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Content analysis of pictograms used in pharmaceutical leaflets in Turkey

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ABSTRACT

This study investigates the use of pictograms in pharmaceutical leaflets in Turkey as a means to enhance patient understanding and compliance with medication instructions. The research examines the frequency, characteristics, and effectiveness of pictograms in drug instructions licensed by the Turkish Medicines and Medical Devices Agency. A cross-sectional, exploratory, and descriptive approach was used to analyze 17,709 drugs, with a focus on 1,959 drugs that feature at least one pictogram. Findings indicated that 11.1% (n=1,959) of licensed drugs utilized pictograms, mainly for sensory organ and respiratory system medications requiring specific administration. The study found most pictograms to be simple, averaging under seven images. Notably, 55.95% (n=1,095) included human figures, yet only 32.8% (n=359) depicted full faces or bodies. Pictograms with accompanying text were infrequent, but 96.3% (n=428) of the included text was readable. Consequently, promoting the widespread use of a standardized pictogram set within the Turkish pharmaceutical sector is crucial.

Keywords: health communication, medication adherence, pharmaceutical leaflets, pharmaceutical pictograms, Turkey

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INTRODUCTION

Medicines, defined as chemicals or compounds used for the treatment, prevention, and management of diseases, are the most common intervention in healthcare[1]. Although thousands of medicines have been developed to combat diseases today, medication adherence is the cornerstone of treatment effectiveness and success[2]. According to the World Health Organization, medication adherence is defined as "the extent to which a person's behavior coincides with the recommendations of the healthcare provider"[3]. Medication non-adherence, a global health issue, is viewed as the failure to translate decades of enormous financial and human capital investment into the development of proven treatments that improve clinical outcomes[4]. Despite more than half a century of dedicated work and interventions, it has been reported that global medication adherence still does not exceed the 50% reported twenty years ago[5] and this continues to negatively affect the quality of life, life expectancy, health outcomes, and healthcare costs worldwide[6,7].

Medication non-adherence can be caused by various factors related to treatment, the patient, or the healthcare system[8]. However, especially in outpatient settings, it is the patient's responsibility to apply the information provided about medical treatment appropriately[9]. Understanding medication therapy is critical for adherence and the safe and effective use of medicines. One of the risk factors for medication non-adherence is the inability to retain verbal information[10]. Studies show that 40-80% of the information provided by healthcare professionals is quickly forgotten, as patients tend to focus more on clinical diagnosis information and often cannot recall information about medication therapy[3,11,12]. This situation worsens when health literacy is low[13,14]. Moreover, it is recognized that text-based instructions, which are the most accessible and frequently consulted source of information for patients, are difficult to understand even for literate individuals due to their complex designs, layouts, technical terms, and language[12,15]. This challenge is even greater for immigrants and tourists due to language barriers[9].

One way to facilitate patients' understanding of prescribed pharmacotherapy is by supplementing labels and instructions with visual tools such as pharmaceutical pictograms[9,16]. Pictograms represent actions (e.g., putting drops in the eye) graphically to ensure that the underlying meaning is understood independently of the patient's literacy skills[17]. A pictogram is defined as a two-dimensional figurative/ metaphorical drawing designed to attract attention and convey information or express an idea[18]. Studies have shown that pictograms improve patients' understanding of the correct use of medicines and, consequently, their adherence[9,15,19,20,21,22].

The use of pictograms has gained increasing attention in recent years, likely due to growing awareness among healthcare professionals of the need to provide sufficient information to patients who have difficulty understanding their treatments, such as the elderly, children, and those with low literacy levels[23-26]. In pharmacy, two reference systems are commonly used for pictograms: The United States Pharmacopeia (USP) and the International Pharmaceutical Federation (FIP). The USP offers 82 pictograms that are available for free download after accepting the license agreement[27]. USP pictograms are standardized graphic images designed to help communicate drug instructions, precautions, and/or warnings to patients and consumers, and they are widely used in Western countries. However, studies on their availability and comprehensibility in countries like South Africa have highlighted potential limitations[6]. In contrast, FIP pictograms, developed in June 2009, have been pre-tested in different populations and were most recently updated in February 2017 to address comprehensibility issues[28-29].

