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Pulmonary Rehabilitation Guideline Referral in COPD – a FHIR mapping proposal

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a highly prevalent progressive respiratory disease, characterized by airflow limitation, respiratory symptoms, and exercise intolerance, which greatly impacts patient's daily life. Pulmonary Rehabilitation (PR) is a well-recognized, cost-effective, and safe intervention with known benefits, recommended by COPD management guidelines. Despite this, there is a potential sub-diagnosis of the condition and low access rates to PR in the COPD population. Reasons may include a lack of detailed knowledge about how to refer potential patients to PR and the lack of specific criteria for the referral. Information about the patient's status and available services also plays a vital role in referrals. Additionally, there is high heterogeneity of outcomes and measures reported in the literature for PR, hindering the benchmark and dissemination of its efficacy and evidence synthesis; it also prevents communication and inter-institutional and international work. Thus, improving information availability and flow can facilitate a more efficient process.

This study aims to develop an interoperable digital protocol for PR referral, to support healthcare professionals in the data collection and referral process, making the process simpler and more efficient while also contributing to a transparent and coherent inter-institutional data exchange and continuous workflow.

The variables and associated outcomes recommended by the Portuguese General Health Direction (Direção Geral da Saúde, DGS) in the standard 014/2019 regarding PR programs referral in primary care were described and translated to the HL7-FHIR health data standard. The flow of the protocol was also presented.

This work aims to contribute to facilitating the process of PR referral by proposing a FHIR-based approach for describing relevant information and the decision-making process for PR referral, aiming to contribute for the support of health professionals in the referral decision-making process in primary care, making it simpler and more efficient while also contributing to inter-institutional workflow articulation and information availability.

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1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a highly prevalent progressive respiratory disease, being the 4th leading cause of death and 7th leading cause of disability-adjusted life years [1, 2]. In Portugal, it represents 2.2% of total deaths, and, as in other countries, there is a problem of underdiagnosis due to its clinical and etiological characteristics [3]. COPD is characterized by persistent airflow limitation, respiratory symptoms (such as dyspnoea, cough, and sputum production), and exercise intolerance due to abnormalities of the airways (bronchitis, bronchiolitis) and/ or alveoli (emphysema), which greatly impacts patient's daily life [4]. Pulmonary Rehabilitation (PR) is a well-recognized comprehensive, cost-effective, and safe intervention consisting of multidisciplinary patient-tailored therapies improving physical and psychological health and promoting long-term adherence to health-enhancing behaviours [5]. The 6 to 12 week intervention includes exercise training, education, nutritional, psychological, and social support for patients and caregivers [4, 6]. Despite its proven benefits and recommendation by COPD management guidelines, there is high heterogeneity of outcomes and measures reported in the literature for PR – measuring different outcomes and using other measures between centres and studies hinders the benchmark of its efficacy, evidence synthesis, and marketing strategies to promote PR amongst payers, clinicians, and patients; it also prevents communication, inter-institutional and international work [7]. A recent study initiated the more rigorous definition of a core outcome set for PR, which has the potential to tackle some of these issues. However, the measures associated with each outcome are still to be defined, and it does not include the referral decision-making process [8]. In some countries, PR referral is still based on the severity of lung function impairment and/ or limited to patients in a stable condition, although the evidence shows that symptoms and functional status should also be considered and that PR can be beneficial in diverse conditions and comorbidities, including exacerbations [9]. Additionally, improving the offer, equity of access, and response capacity of these programs, whether in a hospital, primary care, or community setting is essential. In Portugal, in addition to the sub-diagnosis, low access rates to PR are observed in the COPD population [6]. The variable access to PR creates disparities in quality, evidence-based healthcare, mainly due to a lack of adequate infrastructure, geographic inaccessibility, limitations on eligibility considering disease severity, patient-level barriers or the limited number of PR health professionals [9]. Demonstrating the return on investment of PR and increasing the options available (geographic and capacity-wise), and transparency of referrals are some steps to improve PR access [9]. According to the recommendations from the American Thoracic Society and the European Respiratory Society, there is a need to identify the number of patients potentially suitable for PR and focus on selection criteria and policy measures to improve patient referral [9]. Some barriers to patient referral include a lack of detailed knowledge about how to refer potential patients to PR and the lack of specific criteria for the referral [10]. Information about the patient status and available services also plays a vital role in referrals; thus, improving information availability and flow can facilitate a more efficient process [10, 11].

