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Study Protocol and Methodological Design for an Integrated Anderson - Donabedian Framework Analysis

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Abstract

Primary Health Care (PHC) plays a main role in the promotion of equitable access, continuity of care and progress towards Universal Health Coverage. Nevertheless, understanding healthcare utilization needs consideration on the one hand of individual determinants of healthcare-seeking behavior and on the other hand, of the organizational conditions under which services are delivered. The current paper proposes an integrated conceptual and methodological framework. The framework concerns primary healthcare utilization and quality's assessment within the Albanian public healthcare system. The framework combines Andersen's Behavioral Model of Health Services Use with Donabedian's Structure-Process-Outcome model. Thereby, it links patient-level predisposing, enabling and need factors with healthcare-center-level structures, with care processes and finally, with the results that are patient-reported. The study adopts a quantitative, explanatory, whose design is cross-sectional. It integrates data that are collected from adult PHC users with organizational information obtained through structured assessments of the healthcare centers that participated. A stratified multistage sampling strategy is proposed. It covers urban, peri-urban and rural settings across Albania. There is an anticipated research sample of approximately 350-420 patients from 32-35 primary healthcare centers. As for the patient-level measures, they include healthcare utilization, accessibility, care experience, trust and satisfaction. Organizational measures include staffing, infrastructure, equipment, medicines, documentation systems and organizational protocols. The analytical strategy combines multivariable and multilevel regression with Structural Equation Modelling. Therefore, it examines direct, indirect and moderating relationships among the constructs of the study. By the integration of behavioral and organizational perspectives, the current proposed framework addresses the fragmented examination of PHC utilization and healthcare quality in previous Albanian research. Finally, the current study is expected to offer a holistic methodological basis for the identification of determinants of access, continuity, patient experience and quality of care. It is also expected to generate evidence that is relevant to the primary healthcare service's further strengthening in Albania.

Keywords: Primary Healthcare; Healthcare Utilization; Andersen Behavioral Model; Donabedian Model.

1. Introduction

PHC is concerned as the foundation of effective and sustainable health systems. Besides, it is the first and most continuous point of contact that exists between individuals and healthcare services and PHC encompasses health promotion, including disease prevention, early diagnosis, treatment, chronic disease management, referral and continuity of care. It plays a role that extends beyond the basic medical services' provision. It, furthermore, includes the coordination of care across different levels of the health system. Strong PHC systems have been linked with improved accessibility and greater equity. They are also characterized by more efficient use of healthcare resources and this is even more intensive, in the cases of which services are responsive to the needs of the populations that they serve (WHO, 2019).

The PHC's importance is connected to the international objective of achieving Universal Health Coverage (UHC). UHC needs individuals and communities to have access to the health services that they need, and they might do so without experiencing financial hardship. PHC represents a main mechanism, through which this exact objective might be achieved. The reason is that it brings essential services closer to communities. It also offers an entry point into the wider healthcare system. However, the existence of PHC facilities alone does not guarantee effective coverage. The UHC's achievement, also, depends on whether populations are able to access and use available services. It also depends on whether healthcare organizations have adequate resources and capacities, and whether the services that are delivered meet the quality's acceptable standards. Therefore, international evidence emphasizes the existence of the need of the examination of access, use and quality, as three dimensions that are interconnected and that they concern healthcare systems' performance (WHO, 2019).

These considerations are also relevant in Albania. More specifically, in Albania the healthcare system has undergone reforms, whose aim was to strengthen primary care and to improve health services' accessibility and quality. Albania has made progress in the expansion of preventive services and also in strengthening the role that is played by the primary healthcare. Nevertheless, there are still some barriers in the PHC's transformation towards a family medicine-based model. The rapid Albanian PHC's assessment that has been conducted by the WHO (2018), identified continuing challenges. It has also highlighted, among other priorities, the existing need to strengthen clinical practices and to clarify professional roles, to empower healthcare managers and improve coordination across sectors, as well (WHO, 2018).

Similarly, Saric et al. (2021), in their assessment of the facilities of PHC in two Albanian regions, identified quality-of-care challenges. These challenges involved governance, accessibility, infrastructure and the healthcare workforce. Their findings are important, due to the fact that they show that variations in PHC's performance might not be attributed only to patient characteristics. Organizational and structural conditions in

healthcare facilities also contribute to the quality of services that are experienced by the patients.

