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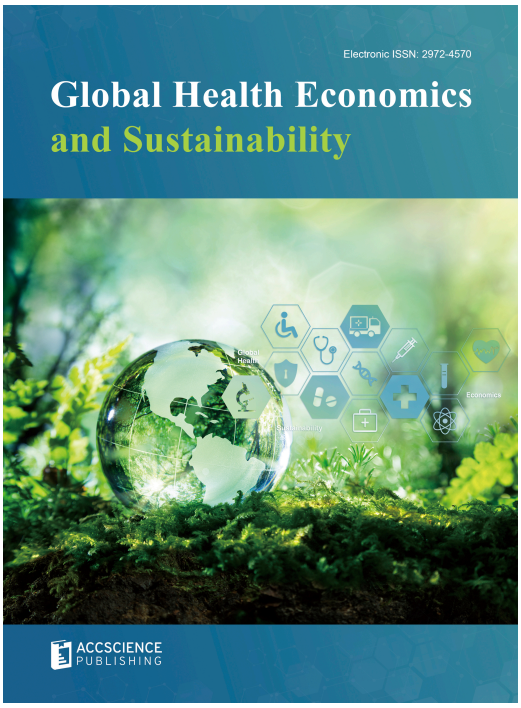

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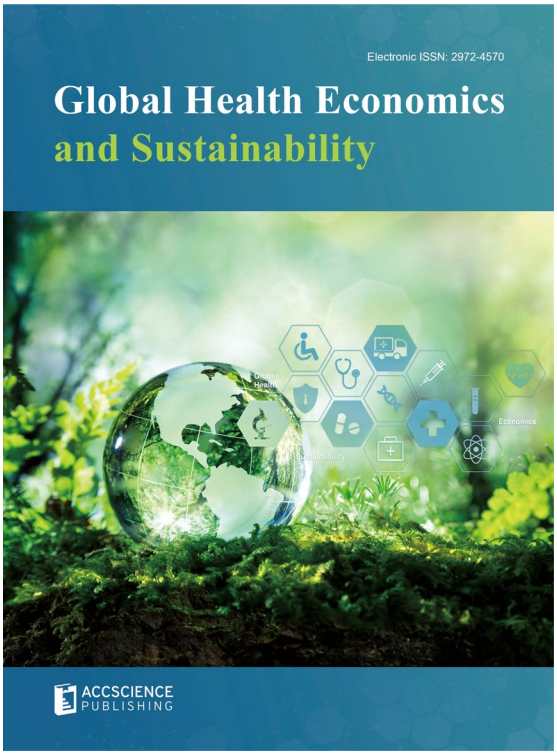

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REVIEW ARTICLE

Self-directed online learning in support of students' mental health to promote positive psychosocial outcomes in public schools

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Abstract

Negative mental health among students is currently categorized as a global crisis, and those at both ends of the academic achievements are considered at greatest risk. Public schooling, reproducing accepted psychosocial beliefs through standardized learning, has traditionally evolved independently of the imperative to address student mental health. Unlike standardized learning, self-directed learning in public schools aims to establish relevant support structures for student mental health, thereby promoting positive psychosocial outcomes. The detachment of public schooling from mental health and self-directed learning was first acknowledged – and lamented – by John Dewey over 100 years ago, who anticipated the ubiquity of the present-day mental health crisis. However, as a response to the challenges posed by COVID-19 restrictions, self-directed learning became an acknowledged learning method in public schools, potentially able to be regularly accommodated by them in support of mental health through the use of online technology. This review investigates the results of self-directed online learning in public schools during the COVID-19 pandemic through a Google Scholar search of peer-reviewed studies on self-directed learning, online learning, mental health, and public schools during COVID-19. The findings suggest that, for self-directed online learning to continue and positively impact public school students' mental health post-COVID-19, it should be embraced without bias, supported by stable internet connections, and self-initiated with relaxed parental expectations regarding standardized learning.

Keywords: Mental health; Self-directed learning; COVID-19; Online learning; Public schools; Psychosocial outcomes

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1. Introduction

Negative mental health in children and adolescents has been categorized as a global crisis (Benton *et al*., 2021). To address this concern, the World Health Organization (WHO) launched the WHO Special Initiative for Mental Health (2019 – 2023): Universal Health Coverage for Mental Health (WHO, 2023), emphasizing the alarming statistics that list suicide as the leading cause of death among young people (Ghebreyesus, 2019). Concurrently, research has highlighted an intriguing pattern: young people experiencing mental health challenges tend to be the highest achievers in standardized school settings (Wu *et al*., 2023). This counterintuitive relationship between mental health and academic

achievement is well-documented in scientific literature (Agnafors *et al*., 2021). In contrast, those who struggle academically and eventually drop out of school face an increased risk of developing major depressive symptoms in adulthood, likely linked to their previous poor academic performance, resulting in lower income and limited prospects in the labor market (Sörberg Wallin *et al*., 2019). As a consequence of this youth mental health crisis, it is acknowledged that standardized learning has a direct and lasting negative mental health effect on both the highest-achieving and the least capable students.

The public schooling model fundamentally is rooted in the long-accepted understanding of education itself (Laguardia & Pearl, 2009). In 1916, the philosopher, psychologist, and educational reformer John Dewey substantiated the purpose of education as the preparation of young people to become full members of society, equipped with both the responsibilities and privileges of adult life (Dewey, 1916). Schools serve as institutions dedicated to this very mission. Public schools, as a subset of educational institutions, are designed with the goal of providing common education to the masses through the constructive use of governmental agencies to promote the public good while preserving personal initiative. However, Dewey highlighted that these public schools often present a paradox by imparting both excessive and insufficient information to students, emphasizing a passive role where students are merely recipients of knowledge ("what others pour into them"). In all, Dewey found a "peculiar artificiality attaches to much of what is learned in schools" (Dewey, 1916). Remarkably, despite being penned over 100 years ago, Dewey's insights into education and public schools continue to resonate with our present understanding (Frank, 2019).

As designed instruments for reproducing power relations in society, public schools, managed by those associated with the dominant culture controlling public resources (Bourdieu, 2018; Wilson & Urick, 2021), are government-sponsored instruments to stabilize and reproduce public social values intended to shape individual psychological development across generations (Feinberg, 2016). Starting from the 1860s, these institutions introduced standardization into the learning process (Gutek, 2022) with the primary aim of categorizing students into two groups: those who understand the most – expected to maintain the accepted psychosocial belief system – and those who understand the least – anticipated to demonstrate psychosocial deviance (Sleeter & Carmona, 2017). In this context, the fundamental purpose of standardized educational assessment is to discriminate students based on their demonstrated knowledge, skills, and abilities (Howard *et al*., 2017) concerning accepted psychosocial standards.

According to Dewey's estimation, the establishment of public schools did not prioritize the promotion of positive mental health in students, as it was assumed that student's mental habits would conform to the desired standardized teaching methods over time. Nevertheless, Dewey considered this assumption to be grounded in a "thoroughly false psychology of mental development" because students are not passive recipients of sensory input. At the time, Dewey noted that when "variations are suppressed in the alleged interests of uniformity, and an attempt is made to have a single mold of a method of study and recitation, mental confusion and artificiality inevitably result. Originality is gradually destroyed, confidence in one's own quality of mental operation is undermined, and a docile subjection to the opinion of others is inculcated, or else ideas run wild." In this regard, Dewey's insights into the outcome of standardized education in public schooling foretold the contemporary crisis in student mental health (Dewey, 1916).

At present, public schooling has been greatly affected by the COVID-19 pandemic (Flores & Swennen, 2020). COVID-19, a previously unknown coronavirus, was declared a pandemic by the WHO on March 11, 2020 (WHO, 2023). However, on May 4, 2023, the WHO reclassified COVID-19, no longer categorizing it as a public health emergency of international concern (WHO, 2023). Several individual countries have since classified COVID-19 as endemic (Badlou, 2023). Over the course of 3 years of the COVID-19 pandemic, schools were forced to contend with limitations in education delivery that often included full school closure, necessitating a rapid shift to online learning (Adedoyin & Soykan, 2023) – an education delivery method reliant on internet-based platforms (Singh & Thurman, 2019), even extended to areas of the world where online learning was underdeveloped (Akabayashi *et al*., 2023). Teachers were required to swiftly acquire online teaching skills (Chen *et al*., 2020), while students had to adapt to a primarily self-directed mode of learning (Gerard *et al*., 2022; Li *et al*., 2023; Safa & Wicaksono, 2022).

Self-directed learning, defined as the ability to learn independently (Knowles, 1975), is commonly associated with adult education (Knowles, 1978; Loeng, 2018) because the need for self-direction may not yet be recognized by young people (Loeng, 2020). The significance of self-directed learning in public school students became particularly important regarding various psychosocial factors following the shift from teacher-centered classrooms to learner-centered approaches, especially with the shift to online learning during the COVID-19 pandemic (Toh &

Kirschner, 2020). With respect to online learning, a notable relationship exists between digital literacy competence, academic performance, and readiness for self-directed learning (Sari, 2022). For self-directed learning to be effective, it must originate from students' self-initiated motivations and personal values rather than being imposed by external factors (Loeng, 2018; Nash, 2020; Schweder & Raufelder, 2022). In contrast to achieving high academic results through standardized learning, high academic achievers who engaged in student-initiated self-directed learning during the COVID-19 pandemic experienced positive psychosocial outcomes (Kuntz & Manokore, 2022; Mathana & Galdolage, 2023). However, for those students who did not initiate self-directed learning and lacked readiness for it, the experience of being required to engage in self-directed learning during the COVID-19 pandemic was found to have detrimental effects (Al-Adwan *et al*., 2022). Challenges associated with self-directed learning have the potential to hinder students' academic success and mental health if not adequately recognized and addressed, particularly those associated with parental expectations (Al-Adwan *et al*., 2022; Maltais *et al*., 2021)

Parental expectations encompass a range of assumptions that parents hold regarding their children's academic success, which may manifest through various behaviors. These behaviors include expressing their expectations regarding their children's academic achievement and actively participating in their children's education, both at home and/or in school, with the aim of enhancing their children's educational outcomes (Pinquart & Ebeling, 2020; Yu *et al*., 2022). These expectations represent an important yet complex variable regarding their children's mental health (Almroth *et al*., 2019). However, parental expectations are not the sole influencing factor on students' academic achievement and mental health. The self-initiation of self-directed learning by students is pertinent (Cronin-Golomb & Bauer, 2023), as it has been identified as a dependent variable for positive psychosocial outcomes associated with self-directed learning (Kuntz & Manokore, 2022; Mathana & Galdolage, 2023).

To alleviate the mental health crisis in students, it is essential to foster positive psychosocial outcomes (Hossain *et al*., 2020). These outcomes, within the context of public schooling, encompass the reduction of anxiety, enhancement of resilience, improvement of well-being, and the promotion of positive mental health in children and adolescents (Andermo *et al*., 2020). With online learning now established as a viable option for public schooling due to the impact of COVID-19, the capacity to support self-directed online learning has emerged as a potentially sustainable feature of public schooling (Karatas & Arpaci, 2021). This shift offers the prospect of promoting positive psychosocial outcomes in a way that, both fundamentally and historically, has not been achievable through standardized learning in public school settings (Ghorbani & Golparvar, 2020).

This study has two main objectives: (i) To highlight the findings obtained from a brief Google Scholar search, which focused on relevant peer-reviewed articles related to self-directed learning, online learning, mental health, and public schools for students during COVID-19, and (ii) to propose a framework for addressing the difficulties in these articles, particularly concerning self-initiated learning and reduced parental expectations related to standardized learning. The ultimate aim is to facilitate the appropriate use of self-initiated self-directed learning in online learning, with the goal of improving the mental health of public school students and achieving positive psychosocial outcomes.

This study is significant as it is the first attempt to evaluate the impact of self-directed online learning on the mental health of public school students during COVID-19 from three perspectives: (i) whether the learning was self-initiated and/or parents relaxed their expectations of standardized learning; (ii) the challenges related to internet connectivity; and (iii) any biases in the initial assumptions made by the authors of these studies regarding self-directed learning, online learning and/or mental health. This research holds importance because self-directed online learning, when self-initiated and unhampered by parental expectations, has shown the potential to promote students' positive mental health and lead to positive psychosocial outcomes (Kuntz & Manokore, 2022; Mathana & Galdolage, 2023), in contrast to the standardized learning of public schooling (Ghorbani & Golparvar, 2020), deplored by Dewey (1916). In conclusion, the challenges identified in studies related to self-directed learning in public schooling during COVID-19 can be addressed through reliable internet access for students and by considering potential researcher bias when assessing mental health in the context of self-directed online learning. By prioritizing self-initiation of self-directed learning, unimpeded by parental expectations tied to standardize learning, online education has the potential to yield positive psychosocial outcomes, thereby contributing to improvements in the mental health of public school students in ways inaccessible through standardized learning – potentially aiding in alleviating the current internationally recognized mental health crisis in students.

2. Data and methods

In this concise review, the parameters were explored by searching for articles containing the keywords

"self-directed learning, online learning, mental health, public schools, COVID-19." Figure 1 illustrates the data gathered in this study, identified through a Google Scholar search conducted on May 30, 2023. Google Scholar was chosen for its widespread use among academics despite its lower precision and limited support for systematic search features (Gusenbauer & Haddaway, 2020). Based on our assessment of Google Scholar returns, it is important to clarify that this review neither classifies as a systematic review nor a scoping review (Page *et al.*, 2021). Its primary objective is to provide examples of peer-reviewed research pertaining to the predefined set of keywords. Nevertheless, for transparency in presenting the author's methodology for gathering materials, the author adapted the Standardized Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) flowchart. This adaptation reflects those articles retrieved, along with established inclusion and exclusion criteria (Moher *et al.*, 2009). To illustrate the flow of information – demonstrating the actual flow rather than merely the flow of remaining articles under consideration – the standard PRISMA chart has been adjusted by the author for the purpose of this particular review.

The search of Google Scholar continued until all ten results per page did not contain all the specified keywords. This process required viewing 11 pages of returns, totaling 110 distinct entries. All entries were subsequently copied to a Word document to identify duplicates, and none were found. To facilitate the assessment, a tab was opened in the Safari browser for each of the 11 pages. The abstract of each individual search result was examined to determine if

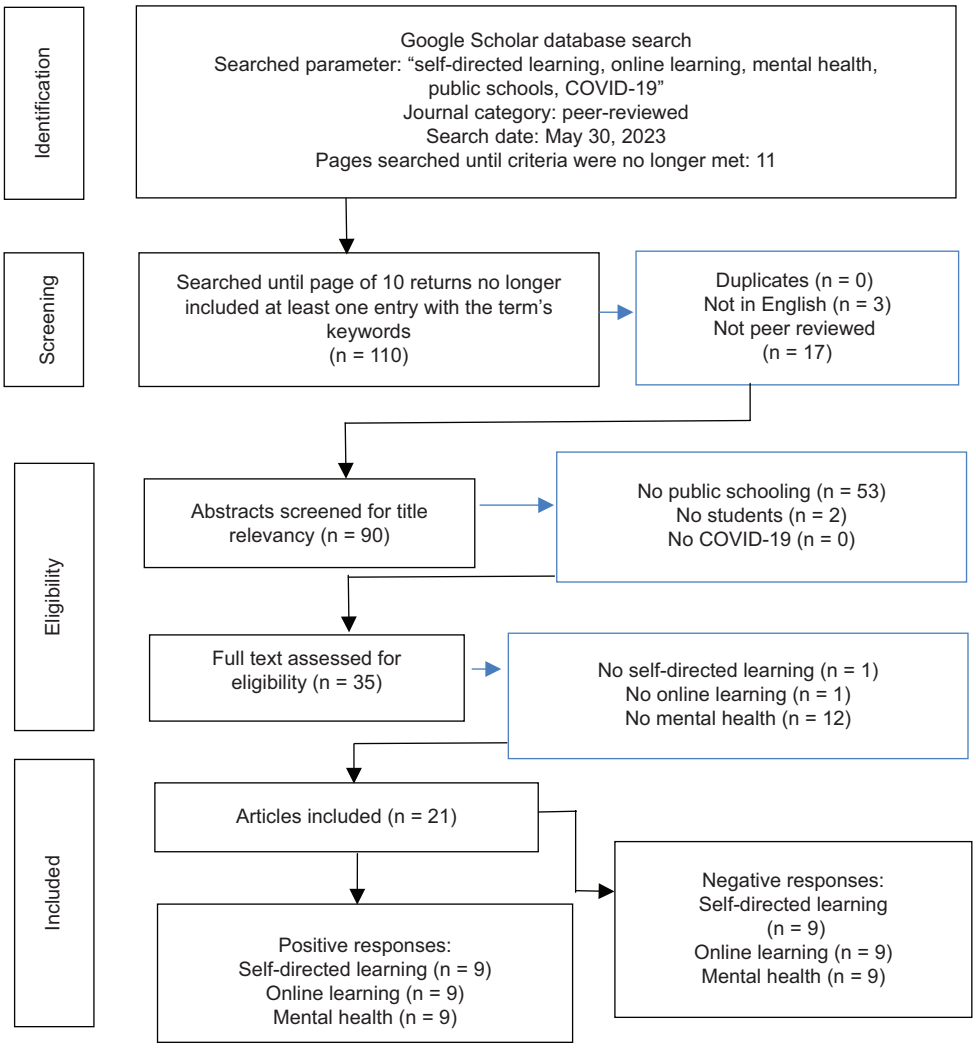

Figure 1. The author-created flow of information (inspired by the PRISMA original diagram (Moher *et al.* 2009) for a Google Scholar search of the parameter containing the keywords "self-directed learning, online learning, mental health, public schools, COVID-19," conducted on May 30, 2023. Arrows and information in blue represent the process and result of eliminating articles from consideration, respectively.

the article was written in English and whether it originated from a peer-reviewed journal. This examination led to the exclusion of three articles not written in English and 17 articles published in non-peer-reviewed journals, leaving a total of 90 articles.

To determine the eligibility of the remaining 90 articles, the abstracts were scrutinized to determine whether they mentioned public schools or COVID-19 and whether the term "student" appeared. Among these articles, 53 did not include public schooling, 2 did not mention students, and none lacked consideration of COVID-19, resulting in 35 eligible articles. These remaining articles underwent further evaluation through a word search to identify whether they were missing any of the following terms: "self-directed learning," "online learning," or "mental health." This analysis revealed that 1 article did not mention "self-directed learning," 1 did not reference "online learning," and 12 failed to mention "mental health." This process ultimately yielded 21 articles that were included in the final assessment.

The remaining 21 articles were then scrutinized to determine whether the article presented a positive or negative perspective on any of the following: self-directed learning, online learning, and mental health. This examination involved thoroughly reviewing the content of the articles related to these terms. The positive responses were 9 for self-directed learning, 9 related to online learning, and 6 concerning mental health. In contrast, the negative responses are summarized as 12 regarding self-directed learning, 12 for online learning, and 15 with respect to mental health.

3. Results

The results of applying these methods produced 21 articles for inclusion as the materials. The topics of these articles are as follows: impact of information literacy (Li *et al.*, 2023); motivating online learning (Chiu *et al.*, 2021); learning in isolation (Tacogue *et al.*, 2022); high school student-athlete experiences (Shepherd *et al.*, 2021); high school experience of online learning (Yates *et al.*, 2021); self-directed learning on learning outcomes in massive open online courses (MOOCs) (Doo *et al.*, 2023); students' self-directed learning in English (Dwilestari *et al.*, 2021); guiding teaching strategies (Zhao *et al.*, 2020); students' acceptance towards online learning (Harun & Abd Aziz, 2021); self-directed learning and attitude on online learning (Shao *et al.*, 2022); mental health of high school students (Garcia *et al.*, 2022); school connectedness still matters (Perkins *et al.*, 2021); implementation and challenges of online education (Zhu *et al.*, 2022); challenges and opportunities in online distance learning (Manalo *et al.*, 2022); student evaluations of transitioned-online courses (Garris & Fleck, 2022); adaptability and high school students' online learning (Martin *et al.*, 2021); the impact of learning on science, social and digital literacy (Amina & Susilo, 2022); factors affecting students' happiness on online learning (Ong *et al.*, 2022); a comparison of online learning challenges (Manoharan *et al.*, 2022); "Teachers act like we're robots" (Literat, 2021); and a literature review on teaching and learning (Pokhrel & Chhetri, 2021).

These 21 articles are listed in Table 1, with respect to their authors and publication dates. The table also includes an assessment of whether each article had a positive or negative perspective on self-directed learning, online learning, and student mental health. Out of the total, 12 articles (57.1%) expressed negative views on self-directed learning, 12 articles (57.1%) presented negative evaluations of online learning, and 15 articles (71.4%) conveyed negative views regarding the mental health of students. Among the included articles, 14 out of 21 (66.7%) exhibited consistent assessments, with either all negative or all positive perspectives on the three variables. Out of

Table 1. Articles returned from a Google Scholar search on May 30, 2023, and filtered according to the criteria mentioned in Section 3

Authors and publication years of articles	Self-direction	Online learning	Mental health
Li *et al.* (2023)	+	+	+
Chiu *et al.* (2021)	+	–	–
Tacogue *et al.* (2022)	–	–	–
Shepherd *et al.* (2021)	–	–	–
Yates *et al.* (2021)	–	+	–
Doo *et al.* (2022)	+	+	+
Dwilestari *et al.* (2021)	+	–	+
Zhao *et al.* (2020)	+	+	+
Harun & Abd Aziz (2021)	–	+	–
Shao *et al.* (2022)	–	–	–
Garcia *et al.* (2022)	+	+	+
Perkins *et al.* (2021)	–	–	–
Zhu *et al.* (2022)	–	–	–
Manalo *et al.* (2022)	+	+	–
Garris & Fleck (2022)	–	–	–
Martin *et al.* (2021)	–	+	–
Amina & Susilo (2022)	–	–	–
Ong *et al.* (2022)	+	+	+
Manoharan *et al.* (2022)	–	–	–
Literat (2021)	–	–	–
Pokhrel & Chhetri (2021)	+	–	–

these, five articles offered entirely positive evaluations of self-directed learning, online learning, and mental health, while the remaining nine had entirely negative assessments of self-directed learning, online learning, and mental health.

Among the articles that did not exhibit entirely positive or entirely negative assessments of self-directed learning, online learning, and mental health in public school students during COVID-19, the following patterns emerged:

(i). One article had a positive outlook on both self-directed learning and the mental health of public school students during the COVID-19 pandemic but held a negative view of online learning.
(ii). One article found both self-directed learning and online learning to yield positive results during the pandemic, but at the same time, these forms of learning had negative implications for student mental health.
(iii). There were no articles that were positive about online learning and mental health but negative regarding self-directed learning.
(iv). Two articles expressed positivity about self-directed learning but were negative with respect to both online learning and the student's mental health.
(v). Three articles were positive about online learning but had negative assessments for both self-direction and mental health of public school students.
(vi). None of the articles had authors who were positive about the mental health of public school students while being negative regarding both self-directed learning and online learning.

4. Discussion

This discussion examines articles retrieved from the Google Scholar search conducted on May 30, 2023. The focus is on articles that explore the relationship between self-directed online learning and positive mental health. The examination aims to identify whether these articles acknowledged the importance of self-initiation in learning and reduced parental expectations. The articles that specifically mentioned poor internet connectivity as a barrier to effective online learning are noted. Furthermore, articles exhibiting author bias are discussed, establishing why their research results are questionable. Finally, this discussion includes a section on the study's limitations, which is derived from the results of this examination.

4.1. Positive assessments for each of the three variables

The articles that had a positive evaluation of all three variables, namely, self-directed learning, online learning, and mental health of public school students during the COVID-19 pandemic, are listed in Table 1 as follows: Li *et al.* (2023), Doo *et al.* (2023), Zhao *et al.* (2020), Garcia *et al.* (2022), and Ong *et al.* (2022). Three additional articles did not consider each of these variables as positive; however, this lack of positive assessment stems from contingent limitations identified by the authors. These limitations, had they not been present, would likely have resulted in positive findings. These three articles are Shao *et al.* (2022), Zhu *et al.* (2022), and Manoharan *et al.* (2022). In the assessment of whether each of the relevant variables can be considered positive or has the potential to be positive, it is essential to determine which of these articles emphasize the importance of self-directed learning as self-initiated and underscore the importance of parents reducing their expectations for standardized academic achievement.

Among the five articles listed in Table 1, one investigates the impact of information literacy in a study conducted on Chinese public school students (Li *et al.*, 2023). While this article identifies a positive correlation among self-directed learning, online learning, and positive mental health, it is important to note that the authors' interpretation of self-directed learning differs from the conventional understanding of the term, which is learning guided by the student's personal values (Loeng, 2018; Nash, 2020; Schweder & Raufelder, 2022). To align with the authors' vision of self-directed learning, they advocate for the cultivation of students' self-directed learning skills. From their perspective, this can be achieved through the efforts of teachers in establishing a "harmonious and independent online learning atmosphere" designed to enhance student motivation, with an additional focus on encouraging teamwork among students. This goal can be accomplished by assigning specific homework tasks, a collaborative effort between teachers and parents, who assume the role of "guardians of the students' self-directed learning." The article does not discuss the role of standardized expectations of parents.

The second article, providing a positive assessment of all three variables – focused on the impact of self-directed learning on learning outcomes in MOOCs – does not mention self-initiated learning (Doo *et al.*, 2023). However, it does refer to self-regulated, self-managed, and self-monitored learning. On a thorough examination of the article, it becomes evident that the authors perceive self-directed learning as stemming from learning engagements preferred by the students rather than the development of skills facilitated by teachers and parents, as emphasized in Li *et al.* (2023). These authors focused on MOOCs, which they recognized as learning environments that provide learners with "unprecedented autonomy in learning." It is this autonomy afforded to learners within MOOCS

that is associated with positive mental health outcomes. With respect to the role of educators, these authors recommended that teachers "need a deeper understanding of the impact of motivation, self-monitoring, and self-management to improve the learning outcomes in MOOCs and to facilitate SDL as a critical factor for MOOC learners' success." The article does not discuss the role of reducing parental expectations concerning standardized learning.

The third article, finding a positive connection among self-directed learning, online learning, and mental health, focuses on guiding teacher strategies (Zhao *et al*., 2020). Once again, this is an article from China in which self-directed learning is characterized as involving "self-exploration, self-discovery, and self-acquisition of knowledge." In this context, the teacher's role is perceived as strengthening this form of autonomous learning by providing homework materials to students. The authors advocate for the use of "Strict Management of Online Teaching" as one of their section headings, highlighting two important goals for teachers: behavior management and emotional management of the students. Concurrently, the parents are encouraged to maintain regular communication with teachers to form "a good home-school co-education model." According to the authors' assessment, it is through this strict management approach that positive mental health can be expected. As a result, while this article expresses positive regarding each of the variables, it does not actually refer to self-directed learning – it can more accurately be considered as self-controlled learning. In this regard, this article does not consider the necessity of self-initiation since its primary focus lies beyond the realm of self-directed learning *per se*.

The fourth article investigates the mental health of high school students (Garcia *et al*., 2022), presenting a positive perspective on all three variables. In contrast to the previous articles – all positive with respect to their assessment of self-directed learning, online learning, and mental health – that uniformly assessed each variable, this paper places its primary focus on students' mental health. While the concept of students self-directing their learning online is mentioned, it is only a tangential interest. The central message of the article revolves around how, despite initially suffering from anxiety related to COVID-19, students managed to adapt to the pandemic and their self-directed online learning, resulting in positive mental health outcomes. There is no actual discussion concerning the students' learning, making it challenging to ascertain why these authors held a positive assessment of self-directed online learning, except that this learning did not appear to adversely affect the mental health of the students. This article does not delve into the role of parents.

The final article that provides a positive assessment of all three variables focuses on factors affecting students' happiness with online learning (Ong *et al*., 2022). From the perspective of these authors, who are interested in identifying what contributes to students' happiness, the need for autonomy "to feel free and self-directed" is imperative. Consequently, any form of learning that improves the ability of students to self-direct their learning is considered to increase their happiness. Thus, the self-directed online learning required due to the COVID-19 pandemic had the potential to boost students' happiness if they felt free to self-direct their learning. Furthermore, these authors observed that when students truly felt that they could self-direct their learning, they also expressed a stronger sense of connection with fellow online learners. The findings of the article are in support of the previous research that has highlighted self-directed learning as a positive experience, particularly when this learning is self-initiated. The article does not discuss the role of parents.

A study investigating self-directed learning and attitudes toward online learning specifically examined both self-directed learning and online learning in relation to the mental health of public school students (Shao *et al*., 2022). Nevertheless, unlike the articles that held positive assessments for all three variables, the study ultimately evaluated self-directed learning, online learning, and mental health as negative for public school students during the COVID-19 pandemic. However, this assessment was the result of a thorough examination of both the positive and negative factors involved. The authors clearly believed that for students who self-initiated their learning, self-directed online learning was positive and correlated with positive mental health. The problem identified by the authors is that the majority of students do not belong to this category. Consequently, for most students, their experiences during the COVID-19 pandemic were entirely negative. According to these authors, their results indicate that a student's ability in self-directed learning in this regard can serve as a predictor of their mental state, indirectly influencing the effectiveness of online learning. The study did not address the impact of reducing parental expectations regarding standardized learning on fostering self-initiation in their children.

Another article, which delves into the implementation and challenges of online education (Zhu *et al*., 2022), presents another balanced approach to the consideration of online learning, although with negative assessments for all three variables concerning most students. What is particularly interesting about this study is its scope, involving a sample of 28,334 children in China. In contrast to other studies conducted in China, the article does not

consider the transition to self-directed online learning as a positive development. Instead, it associates this shift with negative mental health in the children. Notably, the study aligns with previous research (Al-Adwan *et al*., 2022; Maltais *et al*., 2021) by attributing these negative results primarily to parental expectations regarding their children's learning during the lockdown. The authors suggested that in the absence of these expectations, mental health in online learning would be positive. While the study maintains a balanced assessment of the three variables, it does not delve into the importance of self-initiated learning.

A comparative analysis of online learning challenges was undertaken in another study, which resulted in a negative assessment of self-directed learning, online learning, and the mental health of both adults and public school students during the COVID-19 pandemic (Manoharan et *al*., 2022). The authors initially assert that online learning represents an "education revolution." However, when it comes to the evaluation of public school students, they attribute the negative perception of self-directed online learning to inadequate support from parents and teachers. This lack of support negatively affects students' mental health. In the view of these authors, this negative assessment can only be improved through enhanced online learning support provided by these adults. Thus, it is implied that such support will inevitably become more prevalent due to the increasing importance of online learning. Once again, the study does not address the importance of self-initiated learning for achieving a positive assessment of self-directed learning.

4.2. Articles with negative assessments resulting from poor internet connectivity

The success of self-directed online learning for public school students hinges on their access to a stable internet connection (Basar *et al*., 2021). Therefore, it is pertinent to examine the extent of retrieved articles addressing internet connectivity issues. Notably, two articles explicitly discuss this concern: Dwilestari *et al*. (2021) and Pokhrel & Chhetri (2021).

The article, which explores self-directed learning in the context of English language learning (Dwilestari *et al*., 2021), provides insights into the emergence of three different types of self-directed learners when the COVID-19 pandemic demanded self-directed online learning. The first group comprises students who self-initiated their learning and preferred self-directed learning. For these students, self-directed learning is a positive experience, consistent with findings in the previous research (Kuntz & Manokore, 2022; Mathana & Galdolage, 2023). The second group consists of students who were not inclined to begin self-directed learning but, with the right support from teachers, transitioned into becoming self-directed learners. In this group, the teachers placed significant emphasis on their role in fostering self-directed learning, leading to a number of students in the second group developing a positive outlook on their self-directed learning. For the last group, they displayed neither an interest in self-directed learning nor the ability to benefit from the accommodations provided by the teachers. Consequently, it was only within this group that self-directed learning was not viewed positively. However, what also differed in this group was, unlike the other two, they lacked the same positive motivation to learn English. Consequently, they began with negative mental health in relation to their studies. A common thread among all the students was the challenge of poor internet connections. The difficulty in consistently and regularly accessing online learning due to these connectivity issues led to a negative assessment of online learning. On the other hand, had the connection been reliable, the article would have been included among those with positive assessments for all three variables. This article does not delve into the role of parental expectations, nor does it clarify whether the self-directed learning encouraged by the teachers was self-initiated by the students.

In the context of the literature review examining the impact of COVID-19 on teaching and learning, the article of Pokhrel & Chhetri (2021) represents the second of two papers that held a positive view of self-directed learning but negative concerning both online learning and mental health. The authors assume that self-directed learning is the preferred method of learning. Nevertheless, predominantly due to poor internet connections, students had a negative experience with online learning. However, it is crucial to note that the negative perspective on the mental health of the students under study was not a result of either self-directed learning or online learning. Instead, this negative perspective on mental health was attributed to the rise in domestic violence and child abuse cases that occurred as a consequence of children being required to stay at home for extended periods during the COVID-19 pandemic. This paper did not comment on whether self-directed learning is self-initiated or on the role of parental expectations in maintaining standardized learning.

4.3. Articles presenting biased perspectives

In assessing the articles obtained from this Google Scholar search, it is important to consider the objectivity of the authors in making their assessments regarding the mental health of students with respect to self-directed online learning. Out of the 21 articles, 8 (38%) reached specific

conclusions that were influenced by the particular biases with which the authors began their research (Chiu *et al*., 2021; Harun & Abd Aziz, 2021; Li *et al*., 2023; Ong *et al*., 2022; Perkins *et al*., 2021; Shepherd *et al*., 2021; Tacogue *et al*., 2022; Zhao *et al*., 2020). These biases must be taken into consideration when assessing the value of the authors' conclusions.

The paper by Chiu *et al*. (2021) focused on motivating online learning assumes the assumption that self-directed learning is valuable and that all learning should progress in this direction. However, despite recognizing the positive perspective on self-directed learning, self-initiated learning is not mentioned. This omission is likely due to the article's emphasis on the challenges posed by self-directed learning during the COVID-19 pandemic, particularly in relation to students' engagement with online learning. While the authors appreciate the autonomy that online learning affords, their negative opinion of online learning may stem from their consideration of in-person social engagement, both with teachers and peers in school, as fundamental to fostering positive mental health. Since the type of in-person social engagement with teachers and peers that these authors deem essential cannot be provided with online learning, and this absence is viewed as a contributor to poor mental health, both online learning and mental health are evaluated as negative in the context of the transition to online learning during the COVID-19 pandemic.

The article by Harun & Abd Aziz (2021) assesses the impact of COVID-19 on students' readiness to embrace online learning. The authors viewed online learning as the new educational norm, and consequently, online learning was necessarily assessed positively. The primary aim of the article is to identify the factors hindering students from fully embracing online learning. In this regard, the requirement for self-directed learning was perceived as a burden by the students under study because they lacked the necessary mental readiness. This negative aspect of their mental health dampened their motivation to embrace online learning. Unlike other articles that yielded similar findings but assessed online learning negatively, these authors attributed the problem not to online learning but rather to poor self-directed learning and compromised mental health.

Regarding the study by Li *et al*. (2023) discussed in Section 4.1 above, it is important to highlight that their interpretation of self-directed learning is at odds with demonstrating trust in students' ability to genuinely self-direct their learning. In this way, it is evident why the article does not delve into self-initiated learning – as the type of learning perceived by these authors is opposed to that which is self-initiated. Thus, the success of online learning and positive mental health observed in the study can be attributed to learning methods devised by teachers and parents rather than genuine self-directed learning.

While Ong *et al*. (2022), also discussed in Section 4.1, held a positive view of self-directed learning, online learning, and mental health during the COVID-19 pandemic, their perspective was centered on promoting happiness rather than focusing on the learning aspect. It is noteworthy that their viewpoint aligns more closely with Dewey's understanding of the role of education in enhancing positive mental health. The authors considered self-directed learning as a pathway to happiness due to its endorsement of autonomy. In this regard, these authors were conceptually compelled to regard each of the three variables positively due to their perspective on happiness.

The article by Perkins *et al*. (2021) emphasizes the importance of school connectedness and assesses all three variables as negative. It begins with a biased perspective that school connectedness is best experienced in school. Consequently, these authors inevitably concluded that self-directed learning, online learning, and mental health were all negative as a result of the school closures brought on by COVID-19 merely because students were not physically present in school. This result indicates that all negative results regarding the three variables often stem from the authors' preconceived viewpoints, which are not directly related to the three variables. However, due to these viewpoints, the three variables are subsequently assessed as negative.

Shepherd *et al*., 2021, presumed that online learning would not satisfy learners during the COVID-19 pandemic due to their focus on high school athletes. These athletes relied on physical contact and team engagements for their learning. Therefore, the social distancing measures imposed during the COVID-19 pandemic, which banned team sports (Yomoda & Kurita, 2021), made self-directed online learning unsatisfying in comparison to in-person classes. This, according to the authors, led to negative mental health among the students under study. However, the article did not consider students who did not prefer in-person physical education classes due to their disinterest in the physical contact involved in team sports. Other research (McGuine *et al*., 2021) has shown that such students experienced positive mental health during the COVID-19 pandemic. By not accounting for students other than those excelling in team sports, these authors introduced bias into their assessment of self-directed online learning.

Focusing on the isolation experienced by students during the COVID-19 pandemic, Tacogue *et al*. (2022)

contended that this isolation inevitably led to negative mental health. They argued that the students' perceived negative mental health hindered their engagement with self-directed learning, and online learning exacerbated their sense of isolation – providing the basis for their negative assessments of both. However, by equating working independently with feeling isolated, these authors failed to consider the potential benefits of both self-directed learning and online learning, revealing their particular bias. Nevertheless, even though their primary focus was on isolation, these authors did report a recurring theme among students who recognized the advantages of self-directed learning. Still, they concluded their discussion by characterizing self-directed learning as a "plight in solitary learning."

Zhao *et al.* (2020), as discussed in Section 4.1, exhibit a bias in their assessment of self-directed learning, perceiving it as a form of self-controlled learning that relies on teacher management. Given that this interpretation deviates from the accepted definition of self-directed learning, it is essential to assess and evaluate the article's conclusions in light of this perspective.

4.4. Limitations

The primary limitation of this research is its dependency on time-sensitive results, as the search was limited to Google Scholar, which represents a supplementary database. Had the author opted for a scoping review, primary databases would have been included, eliminating this limitation. Moreover, the choice of conducting a systematic review with a meta-analysis would have allowed for the inclusion of relevant statistical analyses. Overcoming these limitations would be a valuable direction for future research in this area.

Another limitation is that the evaluation of articles for the authors' perspectives on self-directed learning (particularly with respect to self-initiation of that learning), online learning, mental health, and the role of parental expectations, relied on the review conducted by the author of this paper. While this paper aimed for objectivity, it is possible the author had an unrecognized cognitive bias (Neal *et al.*, 2022). Such cognitive biases among researchers were identified in 8 of the 21 studies (38.1%) included in the examination (Chiu *et al.*, 2021; Harun & Abd Aziz, 2021; Li *et al.*, 2023; Ong *et al.*, 2022; Perkins *et al.*, 2021; Shepherd *et al.*, 2021; Tacogue *et al.*, 2022; Zhao *et al.*, 2020). Various frameworks have been developed to mitigate research bias. However, there is limited research on the efficacy of these models. Therefore, the recognition and reduction of cognitive bias remain areas in need of further research (Neal *et al.*, 2022).

When assessing the role of self-initiation in relation to self-directed learning, online learning, and the mental health of public school students during the COVID-19 pandemic, it is a limitation that only a few of the articles retrieved in the Google Scholar search on May 30, 2023, considered self-initiation. Out of the 21 articles that were ultimately included, only 5 (Doo *et al.*, 2023; Dwilestari *et al.*, 2021; Li *et al.*, 2023; Ong *et al.*, 2022; Shao *et al.*, 2022) examined the role of self-initiation in self-directed learning. Three of these articles provided positive assessments for self-directed learning, online learning, and mental health (Doo *et al.*, 2023; Li *et al.*, 2023; Ong *et al.*, 2022). However, Li *et al.* (2023) assumed a definition of self-directed learning that depended on teachers and parents rather than self-initiation based on individual learner preferences. Another study (Dwilestari *et al.*, 2021) viewed only self-directed learning and mental health as positive aspects of self-initiated learning. However, those surveyed students predominantly had poor internet connections, leading to a negative assessment of online learning. In contrast, the paper by Shao *et al.* (2022) considered self-initiated learning, and assessed all three variables as negative. As mentioned in the discussion, this was because the authors recognized that few of the students affected by the COVID-19 limitations were willing or able to self-initiate their learning. The limited number of articles retrieved in the Google Scholar search on May 30, 2023, that mention self-initiation concerning self-directed learning represents a limitation that warrants further research in this area.

The lack of research on the effect of parental expectations on the mental health of students with respect to self-initiated self-directed online learning is a notable limitation. Although it has been acknowledged that the expectations of parents related to standardized learning can directly impact students' mental health concerning self-directed online learning (Al-Adwan *et al.*, 2022; Maltais *et al.*, 2021), only 2 articles considered the role of parental expectations as hindrances to self-directed online learning (Manoharan *et al.*, 2022; Zhu *et al.*, 2022). In addition, there were only four papers that explored parent support of self-initiated self-directed learning (Doo *et al.*, 2023; Dwilestari *et al.*, 2021; Ong *et al.*, 2022; and Shao *et al.*, 2022). Among these, the authors of Doo *et al.* (2023) provide insights into the type of support parents should offer to their children to promote self-initiated learning. However, they do not address the challenges associated with maintaining standardized expectations, which can hinder self-initiated learning. In the study by Dwilestari *et al.* (2021), although the role of teachers is mentioned in supporting learners initially reluctant to engage in self-initiated learning, the paper lacks information regarding

how parental expectations to maintain standardized learning can jeopardize this self-initiation. Surprisingly, in the study by Ong *et al.* (2022), an article that explores student happiness and emphasizes the importance of self-initiation in self-directed learning for promoting happiness, there is no mention of the role of parental standardized expectations in potentially reducing happiness. Finally, in a balanced assessment like that of Shao *et al.* (2022), which highlights the importance of self-initiated learning in the success of self-directed learning, it remains unclear why the authors did not consider the potential negative role of parental expectations for the continued standardized learning of their children during the COVID pandemic. This gap in research on parental expectations regarding self-initiated learning is an important issue that warrants future investigation.

However, in this review of reports studying "self-directed learning, online learning, mental health, public schools, COVID-19", one important aspect was not considered: the effect of students' personal experiences with COVID-19. These experiences include household financial stress, student or family member illnesses, family bereavements, reduced physical activity, resource-sharing within the family, managing relationships with family members, and having multiple school-aged siblings. All of these factors may have affected the students' ability to self-direct their learning, the amount of time they could allocate to online learning, their capacity to self-initiate their learning, their parents' expectations, and their mental health. Consequently, there is a substantial need for further research to examine the influence of these variables in future studies.

