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Assessing the feasibility of quick response codes for patient information delivery in the Tshwane district

by

Githa Singh

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Abstract

The inclusion of a patient information leaflet (PIL) in medicine packaging is a legal requirement in most countries and ensures the patient has the latest product information to enable compliance. With the advancement in technology, more countries are implementing electronic patient information leaflets (ePILs) via the addition of quick response (QR) codes on medicine packaging. This study aimed to assess the feasibility of QR codes for patient information delivery in the Tshwane district in the general outpatient department. The objectives were to assess patients, pharmacists and pharmacist assistants' ability and willingness to scan the QR code as well as the ease of implementing the QR code for patient information delivery.

The study involved a cross-sectional survey among 333 patients and 17 pharmacists/pharmacist assistants at Tshwane District Hospital and a focus group study among 18 regulatory affairs pharmacists. Ethics approval was received from the Faculty of Health Sciences, Health Research Ethics Committee (444/2022). Inclusion criteria included patients over the age of 18 who spoke English as primary/secondary language. The data collected were analysed using the Statistical Software Package developed for the Social Sciences (SPSS).

Participants in the 26–55-year age group constituted the largest portion (67%) of the 333 patients. Females represented 71% of the total population. Irrespective of patient age, gender, 85% were willing, and 80% were able to scan the QR code. Of the patients who scanned the QR code, over 95% found it easier to read the ePIL (C=0.487, p <0.001) and to locate the information they needed on the ePIL (C=0.521, p <0.001). Patients showed a positive sentiment towards the ePIL, with 80% of the population preferring either the ePIL (35%) or ePIL with a hardcopy (45%). Of the pharmacists and pharmacist assistants, 56% were willing and able to scan the QR code, whereas 69% preferred the provision of the ePIL (31%) or both the ePIL with a hardcopy (38%). All the regulatory affairs pharmacists preferred

the QR-coded PIL over “100 pieces of paper,” and indicated that it was an easy process to create a QR code for a PIL.

Schooling level and age played a major role in the ability to scan the QR code. Patients with no schooling or primary school (C=0.263, p <0.001) and patients in the age group of 56–85 years (C=0.306, p <0.001) required more assistance to scan the QR code. More than 97% of patients who scanned the QR code found it easy to read (C=0.487, p <0.001) and locate the information on the ePIL (C=0.521, p <0.001). Whilst 89% of pharmacists and pharmacist assistants who scanned the QR codes found it easy to read the ePIL (C=0.746, p <0.05), 78% confirmed they could locate the information on the ePIL (C=0.630, p <0.05) and would utilise the ePIL to counsel patients. The regulatory affairs pharmacists were concerned about patients’ accessibility to the ePIL, as a QR code scanning device is required.

Neither patients nor pharmacy staff appear ready to fully transition to paperless medicine packaging as they prefer a dual system including a QR-coded PIL and a hardcopy PIL. Provision of an ePIL via a QR code provides the advantage of being applied to patient-ready packs, where a leaflet is not included, increasing the possibility of correct medication use, which ultimately will result in improved patient compliance. Other benefits of the ePIL include improved readability, easy access, the ability to search, and management of safety and product information updates in real-time.

Keywords: Quick Response codes, QR codes, patient information leaflet (PIL), professional information (PI)

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List of abbreviations

C	Contingency coefficient
DTC	Direct to consumer
eCTD	Electronic common technical document
EC	European Commission
3G	Third generation broadband
4G	Fourth generation broadband
GCC	Gulf Cooperation Council
e-label	Electronic label
e-labelling	Electronic labelling
EMA	European Medicines Agency
ePI	Electronic professional information leaflet
ePIL	Electronic patient information leaflet
EU	European Union
EFPIA	European Federation of Pharmaceutical Industries and Associations
GMP	Good Manufacturing Practice
HCP	Healthcare professional
HMA	Heads of Medicines Agencies
ICASA	Independent Communications Authority of South Africa
IPASA	Innovative Association of South Africa
LTE	Long-term evolution
n	Sample
n_i	Sub-sample of n
NRF	National Research Foundation
OPD	Out-patient department
PDF	Portable document format
PGEU	Pharmaceutical Group of the European Union
PI	Professional information
PIL	Patient information leaflet

POPIA	Protection of Personal Information Act
QR	Quick response
SAHPRA	South African Health Products Regulatory Authority
SAPRAA	South African Pharmaceutical Regulatory Affairs Association
TGA	Therapeutic Goods Agency
UK	United Kingdom
URL	Uniform resource locator
US FDA	United States Food and Drug Administration

Glossary of terminology

eCTD: Electronic common technical document is a set of specifications for the application for registration of medicines.

eHealth: Electronic health encompassing telehealth, mobile health, electronic health records, eLearning in health sciences,

ePI: Electronic professional information leaflet. The EU uses this terminology for electronic product information, inclusive of both professional and patient information leaflets

ePIL: Electronic patient Information leaflet

Healthcare professional: In the current study, the term refers to doctors, pharmacists and pharmacist assistants.

