



Provision and Need for Medicine Information in Asia and Africa: A Scoping Review of the Literature

Pitchaya Nualdaisri^{1,2} · Sarah A. Corlett² · Janet Kraska²

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Abstract

Published reviews of written medicine information (WMI) have mainly drawn on studies published in high-income countries, including very few Asian or African studies. We therefore set out to scope the research literature to determine the extent and type of studies concerning WMI for patients/consumers across these two continents. We sought empirical studies published between January 2004 and December 2019, conducted in any Asian or African country, as defined by the United Nations, in English or with an English abstract. The majority of the 923 papers identified were from high-income countries. We retained 26 papers from Africa and 99 from Asia. Most African studies ($n = 20$) involved patients in the development of PILs, in the assessment of the effectiveness of PILs or in surveys. In contrast, the highest proportion of Asian studies concerned the content of WMI ($n = 42$). WMI is desired, but needs to be in local languages, and there needs to be more use made of pre-tested pictograms. Existing WMI frequently does not meet local regulatory requirements, particularly locally manufactured products. A number of studies reported potentially positive impacts of providing WMI on knowledge and medicine use behaviours. Provision of medicine information is essential for safe use of medicines in all countries. Internationally agreed guidelines, incorporating good design principles, are needed to ensure the optimal content and design of WMI. The World Health Organization should support African and Asian regulatory bodies to share best practice in relation to WMI for patients/consumers and to develop and implement pan-continental guidelines that take into account consumer needs and preferences.

1 Introduction

Much research has been conducted into the need for and design of written information about medicines for patients in order to improve adherence and minimise toxicity. A comprehensive systematic literature review published in 2007 included 28 papers from 27 studies covering the role and value of written medicine information (WMI) [1]. The studies included spanned three continents—Europe, North America (USA) and Australia. This review also considered 43 trials that assessed the effectiveness of WMI in improving patients' knowledge, attitudes and behaviours, particularly adherence [1]. Of these latter studies, the majority were conducted in Europe ($n = 26$) and North America

Key Points

There is a paucity of published research into the use and provision of written medicine information from African and Asian countries; reviews have focused on studies from high-income countries.

Studies show that simple written medicine information, in local languages, with pictograms to aid understanding, is desired by patients/consumers in Asia and Africa.

Analysis of the written information available shows much is designed for health professionals, is difficult to understand and may not meet requirements.

✉ Janet Kraska
j.kraska@kent.ac.uk

¹ Faculty of Pharmaceutical Sciences, Prince of Songkla University, Hatyai, Thailand

² Medway School of Pharmacy, Universities of Kent and Greenwich, Chatham Maritime, Kent, UK

($n = 15$), with only two from Asian countries and none at all from Africa.

Some of these studies have informed regulations in many countries in relation to the provision of WMI to patients, which vary widely. European legislation has required manufacturers of medicines to provide a patient

information leaflet (PIL) with all medicines since 1999, while in the USA, there is a range of information, including Patient Package Inserts (PPI) and Medicine Guides (MG), the latter being required for medicines with serious side effects or other concerns, but there is no requirement placed on manufacturers to provide a patient leaflet or insert with all medicines. In Australia, pharmacists print out information for patients with dispensed medicines, known as Consumer Medicine Information leaflets (CMI), which are downloadable from a central website [2].

The review found that patients had concerns about the potential conflicts of interest arising from the requirement for a leaflet to be produced by the manufacturer of the medicine [1]. It also concluded that patients valued verbal information provided by health professionals more highly than WMI, although they recognised that WMI could be retained for future reference and potentially could provide a degree of patient empowerment. From a research perspective, the review concluded there was a need for more research to: determine the best content, layout and delivery of WMI, in particular, PILs; evaluate medicine information on the Internet; and provide more qualitative research [1].

European law in 2005, subsequent to the period covered by the review, required manufacturers to subject the PILs for their products to user-testing, to ensure they are legible, clear and easy to use, and guidelines on user-testing of PILs were published by the European Medicines Agency (EMA) in 2009 [3].

From the industry perspective, PILs, information for prescribers and product labels on medicines are based on templates, which regulators may provide or approve. The European PIL template specifies a fixed sequence of headings, specific information to be included under each and some of the wording. The Australian CMI template differs from the EU template in the wording of headings and their order, while the US template for MG, which applies to medicines only with particular safety concerns, differs again from the Australian and European templates [4]. Differences in the regulations concerning information for patients may impact on patient knowledge and medicine use [2].

Written information for health professionals is also subject to regulation, and is an additional requirement to information for patients in these countries [2]. Such material (known, for example, as the Summary of Product Characteristics [SmPC], package insert [PI] or product information) is more widespread, since these documents are the main sources of detailed, essential, up-to-date information available to prescribers about individual products. In many countries worldwide, PIs may be the only source of written information also available to patients, despite the level of technical detail.

While much research on developing and testing of PILs has been conducted globally, the comprehensive landmark review of 2007 included only two studies conducted outside of the European Union (EU), Australia or North America, both of which involved the provision of specially developed information sheets for selected patient groups [5, 6]. Scrutiny of the excluded studies found that although further studies were identified from countries across Asia and Africa, none met the review inclusion criteria [1].

A subsequent narrative review that sought to determine what patients want from WMI also effectively excluded work carried out on these continents [7]. The latter review, which focused on the design and content of PILs, included only studies from Europe, Australia, New Zealand and the USA. Furthermore, a scoping review evaluating patients' medicine information needs included 15 studies, only three of which derived from Asian countries, and none were from Africa [8]. Given that scoping reviews tend to be less restrictive in their inclusion criteria than systematic reviews, the small number of studies in this review seems surprising.