Patient referrals frequently involve numerous health institutions and various health information systems (HIS), making it essential to ensure a transparent flow of information. Promoting interoperability is necessary for effective information management across different HIS. Systematically reviewing the relevant knowledge base [12] and adopting standardized protocols for communication and information representation is fundamental to ensure seamless data exchange [13]. This effort can contribute to improving the referral for a PR program in a different care context through a straightforward approach, contributing to a clearer and more efficient inter-institutional communication and workflow. One of the existing standards for healthcare data electronic exchange, FHIR – Fast Healthcare Interoperability Resources (published by HL7®), is playing an important role in fostering seamless health information exchange and is being used in different case-studies and conditions, such as dementia or type-2 diabetes [14-17]. It describes a data format and structured elements for the representation and exchange of clinically relevant information using recent information systems development technologies (eg: JSON, REST) [14]. FHIR holds healthcare data

through a set of comprehensive building blocks, Resources, that represent main concepts such as patients, medications, or observations, each with its unique identifier set of data elements and rules/ constraints [14]. This promotion of data interchange allows for a safer decision-making process, as it standardizes information and promotes the increase of valuable information at the point of care.

This work aims to contribute to facilitating the process of PR referral by proposing a FHIR-based approach for describing relevant information and the decision-making process for PR referral, aiming to contribute for the support of health professionals in the referral decision-making process in primary care, making it simpler and more efficient while also contributing to inter-institutional workflow articulation and information availability. This paper is organised as follows: section 2 includes the procedures performed to identify and describe the variables under study, while Section 3 describes the results and the correspondence of these variables to FHIR resources, with a proposal of a FHIR Implementation Guide (IG) for PR referral. Sections 4 and 5 present the discussion and conclusion of this work, its contribution to healthcare and future work.

2. Methods

Considering the need for common ground and homogeneity regarding PR outcomes and measures, as well as the ability to enable the exchange of information between institutions, the FHIR standard will be used to translate the described variables into adequate resources. Some steps, identified in Fig. 1, were taken in the process of creating the FHIR IG for PR referral.

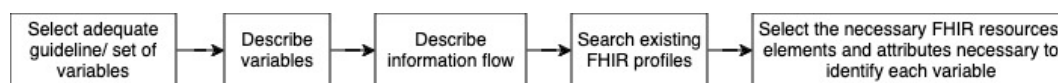


Fig. 1 – Flowchart describing the steps to achieve the FHIR Implementation Guide.

The guideline 014/2019 from the Portuguese General Health Direction (Direção Geral da Saúde, DGS) was analysed thoroughly regarding the PR referral decision-making process in primary care. This guideline was chosen as it is the current process in use by the national healthcare service in Portugal, thus trying to contribute to improving referrals in this context. The variables were identified, described, and then mapped to the adequate HL7-FHIR resources [14, 15]. Existing FHIR profiles were searched for each variable (<https://simplifier.net/>). This work was reviewed and validated by the study team, which has background and experience in chronic respiratory disease data and health information standards adoption. The IG describing resources is under development and will be submitted for validation by the HL7 community.

These variables are collected and registered by the general practitioner at primary care consultation to assess PR eligibility. A FHIR Questionnaire Resource is used to convey this decision-making process, identifying the dependencies of information and incorporating the decision branching present in the guideline. With this in mind, a Questionnaire was created using the NLM Form Builder [18]. This web widget renders input forms based on FHIR Questionnaire JSON representation, with features such as question sections, cardinality specification, score calculation, or help messages. This allows the creation of forms that can be pre-populated with the already existing information from the EHR and completed by the doctor during consultation. Some of the information needed in the decision process may already be available in the patient's electronic health record (EHR), which allows for an automated approach in data collection.

The outcomes and measures present in the guideline for the referral of PR are described in Table 1. Additionally, the guideline also recommends that the discharge report includes clinical history and referral for PR, the description of the program that was carried out, and an action plan to guide the patient. However, this work will focus on the PR referral decision-making process and relevant information.

Table 1 - Variables recommended for the referral of pulmonary rehabilitation according to the guideline 014/2019 from DGS.