Labelling: Labelling of medicine includes the secondary and primary packaging, the professional information and the patient information leaflet.

Patient information leaflet: An information leaflet supplied with each medicine to the patient or caregiver.

Professional information: An information leaflet available for each medicine for the healthcare professional. Commonly included in medicine packs.

QR code: A type of matrix bar code or two-dimensional code that can store data information and is designed to be read by smartphones and other mobile devices. QR stands for “Quick Response” indicating that the code contents should be decoded very quickly at high speed. The code consists of black modules arranged in a square pattern on a white background. The information encoded may be text, a URL or other data.

Regulatory affairs pharmacists: Pharmacists responsible for the registration of medicines.

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Chapter 1 Introduction

1.1 Background

The inclusion of a patient information leaflet (PIL) in the medicine pack is a legal requirement in most countries in the world, South Africa being no exception. South Africa has had and still has paper leaflets in the medicine pack for the last 58 years, since the inception of the Medicines Act 101 of 1965.[1] The PIL is critical to ensure the patient has the latest product information to ensure the safe and effective use of the prescribed medicine.[2] With the advancement in technology, more countries are implementing ePILs.[3,4] The quick response (QR) code is a smart way of ensuring the PIL is on the medicine pack and has already been instituted in some countries such as Australia, New Zealand, the United States, Japan and India. On the other hand, countries such as those in the European Union, Canada and Brazil have implemented a dual system whereby the PIL and ePIL are both included.[3,4] According to Roberts *et al.*,[5] the advantages of e-labelling include, but may not be limited to quick and easy access to product information; the ability of companies to update product information rapidly by including new safety information as it becomes available, making this information readily accessible to both prescribers and patients; ability to search label content; ability to modify font size and improve readability; improved production timelines; and a reduction in the use of paper, which is more environmentally friendly.[5] South Africa is currently moving in the direction of electronic Professional Information (ePI) through the setup of an online PI/PIL repository and the inclusion of only the PIL in the medicine pack referring to the location of the professional information (PI).[6-8]

Advances in technology have allowed medicine applications for registrations in South Africa to be submitted using the electronic common technical document (eCTD), enhancing readability and navigation. The PI and PIL form part of the labelling of the medicine and are included in the eCTD submission.[9,10] The patient receives the registered medicine and a lengthy paper document, the PIL.

Globally, regulators are currently at various stages of implementing e-labelling. Certain countries have made e-labelling possible through the application of a quick response (QR) code on the pack of the product. Scanning the code directs the patient to the PIL.[5]

Current regulations in South Africa do not allow for the e-labelling of the PIL. The regulations and guidelines would need to change to support the process.[6-7] It would be important for regulators to determine whether patients are currently reading the PIL and to gauge their willingness to scan a QR code to access the ePIL. Other key stakeholders who would provide valuable input include pharmacists, pharmacist assistants as well as regulatory affairs pharmacists. The pharmacist and pharmacist assistant will be able to advise on their use of the QR code to access the PIL to enable patient counselling, whilst the regulatory affairs pharmacist will be able to provide input into the operational implications of moving from paper to a QR code.

1.2 Literature overview

1.2.1 Legal requirements of a patient information leaflet

Each country has a medicines regulatory body that guides clinical trials and medicines registration, including the labelling requirements of the medicine pack. The medicines regulatory bodies are governed by legislation. In South Africa this is the Medicines and Related Substances Act 101 of 1965 (commonly known as the Medicines Act 101 of 1965) and its related regulations. The Medicines Act 101 of 1965 was promulgated on 1 April 1966 to provide for the registration of drugs intended for human use, for the establishment of a Drugs Control Council and for matters incidental thereto such as manufacture, distribution and control of medicines.[1] The regulatory body also prescribes the content of the PI and the PIL. In South Africa, the paper PI in the medicines pack has been in effect since the introduction of the Medicines Act 101 of 1965 and was replaced in 2019 by the paper PIL in the medicines pack. The PIL is based on the PI and, therefore, similar in nature with modifications to cater for the patient.[6,7]

In the United States (US), the Food and Drug Administration (FDA) is the authority to determine this information. The first PIL requested by the US FDA was in 1970.[11,12] The inclusion of the PIL is meant to increase the patient's knowledge of the safe and effective use of the medicine and should be structured in plain language, thereby aiding patient compliance. Periodically, the PI and PIL are updated based on the latest safety data.[11,12]