Another limitation is that, although self-directed online learning became the primary mode of learning for most public school students during COVID-19 – and what hindered many from fully participating was poor internet connectivity – for some more disadvantaged students, their computer skills were insufficient for engaging in this self-directed learning. For example, in the economically disadvantaged areas of California, certain public schools refrained from implementing online learning for this reason, and instead, during the COVID-19 pandemic, distance learning meant distributing books and paper packets to students for at-home learning (Schulz & Robinson, 2022). For students who were unable to participate in online learning due to a lack of computer skills, the potential benefits of self-directed online learning for enhancing their mental health were not accessible during the COVID-19 pandemic. Assessing the extent of public school students who still lack computer skills and, consequently, are unable to participate in online learning is another area that warrants further research.

Finally, not all online learning was self-directed during the pandemic, especially for those students who felt most comfortable with maintaining the practices of standardized learning where teachers were willing to accommodate this learning preference. In these cases, teachers employed a range of teaching practices to cater to students' needs. According to a study by Yates *et al.* (2021), these practices included direct instruction, feedback provision, multimedia resources, class discussions, clear communication, interactive activities, and gamification. As one student reported in this study, "Just being able to listen to the teacher and take down notes in a lecture-styled way. Although some teachers worried it would be too boring, it was more straight to the point and less time-consuming than "active activities."" Future research in this area could focus on comparing the different types of online learning that students experienced during the COVID-19 pandemic.

5. Conclusions

Students positive psychosocial outcomes are essential to address regarding the recognized mental health crisis in youth (Hossain *et al.*, 2020). These outcomes encompass reducing anxiety, increasing resilience, enhancing well-being, and promoting positive mental health in children and adolescents (Andermo *et al.*, 2020). Dewey emphasized the importance of positive mental health in public school students over 100 years ago, highlighting that standardized learning did not address this need (Dewey, 1916). Unlike the standardized learning that has prevailed in public education since the 1860s, self-initiated self-directed learning has been identified as a means to promote positive psychosocial outcomes (Kuntz & Manokore, 2022; Mathana & Galdolage, 2023). During the COVID-19 pandemic, when the majority of public school students were compelled to transition into self-directed online learners, the crucial role of self-initiation of self-directed learning became evident. Alongside the need for a reliable internet connection and relaxed parental expectations regarding standardized learning, self-initiation emerged as paramount for evaluating self-directed learning, online learning, and mental health positively. Conversely, when self-initiation was lacking, self-directed learning was assessed as negative (Al-Adwan *et al.*, 2022). This result has become clear from a Google Scholar search using the parameter containing the following keywords: "self-directed learning, online learning, mental health, public schools, COVID-19." Among the 21 articles examined, 4 included mention of self-initiation in self-directed learning (Dwilestari *et al.*, 2021, Doo *et al.*, 2023, Ong *et al.*, 2022, Shao *et al.*, 2022). In support of previous research regarding self-initiation in self-directed learning, all of

them identified that it is because of self-initiation that self-directed learning promotes positive psychosocial outcomes – the outcomes identified by John Dewey over 100 years ago as the fundamental goal of public schooling. In addition, only two articles (Manoharan *et al*., 2022; Zhu *et al*., 2022) considered parental expectations of standardization – both finding these expectations detrimental.

Recognizing the importance of self-initiated self-directed learning for positive mental health, it became evident during the COVID-19 limitations related to in-person public school attendance that public schools have the capability to support self-directed online learning independently of in-school learning. While some students did not experience positive self-directed online learning or positive mental health during this period, others – the self-initiated self-directed online learners – did experience positive results in self-directed learning, online learning, and their mental health. This positive experience improved their psychosocial outcomes, with much of the variation in success attributed to both a reliable internet connection and parental expectations that were not tied to standardize learning (Al-Adwan *et al*., 2022; Manoharan *et al*., 2022; Maltais *et al*., 2021). Furthermore, with the appropriate teacher support, students who initially lacked an interest in self-directed learning were observed to develop a positive experience with self-directed learning (Amina & Susilo, 2022; Dwilestari *et al*., 2021; Manoharan *et al*., 2022).

Consequently, public schools are encouraged to continue providing online learning for students who are self-initiated self-directed online learners rather than insisting that they return to in-person standardized learning. It is acknowledged that the latter is unable to produce positive psychosocial outcomes, both for the highest-achieving (Agnafors *et al*., 2021; Wu & Zhang, 2023) and lowest-achieving students (Sörberg Wallin *et al*., 2019). By providing these students with reliable internet connections and relieving them from parental expectations tied to standardized learning, some of these highest- and lowest-achieving students may be safeguarded from the ongoing global mental health crisis of public school students.

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PERSPECTIVE ARTICLE

Max Weber and Harriet Martineau in physical education: Nuances of historical parallelism and gender bias in the sociological method

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Abstract

Physical education has been constituted in a complex scenario, and despite this epistemological debate, we can find the existence of a "sociology of sport," a relatively recent field of study dominated by names such as Karl Marx, Norbert Elias, Pierre Bourdieu, and Michel Foucault, while the name of Max Weber and Harriet Martineau, the first woman sociologist, is absent of research in the "sociology of sport." This article aims to explore two possible phenomena to explain this failure: Historical parallelism and gender bias. This research applies the bibliographic method with a descriptive approach, based on the works of Max Weber and Harriet Martineau, including supporting theoretical references. As the main result, Weber considered sociology as a science that seeks to interpretively understand social action and explain it causally in its course and effects. According to Weber, scientists must be skilled in separating judgments of reality (what is) and judgments of value (what ought to be) in scientific analysis, to pursue genuine knowledge, and he organized his sociological analysis method based on two main tools: (1) Ideal types and (2) types of social action. Temporarily before Weber, Martineau (1802 – 1876) pointed to aspects related to the observation process, and provided examples related to the different classifications of what Weber referred to as "social action." She emphasized the need to engage with the people and groups from which one seeks to gather information, and two elements stand out: (1) The recommendation to study things, using people's discourse as if it was a commentary on them and (2) the occasional need to distance oneself a little to have a more accurate view of the phenomenon. Martineau provided relevant indications regarding the recording of facts, previously to Weber. In conclusion, it is expected that researchers from different areas, including physical education, who employ research methods from the social sciences, field diary observations, and interviews, can appropriate what was previously produced before Max Weber, in this case, by Harriet Martineau.

Keywords: Physical education; Sociology; Sports; Research projects; Gender role

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1. Introduction

Physical education is an area of knowledge that dialogues with the social sciences, which has been constituted in a complex scenario because, despite this epistemological

debate, we can find an existence of a "sociology of sport" (Betti, 2005; Dart, 2014). In this sense, at the same time, two discourses emerged: (1) The first discourse as a scientific matrix, which considers it as an area of scientific knowledge and (2) a pedagogical matrix, which conceives it as a pedagogical practice and, therefore, a field of social action for intervention (Betti, 2005). Such tension generates various clashes, as a false polarization between such discourses is often constructed.

The first speech comes from the inclusion of physical education in a perspective associated with natural sciences, especially in the area of health sciences (Brasil, 2014). The second stems from a strong insertion in the school environment, with very intense pedagogical practices and cultural approaches, which would bring it closer to the social and human sciences (Betti, 2005). It is worth highlighting that the incorporation of scientific practice into physical education began as a result of the pressure of scientism within the academic environment, the impetus of the sports phenomenon, and the emergence of various sports sciences on the international scene (Lazzaroti Filho *et al*., 2018; Amstel & Marchi Jr., 2021). This convergence of movements ends up reinforcing and, to some extent, maintaining such dichotomy. At the same time, it is frequently recognized that physical education should encompass the specificity of an interdisciplinary field, thus requiring the articulation of elements from both the biological and social sciences (Lazzaroti Filho *et al*., 2018).

To overcome this dualism within the theoretical-epistemological field of physical education, Betti (1996) proposed a theory of physical education, which emerges as a "dynamic field of research and reflection" aiming to systematize and critically analyze scientific and philosophical knowledge, and to receive and contribute to social practice, as well as various areas of science and philosophy. Despite this epistemological debate, physical education is still consolidating as a knowledge-producing field predominantly related to the natural sciences, but with significant research efforts in the social and human sciences. This is because physical education also seeks to incorporate scientific knowledge from large monodisciplinary areas, as Bracht (1999) would say, with sociology being particularly highlighted. Thus, the concept of "culture of body movement" is identified as both a distinct knowledge and an investigative object of physical education (Bracht, 1999), understood as "that part of general culture which encompasses the cultural forms that have historically been produced, both materially and symbolically, through the exercise of human motor skills" (Betti, 2005, p. 187).

Thus, from a sociological perspective, and seeking a critical appropriation of body culture, consistent research methods are also required to respect the ethical and normative dimensions inherent in its practice (Betti, 2005). Considering physical education as a practice that encompasses elements of culture in its theoretical spectrum, it is inevitable that sociological methods of scientific investigation are employed in the actions and practices of knowledge production. In fact, this reveals the existence of a "sociology of sport," a relatively recent field of study dominated by names such as Karl Marx, Norbert Elias, Eric Dunning, Pierre Bourdieu, and Michel Foucault (Dart, 2014). Curiously, we can highlight two interesting points: (1) The name of Max Weber (1864 – 1920) is almost absent from research in the sociology of sport (Amstel & Marchi Jr., 2021) and (2) despite her contribution to sociology, Harriet Martineau still has no space in this knowledge area.

This likely occurred because Weber did not develop a theory or a method directly applied to physical education and sports, despite his concerns with the subject in certain passages of *The Protestant Ethic and the Spirit of Capitalism* and *Economy and Society: An Outline of Interpretive Sociology*, some posthumous works published by his wife, Marianne Weber (Amstel & Marchi Jr., 2021). Moreover, other sociological canons, such as Karl Marx and Émile Durkheim, rarely appear in manuscripts related to physical education and sports (Ferreira *et al*., 2009). This fact is surprising, as Weber holds a prominent place in constructions related to culture, for example, "with regard to rationalization, a decisive factor in understanding the social actions that structure the lifestyle present in industrial capitalism, inevitably encompassing sport in this chain of events" (Amstel & Marchi Jr., 2021, p. 507). It is worth highlighting the absence of texts that explore the relevance of Harriet Martineau in the field of sociology of physical education and sports, particularly for researchers who employ the sociological method in knowledge production. In addition, understanding why this occurs is essential for a better comprehension of this knowledge area, its tensions, and disputes (Mariano, 2008).

Therefore, the main objective of the present article is to explain historical parallelism, as well as to demonstrate that there is gender bias in sociological methods. The second aim is to detail aspects of Martineau's work, and how they could be applied in the sociology of physical education and sport. For this work, the productions of two representative authors of the area will be analyzed, Max Weber (1864 – 1920), a widely known man in the field of sociology, and Harriet Martineau (1802 – 1876), a woman who structured relevant aspects of the sociological method before by Max Weber.

2. Methods

This research applies the bibliographic method, with a central focus on comparing the works of Max Weber and Harriet Martineau. Thus, the present investigation employs a descriptive approach and, for an argumentative foundation, utilizes some of Weber's productions, especially *The "Objectivity" of Knowledge in the Social Sciences*, and Martineau's work *How to Observe: Morals and Manners*, some additional theoretical references, including books and articles located from different databases, namely: Google Scholar, Web of Science, Education Resources Information Center (ERIC), and JSTOR Digital Library, from August to December 2022.

3. Results

Sociological research and its methods have shown a huge improvement in recent years. However, sociology, as a scientific discipline, has its origins in the 19th century and is shaped by diverse historical and social contexts. Although the focus of this text is not to delve into the origins of sociology, it emerged in the wake of various economic events such as the Industrial Revolution, political events like the French Revolution, and cultural movements like the Renaissance and, later, the Enlightenment. These events profoundly transformed the foundations of society and redirected the course of history, giving rise to new social relations (Sell, 2017).

In modernity, the emergence of science is often attributed to René Descartes (1596 – 1650), who developed the idea of "methodical doubt" and broke with various medieval dogmas. Subsequently, in line with Cartesian ideals, empiricist philosophers began to emphasize the observation of facts, thereby reinforcing the empirical basis of systematic scientific knowledge. As a synthesis of these movements, in the 17th century, Francis Bacon laid the foundations of what would later be called the "scientific method," characterized by systematic observation, formulation of hypotheses, experimentation, and subsequent inferences. Sell (2017) points out that three major motivations prompted the use of the scientific method in the establishment of sociology: (1) What are the causes of social transformations? (2) What are the characteristics of modern societies? and (3) What should be done in the face of social transformations?

With the aim of approaching the resolution of these questions, Auguste Comte developed the idea of establishing a "social physics" and published the book *Course of Positive Philosophy* in 1830, proposing the application of the scientific method to the study of society. In 1836, he changed the name of this science to sociology (from the Latin *socius* + *logos*, meaning the study of the social), positioning sociology as a scientific interpretation of social reality (Sell, 2017).

From the early proposal of Comte, various research methods specific to the social sciences have been developed. These include historical, comparative, monographic, statistical, functional, structural, and ethnographic methods (Marconi & Lakatos, 2010). In addition to these methods, one of the most well-known, the typological method, was developed by Max Weber, one of the key figures in sociology (Sell, 2017).

3.1. Relevance of Weber in the scientific methodology of social sciences

Maximilian Karl Emil Weber was born on April 21, 1864, in Erfurt, Prussia, but his family moved to Berlin in 1869. He was the son of a lawyer and politician, Max Weber Sr., and Helene Weber, who was the daughter of poet George Friedrich Fallenstein (1790 – 1853). Weber grew up in a household with family tensions between his father, who was more dedicated to worldly pleasures, and his mother, a Calvinist who led an ascetic life with ideas of moral absolutism (Ritzer & Stepnisky, 2022). It is important to note that since his childhood, Weber had contact with many personalities in the academic world of Prussia, including Dilthey and Mommsen (Alcantara, 2020), which likely influenced his subsequent formation. He studied law, economics, and history at three different universities (Heidelberg, Berlin, and Göttingen). Weber died in 1920, and although he left behind an extensive body of work, many of his manuscripts were published posthumously, and his scientific analyses and assumptions maintained a direct relationship with his political activity (Alcantara, 2020).

Unlike Comte and other sociologists who criticized the assumptions of positivism, Weber considered sociology as a science that seeks to interpretively understand social action and explain it causally in its course and effects (Weber, 2012). He centered his comprehensive sociological theory on the relevance of the subject, rather than the object, based on the idea that the person who apprehends the facts is the central element in the analysis of social reality, which constitutes a revolution in the social sciences (Sell, 2017). According to Weber, scientists must be skilled in separating judgments of reality (what is) and judgments of value (what ought to be) in scientific analysis, to pursue genuine knowledge (Marconi & Lakatos, 2010). However, this does not imply that the analysis of judgments should be suppressed, as Weber stated: "By no means are value judgments, because they ultimately rest on specific ideals and therefore have a "subjective" origin, excluded from scientific discussion. This is repeatedly contradicted by the practice and aim of our journal. Criticism does not stop

at value judgments. The question is: What does scientific criticism of ideas and value judgments mean and intend?" (Weber, 2006, p. 15).

In this sense, Weber (2006) suggested that value judgments should be treated scientifically to become comprehensible and subject to critical evaluation. In addition, sociology, as an empirical science, does not generate imperatives or absolute truths but analyzes and clarifies the existing facts in a particular society, location, time, and historical moment. Furthermore, in his work titled *The "Objectivity" of Knowledge in the Social Sciences*, Weber made it clear that the person endowed with will "...weighs and chooses among the values involved according to his conscience and his conception of the world" (Weber, 2006, p. 17). In other words, Weber (2006) substantially modified the idea of the positional neutrality of the observer, indicating that it is up to the observer to take a position in favor of or against certain values according to their conception of the world. However, he emphasized the need to know the meaning of such observed phenomena.

Carlos Sell, a Weber lecturer, also pointed out that the author addresses problems of two orders to be considered by the social sciences: the problem of rationality from the actor's perspective (known as first-order observation) and the problem of rationality from the observer's perspective (second-order observation), which can be used as a resource of social sciences to explain social reality based on the intersubjective world of everyday life (Sell, 2013).

Weber organized his sociological analysis method based on two main tools: (1) Ideal types and (2) types of social action (Sell, 2017). Regarding the first tool, he clarified that there must be a logical function and structure of the concepts on which social science relies and develops its interpretation of facts, suggesting that human knowledge only captures the relationships between existing things, never in an exhaustive and precise manner (Weber, 1977). Within this framework, "sociology does not capture the essence of reality entirely: Sociological explanation can only capture certain elements of reality, which are conditioned by the culture in which the researcher is immersed" (Sell, 2017, p. 55). Thus, Weber (1977) believed it is necessary to consider an ideal type: "…by means of the one-sided accentuation of one or several points of view, and by the conceptual linking of a great many discrete individual phenomena, diffused and scattered, that can be shown to occur in a greater or lesser number or can be totally absent, and that are arranged according to those one-sidedly emphasized viewpoints to form a logically homogenous thought construct" (Weber, 2006, p. 106). In other words, the ideal type is a mental construction of the researcher that emphasizes aspects they wish to study in the object or phenomenon in question. It should be noted that the ideal type is not found in everyday reality but serves as a comparative parameter for analyzing observable social facts that lend themselves to a dichotomous division into "type" and "non-type" (Marconi & Lakatos, 2010).

It is worth highlighting that the construction of the ideal type is not merely arbitrary cognitive subjectivism on the part of the researcher but rather a research instrument that allows for a more objective approximation to reality, understanding it as diverse and heterogeneous, and enabling a constant comparison of theories (Ideal Types) with the researched reality (Sell, 2017). Max Weber's typological research method has been successfully used in some studies in the field of sports, notably the works of Guttmann (2007) and Overman (2011). Amstel and Marchi Jr. (2021) also point out that Weber already introduced in *Economy and Society: An Outline of Interpretive Sociology* a notion of sport that would be further developed by Norbert Elias and Eric Dunning in the work *The Quest for Excitement in Sport*, in which they consider that sports practices promote the pacification of customs and the control of violence.

In addition to ideal types, Weber also concerned himself with intentionality in research and, in this regard, sought to systematize action in sociological research (Weber, 2012). Thus, action in comprehensive sociology is associated with behaviors that: (1) In terms of the subjectively intended meaning of the actor, are related to the behavior of others, (2) are codetermined in their course through this relationship, and therefore (3) can be explained intelligibly in terms of this intended meaning. According to Weber, emotional actions, and feelings, which are indirectly relevant to the course of action, are also related in terms of subjective meaning to the external world and, especially, to the actions of others (Weber, 1981).

From such reflections, the construction of the idea of social action is structured. It refers to any human action whose subjective meaning is directed toward the behavior of other individuals. This concept emerged in a manuscript titled *Some Categories of Interpretive Sociology*, initially published in 1913 (Weber, 1981). It is organized into four distinct types: (1) Social action referring to ends: When a person determines a goal to be achieved and devises strategies to accomplish it; (2) social action referring to values: It concerns actions in which people act without consciously thinking or planning the result, but rather with the intention of upholding a value – for example, ethics – and is related to the preservation of a particular worldview; (3) affective social action: Characterized by impulsive and momentary actions, without considering the consequences. It focuses on satisfying an immediate desire; and (4) traditional social action: It pertains to actions that

occur due to customary and habitual practices, employing superficial rationality (Alcantara, 2020).

In Weber's Comprehensive Sociology, he considered two levels of sociological analysis: A micro-sociological level, where the discussion revolves around the actor and the action (social relationship), and a macro-sociological level, where the discussion focuses on the social structure, that is, the social order (Garcez, 2014). Although Max Weber did not have a sociological production process centrally focused on men, he failed to meet the demands of including the discussion on gender in knowledge production (Mariano, 2008). Furthermore, he also did not incorporate information previously produced by women, even if such productions resemble his way of thinking and conducting scientific knowledge.

3.2. Harriet Martineau as a proponent of a sociological research method

Harriet Martineau is a historical figure who has become highly significant in sociology in recent years. In a scientific field that has predominantly been male-dominated, Martineau stood out (Sell, 2017; Alcantara, 2020). It is noteworthy that "the absence of women among the classics would be justified, therefore, by the supposed condition of being excluded from history" (Daflon & Sorj, 2021, p. 10). Interestingly, it is sometimes claimed that "those who eventually managed to write and publish did not address the truly relevant topics for the development of sociology..." (Daflon & Sorj, 2021, p. 11). However, this argument can be widely refuted by numerous works and analytical perspectives. To cite two books, *Classics of Social Thought: Women and Feminisms in the 19th Century* (Daflon & Sorj, 2021) and *Pioneers of Sociology: Intellectual Women in the Centuries XVIII and XIX* (Daflon & Campos, 2022) presented the stories of over a dozen women who made significant contributions to sociological thought.

Within this context, we find Harriet Martineau, an Englishwoman born in 1802, who had the opportunity to receive education alongside her seven brothers. She studied Latin, arithmetic, French, and religion. There is biographical and autobiographical material available about this woman who, driven by a sense of exclusion stemming from her childhood, developed what came to be known as the "need to express herself," which she did through writing. In her adult life, she faced severe health limitations, including heart and uterine diseases, as well as early deafness. Nevertheless, these challenges did not prevent Martineau from becoming "one of the leading intellectuals and writers of the Victorian Era" (Daflon & Campos, 2022, p. 77).

In addition to her extensive literary production in the field of sociology, including her 1850 translation of Auguste Comte's classic work *Course in Positive Philosophy*, Harriet Martineau had interactions with a wide array of thinkers, such as Charles Dickens, Charlotte Brontë, George Eliot, Thomas Malthus, Florence Nightingale, and Charles Darwin. These individuals undoubtedly influenced her way of thinking and acting. In 1834, Martineau embarked on a 2-year journey through America during which she "began to outline some ideas on how to be a "philosophical traveler," an "observer of morals," that is, how to employ a specific method for observing and rigorously reporting on the habits and ways of life of other societies" (Daflon & Campos, 2022, p. 77). This effort gave rise to her book *How to Observe: Morals and Manners* (Martineau, 2021), first published in 1838, which has been considered the first book to systematize methods for social science research (Daflon & Campos, 2022). It is noteworthy that "Martineau reflected on what it meant to produce knowledge about human beings, valuing symbols, meanings, and emotions, thus seeking to develop a methodology capable of capturing these dimensions" (Daflon & Campos, 2022, p. 83). From a methodological point of view, her work was compared with several authors such as Alexis de Tocqueville, and her influence on other individuals such as Emile Durkheim (Hill & Hoecker-Drysdale, 2001).

The content of her methodological work, *How to Observe: Morals and Manners*, bore a strong resemblance to what would come to be known as the interpretive paradigm of the social sciences, as formulated by Max Weber (Seymour Martin Lipset, 1962, cited in Daflon & Campos, 2022, p. 91). Initially, Martineau argued that the observing person, often referred to as a "traveler" in her work, needs to possess certain requirements for observation, which can be grouped into philosophical requirements, moral requirements, and mechanical requirements, the latter depicting the modes of transportation used by the observer (carriages, trains, walking, etc.) and the best times to do so. In this regard, she emphasized that "...the powers of observation can be trained, and habits of methods in the organization of materials presented to the eyes must be acquired before the student possesses the requirements to understand what they contemplate" (Martineau, 2021, p. 25). Regarding the basic requirements, it is indicated that the observer should not make hasty decisions about what they observe, nor should they generalize about the place they observe, as this could lead to the error of engaging in flawed inductive reasoning.

Regarding the philosophical requirements, the author explicitly stated that "...the mind of the observer — the instrument by which the work is done — is as essential as the material to be wrought. If the instrument be out of order, it will produce bad work" (Martineau, 2021, p. 35). Moreover, a clear connection can be seen with Max Weber's

ideal typological method when she indicated that: "It is not enough (…) for equal and active comprehension, leading to accurate perception of individuals facts themselves; he must also be in possession of principles which may serve as a meeting point for his observations, and without which he can neither determine his bearings nor be secure of putting a right interpretation on them" (Martineau, 2021, p. 38). In this sense, just as Weber emphasized the need to construct an ideal type before the process of observation, Martineau pointed out that "the true philosopher, the worthy observer, first contemplates in imagination the range of humanity, and then ascertains what principles of morals are applicable to them all, and judges by those" (Martineau, 2021, p. 40).

Harriet Martineau also provided examples related to the different classifications of what Weber referred to as "social action." In this regard, she indicated that "knowing that some influences act upon the minds of all persons in all countries, he seeks everywhere certain feelings of right and wrong, which are as certain to be in every human mind as if they were born with it" (Martineau, 2021, p. 44), and she showed many examples in the pages 44 to 46 from *How to Observe: Morals and Manners*. Indeed, many of the types of social action presented by Weber are explicitly explained by Martineau in different contexts, including various examples related to religious customs and suicide (Martineau, 2021, p. 113).

In addition to philosophical requirements, Martineau also indicated moral requirements that should guide the observation of morals and customs. Under the influence of a positivist perspective, she suggested that "an observer, to be perfectly accurate, ought to be himself perfect" (Martineau, 2021, p. 61); however, she emphasized that "...as we do not expect to be perfect, (...) we must be content with discovering, to prevent our task from being hopeless, and how we may put ourselves in a state to learn at least something truly" (Martineau, 2021, p. 61).

Martineau further pointed out that a person concerned with the quality of the information to be observed "must have sympathy, and his sympathy must be untrammeled and unabated. (...) an observer of morals and customs will be disappointed at every turn if he cannot find his way into hearts and minds" (Martineau, 2021, p. 62). Although Martineau does not explicitly explain what sympathy is, she reinforced the idea that with sympathy, "...everything that he [the observer] sees will be instructive, and the most important matters will be most clearly revealed. If he is unsympathetic, the most important things will be hidden from him, and the symbols (with which every society abounds) will be nothing but absurd or trivial forms" (Martineau, 2021, p. 67).

Importantly, while she emphasized the need to engage with the people and groups from which one seeks to gather information, two elements stood out: (1) The recommendation to study things, using people's discourse as if it were a commentary on them and (2) the occasional need to distance oneself a little to have a more accurate view of the phenomenon. She also reinforced the idea that the greater the number of observers (three to four), the better the accuracy of the description tends to be. Furthermore, if the goal is to understand the morals and customs of a people, considering only "the discourse of individuals is a hopeless undertaking" (Martineau, 2021, p. 86). She argued for a greater variety of data sources, suggesting the possibility of data triangulation for a better study of a specific phenomenon (Patton, 2014). She provided examples of these procedures in the study of religion, stating that "a shorter and safer method is to examine the places of worship, the condition of the clergy, popular superstitions, the observance of holy days, and some other peculiarities of the kind" (Martineau, 2021, p. 102). Clearly, such examples can be applied, for instance, to sports phenomena, such as football. What are the stadiums like, the dressing rooms, and the daily lives of the workers in that space? What is the surrounding area of the stadiums like on match days, and what are the movements of the fans? In other words, for Martineau, a thorough analysis involves more than just people's words; it also includes observing the various contexts surrounding them.

Regarding methodological aspects, she incorporated insights from Quetelet's statistical method (Marconi & Lakatos, 2010) when discussing the systematization of data on the health of a community. In this regard, she suggested that the construction of tables and the examination of averages can help in understanding and observing morals and customs. In addition, she provided relevant indications regarding the recording of facts, which she referred to as mechanical methods. In this regard, she suggested having three instruments for systematic observation: (1) a list of questions: "...he should provide himself, before setting out, with a set of questions, so framed as to include all the great classes of facts connected with..." (Martineau, 2021, p. 237). She reinforced that "these questions are not meant to be thrust into the hand of anyone who may have the information to give. They should not even catch their attention. The traveler who appears to be taking notes amid conversation is at risk of carrying imperfect information as far as they go, and much restricted in quantity compared to what it would be if allowed to be forgotten (…). If they let the conversation flow naturally, without verifying it through the production of pens and notebooks, they will, even if their memory is not the best, have more to establish by the end of the night than if they were to take notes on the spot, as evidence…" (Martineau, 2021, p. 238). She also suggests that the observer should constantly add to this list

of questions as he proceeds and as new subjects arise, and, in addition to this dynamic list of questions, recommends using (2) a diary, which should be employed to record facts, emphasizing that "the manner of doing this is not to depend on the rule of note-paper, but on the nature of the traveler's mind" (Martineau, 2021, p. 239). At this point, two relevant aspects emerge regarding the logistics of recording data in the diary: (i) It should be filled in during moments of distance from observation (at night or the morning following the observations and routines), and (ii) it should include what is most likely to be forgotten by the observer, relying on memory for what is preferred and valued by the observer, which would prevent forgetting. Finally, she suggests a third tool for observation, (3) a notebook "(...) (always at hand), not to be drawn before people's eyes for the entry of connected facts, but to be used to protect the transient appearances which, though revealing much to an observant mind, cannot be remembered with entire precision" (Martineau, 2021, p. 241).

According to Martineau, the study of morals (as she considered what we now know as sociology) demanded from the researcher reflexivity, objectivity, and "empathy," which is the ability to exchange positions with the subjects of research and engage in patient and non-judgmental listening. In this manner, the author advocated pioneeringly for the necessity of developing specific rules to produce sociological knowledge (Campos & Daflon, 2023). She was convinced of the transformative "power of education" (Watts, 2011), and her conceptual potential is huge, including new vocabularies, new precedents, new systems of relevance, new models of engaged sociological practice from her substantive and systematic observations of society, which is relevant to historical and comparative sociologists (Hill & Hoecker-Drysdale, 2001). In this sense, she is recognized as the pioneer of sociology in Britain, but little scholarly attention has yet been paid to the early reception of her work far from there (Lecaros, 2022).

As widely recognized in the fields of physical education, sports science, and epidemiology, for a comprehensive understanding of how a society functions and is organized, the recommended methodological approach is to initiate research by outlining the most general characteristics of collective life, such as subsistence, birth, mortality, and overall communal ideas (Campos & Daflon, 2023). In the physical education research area, her contributions could significantly enhance the study of the sociology of sport's methodology, morals, racism, educational principles, gender-related issues, and feminism, as well as ideal-type observation procedures. Indeed, despite her relevant thinking related to morals and costumes, a potential gender bias might have diminished Harriet Martineau's contribution to physical education over the last two centuries, likely due to the male hegemony in knowledge construction (Jefferson-Buchanan, 2023).

3.3. Harriet Martineau before Max Weber: Beyond parallelism, a gender bias?

As indicated by Lipset (1962) and Daflon & Campos (2022), in Martineau's *How to Observe: Morals and Manners* (1838), there were many methodological traits like those presented by Max Weber in his various works on the sociological research method, all published after 1900. From this point on, two hypotheses can be highlighted regarding methodological overlap and the absence of citation of Martineau in manuscripts related to the scientific method applied to social sciences. Regarding methodological overlap, the idea of historical parallelism initially emerges. According to the Collins Dictionary (Parallel, 2022), historical parallelism refers to events or the existence of similar facts in different places or periods. Such a phenomenon has examples in the field of sociology, such as Durkheim's concept of "collective representation" and Georg Simmel's notion of "sociability" (Lu, 2019).

The absence of Martineau in subsequent studies after her publications may be due to the lack of awareness and gender bias. While the possibility of the lack of awareness cannot be disregarded, we must not forget that gender inequality is prevalent in academia and science, even today, as evidenced by what is known as the "Matilda effect," which involves a repetitive pattern of ignoring, not recognizing, or concealing women in science (Lincoln *et al*., 2012). The lack of visibility of women's participation and the marginalization of female contributions align with the androcentric character of thought, where prevailing patterns of male dominance from society are assimilated and, at times, legitimized as scientific knowledge. This phenomenon has historically manifested in disciplines such as history, philosophy, literature, and psychology – as well as – physical education, spanning diverse fields of knowledge generation. As a result, it perpetuates a tradition that extends across various domains, encompassing different schools of thought and intellectual currents (Mariano, 2008). In fact, it is indicated that the scientific community has excluded, removed, and silenced women from its inception. "With this postulate, the ability to do science has been removed from women and attributed to men, who should be "endowed with reason". Over time, many women who challenged this paradigm were ignored, minimized, and at times, usurped by their male counterparts" (Oliveira-Ciabati *et al.*, 2021, p. 9).

Martineau emphasized the need to consider the entirety of a particular society in its study. This includes

its economic, demographic, and geographical foundations, the "degree of civilization," which pertains to the level of freedom and equality among its members, particularly women. In addition, it involves analyzing class structures, systems of values, and customs, while also examining aspects such as culture, religion, and their implications (Campos & Daflon, 2023). In this sense, from an academic point of view, the inclusion of Martineau's work can be applied in sociological theory and sociological research methods, as well as, the feminist tradition in sociology. Studies conducted by Martineau are still being discovered nowadays and provide insightfully articulated possibilities with the principles and methods of empirical social research (Hill & Hoecker-Drysdale, 2001).

4. Final considerations

The present study aimed to address the knowledge production of two sociological figures and how such production could relate to physical education and sports. While Max Weber's work is already closely related to this field (Amstel & Marchi Jr., 2021), Harriet Martineau's extensive methodological contributions remained relatively unknown, likely due to gender bias. Consequently, the study faces some epistemological limitations. First, it involves the decomposition and analysis of Martineau's entire body of work, which has been subject to study in various knowledge areas. Second, it pertains to the process of bridging Martineau's contributions with physical education, as her work has yet to receive adequate recognition and has not been widely utilized in this field, despite rational evidence of its plausibility. The third limitation concerns the need for empirical verification of the validity of these procedures in data collection and analysis within the sociology of sports.

Nevertheless, this study contributes to the deconstruction of a sociological canon that is evidently dominated by male perspectives, despite women making significant contributions to sociology, including the study of sports. This perspective highlights the importance of exploring and acknowledging the valuable insights brought forth by female scholars in the field of physical education and sports sociology. To Martineau, social change arises from the tension between shared understandings and the practices, patterns, and institutions that humans create (Campos & Daflon, 2023). In this sense, *How to Observe: Morals and Manners* is a precedent-setting work of theory and, before Karl Marx, and decades before Émile Durkheim and Max Weber, Martineau sociologically examined social class, forms of religions, national character, and the intricate interrelationships between repressive social institutions and the individual.

Likely, the utilization of the methodological procedures proposed by both authors and their comparison throughout the knowledge production in the field of physical education will enable (1) a historical recognition of women who have contributed to sociological methodology, (2) a comparison of actions and practices from various perspectives, and (3) the expansion of knowledge in the realm of sociology of physical education and sports. Thus, with this present study, it is expected that researchers in arts, sociology, and, specifically, physical education, who employ research methods from the social sciences, particularly the typological method, field diary observations, and interviews, can appropriate what was previously produced before Max Weber. Furthermore, it is desired that the understanding of these concepts, facts, and arguments allows for the consideration of including the methodological procedures suggested by Harriet Martineau in their investigative routines of an observational nature.

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The authors declare that they have no competing interests.

Author contributions

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ACCSCIENCE PUBLISHING

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ORIGINAL RESEARCH ARTICLE

Assessing the impact of fast-track drug registration by Anvisa in Brazil: A descriptive study of new drug registrations from 2017 to 2022

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Abstract

Prompt release of novel pharmaceuticals is very much sought after during critical circumstances to aid patients and society in need. Nonetheless, the expeditious availability of these medications may jeopardize the well-structured investigations and observations. To tackle this concern, regulatory agencies globally have implemented expedited registration procedures. In Brazil, the National Health Surveillance Agency (Anvisa) has likewise implemented an expedited registration process to cater to patients who cannot afford to wait. The objective of this study is to evaluate the impact of Anvisa's accelerated drug registration on the challenging regulatory environment in Brazil. Data pertaining to medications registered by Anvisa from 2017 to 2022 through the expedited process were procured from the Federal Government's transparency portal and the medication consultation portal. The registration of novel drugs by Anvisa through both standard and expedited processes during this timeframe was analyzed. The introduction of the accelerated registration regulation by Anvisa in 2017 led to a substantial rise in registration requests utilizing this regulatory modality. Furthermore, the data concerning drug registration through all channels unveiled a noteworthy reduction in average response time. Despite concerns pertaining to the effectiveness and safety of drugs registered through the expedited process, often reliant on Phase II studies, the utilization of this process is on the rise worldwide, including in Brazil. To ensure the sustainability of health-care systems, it may be advantageous to implement provisional registration in conjunction with subsequent evaluation through real-world studies and financing based on risk-sharing agreements. In conclusion, the accelerated drug registration process implemented by Anvisa in Brazil has exhibited promising results in terms of reduced response times. Nevertheless, the effectiveness and safety of drugs registered through this process necessitate meticulous evaluation. The implementation of provisional registration and the integration of real-world studies, alongside managed entry agreements, could offer a sustainable alternative for health-care systems.

Keywords: Fast track registration; Drug approval; Anvisa; Brazil; Health-care systems

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1. Introduction

Due to the emergence of novel technologies that provides a more in-depth understanding of molecular intricacy, the health-care sector is currently undergoing substantial transformations, which could affect how therapeutic targets are selected. The industry has exhibited a specific inclination toward the advancement of technologies tailored to addressing rare diseases and exploring niche drugs. This inclination extends to prevalent diseases as well, due to their ability to target niche markets and command exorbitant prices within the market. Moreover, these studies tend to be more cost-effective due to the involvement of a smaller patient cohort, while the costs stemming from advertising and business development are lesser as they are typically managed by a select group of specialists. The considerable and escalating disparity between the therapeutic efficacy of numerous novel niche drugs and their associated price elucidates the rationale behind the pharmaceutical industry's adoption of a new business model centered around these drugs (Gagnon, 2015).

According to epidemiological data retrieved from the Orphanet database (Nguengang Wakap *et al.*, 2020), a total of 6172 rare diseases have been identified, with 71.9% of them being of genetic origin and 69.9% affecting children. The prevalence of these diseases in the general population ranges from 3.5% to 5.9%, equivalent to an estimated 263 to 446 million affected individuals (Nguengang Wakap *et al.*, 2020). In Brazil alone, there are approximately 13 million individuals with rare diseases. Furthermore, the National Cancer Institute (INCA) projects that by 2025, there will be approximately 704,000 new cases of cancer per year in Brazil (INCA, 2022). These conditions present significant challenges to the provision of universal healthcare as mandated by the national constitution, not only in Brazil but also in other countries. Governments worldwide are currently grappling with ethical considerations, access to healthcare, sustainability, and the regulatory frameworks governing the registration of new drugs, which may or may not enhance patients' quality of life and overall survival.

The utilization of precision medicine in studies holds a prominent position in the current medical landscape. Recent advancements in genomics technology, coupled with reduced costs, play a crucial role in enabling the swift identification and selection of therapeutic targets within human cells. The pursuit of drugs incorporating innovative technologies, such as monoclonal antibodies, targeted therapies, oligonucleotides, as well as gene and cell therapies, has emerged as a primary objective in the registration of new clinical trials (Shahryari *et al.*, 2019). Gene therapies represent a subset of pharmaceuticals with exorbitant costs, exemplified by Zolgensma® employed in spinal muscular atrophy (SMA) treatment and Hemgenix® administered for hemophilia B intervention. These therapies currently hold the foremost position in terms of price, commanding a value of 3.5 million dollars. In Brazil, exclusively Zolgensma® has obtained registration, signifying its status as the costliest available medication within the nation, amounting to 1.3 million dollars (equivalent to 6.5 million BRL, based on the 2022 exchange rate from the Organization for Economic Co-operation and Development [OECD]). Our research endeavors involved adjusting the monetary figures to reflect a conversion rate of 5.164 BRL = 1 USD (OECD, 2023). In December 2022, Zolgensma® was granted reimbursement approval by the National Health System (SUS) for pediatric patients up to 6 months of age diagnosed with SMA type I (Ministério da Saúde, 2022). CAR-T cell therapies represent a recent advancement in innovative treatments, accompanied by new regulatory challenges. This approach involves the genetic modification of the patient's own T cells for the purpose of treating specific hematological cancers. Several CAR-T cell products have already obtained approval from the Food and Drug Administration (FDA) (Amini *et al.*, 2022). In 2022, Kymriah® (tisagenlecleucel) became the first CAR-T therapy approved by Brazil's National Health Surveillance Agency (Anvisa), with authorization for the treatment of acute lymphoblastic leukemia and diffuse large B-cell lymphoma (Archanjo, 2022). In addition, in 2022, Anvisa granted approval for the first clinical trial aimed at the national development of a CAR-T product for cancer treatment (ANVISA, 2022a).

The randomized, controlled, and clinical trial is the optimal study design for assessing the efficacy and safety of novel pharmaceutical agents. However, challenges arise when working with limited populations that meet the eligibility criteria, thereby imposing inherent constraints on conducting such ideal evaluations. The credibility of the resultant evidence is compromised by studies featuring small sample sizes, lack of blinding and randomization, and the absence of direct comparators, leading to a heightened risk of bias (Fogel, 2018; Zeng *et al.*, 2015).

Considering the evolving health market landscape, along with mounting pressures from the pharmaceutical industry and patients, as well as the constraints imposed by limited and substandard available evidence, a host of novel challenges has emerged in relation to technology registration, pricing, and evidence-based recommendations for appraisal. These challenges pose a universal defiance for regulatory agencies, which must make deliberations based on the restricted evidence concerning the efficacy and safety of these innovative therapies, while ensuring the

minimal risk to the population (Martin & Shenfield, 2016; Mayer-Hamblett & VanDevanter, 2020).

The accelerated registration of drugs is a procedural mechanism enabling the expeditious assessment and endorsement of pharmaceuticals deemed safe and efficacious in the treatment of severe or life-threatening conditions. This process facilitates swifter patient access to novel compounds with potential life-saving attributes. To qualify for accelerated registration, a drug must fulfill specific criteria, including the demonstration of efficacy, safety, or the ability to address an unmet medical necessity. The precise set of criteria for accelerated registration may vary contingent on the regulatory agency accountable for evaluating and approving the drug (Gammie *et al.*, 2015; Mayer-Hamblett & VanDevanter, 2020).

In the United States, the FDA employs four modalities for expediting the registration process of drugs. These modalities include Priority Review, Breakthrough Therapy, Accelerated Approval, and Fast Track. Under the Priority Review modality, the FDA adheres to a 6-month timeframe, which is significantly shorter than the standard review period of 10 months (Commissioner, 2018).

The European Medicines Agency (EMA) serves as the regulatory authority accountable for the assessment and authorization of pharmaceuticals within the European Union. The EMA incorporates the Committee for Medicinal Products for Human Use (CHMP) and introduces two methodologies to expedite patient accessibility to novel therapies: Accelerated assessment and conditional marketing authorization (EMA, 2018).