Healthcare professionals have reported comparable organizational difficulties, as for instance Mechili et al. (2022) examined the management of patients with multimorbidity in Albanian primary healthcare settings and pointed out problems that involved on the one hand infrastructure and on the other hand availability of materials and equipment, professional communication, coordination, clinical protocols and referral mechanisms. These findings show that effective PHC needs more than physical access to healthcare centers. The organizational environment, in which healthcare professionals operate, might possibly affect healthcare processes. Therefore, it might affect patients' experiences about care.

At the same time, the patient perspective represents a PHC's performance dimension. Gabrani et al. (2020) showed the importance of the examination of users' perceptions of the non-clinical quality of public and private primary healthcare, in Albania. Patients' experience is relevant and the reason is that individuals do not make healthcare decisions only based on the clinical need. Their willingness to access, return to and keep contact with primary healthcare services might be influenced by previous experiences, as well and it might also be influenced by perceived accessibility, communication with healthcare professionals, responsiveness, trust and satisfaction. Therefore, on the one hand the use and on the other hand the quality of care should not be conceptualized as two phenomena that are independent.

The need for the current study is generated by the interaction that exists between the demand and supply sides of primary healthcare. More analytically, on the demand's side, individuals differ in their demographic and socioeconomic characteristics. They also differ in their available resources, health needs and ability to access services, too. All of these factors influence whether and how healthcare is used. On the other hand, on the supply side, healthcare centers differ in staffing and infrastructure. There are also differences in equipment, medicines, organizational systems and service-delivery processes. Since an individual enters the healthcare system, these organizational characteristics might possibly affect the quality of care that is received. They might also affect the patient's subsequent evaluation of that experience. In turn, patients' experience may influence trust, satisfaction, continuity of care and future healthcare-seeking behavior. Even more, except of WHO (2018), the studies that had been conducted by Gabrani et al. (2020), Mechili et al. (2022) and Saric et al. (2021), have examined quality of care, alongside with patient perceptions, access barriers and organizational or professional challenges in the PHC's context. However, these dimensions have been investigated separately. Therefore, an important research gap is about the absence of an integrated analytical approach, that might be capable of explaining the reason why patients use PHC services and the way through which healthcare centers' organizational characteristics influence the processes and outcomes that are linked with that utilization.

The current study covers this gap, and it does so, by the integration of two established theoretical perspectives. The first one is Andersen's Behavioral Model of Health Services Use and the second one is Donabedian's Structure-Process-Outcome model (Andersen,

1968, 1995; Andersen & Newman, 2005; Donabedian, 1988).

More analytically, Andersen's model offers the behavioral perspective that is needed in order to explain healthcare utilization through predisposing and need-related factors. On the other hand, Donabedian's framework complements this perspective, and it achieves this by explaining healthcare quality through the relationships that exist between organizational structure, healthcare processes and the final results. Their integration allows PHC's utilization to be examined as a multidimensional process. In the context of this process, patient-level determinants interact with healthcare-center-level characteristics.

Therefore, this paper's contribution is on the one hand theoretical and on the other hand methodological. Theoretically, this study brings behavioral determinants of healthcare utilization and at the same time, it offers organizational determinants of healthcare quality, into a unified conceptual framework. Methodologically, it enables patient-level information to be examined alongside the PHC centers' organizational characteristics. In the Albanian context, this approach has the potential to create a better understanding of the way through which access and organizational capacity, alongside with quality of care, patient experience and future utilization are interconnected.

2. Literature Review

PHC's utilization is a multidimensional phenomenon, which is shaped by individual characteristics and by the conditions for access, healthcare needs, organizational capacity and patients' experiences with the healthcare services. Andersen's Behavioral Model of Health Services Use offers an established framework for the explanation of the healthcare utilization's demand side. This framework was initially developed by Andersen (1968). It was subsequently refined by Andersen (1995) and Andersen & Newman (2005). It is about a model, that classifies determinants of healthcare use into three main categories. These categories are predisposing, enabling and need factors. Predisposing factors include demographic and social characteristics, that influence an individual's propensity to seek healthcare. On the other hand, enabling factors concern the resources and conditions, that facilitate or restrict access. They also include financial resources, insurance, transportation and geographical accessibility. Finally, need factors concern perceived and clinically evaluated healthcare needs. They represent the most immediate determinants of service utilization.