The FDA announced the electronic distribution of the PI as a requirement in 2015.[3,11,12] The reason being that the FDA was concerned that the printed leaflets in the medicine pack may not be up to date and contain the most recent labelling change approval from the FDA. The FDA requested manufacturers to submit the PI to the FDA for inclusion in a repository on the US FDA website.[3] In addition, the FDA requested medication guides for certain products. These guides are in the form of paper handouts that accompany the prescription medicines and are printed by the pharmacy or can be accessed on the US FDA repository.[13] The guides address issues that are specific to a particular medicine or medicine class. They contain FDA-

approved information that can help patients avoid serious adverse events. The National Institutes for Health (NIH) website also houses the DailyMed.[13] The latter is an up-to-date resource containing both information for the prescriber as well as the patient.[13]

Electronic patient information for selected human medicines harmonised across the European Union (EU) have been published by the Heads of Medicines Agencies (HMA), the European Commission (EC) and European Medicines Agency (EMA). A printed package insert is also included in the medicine pack.[14,15] The EMA launched a public consultation on its "key principles" for ePI, given that most people were found to throw the PIL away.[14,16] The reasons mentioned were that patients found the PIL difficult to understand and that the majority of people search for health information online.[16]

Key opportunities identified by the EMA include making the PIL available for the patient when and where it is needed in all EU languages.[16] The ePI allows for easier readability and better use of visuals without being constrained by the print format.[16] It also allows for portability, allowing the patient to access their PIL on a smartphone/device, even when travelling.[16] It further allows for the inclusion of search functions, adapting the presentation of the PIL for people with disabilities, e.g. through the use of large text or audio formats. Importantly, the ePI allows for information on the PIL to be updated quicker and therefore be made available to the patient timeously.[16] Although the advantages provided for the PIL above are evident, the disadvantages of requiring access to the Internet and the fact that the PIL, even in electronic format, may not be read, must be considered.

A survey carried out by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2017 reported that authorities in countries such as Austria, Bulgaria, Denmark and France have created repositories that are kept up to date.[17] Individual companies can also store the most recent regulator-approved labels on their website.[3,14] Countries that are spearheading this area and allowing for e-labelling through QR codes in the EU include Denmark, Germany and Spain. Countries outside the EU include Japan and the USA.[17] In August 2021, Japan revised the Pharmaceutical Machinery Law, allowing for a transition to e-labelling for prescription medicines and abolishing the need to include a paper package insert

in the product.[18] The law allows for a two-dimensional (2D) barcode to be attached to the pack of the product, which is readable using mobile device applications.[18]

Regulation 12 of the Medicines Act 101 of 1965 of South Africa requires the PIL to be included in the medicine pack.[6] As per the South African Health Products Regulatory Agency (SAHPRA) guideline, the following information needs to be included in the PIL[7]: scheduling status, product name, what one needs to know before you take this medicine, how to take the medicine, possible side effects of the medicine, how to store the medicine, and the contents of the pack and other information. The guideline also requires that the PIL be published in English and one other official language.[6,7] Although SAHPRA acknowledges the advantages of e-labelling through amendment of the regulations to the Medicines Act 101 of 1965 allowing an electronic PI, this has not been allowed for the PIL.[19]

1.2.2 Digitisation versus digitalisation in the pharmaceutical industry and the quick response code

In its strictest form, “Digitisation” is the process of changing from analogue to digital form, also known as digital enablement, whilst “digitalisation” is the process of using digital technologies to transform business operations to provide new revenue and value-producing opportunities. e.g. moving from a “walk in store” to an “online platform.” Digital transformation is a broader term describing customer-driven business transformation requiring cross-cutting organisational changes across the business.[20,21] Digital transformation in the pharmaceutical industry includes the digitilisation of pharmaceutical products and related processes with smart connected devices and internet services (e.g. web, mobile apps, etc.) in drug development, clinical trials, supply chain and patient care. Countries are deploying digital transformative initiatives such as eHealth to support universal healthcare as eHealth which includes telehealth, mobile health applications can reach a vast number of citizens.[22] Opportunity to digitise the PIL of a medicine using current technology is possible, evident in Japan and EU.[14,17,18,23,24] Electronic patient information leaflets will revolutionise how information is provided to patients, thereby educating the patient and empowering the patient to ask their HCP relevant questions on their medication.