In 2016, the Australian government made an announcement regarding the establishment of two new pathways by the Therapeutic Goods Administration for the expedited approval of therapeutic advancements with potential life-saving capabilities. These pathways include the priority review pathway and the provisional approval pathway (Bootes *et al.*, 2019; Nash, 2016).

Health Canada, the regulatory authority for drug registration in Canada, possesses a Priority Review process that bestows accelerated status on new drug submissions. This expeditious review system assigns eligible requests a target review timeline of 180 days, significantly shorter than the standard 300-day review period designated for non-priority submissions. Furthermore, Health Canada has implemented the Notice of Compliance with conditions pathway, which facilitates the conditional approval of drugs based on limited evidence. This pathway allows for the timely availability of certain medications exhibiting promising therapeutic benefits, albeit necessitating further data collection and evaluation to substantiate their safety and efficacy. Through this innovative approach, Health Canada ensures that Canadians have access to potentially life-saving treatments while steadfastly upholding the primacy of patient safety and well-being (Canada, 2002).

Anvisa is entrusted with the responsibility of regulating the production, distribution, and utilization of health-care products in Brazil. This encompassing role entails the registration of pharmaceuticals and various other consumer products, among others. Anvisa's drug registration process typically entails the submission of a registration request by the drug manufacturer, accompanied by substantiating data regarding safety and efficacy. Anvisa critically assesses the request and determines whether the drug satisfies the registration criteria. If it does, Anvisa proceeds with a comprehensive review of the data and information provided by the manufacturer. On completion of the process, Anvisa grants approval for the drug to enter the Brazilian market. Furthermore, additional overarching criteria for drug approval may include an evaluation of its potential impact on public health and the availability of alternative treatments for the same condition (ANVISA, 2022b).

In 2016, the regulatory decision (Law No. 13.411) served as a pivotal moment for expediting the registration process of new drugs based on their priority status. The process could proceed through either the regular track or the priority track, depending on the criteria of technical complexity, as well as the clinical, economic, and social benefits associated with the drug. The timeframe for assessing priority drugs was set at 180 days. This category includes, for example, drugs for rare diseases. Conversely, drugs deemed non-priority must receive approval within 365 days (Brasil, 2016).

In 2017, the introduction of a new legislation, RDC 204, prioritized petitions for registration, post-registration, and prior consent in clinical research on medications based on public relevance. The aim was to ensure and expand access to pharmaceutical assistance. Furthermore, RDC 205, also published in 2017, established a specialized procedure for obtaining clinical trial consent, certification of good manufacturing practices, and registration of new drugs intended for the treatment, diagnosis, or prevention of rare diseases. Its objective was to expedite the registration process for drugs targeting rare diseases and to support actions for streamlining bureaucracy, enhancing public administration efficiency, and increasing manufacturers' accountability. This ordinance maintains the requirements for demonstrating quality, safety, and efficacy. However, it allows for the acceptance of safety and efficacy reports when accompanied by completed Phase II studies and ongoing Phase III studies. Alternatively, in cases where

conducting Phase III clinical studies is not feasible, acceptance may be granted if there is demonstrated high therapeutic or preventive efficacy and no comparable therapy or alternative drug exists for that disease (Brasil, 2017a). Resolução RDC n° 204, de 27 de Dezembro de 2017. Agência Nacional de Vigilância Sanitária (Anvisa). However, for drugs approved based on Phase II studies or with Phase III studies still in progress, the company must submit a commitment letter pledging to present the results of the studies to Anvisa. The final approval of drug registration will be contingent on the submission of these results (Brasil, 2017b). Resolução RDC n° 205, de 28 de Dezembro de 2017. Agência Nacional de Vigilância Sanitária (Anvisa).

Table 1 presents a comprehensive overview of the fast-track process characteristics implemented by the primary international regulatory agencies. Given the intricate regulatory environment in the health-care market, our study aims to evaluate the implications of expedited drug registration through Anvisa in Brazil. The primary objective of this investigation is to assess the impact of the recent drug registration legislation in Brazil, by comparing the quantity of new drug registrations by Anvisa, both through regular and fast-track processes, spanning from 2017 to 2022.

2. Methods

The data collection for this study involved accessing and retrieving public registration data from Anvisa through two primary sources: the Transparency Portal and the Anvisa Medication Consultation Portal (Line, 2021). The period of data collection spanned from 2017 to 2022, focusing specifically on medications registered by Anvisa through the fast-track process, as outlined in RDC 204/2017 (prioritization) and RDC 205/2017 (rare diseases).

2.1. Transparency portal

The Brazilian Transparency Portal, a comprehensive tool for accessing public administration information, was utilized to request data on medications registered by Anvisa. To obtain the relevant information, the following steps were followed:

a. Visiting the Brazilian Transparency Portal website.
b. Locating the section dedicated to "Information Request" or a similar option.
c. Completing the required form with detailed specifications regarding the requested data.
d. Submitting the information request electronically through the portal.
e. The information request is processed by Anvisa analysts, and they have a deadline for a response is 30 days, extendable for an additional 30 days on justification.

For our study, in February 2023, we requested information regarding the quantity and the medications that were registered under the fast-track process (RDC 204/2017 and RDC 205/2017) in Brazil from 2017 to 2022.

2.2. Anvisa Medication Consultation Portal

The Anvisa Medication Consultation Portal provided additional insights and data for this study. The portal offers a monthly overview of the analysis queues, based on the current rules applied to the historical document statuses. The following information is presented within the panel:

a. Quantity of documents in the queue at the beginning and the end of each month
b. Median time between document entry to and exit from the queue
c. Quantity of documents that exited the queue within specific time intervals: Up to 90 days, between 90 and 180 days, between 180 and 360 days, between 360 and 720 days, and over 720 days
d. Monthly balance between the number of documents entering the queue and the number exiting
e. Other related indicators

These indicators allow for the analysis of the current queue's evolution, enabling the assessment of queue size, trends in queue growth or reduction, and the median time documents spent in the queues. It is important to note that this panel focuses on analyzing the queues based on the current rules applied to the historical document statuses. Therefore, the historical analysis of the queue may not accurately represent the queue as it was presented on the Anvisa website, as the queue rules may have been different in the past.

2.3. Data analysis

The parameters of interest for this study were focused on medication registration, further divided into different types of registration and those falling under the purview of RDC 204/2017 and RDC 205/2017. These specific subsets of medication registration were chosen to assess the impact and efficiency of the fast-track process introduced by Anvisa. By employing the Transparency Portal and the Anvisa Medication Consultation Portal, we were able to collect a comprehensive dataset that provided insights into the registration process for medications, including the analysis duration and the volume of requests received and processed by Anvisa.

For the analysis of the collected data, linear regression was chosen as the statistical method. Linear regression is a widely used technique in data analysis that allows for the examination of the relationship between a dependent

Table 1. Characteristics of the fast-track process in the main international regulatory agencies

Regulatory agency	Country	Implementation date	Fast-track timeframe	Standard timeframe	Eligibility for approval
Food and Drugs Administration	USA	1987 (a)	180 days (a)	300 days (a)	Any medication developed to treat or prevent a condition without an obvious current therapy is clearly directed towards an unmet need. If there are available therapies, a fast-track medication must demonstrate some advantage over the available therapy (b).
European Medicines Agency	Europe	2005 (a)	150 days (a, b)	210 days (a, b)	It is intended for innovative medications that target a disease for which there is no available treatment or that provide patients with a significant therapeutic advantage over existing treatments (c).
Therapeutic Goods Administration	Australia	2016 (d)	150 days (d)	255 days (d)	The pathway is reserved only for medications that treat severe conditions and with risk of life. Priority review involves the same amount and type of evidence as the standard review process and therefore does not have an impact on the level of safety, quality, or efficacy of the medication (e).
Health Canada	Canada	1996 (f)	180 days (f)	300 days (f)	It may be granted to submissions of medications intended for the treatment, prevention, or diagnosis of severe diseases or conditions, with risk of life or severely debilitating, when there is no existing medication on the Canadian market with the same profile, or where a new product represents a significant improvement in the benefit/risk profile compared to existing products (f).
Brazilian Health Regulatory Agency	Brazil	2017 (g)	120 days (g)	250 days (h)	I – Medication used for neglected, emerging or re-emerging disease, public health emergencies, or serious debilitating conditions, in situations where there is no available alternative therapy or when it presents a significant improvement in safety, efficacy, or treatment adherence; II – New medication, new pharmaceutical form, new therapeutic indication, or new concentration intended for the pediatric population; III – Vaccines or hyperimmune serum to be incorporated into the National Immunization Program of the Ministry of Health; IV – Innovative or new medication, for active pharmaceutical ingredient manufactured in the country; V – The first three petitions for novel generic medication for each active pharmaceutical ingredient or association and pharmaceutical form, from distinct economic groups; VI – Medication included in the list of strategic products, within the scope of the National Health System (SUS) that is subject to the Productive Development Partnership (PDP), on the complete initial submission of all documents and studies provided in the current regulation (i).

Notes: (a) Hwang, T.J., Ross, J.S., Vokinger, K.N., & Kesselheim, A.S. (2020). Association between FDA and EMA expedited approval programs and therapeutic value of new medicines: Retrospective cohort study. *BMJ*, 371:m3434. https://doi.org/10.1136/bmj.m3434 (b) Fast Track FDA. Available from: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track [Last accessed on 2022 Dec 22]. (c) Fast Track Routes for Medicines that Address Unmet Medical Needs. European Medicines Agency. Available from: https://www.ema.europa.eu/en/news/fast-track-routes-medicines-address-unmet-medical-needs [Last accessed on 2022 Dec 22]. (d) Bootes, A., Maundu, J., Golding, S., McDonald, M., & Lombard, J. (2019). Fast-track pathways for drug approvals: The Australian experience so far. *Australian Prescriber*, 42 (4):118-119. https://doi.org/10.18773/austprescr. 2019.044 (e) Fast Track Approval Pathways Therapeutic Goods Administration (TGA). Available from: https://www.tga.gov.au/fast-track-approval-pathways [Last accessed on 2022 Dec 22]. (f) Priority Review of Drug Submissions (Therapeutic Products)-Canada CA. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/priority-review-drug-submissions-therapeutic-products.html [Last accessed on 2022 Dec 22]. (g) Agência Nacional de Vigilância Sanitária-anvisa. RDC No 204, 2017. Available from: https://antigo.anvisa.gov.br/documents/10181/2718376/rdc_204_2017_pdf/b2d4ae64-2d91-44e9-ad67-b883c752c094 [Last accessed on 2022 Dec 22]. (h) Resolução-RDC No 336, 2020-DOU-Imprensa Nacional. Available from: https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-336-de-30-de-janeiro-de-2020-240823596 [Last accessed on 2022 Dec 22]. (i) Priorização de Análise de Medicamentos-Português (Brasil). Available from: https://www.gov.br/anvisa/pt-br/acessoainformacao/perguntasfrequentes/medicamentos/priorizacao-de-analise-de-medicamentos [Last accessed on 2022 Dec 22].

variable and one or more independent variables. In this study, the dependent variable of interest is the analysis duration, or the time taken for medications to be registered through the fast-track process, while the independent variables include the volume of requests received and processed by Anvisa, as well as the specific subsets of medication registration falling

under RDC 204/2017 and RDC 205/2017. By applying linear regression to the dataset, we can determine the significance and strength of these relationships and analyze the trends in the registration process over the period from 2017 to 2022. Furthermore, linear regression allowed us to establish a trend line that represents the overall pattern of the analysis duration and provides insights into the efficiency and impact of the fast-track process introduced by Anvisa. The *p*-values obtained from the linear regression analysis were used to assess the statistical significance of the relationships and 95% of confidence intervals were determined to estimate the precision and uncertainty associated with the estimated regression coefficients.

3. Results

The data retrieved from the Anvisa transparency portal revealed a noteworthy increase in the number of fast-track requests, from just one in 2018 to 32 in 2021. Furthermore, in the year of 2022, a total of 40 fast-track registrations were made (Figure 1).

Figure 2 displays the queue finalization time for medication-related requests. The analysis revealed a maximum time of 548 days and a minimum time of 73 days, with a median duration of 159 days. Notably, a linear regression analysis showed a significant trend of decreasing average finalization time, corroborated by $p < 0.001$ (95% confidence interval).

Figure 3 illustrates the queue time until finalization for medication registration. The analysis indicates a maximum time of 611 days and a minimum time of 58 days, with a median duration of 176 days. Similar to the previous result, the linear regression analysis demonstrates a significant trend of decreasing average of queue length, supported by $p < 0.0000001$ (95% confidence interval).

The analysis focused on the queue of finalization time for drug registration through prioritization (RDC 204/2017) and/or rare diseases (RDC 205/107) presented in Figure 4. The maximum length of time observed was 120 days, with an average of 15 days. However, it should be noted that these resolutions have just been recently implemented, resulting in limited data availability for calculating the median. This limitation stems from the fact that the dataset used for the analysis comprised a relatively small sample size, which may not adequately represent the entire population of registrations. Despite these limitations, a linear regression analysis was conducted to explore any potential trends in the average registration time. The regression analysis revealed a slight upward trend, indicating a potential increase in the average time required for registration. Notably, the *p*-value associated with this trend was calculated to be $p = 0.054$ (95% confidence interval), suggesting a statistically significant relationship between time and the registration process. However, it is important to interpret this *p*-value with caution, as the limited data available may have influenced the statistical analysis.

4. Discussion

The data obtained in this study from the Anvisa Transparency Portal highlight a significant rise in fast-

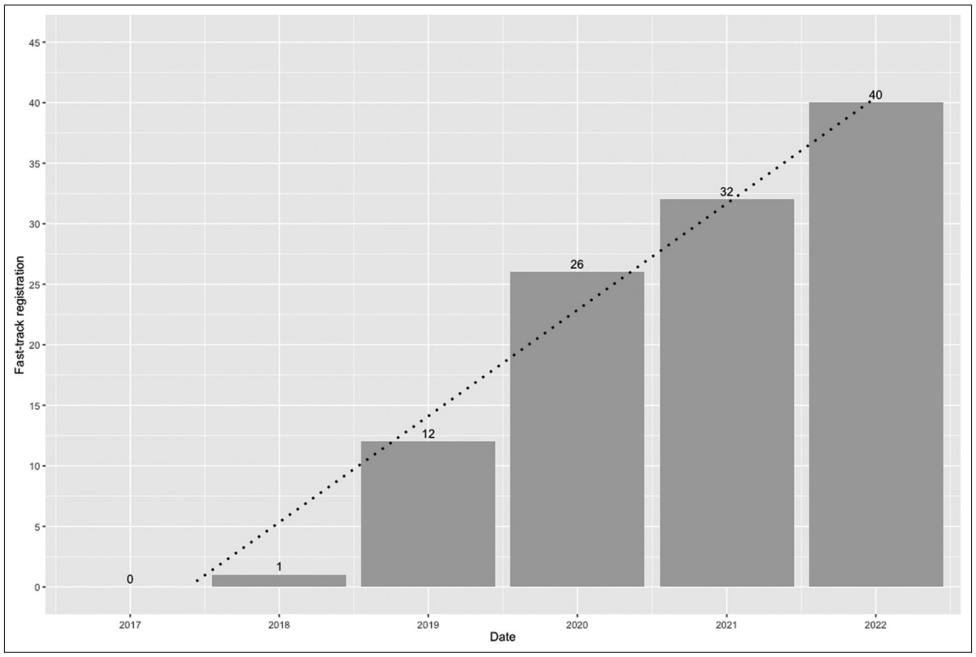

Figure 1. Fast-track registrations by Anvisa.

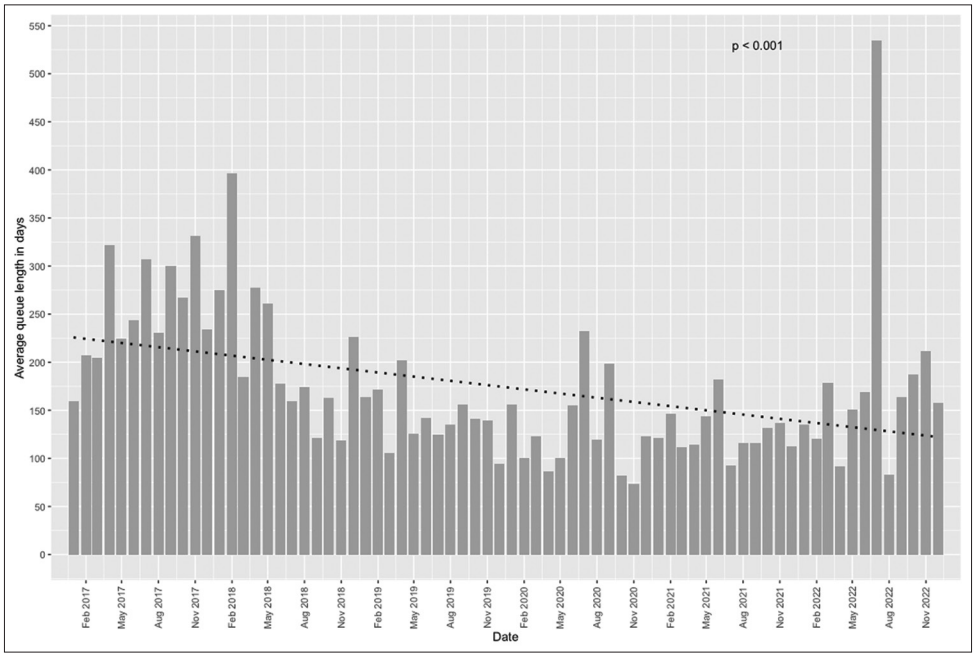

Figure 2. Queue length of time (in days) for any medication-related request.

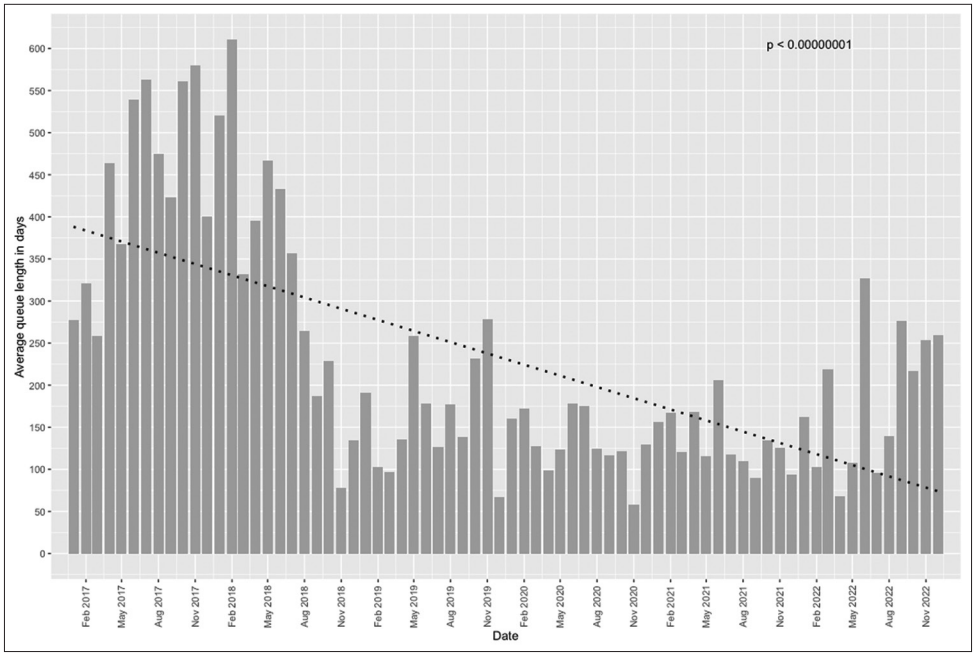

Figure 3. Queue length of time (in days) for drug registration.

track requests for drug registration. The number of such requests increased from one in 2018 to 32 in 2021 and further rose to 40 in 2022. Statistical analysis confirmed the significance of this upward trend. In addition, an examination of the queue finalization time for medication-related requests indicated a decreasing average duration, as demonstrated by a linear regression analysis. Similar results were observed for the queue time until finalization for medication registration. However, the analysis of the queue of finalization time for drug registration through prioritization and rare diseases revealed limited data availability due to recent implementation, making it challenging to determine meaningful trends. Nonetheless, a linear regression analysis hinted at a potential increase in

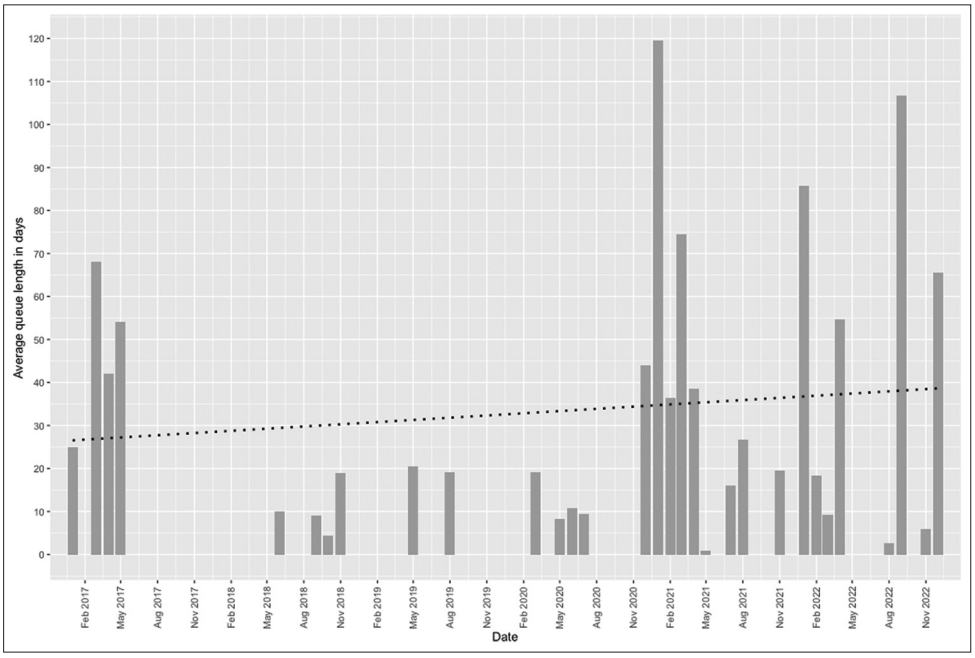

Figure 4. Queue length of time (in days) for drug registrations by prioritization (RDC 204/2017) and/or rare diseases (RDC 205/107).

the average registration time, although caution should be exercised due to the small sample size.

Fast track is a process created to accelerate the market availability of drugs to treat rare conditions and unmet medical needs. The goal is to provide patients with early access to new drugs with clinically relevant results. Fast track applies to a wide range of severe illnesses, mostly chronic diseases. According to a regulatory specialist and former General Manager of Medicines and Biological Products at Anvisa, the fast-track process brought Brazil to the first wave of submission worldwide (Line, 2021). Before these regulatory movements, most pharma companies only decided to call for registry in Brazil after approval in the United States or Europe. The criteria for judging the severity of a disease are varied, including whether the drug will affect the patient's daily routine, survival, or the risk that, without treatment, the condition may evolve to a more severe state (Commissioner, 2018).

The data presented in this study show that since 2017, when accelerated registration mechanisms were implemented by Anvisa in Brazil, there has been a large annual increase in numbers of registration requests using this process, with a mean response time much lower than standard registration. It is noteworthy to point out that the length of drug registration, covering all process, had significantly reduced in terms of the average response time.

Many fast-track registrations had only Phase II studies available to support their decision. Treatments that are registered based on Phase II trials, or preliminary data from Phase III studies, expose patients to large uncertainties in efficacy and safety. The eligible population receiving the medication, which is still under research prospection, is subject to high risk of bias; the medication costs are usually borne by the health-care system or the patients (and their family). Furthermore, these drugs are usually very costly, and given that Phase II studies are conducted in a limited population, there are concerns about the external validation about efficacy and safety.

A study by Wong *et al.* (2019) evaluated medication records from 2000 to 2015 registered by the FDA. The authors found an average of 13.8% of success rate for drugs – success is defined as the registration of a molecule that passed through all phases of the study showing consistent efficacy and low-risk profile. Approximately 21% of Phase II studies presented satisfactory results and received registration. When evaluating medications for rare diseases, 12.7% of Phase II studies reached approval. For oncologic drugs, < 40% progressed from Phase II to Phase III, and 2.8% received approval.

Bypassing the traditional drug approval process is equivalent to transferring important stages of clinical studies to the real world. Medications will be used in clinical practice before their safety and efficacy are fully known and without the rigorous monitoring and protection provided by clinical trials (Linger & Martin, 2018).

The transfer of responsibility for monitoring outcomes of drugs registered through accelerated routes to the real world will make pharmacovigilance the main source of

data. Manufacturers are required to report any negative results of which they become aware, but there is no requirement that they actively seek out negative results. As clinical reporting will remain voluntary, it is likely that adverse reactions to drugs with accelerated approval will be significantly underreported, although through hospital notification systems, adverse drug events for specialist-only medications, such as immunotherapies, may be detected and reported at a higher rate (Linger & Martin, 2018).

Concerns about the safety of drugs registered through fast track have been raised after the provisional approval process was implemented in Canada. When compared to drugs approved through a standard registration process, there is a statistically significant risk that these drugs will generate more serious adverse events or even be removed from the market (Lexchin, 2015a).

A study by Mostaghim *et al.* (2017) reported an increase in safety-related changes in drug labels and highlights the importance of active safety monitoring for all drugs after initial registration, particularly those approved through accelerated routes. The FDA receives voluntary reports of adverse events related to drugs, which can lead to changes in the market authorizations. Since 2007, the FDA's electronic monitoring of health data and other sources through the Sentinel system has provided a critical mechanism to conduct active observational studies to complement the voluntary reporting system. Compared to non-accelerated drugs, accelerated drugs had a 48% higher rate of changes in warnings and contraindications on their market authorization. A qualitative review of changes in the warning section of the label revealed that < 5% were changed to account for a reduction of risk to patients.

The therapeutic value of drugs approved through fast-track pathways has become a topic of interest and concern within the medical and regulatory communities. A 2020 study examined drugs approved by the US FDA and EMA between 2007 and 2017 and found that less than a third of these drugs were rated as having high therapeutic value by independent organizations. The study also revealed that expedited drugs were more likely to receive high ratings, but a significant number of expedited drugs approved by the FDA were considered to have low therapeutic value (Hwang *et al.*, 2020). In the similar vein, a cohort study conducted on Health Canada's priority review process for new drugs, published in 2014, found that the assignment of priority approval by Health Canada was only a fair predictor of a drug's therapeutic value once it entered the market. The study emphasized the need for Health Canada to review its criteria for using priority reviews to ensure accurate identification of drugs that represent significant therapeutic advancements. These findings indicate that the current expedited approval processes may not consistently align with the expected therapeutic benefits for patients (Lexchin, 2015b).

These studies highlight the importance of critically evaluating the therapeutic value of drugs approved through fast-track pathways. The discrepancy between expedited approvals and independent assessments of therapeutic value raises concerns about the potential compromise in rigorous evaluation during expedited review processes. Therefore, it is crucial for regulatory agencies to establish clear guidelines and post-marketing surveillance to monitor the real-world therapeutic value and long-term benefits of drugs approved through expedited pathways. By doing so, regulatory agencies can ensure that expedited approvals truly deliver meaningful clinical advances to patients in need.

Accelerated access to new drugs can represent a way of adapting the regulatory landscape as current regulations do not adequately deal with advanced therapies. Due to a deeper understanding of the causes of diseases, these drugs are generally tested in small clinical trials with patients whose genetic profiles are known. On the other hand, this approach can put patient at risk and increase financial risks for individuals and society. In addition, the process of accepting regulatory decisions made in other countries is often complicated by variable evaluation criteria and differences in clinical practices, which can make the extrapolation of these decisions dangerous in other countries (Kubler, 2018).

Managed entry agreements are a set of tools used to mitigate the impact of uncertainty and financial burden when registering a new drug. They can be subdivided into payments that are tied to health outcomes or financial considerations, where the price is defined based on quantitative measures such as estimated consumption of the technology in question. These agreements can enable health systems to reduce their expenditure on advanced therapies, especially where there is significant uncertainty around safety and efficacy, as well as around the value of a new drug. Managed entry agreements can be potentially important tools for improving scientific capability and knowledge within health systems, whether public or private, while providing access to innovative and high-cost new drugs and seeking to minimize the opportunity costs of decisions (Zampirolli Dias *et al.*, 2020).

5. Conclusion

With the advancements in drug development, regulatory agencies must reorganize to meet the increasing demands for registration, considering the questionable levels of evidence, and ensuring the rapid access of the population to new safe and effective therapies. Considering the

uncertainties in the efficacy and safety of a drug registered through the fast-track process, which often relies on Phase II studies, the implementation of provisional registration with real-world evaluation of outcomes, along with managed entry agreements, may present a sustainable alternative for health-care systems.

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Conflict of interest

The authors declare that they have no competing interests.

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Further disclosure

Not applicable.

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ORIGINAL RESEARCH ARTICLE

An epidemiological study of social support, pain self-efficacy, and health locus of control among elderly patients with musculoskeletal disorders: Which is the role of sociodemographic and clinical variables?

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Abstract

The musculoskeletal system is a human body system that provides our body with the ability to move or stand. Thus, naturally, musculoskeletal disorders could hamper these natural functions. The purpose of this study is to investigate opinions of elderly people with musculoskeletal disorders regarding social support, pain self-efficacy, and health locus of control. A semi-structured questionnaire covering five sections was employed to survey the study participants. The first section was set to solicit demographic data; the second was used to survey about the state of health; the third about the perception regarding social support on a multidimensional scale; the fourth about the pain self-efficacy; and the fifth about the health locus of control. The mean age of the participants recruited in this study was 76.1 years and the majority were female, primary school graduates and retirees. Furthermore, most of them had been employed for moderate/mild manual labor, had average financial status, and was receiving medications for musculoskeletal problems. The results showed that family, social support, and financial status have positive effect on self-efficacy in pain. This study also showed that women took control of more their health better than men and the divorcees underperformed relative to the married individuals in taking control of their health. In summary, social support and internal health beliefs (locus of control) positively affect pain self-efficacy in elderly with musculoskeletal diseases.

Keywords: Elderly; Musculoskeletal disorders; Social support; Pain; Self-efficacy; Health locus of control

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1. Introduction

Musculoskeletal diseases refer to disorders of the musculoskeletal system, *that is*, the body system that provides the body with the ability to move or stand, as a result of which its normal function is hindered. Musculoskeletal diseases cover a spectrum of pathological conditions associated with damage to the muscles, bones, joints, and connective tissues, which cause a decline in functionality and a reduction in the quality of life, especially in the elderly. These disorders can be hereditary or acquired due to inflammatory, infectious, degenerative, developmental, traumatic, and metabolic causes. The factors

that accelerate the progression of musculoskeletal diseases are related to lifestyle, type of work (heavy manual work, standing, poor posture), lack of sleep, fatigue, diet, age, gender, and lack of physical exercise as well as pre-existing conditions (Minetto *et al.*, 2020; Theofilou *et al.*, 2022).

Disorders affecting joints include osteoarthritis, rheumatoid arthritis, psoriatic arthritis, gout, and ankylosing spondylitis. The most common muscular disorder is sarcopenia, while the common bone diseases include osteoporosis, osteopenia, and fractures due to disease or injury. Furthermore, tendinopathy is a common disorder, especially in hands, causing pain, reduced load bearing capacity and reduced functionality. Musculoskeletal diseases can affect more than one area or system of the human body. This happens either locally as with the pain in the waist or neck, or extensive as in the case of fibromyalgia or some inflammatory conditions; for example, the systemic lupus erythematosus or an amputation can cause further musculoskeletal damage through vasculitis and connective tissue inflammation. Injuries due to vulnerability are often a consequence of musculoskeletal diseases, further burdening the patient's condition (Minetto *et al.*, 2020; World Health Organization, 2022).

The prevalence of musculoskeletal disorders increases with age; however, they can occur at any age, either suddenly and for a short period of time as in the cases of fractures, sprains, low back pain, or for over a period of years as in the case of osteoarthritis. These disorders are usually characterized by pain, which is persistent in many cases, and are responsible for an increased risk of falls, reduced mobility, and even disability. Due to the increase in life expectancy, the number of elderly people with these disorders is increasing. The Global Burden of Disease program showed that approximately 1.71 billion people worldwide suffer from musculoskeletal conditions, such as low back pain, neck pain, osteoarthritis, and rheumatoid arthritis, in 2019 (Minetto *et al.*, 2020; World Health Organization, 2022).

By current definition, the old age is often associated with the Third Age, during which a multitude of changes occur in the individuals at every level. It is challenging to determine the exact time when old age begins because aging is a unique and complex biological process, although old age is typically set at the 65th year of one's life. Aging refers to the inevitable, gradual decline of operating mechanisms of the body systems, such as cardiovascular system, musculoskeletal system, and more. It is a progressive, irreversible condition where degenerative processes alter cellular and tissue functions, resulting in physical, mental, and psychological disorders. Various theories attribute the cause of aging to an array of factors, such as continuous shortening of telomeres that eventually results in apoptosis, reduction of DNA methylation, oxidative stress, ionizing and ultraviolet radiations, tumorigenic activity, mitochondrial malformations, and epigenetic modifications as well as environmental factors (Perry *et al.*, 2002; Reddy, 2011; Xu & Teixeira, 2019).

The number of pathological conditions that can occur increases with the age of a person. Some of them are Type 2 diabetes, cardiovascular diseases, arthritis, atherosclerosis, kidney failure, and neurodegenerative diseases such as Alzheimer's and Parkinson's. Aging is strongly related to the reduction of an individual's functionality, which poses difficulty to fully satisfy basic needs, increases risks for diseases, and reduces survivability. The elderly are often characterized by lack of energy, mental impairment, and impaired perception and memory. These impediments negatively, and to a large extent, affect the interpersonal relationships, autonomy as well as psychosynthesis of the affected individuals (Calcinotto *et al.*, 2019; Reddy, 2011).

During the transition to Third Age, older adults report having fewer friendships and social relationships compared with when they were younger adults (Hung *et al.*, 2017; Miaskowski *et al.*, 2020). Based on research, loneliness prevails in the elderly at a rate of over 43% and is a precursor of undesirable conditions such as mortality (Perissinotto *et al.*, 2012), while it has been shown that the occurrence of chronic pain is closely related to loneliness and social isolation (Emerson *et al.*, 2018). Another study in older adults showed that reduced social support was associated with higher rates of pain intensity (Richmond *et al.*, 2018).

The purpose of this study is to investigate the opinions of elderly people with musculoskeletal health problems on pain self-efficacy, perceived social support, and health locus of control. More specifically, the following research question is investigated: "How do the elderly with musculoskeletal health problems evaluate their pain self-efficacy and social support as well as health locus of control and what factors (sociodemographic and clinical) influence them?"

2. Methods

A quantitative and cross-sectional study adopting social support, pain self-efficacy, and health locus of control as dependent variables, as well as clinical and sociodemographic characteristics as independent variables, was conducted. A sample of 106 elderly people with musculoskeletal health problems was recruited. Elderly people with other significant health problems, other than musculoskeletal ones, were excluded from this study. The subjects were enrolled from the "Help at Home" program and the Elderly Care Unit Center (K.A.P.H) in the area of Patras during the period of April to June 2023.

In this study, a semi-structured questionnaire was used, covering five sections: (i) The first section concerns demographic data of the sample (sex, age, marital status, number of children, education level, professional status, type of professional work, number of family members in the same household, paid/unpaid helper, financial status, place of residence, and insurance cover). (ii) The second section concerns the state of health (duration treatment of musculoskeletal health problems, taking medication for treatment of musculoskeletal health problems, duration of taking medications for the treatment of musculoskeletal health problems, and severity of musculoskeletal health problems). (iii) The third section concerns the perceived social support (based on the Multidimensional Scale of Perceived Social Support, MSPSS) (Zimet *et al.*, 1988). The scale includes 12 questions (1 = Strongly disagree; to 7 = Strongly agree), which are divided into three sub-dimensions: (a) Support from significant other (1, 2, 5, and 10; Cronbach's alpha = 0.876), (b) support from the family (3, 4, 8 and 11; Cronbach's alpha = 0.930), and (c) support from friends (6, 7, 9, and 12; Cronbach's alpha = 0.964). For the overall scale of perceived social support, the reliability index Cronbach's alpha = 0.890. The score for each scale was calculated by finding the average of scores given to the questions in each section. The translation and cultural adaptation of this scale into Greek was done by Theofilou (2015). (iv) The fourth section concerns the pain self-efficacy (based on the Pain Self-efficacy Questionnaire) (Nicholas, 1989) of the respondents. This section contains 10 questions (0 = Not at all sure, to 6 = Completely sure). The scale score was determined by summing the scores given to all questions in this section, with a total score range of 0–60 (Cronbach's alpha = 0.945). The translation and cultural adaptation of this scale into Greek was done by Theofilou *et al.* (2014). (v) The fifth and last section contains 18 questions (1 = Strongly disagree, to 6 = Strongly agree) derived from the Health Locus of Control Scale (MHLC) (Wallston *et al.*, 1994). The questions in this section can be sub-categorized into four sections: (a) Control focus (internal) (1, 6, 8, 12, 13, 17, [6–36]; Cronbach's alpha = 0.762), (b) control focus (chance) (2, 4, 9, 11, 15, 16, [6–36]; Cronbach's alpha = 0.793), (c) control focus (physicians) (3, 5, 14, [3–18]; Cronbach's alpha = 0.754), and (d) control focus (other people) (7, 10, 18, [3–18]; Cronbach's alpha = 0.851). The score for each section was calculated by adding up the questions included in each section.

The participants were informed about the purpose of the research as well as the absolute assurance of their anonymity. They were also informed that their participation was purely voluntary and they were allowed stop participating any time they wish. This study was conducted in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and the Declaration of Helsinki 1975.

Statistical analysis was performed using descriptive statistics and inductive statistics. Descriptive statistics captured the demographics of the sample as well as their responses to the core survey section. In addition, through inductive statistics, the relationships between the variables were examined. The statistical program IBM SPSS v.22.0 and Microsoft Office Excel were used for the analysis.

3. Results

This study included 106 elderly people with musculoskeletal diseases, of which 32 (30.2%) were men and 74 (69.8%) were women (Table 1).

According to Table 2, the survey participants had a mean age of 76.1 years with a standard deviation of 7.9 years. The oldest respondent was 98 years old, while the youngest was 65. Furthermore, the average number of children per participant was 1.8 (with a standard deviation of 1.0), with the lowest number of children being 0 and the highest being 4. Furthermore, the average number of family members residing in the same household was 1.3 with a standard deviation of 1.2. The lowest number of family members was 0 and the highest was 6. Finally, it was found that 37 out of 106 people (34.9%) lived alone.

Furthermore, 40.6% of the sample were married, 40.6% were widowed, 10.4% were single, and the remaining 8.4% of the sample were divorced.

As shown in Table 3, the majority of the sample, that is, 39.6% have an elementary education, while 23.6% have a high school education, 17.0% have an education from lyceum, 11.3% have a higher education, and the remaining 8.5% have a post-high school education.

Table 1: Gender

	N	%
Male	32	30.2
Female	74	69.8
Total	106	100.0

Table 2. Age, number of children, and number of family members in the same household

	Minimum	Maximum	M	SD
Age	65.0	98.0	76.1	7.9
Number of children	0.0	4.0	1.8	1.0
Number of family members in the same household	0.0	6.0	1.3	1.2

Abbreviations: M: Mean; SD: Standard deviation.

According to Table 4, most of the sample (78.3%) had retired, 16.0% were homemakers, 3.8% were workers, and the remaining 1.9% were unemployed.

Regarding the type of occupational status in the past, 50.0% of the sample had an occupation involving moderate/light manual work, 29.2% of the sample were involved in heavy manual work, and the remaining 20.8% of the sample reported non-manual work.

Based on Table 5, 21.7% of the sample reported having a paid/unpaid helper, while 78.3% of the sample did not have a helper. Moreover, 35.8% of the sample reported that they were in a good financial condition, 37.7% in a moderate financial condition, and the remaining 26.4% in a poor or very poor financial condition. It was also observed that 41.5% of the sample lived in semi-urban area, 39.65 in an urban area, and the remaining 18.9% in a rural area.

Regarding the insurance coverage, 86.8% of the sample reported having public insurance coverage, 5.7% having private insurance coverage, and 7.55% having both private and public insurance coverages (Table 6). The sample also reported that they spent an average of 16.6 years (with a standard deviation of 14.1 years) in dealing with musculoskeletal health problems, with 1 year being the shortest while 70 years being the longest.

According to Table 7, 55.7% of the sample reported taking medication to treat musculoskeletal health problems while the remaining 44.3% reported otherwise. Further, for 55.7% of the sample that reported receiving medications to treat musculoskeletal health problems, the mean duration of taking these drugs was 10.5 years with a standard deviation of 10.6. The shortest duration was 1 year and the longest was 60 years. Furthermore, 51.9% of the sample described their musculoskeletal health problems as at least quite serious, while 48.1% of the sample characterized their situations as not at all or somewhat serious.

According to Table 8, the health locus of control of the sample was at moderate level regarding internal (24.3±4.8), chance (20.2±5.1), doctors (13.9±2.8), and others (11.5±3.8). We also observed that the pain self-efficacy of the respondents was at a moderate level (32.0±13.5).

According to Table 9, overall social support (4.6 ± 0.9), family support (5.1 ± 1.2) and support from significant others (5.0 ± 1.2) were at high level, while the support from friends was at a moderate level (3.6 ± 1.5).

Kolmogorov–Smirnov and Shapiro–Wilk tests revealed that the data follow the normal distribution (Table 10). Based on the results, the values of most variables do not present a normal distribution. To investigate whether the deviation from the normal distribution is large, normalized values of skewness and kurtosis were computed (Table 11).