Since Andersen's model explains why individuals access healthcare, Donabedian's Structure-Process-Outcome framework gives a complementary perspective about the quality of care they encounter after entering the healthcare system. In more analysis, Donabedian (1988) conceptualized healthcare quality through three interrelated dimensions. Structure is about organizational conditions and resources. It includes staffing, infrastructure, equipment and facilities. Then, process concerns how healthcare is delivered and it includes communication, coordination and professional practice. Finally, outcomes represent the consequences of care. They also concern the health-related and patient-reported results. The framework assumes that adequate organizational

structures support better healthcare processes and that these processes increase the likelihood of favorable results.

The integration of these two theoretical perspectives offers a broader framework for understanding PHC's utilization. Andersen's model captures the individual and access-related determinants about entering the healthcare system. On the other hand, Donabedian's framework captures the organizational and quality-related conditions that frame what occurs following access. Therefore, in an integrated model, healthcare utilization is able to be understood as a continuing process. In the context of this process, individual characteristics and needs influence initial utilization and at the same time, organizational structures shape healthcare processes, while the resulting patient experiences affect trust and satisfaction, alongside with continuity of care and subsequent healthcare utilization.

It is about a perspective, that is relevant due to the fact that PHC utilization goes beyond the occurrence of an individual healthcare visit. It is a fact that effective primary care needs sustained accessibility and continuity, while at the same time, appropriate engagement with services is also necessary. Even more, local management and organizational capacity influence whether PHC centers can deliver such care, while staffing, medical equipment, infrastructure, availability of medicines, organizational protocols, documentation systems and referral mechanisms are important conditions that affect the delivery of the healthcare services. Especially, in the case of Albania, organizational challenges about infrastructure, equipment, professional communication, coordination, protocols and referral mechanisms have been reported in the PHC settings (Mechili et al., 2022). Also, assessments of PHC facilities have identified challenges about governance, accessibility, infrastructure and about the capacity of the healthcare workforce, too (Saric et al., 2021). Even more, WHO (2018) identified the need to strengthen managerial capacity and that there is also a need about the coordination within Albanian primary healthcare.

Patient experience represents one further component, that links healthcare quality with its utilization, since patients' evaluations of communication, responsiveness, accessibility, coordination and continuity end up influencing their overall satisfaction and trust in healthcare. In that context, Gabrani et al. (2020) identified differences in users' perceptions of non-clinical quality across public and private PHC settings, in Albania. Then, Saric et al. (2021) incorporated patient satisfaction and trust into an overall and wider assessment of PHC quality. It is about evidence, that proposes that patient experience should be considered on the one hand as an outcome of healthcare delivery and on the other hand, as a potential influence on future healthcare-seeking behavior.

At this point, it is mentioned that despite the ongoing reforms, Albania is still facing interconnected challenges, which are about the access of healthcare services, the existing organizational capacity, the overall healthcare processes that are followed and finally, the patients' experience (Gabrani et al., 2020; Mechili et al., 2022; Saric et al., 2021; WHO, 2018). However, the available literature that concerns the case of Albania has generally examined these dimensions separately. Therefore, an important research gap

remains, and it is about the simultaneous assessment of patient-level determinants of healthcare utilization and quality's healthcare-center-level determinants. The integration of Andersen's Behavioral Model with Donabedian's Structure-Process-Outcome framework, that is done in the present study, covers this exact gap. It also offers a unified basis for the examination of the way through which individual characteristics, organizational structures, healthcare processes and patient experiences interact in framing PHC utilization and results, in Albania.

3. Conceptual Framework

The utilization of the Primary Health Care (PHC) is a multidimensional process. It is influenced by several factors such as patients' individual characteristics, the patient's experience while receiving the health services, organizational capacities of the healthcare centers, etc. The interactions of such factors influence on the approach on how the population utilise the services. The present study attempts to integrate these different perspectives into a single explanatory model. The proposed model captures both sides mentined above, the demand side and the supply side. The study adopts an integrated conceptual framework combining Andersen's Behavioural Model of Health Services Use with Donabedian's Structure-Process-Outcome model. This integration provides a broader understanding of why patients use primary healthcare services, and, on the other side, it explains how the healthcare centers organisation influences the quality of the services offered.

