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Establishment Of Institutional Diagnostic Reference Levels (DRL) For Gallium-68 (Ga-68) FAPI PET/CT: A Preliminary Single-Center Pilot Study In Indonesia

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The radiopharmaceutical Gallium-68 Fibroblast Activation Protein Inhibitor (Ga-68 FAPI) offers high diagnostic superiority in nuclear oncology. However, as a modality that has only recently been adopted in Indonesia, there is currently a lack of reference dose data or Diagnostic Reference Levels (DRLs) to guide radiation protection optimization. Consequently, this study aims to establish institutional DRLs for injected activity and CT dose parameters (CTDIvol and DLP) specifically for Ga-68 FAPI PET/CT. A retrospective pilot study was conducted on 46 patients (15 males, 31 females; mean age 57 years) who underwent examinations at the Department of Nuclear Medicine between September 17 and November 26, 2025. All examinations were performed using a GE Discovery IQ Gen 2 PET/CT system. Diagnostic image quality was qualitatively assessed to ensure all scans included in the analysis were clinically acceptable. The institutional DRL was determined as the 75th percentile value (P75) with 95% Confidence Intervals (CI). The mean patient body weight was 54.68 ± 10.5 kg. The established institutional DRL values are Injected Activity of 118.23 MBq, CTDIvol of 6.75 mGy, and DLP of 917.45 mGy.cm. Based on the DLP/CTDIvol ratio, the mean scan length was estimated at 135.9 cm. This study presents the first preliminary DRL data for Ga-68 FAPI in Indonesia. While limited by sample size, the results demonstrate the feasibility of optimized radiation doses using high-sensitivity detector technology. These values serve as a baseline for future multi-center surveys.
Keywords: CTDIvol, Diagnostic Reference level, DRL, Ga68, Injected activity.

I. INTRODUCTION

Diagnostic Reference Levels (DRLs) are recognized globally as essential tools for optimizing patient protection in medical imaging. According to the International Commission on Radiological Protection (ICRP) Publication 135, DRLs serve as a standard metric to identify imaging procedures where patient dose levels are unusually high or low, thereby triggering a review to ensure optimization . In the context of nuclear medicine, the establishment of DRLs is particularly complex due to the hybrid nature of Positron Emission Tomography/Computed Tomography (PET/CT). This modality combines metabolic imaging with anatomical information, meaning the total patient dose is the sum of two distinct exposures: the internal exposure from the injected radiopharmaceutical activity and the external exposure from the CT acquisition used for attenuation correction and localization (1). Consequently, optimizing patient safety necessitates the independent evaluation of both components.

In the evolving landscape of molecular imaging, Gallium-68 Fibroblast Activation Protein Inhibitor (Ga-68 FAPI) has emerged as a significant breakthrough. Foundational research by Giesel et al. (2019) confirmed that FAPI possesses a superior signal-to-background ratio compared to the standard F-18 FDG, particularly in detecting malignancies with low glucose uptake [2]. However, despite these diagnostic advantages, the introduction of new radiotracers introduces new challenges in dosimetry. While DRLs for

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established procedures like F-18 FDG are well-documented in international guidelines, data regarding novel tracers like Ga-68 FAPI remains scarce.

In Indonesia, the Nuclear Energy Regulatory Agency (BAPETEN) mandates the implementation of DRLs as part of the radiation protection program. While BAPETEN has successfully initiated the establishment of national DRLs (I-DRLs) for general radiology modalities such as X-ray and CT scans, specific national DRLs for nuclear medicine procedures especially for novel tracers like Ga-68 FAPI—have not yet been established[3]. This situation mirrors challenges faced globally, similar to the context described in the Istisan Report 20/22 in Italy, which highlights that while DRLs for major procedures exist, guidelines for new PET tracers and the associated low-dose CT components are often unavailable or outdated [4].

Given the dynamic nature of nuclear medicine, where technological innovations in scanners and new tracers are rapidly adopted, relying on static or generic DRLs is insufficient. There is an urgent need for a dynamic process to set and update DRL values that reflect current clinical capabilities. This is especially pertinent when utilizing state-of-the-art technology, such as the digital PET/CT systems, which offer higher sensitivity and the potential for significant dose reduction.

Therefore, to bridge the gap between the rapid clinical adoption of Ga-68 FAPI and the lack of regulatory dose benchmarks in Indonesia, this study aims to establish a Local Diagnostic Reference Level (LDRL) based on clinical practice. Utilizing the latest generation of PET/CT technology, this study provides a preliminary reference for both injected activity and CT dose parameters (CTDIvol and DLP), serving as a baseline for future optimization efforts in the region.