Implementation of a QR code to access the PIL will become a fast-growing reality in terms of digitisation.[23,24]

Patient information leaflets can be accessed using a QR code, which directs the reader to a uniform resource locator (URL).[3,14,18] Quick response codes are a relatively recent addition to the portfolio of mobile marketing approaches and were only developed in 1994.[25] This development was initiated by the Toyota subsidiary Denso Wave as a means to track inventory in vehicle parts manufacturing.[25] The QR code workflow is provided in Figure 1.[25]

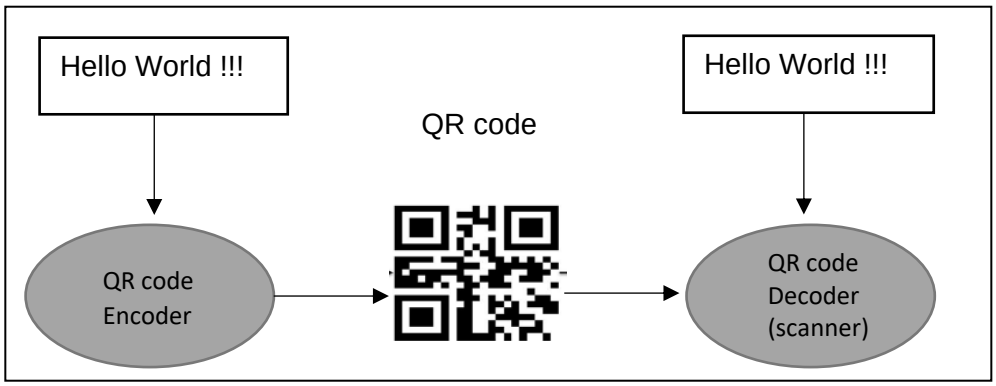

Figure 1: Working (overview) of the quick response code. (Reproduced with permission[25])

The QR code can support numeric and alphabetic characters, binary, Kana, Hiragana, Kanji, symbols and control codes.[25] The QR code either directs the reader to a document or to a link, i.e., a URL on the Internet, which contains the required information.[25,26] The QR code has also evolved to allow micro QR codes to be printed in a very small space.[25] The main advantage of a QR code is the ability to encode large amounts of data in a small space, which can be downloaded rapidly.[25] The code is also readable from any direction and may contain an appending feature of up to 16 separate smaller symbols, each of which contains unique information.[25,26]

To read a QR code, a reading device such as a hand or fixed scanner is required. The most common and convenient devices for reading QR codes are smartphones or tablets equipped with a camera.[25,26] The need for a device or software for scanning can be regarded as a disadvantage; however, most individuals possess a smartphone, and the QR code scanner

can be downloaded for free.[26] Since a QR code can revert the user to a URL, which can hold any information or may request the user to input information, this questions personal intrusion and privacy.[26] It should be noted that QR codes make use of a ‘pull’ rather than ‘push’ technology. 'Push' technology is related to information initiated by the advertiser, whilst 'pull' technology is initiated by the consumer.[27] As such, the user is in control and can determine whether they wish to scan a QR code or not.[27] It is important to also note that QR codes for PILs will involve performing a quality control check to ensure the correct URL is accessed prior to printing the code on the medicine pack. This process will be part of the quality control check for all commodities prior to printing and is part of good manufacturing practice (GMP). The QR code can further be quality control checked prior to local release on the market.[28]

Since its implementation, the use of QR codes has expanded to areas such as commercial tracking, entertainment, in-store product labelling, and applications that are aimed at smartphones and other mobile devices.[25,26,29] QR codes can be self-created using any QR generator software available online.[26] The technology for producing a QR code is available at no cost, making it possible for companies to embrace QR coding of the PIL.[26]

The pharmaceutical industry supply chain has already adopted the use of QR codes, also known as the 2D data matrix code, which allows for tracking, tracing, product recall and preventing counterfeiting of medication.[29-34] In this development, the EU led the way when it was initiated in 2011.[30] The 2D data matrix code has revolutionized the pharmaceutical supply chain by allowing for tracking and tracing of medication from manufacturer to end-user.[30,31] This has increased efficiency in the supply chain by allowing for early detection of stock expiry and the ability to recall medications to the level of the consumer.[30] The latter is possible, as each stakeholder handling the product enters traceability data into a central repository or database, which is maintained by a regulatory body. [30,31]

Countries that have implemented regulations relating to the 2D data matrix QR code on the African continent include South Africa, Ethiopia, Nigeria and Zambia. This indicates a strong move towards the adoption of digitisation in Africa using a QR code system.[31-34] The potential to move to a QR-coded PIL is therefore possible.