The Behavioural Model initially was proposed by Andersen (1968). Additionally, it was further refined (Andersen, 1995; Andersen & Newman, 2005), by explaining that the healthcare utilization is determined by three groups of individual characteristics: predisposing, enabling and need factors.

The predisposing factors typically include factors such as as age, gender, martial status, education and health benefits, which compose the socio demographic characteristics. These characteristics influence their tendency to seek the healthcare.

On the other side, the enabling factors refer to the resources that set back or facilitate their access to the services. Such factors refer to: waiting time, geographic access, transportation accessibility. While the third group, the need factors, represent the most immediate determinants of healthcare utilization. This group include both evaluated need (clinically diagnosed illness) and perceived need (individual assessment of health status). For this study, the healthcare utilization is conceptualised as the use of primary healthcare facilities by the patients. It is measured through the frequency of visits, continuity of care and the choice between primary healthcare centres, emergency departments and private providers. As explained above, the Andersen's model contributes with the behavioural perspective. To complement this approach, this study incorporates the Donabedian's Structure-Process-Outcome (SPO) model, which refres to evaluation of healthcare quality (Donabedian, 1988).

As per the Donabedian model, there are three dimensions that assess the healthcare quality: structure; process and outcomes. The structure refers to resources as: medical

equipment's; infrastructure; human resources; medicines; quality of facilities (even though the infrastructure directly guarantees the quality). The dimension of process refers to delivery of the healthcare, the interaction that the resources are transformed into healthcare services. The process refers to the communication with the patients, coordination, professional standards, continuity of care. While the third dimension of outcomes refers to the patient's satisfaction, symptoms status control, perceived quality. The model is linear: structure influences process and the process defines the outcomes. According to the integrated framework, together the predisposing characteristics, enabling resources and healthcare needs, influence the decision to seek primary healthcare. This shows that the healthcare utilization begins with individual-level factors described by Andersen's Behavioural Model, while the quality of care received affects patients' future healthcare choices. Once the patients perceive a positive experience, they are encouraged to continue the use of primary healthcare services. This integrated framework assumes that the healthcare utilization is a continuous process. To better capture the complexity of primary healthcare utilization, the proposed integrated model incorporates also mediation and moderation mechanisms.

As mentioned above, when patients have positive experiences with healthcare providers, they are more likely to trust the service and return to primary healthcare services when needed again. This brings to the mediating role of patient trust and satisfaction between the quality of healthcare processes and future healthcare utilization. Another mediating role in the model has the quality of healthcare processes, which mediate the relationship between organizational structure and patient outcomes. Another mediating role remains with the contextual factors. For example, socioeconomic status may influence access to healthcare and the way patients perceive the quality of care. On another example, patients living in rural areas often have fewer healthcare options and may depend more on local primary healthcare services.

4. Methodology

4.1 Research Design

The current study adopts a quantitative, explanatory, cross-sectional research design, in order to examine the PHC's utilization determinants and in order to influence of organizational quality on patient-reported outcomes, in Albania's case. The research integrates a behavioural and quality-of-care perspectives. It investigates individual-level determinants of healthcare utilization and primary healthcare centres' organizational characteristics.

A multilevel analytical approach is employed, and the reason is that the current study combines data, that are collected from two distinct units of analysis. More analytically, the first level consists of individual patients that receive services from PHC. On the other hand, the second level comprises the healthcare facilities. Therefore, it is about a hierarchical structure, that acknowledges that patients are nested within healthcare centres. It also recognizes that organizational characteristics may influence patient experiences beyond individual characteristics. The current proposed research design

enables the simultaneous examination of direct, indirect and moderating relationships, that exist among the study variables through Structural Equation Modelling (SEM) and multilevel regression analysis.

4.2 Sampling Strategy

A stratified multistage sampling strategy is going to be implemented. Therefore, geographical representation of the Albanian primary healthcare system is going to be ensured.

PHC centres will first be selected across the country's twelve administrative regions, incorporating urban, peri-urban and rural settings. Approximately 32-35 PHC centres will participate in the current study. In each participating centre, consecutive adult patients that attend routine consultations during the period of the research data collection, are going to be invited to participate.

The anticipated sample comprises approximately 350-420 patients. They correspond to an average of 10-12 participants per healthcare centre. This sampling strategy offers a sufficient geographical diversity. At the same time, it supports both multilevel analyses and Structural Equation Modelling.