In Turkey, the information that must be included in the packaging and instructions for use of licensed or authorized human medicinal products to ensure their correct use for the health and safety of individuals is regulated by Law No. 30048, dated April 25, 2017, which states that symbols and pictorial diagrams that are useful to users and other information consistent with the summary of product characteristics may be included[30]. Thus, there is no standard or requirement for the use of pictograms. To date, no research has been found in the literature that evaluates the use of pictograms in drug instructions in Turkey. Considering current legal regulations and the literature, it is necessary to determine the characteristics of pictograms used in licensed drugs in Turkey. This exploratory and descriptive study aims to determine the frequency of pictogram use in the instructions for use of licensed drugs in Turkey and to reveal the qualitative and quantitative characteristics of the pictograms used. Considering that medication compliance plays a vital role in achieving positive health outcomes, easily understandable and consistent pictograms can greatly enhance patients' ability to follow their medication instructions accurately. Consequently, this research holds the potential to highlight areas for improvement in medication adherence through the strategic implementation of standardized visual cues.

METHODOLOGY

This cross-sectional exploratory and descriptive study was conducted to determine the frequency of pictogram use in the patient information leaflets of the drugs licensed by the Turkish Medicines and Medical Devices Agency and to examine the characteristics of the pictograms used[31]. The population of the study consists of 17,709 drugs licensed by the Turkish Medicines and Medical Devices

Agency and listed in the summary of product characteristics/patient information leaflets list on the agency's website as of January 2024. In the first stage of the study, no sampling was conducted, and the patient information leaflets of all drugs in the list were examined. Content analysis was performed for 1,959 drugs with pictograms in their patient information leaflets. These pictograms are manufacturer-generated as no standard pictogram set exists in Turkey for pharmaceuticals. Content analysis, originally developed for analyzing written and verbal texts, was used in this study based on its definition as "the systematic, objective, and quantitative analysis of message characteristics"[32]. Visual content analysis involves methodologically examining and analyzing a series of images for the presence of common visual elements and the frequency of repeated visual elements[32]. The visual content analysis followed four steps: 1) defining the criteria for selecting pictograms, 2) developing categories for coding, 3) coding the images, and 4) analyzing the results[33]. The inclusion criterion for pictogram selection was that the images in the patient information leaflets should consist of at least two images, or if there was only one symbol/image, it should have a reference/meaning related to the application/use. There is no standard or tool for evaluating the appropriateness of pharmaceutical pictograms. Based on the literature, the following categories were determined for the content analysis of the pictograms, allowing for a more objective assessment[34]:

1. Concrete or abstract nature of the pictogram: Pictograms depicting real objects were considered concrete, while design elements that did not pictorially represent objects (e.g., arrows, lines, shapes, and letters) were considered abstract.

2. Drawing/real image status.

3. Use of a human face/body in the pictogram.

4. Complexity or simplicity of the pictogram: Pictograms with more visual elements and details were considered complex, while those with fewer visual elements and details were considered simple, and the number of visuals in the pictogram was used as a measure.

5. Clarity of the pictogram: Assessed based on whether the pictogram was clear or blurry.

6. Use of text in the pictogram: Assessed based on the presence of text in the pictogram and the readability of the text.

Python programming language was used for coding the pictograms and for visual content analysis. The images were uploaded to the Colab editor and opened with the Pillow library. Tesseract OCR (Optical Character Recognition) was used to

separate and analyze the texts. Features such as clarity and the number of shapes in the images were evaluated using the OpenCV library. The results obtained were divided into separate rows using the Pandas library and saved as an Excel document. The results were also manually checked by comparing them with the images.

In addition to visual content analysis, some pharmaceutical information about the drugs was obtained from the Turkish Medicines and Medical Devices Agency database:

- The pharmaceutical form of the drug.
- The drug's ATC code.
- Prescription type.
- Status on the essential/children's essential drug list.

All variable data for the 1,959 drugs included in the study were combined into an Excel file. Descriptive statistics were used to evaluate the analysis results.