Another application of digitisation by pharmaceutical companies includes a QR code on the promotional material for newly registered products to allow quick and easy access to the URL of the PI and/ or PIL since it has been mandated by regulation 42 (7) of the Medicines Act 101 of 1965 to provide the professional information for medicines for human use.[1] This application of the QR code is an example of e-labelling and indicates that companies are able to generate QR codes for PILs.[19]

Since the coronavirus (COVID-19) pandemic, the use of QR code, which was invented 30 years ago, has definitely accelerated, as it facilitated contactless access to items such as COVID-19 sign and symptom checks, access entry, contactless tracing and, on the retail side, provided a means for contactless menus, and booking systems among others.[35] A digital divide existed in society prior to the COVID-19 pandemic between younger and older people. The digital divide is defined as the divide between "those who have access to a particular technology and those who do not."[36] It is also commonly referred to as the "information gap," resulting in the digital divide being translated over a variety of contexts such as socio-economic status, sex, age, race or geography.[37] For many years, older adults avoided the Internet as it was regarded by them as 'non-essential'.[38] The increase in penetration of broadband, mobile devices such as smartphones, tablets, and services, including online shopping and banking, indicates the Internet is part of daily life.[38,39] However, physical, technical, and cognitive barriers may prevent older people from genuine two-way smartphone interaction. Their lack of familiarity/use and trust leads to low acceptance of technology, preventing behaviour change. This group of the population will need support in scanning a QR code as well as with other digital interactions.[21,38-40]

1.2.3 Advantages and disadvantages of implementing a quick response code for the patient information leaflet

Quick response codes ensure real-time availability of the most up-to-date regulator-approved label to the HCP/patient.[3,14] Quick response codes will allow marketing authorization holders to update their labels on the URL based on the latest regulator-approved safety data/new indications and directions for use within minutes, thus making the label available to the

HCP/patient in real-time. This prevents delays in printing a new PIL each time there is an update.

A report on “Electronic product information for medicines in the EU” produced by EMA indicated that providing patients and HCPs with the latest safety information and conditions for use was a public-health priority, whilst the US FDA indicated that it was a “public good”.[3,14] This can be attributed to the latest labelling safety information being available immediately allowing for informed healthcare decision making by both the HCP and the patient.[3,14]

An electronic PIL (ePIL)/PI (ePI) improves patient and HCP readability.[14] Current guidelines in South Africa require the font type and size to be Helvetica 6 point.[6,7] An ePIL/ePI would offer the ability to increase the font size as well as searchability. Improving readability will lead to enhanced patient understanding and compliance with medication usage. It can also allow for translation to multiple languages.[14]

Electronic PILs also offer efficiency gains for both the regulator as well as the marketing authorisation holder.[3] In 2014, the US FDA indicated that there were 500 safety updates made annually between 2003 and 2013.[3] Updating of ePILs based on the latest regulatory approval across various countries can take place immediately and can be made available to the HCP/patient in real-time, preventing the need of updating the hard copy PIL for print in multiple countries.[3] The hard copy PIL must still be printed and be at the manufacturing site for packaging prior to the country importing.[13] This also entails destroying outdated PI or PILs.[3] First-hand experience on implementation of the new PIL in the pack indicated importation into South Africa can take anywhere between 6 to 8 months. The application of a QR code on the product pack to enable access to the PI or PIL negates the need to print commodities each time there is an update to the leaflet.[6] This efficiency gain will also lead to cost-effectiveness, as the production of a leaflet to be placed in the medicine pack will no longer be required.[3] It will reduce packaging costs.[3] Distribution costs will also be impacted as removal of the leaflet will lead to a reduction in the weight and volume of the product, lending itself to a reduction in the number of shipments to the country, ultimately leading to a decrease in the carbon

footprint.[3] In addition, the removal of paper leaflets from the medicine pack will reduce the use of paper, contributing to the protection of the forests.

The main disadvantage of incorporating a QR code is the cost for companies to set up a URL for electronic leaflets to which the QR code will directed.[25] Also, access to a smart device or the Internet is required to decode the QR code.[3] Furthermore, there may be reluctance from patients to adopt the technology, and it may not be possible to apply a QR code on very small medicine packs.[16,25]