The multistage sampling approach is expected to improve representativeness, and it might achieve this by capturing organizational variability across healthcare centres. At the same time, it might reflect individual differences in healthcare utilization.

4.3 Data Collection Procedures

Data collection is going to involve two complementary instruments, that will be administered simultaneously. The first instrument is a structured patient questionnaire, that is designed to measure individual determinants of healthcare utilization, healthcare experiences and patient-reported results. The questionnaire includes validated measurement scales, that are adapted from internationally recognised instruments. They include Andersen's Behavioural Model, the Primary Care Assessment Tool (PCAT), the Wake Forest Physician Trust Scale and EUROPEP.

Then, the second research instrument is a structured organizational audit, that is going to be completed at each participating healthcare centre. It is about a checklist, that records organizational characteristics. These characteristics include, for instance, staffing levels, infrastructure, medical equipment, availability of medicines, electronic health records, clinical protocols, continuity systems and organizational resources, as well. The collection of research data from both patients and healthcare facilities allows the integration of individual-level and organizational-level variables in a single analytical framework. At the same time, it helps reducing common-source measurement bias.

4.4 Measures and Operationalisation

The integrated conceptual framework consists of constructs, that are measured at both the patient and healthcare-centre levels. More analytically, individual-level constructs include predisposing factors, enabling factors and healthcare needs, that are operationalised according to Andersen's Behavioural Model. Predisposing variables

include age, gender, educational attainment and employment status. Then, enabling variables include insurance status, travel time to the healthcare centre, transportation, waiting time and out-of-pocket expenditure. Finally, need variables comprise self-rated health status, chronic disease status and perceived symptom burden.

Primary healthcare utilization is measured through the number of visits to primary healthcare facilities, and through continuity of care. It is also measured through patients' preferred source of healthcare, too. At the organizational level, healthcare structure is measured through an audit instrument, that assesses staffing, equipment, clinical infrastructure, availability of medicines, electronic documentation systems and organizational protocols. Healthcare processes are assessed by the use of indicators that are derived from the Primary Care Assessment Tool (PCAT). They include communication, coordination, continuity of care and referral management.

Then, patient trust is assessed by using items that are adapted from the Wake Forest Physician Trust Scale. Whereas patient satisfaction is measured using selected EUROPEP indicators. Patient-reported outcomes include perceived health improvement, alongside with avoidance of unnecessary emergency care, perceived effectiveness of care and overall confidence in primary healthcare services.

4.5 Validity and Reliability

The study employs measurement instruments that have previously showed acceptable psychometric properties in international healthcare research. Prior to the main research, the integrated questionnaire is going to undergo linguistic adaptation and pilot testing. Therefore, it will be ensured that there are efficient conceptual clarity and cultural appropriateness in the Albanian healthcare context.

As for the internal consistency of multi-item constructs, it will be evaluated through Cronbach's alpha and Composite Reliability (CR). Construct validity is going to be examined through Confirmatory Factor Analysis (CFA). Then, convergent validity will be assessed by using Average Variance Extracted (AVE). Finally, discriminant validity will be evaluated using the Heterotrait–Monotrait ratio (HTMT). It is also noted that measurement invariance across urban and rural populations will also be assessed before the conduction of multigroup analyses.

4.6 Statistical Analysis

Data analysis will be performed using IBM SPSS Statistics and Structural Equation Modelling software (AMOS or SmartPLS). The analytical strategy will proceed through the following stages:

First, descriptive statistics are going to summarise participant characteristics, healthcare utilization patterns and organizational characteristics of the participating healthcare centres. Continuous variables are going to be presented as means and standard deviations. On the other hand, categorical variables will be reported as frequencies and percentages. Second, preliminary analyses will assess missing data, outliers, normality and multicollinearity.

Third, measurement quality is going to be evaluated through Confirmatory Factor

Analysis, reliability analysis and construct validation.

Fourth, multivariable regression analyses will examine the effects of predisposing, enabling and need factors on primary healthcare utilization.

Due to the fact that patients are clustered within healthcare centres, multilevel regression models are going to estimate the influence of organizational structure on healthcare processes, while accounting for within-centre correlation. Finally, Structural Equation Modelling will be conducted, in order to test the integrated conceptual framework. More analytically, direct, indirect and total effects will be estimated. Model fit is going to be evaluated by using multiple goodness-of-fit indices. These indices include, for instance, the Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA) and Standardised Root Mean Square Residual (SRMR). Conventional threshold values, that are recommended in the SEM literature, are going to be adopted, in order to determine model adequacy. Mediation analyses will be conducted, through the use of non-parametric bootstrapping with 5,000 resamples. Whereas moderation effects of urban–rural residence and socioeconomic status are going to be examined by using interaction terms and multigroup SEM.