Another recent systematic review, covering the effectiveness of various forms of WMI provision, including PILs, focused on design principles [9] and summarised the evidence supporting best practice for such information. Country of origin was an inclusion criterion for this review; thus, only studies conducted in the USA, Canada, the UK, Australia and South Africa were included. The review found some evidence of a potential benefit from including pictograms within WMI. The involvement of medicine users in the design and evaluation of pictograms in WMI was the subject of a further systematic review, which did include many papers from South Africa as well as some from India, although the largest number of studies originated from the USA and evaluated pictograms from the United States Pharmacopeia [10].

It is thus clear that relatively few studies conducted in Asia or Africa have contributed to reviews on WMI. While it is acknowledged that there may be limited research in many of the countries across these continents, medicine users all across the globe have a right to be informed about their medicines, and it is important to ensure that any medicine information meets their needs in terms of accessibility, language and cultural context. While the World Health Organization (WHO) advocates the provision of information to empower patients in making informed decisions about the medicines they use [11], as yet no internationally agreed guidance exists on how to provide such information for all medicines. Indeed, WHO-recommended PILs apply only to a small number of medicines for specific diseases, and do not accord with good design principles [12].

We therefore set out to characterise published research on WMI reported from any of the countries in Asia and

Africa in order to inform future development of WMI for these populations.

Our objectives were:

1. To quantify and map the studies published in the English language concerning WMI arising from all countries in Africa and Asia
2. To characterise these studies depending on their focus and the extent of involvement of patients/the public

2 Method

We sought empirical studies published between January 2004 (after the period covered by the previous systematic review) and December 2019 that looked at the content of PILs or PIs, the desire for or use of information about medicines by patients/consumers or sources of medicine information accessed, and also included studies identified through citation and reference searching.

Key terms and subject headings selected included the following: Medic* information, Drug information, Drug labelling, Illustrated medic* information, Medic* package leaflets, Medic* information leaflets, Package inserts, Package leaflet, Patient information leaflet, Written medic* information, Consumer drug leaflet and Patient information sheet. Searches were conducted by PN in December 2019, using the following databases: Medline, CINAHL, Web of Science and Scopus. An example search strategy is provided in the Appendix (see the electronic supplementary material).

Studies were included if they were conducted in any Asian or African country, as defined by the United Nations, and concerned medicine information designed for patients. Excluded studies were those describing information for health activities, behavioural changes or medicine information services, views of health professionals, protocols, letters or non-empirical studies, including reviews. Articles written entirely in a language other than English were excluded; however, those with an English abstract were included.

A single database containing the article details from each search was created by combining the searches into one datasheet. Duplicate publications were removed using reference management software by PN, then titles or author affiliations and, in some cases, abstracts were reviewed by JK to check for country of origin. Abstracts of potentially relevant studies were read by two or all three team members to reach agreement on possible inclusion, and where there was uncertainty, full papers were accessed. Full papers of all potentially included studies were read by all team members, and each study was categorised or excluded independently. Discussions then

took place to reach agreement on inclusion/exclusion and category.

A categorisation system was developed iteratively through repeated review of the articles identified, to enable classification (see Table 1). This had three main areas of study: (1) intervention or other studies assessing impact, use of or views on PILs or PIs, including patient/public surveys and qualitative studies; (2) studies that assessed the content plus design or format of PILs or PIs; and (3) studies that assessed only the content of PILs or PIs. Within these areas, the studies were further sub-divided based on methodological considerations, as outlined in Table 1.

Data extracted from all included articles were as follows: authors, year, country, type of medicine(s) and study design. Individual data collection forms were iteratively designed for each study type to ensure that relevant aspects were captured. These included number of patients/participants or number of leaflets, as appropriate, measures assessed, method of assessment and key findings.

3 Results

A total of 923 articles were identified (Fig. 1). We excluded 798 of these because they were not conducted in one of the target countries ($n = 482$), were not specific to the provision of medicine information relating to allopathic products for patients ($n = 187$), were not empirical studies ($n = 82$), were surveys of health professionals ($n = 4$) or were unavailable, out of the date range or duplicated reports ($n = 43$). There were 26 and 99 studies identified from Africa and Asia, respectively (Table 1).

3.1 Summary of Study Types

There was a very small number of African studies overall; only 26 originating from eight of the 54 countries on the continent; however, data from a further five African countries were included within two studies (Table 2). More studies were reported from Asia—99 in total, from 22 of the 49 countries of Asia (Table 3), giving a total of 125 studies from the two continents.

The majority of African studies involved patients in the development of PILs, in the assessment of the effectiveness of PILs or in surveys, with only six which assessed the content of the written information provided. Although more studies originated from Asian countries, over 40% of the 99 studies ($n = 42$) related to the content of PIs or PILs, with a further 20 modifying or assessing readability and/or format and only 12 evaluating impact on behaviours. A total of 25

Table 1 Categories of studies identified (2004–2019)

Type of study	Methodology	Category	Africa	Asia	Total
Patient views/attitudes and/or impact of PIL/PI on patient knowledge or behaviour	Randomised study	1A*	6	6	12
	Non-randomised comparative study	1A	2	6	8
	Qualitative study	1B	1	0	1
	Cross-sectional survey	1C	5	25	30
Content plus design of leaflets including PIL/PI—including language and/or format	Formal user-testing in randomised study	2A*	1	3	4
	Formal user-testing in before-and-after or cross-sectional study	2A	3	2	5
	Evaluation using recognised criteria	2B	3	5	8
	Evaluation using in-house method	2C	3	10	13
Content of leaflets only including PIL/PI	Comparison to regulatory requirements	3A	1	27	28
	Descriptive or comparison to literature	3B	1	15	16
Total			26	99	125

