can or should be considered as a comforter or carer or as a member of the public
- To explain differentiation between limits and constraints and propose constraints for the public and comforters and carers for nuclear medicine procedures. This should involve national competent authorities and HERCA.

To conclude...

- The release process of nuclear medicine patients following both therapeutic and diagnostic procedures still vary widely
- Simplerad project confirmed this finding, identified factors and proposed potential remedies
- Different initiatives at different decision levels could help to harmonise

Thanks for the attention