5. Ethical considerations

The study will be conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval is going to be obtained from the appropriate institutional ethics committee, before the process of the data collection commences. All the research data that will be collected, are going to be anonymised prior to their analysis. They will also be stored securely in accordance with applicable data protection regulations. Also, only aggregated results are going to be reported, and this ensures that neither individual participants nor healthcare facilities might be identified. Analytically, participation will be voluntary and all of the respondents will offer their written informed consent before the completion of the questionnaire. Also, participants will be informed about the purpose of the study and for the confidentiality procedures, their voluntary participation and the right that they have to withdraw at any stage of this research, without having any consequences.

6. Expected Scientific and Policy Contributions

The current study is expected to contribute to both the theoretical development of health services research and the evidence base supporting primary healthcare policy, in the Albanian context. This study does not present empirical findings at this stage, but despite that fact, its methodological design addresses important gaps, that are identified in previous research on primary healthcare utilization and on the quality assessment, as well.

More analytically, from a theoretical perspective, the main contribution of this study lies in the integration of two of the most influential conceptual frameworks in health services research, i.e., Andersen's Behavioural Model of Health Services Use and Donabedian's

Structure-Process-Outcome model. Both frameworks have traditionally been applied independently, but the proposed model combines behavioural determinants of healthcare utilization with healthcare quality's organizational determinants in a single multilevel explanatory framework.

The integrated model extends the already existing approaches, and it does so, by conceptualising primary healthcare utilization as a dynamic process and not as a single healthcare event. Individual characteristics determine the entry into the healthcare system, while at the same time, organizational factors influence the quality of care that is delivered, and finally, patients' experiences shape future healthcare-seeking behaviour through a mechanism that is based on the patients' feedback. Therefore, it is about a dynamic perspective, that offers an understanding of healthcare utilization, that models that focus exclusively on either patient behaviour or healthcare quality cannot offer. Furthermore, the mediation and moderation mechanisms' inclusion enables a wider examination of the way through which organizational characteristics are translated into patient outcomes and how these relationships might vary across different socioeconomic and geographical contexts.

Except of the previous analysis, this study also offers an important methodological contribution. It does so, through the development of a multilevel analytical framework. It is about a framework, that integrates patient-level and healthcare-centre-level data. More specifically, unlike many previous studies, that rely only on patient-reported information, the proposed design combines two complementary sources of data. Individual data, that are collected through the patient questionnaire, are integrated with organizational data, that are obtained from structured facility evaluations. It is about a dual-source approach, that reduces common-source bias. This approach also allows organizational characteristics to be analysed independently from the patients' perceptions, that might be subjective.

Also, the proposed use of Structural Equation Modelling (SEM) strengthens the current papers' methodological contribution. More analytically, SEM enables the estimation of multiple direct, indirect and moderated relationships, that are developed among latent constructs. Thereby, it offers a wider evaluation of the conceptual framework, than the one that is offered by the conventional regression models. In addition, the multilevel regression techniques' incorporation recognises the hierarchical structure of healthcare data, in which patients are nested in the healthcare facilities.

6.1 Empirical Contribution

The current proposed study is expected to create one of the first integrated datasets, that combine patient experiences with organizational characteristics of PHC centres across many different administrative regions of Albania. This kind of evidence has the potential to improve the existing understanding of regional inequalities in healthcare access, organizational performance and perceived quality of care.

Empirical evidence about the determinants of PHC utilization in Albania is still fragmented, as it was mentioned in the context of the above literature review, since the already existing studies have generally focused on specific dimensions of access,

healthcare financing or patient satisfaction. This means that they have not examined behavioural, organizational and contextual determinants, simultaneously.

Finally, the inclusion of urban and rural healthcare centres creates an opportunity to examine geographical disparities in service delivery. It also generates an opportunity to identify contextual factors, that are associated on the one hand with variations in healthcare utilization and on the other hand in patient outcomes.