PI package insert, PIL patient information leaflet

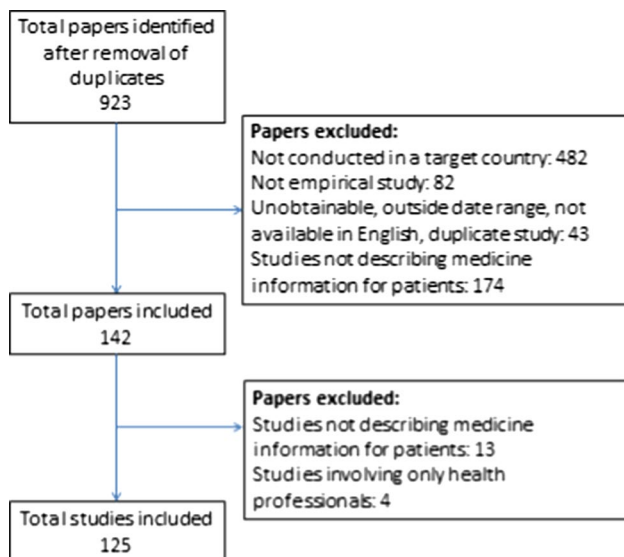


Fig. 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) diagram

surveys of patients/the public were found, but we found no qualitative studies from any Asian country.

3.2 African Studies

Almost half the studies originated from South Africa (Table 2), and mostly involved one research group [13–24]. In an extensive series of studies, researchers described the development of pictograms with input from a graphic artist and local populations [24], and also assessed the comprehension of locally developed compared to widely available pictograms [15], showing that local pictograms were preferred by all language speakers. They have developed and assessed

the acceptability of simple PILs based on a number of published guidelines for consumer medicine information using simple language and incorporating pictograms [21] and have undertaken extensive testing of these in low-literate groups [20, 22, 23]. Studies have assessed the effect of simple PILs with pictograms on overall and side-effect knowledge and adherence to a range of medicines, including antiretroviral therapy (ART), co-trimoxazole, antibiotics and inhalers, using both randomised controlled trials (RCTs) and before-and-after designs [13–18], one of which also measured self-efficacy [16]. All studies reported that the simple PILs were superior to standard care without PILs or to standard PILs for all outcome measures and participants consistently expressed a desire for pictograms in written information.

The only qualitative study identified [19] found that low-literate Xhosa-speaking people sought little information, mostly from health professionals, family and friends, and again desired illustrated written information.

A further study by the same group was undertaken in Tanzania [35] using similar materials for ART in Kiswahili, with pictograms, and again reported the acceptability and comprehensibility of this form of written information. An Ethiopian RCT found that pictograms aided the identification of medicines, but not identification of ADRs [34]. Pictograms were preferred by 41% of patients in a study in Cameroon, but symbols were most easily understood, by 90% [32]. A before-and-after study in Uganda combined written information with counselling and other strategies, but not explicitly pictograms, which increased adherence to ART compared to standard care [36].

Among the 26 studies, only five surveys involving patients/the public were identified that sought their views on medicine information provision. One survey of 500 patients in Nigeria found that, although 96% claimed to read the PI, they desired simple English and local language leaflets,

Table 2 Sources and types of studies across Africa ($n = 26$)

Country	Number	Classes of study (n)	Brief description of studies
South Africa [13–24]	12	1A* (5)	RCTs of PILs for ART and other medicines; effects on knowledge, including retention of side-effect knowledge, understanding, adherence [13–17]
		1A (1)	Impact of illustrated PIL on correct inhaler use [18]
		1B (1)	Focus groups exploring information needs [19]
		2A* (1)	Effect of pictograms on readability [20]
		2A (2)	Development, evaluation (acceptability, readability) of PILs for ART [21, 22]
		2C (2)	Development and comprehension of pictograms for PILs [23, 24]
Ghana [25–28]	4	1C (3)	Surveys of PILs provision in hospital out-patients, patient experiences of using PILs and information sources used by patients [25–27]
		3B (1)	Analysis of language used in PILs [28]
Nigeria [29–31]	3	1C (1)	Survey of patient views on PILs [29]
		2B (2)	Readability or usability of PILs [30, 31]
Cameroon [32]	1	2C (1)	Comprehension of medication instructions [32]
Egypt [33]	1	1C (1)	Sources of information used by patients, including PIs [33]
Ethiopia [34]	1	1A* (1)	RCT of PILs with pictograms to support identification of drugs and ADRs [34]
Tanzania [35]	1	2A (1)	Comprehension of PILs for ART [35]
Uganda [36]	1	1A (1)	Effect of combined counselling, PILs and other strategies on adherence to ART [36]
Multi-country [37, 38]	2	2B (1)	Content and design of PIs and PILs [37, 38]
		3A (1)	

ADR adverse drug reaction, ART antiretroviral therapy, PI package insert, PIL patient information leaflet, RCT randomised controlled trial

covering dose, indication, side effects, contraindications and safety precautions, whereas the leaflets also included chemistry, pharmacology and interactions [29]. A study involving 366 respondents in Egypt found 65% reported reading about side effects, 60% contraindications and 36% drug interactions, although almost half used family and friends as information sources, in addition to physicians and pharmacists [33]. A Ghanaian survey of hypertensive and diabetic people in contrast found that 78% sought information from public health facilities [27]. Two further surveys carried out in Ghana, involving 531 general hospital out-patients [25] and 400 ophthalmic patients [26], found that the majority recalled receiving a PIL with their medicine (79% and 94%, respectively). Among general out-patients, 76% read or had the leaflet explained to them, and 70% of those who read it found the leaflet easy or very easy to read, whereas only 23% of the ophthalmic patients read it. Encouragement by a pharmacist increased reading rate sixfold in the first study [25], while having a chronic eye condition and higher educational level increased reading in the second [26].