The normalized values of skewness and kurtosis were within the range of −2 – 2 for almost all variables with the exception of three variables, that is, family support, duration of treatment of musculoskeletal health problems,

Table 3. Level of education of respondents

Education	N	%
Primary education	42	39.6
High school education	25	23.6
Lyceum education	18	17.0
Higher education	12	11.3
Post-secondary education	9	8.5
Total	106	100.0

Table 4. Professional status of respondents

Professional status	N	%
Pensioner	83	78.3
Worker	4	3.8
Housework	17	16.0
Unemployed	2	1.9
Total	106	100.0

Table 5. Status of having paid/unpaid helpers

Helpers	N	%
Yes	23	21.7
No	83	78.3
Total	106	100.0

Table 6. Insurance coverage

Insurance	N	%
Public	92	86.8
Private	6	5.7
Both	8	7.5
Total	106	100.0

Table 7. Number of respondents taking medications to treat musculoskeletal health problems

Medications	N	%
Yes	5	55.7
No	47	44.3
Total	106	100.0

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Table 8. Health locus of control of respondents

Dimensions	Minimum value	Maximum value	M	SD	Range scale (M)
Health locus of control (internal)	15.0	36.0	24.3	4.8	6 – 36 (21)
Health locus of control (chance)	6.0	29.0	20.2	5.1	6 – 36 (21)
Health locus of control (doctors)	6.0	18.0	13.9	2.8	3 – 18 (10,5)
Health locus of control (others)	3.0	18.0	11.5	3.8	3 – 18 (10,5)

Abbreviations: M: Mean; SD: Standard deviation.

Table 9. Perceived social support of the respondents

Subscales	Minimum value	Maximum value	M	SD	Range scale (M)
Support from significant others	2.0	7.0	5.0	1.2	1–7 (4)
Support from family	1.0	7.0	5.1	1.2	1–7 (4)
Support from friends	1.0	7.0	3.6	1.5	1–7 (4)
Overall social support	2.0	6.6	4.6	0.9	1–7 (4)

Abbreviations: M: Mean; SD, standard deviation.

Table 10. Results of normality test

Variables	Kolmogorov–Smirnov			Shapiro–Wilk		
	Stat	df	*p*	Stat	df	*p*
Age	0.096	106	0.019	0.956	106	0.002
Number of family members in same household	0.229	106	0.000	0.839	106	0.000
Financial condition	0.192	106	0.000	0.904	106	0.000
Duration of treatment of musculoskeletal health problems	0.158	106	0.000	0.867	106	0.000
Severity of musculoskeletal health problems	0.241	106	0.000	0.866	106	0.000
Pain self-efficacy	0.087	106	0.048	0.972	106	0.026
Social support (significant others)	0.112	106	0.002	0.966	106	0.008
Social support (family)	0.105	106	0.006	0.937	106	0.000
Social support (friends)	0.064	106	0.200	0.973	106	0.032
Social support (overall)	0.080	106	0.095	0.980	106	0.105
Health locus of control (internal)	0.111	106	0.003	0.972	106	0.024
Health locus of control (chance)	0.075	106	0.173	0.978	106	0.082
Health locus of control (doctors)	0.121	106	0.001	0.959	106	0.003
Health locus of control (others)	0.125	106	0.000	0.956	106	0.002
Number of children	0.252	106	0.000	0.894	106	0.000

and number of family members in the same household (Table 11). Since this condition holds, we can assume that the assumption of normality of the data is satisfied (George & Mallery, 2016). In addition, the normalized values of skewness and kurtosis of two of the three variables did not fall within the range of −2 – 2; thus, for reasons of uniformity, parametric tests, Pearson index, *t*-test, and ANOVA were employed for analysis.

Table 12 shows that women manifested a higher level of internal health locus of control compared to men ($p < 0.05$).

Based on Table 13, the subjects who did not have a helper versus subjects who had a helper showed a higher level of pain self-efficacy ($p < 0.05$). Furthermore, people who did not have a helper had a higher level of health beliefs about others compared to people who had a helper ($p < 0.05$).

According to Table 14, health locus of control (others) is the only variable that is significantly different among people with different marital status ($p < 0.05$). To exactly determine the marital status categories that show significant differences, Bonferroni's *post hoc* test

Table 11. Normalized values of skewness and kurtosis

Variables	Skewness			Kurtosis		
	Skewness	Standard error	Z score	Kurtosis	Standard error	Z score
Age	0.389	0.235	1.655	−0.572	0.465	−10.230
Number of family members in same household	0.611	0.235	2.604	0.754	0.465	10.622
Financial condition	−0.055	0.235	−0.233	−0.455	0.465	−0.979
Duration of treatment of musculoskeletal health problems	1.418	0.235	6.043	2.304	0.465	4.953
Severity of musculoskeletal health problems	0.075	0.235	0.320	−0.883	0.465	−1.899
Pain self-efficacy	0.169	0.235	0.721	−0.872	0.465	−1.875
Social support (significant others)	−0.158	0.235	−0.673	−0.497	0.465	−1.068
Social support (family)	−0.938	0.235	−3.998	1.618	0.465	3.478
Social support (friends)	0.016	0.235	0.068	−0.655	0.465	−1.408
Social support (overall)	−0.232	0.235	−0.988	−0.083	0.465	−0.178
Health locus of control (internal)	0.092	0.235	0.393	−0.639	0.465	−1.374
Health locus of control (chance)	−0.268	0.235	−1.142	−0.463	0.465	−0.995
Health locus of control (doctors)	−0.353	0.235	−1.503	−0.453	0.465	−0.973
Health locus of control (others)	−0.324	0.235	−1.380	−0.833	0.465	−1.791
Number of children	−0.185	0.235	−0.789	−0.291	0.465	−0.626

Table 12. Differences between males and females in pain self-efficacy, perceived social support, and health locus of control

Variables	Gender				Levene's test		*t*-test		
	Male		Female						
	M	SD	M	SD	F	*p*	t	df	*p*
Pain self-efficacy	28.59	13.78	33.50	13.24	0.030	0.863	−1.731	104	0.086
Support from the significant other	4.78	1.29	5.13	1.15	0.005	0.942	−1.391	104	0.167
Support from family	5.02	1.05	5.15	1.30	0.969	0.327	−0.525	104	0.601
Support from friends	3.61	1.42	3.57	1.55	0.497	0.482	0.120	104	0.904
Overall social support	4.47	1.11	4.62	0.91	1.935	0.167	−0.725	104	0.470
Health locus of control (internal)	22.53	4.53	25.03	4.82	0.152	0.698	−2.492	104	0.014*
Health locus of control (chance)	21.37	3.64	19.72	5.50	7.396	0.008	1.828	86.502	0.071
Health locus of control (doctors)	13.19	2.51	14.15	2.88	1.011	0.317	−1,638	104	0.105
Health locus of control (others)	11.81	2.90	11.38	4.09	5.449	0.022	0.621	81.545	0.536

Abbreviations: M: Mean; SD: Standard deviation. *$p<0.05$.

was performed. Furthermore, the Bonferroni correction was used to determine the new adjusted *p*-value ($\alpha^* = \alpha/6 = 0.05/6 = 0.008$). The results showed that divorcees had lower level of health locus of control for others than married individuals and widowed.

No statistically significant differences were observed among individuals of different educational backgrounds in terms of pain self-efficacy, perceived social support, and health locus of control ($p > 0.05$; Table 15).

Furthermore, individuals with different professional backgrounds had statistically significant differences in health locus of control (chance) ($p < 0.05$). To determine which occupational categories differed from each other, Bonferroni's *post hoc* test was performed. The Bonferroni's correction was used to determine the adjusted *p*-value ($\alpha^* = \alpha/3 = 0.05/3 = 0.017$). No statistically significant differences were found.

Moreover, people with different professional backgrounds manifested statistically significant differences in support from family, support from friends, and overall social support ($p < 0.05$). To determine which professional backgrounds differed, Bonferroni's *post hoc* test was performed. Furthermore, the Bonferroni's correction was used to determine the adjusted *p*-value ($\alpha^* = \alpha/3 = 0.05/3 = 0.017$).

Table 13. Differences between people who had and did not have a helper in terms of pain self-efficacy, perceived social support, and health locus of control

Variables	Having a paid/ unpaid helper		Not having a paid/ unpaid helper		Levene's test		*t*-test		
	M	SD	M	SD	F	*p*	t	df	*p*
Pain self-efficacy	22.52	8.31	34.65	13.55	7.770	0.006	−5.314	57,934	0.000*
Support from the significant other	5.11	1.00	5.00	1.25	1.141	0.288	0.373	104	0.710
Support from family	4.88	1.25	5.17	1.22	0.160	0.690	−1.021	104	0.310
Support from friends	3.49	1.48	3.61	1.52	0.368	0.546	−0.336	104	0.738
Overall social support	4.49	0.75	4.60	1.03	2.463	0.120	−0.446	104	0.656
Health locus of control (internal)	23.13	4.20	24.59	4.99	0.657	0.420	−1.282	104	0.203
Health locus of control (chance)	21.13	4.66	19.96	5.15	0.676	0.413	0.980	104	0.329
Health locus of control (doctors)	12.91	2.71	14.12	2.78	0.116	0.734	−1.854	104	0.067
Health locus of control (others)	14.00	2.58	10.82	3.76	8.667	0.004	4.698	50.809	0.000*

Abbreviations: M: Mean; SD: Standard deviation. *p<0.05.

Table 14. Differences among people of different marital status in terms of pain self-efficacy, perceived social support, and health locus of control

Variables	Marital status								Levene's test		ANOVA		
	Married		Single		Widowed		Divorced						
	M	SD	M	SD	M	SD	M	SD	F (3, 102)	*p*	F	df1, df2	*p*
Self-efficacy in pain	35.44	12.51	27.36	12.41	29.23	14.24	34.67	13.39	0.128	0.943	2.143	3, 102	0.099
Support from the significant other	5.38	1.02	4.68	1.29	4.88	1.20	4.44	1.57	1.220	0.306	2.566	3, 102	0.059
Support from family	5.40	1.06	4.39	1.57	5.07	1.19	4.81	1.39	1.454	0.232	2.387	3, 102	0.073
Support from friends	3.58	1.55	4.25	1.91	3.59	1.34	2.72	1.25	1.240	0.299	1.744	3, 102	0.163
Overall social support	4.79	0.84	4.44	1.23	4.52	0.93	3.99	1.29	1.963	0.124	1.941	3, 102	0.128
Health locus of control (internal)	25.26	4.27	22.64	4.43	23.95	5.17	23.11	6.09	1.197	0.315	1.250	3, 102	0.296
Health locus of control (chance)	19.30	5.62	21.18	4.00	20.95	4.50	19.89	5.86	1.275	0.287	0.919	3, 102	0.435
Health locus of control (doctors)	13.84	2.82	13.73	2.80	14.02	2.77	13.33	3.20	0.031	0.993	0.161	3, 102	0.923
Health locus of control (others)	11.91	3.42	11.91	3.30	11.88	3.81	7.33	3.57	0.715	0.545	4.442	3, 102	0.006*

Abbreviations: M: Mean; SD: Standard deviation. *p<0.05.

No statistically significant differences were found in support from the family and support from friends. We observed that individuals who did no manual labor had a higher level of social support than individuals who did heavy manual labor (p = 0.006). In addition, we found no statistically significant differences among the individuals living in different residential areas in terms of pain self-efficacy, perceived social support, and health locus of control (p >0.05).

Individuals with different insurance categories had statistically significant differences in support from significant other (p <0.05). To determine which insurance categories differed, the Bonferroni's *post hoc* test was performed. Furthermore, the Bonferroni's correction was used to determine the adjusted p-value ($\alpha^* = \alpha/3 = 0.05/3 = 0.017$). We found that individuals who had both private and public insurance showed a higher level of support from the significant other than those covered by public insurance only (p = 0.011).

4. Discussion

The purpose of this research is to study the opinions of elderly people with musculoskeletal health problems regarding pain self-efficacy, perceived social support, and health locus of control. This study attempted to investigate several important factors associated with the elderly suffering from musculoskeletal diseases, which are among the most common disorders that someone can experience, especially at older ages. More specifically, we investigated how the elderly people with musculoskeletal health problems evaluate their pain self-efficacy and social support as well as health locus of control and what factors

Table 15. Differences between individuals of different educational backgrounds in pain self-efficacy, perceived social support, and health locus of control

	Education										Levene's test		ANOVA		
	Primary education		High school education		Lyceum education		Post-secondary education		Higher education						
	M	SD	M	SD	M	SD	M	SD	M	SD	F (4, 101)	*p*	F	df1, df2	*p*
Pain self-efficacy	29.00	13.54	31.80	14.62	37.00	11.63	35.22	13.31	33.17	13.16	0.215	0.930	1.297	4, 101	0.276
Support from the significant other	5.13	1.25	4.56	1.27	5.25	0.97	5.17	1.19	5.19	1.08	0.290	0.884	1.287	4, 101	0.280
Support from family	5.20	1.16	4.87	1.15	5.24	1.27	4.78	1.84	5.37	1.01	1.106	0.358	0.639	4, 101	0.636
Support from friends	3.23	1.61	3.71	1.47	3.76	1.14	4.03	1.63	3.96	1.51	1.274	0.285	1.090	4, 101	0.366
Overall social support	4.52	0.97	4.38	1.08	4.75	0.77	4.66	1.14	4.84	0.94	0.806	0.524	0.665	4, 101	0.618
Health locus of control (internal)	23.69	4.67	24.24	4.94	24.94	4.84	24.44	6.64	25.25	4.33	0.836	0.505	0.354	4, 101	0.841
Health locus of control (chance)	21.29	5.50	19.80	4.16	20.11	4.59	18.67	4.33	18.67	6.14	1.246	0.296	1.009	4, 101	0.406
Health locus of control (doctors)	13.19	3.12	14.68	2.34	14.33	2.14	14.56	2.46	13.25	3.25	1.550	0.194	1.585	4, 101	0.184
Health locus of control (others)	12.69	3.54	11.36	3.67	10.00	3.97	10.22	4.44	10.92	3.03	0.470	0.757	2.206	4, 101	0.074

(sociodemographic and clinical) influence them. The sample employed in this study includes people over 65 years old with the majority being women (74 people), while the average age was 76 years. These findings were consistent with prior research studies on this particular issue.

Our results showed that age is one of the factors that influence pain self-efficacy and has a negative effect, since the older participants presented lower levels of self-efficacy. This means that over the years, these participants were unable to manage their pain as effectively as they were in the past, indicating that advanced age is a factor that may burden their lives. This finding concurred with the research results on pain self-efficacy by Terzaki *et al.* (2023).

Subsequently, we found that people who did not have a helper had a higher level of pain self-efficacy as compared to people who had a helper; this has also been confirmed previously (Warner *et al.*, 2011). The findings of this study are reflective of the need and the desire of these patients in gaining control of their own lives as they are responsible towards themselves. These findings also shed light on the issue of social support from family or friends and their importance in the context of chronic disease management.

The financial condition also seemed to play a role in this regard, as evidenced by the better pain management by older people with higher incomes, which has also been observed in other studies (Grol-Prokopczyk, 2017). The study also showed that people who had private insurance or both private and public insurance coverages had a higher level of pain self-efficacy than those having public insurance coverage only. Similar observations were made in the present research for the individuals who had private and public insurance as they showed a higher level of perceived support from an important person compared to people with public insurance. Furthermore, the elderly individuals who had never engaged in manual labor appeared to receive more overall social support than those engaged in heavy manual labor. The effect of socioeconomic factors on the social support received by the individuals is significant.

In addition, individuals who did not have a helper showed a higher health locus of control on others compared to those who did have a helper, while the divorced, as opposed to the married and bereaved, showed a lower level of health locus of control on others, indicating that the absence of a partner leads to the belief that they did not experience control others did otherwise. Furthermore, it should be noted that elderly women showed a higher level of health locus of control on the internal compared with their male counterparts, consistent with findings by Zhang & Jang (2017), showing that women are more inclined to control their health issues, as compared with men.

We acknowledge several limitations of the present study. Due to time constraint, a relatively small sample of only 106 people was recruited in this study. Furthermore, the study participants were not randomly sampled but selected out of convenience. Consequently, the findings, although consistent with other literature and research results, are not feasible for generalization in other populations.

5. Conclusion

Musculoskeletal disorders are an inevitable set of pathological conditions strongly associated with aging, and they can

negatively impact the functionality of the elderly. The present study highlighted the factors that adversely influence the physical and mental health of the elderly individuals. Future studies should be conducted to dissect the complex mechanisms underlying the impacts of musculoskeletal disorders on the elderly adults, so that more effective interventions can be devised to promote their well-being and quality of lives.

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Conflict of interest

The authors declare that they have no competing interests.

Author contributions

Conceptualization: All authors

Formal analysis: All authors

Investigation: All authors

Methodology: All authors

Writing – original draft: All authors

Ethics approval and consent to participate

The present study was approved by the Institutional Review Board (IRB) of the program "Help at Home" and the Elderly Care Unit Center (K.A.P.H) in the area of Patras, Greece (approval number 2156/2023-5-31).

Consent for publication

Not applicable.

Availability of data

Data supporting these findings are available within the article or can be obtained from corresponding author following formal request.

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ACCSCIENCE PUBLISHING

Global Health Econ Sustain

ORIGINAL RESEARCH ARTICLE

Antimicrobial silver-loaded starch-based bioplastic grafted with poly(4-vinylpyridine) as a novel eco-friendly material

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Abstract

The incorporation of polymer materials into disposable medical devices proves to be valuable due to their chemical and physical properties that make them practically unique. Approximately 25% of hospital waste consists of plastics, prompting various efforts to mitigate their environmental impact, such as reusing or reprocessing. In this study, we attained a hybrid material (organic-inorganic) with antibacterial properties through surface modification of a starch-based polymer matrix and subsequent silver immobilization. The raw material, which is a commercially available biodegradable product, was grafted at room temperature with the monomer 4-vinylpyridine through a "grafting-from" method initiated with high-energy gamma rays from a Co-60 source, using absorbed doses of 10 – 50 kGy and monomer concentrations of 10 – 100 vol%. Grafted films were loaded with silver at room temperature using natural radiation. Our results demonstrate that the modified materials exhibit antimicrobial activity against the pathogens *Staphylococcus aureus* and *Pseudomonas aeruginosa*, as confirmed through the Kirby-Bauer disc diffusion assay.

Keywords: Antimicrobial materials; Bioplastics; Gamma-rays; Grafting; Poly(4-vinylpyridine); Silver-immobilization; Starch

1. Introduction

Environmental pollution resulting from non-biodegradable plastic waste, including polyethylene terephthalate (PET), polyvinyl chloride (PVC), and polystyrene (PS), among other polymers, is a widespread issue. These materials are integral to various industrial sectors such as food packaging, building, automotive, textile, and technology. Even medical-grade plastic materials contribute to this issue, with estimates suggesting that at least 25% of hospital waste is comprised of plastic (Jain & LaBeaud, 2022).

Disposable medical devices are a major contributor to this waste, accounting for 70% of it, and are often manufactured using non-biodegradable polymers, as previously mentioned (Gill *et al.*, 2022). While proper disposal of single-use plastic waste has a significant environmental impact, it is challenging due to the enduring nature of plastics, stemming from their positive attributes (chemical and physical). Although plastic waste largely consists of macroplastics, the real problem revolves around microplastics (Tudor *et al.*, 2019). Disposable medical devices are abundant and continually contribute to environmental pollution. Examples include gauze, catheters, patches, probes, bandages, and sample collection vessels, as well as intravenous and colostomy bags. While the impact of medical microplastics remains an ongoing subject of study, research indicates that the presence of microplastics in living organisms may signal serious environmental consequences resulting from the significant presence of microplastic waste (Chae & An, 2017; Eerkes-Medrano *et al.*, 2015; Geyer *et al.*, 2017).

Numerous manufacturers of disposable products, spanning from packaging and containers to housings and even high-tech devices, are currently exploring eco-friendly alternatives to replace environmentally polluting materials (Abe *et al.*, 2021; Avramescu, 2023; Bartolucci *et al.*, 2023). For instance, disposable cups are widely used globally, and a complete transition to reusable cups may be impractical. Thus, a viable ecological alternative using fully or partially biodegradable or bio-based materials can help reduce the waste from non-biodegradable or non-biobased polymers, such as polypropylene (PP) or PS, which are commonly used for manufacturing these containers (Nisha *et al.*, 2022). The term "bioplastic (BP)" usually refers to bio-based and/or biodegradable materials, but it extends to broader concepts. BPs are materials that meet one or more of the following criteria: (i) Their monomers for polymerization come from renewable sources, (ii) their polymer matrix is extracted from renewable resources, (iii) they are biodegradable, or (iv) they are produced through biological processes. These criteria define the different characteristics that a material must possess to be considered a BP. The advantages of using bio-based and/or bio-degradable plastics (named BPs) include diversifying the acquisition and disposal of plastic materials, which forms an integral part of a comprehensive strategy to address pollution resulting from fuel-based plastics (Moshood *et al.*, 2022). Examples of this green approach to BPs represent the path that global economies should embrace for the future.

In this study, we investigated a BP material presented by Ecoshell® — specifically, a biodegradable cup composed of a mixture of starch and aliphatic polyester. Detailed information about this material can be found on the manufacturer's website (www.ecoshell.com.mx). According to the supplier, this BP does not cause contamination to the environment once its life cycle concludes. BPs, known for their affordability and durability, offer potential applications in generating antimicrobial surfaces (Ali *et al.*, 2023; Jiang *et al.*, 2022; Li *et al.*, 2022). They represent an alternative to traditional plastic devices, with the added benefit of antimicrobial properties, making them both promising and noteworthy (Kumar *et al.*, 2018). One method to modify the novel Ecoshell® BP material is through polymer grafting. The grafting process involves introducing chains capable of immobilizing an antimicrobial agent on the surface, preventing the growth of biofilms or pathogens (Muñoz-Bonilla & Fernández-García, 2012). Poly(4-vinyl pyridine), abbreviated as poly(4VP), is a biomaterial that can be grafted onto various surfaces using the "grafting-from" method, using chemical initiators (Sen *et al.*, 2003) or gamma irradiation (Flores-Rojas *et al.*, 2023). In this work, we propose grafting poly(4VP) onto the Ecoshell® BP matrix to load silver (a well-known antimicrobial agent) (Ghazzy *et al.*, 2023; Mehta *et al.*, 2023). The resulting material, named BP-g-4VP®Ag, was examined as an antimicrobial agent against *Staphylococcus aureus* and *Pseudomonas aeruginosa* (Figure 1). These microorganisms are well-known nosocomial pathogens and exhibit widespread

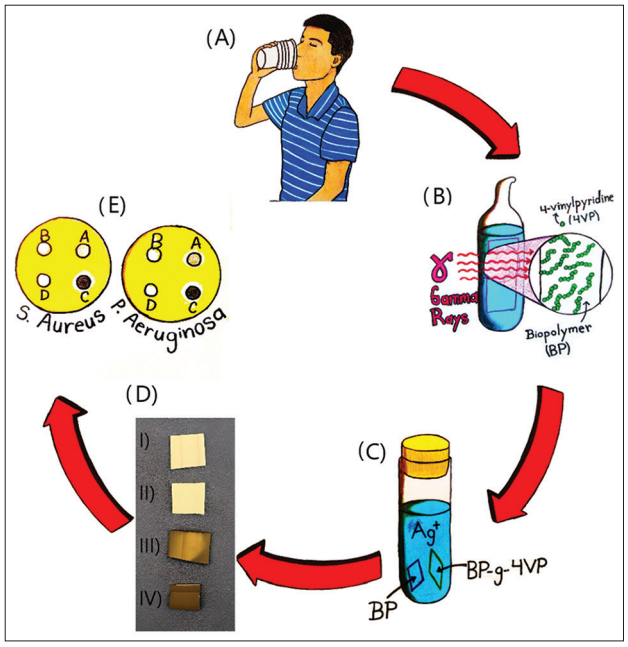

Figure 1. Reuse of bioplastics, as BP-g-4VP®Ag. (A) The material is a commercial eco-cup. (B) Grafting with 4VP through the "grafting-from" method using gamma radiation as an energy source. (C) Silver-loading process. (D) Modified film and controls: (I) BP, (II) BP-g-4VP, (III) BP®Ag, and (IV) BP-g-4VP®Ag. (E) Drawing of the evaluation against *Staphylococcus aureus* and *Pseudomonas aeruginosa in vitro*.

antibiotic resistance (Khan *et al.*, 2022; Kluytmans *et al.*, 1997). Therefore, it is crucial to inhibit their proliferation. Finally, we conducted a comprehensive physicochemical, thermal, and spectroscopic characterization of the products in this study.

2. Materials and methods

2.1. Materials

BPs were obtained from Ecoshell® cups. According to the manufacturer, the Ecoshell® wfp-02 material consists of a biodegradable blend of corn starch, aliphatic polyester, and unspecified additives (potentially plasticizers and/or dyes). The 4VP monomer (99% purity), reagent-grade methanol, and bidistilled water were procured from Sigma-Aldrich. Before use, the 4VP monomer was distilled under reduced pressure to eliminate any oxides and inhibitors.

2.2. Cleaning of pristine BP films

BP was cut into small pieces measuring 1 × 2 cm. These pieces were washed with detergent and water, followed by a 24-h rinse in MeOH/water at room temperature with mechanical stirring. Finally, these pieces were dried in a vacuum oven at 60°C. This cleaning process aimed to eliminate residues and additives, ensuring homogeneity in the grafting process (Figure S1).

2.3. Grafting 4VP onto BP to create BP-g-4VP

The pre-washed BP films were placed into an ampoule containing a solution of 4VP/MeOH at various monomer concentrations (10, 25, 50, 75, and 100 vol%), which was then degassed by bubbling Ar for 12 min and sealed to maintain an inert atmosphere. Subsequently, the samples were exposed to gamma radiation using a Co-60 source, with varying absorbed doses (0, 20, 30, 40, and 50 kGy) and irradiation rates of 8.6 and 9.0 kGy/h. Finally, the resulting material was subjected to a 24-h wash with a 50/50 vol% MeOH/H_2O mixture and was dried in a vacuum oven for approximately 6 h. The grafting degree (graft%) was calculated using Equation I.

$$\text{Graft } \% = \left(\frac{wf - w0}{w0} \right) * 100\% \quad \text{(I)}$$

Where *wf* corresponds to the weight of the grafted samples, and *w0* corresponds to the weight of the samples before grafting.

2.4. Swelling tests

BP-g-4VP samples with varying graft percentages (0.0, 7.9, 11.1, 18.5, 22.8, 32.4, 45.3, 58.6, and 65.7 g%) were immersed in bidistilled water to assess their water retention capacity. Swelling tests were conducted by submerging the samples in water, followed by carefully removing excess water using absorbent paper. The weight of each sample was recorded at predetermined time intervals. The degree of swelling (Swelling, s%) was calculated using Equation II.

$$\text{Swelling } \% = \left(\frac{ws - wd}{wd} \right) * 100\% \quad \text{(II)}$$

Where *ws* corresponds to the weight of the swollen sample, and *wd* corresponds to the weight of the dry sample.

2.5. pH-response studies

The pH-response studies of BP-g-4VP films were carried out using 0.1 N buffer solutions ranging from pH 2 – 12. These buffer solutions were prepared using boric acid, citric acid, and trisodium orthophosphate. The pH values were adjusted from 2 to 12 using a potentiometer (exact values: 2.01, 3.01, 4.00, 5.03, 5.99, 7.00, 7.99, 9.00, 10.03, 10.99, and 11.98). The BP-g-4VP samples were immersed in each of these buffer solutions at room temperature for 4 h. Afterward, any excess liquid was carefully removed using absorbent paper. The degree of swelling (s%) was determined gravimetrically using Equation II.

2.6. Silver loading to create BP-g-4VP@Ag and BP@Ag

BP-g-4VP films with different percentages (30.1 and 32.4 g%) and pristine films (BP) were loaded with Ag using a freshly prepared aqueous solution of $AgNO_3$ (1000 ppm). The samples were immersed in the $AgNO_3$ solution at room temperature for 96 h while being exposed to solar radiation. After the specified time had elapsed, the pristine BP@Ag and BP-g-4VP@Ag samples were rinsed with bidistilled water to remove Ag that was not strongly attached or immobilized. Finally, the samples were dried at 60°C for 24 h and stored at room temperature.

2.7. Kirby-Bauer disc diffusion assay

The samples, including BP@Ag, BP-g-4VP (30.1 g%)@Ag and BP-g-4VP (32.4 g%)@Ag, as well as BP, BP-g-4VP (30.1 g%) and BP-g-4VP (32.4 g%) (used as respective controls), were cut into 6 mm circles and sterilized before use. These samples were individually placed in agar cultures inoculated with *S. aureus* and *P. aeruginosa* and then incubated at 25°C for 24 h. The inhibition capacity of each sample was measured by determining the inhibition zone using a Vernier caliper for each sample.

2.8. Instrumental analysis

2.8.1. Contact angle

Contact angles were measured on BP-g-4VP samples with different weight percentages (0.0, 7.9, 11.1, 18.5, 22.8, 32.4,

45.3, 58.6, and 65.7 g%) using a Krüss DSA 100 drop-shape analyzer (Matthews, NC, USA) at time intervals of 0, 1, and 3 min. The distance between the water droplet and the film was fixed at 1 cm.

2.8.2. Fourier transmittance infrared-attenuated total reflection (FTIR-ATR)

Infrared spectroscopy was performed using a Perkin-Elmer Spectrum 100 equipped with a diamond-tipped DiCompTM Crystal ATR (Norwalk, CT, USA). A total of 16 scans were recorded over a range from 4000 cm^{-1} to 650 cm^{-1}. The acquired data were normalized and baseline-corrected. Spectra were analyzed from different samples, including BP (0 g%), BP-g-4VP (6.2, 32.4, and 96.4 g%), and poly(4VP).

2.8.3. Thermogravimetric analysis (TGA)

TGA was carried out using a TGA Q50 from TA Instruments (New Castle, DE, USA). The heating rate was set at 10°C/min under a nitrogen atmosphere. Prior to analysis, samples were dried in an oven at 60°C for 48 h. Thermograms were obtained for pristine BP, poly(4VP), BP-g-4VP (32.4 g%), and BP-g-4VP (32.4 g%)@Ag. The native software was used to determine decomposition temperatures (TD) and residue.

3. Results and discussion

The modification of the BP and BP-g-4VP films consisted of a two-step process. First, the 4VP monomer was grafted onto the films, and then the Ag-modified film was loaded to obtain the final product BP-g-4VP@Ag. The results of these modifications and the evaluation of their antimicrobial activity in Kirby-Bauer tests are analyzed in detail in this section.

3.1. Results of 4VP grafting

Before the grafting process, the samples were washed to remove the MeOH-soluble impurities and retained water, as these factors can affect the polymerization with 4VP (Figure S1). The samples were then exposed to gamma radiation at a mean dose rate of 8.85 ± 0.10 kGy/h and absorbed doses of 10, 20, 30, 40, and 50 kGy, respectively, using the direct method. This method involves the simultaneous exposure of the monomer BP to gamma rays under inert atmosphere conditions, at room temperature, using 4VP/MeOH solutions of 10, 25, 50, and 75 vol%, as well as solvent-free 4VP at 100 vol% conditions. A total of five series of five experiments at different doses and monomer concentrations were conducted to determine the graft% to obtain an optimal BP-g-4VP, as illustrated in Figure 2. The results revealed that increasing the dose yielded higher graft degrees, especially at concentrations equal to or >50 vol%, even exceeding 100% of graft

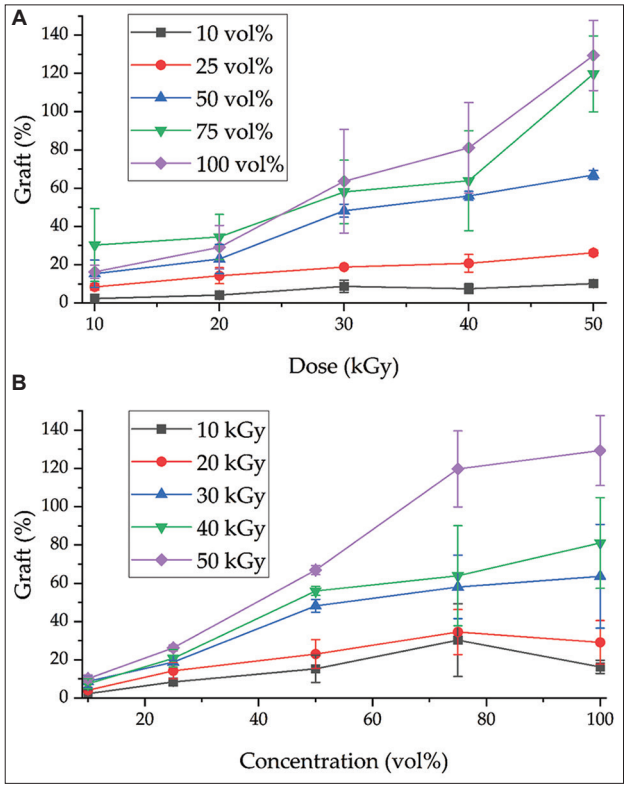

Figure 2. 4VP grafted onto BP under an inert atmosphere. Experiments were carried out in MeOH as a solvent and irradiated at room temperature. (A) Graft as a function of the dose and (B) as a function of the monomer concentration.

degrees. In addition, even a relatively low dose of 10 kGy was sufficient to achieve graft degrees exceeding 20%. For the intended purposes and in terms of reaction efficiency, low doses and concentrations are preferred. The aforementioned results showed that the grafted BP-g-4VP films exhibited superior hydrophilic properties compared to the pristine BP material, as further described in the section discussing swelling behavior.

3.2. FTIR-ATR analysis

Spectroscopic differences were first observed between unwashed BP (directly obtained from the supplier) and washed BP. In the washed BP, the signal of OH chemical groups between 3500 cm^{-1} and 3250 cm^{-1} weakened, which can be attributed to the elimination of additives and/or water, possibly a plasticizer (usually containing OH groups). Water is indeed a part of the structure (Figure S2A).

For this reason, all samples were washed before being grafted. In addition, as a reference, the poly(4VP) spectrum clearly differentiates the signals corresponding to the grafting process from those of BP. Although poly(4VP) had been dried in the oven at 60°C for 24 h, the analyzed sample displayed a strong signal at 3246 cm^{-1}, which corresponds

to the OH, likely attributed to absorbed moisture from the surroundings or strongly occluded water (Figure 3).

In the analyzed grafted samples, with low grafting at 6.2 g%, intermediate grafting at 32.4 g%, and high grafting at 92.4 g%, the intensity of the OH bands increased around 3394 cm^{-1}. This signal could originate from BP as well as water, with the latter suggesting that the modified materials are hydrophilic or even hygroscopic. Band assignments were further corroborated by the presence of an aromatic C-H band characteristic of poly(4VP) between 3200 cm^{-1} and 3000 cm^{-1}, aromatic overtones between 2500 cm^{-1} and 2000 cm^{-1}, and a band between 1750 cm^{-1} and 1500 cm^{-1} corresponding to C=C in the ring (Table 1). These doublet bands were congruent across all grafted samples, with the only difference being the intensity. Therefore, the presence of these two bands and overtones in all the spectra of grafted samples proved that the grafting was effectively carried out, involving the addition of the vinyl compound through double bond addition onto the starch-based polymer matrix.

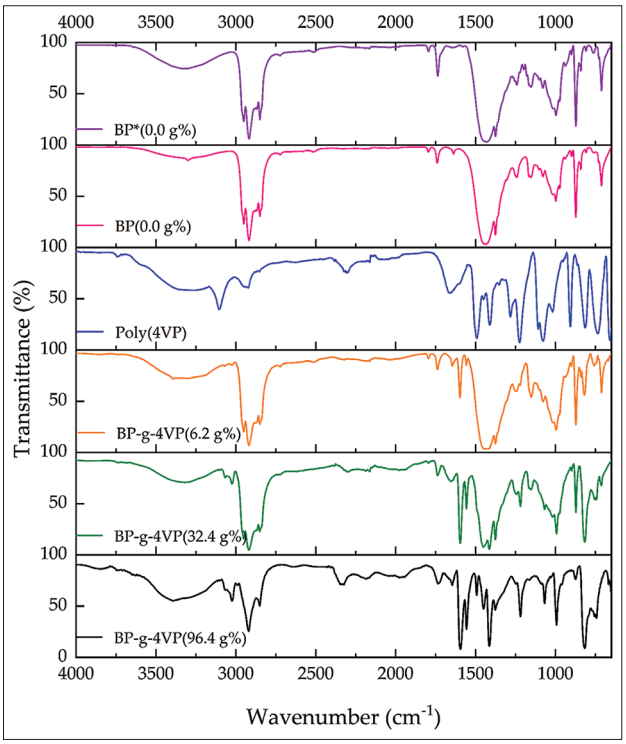

Figure 3. Fourier transmittance infrared spectra of pristine BP, poly(4VP), and BP-g-4VP. Note: BP* represents unwashed BP.

3.3. Contact angle and swelling tests

The contact angle of the water droplet was analyzed across different samples (Figure 4). The contact angles measured at different time points (0, 1, and 3 min) exhibited no significant variations, and only a subtle trend was observed based on the degree of grafting. Interestingly, the BP-g-4VP (7.9 and 11.1 g%) samples displayed higher wetting capabilities (contact angles of 88.2° and 81.8°, respectively) compared to the pristine BP (0 g%) film, which exhibited a higher contact angle of 100°, indicative of a hydrophobic surface (Huang *et al.*, 2022). While the wettability of BP-g-4VP (18.5 and 22.8 g%) samples remained similar to that of the original material, this characteristic can be attributed to conformational effects and polymer chains size, taking into account that poly(4VP) chains possess an aliphatic part. Furthermore, as the grafting degree increased, the surface exhibited greater hydrophilicity, ultimately reaching the smallest angle of 80.1°, corresponding to BP-g-4VP (65.7 g%).

Swelling of the pristine BP materials in water was minimal (<2.5 s%). This property is suitable for its intended use as a container for hot and cold drinks. The impermeability of the BP material is another good feature for container use; however, it limits its effectiveness in immobilizing organic or inorganic compounds. Therefore, there is a need to enhance its surface energy and hydrophilicity, as these properties are often interconnected (Çaykara *et al.*, 2020). In the swelling test, the films grafted with 4VP, ranging from 7.2 ± 0.9 to 64.9 ± 1.1 g%, exhibited swelling percentages at 24 h ranging from 5.9 ± 1.10% to 18.7 ± 2.1%, respectively. The maximum swelling was typically reached at around 4 h. The hydrophilic properties of these films varied from moderate to strong, with water retention capacity depending on the graft%, particularly for grafting percentages lower than 30 g%

Table 1. Assignment of FTIR representative bands, wavenumber units are cm^{-1}

Sample	OH st	CH st	Aromatic overtones	C=C	CH b
Pristine BP*	3338	2950, 2917, 2840	-	-	1453,1375
Pristine BP	3300	2950, 2917, 2850	-	-	1434, 1375
Poly (4VP)	3246	3106, 2941	2323, 2186, 2051	1659	1494, 1413
BP-g-4VP (6.2 g%)	3394	2950, 2918, 2850	2323, 2162, 2043	1597	1433, 1375
BP-g-4VP (32.4 g%)	3320	2950, 2918, 2850	2229, 2184, 2162	1596	1449, 1376
BP-g-4VP (96.4 g%)	3395	3024, 2919, 2851	2324, 2185, 2014	1595, 1556	1413, 1376

Notes: *In the unwashed BP, there is a band in the range 1738 – 1592 cm^{-1}, possibly from plasticizer. Notes: Stretching (st) and bending (b).

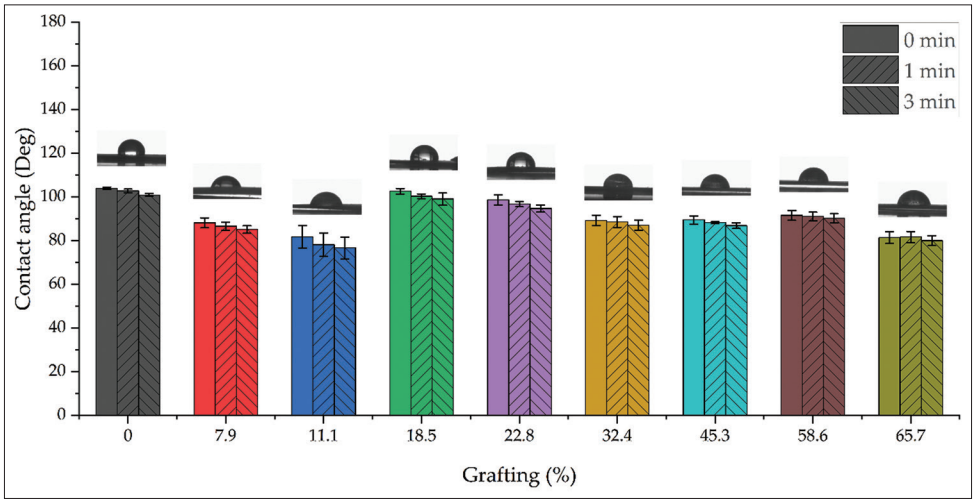

Figure 4. Contact angle by dropping water onto BP-g-4VP with different graft degrees.

(Figure 5). There were no significant variations in swelling for grafted films with grafting percentages exceeding 30 g%, with maximum swelling reaching around 17 wt%. This water uptake capability modulated the Ag loading capacity, as observed in the subsequent step. Higher swelling allowed the absorption of more Ag particles on the surface and within the grafted poly(4VP) chains.

Given that these grafted films will come into contact with water, the dimensions of the samples were measured to check for any potential increase in length, thickness, or volume. We found that the changes were negligible, approaching Δ0 mm. Therefore, despite their improved water absorption capacity, the grafted films retained their dimensions without any apparent changes, reaffirming that the grafting primarily occurred on the surface (Huang *et al.*, 2022).

Swelling tests were conducted at different pH levels to determine the critical pH, and the results are presented in Table 2. While the pristine BP (0.0 g%) exhibited consistent swelling behavior across all pH values, most of the grafted samples showed a transition from hydrophilic to hydrophobic behavior within the pH range of 6 – 8, with a calculated critical pH of 7.2 ± 0.7 (Figure 6). Significantly higher degrees of swelling were observed under acidic conditions. In general, it was observed that higher grafting percentages led to increased swelling, possibly due to the strong adhesion of salts (from the buffer solution) to the grafted surfaces. This phenomenon explains the observed difference in swelling behavior compared to pure water.