1.2.4 Decoding the quick response code

To decode a QR code on a label, the HCP/patient would need a smartphone or device. As Klaus Schwab, founder of the World Economic Forum, states: “We stand on the brink of a technological revolution that will fundamentally alter the way we live, work, and relate to one another,” and he continues to explain that the fourth industrial revolution (4 IR) is evolving at an exponential rather than a linear pace.[41] The 4 IR has brought with it rapid advances in technology such as computer-aided product design, 3D printing, artificial intelligence, robotics, access to the Internet, and as Schwab describes, “mobile devices connecting billions of people, with unprecedented processing power, storage capacity and access to knowledge is limitless”.[41] There were an estimated 4.66 billion active Internet users globally in January 2021.[42] This number equates to 59.5% of the global population having access to the Internet. Of the 59.5%, 92.6% (4.32 billion) accessed the Internet via mobile devices.[42] The percentage of users who accessed the Internet in South Africa in January 2023 was 72.5%, with 97% of them owning a smartphone.[43] The percentage of South African population with a mobile phone was confirmed to be 97.6% (ICASA report, 2022).[44] The national population coverage for broadband 3G increased from 99.9% in 2021, whilst 4G/LTE was at 97.7% (ICASA report, 2022). The highest rural population network coverage of 4G/LTE was in Gauteng at 99%, followed by Mpumalanga and North West at 98%. The lowest rural population network coverage at the provincial level was in the Northern Cape, with 4G/LTE at 95% and KwaZulu Natal at 93%. ICASA recorded 60 million smartphone subscriptions in 2021.[44] This data

indicates that a high percentage of the population does have access to the Internet and, therefore, should know how to or have the means to scan a QR code.

Researchers at the Queen Victoria Hospital in the UK assessed the willingness of patients to use the QR code.[45] It was reported that 80% of respondents had a device to scan the QR code, with 96% of respondents finding it easy to scan the QR code and only 18% requiring assistance to scan the QR code. Furthermore, the majority (72%) preferred access to an electronic leaflet via a QR code instead of a paper leaflet. A considerable proportion of female participants preferred QR codes (69%).[45] In southeast Sweden, almost half of the participants were positive (41%, n=168), 32% (n=131) were hesitant/uncertain and 26% (n=107) were neutral regarding the ePIL, with 17% preferring the ePIL.[46] The younger respondents were most positive and accepting of the technology, whilst the older age group indicated they would request the old-fashioned paper PIL.[46] Similarly, a survey of almost 600 people living in Dublin, Ireland, demonstrated that people's willingness to embrace the ePIL is very much age-dependent. The youngest age group, < 25 years, was most willing to use an ePIL.[47] From July 2011 – June 2012, age differences in the knowledge and usage of QR codes were tested amongst 982 young adults (ages 25–39 years), 2654 middle-aged adults (ages 40–59 years) and older adults (ages 60–94 years) in the United States.[48] They were asked to assess awareness, knowledge and usage of QR codes. There were significant age-related differences in awareness, knowledge and usage of QR codes among the three age groups.[48] Similar to the study in Dublin, awareness, knowledge, and usage were highest for younger adults and lowest for older adults. The differences were attributed to lower rates of smartphone usage by older adults.[48]

A QR code can be read by smartphones, digital tablets, downloadable free scanners and other electronic devices. Ozkaya et al. (2015) reviewed factors influencing consumer usage of QR codes.[49] The study carried out amongst college students, found low familiarity due to the novelty of the technology and reduced access to smartphones at the time contributed to low scanning.[49] A study carried out in Trivandrum, India, found the top two factors inhibiting usage of QR codes as difficulty in usage followed by unavailability of smartphones.[50]

A static QR code redirects the user to a specific word or portable document format (PDF) PIL, whilst a dynamic QR code redirects the user to a URL which houses the PIL.[26] The advantage of redirecting the patient to the URL is that it does not require the updating of the QR code on the medicine pack each time a change on the PIL is approved by the regulator, nor does the number of characters that need to be present to generate the QR code limited.[3,14,26] The disadvantage is that it requires updates to the PIL on the URL when changes are approved by the regulator.[3]

1.2.5 Literacy in South Africa and patient's understanding of the patient information leaflet

Even though placing the PIL in a medicine package is a legal requirement, it is imperative to know if patients do read the PIL or a portion of the PIL. David Sless (2006) summarised the common characteristics of a PIL reader in his book, "Writing about Medicines for People: Usability Guidelines for Consumer Medicine Information:"[51]

1. Readers rarely, if ever, read the entire document from start to finish.
2. Readers are reluctant to read more than they think they need to read.
3. If they know or think they know how to use a medicine or product, they are unlikely to consult the PIL until a problem occurs.
4. Good layout and structure make a document easy to read. A cluttered, small font size, poorly printed document is less likely to be read.
5. Readers regularly scan documents to find what they want or need.

The above was confirmed in a qualitative study on patients' experiences and perspectives receiving written medicine information about medicines in Thailand. Most patients read the safety advice, adverse effects and drug interactions.[52]

In South Africa, approximately 90% of persons over the age of 20 had either primary, secondary, grade 12 or higher education, where adult literacy qualified as anyone older than age 15 with a grade of 7 or higher education (General Household Survey, South Africa, 2021).[53]

Health literacy may be a more accurate measure to determine a patient's ability to understand their disease and the use of medication. In an attempt to determine health literacy in limited literacy populations, a study was carried out in two small peri-urban towns in the Eastern Cape.[54] Only 17.6% of the respondents were found to have adequate health literacy levels.[54] The health literacy rate was measured among isiXhosa-speaking patients with a maximum of 12 years of schooling. Measurement of health literacy in South Africa is still in its infancy, and there is no public policy or guideline on the matter yet. The results of the HELT-LL study by Dowse and Marimwe are in stark contrast to the education levels measured in the General Household Survey 2021.[53,54] It may, therefore, not be appropriate to equate educational levels to a patient's ability to understand the PIL.