Terminology, language and font size were described as problematic in this latter study, which also assessed readability of 23 PILs using the Flesch Reading Ease (FRE) score, 21 of which had scores requiring college or tertiary education reading ability [26]. Readability was not assessed in a further Ghanaian study that examined the language used in PILs [28], but three studies from other countries did assess readability [30, 31, 37]. One covered 107 ART products available in five countries (Burkina Faso, Democratic

Republic of the Congo, Rwanda, Nigeria and Zambia) [37], only 28 of which (26%) included a PIL, none of which met standard criteria for layout, all had small font and only 12 were written in easily understood language. Small font size was also problematic in two Nigerian studies, one assessing 45 leaflets for malaria medicines [30] and the other assessing 66 medicine leaflets for a range of conditions [31]. Readability scores in both studies indicated a college or tertiary education level was required. Few leaflets in either study contained pictograms, and the local language was used in only 2% and 38%, respectively. A further multi-country study assessed the basic content of 99 PIs for six commonly used medicines in Tanzania, Uganda and Kenya, finding that while the majority included most of the required information, some sections were absent or incomplete [38].

3.3 Asian Studies

3.3.1 South Asia

The most common type of Asian study involved reviewing content of PIs. Sixteen of these studies originated from India, which had the highest number of studies overall ($n = 24$). Twelve of these [51–62] assessed only the content of PIs in comparison to regulatory requirements or product information and consistently found deficiencies. One study assessed 60 leaflets for readability using the FRE score, most of which scored as being difficult to read, and only 3% were in a language other than English [49]. One study involved

Table 3 Sources and types of studies across Asia ($n = 99$)

A. Studies from South Asia (31)			
Country	<i>N</i>	Classes of study (<i>n</i>)	Brief description of studies
India [39–62]	24	1A (4)	Assessment of PILs on knowledge (3), information provision on medicine use (1) [39–42]
		1C (4)	Surveys of awareness, knowledge, attitudes and content of PILs among patients, public and doctors [43–46]
		2B (3)	Readability, layout and consumer views on PILs, comprehension of pictograms for ADRs in HIV [47–49]
		2C (1)	Development of pictograms for counselling on HIV-TB medicines [50]
		3A (12)	Content analysis of PI or PIL compared to SmPC or regulations [51–62]
Pakistan [63–66]	4	1C (2)	Reading and comprehension of PIs; use of information sources [63, 64]
		3B (2)	Content analysis of PIs [65, 66]
Sri Lanka [67, 68]	2	1C (1)	Patient knowledge of prescribed medicines [67]
		3B (1)	Content analysis of PIs [68]
Bangladesh [69]	1	3B (1)	Content analysis of PIs [69]
B. Studies from South East Asia (13)			
Country	<i>N</i>	Classes of study (<i>n</i>)	Brief description of studies
Thailand [70–75]	6	1A* (1)	Effect of education on adherence [70]
		1A (1)	Effect of information on knowledge and behaviour [71]
		1C (2)	Patient views on PILs [72, 73]
		2A (1)	User-testing of specially developed PILs [74]
		3A (1)	Content analysis of PILs [75]
Singapore [76–79]	4	1C (2)	Patient need for and sources of information [76, 77]
		2A* (1)	Effect of bilingual text and pictograms on understanding [78]
		3A (1)	Content analysis of PIs [79]
Malaysia [80, 81]	2	1C (1)	Use of medicine information [80]
		3A (1)	Content analysis of PILs [81]
Indonesia [82]	1	1A (1)	Effect of leaflet plus counselling on adherence [82]
C. Studies from East Asia (22)			
Country	<i>N</i>	Classes of study (<i>n</i>)	Brief description of studies
Japan [83–90]	8	2A (1)	User-testing of a PIL [83]
		3A (5)	Comparison of PIs with those of the UK and USA [84–88]
		3B (2)	Comparison of PIs with regulations [89, 90]
South Korea [91–94]	4	1C (2)	Understanding of instructions and PIs [91, 92]
		2C (1)	Readability of PIs [93]
		3B (1)	Content analysis of PIs compared to Japan, the UK and the USA [94]
China [95–97]	3	1C (1)	Medicine literacy in pregnant women [95]
		3B (2)	Content analysis of PIs [96, 97]
Hong Kong [98, 99]	2	2A* (1)	Effect of pictograms on comprehension [98]
		2C (1)	Assessment of pictogram interpretation [99]
Taiwan [100, 101]	2	2C (2)	Preferences for pictograms [100] Evaluation of information provision on the Internet [101]
Multiple countries [102–104]	3	3A (2)	Content analysis of PIs in Asian and Western countries [102, 103]
		3B (1)	Content analysis of PIs for one product in 17 countries, including China, Japan and Korea [104]

Table 3 (continued)

D. Studies from Western Asia (33)

Country	<i>N</i>	Classes of study (<i>n</i>)	Brief description of studies
Saudi Arabia [105–114]	10	1C (4)	Views and understanding of PILs and medicine instructions in patients and consumers; use of information [105–108]
		2A* (1)	Format of risk information [109]
		2C (3)	Readability and format of PIs [110–112]
		3A (1)	Accuracy of PIs [113]
		3B (1)	Content analysis of PI compared to BNF [114]
Palestine [115–121]	7	1C (2)	Views of patients and public on PIs [115, 116]
		2C (1)	Content and design of PIs [117]
		3A (1)	Content analysis of PIs [118–121]
		3B (3)	
Iran [122–127]	6	1C (2)	Sources of information used by patients [122, 123]
		2B (1)	Readability of PILs [124]
		3A (2)	Content analysis of PIs [125–127]
		3B (1)	
Qatar [128–130]	3	1A* (2)	RCT of pictograms on medicine labels on understanding of instructions [128, 129]
		2B (1)	Readability assessment of PIs [130]
Kuwait [131, 132]	2	1A* (2)	RCTs of information provision on knowledge and adherence [131, 132]
United Arab Emirates [133, 134]	2	2C (1)	Understanding of pictograms by students [133]
		3A (1)	Content analysis of PIs [134]
Armenia [135]	1	1C (1)	Views and use of PIs and verbal information provision by pharmacists [135]
Israel [136]	1	1C (1)	Use of PIL and association with adherence and anxiety [136]
Turkey [137]	1	1A* (1)	RCT of information provision on knowledge, behaviour and clinical outcome [137]