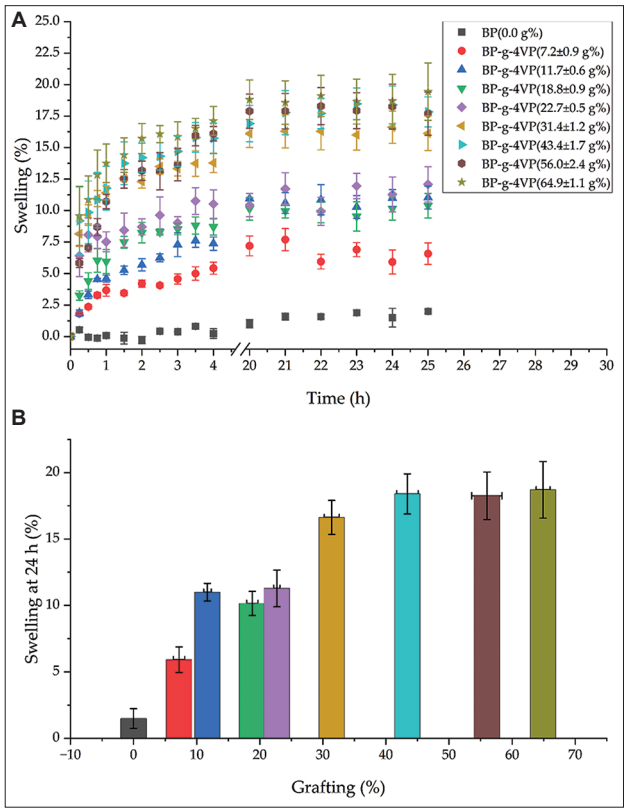

Figure 5. Swelling curves in water at room temperature testing samples of different grafting degrees (A) from 0 to 25 h and (B) at 24 h. It is observed that higher graft% produces higher limit s% until 17%, where the value is constant for samples BP-g-4VP (30 – 65 g%).

3.4. Silver loading

Functionalization with Ag was the second step in the modification process of BP. Both BP-g-4VP and pristine BP were loaded with Ag from $AgNO_3$ in a reaction conducted at room temperature, under sunlight, and in a neutral pH medium. These specific reaction conditions were selected. While the grafted samples exhibited higher swelling percentages at acidic conditions, Ag nucleation is favored only under alkaline conditions (Pacioni *et al.*, 2015). However, the samples (as verified in the swelling

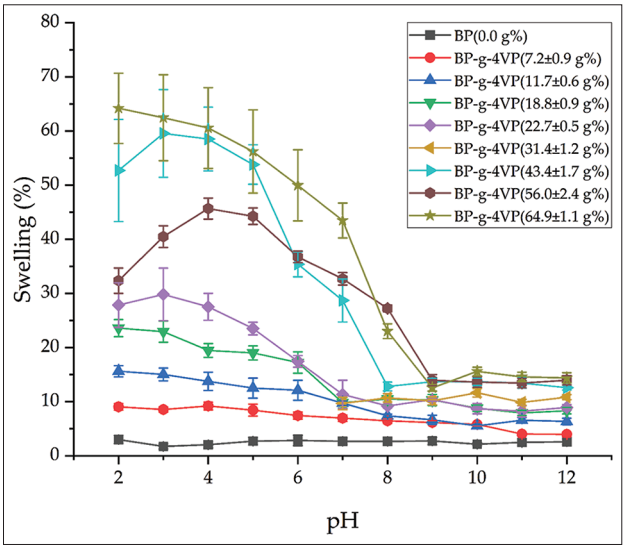

Figure 6. Swelling at different pH (the critical pH mean was 7.2 ± 0.7).

experiments at different pH) showed less swelling in the alkaline solution. Moreover, instead of a phosphate buffer medium, pure water was determined to be a more effective solution for promoting Ag nucleation. This choice prevents the adhesion of salts from the buffer. Furthermore, the antimicrobial analysis revealed differences between BP-g-4VP@Ag and BP@Ag, suggesting that grafting enhances the effectiveness of Ag immobilization.

3.5. Thermal analysis

TGA analysis revealed distinct decomposition temperatures (TD) for the BP polymer matrix (Table 3), while the poly(4VP) homopolymer exhibited a single TD at 407.2°C, with a small residue that tends to 0 wt% (Table 4). The multi-step thermal decomposition pattern in BP suggests its heterogeneous nature and highlights differences between its constituent parts, each contributing to the overall weight% of the mixture. First, there was approximately a 3% weight loss observed below 250°C, likely attributed to interactions between water and additives (Salaberria *et al.*, 2015). These interactions may involve water retained by plasticizers or structural water (See supplementary Figures S4 and S5). Subsequently, in the temperature range of 250 – 400°C, a weight loss of around 20% may correspond to low molecular weight or amorphous starch (Vega *et al.*, 1996). Moving into the 400 – 550°C range, the weight loss reached approximately 45%, precisely at 477.0°C. This TD can be attributed to aliphatic polyester, consistent with literature reports (Kong *et al.*, 2014). In the range of 550 – 750°C, a weight loss of approximately 10.5% occurred, primarily attributed to the degradation of char and inorganic ashes. This behavior aligns with the thermal characteristics of biodegradable

Table 2. The obtained critical pH points, including additional mathematical parameters from Boltzmann fitting

Sample	Critical pH	R^2	Chi-square
BP-g-4VP (7.2±0.9 g%)	11.0	0.95	1.10
BP-g-4VP (11.7±0.6 g%%)	6.8	0.97	1.06
BP-g-4VP (18.8±0.9 g%)	5.5	0.96	1.49
BP-g-4VP (22.7±0.5 g%)	5.8	0.95	1.96
BP-g-4VP (43.4±1.7 g%)	6.0	0.97	1.61
BP-g-4VP (56.0±2.4 g%)	8.0	0.95	7.39
BP-g-4VP (64.9±1.1 g%)	7.4	0.94	2.82

Table 3. Decomposition temperatures (TD) of BP, poly (4VP), BP-g-4VP, and VR-g-4VP@Ag

T (°C)	BP	Poly (4VP)	BP-g-4VP (31.6 g%)	BP-g-4VP (31.6 g%)@Ag
25 – 199	143.6	-	166.8	-
200 – 299	-	-	-	293.2
300 – 359	330.5	-	352.5	335.7
360 – 449	-	407.2	371.8	364.5
450 – 479	477.0	-	479.7	479.4
480 – 800	690.6	-	674.2	692.4

Table 4. Temperature at 10% loss in weight and residue at 800°C of the pristine BP, poly (4VP), BP-g-4VP (31.6 g%), and BP-g-4VP (31.6 g%)@Ag

Sample	Weight loss 10% (°C)	Residue at 800°C (weight%)
Pristine BP	317.8	19.9
Poly (4VP)	362.7	1.2
BP-g-4VP (31.6 g%)	327.3	7.2
BP-g-4VP (31.6 g%)@Ag	318.2	13.1

products derived from corn starch (Patnaik *et al.*, 2020). Finally, in the last stage, at 800°C, around 20% residue remained, primarily composed of inorganic compounds. The residue percentage for starch or polyester alone is typically lower. Inorganic compounds remained in the microbalance even at the maximum temperature studied.

The TDs of both the BP polymeric matrix and poly(4VP) are congruent with those observed in the thermogram of the modified material BP-g-4VP (31.6 g%), which exhibited five TDs. Notably, while these TDs are similar, they are not identical, indicating that grafting involves a chemical modification.

Finally, BP-g-4VP (31.6%)@Ag exhibited a decomposition thermogram that was not significantly different from that of pristine BP. The main differences in the material loaded

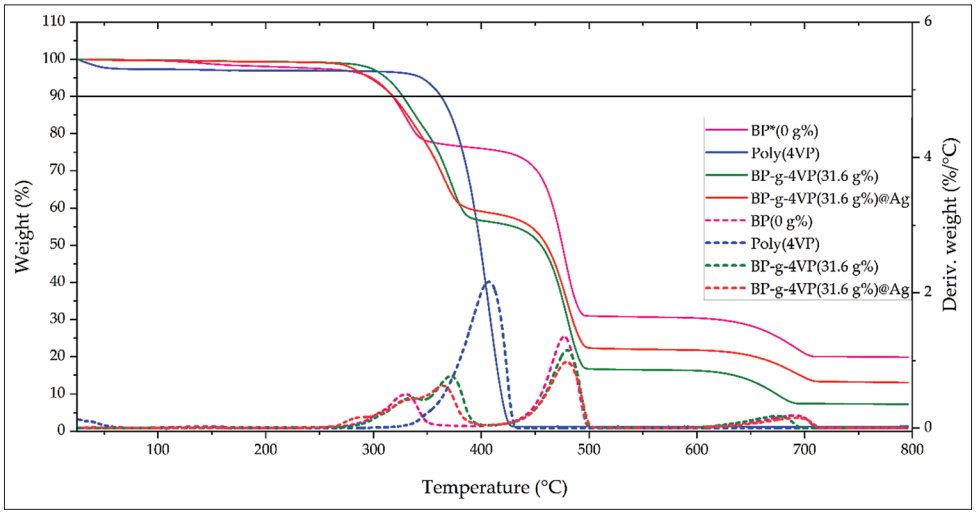

Figure 7. Thermogravimetric analysis thermograms of the samples. Experiments were run up to 800°C under a nitrogen atmosphere and at a heating rate of 10°C/min. The Y1 axis corresponds to the loss in weight, and the Y2 axis corresponds to the derivative of weight with respect to temperature (X-axis).

with Ag were a TD displacement from 166.8 to 293.2°C and a higher residue weight percentage, which is consistent and can be attributed to metal loading (Figure 7).

3.6. Antimicrobial tests

Kirby-Bauer tests were conducted to evaluate the antimicrobial properties of the tested materials. Two bacterial cultures, *S. aureus* (Gram-positive bacteria) and *P. aeruginosa* (Gram-negative bacteria), were used in these assays. *S. aureus* (Idrees *et al.*, 2021) has spherical morphology and aerobic metabolism (although it can survive in anaerobic conditions), and *P. aeruginosa* is straight-rod shaped with a mobile flagellum and has aerobic metabolism (Khan *et al.*, 2022). Differences among these bacteria become relevant since both Ag(0) nanoparticles and Ag^{1+} ions have exhibited antimicrobial properties against diverse pathogenic bacteria through different mechanisms (Prabhu & Poulose, 2012). In the case of the hybrid system BP-g-4Vp@Ag, the inhibitory effect of Ag against both cultures was verified.

Poly(4VP) chains alone can exhibit some bacteriostatic capacity (Tashiro, 2001), indicating that grafting enhances the antimicrobial effect. Notwithstanding, in this system, the poly(4VP) chains primarily served to enhance the Ag loading onto the surface. Controls without Ag did not exhibit any inhibition zones (Figure 8B and D), while samples from the grafted system BP-g-4Vp@Ag (Figure 8C) showed greater inhibition, with zones measuring 11.9 ± 0.16 mm for *S. aureus* and 9.8 ± 0.07 mm for *P. aeruginosa*. This qualitative confirmation demonstrates the Ag-loaded material's functionality as a broad-spectrum antimicrobial. In addition, it is highlighted that BP@Ag (Figure 8A) also displayed significant activity against *S. aureus*

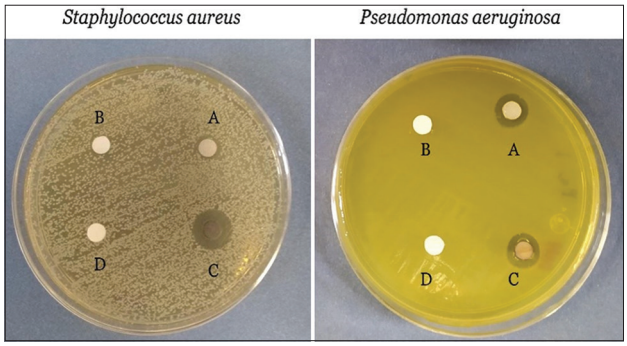

Figure 8. Bacterial cultures with the samples loaded with Ag ([A] BP@Ag, [C] BP-g-4VP@Ag) and the controls without Ag ([B] BP and [D] BP-g-4VP).

(9.8 ± 0.07 mm) and *P. aeruginosa* (7.7 ± 0.38 mm). This result corresponds to the TGA characterization, indicating that the pristine BP can load Ag on its surface thanks to the organic groups from starch. However, for our specific purposes, grafting played a fundamental role in enhancing Ag loading, as suggested by the analysis.

4. Conclusion

In this study, radiation-induced grafting using a biodegradable starch-based matrix was proven to be effective. Grafting with 4VP chains improved hydrophilicity, enhancing its affinity in an aqueous medium and facilitating Ag loading. Furthermore, while the thermal stability of BP-g-4VP@Ag was improved, this may not be a significant factor for applications at room temperature. The resulting product, BP-g-4VP@Ag, exhibited a strong antimicrobial activity, effectively inhibiting both *S. aureus* and *P. aeruginosa*. This demonstrates the creation of a hybrid material, partially biodegradable, with the potential for use in systems that

require a pathogen-free medium, a highly desirable trait in eco-friendly materials intended for sanitary disposables.

While this study is limited to the construction of the hybrid material BP-g-4VP@Ag, which is only partially biodegradable, it presents a more environmentally friendly alternative to antimicrobial materials made from non-biodegradable plastics. This reduction in environmental impact underscores the importance of every small contribution in addressing the widespread problem of plastic pollution worldwide.

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Conflict of interest

The authors declare no conflict of interest.

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Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data

Data can be obtained from the corresponding author following a formal request.

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ORIGINAL RESEARCH ARTICLE

Stochastic modeling of age at menopause for Nepalese women and development of menopausal life table

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Abstract

Menopause, which connotes the end of a woman's fertility, is a key turning point in her reproductive life. Women's age at which menopause occurs is affected by several biological, social, as well as economic factors. The previous studies on age at menopause mainly concerned with describing the status, differential, determination, and consequence of it on women's health. Stochastic analysis of distributional patterns of the age at menopause has been paid little attention by researchers. Therefore, probability distributions are applied to analyze the timing of menopause stochastically. The results of the fitted model are used to construct the menopausal life table. The main aim of this research was to identify an efficient probability distribution to explain the age at menopause in Nepalese women. This involved identifying the model that best fits the data, determining the characteristics of age at menopause described by the model, and constructing a menopausal life table to compute the waiting time of menopause for women. Further, the probability of having menopause and not having menopause at a particular age was presented. To achieve these objectives, secondary data sets were used to fit probability models, and a range of statistical tools were employed to test and validate the model fitting. The results showed that the logistic distribution better captured the menopausal information of Nepalese women and can be applied to formulate the menopausal life table. Further, out of several parameter models used, the Rayleigh-generated log-logistic model better fitted the data so it was considered to construct a menopausal life table. This study provided a distributional pattern of the current and future menopausal timing of Nepalese women. Furthermore, it provided insights into the factors that influence this important milestone in women's reproductive life. These findings could be helpful to medical personnel who are dealing with the consequences of menopause and post-menopause, policymakers who aim to improve women's health, and researchers who are working in this field.

Keywords: Menopause; Logistic; Log-logistic; Menopausal life table; Nepal

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1. Introduction

In a woman's reproductive lifetime, menopause is an inevitable phenomenon that indicates the end of menstruation. A woman is normally diagnosed with menopause if she has gone without a monthly cycle for 12 consecutive months. From a biological perspective, a

woman's lifespan is typically categorized into the following phases: infancy; puberty (adolescence); sexual maturation (reproductive age); climacteric period; and post-climacteric years (Takeda, 2010). Two events, the starting and the termination of natural menstruations, also known as menarche and menopause, are considered milestones in women's reproductive life as they are markers of the starting and the ending of women's reproductive life. The term "menopause" was first introduced by French physician Gordanne in 1821 and was reported on the trends in the age at menopause by researchers since Sanes's research work (Sanes, 1918). According to the World Health Organization's fact sheet on menopause, the majority of women go through menopause as a result of natural aging around the age of 45 – 55 (WHO, 2022). Researchers around the globe have focused on describing the status and determinants of menopause, yet mathematical modeling of menopausal timing has not been explicitly explained. In this article, a stochastic analysis of age at menopause was performed. Mathematical and probabilistic analysis of age at menopause helps to predict the current and future scenario.

Different factors contribute to the timing of menopause in women. Gold *et al.* (2001) identified the factors for the timing of menopause, namely, genetics; living factors like body weight, smoking, prior use of oral contraceptives, and alcohol consumption; environmental factors like exposure to certain chemicals or pollutants; medical conditions; and race/ethnicity. This study focused on describing the distributional pattern of the age at menopause, and some probability distributions were used to model the data. The logistic and Rayleigh-generated log-logistic (RGLLog) distributions were found to be appropriate to describe the age at menopause of Nepalese women.

2. Age at menopause of women

The age at menopause of women is a pivotal stage of women's reproductive life which is a marker of aging as well as the health status of women. Research on the analysis of menopause around the globe is confined primarily to determining the average age at menopause. Jaszmann (1976) showed that the average age at menopause for the Netherlands women was 51.4 years with a variability of 3.8 years. He found that the timing of menopause is not associated with environmental factors, education, physical type, age at menarche, and pregnancy outcomes. Similarly, the average age at menopause reported by the World Health Organization was 51 years for industrialized countries in the 1990s (WHO, 1996). Greer *et al.* (2003) estimated the average and median age at menopause for Saudi Arabian women were 48.94 and 50 years, respectively. Furthermore, Priya *et al.* (2009) found an average age at menopause of 46.04 years among Kshatriya females in India. Palacios *et al.* (2010) determined that age at menopause was significantly different for women who were married and never married. The mean age at menopause for 2200 US respondents who had experienced natural menopause is found to be 50.5 to 51.4 years, it was 43.8 to 53 years for European and Latin American women as well as 42.1 to 49.5 years for Asian women. They claimed that the natural menopausal age was affected by their lifestyle, reproductive behavior, and genetic factors.

A similar pattern of mean age at menopause has been found in the case of Nepalese women. A cross-sectional survey of two rural districts of Nepal by Aryal & Yadava (2005) estimated that the median menopausal age was 47 years using the life table technique and 46 years using data computation. They also estimated that different ethnicities and working females have slightly higher ages at menopause than non-working females. Another sample survey by Rajbhandari *et al.* (2013) found that the mean menopausal age was 47 years with a standard deviation of 5 years; furthermore, the data were differentiated for different ethnicities and it was reported that the Gurung community women had the highest menopausal age of 50 years whereas the Bahun/Chhetri community's women had the lowest menopausal age of 44 years. Another descriptive study conducted in the Kapilvastu district of Nepal found that the average and median age at menopause were 46.3 and 47 years, respectively (Ghimire *et al.,* 2015).

Apart from the status and differentials of menopause, some researchers studied to find the associated factors of age at menopause. Gupta *et al.* (2016) identified that menopausal symptoms were common among rural women visiting Nepal's district hospital. Khadka *et al.* (2018) established among post-climacteric females having osteoporosis, the year since menopause is positively correlated with body mass index, inorganic phosphorus, and alkaline phosphatase, but negatively correlated with the levels of calcium and vitamin D.

Around the globe, the mathematical modeling of demographic variables has given considerable effort by researchers, but it is less in Asian countries (Gaire & Aryal, 2015). One of the primary demographic indicators, along with migration and death, is fertility, which is directly affected by the age at menarche and menopause. Krailo & Pike (1983) found that the logistic distribution best fitted for American women's menopausal age. Greer *et al.* (2003) described the distribution of menopausal age using the quadruple-Gaussian curve. Jaszmann (1976) showed that the age at menopause for Netherlands women is approximately normally distributed. Boldsen & Jeune (1990) analyzed the timing of menopause using the Probit method and expressed the distribution in the Probit diagrams depicting frequency distribution similarly to a normal distribution. Aryal & Yadava (2005) forwarded the concept of fitting probability distribution to explain the timing

of menopause using data from Nepalese women. Among several distributions, they used the type-I extreme value model to describe the distribution of the menopausal timing of Nepalese women. By observing the right skew nature of data, normal, Weibull, logistic, and log-logistic distributions have been used in this paper to describe the distributional pattern of Nepali women. Logistic distribution was found to better capture the distributional pattern in this study. Furthermore, a new four-parameter RGLLog distribution was tested for the goodness of fit. This distribution was applied since it has four parameters and the result may create a more realistic menopause prediction pattern.

3. Methods and models

In this article, we used quantitative data on the menopausal age of Nepalese women to analyze the distributional pattern stochastically so the ontological position of this research was objectivism. We tried to establish the probabilistic relationship between the age of women at menopause as the independent variable and the probability of menopause at a specific age as the dependent variable. Hence, the epistemological position of this research was positivism.

3.1. Data

To analyze the age at menopause, two secondary data sets were taken. The first one was from the cross-sectional survey entitled "Demographic Survey on Fertility and Mobility" conducted in two rural districts of Nepal taken from Aryal & Yadava (2005). The sample survey consisted of 811 households comprised of a sample of 1019 married females and 114 reached menopause. The second data set was taken from Koirala & Manandhar (2018) where they collected data about the menopausal age from 154 women from the 240 respondents aged 45–60 who visited the district hospital.

3.2. Probability distribution models

To model the age at menopause of Nepalese women, different probability distributions have been applied. The mathematical expressions of the models used to fit the distributional pattern of age at menopause of Nepalese women were expressed in the following subsections.

3.2.1. Logistic probability distribution

If x represents the age at menopause of women, then the probability density function (PDF) and cumulative distribution function (CDF) that follow a logistic distribution were given as:

$$f_1(x) = \frac{e^{-\left(\frac{x-\gamma}{\beta}\right)}}{\beta\left(1+e^{-\left(\frac{x-\gamma}{\beta}\right)}\right)^2} \tag{1}$$

$$F_1(x) = \frac{1}{1+e^{-\left(\frac{x-\gamma}{\beta}\right)}} \tag{2}$$

Where $\gamma > 0$ is any arbitrary threshold parameter and $\beta > 0$ represents the scale factor of the model. The mean and variance of the distribution were computed using the relation as γ and $\frac{\beta^2\pi^2}{3}$, respectively (Johnson *et al.,* 1995).

3.2.2. Log-logistic distribution

If x denotes the age at menopause of women, the PDF and the CDF that follow the log-logistic (LLog) distribution with three parameters were given as:

$$f_2(x) = \frac{\frac{\alpha}{\beta}\left(\frac{x-\gamma}{\beta}\right)^{\alpha-1}}{\left(1+\left(\frac{x-\gamma}{\beta}\right)^{\alpha}\right)^2}, \text{for } x > \gamma \tag{3}$$

$$F_2(x) = \frac{\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}{\left(1+\left(\frac{x-\gamma}{\beta}\right)^{\alpha}\right)}, \text{ for } x > \gamma \tag{4}$$

Where $\alpha, \beta > 0$ represent the shape and scale of the distribution. When the shape parameter α is greater than one, the LLog distribution is a uni-model. The basic properties of the LLog distribution were found in the previous studies (Kleiber & Kotz, 2003; Lawless, 2003; Ashkar and Mahdi, 2006). The k^{th} order moments were derived by Tadikamalla (1980) for $k < \alpha$ and the moment had been derived and expressed as:

$$E\left(X^k\right) = \gamma + \frac{k\pi\beta^k}{\alpha\sin\frac{k\pi}{\alpha}} \tag{5}$$

In particular, the mean of the LLog distribution is $\gamma + \frac{\pi\beta}{\alpha\sin\frac{\pi}{\alpha}}$ for $\alpha > 1$ and the variance is $\frac{2\pi\beta^2}{\alpha\sin\frac{2\pi}{\alpha}} - \left(\frac{\pi\beta}{\alpha\sin\frac{\pi}{\alpha}}\right)^2$ for $\alpha > 2$.

3.2.3. Weibull distribution

The PDF and CDF of the two-parameter Weibull distribution were expressed in the following equations:

$$f_3(x)=\frac{\alpha}{\beta}\left(\frac{x}{\beta}\right)^{\alpha-1}\exp\left(-\left(\frac{x}{\beta}\right)^{\alpha}\right),\ \text{for}\ x>0 \tag{6}$$

$$F_3(x)=1-\exp\left(-\left(\frac{x}{\beta}\right)^{\alpha}\right),\ \text{for}\ x>0 \tag{7}$$

Where $\alpha, \beta > 0$, and this constant is used to determine the appearance or shape of the distribution, and $\beta > 0$ is the scale parameter of the Weibull distribution. The mean of the distribution at the point $x=\beta\Gamma\left(1+\frac{1}{\alpha}\right)$, the median of the distribution at the point $x=\beta(\log 2)^{\frac{1}{\alpha}}$, and the mode at the point $x=\begin{cases}\beta\left(\frac{\alpha-1}{\alpha}\right)^{\frac{1}{\alpha}}, \text{for}\ \alpha>1\\ 0\ \text{for}\ 0<\alpha\le 1\end{cases}$.

3.2.4. Normal distribution

The PDF and CDF of a normal distribution with mean γ and the standard deviation β were expressed as:

$$f_4(x)=\frac{1}{\beta\sqrt{2\pi}}\exp\left(-\left(\frac{x-\gamma}{\beta}\right)^{2}\right) \tag{8}$$

$$F_4(x)=f\left(\frac{x-\gamma}{\beta}\right) \tag{9}$$

3.2.5. Several parameter distributions

For comparison of the result of menopausal age distribution fitting, we chose the following three generalized versions of the LLog distribution, such as the CDF of Rayleigh-generated log-logistic (RGLLog) distribution introduced and studied by Gaire & Gurung (2023) in equation (10); the CDF of Kumaraswamy LLog (KuLLog) distribution introduced by De Santana *et al.* (2012) in equation (11); and the CDF of transmuted LLog (TrLLog) distribution proposed by Aryal (2013) in equation (12).

$$F_5(x)=1-\exp\left\{-\theta\left(\frac{\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}{1+\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}\right)^{2}\right\} \tag{10}$$

$$F_6(x)=1-\left[1-\left\{\frac{\left(\frac{x}{\beta}\right)^{\alpha}}{1+\left(\frac{x}{\beta}\right)^{\alpha}}\right\}^{\lambda}\right]^{\theta} \tag{11}$$

$$F_6(x)=(1+\lambda)\left\{\frac{\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}{1+\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}\right\}-\lambda\left\{\frac{\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}{1+\left(\frac{x-\gamma}{\beta}\right)^{\alpha}}\right\}^{2} \tag{12}$$

3.3. Model validation tools

To confirm the validity as well as the suitability of used models for the Nepalese women's menopausal age distribution fitting, the negative log-likelihood (NLL) value of the probability distribution, Akaike information criterion (AIC), Bayesian information criterion (BIC), and Chi-squared test statistics were applied. To fit the model, a simulation was performed to estimate the parameters of the model.

The formulae of the AIC and BIC for the fitted models were given as:

$$AIC=2\nu-2LL \tag{13}$$

$$BIC=\nu\,Ln(n)-2LL \tag{14}$$

Where ν represents parameters associated with the probability model, n is the number of observations, and LL is the log-likelihood function at the maximum likelihood estimate of the distribution.

3.4. Construction of menopausal life table

Here, the observed distributional pattern of menopause was a skewed curve and deviated from the normality. Hence, the logistic model was proposed and used to describe the distributional pattern of age at menopause of Nepalese women. The menopausal life table was constructed using the results of probabilistic model fitting. In this section, the empirical results of probability models used to fit the distributional pattern of age at menopause were used to construct the menopausal life table. All the procedures were adopted from the concept of an actuarial life table. It is assumed that menopause is a universal event and every woman has to go through it in life; hence, the number of women who got menopause at a certain age is considered as death cases in the actuarial life table. From the fitted result of the logistic distribution, the proportion of women not reaching menopause in a specified age or age group is

considered as the proportion of survival. The following procedures were used to construct the menopausal life table.

Thus, from the fitted results of the logistic and RGLLog models, it was assumed that F_x is the empirical result of the proportion of women having menopause at age x year or less and $S_x = 1-F_x$ is the survived proportion or not reached menopause at age x. From the concept of the actuarial life table technique, let l_0 be the cohort of women, followed by the number of women not having menopause at age x (l_x) using the equation $l_x = l_x S_x$. The probability of reaching menopause from age x to x+1 year (q_x) was computed as:

$$q_x = \frac{F_{x+1} - F_x}{1 - F_x} \quad (15)$$

Other symbols such as L_x is the total number of women-years having menopause by the cohort at age x, T_x is the total number of women-years having menopause by the cohort above age x, and e_x is the mean expected age of menopause at age x were calculated using the following formula as in the actuarial life table:

$$L_x = \frac{k(l_x + l_{x+k})}{2}, T_x = \sum_{x}^{n} L_X + L_{X+1} + \ldots + L_{X+n} \quad (16)$$

Where k is the number of years between years n to n+k.

$$T_{x+1} = T_x - L_x, \text{ and } e_x = \frac{T_x}{l_x} \quad (17)$$

4. Results and discussion

The distributional pattern of age at menopause of Nepalese women was fitted using the four probability models and the fitted results along with different test statistics results are presented in Table 1 for the first data set and Table 2 for the second data set. The logistic distribution was significantly better fitted with the menopause data as compared to other distributions. The observed value of *AIC*, *BIC*, *SSQ*, and χ^2 were found as the lowest for logistic distribution, and the result of *NLL* was found as the highest for logistic distribution as compared to other distributions used in this research.

The graphical representation between the observed and expected frequencies of women at the age of menopause is shown in Figure 1. From the analysis and graphical presentation, the logistic distribution was found to be a good fit so it was recommended to use this distribution for describing the age pattern of women at menopause.

After fitting the logistic distribution, the fitted value of cumulative distribution was used to compute the other components of the menopausal life table which are shown in Table 3. From the analysis, the expected age of menopause at the birth of girls was estimated as 45.511 years. However, the expected age of menopause was considered when girls have menarche. If the average age of menarche was considered as 15 years then the expected age of menopause was after 30.507 years of menarche.

If the woman was 30 years old, the expected age of menopause was estimated as after 15.565 years. The probability of having menopause when the age of women was 35 years is 0.018 (1.8%) whereas when the age of women was 45 years the chances of having menopause is 0.484 (48.4%).

Several parameter probability distributions were also computed to better predict the waiting time for menopause and the probability of having menopause at a particular age (Table 4).

Table 1. Observed and expected value of the number of women by different distributions (2005)

Age group	Observed	Expected number of women by			
		Normal	Weibull	LLog	Logistic
Below 35	1	0.256	2.358	0.476	0.411
35–37	2	0.943	2.614	1.002	1.995
37–39	5	3.147	4.988	2.776	3.294
39–41	7	7.940	8.898	6.894	7.279
41–43	11	15.157	14.504	14.384	14.240
43–45	24	21.887	20.743	22.760	22.217
45–47	25	23.911	24.321	24.951	24.832
47–49	18	19.763	20.983	18.974	19.240
49–51	10	12.358	11.308	11.065	11.101
51–53	6	5.846	2.998	5.595	5.347
53–55	5	2.793	0.284	5.123	4.043
α		-	13.638	20.562	-
β		3.742	46.478	45.679	2.241
γ		45.634	-	0.000	45.598
χ^2		2.601	5.811	2.379	1.661
NLL		−43.027	−41.016	−40.989	−39.086
AIC		90.054	86.033	85.977	82.172
BIC		90.849	86.829	86.773	82.968

Table 2. Descriptive statistics of age at menopause data of 2018 according to their occupation

Occupation of respondents	Mean	No. of women	Standard deviation
Service	49.667	6	0.516
Business	50.667	12	1.969
Agriculture	49.968	31	2.273
Housemaker	49.653	98	1.663
Others	49.000	7	0.817
Total	49.766	154	1.785

Table 3. Menopausal life table using logistic distribution (2005)

Age group	F_x	S_x	l_x	q_x	L_x	T_x	e_x
Below 35	0.004	1.000	100,000.000	0.018	3,493,692.000	4,551,085.000	45.511
35–37	0.021	0.996	99,639.570	0.030	197,529.300	1,057,393.000	10.612
37–39	0.050	0.979	97,889.690	0.067	192,890.000	859,863.700	8.784
39–41	0.114	0.950	95,000.300	0.141	183,615.200	666,973.700	7.021
41–43	0.239	0.886	88,614.940	0.256	164,739.000	483,358.400	5.455
43–45	0.434	0.761	76,124.080	0.385	132,759.500	318,619.400	4.186
45–47	0.651	0.566	56,635.380	0.484	91,488.200	185,860.000	3.282
47–49	0.820	0.349	34,852.830	0.542	52,828.170	94,371.750	2.708
49–51	0.918	0.180	17,975.340	0.569	26,212.710	41,543.580	2.311
51–53	0.965	0.082	8,237.374	0.582	11,784.120	15,330.870	1.861
53–55	0.985	0.035	3,546.746	–	3,546.746	3,546.746	1.000

Table 4. Observed and expected value of the number of women by several parameter distributions (2005)

Age group	Observed	Expected number of women by		
		TrLLog	KuLLog	RGLLog
Below 35	1	0.578	1.621	0.236
35–37	2	1.124	1.577	0.685
37–39	5	2.957	3.006	2.264
39–41	7	7.017	5.863	6.316
41–43	11	14.192	12.050	13.918
43–45	24	22.271	22.791	22.298
45–47	25	24.678	25.351	24.447
47–49	18	18.985	16.951	18.590
49–51	10	11.123	9.908	10.827
51–53	6	5.663	5.783	5.536
53–55	5	2.749	3.435	2.772
α		19.596	49.378	12.701
β		46.600	44.772	46.938
γ		0.000	-	0.000
λ		0.3907	0.240	-
θ		-	0.259	3.760
NLL		−45.790	−113.210	−42.151
AIC		99.580	234.421	92.303
BIC		101.172	236.013	93.895

Similarly, the graphical representation between the observed and expected frequencies of women at the age of menopause (2005) data is shown in Figure 2. From the analysis and graphical presentation, the RGLLog distribution is found to be a good fit so it is recommended to use this distribution for describing the age pattern of women at menopausal data of 2005.

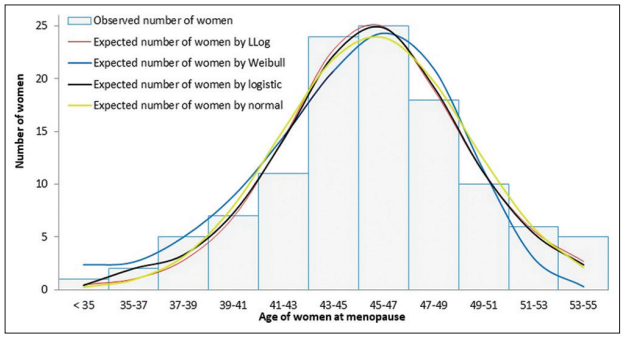

Figure 1. Observed and expected value of the number of women for age at menopause (2005).

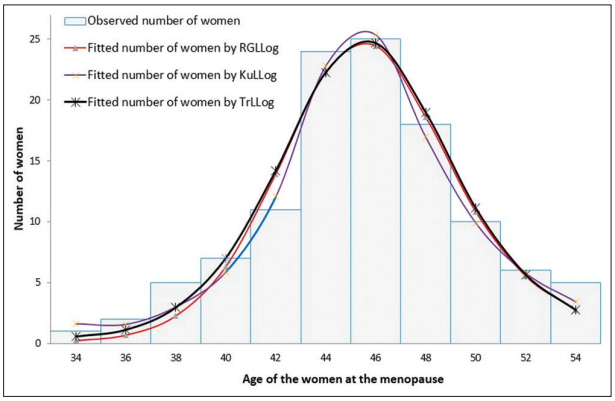

Figure 2. Observed and expected value of the number of women for age at menopause by several parameter distributions (2005).

Similarly, after fitting the RGLLog distribution, the fitted value of cumulative distribution was used to compute the other components of the menopausal life table which are shown in Table 5. From the analysis, the expected age of menopause at the birth of girls was estimated as 46.131 years. However, the expected age of menopause was

considered when girls have menarche. If the average age of menarche is considered as 15 years then the expected age of menopause is after 31.146 years of menarche.

Another data set of Nepalese women's age at menopause was taken from Koirala & Manandhar (2018) and the fitted results were compared with the results of 2005 data. Table 2 shows the descriptive measures of the second data set.

The box plots for age at menopause of Nepalese women and for different occupations are shown in Figure 3.

The test statistics one-way analysis of variance (ANOVA) was performed to test the hypothesis of whether the mean age at menopause had a significant difference for the different occupations, and it was found to be not significantly different with *P*-value of 0.274 (Table 6).

Table 7 presents the distribution-fitted result and the empirical data of age at menopause for the 2018 data.

Furthermore, Figure 4 presents the graphical representation between the observed and expected frequencies of women at the age of menopause from 2018 data. From the analysis and graphical presentation, the logistic distribution was found to be a good fit so it was recommended to use this distribution, calculate the waiting time for menopause, and describe the age pattern of women at menopause.

Moreover, after fitting the logistic distribution, the fitted value of cumulative distribution was used to compute the other components of the menopausal life table for 2018 data which is shown in Table 8. From the analysis, the expected age of menopause at the birth of girls was estimated as 49.135 years. However, the expected age of menopause was considered when girls have menarche. If the average age of menarche was considered as 15 years, then the expected age of menopause was after 34.973 years of menarche.

To better predict the waiting time for menopause and the probability of having menopause at particular years, four-parameter probability distributions were used to fit the age data of menopause for 2018 data and the results are shown in Table 9.

Table 5. Menopausal life table using RGLLog distribution (2005)

Age group	F_x	S_x	l_x	q_x	L_x	T_x	e_x
Below 35	0.002	1.000	100,000.000	0.006	3,496,374.000	4,613,075.000	46.131
35–37	0.008	0.998	99,792.810	0.020	198,984.800	1,116,701.000	11.190
37–39	0.028	0.992	99,191.960	0.057	196,397.800	917,715.800	9.252
39–41	0.083	0.972	97,205.850	0.133	188,871.300	721,318.000	7.421
41–43	0.205	0.917	91,665.500	0.246	171,122.000	532,446.600	5.809
43–45	0.401	0.795	79,456.460	0.358	139,353.60	361,324.700	4.547
45–47	0.615	0.599	59,897.100	0.424	98,349.220	221,971.100	3.706
47–49	0.779	0.385	38,452.130	0.429	60,597.060	123,621.900	3.215
49–51	0.874	0.221	22,144.930	0.384	34,792.770	63,024.830	2.846
51–53	0.922	0.126	12,647.830	0.312	20,439.950	28,232.070	2.232
53–55	0.946	0.078	7,792.116	-	7,792.116	7,792.116	1.000

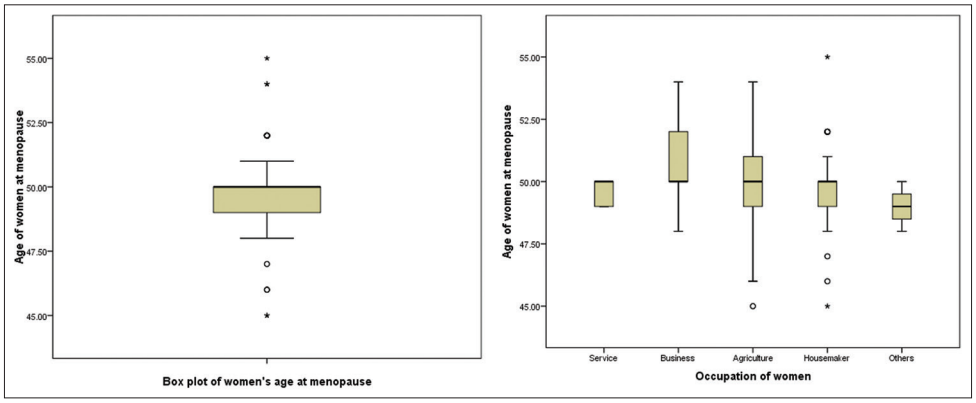

Figure 3. Box plots of age at menopause of women and for different occupations for 2018 data.

Table 6. One-way analysis of variance between occupations for age at menopause

	Sum of squares	df	Mean square	F	Sig.
Between groups	16.413	4	4.103	1.298	0.274
Within groups	471.172	149	3.162		
Total	487.584	153			

Table 7. Observed and expected value of the number of women by different distributions (2018)

Age group	Observed	Expected number of women by			
		Normal	Weibull	LLog	Logistic
45–47	8	0.411	3.708	0.046	1.660
47–49	21	26.131	26.281	24.182	25.684
49–51	95	98.959	97.613	97.299	97.481
51–53	23	28.023	26.399	26.967	27.380
53–55	5	0.476	0.000	4.211	1.703
55–57	2	0.000	0.000	0.894	0.087
α		-	52.423	5.870	-
β		50.026	50.451	3.994	0.670
γ		1.086	-	45.999	50.027
χ^2		0.465	0.594	1.128	0.187
NLL		−29.955	−275.530	−50.646	−26.028
AIC		63.910	555.059	105.292	56.056
BIC		64.706	554.643	104.876	55.639

Furthermore, the graphical representation between the observed and expected frequencies of women at the age of menopause for 2018 data is presented in Figure 5. From the analysis and graphical presentation, the RGLLog distribution is found to be a good fit so it is recommended to use this distribution for describing the age pattern of women at menopausal data of 2018.

In addition, after fitting the RGLLog distribution, the fitted value of cumulative distribution was used to compute the other components of the menopausal life table for 2018 data sets which are shown in Table 10. From the analysis, the expected age of menopause at the birth of girls was estimated as 51.179 years. However, the expected age of menopause was considered when girls have menarche. If the average age

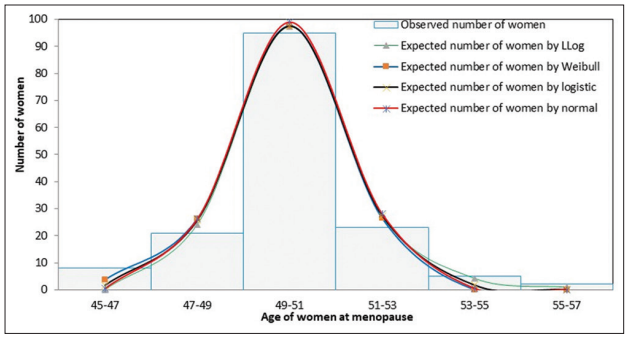

Figure 4. Observed and expected value of the number of women for age at menopause (2018).

Table 8. Menopausal life table using logistic distribution (2018)

Age group	F_x	S_x	l_x	q_x	L_x	T_x	e_x
45	0.112	1.000	100,000.000	0.035	4,248,589.600	4,913,514.632	49.135
46	0.143	0.888	88,826.200	0.045	87,249.562	688,147.260	7.747
47	0.182	0.857	85,672.900	0.057	83,742.444	619,446.719	7.230
48	0.228	0.818	81,812.000	0.070	79,499.784	550,339.273	6.727
49	0.282	0.772	77,187.600	0.085	74,490.221	482,268.996	6.248
50	0.343	0.718	71,792.800	0.102	68,741.128	412,776.322	5.750
51	0.410	0.657	65,689.400	0.119	62,354.296	344,035.194	5.237
52	0.480	0.590	59,019.200	0.137	55,509.470	281,680.898	4.773
53	0.551	0.520	51,999.800	0.154	48,450.121	226,171.428	4.349
54	0.620	0.449	44,900.500	0.170	41,451.780	177,721.307	3.958
55	0.684	0.380	38,003.100	0.184	34,780.716	136,269.527	3.586
56	0.742	0.316	31,558.400	0.197	28,655.466	101,488.811	3.216
57	0.793	0.258	25,752.600	0.207	23,222.272	72,833.345	2.828
58	0.836	0.207	20,692.000	0.216	18,549.022	49,611.073	2.398
59	0.871	0.164	16,406.100	0.223	14,634.998	31,062.051	1.893
60	0.900	0.129	12,863.900	0.229	11,429.507	16,427.054	1.277
61	0.923	0.100	9,995.090	-	4,997.547	4,997.547	0.500

of menarche was considered as 15 years, then the expected age of menopause was after 36.480 years of menarche.