6.2 Policy Implications

The findings that are going to be generated by the proposed research are expected to offer practical evidence, that might support ongoing reforms of the Albanian PHC system. The identification of the relative importance of individual characteristics, organizational resources and healthcare processes, makes the results of this study able to assist policymakers in prioritising interventions, that might improve accessibility, alongside with the continuity of care and the delivery of patient-centred services. Data concerning organizational determinants of quality might also inform future investments in workforce development and infrastructure, digital health systems and quality improvement initiatives, as well.

Moreover, the regional differences' identification in healthcare utilization might possibly support more equitable allocation of healthcare resources, across both urban and rural areas. Even more, the understanding of the way through which patient trust and satisfaction influence continuity of care could also contribute to strengthening the gatekeeping role that is played by PHC within the Albanian health system. It might also help reducing unnecessary utilization of emergency and specialist services. Therefore, this study may contribute on the one hand to academic knowledge and on the other hand, to evidence-informed decision-making within the Ministry of Health and Social Protection, the Health Insurance Fund and other institutions, that are responsible for planning and managing PHC services.

6.3 International Relevance

The current study is conducted within the Albanian healthcare system, but despite that fact, its conceptual framework has wider applicability to other lower-middle-income and upper-middle-income countries, that are into primary healthcare reforms. Many health systems continue to face similar challenges, that are related to organizational capacity, regional inequalities, continuity of care and patient-centred service delivery. Therefore, the integrated Andersen-Donabedian framework proposed in this study might serve as a transferable methodological model for future comparative studies. These studies might be conducted in countries, that have comparable healthcare structures with Albania.

This means that the current study contributes to the broader international literature on PHC utilization. It achieves this, by showing how behavioural and organizational determinants might possibly be examined in an analytical framework that is unified.

6.4 Strengths and Expected Limitations

The proposed research presents several methodological strengths, which include

the integration of two established theoretical frameworks and the use of validated international measurement instruments, including the combination of patient-level and facility-level data, and the application of advanced statistical techniques, that are capable of modelling complex causal pathways. Nevertheless, there are also some limitations, that should also be acknowledged.

More specifically, the cross-sectional design of this study limits its ability to create causal relationships between the variables that are examined. Also, patient-reported measures may be affected by recall and social desirability biases. The organizational data represent conditions, that are observed at a single point in time. Furthermore, the current research sample is designed to achieve geographical representation, but despite this, the research findings may not be directly generalisable to private healthcare providers or to specialised hospital services.

7. Discussion

PHC is still the cornerstone of effective and sustainable health systems. However, understanding why individuals utilize PHC services and the way through which organizational quality influences patient outcomes, continues to represent a complex challenge for health services research. The current study responds to this challenge, and it achieves this by proposing an integrated analytical framework. This framework combines behavioural determinants of healthcare utilization with healthcare quality's organizational dimensions, in a single multilevel conceptual model.

The principal innovation of the current proposed framework lies in its ability to bridge two complementary research traditions. Andersen's Behavioural Model has been used to offer an explanation on healthcare-seeking behaviour. On the other hand, Donabedian's Structure-Process-Outcome model has been applied to assess healthcare quality. Both frameworks have created substantial empirical evidence independently. At the same time, relatively few studies have attempted to integrate these two frameworks into a unified explanatory model, that might be able to examine on the one hand patient behaviour and on the other hand, healthcare quality.

These perspectives' combination makes the current proposed framework capable of conceptualising PHC utilization as a process, that extends beyond the initial decision to seek care. Healthcare utilization is viewed as the result of the interactions that exist between individual characteristics and organizational capacity. At the same time, subsequent healthcare experiences frame the future utilization behaviour and they do so, through mechanisms of patient trust and perceived effectiveness of care. This cyclical interpretation offers a better understanding of healthcare utilization, in comparison with the conventional linear models.

A further and equally important contribution of the proposed methodology is its recognition of the multilevel nature of PHC systems. More analytically, patients do not experience healthcare independently of the organisations providing care. Instead, their experiences are integrated in the organizational environments, that are characterised by differences in staffing, infrastructure, managerial practices and service delivery processes.

The analysis of the patient-level determinants, without considering organizational context, risks the overlooking of important sources of variation in both healthcare utilization and quality.