ADR adverse drug reaction, *BNF* British National Formulary, *HIV* human immunodeficiency virus, *HIV-TB* human immunodeficiency virus/tuberculosis coinfection, *PI* package insert, *PIL* patient information leaflet, *SmPC* Summary of Product Characteristics, *RCT* randomised controlled trial

consumers in assessing design and layout of 19 leaflets [48], five of which were judged poor, five standard and nine above standard, based on Baker Able Leaflet Design (BALD) principles; 40% of 1500 consumers rated the poor leaflets, 53% the standard leaflets and 51% the above standard leaflets as good/very good, although most had a tertiary level of education. Two further studies described the development of pictograms for describing ADRs in the treatment of human immunodeficiency virus (HIV) infection [50] and to support pharmacist counselling on medicine use for HIV infection [47].

Four intervention studies were found; two evaluated the effect of providing specially developed PILs on patient knowledge using before-and-after designs [40, 41], and one was a non-randomised comparison [39], which also assessed adherence, all reporting a positive benefit. For the latter study, PILs were in Hindi and contained only indications, dosage, frequency and duration of administration, storage requirements, common side-effects and important points to remember. The PILs for the before-and-after studies were assessed for readability and good design using the FRE score and BALD, before being translated into Tamil and/or Malayalam. A further study used written information about

medicines generally, combined with lectures, to modify medicine purchasing and usage [42].

Four surveys in India described the use of PIs by patients and the general public, involving a total of 700 individuals [43–46]. The proportion who claimed never to read PIs varied from 24 to 62%, the proportions who wanted a leaflet in a local language or had a language barrier ranged from 12 to 50%, while other findings were small font size, too long and too much medical terminology. PIs were perceived as adverts in one study. Two studies listed sections most often read or most desirable: indication, adverse effects, contraindications [44], dose and uses [45].

Seven studies were found from other South Asian countries—Pakistan (*n* = 4), Sri Lanka (*n* = 2) and Bangladesh (*n* = 1). Studies from all three countries analysed the content of PIs. The studies in Pakistan found that not all leaflets were in Urdu and that important information, including how to use the product, was missing or inadequate [65, 66]. The study from Sri Lanka also found that some of the 100 PIs assessed lacked important information [68], while the Bangladeshi study was more limited, assessing 150 leaflets only for drug–drug interaction information [69].

Two surveys were found from Pakistan, involving a total of 923 people [63, 64]. One found that 23% did not read PIs at all, 24% had difficulty reading them, 30% lacked understanding and half wanted PIs in the local language [63]. The second found that only 29% had received written information, 67% of whom read it, but many had problems with technical terms, language and font size [6]. A study from Sri Lanka noted that information leaflets were not given to patients at all, the only written information provided being instructions on medicine envelopes in English, and that of 200 patients surveyed, 54% were unable to read English [67].

3.3.2 South-East Asia

In South-East Asia, studies were identified from Thailand ($n = 6$), Singapore ($n = 4$), Malaysia ($n = 2$) and Indonesia ($n = 1$). A series of studies emanating mainly from one group in Thailand explored views of patients on PILs [72, 73], and the availability and content of PILs [75], and then developed PILs and subjected them to user-testing [74]. The first survey found that most of the 474 respondents received only partial information from physicians and pharmacists verbally [72]. However, a later survey, published following changes to regulations requiring written information in Thai to be provided with all medicines, found that 91% of 500 patients had received a PI and that 59% had read them [73]. Although a desire was expressed for PILs as opposed to PIs, PILs were rarely provided [75], and most did not meet local requirements, with imported products being superior to locally manufactured products. A further study from this group demonstrated that provision of written information in addition to verbal information increased knowledge of drug allergies and intended behaviour [71]. An RCT, also carried out in Thailand, found that written information about rheumatoid arthritis, which included details of medicines supplied, improved adherence [70].

The only Indonesian study also demonstrated improved adherence to anti-tubercular medication when leaflets were provided in addition to verbal counselling, using a pre-test–post-test comparative design [82]. Provision of medicine labelling instructions in both text and pictograms using either English only or a local language in addition was found to be superior to English text alone, but not to bilingual text alone in ensuring comprehension in an elderly Singaporean population using a randomised study design [78]. Surveys involving 327 patients in Singapore [76, 77] and 888 members of the public in Malaysia [80] sought views on preferred sources of medicine information. In Singapore, for prescription medicines, preferred sources were physicians (83%) and pharmacists (58%), and for over-the-counter (OTC) medicines, the preferred source was friends and family (41%), with PIs being used by 37%, PILs by 11% and the Internet

by 13% [76]. A second survey supported this, with 47% preferring verbal information from health professionals and 36% written information, and only 5% preferring the Internet [77]. In contrast, 49% of those surveyed in Malaysia used the Internet, while 58% obtained information from doctors [80].