RESULTS and DISCUSSION

As of January 2024, it was determined that 11.1% (n=1,959) of the 17,709 drugs licensed by the Turkish Medicines and Medical Devices Agency included at least one pictogram in their patient information leaflets, while 88.9% (n=15,750) did not. Figure 1 shows the distribution of pictogram use by ATC code. As seen in Figure 1, among 17,709 licensed drugs, pictograms were used in 222 (63%) of total 350 drugs for sensory organs and 529 (30%) of total 1,735 drugs for the respiratory system. Pictogram use was lowest for 31 cardiovascular system drugs (1% of total 2,067 drugs) and 29 musculoskeletal system drugs (2% of total 1,161 drugs).

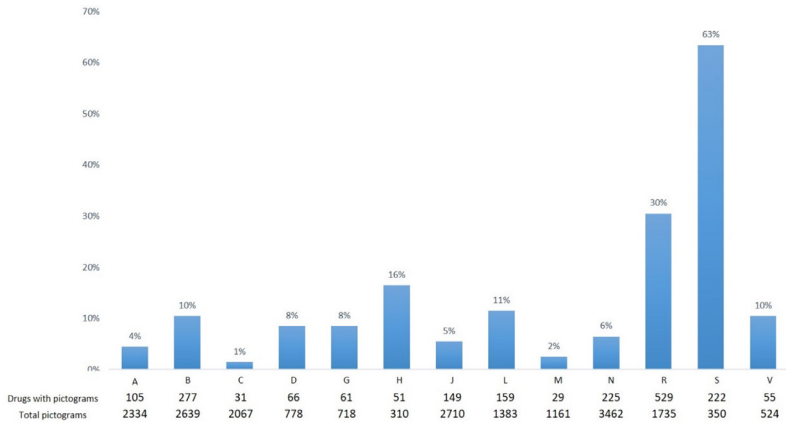

Figure 1. Pictogram use in 17,709 licensed drugs in Turkey by ATC codes (%)

The pharmaceutical characteristics of the 1,959 drugs that included at least one pictogram in their package leaflets are shown in Table 1.

Table 1. Some pharmaceutical characteristics of drugs with pictograms in the patient information leaflets

ATC Code	Number (n)	Percent (%)
A: Gastrointestinal tract and metabolism	105	5.36
B: Blood and blood-forming organs	277	14.4
C: Cardiovascular system	31	1.58
D: Dermatologicals	66	3.37
G: Genitourinary system and sex hormones	61	3.11
H: Systemic hormonal preparations excluding sex hormones and insulins	51	2.60
J: Anti-infective for systemic use	149	7.61
L: Antineoplastic and immunomodulation agent.	159	8.12
M: Musculoskeletal system	29	1.48
N: Nervous system	225	11.49
R: Respiratory system	529	27.00
S: Sensory organs	222	11.33
V: Various	55	2.81
Total	1,959	100
Form of the drug*		
Solid Dosage Forms I	102	5.21
Solid Dosage Forms II	49	2.50
Solid Dosage Forms III	64	3.27
Solid Dosage Forms Pre-Dissolved or Dispersed in Water	67	3.42
Liquid Formulations	108	5.51
Parenteral Preparations I	42	2.14
Parenteral Preparations II	84	4.29
Parenteral Preparations III	543	27.72
Sterile Eye/Ear/Nose Preparations	322	16.44
Locally Acting Semi-Solid Preparations	55	2.81
Locally Effective Liquid Preparations	34	1.74

Preparations applied by different routes (rectal and vaginal)	18	0.92
Powder-Containing Inhaler Preparations	243	12.40
Metered Dose Inhalers and Nebulization Solutions	228	11.64
Total	1,959	100
Prescription Status**		
Normal	1,816	92.70
Purple	58	2.96
Green	16	0.82
Orange	64	3.27
Red	5	0.26
Total	1,959	100
Essential Medicines List Status		
0: Medicines not on the WHO list	1168	59.62
1: Medicines that are fully compatible with the WHO list in terms of active substance, dose and formulation.	418	21.34
2: Medicines that are on the WHO list as active substance but are not compatible with this list in terms of dosage and formulation.	373	19.04
Total	1,959	21.34
Child Essential Medicines List Status		
0: Medicines not on the WHO list	1,468	74.94
1: Medicines that are fully compatible with the WHO list in terms of active substance, dose and formulation.	261	13.32
2: Medicines that are on the WHO list as active substance but are not compatible with this list in terms of dosage and formulation.	230	11.74
Total	1,959	100

*Solid Dosage Forms I; Tablet, Film-Coated Tablet, Sugar-Coated Tablet (Drage), Chewable Tablet Buccal Tablets, Sublingual Tablets.