The waiting time of menopause, when girls get menarche at the age of 15 years, was found to be 30.507 years by logistic distribution and 31.146 by the RGLLog distribution for 2005 data. Similar figures for 2018 data were found as 34.973 years by logistic distribution and 36.480 years by the RGLLog distribution. The probability of having menopause at a particular age was given by fitting probability distribution which was presented in the second column of the menopausal life table. The information about the waiting time for menopause, the probability of surviving or not having menopause at any particular year, and the probability of having menopause at any particular year provided the expected number of pre- and post-menopausal women, which may be helpful to the health personnel and policymakers to make appropriate planning about the health facility and other policies.

Table 9. Observed and expected value of the number of women by several parameter distributions (2018)

Age group	Observed	Expected number of women by		
		TrLLog	KuLLog	RGLLog
45–47	8	0.831	0.549	0.013
47–49	21	25.236	26.211	21.057
49–51	95	97.395	98.753	94.905
51–53	23	27.329	28.010	23.269
53–55	5	2.761	0.476	4.097
55–57	2	0.366	0.001	1.129
α		12.995	17.222	4.436
β		9.673	44.635	4.445
γ		40.740	-	45.630
χ^2		0.550	24.597	-
θ		-	17.009	2.869
NLL		−67.542	−39.554	−34.742
AIC		143.083	87.107	77.484
BIC		141.521	86.274	76.651

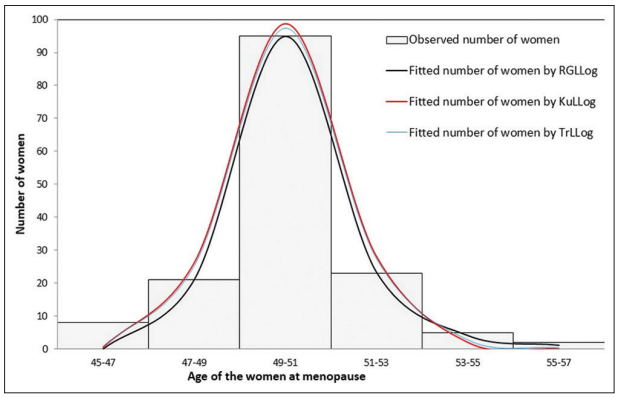

Figure 5. Observed and expected value of the number of women for age at menopause by several parameter distributions (2018).

Table 10. Menopausal life table using the RGLLog distribution (2018)

Age group	F_x	S_x	l_x	q_x	L_x	T_x	e_x
45	0.041	1.000	100,000.00	0.041	4,406,939.000	5,117,934.000	51.179
46	0.081	0.959	95,863.97	0.055	93,896.390	741,362.500	7.733
47	0.131	0.919	91,928.80	0.068	89,411.720	673,769.100	7.329
48	0.190	0.869	86,894.64	0.079	83,961.180	607,072.400	6.986
49	0.254	0.810	81,027.73	0.090	77,821.970	542,682.500	6.697
50	0.321	0.746	74,616.22	0.099	71,276.100	473,913.500	6.351
51	0.388	0.679	67,935.99	0.107	64,582.380	402,637.400	5.927
52	0.453	0.612	61,228.78	0.114	57,959.810	338,055.100	5.521
53	0.515	0.547	54,690.84	0.120	51,580.260	280,095.200	5.121
54	0.573	0.485	48,469.67	0.125	45,568.070	228,515.000	4.715
55	0.627	0.427	42,666.46	0.129	40,004.140	182,946.900	4.288
56	0.675	0.373	37,341.82	0.133	34,932.530	142,942.800	3.828
57	0.7179	0.325	32,523.24	0.135	30,367.930	108,010.200	3.321
58	0.7561	0.282	28,212.62	0.138	26,303.020	77,642.320	2.752
59	0.7897	0.244	24,393.41	0.139	22,715.030	51,339.300	2.105
60	0.8190	0.210	21,036.65	0.141	19,571.300	28,624.270	1.361
61	0.8444	0.181	18,105.94	-	9,052.971	9,052.971	0.500

5. Conclusion

Menopause is a confirmed and non-avoidable event in the fertility life of women. It has different effects on the health, social, and physical status of women. In this paper, we used different probability models to fit the distributional pattern of age at menopause for Nepalese women. Different test statistics were used to validate the model fitting. The logistic distribution better fitted the menopause data of Nepalese women. The four-parameter RGLLog distribution was also found to better fit the menopausal data and used to construct the menopausal table using the fitted probability of this distribution. It was observed that the distribution of the data sets deviated from normality which was consistent with many research findings. The fitted results of the significant model were used to construct the menopausal life table. It was estimated that the expected age of menopause or waiting time of menopause at the birth of Nepalese girls from 2005 data was 45.511 years by logistic distribution and 46.131 years by RGLLog distribution; meanwhile, it was 49.135 years by logistic distribution and 51.179 years by RGLLog distribution for 2018 data. Furthermore, when menopause was expected from the age of menarche, and if girls have menarche at the age of 15, then the expected age of menopause is after 30.507 years by logistic distribution and 31.146 years by RGLLog distribution for 2005 data, and after 34.973 years by logistic distribution and 36.49 years by RGLLog distribution for 2018 data. The results and findings of this research helped to further the projection of trends in the timing of menopause and provided insights into the factors that influence this important milestone in a woman's reproductive life. This research helped to identify the most likely age at menopause, the range of possible age at menopause, and the risk of early or late menopause. The information about the probability of having menopause or not having menopause at any age, and the waiting time for menopause for particular cohorts of women could be helpful to medical personnel who are dealing with the consequences of menopause and postmenopause, researchers who are developing new treatment for menopausal symptoms, and policymakers and organizers who formulate policies and programs regarding women's health. The finding of menopausal age probability fitting could be beneficial in understanding and managing menopause.

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Conflict of interest

The authors declare that they have no competing interests in publishing this article.

Author contributions

Conceptualization: Arjun Kumar Gaire
Investigation: All authors
Supervision: Yogendra Bahadur Gurung, Tara Prasad Bhusal
Formal analysis: Arjun Kumar Gaire
Writing – original draft: Arjun Kumar Gaire
Writing – review & editing: All authors

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data

Data used for this research can be found in Aryal, T. R., & Yadava, K. N. S. (2005). Age at menopause among Nepalese women. *Journal of Population and Social Studies*, 14(1), 95-114. https://so03.tci-thaijo.org/index.php/jpss/article/view/103943 and https://elibrary.nhrc.gov.np/handle/20.500.14356/1580

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ACCSCIENCE PUBLISHING

Global Health Econ Sustain

ORIGINAL RESEARCH ARTICLE

Determinants of the imports of essential medical products by European Union

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Abstract

The rapid spread of the COVID-19 pandemic has triggered a marked distortion in the trade of medical products needed to combat its severe effects on the health of infected individuals. This study sought to examine the determinants of imports by the 27 countries of the European Union (EU-27), through a panel data analysis for the period 2015 – 2020. The aim is to shed light on the distinct behavior of imports of each of the seven products classified as essential by the World Customs Organization and the World Health Organization. To that end, economic and social characteristics of the buyer country were treated as explanatory variables, along with the origin of the goods and the effect of the virus in 2020. The results showed that several determinants of imports of medical goods have a homogeneous influence on all of these products. This is also in line with gross domestic product per capita and population, which showed positive and significant coefficients for all products. The level of wealth of a country reflects its purchasing power, and thus capacity to purchase essential goods. Furthermore, an aged population in a territory is indicative of the greater need for essential medical products, which was amplified in 2020 due to the high vulnerability of this group to the symptoms of the virus. The present study confirmed that EU-27 trade agreements curbed the mass entry of non-EU products and that COVID-19 pandemic increased imports of certain products.

Keywords: COVID-19; Medical products; Imports; Panel data

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1. Introduction

Coronavirus disease 2019 (COVID-19) had paralyzed the world for months, sparking a global crisis that had hit all aspects of the economy: a fall in trade and production, skyrocketing unemployment, and rising public debt caused by the huge stimulus packages designed to prevent collapse (Gereffi, 2020). These ramifications triggered rapid social reversal, widened the inequalities, and exposed the precariousness of healthcare in almost all the countries affected. In this context, there is a clear need to maintain international trade relations, both to ensure the supply of essential products and to send a signal of confidence to international markets (OECD, 2020a).

The medical treatment of COVID-19 necessitates a huge volume of supplies that no country has ever predicted. COVID-19 has caused a widespread shortage of certain health-care products, most notably in countries hardest hit by the pandemic. Against this backdrop, trade has gone from being occasionally complementary to domestic supply

to being crucial for facilitating the exchange of products and making it possible to save lives. According to statistics provided by Eurostat, European imports of medical products between January and October 2020 were 14.86% higher than in the same period in 2019, while exports have experienced an even greater impact, being 47.92% higher.

In an attempt to adapt to this new scenario, the authorities of various nations have been forced to take measures involving the removal of certain import restrictions. Notable examples include the elimination of import licensing requirements, the reduction of tariffs, and the suspension of anti-dumping duties on medical supplies. However, the response has not consisted entirely of liberalizing measures; at the same time, temporary restrictions have been imposed on the export of these products to guarantee the adequacy of domestic supply (OECD, 2020b; Baldwin & Evenett, 2020; Evenett & Winters, 2020; Evenett, 2021). More specifically, in Europe, the European Commission imposed restrictions in March 2020 on the export of medical products, not only because of existing shortages but also due to the anticipated increase in demand for an indefinite period (Regulation 2020/402). However, according to Leibovici & Santacreu (2020), this situation has not given rise to a common line of action at a global level; indeed, there has been a markedly heterogeneous response, with countries' trade policies being strongly dependent on their trade balances in medical goods. At the outbreak of the pandemic, 86% of the countries with a trade surplus in these goods imposed restrictive export policies, whereas only 46% of countries with a trade deficit did so.

Apart from the needs created by the pandemic, international demand for medical supplies and products has grown exponentially in recent decades. The trigger has been the aging of the population in middle- and high-income countries, which, together with the substantial increase in health-care expenditure in the developing world and very low tariffs, has led to an abundant supply of low-price, high-quality products (Gereffi, 2020).

The aim of this research was to analyze the determinants of the imports of each of the essential medical products by the 27 countries of the European Union (EU-27), for the period of 2015 – 2020 (in the first 10 months of each year1), such that the previous year reflects the effect of COVID-19 on international purchases. This study sought to answer the following questions:

(i) Is the import of various types of essential medical products needed to combat the pandemic determined by the same factors?
(ii) Are extra-EU suppliers at a disadvantage compared to intra-EU suppliers?
(iii) Has there been a significant change in 2020 compared to previous years in imports of medical products classified as essential?
(iv) Is the import of medical products price-sensitive?

Trade statistics provided by Eurostat, classified as extra- and intra-EU imports, were analyzed in this study. Pooled ordinary least squares (OLS), fixed effects (FE), or random effects (RE) estimation of the panel data were carried out, depending on the results of the corresponding validity test.

The impact of COVID-19 on trade flows of goods and services has been analyzed in the literature (Shaker, 2020; Anghelache *et al.*, 2020). Specifically, Minondo (2020) compared the drop in exports during the COVID-19 crisis with the Great Recession of 2008 – 2009, concluding that Spain is the country in Europe that has registered the biggest drop in trade. Other authors have focused on estimating the determinants of total trade in medical products without exploring the differences among them (Fabus, 2020; Makrevska *et al.*, 2020; Jindřichovská & Uğurlu, 2021). Accordingly, the results of the proposed empirical analysis help shed light on novel aspects that could guide future trade policies in a number of ways: (i) the separate analysis of trade determinants by type of product broadens the spectrum of potential action, by providing detailed information on the specific characteristics of each one; (ii) the analysis of the period of time enables an assessment of the impact of the pandemic, which helps identify and explain which products are most affected; and (iii) the composition of the sample used in the empirical analysis depicts the individual patterns of each country, providing the EU trade policy-makers with ex-ante information for the adoption of possible tariff measures.

This study primarily analyzed the European imports of products classified as essential for combatting COVID-19 by the World Customs Organization and the World Health Organization (WHO). These products are grouped into seven categories:

(i) Test kits and diagnostic instruments (*e.g.*, COVID-19 test kits);
(ii) Disinfectants and sterilization products (*e.g.*, medical strength alcohol, sanitizers, sterilizing equipment, chemical disinfectants, and medical grade chemicals);
(iii) Oxygen therapy equipment (*e.g.*, ventilators and artificial respiration apparatus);
(iv) Medical devices and equipment (*e.g.*, thermometers, stethoscopes, electrocardiographs, and ultrasound machines);

1 This limitation is due to the fact that, at the time of conducting the research, information for 2020 was only available from January to October. The same restriction has been imposed on the rest of the years to ensure the comparability of the annual data.

(v) Medical vehicles and furniture (*e.g.*, ambulances);
(vi) Protective garments (*e.g.*, face masks, eye protection, gloves, and other personal protective equipment);
(vii) Medical consumables (*e.g.*, soap, wadding, gauze, bandages, and cotton sticks).

All of these refer to final products and do not include the raw materials and intermediate goods needed for their manufacture. The leaders in the global trade in products that require more advanced technology, such as medical devices, are large, vertically-integrated multinational companies headquartered in highly-developed industrial economies such as the United States, Germany, Switzerland, the Netherlands, and the United Kingdom, and with production facilities around the world (OECD, 2020b). However, the segment of the least technologically sophisticated products, such as protective garments, is more often outsourced to third-party suppliers, usually in developing countries such as Indonesia or Malaysia, with the guarantee of direct oversight and regulatory certification to ensure quality requirements are met (Bamber *et al.*, 2020).

The rest of the article is organized as follows: Section 2 offers a review of the literature on the trade in medical goods, as well as the impact of COVID-19 on these products. Section 3 explains the estimation methodology used and the variables included in the proposed model. Section 4 details the main results of the study. Finally, Section 5 summarizes the most important conclusions drawn from the research.

2. Literature review and conceptual framework

2.1. Literature review

COVID-19 has sparked the interest of the scientific community, giving rise to studies focusing on almost all spheres of interest, from more general areas such as environmental effects (Zambrano-Monserrate *et al.*, 2020; Casado-Aranda *et al.*, 2021), the economic impact (Hossain, 2021; Pham *et al.*, 2021) or food security (Marti *et al.*, 2021; Bukari *et al.*, 2022; Marchetti and Secondi, 2022), to more specific areas such as education (Chertoff *et al.*, 2020; Sintema, 2020) or the health of children (Roberton *et al.*, 2020; Duan *et al.*, 2020). Likewise, the trade in goods that are essential for combatting the pandemic has been analyzed from various perspectives (Baldwin & Tomiura, 2020; Evenett, 2020a; Vickers & Ali, 2020; Barua, 2020; Hayakawa & Imai, 2021).

As the main supplier of medical products, China has been the focus of numerous studies. Shaker (2020) applies an econometric model to analyze the determinants of its exports, concluding that aging population, infection rates in the destination country, and the wealth of the buyer country are the main drivers of the trade under study. Furthermore, after analyzing the trade in masks and other medical equipment, Fuchs *et al.* (2020) demonstrated that having economic ties with the Asian country is the main determinant of buyer countries to import these products.

Focusing on trade policies, Evenett *et al.* (2020) identified a surge in trade policy activism between February and March 2020, alongside the rise in COVID-19 cases, and found marked heterogeneity among countries in terms of the type of measures imposed and how they were implemented. In the same vein, Hoekman *et al.* (2021) concluded that the application of export restrictions on medical products is strongly correlated with the characteristics of prevailing public procurement regimes, based on the analysis of the relationship between public procurement regimes and trade policies during the first 6 months of the pandemic. Likewise, Curran *et al.* (2021) focused their study on the scope and nature of trade policy and its possible compatibility with existing World Trade Organization (WTO) agreements. Their results revealed that the globalizing process taking place in recent decades has slowed down due to the continual political interventions and the growing trade tensions. According to a study that assessed the impact of restrictions imposed by Malaysia on imports of medical supplies, Ayub (2020) argued that trade policies should be used as an instrument to support public health and that any restrictions standing in the way of this should be eliminated.

Another relevant perspective is the focus on global value chains (GVCs), which have been the subject of numerous studies seeking to shed light on the scarcity of medical supplies, providing information that could help decision-makers (Park *et al.*, 2020; Grumiller & Grohs, 2021). Dallas *et al.* (2021) identified the interactions between the type of state intervention and two structural characteristics of GVCs: the geographical distribution of production and the attributes of the product. By so doing, they demonstrated the mutual constraints of states and GVCs and revealed the major role played by structural factors. However, there is no universally agreed line of action to be taken. While some countries call for greater intervention to prevent excessive outsourcing and the consequent foreign dependency, others applaud GVCs for their flexibility, blaming leaders for undermining the operations defined in the GVCs. Studies such as those by Evenett (2020b) and Gopalakrishnan *et al.* (2020) assessed state intervention in medical product GVCs by conducting comparative analyses of France, Germany, the United Kingdom and the United States, and the Commonwealth countries, respectively. Vickers & Salamat (2020) mapped out supply chains, analyzing major exporters and importers and assessing

the impact of recent trade measures on least developed countries. Their results indicated that global cooperation and support play an important role in bolstering health systems in these countries.

The WTO[2] has also published a series of papers, which provide valuable information on the impact of the pandemic on international relations. These studies explicitly pertain to medical products: they analyzed the business of vaccines, both in terms of development and global distribution (WTO, 2020a); they assessed the related export bans and restrictions (WTO, 2020b); and they studied how these products were treated based on the regional trade agreements (WTO, 2020c). Similarly, the WTO (2020d) and Dugiel & Mikołajek-Gocejna (2020) examined the activities of the European institutions in tackling the negative effects triggered by the collapse of international trade both within the EU and globally.

2.2. Conceptual framework

The international trade in the analyzed medical products has some special features that explain its behavior in times of intense demand. During the span of 2015 – 2020, according to statistical data from Eurostat, the supply and demand of these products displayed an upward trend, with an increasingly large positive trade balance, due to the growing gap between exports and imports (Figure 1).

The present empirical study focuses on the analysis of extra- and intra-EU imports, classified by type of product. The analysis by specific product type did not reveal such a uniform trend. First, the analysis focused on the products that registered negative growth in imports in 2020, namely, test kits and oxygen therapy equipment (Figure 2). This decline was the most pronounced in extra-EU imports of test kits (−9.88%) and intra-EU imports of oxygen therapy equipment (−8.15%).

Conversely, due to their technological simplicity and ease of purchase, the import of protective garments and disinfectants showed an upward trend during the pandemic, regardless of the origin of these products (Figure 3). According to Park *et al.* (2020), the huge increase in demand for surgical masks, eye protection, gloves, and gowns had exhausted stocks, significantly driving up prices and causing a backlog in order fulfillment for 4 – 6 months. The primary challenge is to ensure that critical protection products are supplied and assigned to front-line healthcare workers and other stakeholders in affected countries, especially those most vulnerable to the spread of coronavirus.

2 https://www.wto.org/english/tratop_e/covid19_e/covid_reports_e.htm

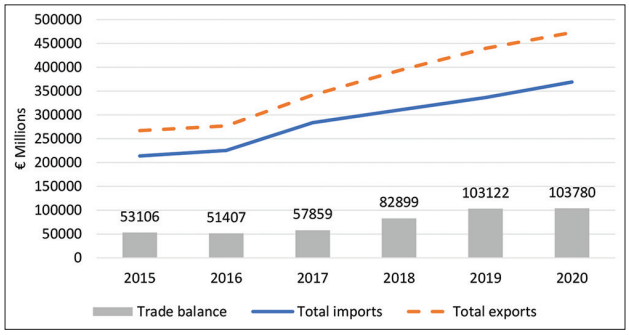

Figure 1. The trend of EU-27 trade in medical products.

Finally, extra-EU import of vehicles and furniture, medical devices, and medical consumables had increased during the pandemic, while intra-EU imports had decreased (Figure 4). Medical devices are produced with advanced technology, with very powerful suppliers in the United States, Switzerland, and the United Kingdom (OECD, 2020b). While medical consumables registered strong positive growth in intra-EU trade in the period 2017 – 2019), the COVID-19 pandemic had in turn amplified the trade with suppliers from outside the EU.

The analysis of all medical products revealed that the intra-EU import volume exceeded the extra-EU volume over the entire period analyzed (Figure 5). These statistics reflect the effectiveness of existing trade agreements among the EU countries, which fosters the development of this type of trade.

Overall, there was a slight increase in 2020 in extra-EU trade in medical goods. This may be due to the uncontrolled demand for these products, which had resulted in a slow-down of trade with member states to meet domestic demand. Although this had prompted a search for other suppliers outside the EU, there was still a considerable gap between intra- and extra-EU trade throughout the period under analysis.

3. Methodology and data

3.1. Methodology

An individual econometric model was specified for each medical product to estimate the determinants of imports by the EU-27 in the period 2015 – 2020. This entails the estimation of seven import functions, one for each product, which include variables associated with the economic and social characteristics of the importing country, as well as the price index and the origin of these products. Special reference is also made to the impact of COVID-19 to detect the possible effects of the pandemic (Equation I).

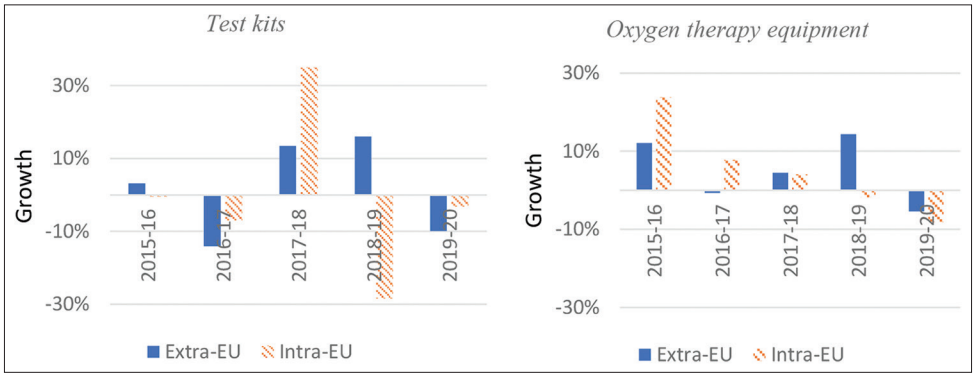

Figure 2. Products with negative growth in imports in 2019 – 2020.

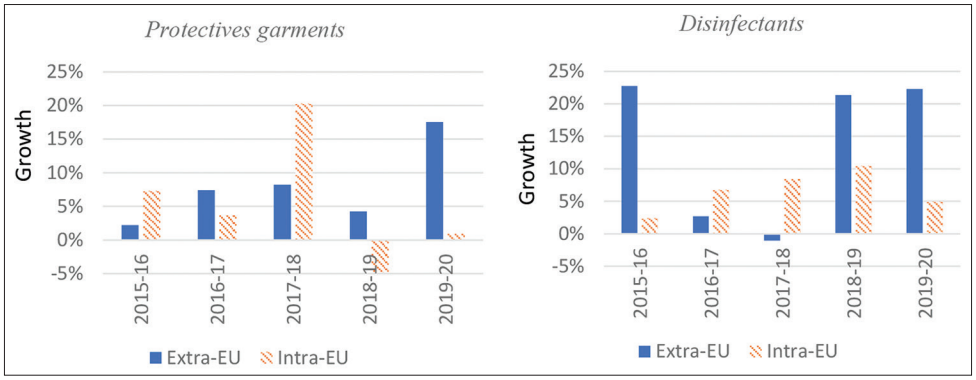

Figure 3. Products with positive growth in imports in 2019 – 2020.

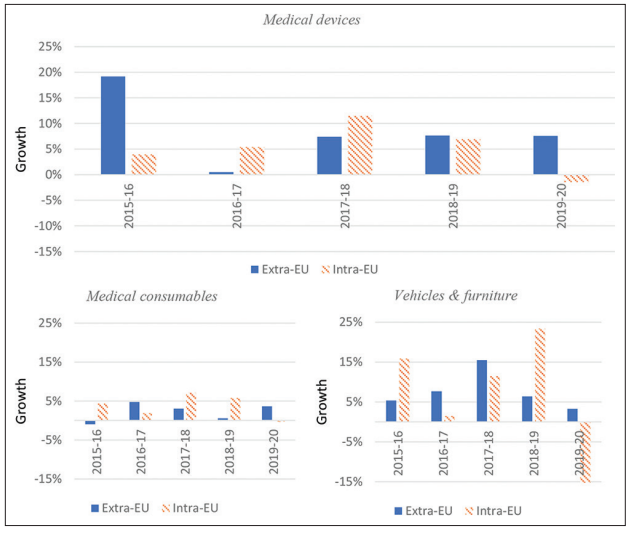

Figure 4. Products with positive and negative growth in imports in 2019 – 2020.

$$Ln(M)_{i,j,t} = \beta_0 + \beta_1 Ln(GDP_{pc})_{j,t} + \beta_2 Ln(Pop65)_{j,t} + \beta_3 Ln(Beds)_{j,t} + \beta_5 HICP_{it} + \beta_4 Dextra + \beta_5 D2020 + \varepsilon_{it} \quad (I)$$

where $Ln(M)_{i,j,t}$ is the napierian logarithm of imports of product "i" by country "j" in year "t"; $Ln(GDP_{pc}))_{j,t}$ is the natural logarithm of the GDP per capita of country "j" in year "t"; $Ln(Pop65)_{j,t}$ is the natural logarithm of the population aged over 65 years in country "j" in year "t"; $Ln(Beds)_{j,t}$ is the natural logarithm of the number of hospital beds in country "j" in year "t"; $HICP_{it}$ is the Harmonised Index of Consumer Price for Health of country "I" in year "t"; Dextra is a dummy variable that takes the value 1 if the imports come from countries outside the EU while the value 0 indicates otherwise; D2020 is a dummy variable that takes the value 1 if the imports were made in the year

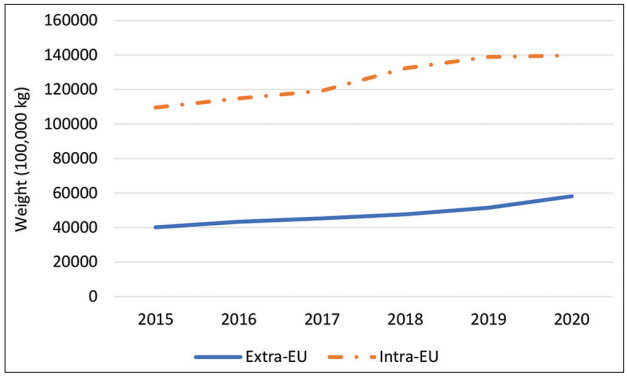

Figure 5. The trend of intra-and extra-EU imports measured in weight.

2020 and the value 0 indicates otherwise; and expected values of $\beta_2, \beta_3, \beta_5 > 0$, and of $\beta_4 < 0$.

In the field of international trade, numerous previous studies have employed regression models with panel data estimated by pooled OLS, FE, and RE (Karagoz & Saray, 2010; Manwa *et al.*, 2019; Tran *et al.*, 2020; Majumder *et al.*, 2020, among others). The Breusch-Pagan and Hausman tests were used to determine the most appropriate estimation method. Based on the interpretation by Wooldridge (2010), pooled OLS assumes that the intercept and slope coefficients are constant across time and space, and the error term captures differences over time and among individuals. The Breusch and Pagan Lagrangian multiplier test was used to select a model, either the pooled OLS or the RE. In this case, two hypotheses were proposed:

H_0: The appropriate model is pooled OLS.
H_1: The appropriate model is RE.

If Prob > Chi2 < 0.05, H_0 can be rejected, and the appropriate model is RE.

To choose between FE and RE, Hausman specification tests were used. Intervariance and intravariability were considered in selecting one model in this case. The proposed hypotheses are:

H_0: The preferred model is RE.
H_1: The preferred model is FE.

If Prob > Chi2 is more than 0.05, H_0 can be accepted, and the preferred model is RE.

3.2. Data and sample

The sample used in the study comprised 324 observations reported by 27 reporters from the EU-27 and 2 partners (one extra-EU and one intra-EU), spanning 6 years (2015 – 2020). Table 1 presents the main statistics of the variables that make up the equations for the panel sample. In addition, two dummies are included: One represents the intra- or extra-EU origin of the products, and the other captures whether COVID-19 had had a notable effect on the trade in these goods. All variables were sourced from Eurostat.

As presented in Table 1, the goods registering the highest volume of imports on average in the period 2015 – 2020 were medical consumables and disinfectants. Germany is the biggest importer of all the medical products analyzed, while the minimum values correspond to extra-EU imports of products by Latvia (test kits), Luxembourg (disinfectants, medical consumables, and oxygen therapy equipment), Estonia (medical devices), and Malta (protective garments and vehicles). Regarding the rest of the variables, the maximum value for GDPpc corresponds to Luxembourg, the maximum number of beds per 100,000 inhabitants and population of people aged over 65 to Germany, and the highest HICP to Finland.

The variable "beds" refers to the available beds in hospitals. Given the lack of information regarding beds for 2019 and 2020, a value was estimated by extrapolating from the trend of the four years before 2019. Regarding population, the analysis was focused on the number of people aged over 65, as this age group is the most vulnerable to COVID-19. GDPpc represents the level of wealth of the importing country valued at market prices; again, the value corresponding to 2020 has been estimated following the predictions by the European Central Bank. As the function in question is an import function, it should

Table 1. Main statistics for the period 2015 – 2020

	Mean	Max	Min	S.D.
Dependent variables: imports (100 kg)				
Medical consumables	994,662	7,852,124	2179	1,476,134
Disinfectants	935,176	14,008,922	529	1,916,699
Protective garments	823,477	5,282,810	11,937	1,023,156
Medical devices	285,353	2,447,977	6757	378,933
Vehicles	127,136	1,455,688	2298	201,364
Oxygen therapy equipment	48,700	535,675	21	92,095
Test kits	47,186	892,633	169	84,692
Independent variables				
GDPpc (Euros per capita)	29,230	102,200	6370	19,420
Beds (per hundred thousand inhabitants)	499	813	200	168
Population of people aged over 65 (persons)	3,268,921	18,090,682	79,805	4,543,532
HICP (annual rate of change)	1.4	7.1	−8.4	1.8

Abbreviations: GDPpc: Gross domestic product per capita; HICP: Harmonized Index of Consumer Price for Health; S.D.: Standard deviation.

include a variable that reflects the price of these products, that is, HICP, which measures the change over time in the prices of consumer goods and services related to the health sector. Table 2 shows the matrix of correlations among GDPpc, beds, population of people aged over 65, and HICP.

Following Gujarati (2004), multicollinearity between independent variables is confirmed if the correlation coefficient is 0.8 or higher and can be classified as severe when the absolute value of the pair-wise correlations between variables is very close to 1. As such, the correlation matrix demonstrates the absence of collinearity.

The statistical information revealed that COVID-19 had impacted the import of almost all essential medical goods, introducing a change to the existing pattern (Figure 6). In 2015, medical consumables had the highest demand, which was superseded by disinfectant in 2020, as the latter is an essential good needed to prevent the transmission of the virus and to sanitize the surfaces in affected areas. Overall, a substantial increase in the volume of import is observed in 2020, with the exception of test kits.

Table 2. Correlation matrix*

	GDPpc	Beds	Pop65	HICP
GDPpc	1			
Beds	−0.373	1		
Pop65	0.007	0.166	1	
HICP	−0.194	0.200	−0.187	1

Abbreviations: GDPpc: Gross domestic product per capita; HICP: Harmonized Index of Consumer Price for Health; Pop65: Population of people aged over 65.

Considering the total import from 2015 to 2020, Table 3 shows the most relevant countries according to their import volume as a share of the total import volume of each product.

Germany led in the intra-EU import (except for disinfectants), accounting for a significantly high share of most products. It is also the leading importer in almost all products in the extra-EU sphere, with the exception of test kits. It is followed by countries such as Belgium, the Netherlands, Italy, and Spain, reflecting their pressing needs arising from the pandemic. In addition, a marked concentration can be observed: the top five importing countries together account for almost 60% of international purchases, rising to 81% in the case of disinfectants. Avendaño (2020) and García *et al.* (2020) reported a similar pattern at the global level: official statistics revealed the high and concentrated participation of developed economies in the trade in medical products, with the United States and Germany occupying the top positions, followed by China.

Figure 7 shows the main suppliers of medical products during the period 2015 – 2020.

Table 3. Top 5 importers of medical product categories (2015 – 2020)

Test kits	Disinfectants	Medical consumables	Medical devices	Oxygen therapy equipment	Protective garments	Medical vehicles & furniture
Extra-EU trade						
DEU (32%)	NLD (37%)	DEU (19%)	DEU (18%)	DEU (44%)	DEU (23%)	DEU (26%)
BEL (14%)	BEL (15%)	NLD (12%)	ITA (14%)	ESP (10%)	NLD (14%)	NLD (12%)
NLD (11%)	SWE (10%)	BEL (11%)	NLD (13%)	NLD (7%)	FRA (14%)	FRA (8%)
FRA (11%)	FRA (8%)	FRA (10%)	ESP (9%)	BEL (6%)	ITA (9%)	ESP (8%)
ITA (7%)	ITA (6%)	IRL (7%)	FRA (9%)	ITA (6%)	ESP (8%)	POL (7%)
Total 75%	Total 81%	Total 59%	Total 63%	Total 79%	Total 69%	Total 62%
Intra-EU trade						
FRA (20%)	DEU (30%)	DEU (17%)	DEU (23%)	DEU (23%)	DEU (17%)	DEU (26%)
DEU (12%)	NLD (16%)	FRA (16%)	FRA (13%)	ESP (19%)	FRA (13%)	FRA (13%)
ESP (11%)	FRA (8%)	BEL (9%)	ESP (10%)	FRA (9%)	BEL (8%)	NLD (7%)
POL (11%)	ITA (7%)	NLD (6%)	BEL (7%)	POL (8%)	CZE (8%)	BEL (6%)
ITA (9%)	BEL (6%)	ITA (6%)	ITA (7%)	ITA (7%)	ESP (7%)	AUT (6%)
Total 63%	Total 67%	Total 54%	Total 58%	Total 66%	Total 53%	Total 58%

Note: A country's import of a product is given as a percentage of total extra- or intra-EU trade in that product (in parentheses).
Abbreviations: AUT: Austria; BEL: Belgium; CZE: Czechia; DEU: Germany; ESP: Spain; FRA: France; IRL: Ireland; ITA: Italy; NLD: The Netherlands; POL: Poland.

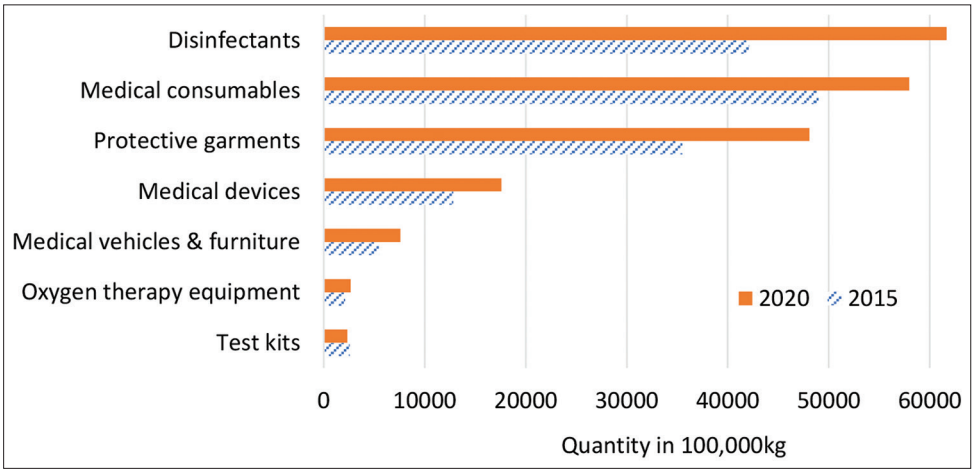

Figure 6. Total import by the EU-27, including extra-EU and intra-EU.

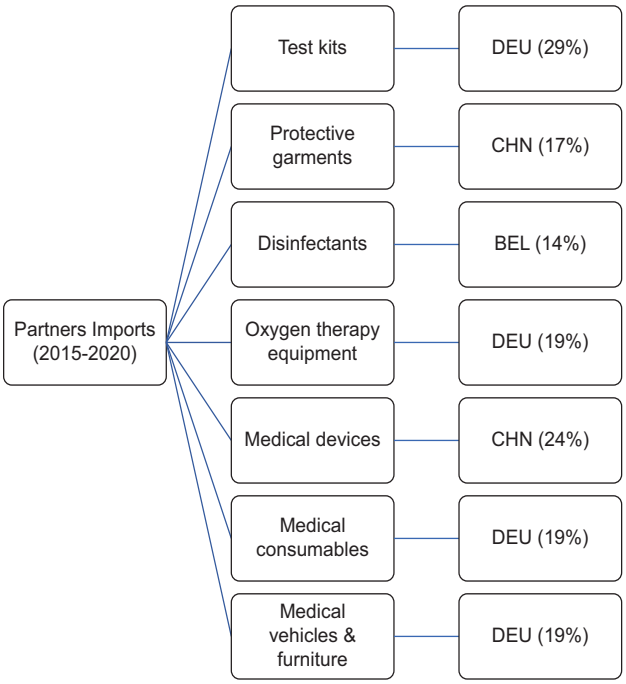

Figure 7. Main suppliers of each product.

According to official statistics, China, Germany, and Belgium led the way in medical supplies. Indeed, China accounts for the supply of 17% of the protective garments and 24% of medical devices sold to the EU-27 as a whole, placing itself in the top position of medical supplies (Figure 7). Germany and Belgium, in addition to holding top positions as suppliers to European countries, are also among the major importers. The OECD (2020b) and García *et al.* (2020) attribute this dual role to the existence of intense intra-industrial trade and the high degree of interdependence between these essential items.

4. Results

Equation I was used for estimation for each of the analyzed products using the most appropriate statistical method. All variables have been log-transformed to eliminate the dependence on the units of measurement and to smooth any variability, thereby standardizing the statistical data and improving the robustness of the estimates.

The results of the Breusch-Pagan and Hausman tests revealed that the estimation of imports of test kits, protective garments, vehicles, and furniture is more consistent when pooled OLS is applied (Prob > Chi2 < 0.05). The Hausman test was significant for three products (disinfectants, medical consumables, and oxygen therapy equipment), indicating that the RE method was more efficient than the FE method in this case. Finally, FE was used for the estimation of medical devices because Prob >Chi^2 < 0.05 in the Hausman test.

In all estimations in Table 4, the goodness of fit (Adj R^2) lies between 0.74 and 0.85; it can thus be confirmed that the set of regressors explains a substantial part of the behavior of the import. GDPpc and population showed positive and significant coefficients for all products, which is expected according to economic theory. The level of wealth of a country reflects its purchasing power, and thus capacity to purchase essential goods. Furthermore, an aged population in a territory has a greater need for essential medical products. The year 2020 saw an increased need for the essential medical products because this age group is the most vulnerable to the symptoms of the virus. In this regard, Shaker (2020) noted that a greater population aged over 65 of the importing country was indicative of a bigger import of medical products from China during the pandemic.

Table 4. Model estimation results

	Pooled OLS	Random effects	Random effects	Fixed effects	Random effects	Pooled OLS	Pooled OLS
	Test kits	Disinfectants	Medical consumables	Medical devices	Oxygen therapy	Protective garments	Medical vehicles and furniture
Ln (GDPpc)	1.380***	0.921***	0.605***	1.034***	0.832***	0.771***	0.884***
Ln (Pop 65)	1.039***	1.081***	0.802***	1.478***	1.229***	0.923***	0.855***
Ln (Beds)	0.502	−0.037	0.311	1.163***	0.382	0.544***	0.646***
HICP	0.010	−0.033**	−0.006	−0.005	0.025*	0.026	0.015
DExtra	−1.703***	−1.756***	−1.735***	Omitted	−1.489***	−0.509***	−0.822***
D2020	0.082	0.400***	0.116***	1.110***	0.063	0.371***	0.117
Cons	−21.56***	−10.59***	−5.69***	−20.53***	−18.76***	−11.32***	−13.76***
Obs	324	324	324	324	324	324	324
Adj R^2	0.857	0.744	0.795	0.805	0.822	0.826	0.857
Breusch-Pagan test							
Chi^2 (1)	0.87	24.24	57.94	11.47	9.36	0.36	0.01
Prob>Chi^2	0.351	0.000	0.000	0.000	0.002	0.547	0.910
Hausman test							
Chi^2 (4)	--	2.60	2.05	16.15	5.23	--	--
Prob>Chi^2	--	0.461	0.725	0.006	0.264	--	--

Notes: (1) Dependent variable: ln imports; (2) ***, ** and * denote significance at the 1%, 5%, and 10% levels, respectively; (4) Degrees of freedom of the statistic.

However, the number of beds, which represents an important element of hospital infrastructure, is only significantly related to the import of vehicles and furniture, medical devices, and protective garments. The number of beds reflects the hospital capacity and is therefore related to the essential equipment for hospitals, which is supplied in accordance with their needs.

It has also been shown that price changes, as indicated by HICP, have only a weakly significant influence on the import of medical products (disinfectant and oxygen therapy equipment). This is due to the fact that they are essential goods and not very sensitive to price changes. They are thus considered very inelastic products. On the other hand, the existence of barriers to trade means that the volume of import from EU member states exceeds those from the rest of the world; this is reflected by the negative sign of the dummy *Dextra* in the estimations for all the medical goods. In this respect, Makrevska *et al.* (2020) also confirmed the preference for European products in a global context. EU countries enjoy trade privileges that foster internal trade and make it harder to purchase from countries outside the European agreement. The latter are penalized not only in terms of tariffs but also in the extra bureaucracy that complicates and slows down transactions.

Finally, the dummy D2020 introduced to capture the effect of COVID-19 turned out to be positive and significant for only four of the seven products (disinfectants, medical consumables, medical devices, and protective garments), confirming the major role they play in the fight against the virus. This is reflected by an increase in imports of these products in the first 10 months of 2020 compared to previous years.