Two studies assessed the content of leaflets. One in Malaysia, which included 133 OTC medicines, found that 69% had a PIL, none of which fully complied with local requirements, and that, as in Thailand, imported products showed superiority over locally manufactured products [81]. A small study in Singapore covering 21 PIs found variable drug interaction information [79].

3.3.3 East Asia

In East Asia, the majority of studies ($n = 8$) derived from Japan, although for several, only an English abstract was available. Seven focused on the content of PIs [84–90], three of which compared aspects of Japanese PIs to those from the USA and UK [84, 87, 90]. One study also compared PIs from South Korea to those from Japan, the USA and UK [94]. Three further multi-country comparative studies were identified, which compared PI content from East Asian countries with that from Western countries [102–104]. All comparative studies found differences in the content of specific aspect of PIs between countries. An important study reported the development and user-testing of revised PILs compared to existing patient information [83], which found the revised PILs had better readability and layout, and improved understanding.

Other studies in South East Asia derived from South Korea ($n = 3$), China ($n = 3$) and two each from Hong Kong and Taiwan. Two South Korean studies involved undergraduate students; both of which found problems with the understanding of many words in PIs [91, 93], the authors of the latter attributing this to use of Sino-Korean language. Small font size was also noted to be problematic. The third, involving 305 adults, found that health literacy was positively associated with reading medicine labels and understanding of instructions [92].

Pictograms were the focus of three studies from Hong Kong and Taiwan. Occupation, age and education affected individuals' ability to guess the meaning of pictograms in Hong Kong Chinese young people [99], while older people favoured adding pictograms to medicine labels and considered they improved understanding [98]. In Taiwan, low-literate patients and doctors had different preferences for pictograms, and in patients, both preferences and understanding differed by age [100].

No studies were found that assessed the content of PIs or PILs in Hong Kong or Taiwan, although one study from Taiwan found variation in the content of publicly accessible hospital drug information websites for digoxin [101]. There

were, however, two studies in China, one of which assessed the content of over 10,000 products, including traditional medicines [97]. Information on allopathic and biological medicines was found to be better than for traditional medicines; however, the provision of key information was very infrequent: indications < 2% and adverse reactions 6%. A second study found errors in translating PIs from English to Chinese [96]. Only one survey was found involving patients in China, which showed that a high proportion of pregnant Chinese women had poor medicine literacy [95].

3.3.4 Western Asia

A total of 25 studies were identified from Arabic-speaking countries: Saudi Arabia ($n = 10$), Palestine ($n = 7$), Qatar ($n = 3$), Kuwait ($n = 2$), United Arab Emirates ($n = 2$), plus Turkey ($n = 1$). Further studies were found from Iran ($n = 6$), Armenia ($n = 1$) and Israel ($n = 1$).

Six of the studies from Saudi Arabia focused on content and presentation of PIs and PILs, ranging from comparing content to various standard sources, such as the British National Formulary, US regulations and Keystone criteria [110, 113, 114], assessing readability [112] and understanding [111, 112] and evaluating format of risk information [109]. Collectively, these studies suggest that WMI, which may be available in Arabic and English, often lacks relevant content and may contain sentences that, although judged easy to read, have poor comprehensibility. As has been found elsewhere, the use of a verbal format for presenting risk information (e.g. common, rare) means that patients may overestimate risks.

Four surveys were found from Saudi Arabia, only one of which determined use of PIs [105]. This study found that 88% of 2029 pharmacy customers claimed to read PIs, with indications and side effects being the most useful sections; however, they found fault with the level of detail, font size and poor graphics and expressed a desire for patient-focused leaflets in Arabic, with better illustrations. Two other studies assessed understanding of instructions provided on dispensing labels for medicines [107, 108], finding that poor understanding was associated with low educational level. The remaining study, carried out online, indicated extensive use of the Internet to search for medicine information [106], with most respondents considering it easy to find and almost half considering it easy to understand.

In Palestine, surveys involving 594 consumers found that 45–52% always read PIs [115, 116]; one also noted that most consumers wanted information in Arabic [116] and that written information was sometimes vague or not useful. A study focusing on administration of oral drops noted inaccurate instructions [118], while four further studies assessed the content of PIs [117, 119–121], consistently finding both incomplete information and PIs for locally manufactured

products having greater deficiencies in content than those for imported products. Such differences were also reported regarding PIs available in Abu Dhabi [134], which concurs with findings from other countries [75, 81]. Shortcomings in PILs for anti-diabetic medicines were also found in Qatar [130]; only 2.2% of 45 PILs had acceptable readability scores assessed using standard methods, and around 20% were in English only, despite multiple languages being common. Another Qatari study assessed the impact of simple information, tailored to the individual's first language, on health-related quality of life, which improved, despite no differences in clinical outcomes [129]. A further RCT in Qatar showed that pictograms combined with verbal information improved comprehension of medicine instructions compared to pictograms alone or text plus verbal information [128]. In contrast, a study in the United Arab Emirates assessed undergraduate students' understanding of 28 US pictograms, only two of which were correctly interpreted by non-pharmacy students [133]. Two RCTs in Kuwait showed that provision of an Arabic PIL for antidepressants improved knowledge, adherence and clinic attendance, with or without counselling from a pharmacist [131, 132], demonstrating a desire for written information [131]. An RCT in Turkey showed that verbal information, written information and a combination of both all improved asthma knowledge at 2 and 12 months, with the combination being superior [137].

Two studies from Iran identified limited access to WMI. A large survey [122] found 28% of 671 community pharmacy users received no information and 54% never used PILs as an information source. A smaller study found that of 237 items dispensed from a hospital pharmacy to 100 patients, 46% lacked any WMI, sometimes because pharmacy staff discarded them prior to dispensing [123]. Most of these 100 patients (84%) claimed to read PIs, which were in English, if received and to consider them useful. Both studies noted that reading WMI was associated with higher educational levels. Approximately 72% of 1059 consumers in an Armenian study read PILs, but only 37% fully understood them. Indication, dose, duration, expiry, side effects and contraindications were the information these respondents most desired [135]. In contrast, only around half the 200 patients in an Israeli study read PILs, and 35% of these found they caused anxiety [136].