II. MATERIAL AND METOHDS

2.1 Study Design and Population

This study employed a retrospective observational design framed as a pilot study. Data were collected from patients who underwent Whole Body Gallium-68 Fibroblast Activation Protein Inhibitor (Ga-68 FAPI) PET/CT examinations at the Department of Nuclear Medicine Dr. Hasan Sadikin General Hospital. Given the novel status of Ga-68 FAPI in Indonesia, a total sampling method was used for the initial period (September 17 to November 26, 2025), resulting in 46 eligible patients. While this sample size is below the general recommendation for national DRLs, it serves as a preliminary institutional benchmark for a new modality.Inclusion Criteria:

1. Adult patients (≥21 years) who underwent a complete whole-body Ga-68 FAPI PET/CT examination.
2. Data on injected activity (MBq) and CT dose parameters (CTDIvol and DLP) were complete and recorded in the dose report.
3. Examinations performed using the standard Whole Body protocol (Vertex to Mid-Thigh).

Exclusion Criteria:

1. Pediatric patients (<18 years).
2. Incomplete examinations or partial scans (e.g., brain-only or limited area).
3. Scans with severe technical artifacts (e.g., patient motion causing misalignment, contrast extravasation) that rendered the images non-diagnostic.

2.2 Data Acquisition and Scanning Protocol

Data were acquired retrospectively using a GE Discovery IQ Gen 2 PET/CT system. A standardized protocol was strictly followed to ensure data consistency and image quality optimization. Patient Preparation and Injection: Unlike FDG PET, strict fasting was not required; however, patients were instructed to maintain adequate hydration. Ga-68 FAPI was injected intravenously. The institutional protocol employs a weight-based guideline of approximately 2 MBq/kg. However, actual administered activity was adjusted based on clinical discretion, vial availability, and radiation safety limits, resulting in a fixed operational range typically between 100-200 MBq for standard adult patients. This hybrid approach accounts for the lower average body weight of the

Indonesian population while ensuring sufficient count statistics. Following the injection, patients underwent a resting uptake period of approximately 60 ± 10 minutes to allow for optimal biodistribution and background clearance. Image Acquisition: The standard scanning range covered from the vertex to the mid-thigh. Although quantitative SNR analysis was not performed retrospectively, all scans included in this study were verified as diagnostically adequate by a qualified nuclear medicine physician. No scans were repeated due to poor image quality or insufficient counts, confirming that the administered activities were sufficient for clinical diagnosis.

1. CT Parameters: A helical CT acquisition was performed primarily for attenuation correction (CTAC) and anatomical localization using a Low-Dose protocol. The acquisition utilized the SmartmA automatic exposure control system with a tube current range of 15–100 mA (adjusted to Noise Index). The scan was acquired with a tube voltage of 120 kVp, a gantry rotation time of 0.8 s, a slice thickness of 3.75 mm, and a helical pitch of 0.984:1.
2. PET Parameters: Immediately following the CT scan, PET emission data were acquired in 3D mode over the same scan range. The acquisition was performed using a multi-bed position technique to cover the vertex-to-mid-thigh range. The acquisition time per bed position was optimized (typically 2–3 minutes) to ensure sufficient count statistics given the short half-life of Gallium-68.

Reconstruction: CT images were used for attenuation correction. PET images were reconstructed using the vendor-standard iterative algorithm compatible with the LightBurst detector technology.

2.3 Statistical Analysis

Statistical analysis was performed using Microsoft Excel. The acquired dosimetric data specifically Injected Activity (MBq), Volume CT Dose Index (CTDIvol), and Dose Length Product (DLP) were compiled and analyzed descriptively. To establish the Local Diagnostic Reference Levels (LDRLs) and Typical Values, the data distribution was calculated as follows:

1. Typical Value: Defined as the median value (50th percentile) of the distribution.
2. Local DRL: Defined as the 75th percentile of the distribution, in accordance with ICRP Publication 135 recommendations [1].

Furthermore, the Scan Length was mathematically estimated from the ratio of DLP to CTDIvol to verify the consistency of the Whole Body coverage relative to patient height. Given the absence of established national DRLs for Ga-68 FAPI in Indonesia, the results were compared with available international literature and guidelines for similar procedures. To address the uncertainty associated with the limited sample size, 95% Confidence Intervals (CI) for the P75 values were estimated using non-parametric methods appropriate for skewed distributions.

III. RESULTS

3.1 Subject Characteristics and General Data

After undergoing the data validation process, a total of 46 patients met the inclusion criteria and were analyzed. The population of patients included in this study consisted of 31 females (67.4%) and 15 males (32.6%). Complete descriptive statistics for the demographic characteristics of the research subjects are presented in Table 1.