5. Conclusion

The economic crisis generated by the measures taken to curb the pandemic has led to major distortions in international trade. Some studies have focused on analyzing important changes in trade policy aimed at mitigating the negative effects of COVID-19, following the imposition of export restrictions and the liberalization of imports. The empirical analysis of this research provides relevant information on the behavior of the determinants of imports of essential medical products, as defined by the WHO, within the EU during the period 2015 – 2020.

In a context in which volume of intra-EU trade generally exceeds that of extra-EU trade, a panel sample of 27 EU countries is used to shed light on the variables that explain the similarities and differences among different types of imported medical products. The wealth of the importing country and the population aged over 65 could explain the volume of import: the greater the purchasing power and the older the population, the higher the volume of imports. However, the number of beds only influences the import

of vehicles and furniture, medical devices, and protective garments needed by hospitals in their fight against disease. It has also been shown that most of the products are not sensitive to price changes because they are inelastic goods indispensable in health sector, which can be hardly replaced by other substitutes. The dummies included in the model indicate, on the one hand, that the pandemic has been the driving force behind the trends in the import of certain products (D2020), and on the other hand, that barriers to trade imposed by the Third-World countries negatively impact the import by European countries (*Dextra*).

The present analysis provides answers to all the questions set out in Section 1:

(i) The import of essential medical products needed to combat the pandemic are generally driven by the same factor, although due to the intrinsic characteristics of each one, some are more dependent on the wealth of the country, while others depend more on the profile of the population.
(ii) Tariff agreements in the EU favor intra-EU trade over goods from other countries.
(iii) The import of some essential products have been severely affected by the growing demand driven by the spread of the virus.
(iv) The essential medical products have low price elasticity as they are essential items.

The research was carried out during the pandemic, coinciding with the first months of the mass vaccination in most high-income countries. The logical continuation of this study would be to analyze the effect of vaccination on the import of medical products, to determine whether the immunization of the population alters demand for these goods. It would also be interesting to study whether countries have adjusted their production to avoid a high degree of foreign dependency and to prevent the collapses during the early months of the spread of the virus. Unfortunately, this study was limited by the lack of a global vision of the problem, which was due to the lack of comprehensive and up-to-date information. We believe that when the pandemic abates to a greater extent, more accurate statistical information will be available for a global analysis to be conducted.

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Conflict of interest

The authors declare no conflicts of interest.

Author contributions

Conceptualization: All authors
Investigation: All authors
Methodology: All authors
Writing – original draft: All authors
Writing – review and editing: All authors

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data

The data used in this research can be obtained from Eurostat: https://ec.europa.eu/eurostat/data/database.

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ACCSCIENCE PUBLISHING

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ORIGINAL RESEARCH ARTICLE

Non-communicable diseases household survey data analysis in Sana'a City, Yemen, 2017

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Abstract

Non-communicable diseases (NCDs) claim 41 million lives annually, accounting for 71% of global mortality. The Middle East sees a rapid increase in NCD cases, yet Yemen remains underexplored in this context. This study aims to investigate NCD epidemiology in Sana'a City, Yemen, for 2017. Raw data from a 2017 house-to-house survey conducted by the Ministry of Public Health and Population were analyzed. Household heads reported any of the following five NCDs in the household: hypertension (HTN), diabetes mellitus (DM), bronchial asthma (BA), mental disorders (MD), and epilepsy. Data were entered and analyzed using Epi info 7.2, using 2017 projections from the 2004 census. The study encompassed 241,310 households, housing 1,592,646 individuals. Among these, 59,061 households (24.48%) included 70,178 individuals with at least one NCD. The overall NCD prevalence was 4.4%, with specific prevalence: HTN 2.3%, DM 2.2%, BA 0.4%, MD 0.27, and epilepsy 0.19%. NCD prevalence was significantly higher among females than males (5.1% vs. 3.8%; odds ratio [OR] 1.35, 95% confidence intervals [CI]: 1.33 – 1.35), a trend mirrored in HTN (3.1% vs. 1.6%; OR = 1.94, 95% CI: 1.90 – 1.98), DM (2.3% vs. 2.1%; OR = 1.11, 95% CI: 1.09 – 1.13), and BA (0.5% vs. 0.3%; OR = 1.56, 95% CI: 1.49 – 1.65). Conversely, MD was more prevalent among males than females (0.35% vs. 0.16%; OR = 2.2, 95% CI: 2.06 – 2.31). NCD prevalence increased with age, with nearly 18% of patients having more than one NCD, including 35.2% of HTN patients also having DM. One-quarter of surveyed households had at least one member with one or more of the five NCDs, emphasizing an overall NCD prevalence of 4.4%. These findings rely only on self-reported diagnosed cases, lacking standardized measures. In light of these findings, it is crucial to increase focus on NCDs, enhance health-care provision, improve data collection, implement an NCDs stepwise survey, and establish an NCD surveillance system.

Keywords: Non-communicable diseases; Hypertension; Diabetes; Bronchial asthma

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1. Introduction

Non-communicable diseases (NCDs), also referred to as chronic diseases, typically manifest as enduring conditions and are influenced by a multitude of genetic, physiological,

environmental, and behavioral factors (World Health Organization [WHO]). The four main categories of NCDs encompass cardiovascular diseases (CVDs), cancers (CAs), chronic respiratory diseases (COPDs), and DM. In 2016, of the 56.9 million global deaths, 40.5 million, or 71%, were attributed to NCDs (WHO, 2018). Significantly, NCDs exhibit a disproportionate impact on low- and middle-income countries, where they account for more than three-quarters of NCD-related deaths, totaling 32 million lives (WHO). Recent projections from the WHO suggest that by 2020, NCDs will contribute to 80 % of the global burden of disease. This alarming statistic predicts that seven out of every 10 deaths in developing countries will be due to NCDs, with half of these fatalities transpiring before the age of 70 years (Ndubuisi, 2021).

The Eastern Mediterranean Region (EMR) is recognized for having one of the highest prevalence rates (PRs) of NCDs worldwide (Slama *et al.*, 2018). In 2012, NCDs accounted for over 2.2 million fatalities in 2012, constituting more than 57% of all deaths (WHO, 2018). Disturbingly, future projections point to a significant surge in the prevalence of NCDs. The four main NCDs could result in as many as 2.4 million deaths in 2025 unless concerted action is taken (WHO, 2018). Notably, low- and middle-income countries bear the weight of this NCD burden, accounting for 80% of these cases (WHO, 2018). Moreover, in low-income countries, up to 50% of NCD-related deaths occur before the age of 60, compared to <10% in high-income countries (13%) (Neyazi *et al.*, 2023).

In 2016, the leading causes of NCD deaths were CVDs (17.9 million deaths, or 44% of all NCD deaths), followed by CAs (9.0 million, or 22% of all NCD deaths), and respiratory diseases, which encompass conditions such as bronchial asthma (BAs) and COPDs (3.8 million, or 9% of all NCD deaths) (WHO, 2018). DM was another significant factor, causing 1.6 million deaths (WHO, 2018). The global prevalence of DM for all age groups was estimated to be 4.8% in 2014. Projections indicate a substantial increase in the number of people affected by DM, expected to rise from 422 million to 642 million worldwide by 2040 (Mirzaei *et al.*, 2020). BA is another prominent NCD, affecting an estimated 300 million people globally, with its prevalence on the rise each year (Ding & Zhong, 2020). The global prevalence of clinical BA (or treated BA) stands at 4.5%, while within the EMR, it is notably lower at 2.99% (To *et al.*, 2012, To *et al.*, 2021). This condition significantly contributes to disability, increased health resource utilization, and poor quality of life on a global scale (To *et al.*, 2021).

Epilepsy stands as one of the most prevalent neurological conditions, transcending age, racial, social class, geographic, and national boundaries (Asadi-Pooya *et al.*, 2023). It is recognized as a spectrum of heterogeneous syndromes that affect individuals worldwide, with a significant proportion of those living with epilepsy residing in developing countries (Sharma *et al.*, 2021). Mental disorders (MD) represent a major global health concern, with conditions like depression alone affecting 4.4% of the global population (Sagar *et al.*, 2017). Alarmingly, many individuals grappling with MD lack access to appropriate treatment and care, particularly in low-income countries with limited resources (Sagar *et al.*, 2017).

Given the current rate of progress, it is unlikely that the world will achieve the Sustainable Development Goal Target 3.4, which aims to reduce premature mortality from NCDs by one-third by 2030 through prevention, treatment, and the promotion of mental health and well-being (WHO, 2018).

This study aims to estimate the burden of the five main NCDs: hypertension (HTN), DM, BA, epilepsy, and MD. This estimation is based on the analysis of data collected during an immunization campaign conducted in 2017, utilizing a specially designed questionnaire for this purpose. In addition, this study encompasses several objectives, which are as follows:

(i) Describe the epidemiology of NCDs in Sana'a City for 2017 by examining demographic, temporal, and geographical aspects.
(ii) Determine the prevalence of NCDs in Sana'a City for 2017.
(iii) Provide evidence-based recommendations to assist decision-makers in planning appropriate interventions to address NCDs.

2. Methodology

2.1. Study setting

Sana'a City (Amanat Al Asimah) comprises ten districts: Old City, Shu'aub, Az'zal, Assafi'yah, As Sabain, Al Wahdah, At Tahrir, Ma'ain, Ath'thaorah, and Bani Al Harith. The total number of households surveyed was 241,310, and the population of Sana'a City in the 2017 census was 2,948,472.

2.2. Data source

The Sana'a City 2017 National NCDs Household Survey was conducted by the Ministry of Public Health and Population (MoPHP), and the data were collected on paper-based forms. During the survey, household heads were asked if any household member had one of the following five NCDs: HTN, DM, BA, MD, and epilepsy. Data on age and gender were also collected for each patient with one of the mentioned five NCDs. In this study, the raw data were obtained with permission from the Directorate of Health Statistics at MoPHP.

2.3. Statistical analysis

A total of 1,149 records, which included data from 241,310 surveyed households, were entered into Microsoft Excel. The database underwent a process of data cleaning and categorization. Subsequently, the survey data were analyzed using Epi info 7.2 version, a software specifically designed for epidemiological analysis. The analysis involved the presentation of data through simple descriptive methods that encompassed temporal, demographic, and geographical factors, as illustrated in Tables 1-13. For the calculation of PR, the population figure for Sana'a City in the 2017 Census (2,948,472) was obtained from immunization program data (NIP). Given the constraint of not having access to the total members of the surveyed households, the calculation was based on a multiplication of the number of surveyed households by the average household size of 6.6, as projected from the 2004 Census.

3. Results

3.1. Demographic distribution of NCDs in the surveyed households

A total of 241,310 households were surveyed, encompassing an estimated 1,592,646 household members. Within this cohort, 59,061 (24.5%) households were found to include 70,178 patients affected by one or more of the following five NCDs: HTN, DM, BA, MD, and epilepsy. The male-to-female ratio among the surveyed population was 1.2. The ages of NCD patients ranged from 0.1 – 150 years, with a median age of 50. Moreover, 12,724 individuals (18% of the 70,178 NCD patients) were managing more than one NCD condition. The overall prevalence of these five NCDs was determined to be 4.4%. A shown in Table 1, we present the distribution of NCDs among the individuals in the surveyed households based on the number of NCDs they are managing. In addition, Table 2 provides disease-specific PRs, with HTN being the most prevalent at 2.3%, while epilepsy exhibited the lowest prevalence, standing at 0.19%. As shown in Figure 1, it is evident that 53% of the NCD patients were female, and Table 3 underscores a significantly higher prevalence of NCDs among females compared to males. Figure 2 illustrates a distinct upward trend in NCD prevalence with advancing age, escalating from 1.9% in the 20 – 29 years of age group to 56.0% in the ≥70 years of age group.

3.2. HTN

Among the 70,178 NCD patients diagnosed with NCDs, 36,200 (42.8%) were found to have HTN, resulting in a PR of 2.3%. The median age within this subset of patients was 55 years, with an age range spanning from 0.7 to 150 years. In Figure 3, the gender distribution is illustrated, with females accounting for 62% and males for 38% of the cases. A significantly higher prevalence of HTN was observed among females compared to males, at 3.1% and 1.6%, respectively, with an odds ratio (OR) of 1.94 (95% confidence interval [CI]: 1.90 – 1.98) and a $p < 0.001$ (Table 4). Figure 4 reveals a distinct pattern in the prevalence of HTN, which increases with advancing age. It starts at 0.51% within the 20 – 29 years age group and rises to 37.00% in the ≥70 years age group. Table 5 provides insights into the comorbidities of the 36,200

Table 1. Distribution of NCDs in the surveyed households by the number of NCDs, Sana'a City, Yemen, 2017

Patient characteristics	At least one NCD (N=70178)	Number of NCD					
		1 (*n*=56579)	2 (*n*=13058)	3 (*n*=504)	4 (*n*=32)	≥5 (*n*=5)	*p*-value
Age (mean±SD)	48.9±17.1	47.3±17.5	55.8±13.6	54.7±14.0	54.9±11.7	48.0±20.8	<0.001
Age group (*n* [%])							
0 – 9 years	1461 (2.14)	1461 (2.14)	44 (0.34)	1 (0.2)	0 (0.0)	0 (0.0)	<0.001
10 – 19 years	2444 (3.58)	2358 (4.29)	82 (0.64)	3 (0.61)	0 (0.0)	1 (25.0)	
20 – 29 years	4389 (6.43)	4141 (7.53)	234 (1.83)	14 (2.85)	0 (0.0)	0 (0.0)	
30 – 39 years	8806 (12.89)	7972 (14.5)	794 (6.21)	37 (7.52)	3 (0.1)	0 (0.0)	
40 – 49 years	13113 (19.2)	11000 (20)	2027 (15.85)	80 (16.26)	6 (0.2)	0 (0.0)	
50 – 59 years	16312 (23.88)	12322 (22.41)	3826 (29.93)	156 (31.71)	7 (0.2)	1 (25.0)	
60 – 69 years	12505 (18.31)	9034 (16.43)	3347 (26.18)	108 (21.95)	14 (0.4)	2 (50.0)	
≥70 years	9270 (13.57)	6744 (12.26)	2431 (19.01)	93 (18.9)	2 (0.1)	0 (0.0)	
Sex (*n* [%])							
Men	32777 (46.77)	26832 (47.49)	5736 (43.96)	191 (37.9)	14 (43.75)	4 (80.0)	<0.001
Women	37310 (53.23)	29665 (52.51)	7313 (56.04)	313 (62.1)	18 (43.75)	1 (20.0)	

Abbreviation: NCDs: Non-communicable diseases.

Table 2. Distribution of the disease-specific prevalence rates of NCDs in the surveyed households, Sana'a City, Yemen, 2017

Type of NCD	Frequency*	Prevalence per 100 population
HTN	36,200	2.3
DM	34,879	2.2
BA	6,212	0.4
MD	4,244	0.27
Epilepsy	3,014	0.19

Note: *The total exceeds 70,178 due to comorbidity (certain patients having more than one NCD). NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; BA: Bronchial asthma; MD: Mental disorder.

Table 3. Prevalence of NCDs by gender, Sana'a City, Yemen, 2017 (*n*=70,178*)

Gender	NCDs		Total	OR (95% CI)	*p*-value
	Yes	No			
Female	37,310 (5.1%)	695,307 (94.9%)	732,617	1.35 (1.33 – 1.35)	<0.001
Male	32,777 (3.8%)	827,252 (96.2%)	860,029		
Total	70,087	1,522,559	1,592,646		

Note: *The gender information is missing in 91 cases out of 70,178 NCD cases. NCDs: Non-communicable diseases; OR: Odds ratio; CI: Confidence interval.

Table 4. Prevalence of HTN by gender in Sana'a City, Yemen, 2017 (*n*=36,200*)

Gender	HTN		Total	OR (95% CI)	*p*-value
	Yes	No			
Females	22,420 (3.1%)	710,197 (96.9%)	732,617	1.94 (1.90 – 1.98)	<0.001
Males	13,744 (1.6%)	846,285 (98.4%)	860,029		
Total	36,164 (2.4%)	1,556,482 (97.7%)	1,592,646		

Note: *Gender information is missing in 36 cases out of 36,200 hypertensive patients. NCDs: Non-communicable diseases; OR: Odds ratio; CI: Confidence interval; HTN: Hypertension.

hypertensive patients, indicating that 14,277 of them (39%) also had other NCDs. DM emerged as the most common comorbidity with HTN, affecting 35.2% of the cases, followed by BA at 2.8%. Epilepsy was observed as the least prevalent comorbidity (0.6%).

3.3. DM

Among the 70,178 patients diagnosed with NCDs, 34,879 were specifically identified as having DM, resulting in a PR of 2.2%. The median age for this cohort was 52 years, with

Table 5. Distribution of comorbid NCDs among patients diagnosed with HTN in Sana'a City, Yemen, for 2017 (*n*=36,200)

NCD	Frequency	Percentage of hypertensive patients with comorbid NCD (%)
DM	12,149	35.2
BA	1,018	2.8
MD	307	0.9
Epilepsy	228	0.6
Total	14,277	39

Abbreviations: NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; BA: Bronchial asthma; MD: Mental disorder.

Table 6. Prevalence of DM by gender in Sana'a City, Yemen, for 2017 (*n*=34,879*)

Gender	DM		Total	OR (95% CI)	*p*-value
	Yes	No			
Females	16,898 (2.3%)	715,719 (97.7%)	732,617	1.11 (1.09 – 1.13)	<0.001
Males	17,940 (2.1%)	842,089 (97.9%)	860,029		
Total	34,838 (2.2%)	1,557,808 (97.8%)	1,592,646		

Note: *Gender information is missing in 41 cases out of 34,879 diabetic patients. DM: Diabetes mellitus; OR: Odds ratio; CI: Confidence interval.

Table 7. Distribution of comorbid NCDs among patients diagnosed with DM in Sana'a City, Yemen, for 2017 (*n*=34,879)

NCD	Frequency	Percentage of diabetic patients with comorbid NCD (%)
HTN	12,149	35
BA	597	1.7
MD	259	0.7
Epilepsy	172	0.5
Total	13,177	38

Abbreviations: NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; BA: Bronchial asthma; MD: Mental disorder.

ages ranging from 0.2 to 130 years. In Figure 5, the gender distribution is depicted, with males constituting 52% and females 49% of the cases. Table 6 reveals that the prevalence of DM was significantly higher among females compared to males, with rates of 2.3% and 2.1%, respectively. The OR for this difference is 1.11 (95% CI: 1.09 – 1.13), with a *p*-value of less than 0.001, indicating a highly significant association. Figure 6 provides a clear illustration of the progressive increase in DM prevalence with advancing age. It starts at 0.51% in the 20 – 29 years age group and rises substantially

Table 8: Prevalence of BA by gender in Sana'a City, Yemen, for 2017 (*n*=6,212*)

Gender	BA		Total	OR (95% CI)	*p*-value
	Yes	No			
Females	3,541 (0.5%)	729,076 (99.5%)	732,617	1.56 (1.49 – 1.65)	<0.001
Males	2,659 (0.3%)	857,370 (99.7)	860,029		
Total	6,200 (0.4%)	1,586,446 (99.6%)	1,592,646		

Note: *Gender information is missing in 12 cases out of 6,212 patients with bronchial asthma. BA: Bronchial asthma; OR: Odds ratio; CI: Confidence interval.

Table 9. Distribution of comorbid NCDs among patients diagnosed with BA in Sana'a City, Yemen, 2017 (*n*=6212)

NCD	Frequency	Percentage of asthmatic patients with comorbid NCD (%)
HTN	1018	16.4
DM	597	9.6
MD	91	1.5
Epilepsy	59	0.9
Total	1765	28.4

Abbreviations: NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; BA: Bronchial asthma; MDs: Mental disorders.

Table 10. Prevalence of MDs by gender in Sana'a City, Yemen, for the year 2017 (*n*=4244*)

Gender	MDs		Total	OR (95% CI))	*p*-value
	Yes	No			
Male	3,041 (0.35%)	856,988 (99.65%)	860,029	2.2 (2.06-2.31)	<0.001
Female	11,99 (0.16%)	731,418 (99.84%)	732,617		
Total	4,240 (0.27%)	1,588,406 (99.7%)	1,592,646		

Note: *Gender information is missing in 4 cases out of 4244 patients with MD. MDs: Mental disorders; OR: Odds ratio; CI: Confidence interval.

to 30.5% in the ≥70 years of age group. Table 7 offers insights into comorbidities among the 34,879 patients with DM, indicating that 13,177 of them (38%) had additional NCDs. HTN emerged as the most prevalent NCD comorbid with DM, affecting 35% of these cases.

3.4. BA

Among the 70,178 patients with NCDs, 6,212 patients were identified as having BA, resulting in a PR of 0.4%. The median age for this cohort was 35 years, ranging from 0.1 to 130 years. As shown in Figure 7, the gender distribution

Table 11. Distribution of comorbid NCDs among patients diagnosed with MDs in Sana'a City, Yemen, for 2017 (*n*=4,244)

NCD	Frequency	Percentage of patients having MD with comorbid NCD (%)
HTN	307	7.2
DM	259	6.1
Epilepsy	131	3.1
BA	91	2.1
Total	788	18.5

Abbreviations: NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; BA: Bronchial asthma; MDs: Mental disorders.

Table 12. Prevalence of epilepsy by gender in Sana'a City, Yemen, for 2017 (*n*=3,014*)

Gender	Epilepsy		Total	OR (95% CI))	*p*-value
	Yes	No			
Females	1,365 (0.19%)	731,252 (99.8%)	732,617	0.98 (0.90 – 1.05)	>0.05
Males	1,642 (0.19%)	858,387 (99.8%)	860,029		
Total	3,007 (0.19%)	1,589,639 (99.8%)	1,592,646		

Note: *Gender information is missing in 7 cases out of a total of 3,014 epilepsy patients. OR: Odds ratio; CI: Confidence interval.

Table 13: Distribution of comorbid NCDs among epilepsy patients in Sana'a City, Yemen, for the year 2017 (*n*=3,014)

NCD	Frequency	Percentage of epilepsy patients with comorbid NCD (%)
HTN	228	7.6
DM	172	5.7
MD	131	4.4
Total	531	17.7

Abbreviations: NCDs: Non-communicable diseases; HTN: Hypertension; DM: Diabetes mellitus; MD: Mental disorder.

is presented, indicating that females constituted 57% of the cases, while males represented 43%. Table 8 reveals that the prevalence of BA was significantly higher among females than males, with rates of 0.5% and 0.3%, respectively. The OR for this difference is 1.56 (95% CI: 1.49 – 1.65), with a $p < 0.001$. Figure 8 illustrates a noticeable trend in the prevalence of BA, which increases progressively with age. It commences at 0.4% in the 20 – 29 years of age group and rises to 2.9% in the ≥70 years of age group. Table 9 provides an overview of comorbidities among the 6,212 patients diagnosed with BA, indicating that 1765 of them (28%) also had other NCDs. The most common NCD comorbid with BA was HTN (16.4%).

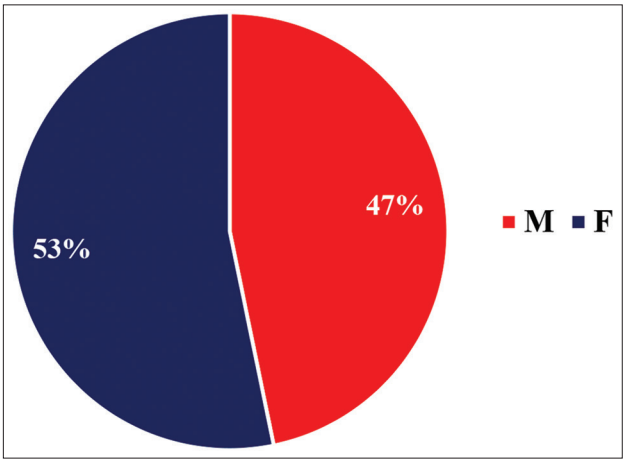

Figure 1. The gender distribution of non-communicable diseases in Sana'a City, Yemen, for 2017 M: Male; F: Female.

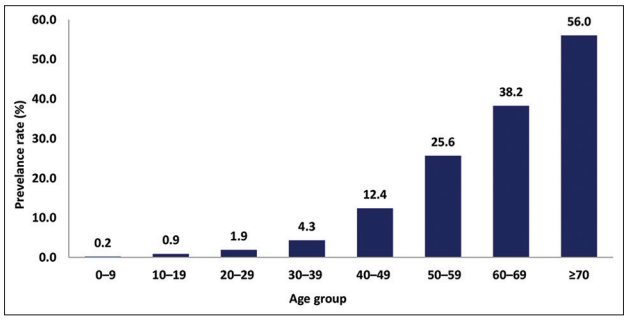

Figure 2. Prevalence of non-communicable diseases (NCDs) across age groups in Sana'a City, Yemen, for 2017 (n = 70,178*). *The age information is missing in 1,877 cases out of 70,178 NCD cases.

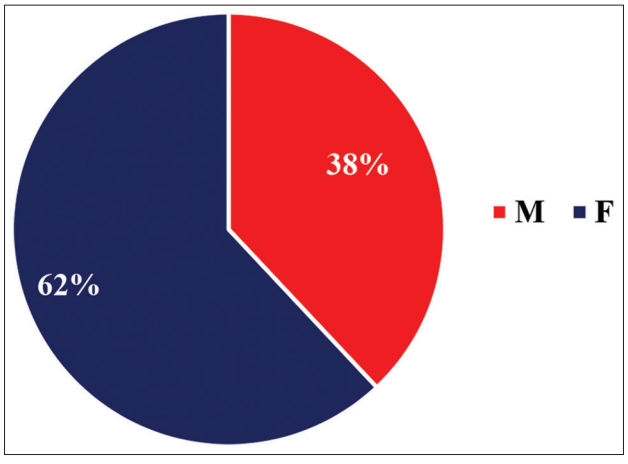

Figure 3. The gender distribution of hypertension in Sana'a City, Yemen, for 2017 M: Male; F: Female.

3.5. MDs

Among the 70,178 patients with NCDs, 4244 patients were diagnosed with MD, resulting in a PR of 0.27%. The median age for this cohort was 35 years, and the age range spanned

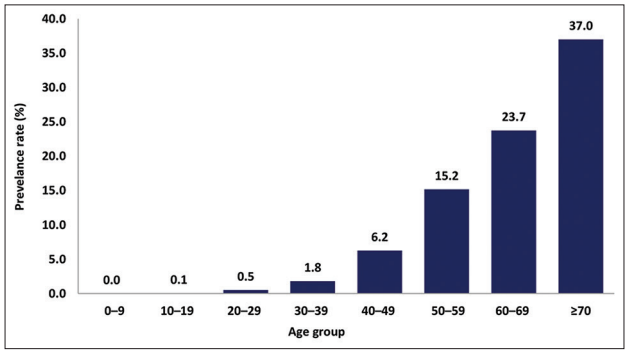

Figure 4. Prevalence of hypertension across age groups in Sana'a City, Yemen, for 2017 (n = 36,200*). *Age information is missing in 919 cases out of 36,200 hypertensive patients.

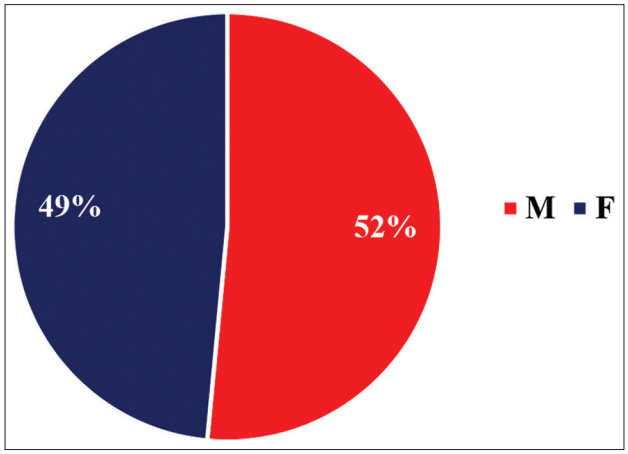

Figure 5. Gender distribution of diabetes mellitus in Sana'a City, Yemen, for 2017 M: Male; F: Female.

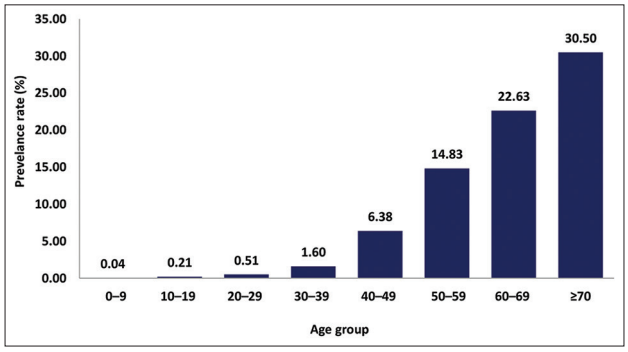

Figure 6. Prevalence of diabetes mellitus across age groups in Sana'a City, Yemen, for 2017 (n = 34,879*). *Age information is missing in 947 cases out of 34,879 diabetic patients.

from 0.5 to 95. As shown in Figure 9, the gender distribution is depicted, with males comprising 72% of the cases, while females accounted for 28%. Table 10 indicates that the prevalence of MD was significantly higher among males than females, with rates of 0.35% and 0.16%, respectively. The OR for this disparity is 2.2 (95% CI: 2.06 – 2.31), with

a $p < 0.001$. Figure 10 provides a clear representation of the progressive increase in the prevalence of MD with advancing age. It initiates at 0.39% in the 20 – 29 years of age group and rises to 1.12% in the ≥70 years of age group. Table 11 offers insight into comorbidities among the 4,244 patients with MD, revealing that 788 of them (19%) also had other NCDs. Notably, the most prevalent NCD comorbid with MD was HTN (7.2%).

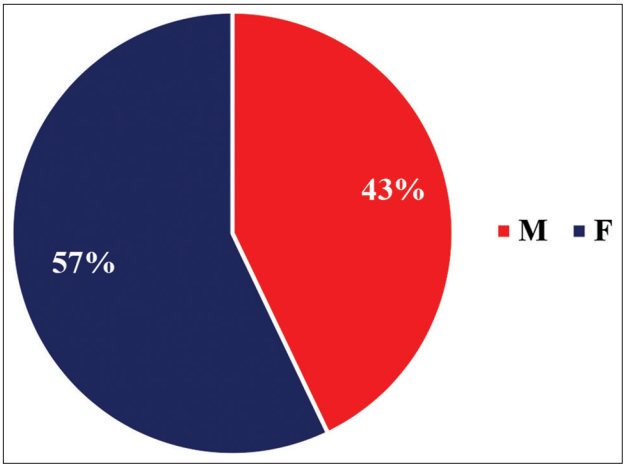

Figure 7. Gender distribution of bronchial asthma in Sana'a City, Yemen, for 2017 M: Male; F: Female.

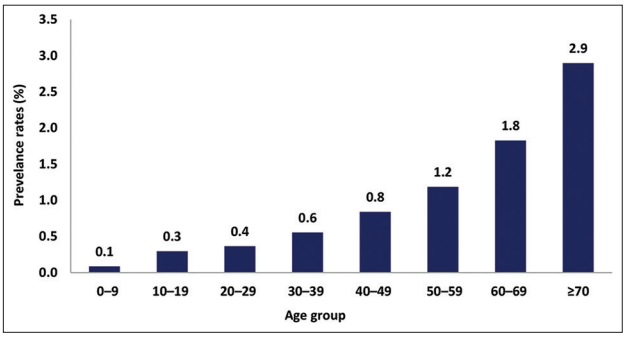

Figure 8. Prevalence of bronchial asthma (BA) across age groups in Sana'a City, Yemen, for 2017 (n = 6,212*). *Age information is missing in 135 cases out of 6,212 patients with BA.

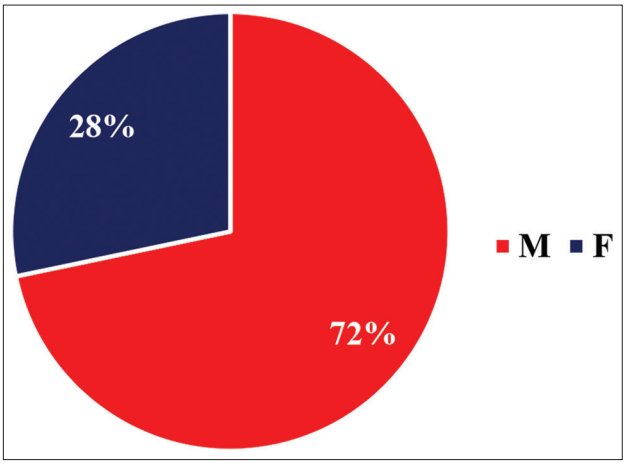

Figure 9. Gender distribution of mental disorders in Sana'a City, Yemen, for 2017 M: Male; F: Female.

3.6. Epilepsy

Among the 70,178 patients diagnosed with NCDs, 3,014 patients were identified as having epilepsy, resulting in a prevalence of 0.19%. The median age for this cohort was 24 years, with an age range from 0.3 to 100. Figure 11 illustrates the gender distribution, with males accounting for 55% of cases and females for 45%. Table 12 shows that there was no significant difference in the prevalence of epilepsy between females and males, both at 0.19%. Figure 12 presents the prevalence of epilepsy progressively increasing with age, starting at 0.25% in the 20 – 29 years of age group and rising to 0.63% in the ≥70 years of age group. Table 13 provides insight into comorbidities among the 3,014 epilepsy patients, indicating that 531 of them (17.6%) also had other NCDs. Notably, the most prevalent NCD comorbid with epilepsy is HTN (7.6%).

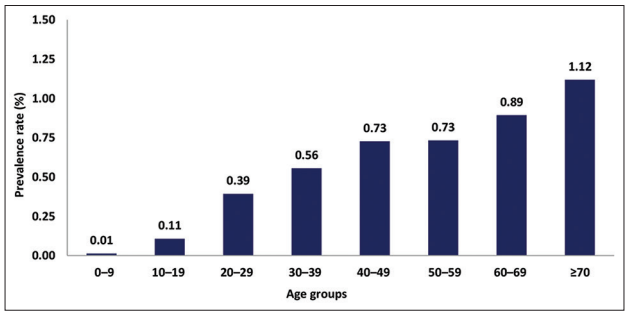

Figure 10. Prevalence of mental disorders across age groups in Sana'a City, Yemen, for 2017 (n = 4244*). *Age information is missing in 110 cases out of 4244 patients with MD.

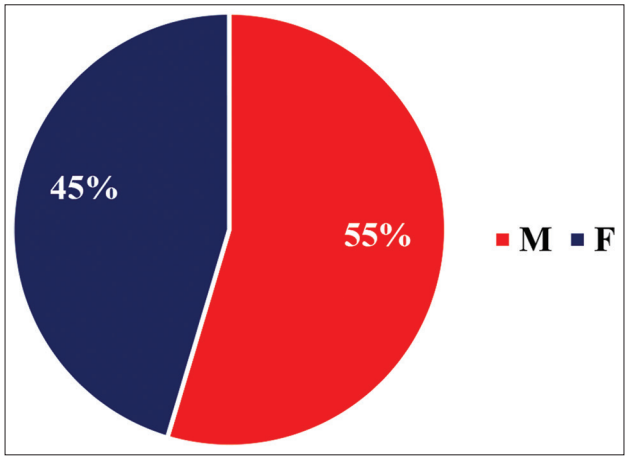

Figure 11. Gender distribution of epilepsy in Sana'a City, Yemen, for 2017 M: Male; F: Female.

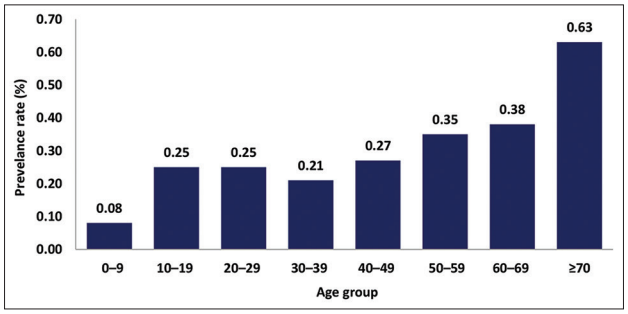

Figure 12. Prevalence of epilepsy across age groups in Sana'a City, Yemen, for 2017 (n = 3014*). *Age information is missing in 75 cases out of 3,014 epilepsy patients.

4. Discussion

The morbidity and mortality associated with NCD in Yemen are still significantly underestimated. This underestimation prompted the first house-to-house survey aimed at actively identifying cases of HTN, DM, BA, MD, and epilepsy. While the data were collected in 2017 from 13 governorates, including Sana'a City, the ongoing crises and a lack of financial support hindered the entry and analysis of the survey data. Fortunately, through the assistance of the TEPHINET mini-grant, data from Sana'a City has now been successfully entered, analyzed, and reported. The findings from this analysis hold the potential to provide the MoPHP with evidence-based data, which will be instrumental in decision-making and the development of a comprehensive plan of action for the prevention and control of NCDs. Furthermore, the results from the analysis of Sana'a City's survey data may contribute to raising awareness among key NCD stakeholders and the donor community about the magnitude of the NCD problem. The heightened awareness, in turn, may facilitate the acquisition of funding required to enter and analyze the data from the 2017 house-to-house NCD survey in the remaining governorates, ultimately offering a comprehensive understanding of the NCD landscape in Yemen.

Our results indicate that one-fourth of the surveyed households have at least one member affected by one or more of the following five NCDs: HTN, DM, BA, epilepsy, and MD. The overall prevalence of these five NCDs is 4.4%, which is notably lower than the 12.2% prevalence reported in the 2013 Yemen National Health and Demographic Survey (YNHDS) (The DHS Program, 2013). This variance may be attributed to the discrepancy in the number of NCDs included in the 2013 YNHDS, which accounted for 26 NCDs compared to only five in this survey. Nevertheless, these findings might only represent a fraction of the actual NCD burden. This is because our results depend on self-reporting of diagnosed cases rather than standardized measures, as demonstrated by a study conducted in India Vellakkal *et al.* (2013).

Based on our findings, the prevalence of NCDs was significantly higher among females than males (5.1% vs. 3.8%). This trend aligns with the 2013 YNHDS (The DHS Program, 2013) as well as with several studies from Ethiopia (Abebe *et al.*, 2017, (The DHS Program, 2013), Esteghamati *et al.*, 2009). It is worth noting that the prevalence of the five NCDs investigated in this study exhibited an upward trajectory with age, consistent with the findings of the 2013 YNHDS (The DHS Program, 2013), Zhao *et al.* (2018).

The current study identified an HTN prevalence of 2.3% among all age groups combined. This finding aligns with the results of the 2013 YNHDS (The DHS Program, 2013)), which reported a nearly similar prevalence of 2.7% among household members in urban areas of Yemen. However, the prevalence identified in this study is lower in comparison to findings in certain studies in different countries, such as 31.9% in Ethiopia (Abebe *et al.*, 2017) and 26.4% in Uganda (Guwatudde *et al.*, 2015), both of which targeted population aged 20 years or older. Our results further demonstrated a highly significant difference in the prevalence of HTN between females and males (3.1% vs. 1.6%). This trend is consistent with the findings of the 2013 YNHDS (The DHS Program, 2013) and a study from Iran (Esteghamati *et al.*, 2009), which also reported a higher prevalence of HTN in females. However, it contradicts the results of a study from Nepal (Aryal *et al.*, 2015), which found HTN to be significantly more common in males. In addition, our study showed that the prevalence of HTN increased with age, consistent with the findings of the 2013 YNHDS (The DHS Program, 2013) and the Uganda study (Guwatudde *et al.*, 2015) that similarly observed an increase in HTN prevalence with advancing age.

In the case of DM, the prevalence was found to be 2.2% among all age groups combined. This finding closely aligns with the results of the 2013 YNHDS (The DHS Program, 2013), which reported a prevalence of 2.3% for urban areas of Yemen. However, the prevalence determined in our analysis is lower than the 4.9% reported in Ethiopia (Abebe *et al.*, 2017). In addition, we observed that the prevalence of DM was significantly higher among females than males (2.3% vs. 2.1%). This trend is consistent with the findings of the 2013 YNHDS (The DHS Program, 2013). However, it contrasts with a study from Saudi Arabia, which reported a higher prevalence of DM in males than females (Sharma *et al.*, 2021). Moreover, the prevalence of DM in our study increased with age, with the highest prevalence observed in individuals aged 70 years or older. This trend is consistent with the findings of the 2013 YNHDS (The DHS Program, 2013) and a study from Saudi Arabia (Sharma *et al.*, 2021).

These findings are corroborated by the observation that the most important demographic change contributing to diabetes prevalence worldwide is the increasing proportion of elderly individuals, a trend seen across all countries (Satman *et al.*, 2023).

In our current survey, the prevalence of BA was found to be 0.4%. This prevalence is notably lower when compared to the 0.8% prevalence reported in the 2013 YNHDS (The DHS Program, 2013) among urban household members. However, our BA prevalence is much lower than that observed in Malawi (5%) (Gowshall & Taylor-Robinson, 2018) and Uganda (11.02%) (Kirenga *et al.*, 2019). This difference may be attributed to variations in the age distribution of the survey participants and differences in genetic or environmental factors. Additionally, we identified a significantly higher prevalence of BA among females than males (0.5% vs. 0.3%). This gender difference may be associated with asthma triggers and allergic comorbidities, such as allergic rhinitis and atopic dermatitis, which are more common in females (Jo *et al.*, 2023). However, this finding contradicts the findings of the 2013 YNHDS (The DHS Program, 2013), which found no gender difference in BA. It contradicts reported findings of a higher prevalence in males in the EMR (Alavinezhad & Boskabady, 2018). Furthermore, the observed increase in the BA prevalence with age aligns with the finding from the 2013 YNHDS (The DHS Program, 2013). However, this pattern contradicts the decreasing prevalence with age reported in the EMR reported by Alavinezhad & Boskabady (2018) and the study from Uganda (Kirenga *et al.*, 2019), which reported a higher prevalence of asthma among those aged 35 – 44 years compared to those either younger or older than this age group. These variations in results could be attributed to differences in the targeted population groups, geographical and environmental variations, and the operational definitions used.