The limited availability of PIs in Iran was confirmed in another study of 100 commonly used medicines, 63% of which had a PI [126] and none of which met all local regulatory requirements, with the authors suggesting superior WMI accompanied imported products. Additional studies found missing information in 104 PIs for psychiatric drugs [125], that 92 PIs for neurological drugs failed to fully meet Iran's local requirements [127] and that the readability of 71% of 33 PIs was graded as difficult [124].

4 Discussion

4.1 Main Findings

Research studies on medicine information published in the English language are relatively few in number across Africa; many of these originated from South Africa, from one research group, thus there are significant gaps in our understanding of WMI across this continent. However, it is clear from the studies we did identify that there is a desire for both verbal and written information to be available. Written information is wanted in local languages, and pictograms appear to be highly desired. The availability of such written information does not meet the desires of people included in surveys, nor does all written information meet local regulatory requirements. The information provided may be in the form of PIs designed for health professional use, but even when written information is designed for patients, as in Ghana, many do not read it. Studies have, however, clearly demonstrated that information designed to meet the needs of local populations can positively affect knowledge of and adherence to medicines.

While the number of research studies published from Asian countries was higher, the majority concerned adherence of PIs to regulatory requirements and the shortcomings of these. One recurring feature was differences between local and imported products in the quality of information. Surveys of patients and the public did demonstrate a desire for information; again local languages were desirable, comprehension of available WMI was variable and pictograms were shown to improve understanding. Further studies appeared to show positive impacts on knowledge and adherence from providing WMI.

The surveys described have involved over 13,000 people across the two continents, with broadly similar findings. Collectively, these show that written information is desirable, and although verbal information from health professionals is for most the preferred source, many people in multiple countries seek additional medicine information from friends and family or the Internet. It must be recognised that survey respondents may require a relatively high level of literacy and that most of the surveys described here are unlikely to be nationally representative.

The lack of qualitative studies identified is of concern, since surveys are usually reliant on researcher perspectives; thus, our findings do not provide insight into attitudes and opinions towards WMI.

The studies also demonstrate that PILs or PIs are widely available, although a high proportion of countries were not represented in our review, particularly in Africa. In many countries, PIs are provided, rather than PILs. Studies from both Africa and Asia that focused on these documents

repeatedly showed that they often fail to meet requirements, they may be incomplete and there is considerable variation in both content and readability. In most studies, the number of leaflets tested was small in relation to the number of medicines available; however, there is some consistency in the findings. Terminology designed for health professionals is often used, which creates difficulties for patients; as does failure to use local languages. Educational level clearly affects leaflet comprehensibility; most of the studies that assessed readability of the text using standard techniques found many required at least a college level of education, while educational level affected patients' reading of leaflets. Some of the sections included in PIs were not wanted or understood by patients, and simpler leaflets that contain key information are desired. Sections repeatedly shown to be most desirable are as follows: dose, indication/use, side effects and contraindications. The use of pictograms to support WMI has been studied in several countries across both Africa and Asia. The studies show that these are seen by patients as desirable and that while it is possible to design pictograms that enhance understanding, this requires considerable effort.

The intervention studies identified, many of which involved randomised comparative designs, suggest that provision of WMI can enhance knowledge and understanding; however, critical assessment of these studies is warranted. Importantly, a key feature of these studies is the development of a specially designed PIL, which may include pictograms and may use minimal text, limited sections and/or local languages. The PILs assessed in these studies are therefore not representative of the leaflets generally available within the countries.

4.2 Strengths and Limitations

We limited our search to articles entirely written or with an abstract in English; hence, we did not include any published studies in other languages, of which there may be many, and we fully acknowledge that our review is limited by this constraint. It is likely that this strategy may have resulted in the omission of many studies from China and Japan, as well as any work published in French from Francophone African countries. It is acknowledged, however, that most scientific research is published in English. We did not restrict our search to any particular study design, in order to ensure we included the many different types of studies reported. Our classification system was an attempt to order these to facilitate summarising the work, but it proved difficult to encompass every different methodology within this, and we acknowledge some studies may fall into more than one category. As this is a scoping review, we have not reported any detail of the quality of studies, nor have we attempted any form of meta-analysis.

4.3 Comparison with Literature

Patient involvement in the development of leaflets for their use is clearly essential, as is the use of good design principles. Many regulatory authorities, such as the EMA, issue guidelines encouraging good leaflet design [3], but research evidence suggests that even where these guidelines exist, there remain many lessons that can be learned from the literature [7, 9, 138]. Various methods of assessing the readability of text have been frequently applied to English language WMI [139–141], and alternative similar methods have been developed for other languages [142–144], though to our knowledge, these have not been applied to WMI. Readability assessment using standard formulae does have limitations, and the perspective of the user is of greater importance. Hence, user-testing is a requirement of PILs within the EU, but our study found only limited application to PILs in Asia. There are also specific methods for assessing PILs [145–147]. A number of the studies identified did apply good design principles, including both assessing readability and evaluating leaflets with patients. Such principles have also been used to develop disease-focused leaflets in India [148–150], and user-testing has been employed in their evaluation [149].