<i>Outcome</i>	<i>Description</i>	<i>Measure</i>
Lung function	Forced spirometry is the most reproducible and objective measurement of airflow obstruction post-bronchodilator (post-BD)	Spirometry – FEV ₁ , FEV ₁ % predicted, FVC, FEV ₁ /FVC ratio
Dyspnoea	Major symptom and cause of disability and anxiety associated with the disease, described as an increased effort to breathe, chest heaviness, or gasping. Persistent, progressive over time, worse with exercise	mMRC - modified Medical Research Council Dyspnoea Scale (1 item, scored from 0 to 4, higher scores meaning more severe dyspnoea)
Quality of life	Impact of COPD in daily life and well-being	CAT - COPD Assessment Test (8 items, scored from 0 to 5, total score ranging from 0 to 40, higher scores meaning higher impact in daily life)
Exacerbation history	Increase in dyspnoea, cough and/ or sputum production that worsens in <14 days, that can also present tachycardia or tachypnoea, usually associated with local and systemic inflammation caused by infection, pollution, or other damage to the airways (in the last year)	A/B - 0 or 1 moderate exacerbation (not leading to hospitalization) C/D=E - ≥2 moderate exacerbations or ≥ 1 leading to hospitalization
Peripheral oxygen saturation (SpO ₂)	Estimate of the percentage of oxygen bound to haemoglobin in the blood	SpO ₂ ≥ 90% - Yes/ No
Comorbidities	Comorbidity occurs when more than one disease or condition is present, often being chronic or long-term conditions	Presence of severe comorbidities - Yes/ No

For referral purposes, after a spirometrically confirmed diagnosis, it is necessary to classify disease severity according to the GOLD ABE assessment tool (updated 2023 version, whose grade "E" is equal to the grades "C" and "D" of the previous version used in the standard, GOLD ABCD). To obtain this, a history of exacerbations and one of the two measures of symptoms (mMRC or CAT) is needed, as described in Table 2.

Table 2 – GOLD Assessment Tool.

<i>Gold Assessment Tool</i>		
≥ 2 moderate exacerbations or ≥ 1 leading to hospitalisation	E (previous C)	E (previous D)
0 or 1 moderate exacerbation (not leading to hospitalisation)	A	B
	mMRC 0-1 CAT < 10	mMRC ≥ 2 CAT ≥ 10

Note: The C and D groups were merged in group E in the 2023 version of the GOLD report.

3. Results

The flowchart for PR referral decision-making rationale derived from the recommendations of DGS is described in Fig. 2, containing the variables previously described in Table 1. Table 3 presents the correspondence to the HL7 FHIR data standard resources and the respective elements necessary to identify each variable, creating the FHIR profiles for this use-case variables.

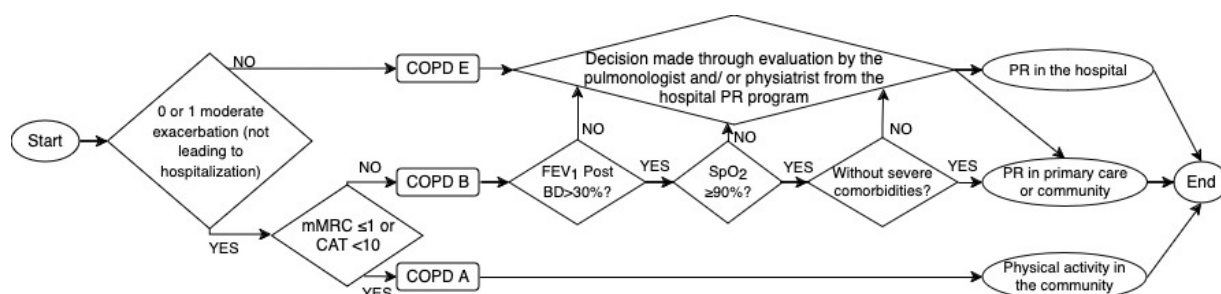


Fig. 2 - Flowchart for pulmonary rehabilitation referral

Table 3 - Correspondence of variables in FHIR resources.