South Africa has 11 official languages, and translation of the PIL into any other language than English may not result in the correct medical translation given that not all the medical taxonomy is available in the different official languages.[55] The current regulations in South Africa prescribe the PIL to be in English and one other official language.[6] It is thus essential to decide on what additional language to English should be present on the electronic PIL or if an additional language is necessary. The difficulty of translating health texts from English to other languages should be kept in mind. Ndlovu categorised and analysed simplification strategies used by the translators in the representative isiZulu health texts.[56] It was reported that certain texts were inaccessible because of the complex linguistic and cultural constraints.[56] South Africa has also not adopted a policy on multilingualism for eHealth.[22]

There are other ways of ensuring the information in a PIL is provided to the patient outside of what is regulated by law. These include patient guides, which are requested by the US FDA.[3,13] The use of pictograms has been suggested in the PIL to enhance readability.[57,58] To ensure consistency, the US Pharmacopoeia provides guidance on set pictograms.[57] However, critical warnings in a PIL which relate, for example, to thrombosis or diverticulitis would be difficult to communicate via a pictogram. In a study in primary healthcare facilities in Cape Town, where the effectiveness of text and pictograms on a label was compared against text only, 64% of the population preferred text and pictograms over text only.[57] A third of the patients found it difficult to understand the leaflet.[57] Importantly, QR codes have evolved to allow for both text and

pictures. Furthermore, a QR code directing to a URL site implies that there does not need to be a limit on the number of characters used.[26]

Direct-to-consumer (DTC) advertising is another way of ensuring patients are well-educated on their medicines, thereby promoting health literacy.[59] In the US and New Zealand, where there are more relaxed regulations relating to the advertising of prescription medicines, DTC advertising is permitted.[59] Patients in these countries are, therefore, more knowledgeable about their medication, including side effects, dosage, and interactions.[59] The advertising of prescription medicines is highly regulated in all other countries. In South Africa, only over-the-counter (OTC) medicines are allowed to be advertised to the public.[6,60] This includes schedule 0 – 1 medication.[60] Medications labelled as schedule 2 and above are only allowed to be advertised to healthcare professionals.[6] Furthermore, strict regulations, as well as the South African marketing code, provide guidance on what can be included in an advertisement related to prescription or OTC products.[6,60] These stringent regulations and codes may also contribute to the patient's low level of understanding of the medications used and health literacy.[6,59,60]

1.2.6. Good pharmaceutical practice and electronic professional information

As per the Good Pharmacy Practice Guidelines, the dispensing pharmacist has a critical role to play in terms of ensuring patients are advised/counselled on how to take their medication, thereby enabling patient compliance. Pharmacist assistants, under supervision of a pharmacist, also takes on the role of providing advise/counselling of a patient on how to take their medication. Counselling is also extremely helpful when patient-ready packs/broken packs are dispensed without a leaflet.[61]

The Pharmaceutical Group of the European Union (PGEU), an association representing community pharmacists in 32 European countries, presented their position paper on ePI.[4] The PGEU indicated that they strongly support the use of ePI as a complementary tool to the current printed PI and that the need for immediate and equal access to production information is crucial to minimize risks, regardless of the equipment and ease of use of technology.[4] The European community pharmacists felt that the ePI should direct the consumer/patient to a trustworthy

site, such as the official website of the EMA or the applicable national competent authority.[4] The pharmacists also highlighted that companies should not utilise the ePI to promote the product and to consider patients who have limited access to digital tools or lack digital skills.[4] Another important consideration was data protection, where it was mentioned that any third-party applications should not store personal information linked to requesting access to ePI, which could then lead to indirect promotional activities.[4]

A study carried out in Hong Kong explored working pharmacists' overall perception of ePI. Key strengths for the ePI articulated where the speed drug information could be retrieved, readily updated and disseminated. Weakness included security risks and cost of maintenance.[62]