Table 1. Descriptive Statistics of Subject Characteristics (N=46)

Parameter	Mean ± SD	Median	Minimum	Maximum
Age (years)	57±15.25	57.5	21	82
Body Weight (Kg)	54.86±10.5	54	32	94
Height (cm)	158.43±7.95	158.00	141	180

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The data in Table 1 depict the demographic profile of the study population. The mean age of 57.00 years represents a typical adult oncology patient population. A significant finding is the mean body weight of 54.68 kg, which is relatively low compared to Western populations. This anthropometric characteristic is a key determinant in dosimetry, as both the radiopharmaceutical distribution volume and the attenuation of X-rays in CT are directly proportional to body mass. The wide range of body weight (32 kg to 94 kg) indicates heterogeneity within the sample, necessitating the use of weight-based injection protocols and automatic exposure control in CT to ensure dose optimization.

3.2 Establishment of Local DRLs and Comparison

Local Diagnostic Reference Level (LDRL) values, which represent the dose practice for 75% of patients (P75), were established in accordance with ICRP Publication 135. These values serve as investigational levels to identify non-optimized practices [1]. The proposed LDRL values for the Ga-68 FAPI Whole Body examination at this institution are 118.23 MBq (95% CI: 98,53-119,80) for Injected Activity, 6.75 mGy for CTDIvol, and 917.45 mGy.cm for DLP. The variance between the theoretical weight-based dose (54.68 kg x 2 MBq/kg ≈ 109 MBq and the LDRL (118 MBq) reflects minor operational variations but remains within an optimized range.The distribution statistics are detailed in Table 2.

Table 2. LDRL Establishment and Typical Values

Dosimetry Parameter	Typical Value (Median/P50)	LDRL (P75)	Mean±SD	95% Confidence Interval
Injected Activity (MBq)	101.57	118.23	109,17±36,80	98,53-119,80
CTDIvol (mGy)	6.02	6.75	6,14±1,31	5,76-6,53
DLP (mGy.cm)	781.50	917.45	817,29±217,21	754,52-880,07

The established LDRL for Injected Activity (118.23 MBq) is significantly lower than the national DRL for conventional F-18 FDG in Indonesia (340 MBq) [1]. This demonstrates a high level of optimization. The efficiency is driven by two factors:

1. Tracer Kinetics: Ga-68 FAPI exhibits a superior target-to-background ratio compared to FDG, allowing for high-contrast images even at lower activities.
2. Scanner Technology: The study utilized the GE Discovery IQ Gen 2, which features high-sensitivity *LightBurst* PET detectors. This technology enhances the count rate sensitivity, enabling dose reduction without compromising image quality.

The LDRL for CTDIvol (6.75 mGy) confirms the strict adherence to a Low-Dose CT protocol intended for attenuation correction and localization. This value is comparable to or lower than international standards for PET/CT tumor imaging, such as those reported in Japan (6.1 mGy) and Korea (5.96 mGy), and significantly lower than diagnostic CT levels. This indicates that the Automatic Tube Current Modulation (SmartmA) system effectively down-regulated the tube current (mA) in response to the lower average body weight of the patient population (54.68 kg).

3.3 Dose Determinants: Scan Length and Body Size

While Body Mass Index (BMI) is often used to stratify doses, the Dose Length Product (DLP) in Whole Body scanning is uniquely influenced by the vertical coverage of the scan.

In this study, the LDRL for DLP was 917.45 mGy.cm. By analyzing the relationship between the integral dose (DLP) and the radiation intensity (CTDIvol), the average Scan Length can be mathematically derived:

$$\text{Scan Length} = \frac{\text{DLP (P75)}}{\text{CTDIvol (P75)}} = \frac{917.45}{6.75} = \sim 135.9 \text{ cm}$$

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This estimated scan length of ~136 cm is highly consistent with the anatomical coverage of a "Vertex to Mid-Thigh" protocol for a population with an average height of 158.43 cm. It implies that approximately 22 cm of the lower extremities (mid-tibia to feet) were excluded from the scan, which is standard practice for oncological screening unless specific distal metastasis is suspected.

This finding confirms that the relatively low DLP values observed in this study are not only due to low radiation intensity (low CTDIvol) but also due to precise scout view planning by the radiographers. By strictly limiting the scan range to the clinically relevant anatomy (Vertex to Mid-Thigh) and avoiding "overscanning" into the lower legs, the total integral radiation burden to the patient is minimized. This highlights the importance of anatomical scan length adaptation as a simple yet effective method of radiation protection optimization.