Solid Dosage Forms II; Capsules, Soft Gelatin Capsule, Hard Gelatin Capsule.

Solid Dosage Forms III; Orodispersible Tablets.

Solid Dosage Forms Pre-Dissolved or Dispersed in Water; Granules, Effervescent Granules Coated Granules, Gastro resistant Granules Powders, Effervescent Powders.

Liquid Formulations; Oral Solution, Oral Drops Syrup, Emulsion Suspension.

Parenteral Preparations I; Ampoule/Vial Containing Solution Ampoule/Vial Containing Suspension, Ampoule/Vial Containing Powder + Solvent Ampoule.

Parenteral Preparations II; Solution for Infusion Vial/Ampoule Concentrate Solution for Infusion Vial/Ampoule Powder for Infusion.

Parenteral Preparations III; Lyophilized Powder/Suspension/Solution in Ready-to-Use

Syringe/Syringe Cartridge Solution/Suspension in Injection Pen.

Sterile Eye/Ear/Nose Preparations; Solution, Suspension, Emulsion, Ointment.

Locally Acting Semi-Solid Preparations; Gel, Cream/Lotion, Ointment.

Locally Effective Liquid Preparations; Solution, Suspension, Emulsion.

Preparations applied by different routes (rectal and vaginal); Enema, Rectal Foam, Suppositories, Pessaries.

Powder-Containing Inhaler Preparations; Capsules/Blister/Inhaler Containing Powder.

Metered Dose Inhalers and Nebulization Solutions; Nebulization Solution (Inhalation Solution) Metered Dose Inhaler / Inhalation Aerosol.

** Color codes[35]:

Normal: Non-controlled drugs are given with a white prescription.

Green: Prescription issued for drugs with a potential for addiction and abuse.

Red: Prescriptions written for drugs containing internationally controlled agents such as opioids and cocaine.

Purple: Prescriptions issued for blood and blood products.

Orange: Prescriptions issued for some blood products for hemophilia patients.

As seen in Table 1, the drug groups in which pictograms were used the most were determined as respiratory system drugs with 27%, and drugs for blood and blood-forming organs with 14.1%. The drug forms in which pictograms were commonly used were Parenteral preparations III with 27.7% (example Figure 2A), and Sterile Eye/Ear/Nose Preparations with 16% (example Figure 2B). 92.7% of the drugs with pictograms in the patient information leaflets are used with a normal prescription. 59.6% of the drugs with pictograms in the patient information leaflets are not included in the essential drugs list, and 74.9% are not included in the essential drugs list for children. Table 2 shows the content analysis results of the pictograms of 1,959 drugs with pictograms in the patient information leaflets.

Table 2. Content analysis results of pictograms in patient information leaflets

Pictogram usage	Number (n)	Percent (%)
Used in more than one leaflet for different doses/forms	1,438	73.40
Used in only one patient information leaflet	521	26.60
Total	1,959	100
Number of images		
<7 image	1,355	69.16
≥7 image	604	30.83
Total	1,959	100
Drawing/actual situation		
Drawing	1,864	95.15
Real image	95	4.85
Total	1,959	100
Clarity of the pictogram		
Clear	1,665	84.99
Blurry	294	15.01
Total	1,959	100
The presence of a human face in a pictogram		
None	864	44.05
Available	1,095	55.95
Total	1,959	100
Integrity of the human face		
Not Complete	736	67.2
Complete	359	32.8
Total	1,095	100
Use of text in pictograms		
None	1,515	77.34
Available	444	22.66
Total	1,959	100
Readability of text in pictogram		
Readable	428	96.3
Unreadable	16	3.60
Total	444	100