Description	FHIR resource	Attributes correspondent to each resource	Values associated with each attribute
CAT score	Observation	code	undefined - no codes found
		status	final - complete with no further actions needed
		subject	patient - information about an individual receiving care or other health-related services
		derivedFrom	other Observation/ Questionnaire*
		value	integer - total score
		referenceRange.low referenceRange.high	0 - minimum score 40 - maximum score
mMRC score	Observation	code	{system: "http://snomed.info/sct"; code: "870179002"}
		status	final - complete with no further actions needed
		subject	patient - information about an individual receiving care or other health-related services
		derivedFrom	other Observation/ Questionnaire*
		value	integer - total score
		referenceRange.low referenceRange.high	0 - minimum score 4 - maximum score
Exacerbation history in the previous year	Observation	code	{system: "http://snomed.info/sct"; code: "723245007"}
		subject	patient - information about an individual receiving care or other health-related services
		derivedFrom	Other Observation/ Questionnaire*
		value	integer - number of exacerbations in the previous year
FEV ₁	Observation - Spirometer Observation FEV ₁ [19]	code	{system: "http://snomed.info/sct"; code: "313223002"}, {system: "ICD-10"; code: "4A09XLZ"}, {system: "http://loinc.org"; code: "20152-5"}
		effective value	dateTime - time the observed value is asserted as being true quantity - actual result, measurable amount
		code	undefined - no codes found
GOLD ABE	Observation	status	final - complete with no further actions needed
		subject	patient - information about an individual receiving care or other health-related services
		derivedFrom	other Observation/ Questionnaire* - according to the answers in the mMRC/ CAT and the exacerbation history
		value	string - actual result, sequence of Unicode characters
		code	{system: "http://loinc.org"; code: "59408-5"}, {system: "ICD-10"; code: "4A03XR1"}
SpO ₂	Observation - VitalSigns Oxygensat [20]	value	quantity.code: % - actual result, measurable amount in percentage

Comorbidities	Condition	code	{system: "http://snomed.info/sct"; code: "398192003"}
		clinicalStatus	active - <i>the subject is currently experiencing the condition</i>
		verificationStatus	confirmed - <i>sufficient evidence to confirm a condition</i>
		subject	patient - <i>who has the condition</i>
		recordedDate	dateTime - <i>date condition was first recorded</i>
		stage.summary	Value set ConditionStage - <i>disease-specific stage/ severity</i>
		stage.assessment	reference to ClinicalImpression/ DiagnosticReport/ Observation

Legend: CAT – COPD Assessment Test; FEV₁ - Forced expiratory volume in the first second; mMRC – modified Medical Research Council; SpO₂ - Peripheral oxygen saturation.
 *Note: Resource "Questionnaire" to request information from the patient during encounter if it is not available in the electronic health record (EHR). When implemented according to defined rules, a final score can be obtained and created in the EHR with the resource "Observation".

Regarding the exacerbation history, an exacerbation is considered moderate when three of the following characteristics apply: Visual Analog Dyspnoea Scale ≥ 5 ; respiratory rate ≥ 24 breaths/ minute; heart rate ≥ 95 bpm; resting arterial oxygen saturation (SaO₂) $< 92\%$ breathing ambient air (or usual oxygen prescription) and/ or change $> 3\%$ when known; C-reactive protein ≥ 10 mg/L [4]. This definition should be readily available for health professionals to correctly assess the patient if the EHR's classification of previous exacerbations/ hospitalisations is unavailable. If this is the case, a more straightforward classification can be used that defines a moderate exacerbation when the patient receives antibiotics, systemic corticosteroids, or both, and severe when the patient visits an emergency room or is hospitalised [21]. When available, the information can be conveyed with the resource "Observation", an element consisting of simple name/ value assertions used for diagnosis, progress monitoring, record of characteristics and test results. The same resource can be used for other elements, such as questionnaire scores (CAT and mMRC), GOLD ABE, FEV₁, and SpO₂, and the respective attributes can be used to define each variable, such as the score range. FEV₁ and SpO₂ had previously published profiles online, whose link is presented, and the elements specified in each profile. The presence of comorbidities is conveyed through the resource "Condition", used to record information about a condition, problem, or diagnosis, that in this case should be an active condition with information regarding severity.

The complete decision process based on these variables is mapped into a Questionnaire resource including branching using the available Questionnaire dynamics. The resource "Questionnaire" allows to request information from the patient through an organized collection of questions. This "Questionnaire" can also be pre-filled with the available data allowing to fill the remaining questions.

When considering questionnaires with a final score, this can be obtained following the rules implemented in the "Questionnaire" resource, with the creation of an "Observation" communicating the final score obtained. Fig. 3 shows an example of the form created with NLM Form Builder [18] that can be used to collect data using the "Questionnaire" resource, and which can be adapted with the necessary rules to result in one of the three PR referral options.