A number of Asian and African studies demonstrate that health professionals' views on medicine information concur with those of patients, that the WMI available to patients is not currently fit for purpose. Pharmacists in Japan considered that existing drug leaflets require modification to be of use to patients [151], and few used them to help their communications with patients [152]. Similarly, pharmacists in Nigeria considered that the PIs provided with medicines need changes to make them patient-friendly [153]. Many doctors surveyed in Sudan did not recommend patients read PIs, despite perceiving a need to provide information, in part because many were not written in the local language [154]. However, both pharmacists and doctors in Thailand agreed that PILs should be more widely available [155, 156].

The small number of research studies found from Africa and Asia contrasts with the large number from high-income countries over the same period. Over 200 studies emanated from both the USA and Europe between 2014 and 2019. In the UK, for example, 46 studies were found; half were either surveys ($n = 15$) or qualitative studies ($n = 8$) exploring patients' beliefs, opinions, attitudes to, satisfaction with and preferences for medicine information as well as receipt, understanding and use of information. This contrasts dramatically with the paucity of qualitative studies and relatively few surveys from African and Asian countries. A number of the UK studies indicated both dissatisfaction with the PILs provided under EU regulations and insufficient provision of verbal information [157–161]. One study

found that although most patients considered PILs easy to access, only 54% considered them easy to understand and 59% trustworthy [162].

Despite PILs having been supplied with all medicines in the UK since 1999, the review of 2007 concluded there was a need for more research to determine the best content, layout and delivery of PILs [1]. It is therefore unsurprising that many studies since have sought to improve them. For example, UK studies have evaluated specific aspects such as presentation of risk information [163], a headline section [164] and benefit information [165], while another study assessed different ways of presenting information more generally, based on good design principles [166]. Only one similar study was found from Saudi Arabia, relating to presentation of risk information [109]. Elsewhere, a review concluded that pictograms enhance patient understanding of how to use medicines, especially when used together with verbal or written instructions [167], and an international study with respondents from 84 countries found that some pictograms may be universally appropriate, while for others, regional preferences were evident [168]. Yet it has been suggested that pictures do not necessarily enhance leaflets [138], whereas in many of the studies described here, pictograms play an important part in aiding understanding.

Furthermore, an evaluation of the European PIL template found that the ordering of material may not match the preferences of PIL users, whereas a revised template enabled readers in the UK and the Netherlands to locate information more efficiently [169]. A New Zealand study concluded that the PILs there did not align with research findings on what patients want from leaflets [170] and advocated tailoring information to individual patients [7]. Entirely novel ways of communicating medicine information have been proposed [171], while the UK Academy of Medical Sciences recommended in 2017 that regulatory agencies should work with patients and pharmaceutical companies to improve comprehension and readability of PILs to ensure an accessible, balanced appraisal of potential benefits and risks [172]. This report also advocated increased availability of accessible WMI via the Internet. Thus it is clear that changes to the provision of medicine information may be needed in developed countries, not just across Africa and Asia.

4.4 Recommendations/Implications for Practice

Whilst information leaflets are required by legislation to be supplied with medicines to patients in the UK, EU, Australasia and the USA [1–4], studies appear to confirm that, despite such guidance and continued research into the format of medicine information, WMI even in high-income countries may not be meeting patients' needs [169, 170, 172].

In Africa and Asia, regulations exist in some countries requiring suitable information leaflets to be supplied for patients, but such guidance is absent from many countries across these continents. Where WMI is available, studies demonstrate that it is often of poor quality; it may not meet regulatory standards where these exist, it typically is not supplied in the local language, it may contain too much information and the general design and readability of the leaflet are often poor. Therefore, many patients in Africa and Asia either do not have access to WMI or are provided with leaflets, PILs or PIs that are of little benefit to them.

Africa has the greatest potential for growth in its market for medicines. Whilst demonstrating wide variability within and between countries, the demand for both prescribed and OTC medicines continues to grow [173]. The variability in access to healthcare across the continent has been largely attributed to differences in urbanization, as increased urbanisation and the associated wealth of the population leads to improved healthcare infrastructure and capacity. This includes increased access to medicines and trained healthcare professionals. It is estimated that by 2025 Africa will have 30 cities across the continent with populations of 2 million or greater.

Pharmaceutical companies are also working closely with organizations such as the Access to Medicine Foundation to improve access to medicines in low- and middle-income countries [174]. The majority of these, identified by the UN human development index, are in Africa and Asia. There is an urgent need to ensure that when patients have access to medicines, they can benefit fully from them. The provision of suitable WMI is important to facilitate the safe and effective use of medicines. However, even within a given country, the optimal design and preference for WMI will vary greatly between individuals, depending on their cultural and contextual environments. Models of provision developed for use in westernised countries may not be appropriate; therefore, research into accessible, preferred models is essential. These will need to take account of variable levels of both literacy and digital access between and within countries.

5 Conclusion

There is ongoing research in many countries within Asia and Africa that has been excluded from reviews on WMI/PILs to date. However, the findings of these studies are important to better understand patients' needs within these countries. The language and design of WMI are only part of the picture, and the cultural context within which the medicines are used must be considered. Whilst the WHO advocates that medicine information should be shared with

all patients, there is a paucity of internationally agreed guidelines on how to achieve this. Once developed, these guidelines should agree with good design principles to ensure the optimal content and design of WMI. Given the increased use of medicines within Africa and Asia, the WHO should work with African and Asian countries and their regulatory bodies to share best practice in relation to WMI for patients/consumers and implement pan-continental regulatory guidelines with which all pharmaceutical manufacturers could conform. These should allow for the tailoring of information to ensure that the information meets the needs of individuals and is culturally and contextually appropriate.

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Author contributions PN conducted searches, screened titles, extracted data, categorised studies and commented on the article. SC reviewed and categorised studies and contributed to drafting the article. JK screened titles, extracted data, categorised studies and drafted the article. All authors have read and approved the final version of the manuscript.

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