As seen in Table 2, 73.4% of the drugs with pictograms in patient information leaflets are also used in the same drug in different doses and forms, while 26.6% are used in only one drug. It was determined that the pictograms in the patient information leaflets with pictograms consisted of an average of 6.55 ± 4.46 images. Less than 7 images were used in 69.1% of the pictograms, while 30.83% had 7 or more images. 84.99% of the pictograms were clear, and 15.01% were blurry (example Figure 2C). It was determined that real images were used in only 4.8% of the pictograms (example Figure 2D). Human faces/bodies were used in 55.95% of pictograms, but only 32.8% of these showed full faces/bodies. (example Figure 2E). It was determined that text was used in 22.66% of the pictograms, and of these, 96.3% of the text was readable (example Figure 2F). Figure 2 shows some examples of pictograms found on drugs licensed in Turkey.

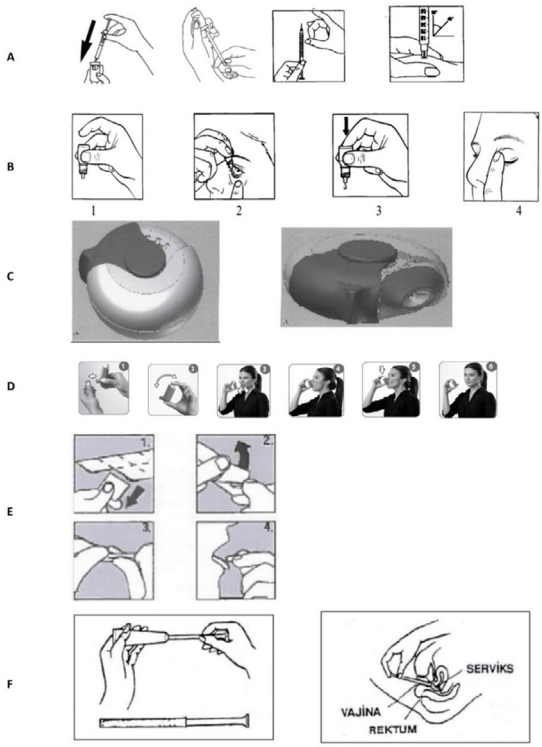

Figure 2. Some examples of pictograms used in patient information leaflets of drugs in Turkey:

2A. An example pictogram for Parenteral preparations III
2B. An example pictogram for Sterile Eye/Ear/Nose Preparations
2C. An example pictogram for blurry pictogram
2D. An example pictogram with real image
2E. An example pictogram with human face
2F. An example pictogram with readable text

Copyright/license: The images have been adapted from patient information leaflets available on the Turkish Medicines and Medical Devices Agency (TITCK) website[31], which provides publicly accessible content.

In this study, conducted to determine the frequency and qualitative and quantitative characteristics of pictograms used in the instructions for licensed medicines in Turkey, the patient information leaflets for 17,709 drugs were examined, and visual content analysis was performed on 1,959 drugs that included pictograms. The most important finding of the study is that the frequency of pictogram use in the leaflets for licensed drugs in Turkey is quite low, at 11.1%. The low use of pictograms at this level can be explained by the absence of a nationally developed standard pictogram set, the fact that internationally developed pictograms such as those by USP and FIP have not yet been validated for the Turkish population, and the lack of legal regulations by the public authority to encourage the use of pictograms. A study conducted by Pires et al. (2015) in Portugal, which examined the leaflets for cardiovascular, nervous system, and musculoskeletal system drugs, also concluded that visual elements were used very little, and the design of the leaflets needed to be carefully reviewed[36].

The second important result of the study is that pictograms are most frequently used in the leaflets for sensory and respiratory system drugs. It is thought that the forms of these drugs, which require more local application than other drug types, such as creams, sprays, drops, and ointments, and their typically more tangible nature, facilitate the use of pictograms. This observation aligns with findings from Dowse and Ehlers (2005), who highlight the potential of pictograms for complex or locally applied medications[25]. Similarly, a scoping review by Sedeh et al. (2022) on communicating with patients through pictograms and pictures in dermatological treatments (a field with frequent topical applications) likely supports the efficacy of visual communication in enhancing patient understanding and adherence for locally applied medications[37].