IV. DISCUSSION

4.1 Optimization of Injected Activity

The established LDRL for injected activity of 118.23 MBq is considered low when compared to conventional nuclear medicine standards. This value is significantly lower than the national DRL for conventional F-18 FDG in Indonesia (340 MBq) [3]. This efficiency demonstrates a high level of optimization driven by two primary factors. First, regarding tracer kinetics, Ga-68 FAPI exhibits a superior target-to-background ratio compared to FDG, allowing for high-contrast images even at lower activities [5]. Second, regarding scanner technology, the study utilized the GE Discovery IQ Gen 2 system equipped with high-sensitivity LightBurst PET detectors. As noted by Surti & Karp, advances in digital detector technology enhance count rate sensitivity, enabling significant dose reduction without compromising diagnostic image quality [6]. This capability allowed the department to adhere to a weight-based protocol (2 MBq/kg) adapted to the Indonesian population's lower average body weight (54.68 kg).

4.2 CT Dose Management and Scan Length Accuracy

Regarding the external radiation component, the LDRL CTDIvol value of 6.75 mGy confirms the strict adherence to a Low-Dose CT protocol intended solely for attenuation correction and localization. This value is well below the typical diagnostic CT range and aligns with the recommendations by Brix et al., who noted that a CTDIvol of <10 mGy is optimal for tumor PET/CT studies to ensure that the patient's radiation burden remains minimal [7]. The achievement of this low-dose level is further facilitated by the SmartmA (Automatic Tube Current Modulation) technology, which down-regulated the tube current in response to the smaller body habitus of the study population.

Furthermore, the derived scan length of ~136 cm (calculated in Section 3.3) correlates strongly with the anthropometric data of the study population. With an average patient height of 158.43 cm, a scan length of 136 cm confirms that the "Vertex to Mid-Thigh" protocol was accurately executed. It implies that approximately 22 cm of the lower extremities were excluded from the scan. This indicates that radiographers have performed precise scout view planning, adapting the field of view to the patient's specific anatomy and successfully avoiding irradiation of unnecessary areas.

4.3 Comparison with FDG and Limitations of Comparison

We compared our Ga-68 FAPI values with the National FDG DRL (340 MBq). It is important to acknowledge that FDG and FAPI are distinct radiotracers with different pharmacokinetics, biodistributions, and positron yields. Therefore, this comparison is not intended to suggest biological equivalence, but rather to highlight the reduced radiation burden facing patients undergoing this specific novel investigation compared to standard oncological PET procedures.

4.4 Limitations and Future Directions

1. Sample Size and Single-Center Design: With 46 patients from a single institution, these results represent Institutional DRLs and cannot be generalized as National DRLs for Indonesia. The small sample size widens the confidence intervals of the P75 estimates. However, as per ICRP guidelines, establishing local levels is the first step towards optimization, especially for new tracers.

2. Image Quality Quantification: This study utilized clinical acceptance (diagnostic adequacy) as the metric for image quality. Future studies should include quantitative metrics such as Signal-to-Noise Ratio (SNR) and Noise Equivalent Count (NEC) density to precisely correlate dose reduction with image clarity.
3. Operator Variability: Data on inter-operator variability was not stratified. Future audits will assess if scan length variations are operator-dependent.

Despite these limitations, these values fulfill a critical regulatory gap for a new modality where no data currently exists in the region.

V. CONCLUSION

This study establishes preliminary Institutional Diagnostic Reference Levels for Ga-68 FAPI PET/CT. Based on the comprehensive analysis of 46 adult patients, the established LDRLs are:

1. Injected Activity: 118 MBq.
2. CTDIvol: 6.75 mGy.
3. DLP: 917 mGy.cm.
4. Estimated Scan Length: 136 cm (Vertex to Mid-Thigh).

These findings demonstrate that the implementation of Ga-68 FAPI imaging at our institution is highly optimized. The relatively low values for both internal (injected activity) and external (CT) dose components reflect the successful synergy between advanced technology and tailored clinical protocols. Specifically, the utilization of high-sensitivity digital detectors (GE Discovery IQ Gen 2) allowed for reduced radiopharmaceutical administration without compromising image quality, while the application of Automatic Tube Current Modulation (SmartmA) effectively minimized the CT dose burden in accordance with the patients' body habitus. The reported values should be interpreted as specific to the GE Discovery IQ Gen 2 system and the examined population. We recommend these values serve as a starting point for a broader, multi-center national survey to establish robust Indonesian DRLs.

Furthermore, the derived scan length of 136 cm serves as quantitative evidence of precise scan planning by radiographers, confirming adherence to the standard "Vertex to Mid-Thigh" oncological protocol and the avoidance of unnecessary irradiation to distal extremities.

In conclusion, these LDRL values are recommended as a preliminary baseline for other nuclear medicine centers in Indonesia adopting Ga-68 FAPI. They underscore the feasibility of low-dose molecular imaging and reinforce the importance of continuous dose monitoring to ensure patient safety in the era of precision medicine. Future research with larger, multi-center cohorts is encouraged to further refine these reference levels on a national scale.

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