Fig. 3 - Example of pulmonary rehabilitation referral questionnaire

The screenshot shows a digital questionnaire form with the following sections and options:

- Exacerbation history:** Radio buttons for "≥ 2 moderate exacerbations or ≥ 1 with hospitalization during the past year" and "0 or 1 moderate exacerbation (not leading to hospitalization) during the past year".
- CAT Total Score:** A list of dropdown menus for CAT 1 through CAT 8, each with "Select one" as the current selection.
- mMRC (Modified Medical Research Council) Dyspnea Scale:** Radio buttons for options 0 through 4. Option 2 is selected: "Walks slower than people of the same age because of dyspnea or has to stop for breath when walking at own pace".
- GOLD Assessment Tool:** Radio buttons for GOLD A, GOLD B, and GOLD E = C/D. GOLD B is selected.
- FEV1% predicted:** A text input field containing "54" and a percentage sign.
- SpO2:** A text input field containing "92" and a percentage sign.
- Presence of comorbidities:** A text input field with a "Type a value" placeholder and a button to "Add another 'Presence of comorbidities'".
- Referral recommendation:** A dropdown menu with "PR in primary care or community" selected.

After obtaining each of these variables, whether through the EHR or during the primary care consultation, the constraints and logic of the flowchart with the respective rules and calculations required can be represented through the FHIR extensions. Lastly, a “Communication” resource can be used, to structure data that needs to be sent, for example, to the PR location, conveying the information that the patient should be followed up at that location.

This mapping shows the flexibility and usefulness of the FHIR resources, that can be adapted to fit the information that needs to be mapped. In this specific case, the questionnaires and corresponding responses play a crucial role in the profiling, as they can be widely adapted to fit the data, whether that is a predefined patient-reported outcome measure (PROM) or a straightforward question regarding the patient clinical history or current status. A FHIR IG for PR is under construction for aggregating all the artifacts here developed, making it available for public discussion and perfecting.

4. Discussion

This paper describes the process carried out for mapping all the variables present in the DGS guideline regarding the referral decision-making process of PR in primary care consultation. This guideline included a recommended measure associated with each variable, facilitating the description of the variables and promoting PR-relevant data homogeneity. The methodology presented allowed for the successful profiling of this specific use-case, with the resources most used being “Observation” and “Questionnaire”, whose elements allowed to accurately represent each variable to the FHIR standard. To further improve data quality in PR, all the remaining dataset elements relevant for the discharge report of PR should be mapped to FHIR resources, as described in the guideline from DGS, such as clinical history, description of the program that was carried out, and an action plan. This mapping should include the evaluation of cardinalities, comparison and adaptation of value sets, and addition of required FHIR elements that currently do not have an equivalent. Pre-existing FHIR profiles should also be considered; in this case, profiles were found for two variables. Regarding the terminologies SNOMED, LOINC or ICD-10, only two of the described variables had no correspondence, which prevents the complete standardisation in the identification of variables to be communicated.

An in-depth comparison of the content included in this guideline and other available international guidelines should be carried out, aiming to foster better data quality and contribute to international health research. Future work should also include the validation of this proposal by experts and the assessment of its feasibility in a real-world implementation. The need for a clearly defined international set of variables recommended for PR referral decision-making process and transversal adoption by HIS is clear, as it would largely contribute to the achievement of common ground and homogeneity of data collected in this field. Facilitating data interoperability and management can advocate for policy decisions that support COPD management programs, such as resource allocation. It can also decrease the burden on healthcare professionals and improve the effectiveness of PR programs by optimising the admission criteria and process. Ultimately, this can result in enhanced patient outcomes and a higher overall quality of life for individuals with COPD. The adoption of recognized standards such as HL7 FHIR is crucial for this purpose, fostering efficient healthcare data management and promoting interoperability enhancements throughout.

5. Conclusion

This work-in-progress aimed to aid in creating a comprehensive FHIR IG for PR referral in COPD based on current guidelines. It requires ongoing and informative contributions from stakeholders involved in PR to address barriers undermining referrals and care provision. Additionally, it promotes the significance of high-quality, accessible, and fluid data exchange concerning patients and services, thus enhancing patient health outcomes and streamlining healthcare delivery throughout. Future studies assessing its validity and feasibility are warranted.

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