The third significant result of the study is that pictograms are mostly prepared to explain the use of injectors/syringes/cartridges containing powder/solution/suspension. It is not surprising that pharmaceutical companies use pictograms to facilitate the usage of these forms, which are more challenging to use, take more time, and are the patient's sole responsibility. Research indicates that clear instructions are crucial for minimizing self-injection errors, suggesting that visual aids like pictograms play a vital role in improving patient understanding and reducing mistakes with these challenging drug delivery methods[38].

In the visual content analysis, the average number of images/shapes used in a pictogram, representing its complexity, was found to be 6.55. It can be stated that 69% of the pictograms use fewer images than the average, and the overall complexity is not high. Dowse and Ehlers (1998), in their review of pictograms in pharmacy, recommended using simple, realistic images with limited content, using full body images as references for body parts, and minimizing the use of abstract symbols[24].

Another significant result of the study is that "drawings" are predominantly preferred in pictograms. The use of "real images" in pictograms is highly debated. While some studies argue that real images increase tangibility[24,39], others suggest that details in real images can distract the user and move focus away from the main point[40,41,42]. Another finding from the visual content analysis is that the criterion often emphasized in the literature, the use of full face/body for pictograms related to drug use, is met in only 32% of the instructions. It is evident that the use of the full face in the instructions for sensory organ drugs will prevent confusion and make usage easier.

Finally, the use of text in the pictogram for information such as dosage/time/action/description can make it possible for the drug to be used solely by understanding the pictogram. Indeed, Levie and Lentz's (1982) systematic review also suggested that the use of captions alongside images would make understanding easier, especially among people with low literacy skills[43]. Houts et al. (2006) also stated that when using a series of images, the sequence should be explained with simple words because people with low literacy skills might not see the connection between sequential images[12]. However, the critical point here is that the text must be legible in terms of size, character, and other attributes. It was found that 22.6% of the licensed drugs contain text in the pictogram, and 96% of these texts are legible. Houts et al. (2006) emphasized that if the text in the image is unclear, the meaning of the images might also be unclear, but if the accompanying text is clear, the images will be easier to understand[12].

It is appropriate to evaluate the study results with some strengths and limitations. The greatest strength of this study is the large sample size, which made it possible to examine the characteristics of pictograms. While the uniqueness of the study lies in the fact that no prior research has been found in the literature evaluating the presence of visual elements, including pictograms, in the patient leaflets for licensed drugs in Turkey, this also creates a limitation in assessing the results. The visual content analysis process followed in the study is time-consuming, and due to the limited studies that provide guidance on this subject, the analysis was conducted with a small number of categories to ensure objectivity. It

is believed that future studies with smaller samples that include more subjective evaluations, and more categories could be beneficial for the development of new pharmacological pictograms specific to Turkish society.

Determining the frequency of pictograms and their characteristics in the leaflets for licensed drugs in Turkey is of great importance for rational drug use and health literacy intervention programs. Considering the study results and the literature review, it is believed that some micro and macro interventions for the use of pictograms in licensed drugs could result in significant gains in terms of medication adherence and health literacy. Micro interventions involve individual and small-scale efforts such as developing user-centered pictogram designs and educating healthcare professionals on their effective use; macro interventions encompass system-wide changes like public authorities encouraging pictogram use and establishing a standardized pictogram set for pharmaceutical companies. Given the potential benefits of well-designed pictograms for the pharmaceutical industry and healthcare system, there is a strong need for initiatives aiming to promote the widespread use of a standardized pictogram set in the pharmaceutical sector in Turkey. For this purpose, it is recommended to develop a comprehensive set of pictograms that pharmaceutical companies can use, with a focus on user-centered designs, in coordination with the fields of graphic design, health communication, and pharmacy. The public authority should also encourage the use of pictograms, and pharmaceutical companies should employ them in the instructions for different forms and treatment groups.

STATEMENTS OF ETHICS

No ethical approvals are required for this study.

CONFLICT OF INTEREST STATEMENT

The authors claim no conflicts of interest.

AUTHOR CONTRIBUTIONS

F.Y. designed and planned the study, analyzed and interpreted the data, and wrote the manuscript; S.D.Y. collected and analyzed the data; D.G.O. and Z.O. revised the manuscript.

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