In the present study, the prevalence of MD is 0.27% among all age groups combined, which is slightly lower than the 0.4% prevalence reported in the 2013 YNHDS (The DHS Program, 2013) among all age groups in urban areas of Yemen. The prevalence determined in our study is lower than that observed among the adult population in several published studies from different countries, such as 5.52% in India (Sagar *et al.*, 2017) and 5.8% in Nigeria (Gureje *et al.*, 2018). Furthermore, we identified a significantly higher prevalence of MD among males than females (0.35% vs. 0.16%). This finding aligns with the results of the 2013 YNHDS (The DHS Program, 2013)and a study from Iran (Mohammadi *et al.*, 2019). However, it contrasts with other studies that found a higher prevalence of MD among females than males in the EMR (Charara *et al.*, 2017). This discrepancy could be attributed to variations in the study population, as the study in the EMR (Charara *et al.*, 2017) specifically targeted cohorts aged above 14 years.

The increasing prevalence of MD with age is consistent with the findings of the 2013 YNHDS (The DHS Program, 2013), which reported a higher PR among individuals aged 40 and above (Petrova & Khvostikova, 2021). However, this trend contradicts a study conducted in Iran (Fakhari *et al.*, 2023), which found that the prevalence of MD in older individuals was similar to that in adults and middle-aged people. These discrepancies may be attributed to variations in sample selection, the operational definition of variables, data collection methods, and assessment tools, all of which are recognized as important factors contributing to inconsistencies in the results. Furthermore, the survey conducted in our study relied solely on self-reporting for diagnosis, which may have led to a lower prevalence compared to studies using standardized measures.

Our study revealed an epilepsy prevalence of 0.19% across all age groups, a figure closely mirroring the 0.2% prevalence reported in the 2013 YNHDS (The DHS Program, 2013) and the estimated prevalence of 0.69% in Arabic countries (Idris *et al.*, 2021). Notably, our findings contradict a higher prevalence reported in India (Panagariya *et al.*, 2018). In terms of gender distribution, our study did not find a significant difference between females and males, in agreement with the findings of the 2016 Global Burden of Disease Study (Beghi *et al.*, 2019). However, this finding diverges from the 2013 YNHDS (The DHS Program, 2013), which reported a doubled PR among males. The observed increase in the prevalence of epilepsy with age is consistent with the 2016 Global Burden of Disease Study (Beghi *et al.*, 2019). This finding may be attributed to the fact that older age groups are more susceptible to developing epilepsy compared to younger populations. Elderly individuals are at greater risk of seizures, whether triggered by acute illnesses ("provoked" or "acute symptomatic" seizures) or occurring without an obvious, immediate cause ("unprovoked" seizures) (Liu *et al.*, 2016, Lee, 2019). Regarding the prevalence of epilepsy in Arabic countries, most studies have reported a higher prevalence among males, with rates being up to 2-fold higher in children and young adults (Benamer & Grosset, 2009). These discrepancies may reflect genuine differences in genetic predisposition and structural or metabolic causes of epilepsy. Furthermore, the absence of a standard and well-accepted definition of epilepsy, along with the stigma associated with epilepsy in certain communities, where it is sometimes viewed as an "evil" attack, could potentially result in underreporting or households refraining from self-reporting cases of epilepsy.

However, the 2017 Household Survey analysis has some notable limitations. First, it lacks data on the exact number of members in each household, necessitating the use of estimated 2017 household member figures based on 2004 National Census data. Furthermore, while the survey was intended to encompass all households in Sana'a City (estimated to be 477,430 households in 2017), only 241,310 households were surveyed. Nevertheless, the sample size remains sufficiently large to derive valid conclusions.

5. Conclusion

The overall prevalence of the five NCDs was found to be 4.4%. The specific PRs for each NCD were as follows: HTN at 2.3%, DM at 2.2%, BA at 0.4%, MD at 0.27, and epilepsy at 0. 19%. Notably, the overall prevalence, as well as the prevalence of HTN, DM, and BA, was significantly higher in females, while the prevalence of MD was significantly higher in males. However, the prevalence of epilepsy did not significantly differ between genders. Nearly 18% of NCD patients had more than one disease, with the most common comorbidity being among HTN patients, where 35.2% of them also had DM. In all NCDs, the PR progressively increased with age. One-quarter of the surveyed households had at least one member with one or more of the five NCDs, contributing to an overall PR of NCDs at 4.4%. However, these data reflect only the tip of the iceberg, as the findings rely on self-reported diagnosed cases rather than standardized measures. To address this growing concern, more attention to NCDs, strengthened health-care provision, the acquisition of high-reliability data, the implementation of an NCDs stepwise survey, and the establishment of an NCD surveillance system are strongly recommended.

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Conflict of interest

The authors declare there is no potential conflict of interest relevant to this article.

Author contributions

Conceptualization: Ghamdan Gamal Alkholidy
Formal analysis: Ghamdan Gamal Alkholidy
Investigation: Ghamdan Gamal Alkholidy
Methodology: Ghamdan Gamal Alkholidy
Writing – original draft: Ghamdan Gamal Alkholidy
Writing – review & editing: All authors

Ethics approval and consent to participate

Ethical approval to conduct this study was obtained from the Directorate of Health Statistics at the MoPHP, Sana'a City, Yemen.

Consent for publication

Not applicable.

Availability of data

The raw data from the 2017 Sana'a City National NCDs Household Survey, conducted by the Ministry of Public Health and Population (MoPHP), was obtained from the Directorate of Health Statistics at MoPHP (https://doi.org/10.5281/zenodo.10028723).

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ORIGINAL RESEARCH ARTICLE

Association of burnout syndrome with mental resilience and quality of life among workers in the public and private sectors

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Abstract

The research investigated the association between burnout syndrome and the variables of mental resilience and quality of life among the workers working in Greek private and public sectors. Data were collected from 112 study participants through a survey conducted using a structured questionnaire. The questionnaire encompassed demographic questions and psychometric tools such as Burnout Assessment Tool version 2.0, brief resilience scale, and Quality of Life Enjoyment and Satisfaction Questionnaire, which were used to measure the three variables examined the research. Pearson and Spearman correlation coefficients were used to test the relationship between two quantitative variables. In conclusion, the present study found a negative correlation between burnout and the variables of mental resilience and quality of life.

Keywords: Burnout syndrome; Mental resilience; Quality of life; Public and private sectors

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1. Introduction

Mental health issues emanating from work and financial pressure are now a growing concern among the working professionals (Theofilou *et al*., 2021a; 2021b, Theofilou *et al*., 2022a; 2022b). The increasing living cost superimposed on a person's already unhealthy financial problems can bring about a feeling of depression, uncertainty and fear, disorganization, isolation, and anxiety about the job market, which catapulted the mentally affected individual into a vicious cycle of mental and professional burnout. In Greece, the actual working style defeats the idealized stereotypes of working in the public and private sectors, and the remunerations for the same role or position are not equivalent for individuals working in the public and private sectors. On the contrary, the insecurity and the feeling of uncertainty that epitomize the mentality of private sector employees, along with the long working hours and work intensity, raise concerns regarding the potential rise of burnout cases. The term "burnout" was first coined by Herbert Freudenberger in 1970 to describe the gradual emotional exhaustion and loss of motivation in volunteers at St. Mark's Free Clinic in the East Village of New York (Schaufeli *et al*., 2009).

According to Maslach and Leiter (1997), burnout is an indicator of discordance between the identity of an individual and the things they are supposed to do. It represents the degradation and erosion of a person's worth, dignity, spirit, and will. Burnout has been described as a disease that spreads and worsens over time, making it impossible for people to escape the downward spiral of this behavior pattern. Indirectly linked to increased levels of burnout in the workplace are, more rarely, panic attacks (Rus *et al*., 2016), which are defined as intense experiences of otherwise normal feelings of fear at inappropriate or unexpected times. In 2016, Maslach & Leiter (2016) has given burnout a new definition that it is a prolonged reaction of the organism to chronic emotional and interpersonal stressors at work. Burnout is categorized into three fundamental dimensions, that is, exhaustion, cynicism, and lack of a sense of accomplishment. The phenomenon of exhaustion occurs with intense and long-lasting emotions that lead to the weakening of a person's emotional and physical resources. Workers who show signs of exhaustion show difficulty in replenishing energy, and this significantly affects their interaction with other people as well as their proper functioning in the environment. Workers who manifest cynicism are characterized by their negativity, hostility, and intention to keep an extreme distance from colleagues at work, and they might also show a lack of idealism. This phenomenon is primarily caused by an individual's reaction to the emotional overload and the exhaustion he/she experiences.

The new concepts and definitions surrounding the term "mental resilience" have surfaced from different disciplines of sciences, such as psychology, sociology, psychiatry, and endocrinology, from time to time. In general, mental resilience refers to the ability of an individual to maintain or recover their mental health and to adapt to adversities optimistically (Herman *et al*., 2011). Depending on the definition, it can be perceived as either a dynamic process or a characteristic possessed by the individual to face the adversities at a certain degree. Resilience is a multifaceted concept as it is greatly influenced by culture, social support, family, and personal characteristics (Herrman *et al*., 2011; Laird *et al*., 2019). In the same vein, there is a wide range of factors that can influence mental resilience and the sense of adversity, and these factors are divided into personal, biological, and environmental categories.

In a broader sense, quality of life is a multidimensional and complex concept commonly applied to evaluate the social well-being and the status of individuals or groups (Felce & Perry., 1995), but it is recognized by many as a concept whose definition changes depending on the science it serves (Haraldstad *et al*., 2019). According to the World Health Organization (WHO), quality of life is defined as the individuals' perception of their position in life and in the context of culture to which they belong, in relation to their goals, expectations, standards, and concerns (Whoqol Group., 1995). In the domain of health sciences, quality of life appears to be of paramount importance. In particular, the use of quality of life assessment tools can lead to a significant improvement of treatment and care as well as to the detection of problems that have huge implications on patients; therefore, quality of life is regarded as a good prognostic and predictive factor (Haraldstad *et al*., 2019). At workplace, the quality of life and interrelationship among the colleagues should be held as important as work-related aspects. Work provides an individual with a clear sense of identity, inner and personal growth, and a role in society. Quality of life, according to the "standard of living" approach, refers to an individual's ability to manipulate the resources that they can utilize to control and shape their living conditions. According to other approaches, the core of quality of life covers the underlying positive evaluations and living conditions perceived by the individuals themselves (Drobnič *et al*., 2010). Apart from that, job quality, evaluated based on five fundamental dimensions, namely, skills, training, task discretion, work-life balance, and job security (Gallie, 2007), also appear to influence the quality of life.

A productive and healthy lifestyle is recognized to be directly related to high rates of satisfaction and quality of life. Studies have revealed that quality of life changes with other aspects in life and work. More specifically, individuals not engaged in shift work presented lower rates of quality of life and higher rates of unhappiness than shift workers, while it is noteworthy to mention that in the USA, medical students with a minority background were more likely to present a low rate of quality of life, along with a low sense of personal success (Dyrbye *et al*., 2006; Anand & Arora, 2009). Regarding the correlation of burnout with quality of life, a study found that a high life satisfaction is correlated with moderate burnout among the executives of multinational companies (Anand & Arora, 2009), attesting to the fact that burnout at work is inevitable if one aspires to maintain a high quality of life.

The purpose of this study is to explore the relationship between burnout syndrome and the variables of mental resilience and quality of life. The findings obtained from the present research are meant to further enrich the existing literature on the burnout syndrome. Any interpretations derived from the research outcomes could lend themselves useful in the formulation of measures targeted at preventing the burnout phenomenon among the susceptible groups, through awareness efforts and mobilization of organizations. In this study, we anticipate that burnout is negatively correlated with quality of life and resilience.

2. Materials and methods

2.1. Sampling procedure and study participants

Convenience sampling was adopted in this study to collect sample. The study participants were recruited from public and private agencies. More specifically, educators (educators, social educators, and social workers) were enrolled from the public sector, whereas administrators were enrolled from private sector. There were no specific requirements with regard to the framework of public and private bodies selected in this study. A total of 112 individuals, comprising 70 women, 41 men, and one belonging to the non-binary gender, participated. All participants voluntarily took part in the survey, which was conducted using a questionnaire form.

2.2. Materials and tools

The questionnaire constitutes several demographic questions about age, gender, occupation, and educational and academic status of the respondents. The survey also includes a standardized tool called burnout assessment tool (BAT) version 2.0 (Schaufeli *et al*., 2019), which contains 30 multiple-choice questions with the choices available from a scale from 1 to 5 (1 = Never, 5 = Always). This standardized instrument measures the principal symptoms of burnout, including exhaustion, mental distance, cognitive and emotional impairment, as well as secondary symptoms such as psychological distress and psychosomatic symptoms. This tool was also properly translated and weighted in Greek by the researchers. Furthermore, the brief resilience scale (BRS) (Smith *et al*., 2008) was incorporated into the survey to measure mental resilience of the respondents. This scale consists of six items, and each question is responded with either "agree" or "disagree." The score range for this scale is between 6 and 30. The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) tool, created in 1993 by Jean Endicott, was also integrated as part of the survey. This questionnaire contains 16 items to measure the level and degree of satisfaction that individuals experience in various areas of their lives (Endicott *et al*., 1993), and it is weighted.

2.3. Research process

Participants were asked to answer 62 questions in Microsoft forms through the Internet, after having provided online written consent and received an identification number for eventual data withdrawal. This study did not pose a threat to the safety, physical integrity, mental health, or well-being of the participants. The online survey was conducted by requesting respondents to answer a set of questionnaires encompassing a short demographic section, the BAT, the BRS, and the Q-LES-Q. After completing the questionnaire, the participants received the de-information form appended with details about the data withdrawal procedure and a thanking note. The research proposal was approved by the ethics committee of the Scientific College of Greece (number TER2023178).

2.4. Statistical analysis

The normality of the quantitative variable data was tested using the Kolmogorov–Smirnov test. Normally distributed data are expressed as mean ± standard deviation (SD), while non-normally distributed data are presented as median and interquartile range. Absolute (N) and relative (%) frequencies are used to describe qualitative variables. To test the relationship between the quantitative variables, the Pearson or Spearman correlation coefficient was used. Two-tailed test was employed to assess the significance levels, and $P < 0.05$ is considered statistically significant. Statistical program SPSS 26.0 was used for data analysis.

3. Results

The sample consists of 112 participants. The majority of the participants, amounting to 50.0%, were those in the age group of 40 – 64 years. Table 1 shows the demographic and occupational data of the participants. The female and male participants account for 62.5% and 36.6% of the sample, respectively, and 60.7% of them were single, while the rest (39.3%) have married. One-third (33.9%) of the participants have a Master's degree and 7.1% of them hold a PhD degree or were, at the time of the survey, engage in a postdoctoral fellowship. Furthermore, 75.0% of the surveyed respondents worked in the private sector, and specifically, 57.1% of them worked as employees. Full details are presented in Table 1.

3.1. Measurement of burnout scale using BAT

Table 2 depicts the descriptors of the dimensions of the burnout scale. The scale consists of 4 dimensions corresponding to the chief symptoms such as exhaustion, mental distance, cognitive impairment, and emotional impairment, as well as two dimensions corresponding to secondary symptoms such as psychological distress and psychosomatic symptoms. Each dimension was measured from a scale of 1 – 5. A higher score indicate a higher level of burnout for each dimension.

The exhaustion dimension ranged from 1.8 to 5.0 points with a mean value of 3.1 points (SD = 0.7 points). The mental distance dimension ranged from 1.0 to 5.0 points with a mean value of 2.4 points (SD = 0.9 points). The cognitive impairment dimension ranged from 1.0 to 5.0 points with a mean value of 2.3 points (SD = 0.8 points). The emotional impairment dimension ranged from 1.0 to 5.0 points with a mean value of 2.2 points (SD = 0.8 points). The overall score

for main symptoms ranged from 1.3 to 4.9 points with a mean value of 2.5 points (SD = 0.6 points). The psychological distress dimension ranged from 1.2 to 4.8 points with a mean value of 2.9 points (SD = 0.9 points). The psychosomatic symptoms dimension ranged from 1.0 to 4.8 points with a mean value of 2.4 points (SD = 0.8 points). The overall score for secondary symptoms ranged from 1.1 to 4.6 points with a mean value of 2.6 points (SD = 0.8 points).

Table 1. Demographics characteristics of the surveyed respondents

Variable	N	%
Gender		
Male	41	36.6
Female	70	62.5
Non-binary	1	0.9
Age		
18 – 39	54	48.2
40 – 64	56	50.0
65+	2	1.8
Marital status		
Single	68	60.7
Married	44	39.3
Educational level		
Gymnasium/lyceum	16	14.3
Post-secondary studies	15	13.4
Bachelor's degree	35	31.3
Master's degree	38	33.9
PhD/postdoc	8	7.1
Current employment status		
Freelancer	19	17.0
Executive/employee in a position of responsibility	29	25.9
Employee	64	57.1
Field of work		
Public sector	28	25.0
Private sector	84	75.0

The Cronbach's alpha for all dimensions exceeded 0.7, indicating acceptable reliability. Table 3 presents the burnout levels of the surveyed respondents based on the similar set of dimensions.

Based on the exhaustion dimension, 5.4% of the participants were experiencing high levels of exhaustion, while the majority suffered from moderate exhaustion (46.4%). The respondents who reported very high levels of mental distance accounted for 7.1% of the sample, and interestingly, the same percentages (7.1%) of respondents also suffered from very high levels of cognitive impairment and emotional impairment. Similar to the exhaustion and mental dimension dimensions, the majority of the participants claimed that they suffered from moderate levels of cognitive impairment (56.3%) and emotional impairment (58%), answered moderate. In terms of secondary symptoms, 6.3% and 5.4% of the participants stated that they experienced very high levels of psychological distress and psychosomatic symptoms, respectively. Resembling the trend in their main symptoms counterparts, more than half of the respondents suffered from psychological distress (50.9%) and psychosomatic symptoms (53.6%) at moderate levels. Full details in this regard are given in Table 3.

3.2. Measurement of mental resilience scale using BRS

Table 4 presents the descriptive data on the mental resilience scale. The scale ranges from 1 to 5 points. A higher value indicates a higher level of mental resilience.

The mental resilience score of the surveyed respondents ranged from 1.0 to 4.8 points with a mean of 3.2 points

Table 2. Scores of the burnout scale

	Minimum value	Maximum value	Mean (SD)	Median (indicative range)	Cronbach's alpha
Main symptoms					
Exhaustion	1.8	5.0	3.1 (0.7)	3.3 (2.5 – 3.6)	0.89
Mental distance	1.0	5.0	2.4 (0.9)	2.4 (1.6 – 3.0)	0.82
Cognitive impairment	1.0	5.0	2.3 (0.8)	2.0 (1.6 – 2.8)	0.89
Emotional impairment	1.0	5.0	2.2 (0.8)	2.1 (1.6 – 2.7)	0.87
Overall score	1.3	4.9	2.5 (0.6)	2.4 (2.0 – 3.0)	0.81
Secondary symptoms					
Psychological distress	1.2	4.8	2.9 (0.9)	2.8 (2.2 – 3.4)	0.81
Psychosomatic symptoms	1.0	4.8	2.4 (0.8)	2.4 (1.8 – 3.0)	0.77
Overall score	1.1	4.6	2.6 (0.8)	2.5 (2.0 – 3.2)	0.77

Abbreviation: SD: Standard deviation.

(SD = 0.7 points). The Cronbach's alpha value of this scale was greater than 0.7, indicating acceptable reliability.

3.3. Measurements of quality of life scale using QQ-LES-Q

The descriptive data on the quality of life scale are presented in Table 5. The scale ranges from 0 to 100 points. A higher value indicates greater enjoyment and satisfaction, which is translated into better quality of life.

In this sample, the scale of quality of life ranged from 3.6 to 100.0 points with a mean value of 58.7 points (SD=0.90 points). The Cronbach's alpha value of this scale exceeded 0.7, indicating acceptable reliability.

Table 6 presents the ratings of the surveyed respondents in the overall satisfaction over the week leading up to the survey and the satisfaction with medication, particularly among those who take medications for treatment purposes.

More than half of the participants (53.5%) reported high levels of overall satisfaction ("good" and "very good") during the week before the survey. Slightly less than a quarter of the respondents (22.3%) had a neutral feeling about the overall satisfaction over the week before the survey. For those taking medication, 30.3% of them were highly satisfied with their medications ("good" and "very good"), while a quarter of them (25.8%) reported neutral level of medication satisfaction. Details regarding the overall satisfaction and medication satisfaction among the surveyed respondents are summarized in Table 6.

3.4. Correlation of the quality of life scale, mental resilience scale, and burnout scale

Table 7 depicts the correlations between the quality of life scale, mental resilience scale, and dimensions of burnout scale.

Table 3. Burnout levels of the surveyed respondents

Dimension	N	%
Exhaustion		
Low	25	22.3
Moderate	52	46.4
High	29	25.9
Very high	6	5.4
Mental distance		
Low	18	16.1
Moderate	60	53.6
High	26	23.2
Very high	8	7.1
Cognitive impairment		
Low	20	17.9
Moderate	63	56.3
High	21	18.8
Very high	8	7.1
Emotional impairment		
Low	19	17.0
Moderate	65	58.0
High	20	17.9
Very high	8	7.1
Psychological distress		
Low	20	17.9
Moderate	57	50.9
High	28	25.0
Very high	7	6.3
Psychosomatic symptoms		
Low	21	18.8
Moderate	60	53.6
High	25	22.3
Very high	6	5.4

Table 4. Score of the mental resilience scale

	Minimum value	Maximum value	Mean (SD)	Cronbach's alpha
Mental resilience scale	1.0	4.8	3.2 (0.7)	0.84

Abbreviation: SD: Standard deviation.

Table 5. Score of the quality of life scale

	Minimum value	Maximum value	Mean (SD)	Cronbach's alpha
Quality of life scale	3.6	100.0	58.7 (18.8)	0.90

Abbreviation: SD: Standard deviation.

Table 6. Overall satisfaction and medication satisfaction among the surveyed respondents

	N	%
Overall satisfaction		
Very little	5	4.5
Little	22	19.6
Neutral	25	22.3
Good	51	45.5
Very good	9	8.0
Medication satisfaction		
Very little	18	27.3
Little	11	16.7
Neutral	17	25.8
Good	15	22.7
Very good	5	7.6

Table 7. Correlations between quality of life, mental resilience, and burnout

	Mental resilience	Dimensions of burnout					
		Exhaustion	Mental distance	Cognitive impairment	Emotional impairment	Psychological distress	Psychosomatic symptoms
Quality of life	0.424***	−0.488***	−0.339***	−0.285**	−0.351**	−0.497***	−0.340***
Mental resilience	/	−0.388***	−0.232*	−0.434***	−0.339***	−0.473***	−0.323**

Note: *P<0.05, **P<0.01, ***P<0.001.

The quality of life scale was found to have a moderate positive correlation with the mental resilience scale (r[110] = 0.424, P < 0.001 [two-tailed]), indicating that greater mental resilience was associated with better quality of life. Conversely, its correlation was moderate and negative with exhaustion (rho [112] = −0.448, P < 0.001 [two-tailed]), mental distance (rho[112] = −0.339, P < 0.001 [two-tailed]), emotional impairment (rho[112] = −0.351, P < 0.001 [two-tailed]), psychological distress (rho[112] = −0.497, P < 0.001 [two-tailed]), and psychosomatic symptoms (rho[112] = −0.340, P < 0.001 [two-tailed]). The correlation of quality of life scale with cognitive impairment dimension was negative and weak (rho[112] = −0.285, p = 0.002 [two-tailed]). In summary, an increase in any dimensions of the burnout scale could imply a reduction in quality of life. The mental resilience scale had a negative and moderate correlation with exhaustion (rho[112) = −0.338, P < 0.001 [two-tailed]), cognitive impairment (rho[112] = −0.434, P < 0.001 [two-tailed]), emotional impairment (rho[112] = −0.339, P < 0.001 [two-tailed]), psychological distress (rho[112] = −0.473, P < 0.001 [two-tailed]), and psychosomatic symptoms (rho[112] = −0.323, P = 0.001 [two-tailed]). The correlation of mental resilience with the mental distance was negative and weak (rho[112] = −0.232, P = 0.014 [two-tailed]). Thus, a increase in any dimensions of the burnout scale is associated with an increase in mental resilience, and *vice versa*.

4. Discussion

The purpose of the study was to investigate the relationship between burnout and the variables of mental resilience and quality of life among the workers in public and private sectors. The results are in agreement with the research hypothesis that burnout presents a negative correlation with quality of life and mental resilience. Based on the research outcomes, we deduce that the cut-throat environment typified by high burnout levels is strongly associated with lower quality of life and reduced mental resilience, indicating that unfavorable conditions may affect other variables, such as mental health and quality of life.

Our analysis also showed that higher levels of mental resilience are correlated with higher levels of quality of life, and *vice versa*, suggesting a positive correlation between these variables. On the contrary, burnout at workplace, which is divided into and different dimensions, could scale down the quality of life and mental resilience, highlighting the negative correlation of burnout levels with these variables. These results congruent with the results in existing literature (Leiter *et al*., 2015; Anand & Arora, 2009).

We acknowledge several limitations in the present study. First, this study used a rather small sample size, with participants recruited from only a few agencies. Second, the overrepresentation of female participants in this study might introduce gender-based biases in the interpretation of findings.

5. Conclusion

This study showed that the burnout level is negatively correlated with the variables of mental resilience and quality of life, confirming the similar association implied in existing literature. Different from the past studies, this research attempted to investigate new parameters such as special characteristics of the work and employment status. We believe that the findings of this study are useful to the senior managers and chief executives of both public and private agencies who aspire to build a well-balanced work environment with the aim of diminishing work burnout. Our findings can also be utilized to inform policy-making targeted at the susceptible groups.

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Conflict of interest

The authors declare no conflicts of interest.

Author contributions

Conceptualization: All authors
Investigation: All authors
Methodology: All authors

Formal analysis: Plemmenos, Theofilou
Writing – original draft: Plemmenos, Theofilou
Writing – review & editing: Plemmenos, Theofilou

Ethics approval and consent to participate

The study was approved by the SCG Ethics Committee (approval numberTER2023178). Informed consent was taken from the participants before their participation.

Consent for publication

Informed consent of study participants has been acquired for publishing their data. The questionnaires were completed anonymously by the participants, and only researchers had access to their data.

Availability of data

Data used in this work are available from the corresponding author on reasonable request.

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REPORT

Assessing chronic community health needs through a pharmacy improvement project

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Abstract

Assessing community health needs is essential for providing comprehensive nursing care. This paper reported the usage of pharmacy supply over a 3-month period in Riverton, Jamaica. During the data collection process, we tracked the use of supplies and medications within the Riverton community during that timeframe. The findings we obtained from this quality improvement project reinforced the observations from the initial windshield survey/tour, which indicated that there are numerous unaddressed chronic health conditions within this community. Tracking pharmacy supply usage can be an alternative approach to conducting a windshield survey/tour. Therefore, these approaches can be employed in other communities to yield accurate data on chronic health conditions within a community.

Keywords: Community health; Chronic conditions; Windshield tour; Pharmacy

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1. Introduction

Comprehensive assessment has always been the first step in delivering nursing care. Community health assessments have historically taken place through windshield tours (McGuirt *et al.*, 2011). This approach enables nurses to survey the population they serve, allowing them to identify community needs and formulate appropriate interventions. However, access to primary care, medical providers, and pharmacologic agents is not a basic right, especially in poverty-stricken areas like Kingston, Jamaica.

The community of Riverton is located in the parish of St. Andrew and is home to approximately 3000 people who face daily struggles to meet their basic needs (Junior Rowe, personal communication [March 12, 2022]). Each year, the community hosts a health fair in conjunction with the University of West Indies to provide primary care services to the residents of Riverton. These residents who need medical care services outside of these pre-established treatment dates must navigate access to local hospitals, often hindered by barriers like lack of transportation and inadequate money to pay for prescriptions.

A school in Riverton is the heart of the local community. It not only serves as an educational center for children aged 3 – 10 but also as the local hub of communication. In addition, when the small attached pharmacy is open at the school, it provides a venue for receiving medical services. Originally intended to cater primarily to ill children during school hours, the pharmacy swiftly transitioned to accommodate other members

living in the Riverton community. The physical space of the pharmacy comprises two rooms, totaling approximately 400 square feet. One room is equipped with cabinets for storing medical supplies and medications, along with an examination table. The other room functions as a triage area, housing the nurse's desk and the basic equipment needed to operate a school nurse's office.

During the authors' first visit to the community in March 2020, interactions with the residents of Riverton highlighted numerous unaddressed health needs. A day of home visits conducted alongside local nursing students led to the discovery of prevalent health issues, including stage four pressure ulcers, uncontrolled hypertension, chronic pain, diabetic foot sores, infected skin lacerations, and malnutrition. As nursing faculty and students sought to access the school pharmacy for essential supplies such as gauze, peroxide, and antibiotic cream required for patient care that day, they were met with empty shelves. This emptiness was attributed to the fact that the school pharmacy relied solely on donations. Within their small community, the citizens of Riverton lacked access to basic healthcare supplies. To access the necessary materials, they had to have resources to travel outside their community, and to many citizens, that was simply not possible. This experience inspired the idea for a pharmacy quality improvement project during the next visit.

The quality improvement project focused specifically on providing necessary medical supplies and over-the-counter (OTC) medications to the community. Onsite, only OTC medications were available because the school pharmacy was not regulated by the government or staffed by a pharmacist. The school principal and three assigned teaching staff members, equipped with basic first aid knowledge, were the only individuals with keys and access to the pharmacy for distributing supplies.

The demand for first-line relief of health-care challenges, particularly in poor, isolated communities across the globe, is often met through some form of a community pharmacy (Hermansyah *et al.*, 2018). Numerous factors driving help-seeking behavior and health service utilization have been identified. Understanding these drivers is vital for providing effective and competent treatment, making it a social justice issue, especially when considering marginalized communities. Clearly, these factors are interconnected, emphasizing the need for a systematic and depth-oriented approach to consideration.

The realities of access in marginalized communities are limited due to the fiscal realities faced by residents. Cost plays a major role in shaping healthcare-seeking behavior (Rutter, 2020). The expenses associated with health-care visits, accessing medical providers, and obtaining prescribed medications present substantial challenges, particularly in marginalized communities that often struggle with the ease of access (Curley *et al.*, 2016). The cost of service directly affects help-seeking behaviors.

Related to general access challenges, there is a growing desire for autonomy among help-seekers (Rutter, 2020). Perceptions about health-care products and the expectations of help-seekers drive this increased desire for autonomy in the context of help-seeking (Sabater-Galindo *et al.*, 2016). Consequently, such help-seeking behavior from a community pharmacy can be viewed, at least partially, as a function of autonomous self-care practices (Hassell *et al.*, 2000).

At least partially, people tend to use what is most accessible and what they believe will be beneficial for them. This decision-making process is far from being purely "objective." Choices are influenced by the usage patterns of others, recommendations they receive, and community-held beliefs about the effectiveness of treatments (Hassell *et al.*, 2000). Behind these choices lies an understanding of the effectiveness and safety of the products. In many cases, this results in a triage type of choice (Curley *et al.*, 2016). In short, if a product is accessible, deemed safe, and effective, it gains community acceptance and is used (Rutter, 2020). An obvious concern is that these culturally driven community practices can lead to the misuse of OTC medications and misdiagnosis (Azzi *et al.*, 2019). When patients lack access to healthcare professionals, they often resort to self-diagnosis and self-prescription. This behavior can be dangerous, as it can lead to delayed diagnoses and masking of symptoms crucial for clinical decision-making (Dunphy *et al.*, 2019).

The 21st century has witnessed a marked growth in the number of OTC medications (Rutter, 2020). While the range of products available may vary based on governmental regulations, the overall number of available medications has increased. Primarily driven by the profit-making strategies of drug companies, the result is an overall increase in OTC products (Rutter, 2020). This expansion has been further supported by the growth of online medical information. Unfortunately, the lack of robust regulatory practices to validate factual content has been linked to misuse (Carney *et al.*, 2018). Taken together, these trends might lead help-seekers to believe that they can manage their needs without consulting a doctor (Rutter, 2020; Curley *et al.*, 2016).

The increased access to OTC medications, coupled with limited financial resources and a shortage of health-care providers in the Riverton community, collectively hindered comprehensive health-care access. The lack of both preventive services and acute care medicine is linked to elevated morbidity and mortality rates, resulting in a

decreased quality of life (Basu *et al.*, 2019). This quality improvement project aims to help restore and rebuild a health-care structure within this underserved Jamaican community, fostering health promotion and improved well-being among its members.

2. Materials and methods

The authors had previously been invited into the community on several occasions, initially focusing on projects aimed at physically improving housing structures. However, on the trip just before this study, the team was tasked with addressing the pharmacy attached to the school due to the presence of nursing faculty and students in the community. The local community liaison compiled a list of needs for the community, supplementing the supplies and medications identified by nursing faculty during her 2020 walking/windshield tour. Fundraising efforts were carried out in the United States before travel, and over USD500.00 worth of donated OTC supplies were brought into the Riverton pharmacy in March 2022. At the time, the shelves were nearly empty, housing only a couple of outdated bottles of aspirin. During a prior visit, the authors had conducted a community needs assessment. The identified community needs were key drivers for purchasing pharmacy supplies for the next visit.

The donated OTC products were divided into six categories: Analgesics (pain pills, pain patches, aspirin, pain cream, and hemorrhoid cream), personal care items (toothbrushes, toothpaste, panty liners/pads, adult pads/diapers, petroleum jelly, hand sanitizer, and nail clippers), orthopedics (knee braces, wrist braces, ankle braces, and ice packs), wound care (antibiotic cream, alcohol pads, band-aids, wound care kits, hydrogen peroxide, and tweezers), OTC medications (probiotics, women's vitamins, anti-itch cream, allergy pills, nasal spray, antacids, anti-diarrheal pills, diabetic foot cream, eye drops, chest rub, and calamine lotion), and children's medications and supplies (children's pain medications, children's allergy medication, baby wipes, electrolyte replacement, and gummy vitamins). No antibiotics, prescription drugs, or controlled medications were transported or brought into the community despite the request of Mr. Rowe, the Riverton school principal. This decision was based on the considerations concerning licensing and prescribing regulations.

Funding for both the school and the attached pharmacy is provided by St. Patrick's Foundation. The yearly operating budget for the school amounts to 11 million Jamaican dollars, approximately USD 72,000/year. This allocation covers expenses such as school supplies, teacher salaries, and day-to-day operational costs (Junior Rowe, personal communication [October 13, 2022]). The school pharmacy relies solely on donations for its funding. Due to financial hardships compounded by the global impact of COVID-19, the Riverton school district had to curtail expenditures, including the role of a part-time school nurse. For the past 2 years, the oversight of the school pharmacy has been undertaken by three teachers within the school district who are unlicensed medical personnel. The distribution of medical supplies in this study is impacted by limited operating hours — 3 – 5 h a week — and the distribution of supplies by unlicensed medical providers.

3. Results

Table 1 illustrates the pharmacy products that were donated and the corresponding usage rates during the first 3 months (March 15, 2022 – June 15, 2022) following the restocking of the pharmacy, as reported by the headmaster of the school where the pharmacy is located.

The results reveal robust usage of the products during the first 3 months after restocking the pharmacy. Among the categories, personal care items and children's medications and supplies exhibited the highest rates of usage, while wound care demonstrated the lowest. The unexpectedly low rate of use for wound care products raised questions, considering the study site was organically constructed on top of the city dump and is littered with broken glass and rusty pieces of metal. In addition, during the team's visit to set up the pharmacy, they provided care to a number of individuals with wound care needs. This prompts speculation that the infrequent use of wound kits might be attributed to a lack of familiarity with their proper use by community members. Another possible reason for the modest supply usage could be that the community members were unaware of the recent replenishment of products. In addition, the cautious distribution of supplies by the school principal, who has experienced shortages in the past, could be a contributing factor. Overall usage rates were high, reflecting a general need for pharmacy products and preventive health-care services within the community.

Although the study only tracked usage of pharmacy products over a 3-month period, continued communication with the principal indicated that all donated products were used within a span of 5 months. These findings further support the main premise of this study: Isolated communities with limited access to medical supplies still grapple with unaddressed needs for their chronic health conditions. Furthermore, once community members become aware of newly donated supplies, there is an increase in the consumption of pharmacy products.

4. Discussion

The Riverton community, like many others worldwide, faces geographical and economic isolation. Poor health-

Table 1. Pharmacy improvement products and usage

Pharmacy product category	Total number of items provided	Total number of items used in the 3-month period of study	Percentage of usage
Analgesics	45	27	60
Personal care items	46	40	87
Orthopedics	15	7	47
Wound care	74	20	27
Over-the-counter medications	60	36	60
Children's medications and supplies	46	30	65

care conditions are influenced by a combination of factors collectively known as the social determinants of health (SDOH) (Craig *et al.*, 2021; Palmer *et al.*, 2019). The five domains of SDOH (health-care access and quality, educational access and quality, social and community context, economic stability, and neighborhood and built stability) are all addressed as an aspect of the community pharmacy improvement project (Miller, 2021). The challenge of health-care access continues to persist for the residents of Riverton. By establishing a de facto community pharmacy within the community primary school, the quality of education provided by the school is improved. Placing the pharmacy in the center of this isolated and impoverished community aligns with the community context. Providing free basic health supplies assists the residents of this community, which is situated on top of a large city dump, and thus promotes neighborhood stability. The fundamental right to basic healthcare is a struggle for most citizens in the Riverton community. They rely on sporadic external donations to support and stock their small community pharmacy. Small communities like these need a sustainable flow of pharmacy products and health-care providers to ensure community health. Building and fostering a sense of community are an essential element in establishing societal sustainability (McKnight & Block, 2010).

Creating a sustainable model for Riverton will require collaboration between local agencies and/or organizations, potentially including colleges from the United States. The initial step in promoting health for the citizens of Riverton, Jamaica, involves the reconstruction and staffing of the school pharmacy with a part-time nurse. Establishing a consistent health-care provider within the community is crucial. This nurse could also serve as a liaison between volunteer medical providers, colleges, and universities, as well as the occasional local doctors and nurses who attend to patients in the community. At present, the Riverton community receives paid visits from doctors, nurses, and assistants 4 times/year. Each visit sees approximately 40 – 60 patients, and the funding comes from an external charity organization (Junior Rowe, personal communication [March 12, 2022]). However, the needs of the Riverton population surpass the quarterly visits by medical professionals each year. This community is burdened with a high prevalence of medical conditions such as hypertension, diabetes, cardiovascular disease (Ferguson *et al.*, 2017), chronic obstructive pulmonary disease, asthma, and other chronic diseases that require closer patient monitoring. As an underserved community, many citizens have become accustomed to addressing their medical needs without access to medical or pharmacy interventions. This could also explain the delayed use of donated wound care supplies. They typically have to make do with what is available when supplies are scarce.

The authors believe that fostering inter-institutional relationships between local and international academic institutions, or a combination of both, holds extreme importance in the development of a sustainable model. Exploring resources both locally and internationally can provide a foundation for acquiring essential resources, with the goal of establishing sustainability using in-country means. In addition, adopting a holistic approach that includes all aspects of the person and/or community is equally important in constructing a sustainable structure. This is accomplished by the inclusion of other health and human services departments. The inclusion of physical therapy, occupational therapy, speech pathology, and social work within this community has been essential for our dedicated work in Riverton. As indicated, medical services are the conduit that paves the way for more comprehensive services, which this community identified as necessary during the windshield survey.

Facilitating the involvement of additional health-care providers to collaborate with the community members within the pharmacy setting will help promote health and address the many chronic health conditions faced by the Riverton citizens. Furthermore, this initiative would provide valuable learning opportunities for students who engage in short-term visits. Specifically, while acute medical needs were indeed observed during the authors'

presence in the community, the data reflects that the most commonly used pharmacy items were the most basic ones — personal care items and children's medications. The fact that these products were the most commonly used appears to reflect the reality that, in this community and other isolated, highly impoverished communities across the globe, the basic SDOH are often left unaddressed. With this understanding in mind, it emphasizes the importance of establishing fundamental pharmacy programs in such communities. It is important to acknowledge the limitations of this study, which are primarily rooted in the small and isolated nature of the participant group consisting of 3000 individuals, potentially limiting the generalizability of the findings to all parts of Jamacia.

5. Conclusion

Conducting windshield tours and tracking the use of pharmacy products offer health-care providers a comprehensive approach to assessing community health needs. Communities worldwide, especially those that are isolated and impoverished, face the challenge of fulfilling the basic needs of their residents. Raising awareness and facilitating sustainable financial support for this community can contribute to the health and well-being of its citizens. Future improvements encompass reinstating the school nurse, regularly replenishing medical supplies, providing preventive health-care education to community members, fostering collaboration with local non-government organizations, and engaging higher education institutions. In summary, the pharmacy serves as the heart of the community for both the school and its adult members. Establishing sustainable solutions to revitalize the small pharmacy, ensuring consistent availability of basic supplies and equipment, will further improve accessibility to unaddressed health-care needs within the community.

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Conflict of interest

The authors declare no conflicts of interest.

Author contributions

Conceptualization: Samantha Ciardi Sassone
Formal analysis: All authors
Investigation: Samantha Ciardi Sassone, Mark A. Primus
Methodology: Jed Metzger
Writing – original draft: All authors
Writing – review and editing: All authors

Ethics approval and consent to participate s

Not applicable.

Consent for publication

Not applicable.

Availability of data

Supporting data can be obtained from the corresponding author following a formal request.

Further disclosure

Part of these findings has been accepted for presentation at the AAC&U 2023 Global Learning Conference in Washington, D.C., USA.

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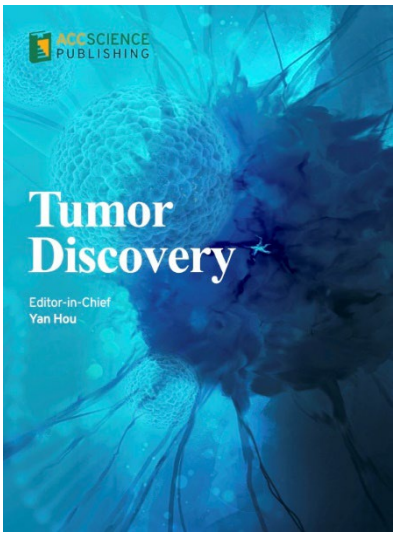

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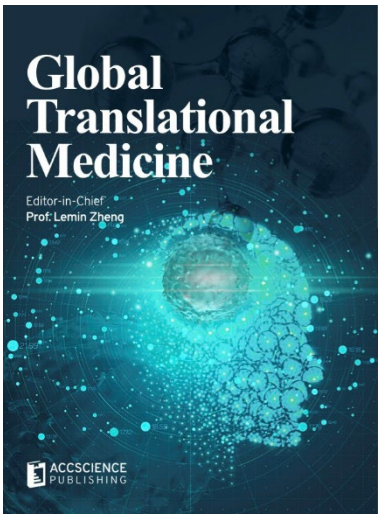

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