The patient-reported measures' integration with structured organizational assessments represents another methodological strength of the proposed design of this study. Previous studies have relied only on patient surveys. Thereby, this limits their ability to distinguish between patients' subjective perceptions and objectively observable organizational characteristics. The inclusion of facility-level audit data offers a better assessment of healthcare quality and at the same time, it reduces the likelihood of common-source measurement bias.

Even more, the proposed application of Structural Equation Modelling represents an important methodological advancement. SEM enables the examination of multiple direct, indirect and moderated relationships that are generated among the latent constructs. It is about an analytical approach, that is appropriate for testing complex conceptual frameworks, in which behavioural determinants, organizational characteristics and patient experiences interact, through many different causal directions.

Despite these strengths, at first, it is mentioned that the proposed study integrates a cross-sectional design and this limits the ability to create temporal ordering and causal inference. The current conceptual framework assumes directional relationships among constructs, but longitudinal studies would provide stronger information about the causal mechanisms and feedback effects, as well. Therefore, the proposed model should be interpreted as representing theoretically informed directions and not definitive causal relationships.

Also, several variables that are included in this study rely on self-reported information, that is offered by the patients. For example, measures of healthcare utilization, satisfaction, trust and perceived outcomes may be influenced by recall bias and response tendencies or by social desirability effects. The incorporation of organizational audit data mitigates these concerns. It does so, by offering an independent source of information about the healthcare-centre characteristics. However, some degree of measurement error is still unavoidable in survey-based research.

Finally, the complexity of the proposed conceptual framework presents important analytical considerations. More specifically, the inclusion of multiple latent constructs, mediation pathways and moderation effects needs a careful evaluation of model identification, construct validity and the overall model fit. The planned application of Confirmatory Factor Analysis, bootstrapping procedures and multiple goodness-of-fit indices is intended to strengthen the empirical analyses' robustness. Nevertheless, model refinement may be needed, after the empirical testing, in order to achieve an optimal balance between theoretical completeness and statistical parsimony.

8. Conclusion

PHC is internationally recognised as the foundation of effective and sustainable health systems. Nevertheless, the understanding of the complex interactions that exist between

individual healthcare-seeking behaviour, organizational capacity and patient-reported outcomes is still a significant challenge for health services research. The already existing studies have generally examined these dimensions independently. This limits the ability that they have to explain how behavioural and organizational determinants jointly influence PHC utilization.

The current study addresses this limitation. It proposes an integrated conceptual and methodological framework. This framework combines Andersen's Behavioural Model of Health Services Use with Donabedian's Structure-Process-Outcome model. The proposed framework conceptualises PHC utilization as a dynamic process. In this process, individual characteristics influence entry into the healthcare system, organizational structures shape healthcare processes, patient experiences determine perceived outcomes. These outcomes subsequently influence future utilization through a continuous feedback mechanism.

Methodologically, this study introduces a multilevel analytical design. It is about a design, that integrates patient-level survey data with organizational assessments of PHC centres. The use of validated international measurement instruments, alongside with multilevel modelling and SEM, generates a robust framework for examining direct, indirect and moderated relationships among PHC utilization's behavioural, organizational and contextual determinants.

Also, the proposed methodology represents one of the first attempts to operationalise an integrated Andersen-Donabedian framework within the Albanian PHC system. The combination of behavioural determinants with organizational quality indicators creates the expectation of this study to generate evidence regarding the factors that influence access to care, continuity of care, patient experience and healthcare quality across different geographical and socioeconomic conditions.

Beyond its national relevance, the methodological framework has the potential to be adapted in other health systems, that face similar challenges, that are related to PHC strengthening and equitable access to care. The integration of behavioural theory, healthcare quality assessment and advanced statistical modelling offers a transferable analytical approach. This approach is capable of supporting comparative international research on PHC systems.

The findings, that are generated through the future empirical implementation of this protocol, are expected to contribute on the one hand to scientific knowledge and on the other hand, to evidence-informed policymaking. More specifically, they might assist healthcare managers in the identification of organizational priorities. They might be also helpful in the improvement of patient-centred service delivery, in strengthening continuity of care and finally, in reducing regional inequalities in PHC utilization. In doing so, this study aims to support the development of a more accessible and responsive PHC system in Albania.

Finally, the current study offers a transparent and theoretically grounded methodological protocol. This protocol might facilitate replication, methodological refinement and future longitudinal investigations, that examine the evolution of PHC utilization and quality in Albania and other comparable healthcare systems.

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