1.2.7. Current day thinking on the use of electronic professional information

"Delivering information to consumers through e-labelling," a position paper recently published by The Global Self-care Federation, confirms that digital tools, e.g., QR codes, can help to deliver medicine information efficiently.[64] Furthermore, the International Conference of Drug Regulatory Authorities, hosted by the World Health Organization in 2021, concluded that e-labelling as a tool should be promoted as a new normal. The International Pharmaceutical Regulators Programme (IPRP) is currently preparing a statement on the importance of e-labelling and its future potential. Currently, there is one of two regulatory pathways followed. Countries supporting no paper leaflets for OTC products (i.e. Australia, New Zealand, United States and India), countries supporting a dual system of ePI and paper leaflets (i.e. EU, Canada and Brazil). [66]

The possibility of using mobile scanning and other technologies as a way of providing medicine product information is also being considered by the National Competent Authorities and supported by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) of the EU.[65] These groups suggest that a mobile technology declaration take place on day 106 of the marketing authorisation application or post-authorisation.[65] The CMDh's recent position paper on the subject supported technology solutions such as the QR code and other 2D barcodes linking the electronic version of the PI.[65] The technology could also be utilised to provide additional information to the patient, such as a risk management plan

(RMP) and videos that may be useful to the patient and healthcare professional, provided it is not promotional. The CMDh suggested the use of different platforms to host the information provided by mobile technologies, such as national competent authority websites, dedicated platforms created by the MAH, and a standalone PDF. The mobile technology feature, such as the QR code, could be included on the outer packaging, primary label or leaflet. For small packages such as eye drops, the suggestion was to include them on the inner lid/flap of the carton.[65]

Other countries supporting online or on-demand PILs include Australia, where The Australian Therapeutic Good Administration (TGA) has indicated OTC products no longer require a paper PIL in the medicine package. The Italian Drug Agency Drug Data Bank retains updated product information, which patients have access to and are allowed to have printed at the pharmacy. In Sweden, the trade association manages the online repository, whilst in the United States, the DailyMed is the US FDA's official provider for ePI, which can also be downloaded by the pharmacist upon request from the patient.[66]

The South African Health Products Regulatory Authority, in partnership with the Self-Care Association of South Africa, announced the commencement of the building of an online directory for OTC SAHPRA-approved medicines. The website provides key information on OTC medicines, including the PI and PIL and therefore, the website could be utilised to generate a QR code for the PI/PIL.[8]

In July 2023, the ministries of health of Bahrain, Kuwait, Omar and Qatar issued circulars informing pharmaceutical companies to apply for QR codes for all registered medicines before the end of 2025, thereby enabling the switch from paper leaflets to electronic leaflets.[67-70]

Advances in technology have changed the way people access information. By 2025, it is expected that 79% of the global population will own a smartphone.[66] Medical information is becoming increasingly digital and accessed on the Internet using a device such as a smartphone.[47.] Many hospitals in the UK have implemented novel quality improvement projects through the set-up of QR codes for PILs, including brochures to enhance eHealth. A study

carried out at the eye unit of St. Thomas Hospital in the UK (2022) indicated that 82% of the cohort owned a smartphone and 54% preferred ePILs.[71] Patients also indicated the ability to enhance the brightness/luminance on their smartphone-aided reading.[71] This is a key parameter defined by the American Optometric Association to be considered for the older age groups, where it has been found that the right amount of luminance improves reading.[72] Another study carried out at the pediatric unit of Addenbrooke's and Lister Hospital in the UK (2021) reviewed QR codes for delivery of pediatric patient information e-leaflets. The study demonstrated that 74% of the cohort were encouraged by the QR code to read the PIL. Qualitative feedback revealed that patients felt that ePILs were 'more eco-friendly', 'offers a wider variety of information' and 'more convenient', with some patients still preferring paper leaflets.[73] An additional study carried out at the rheumatology clinic of Alexander Hospital demonstrated that 43% of patients preferred ePILs.[74] Overall, the quality improvement projects carried out in the UK indicated some patients still do prefer paper leaflets.[71, 73, 74]

The pharmaceutical industry's move towards digitisation and digitilisation is inevitable as we live in the fourth industrial revolution. The COVID-19 pandemic was the perfect storm to accelerate digitalisation in all areas within the pharmaceutical industry as customers and patients became more aware of social distancing and reduced contact. A critical area of concern was the packaging of medicines, which included a PIL, as patients were sanitising all packaging they came in contact with. Electronic PILs would have been the solution. Regulators, pharmacists and patients around the world see the advantage of ePILs; however, the question is whether patients and pharmacists in South Africa are ready for this change. Furthermore, how easy will it be to implement a QR code for a PIL?

1.3 Aim and Objectives

Aim

This study aimed to assess the feasibility of quick response codes for patient information delivery in the Tshwane district in the general outpatient department.

Objectives

The objectives of the study were to:

- assess the ability and willingness of patients and pharmacists, pharmacist assistants to use the QR code to access the PIL
- assess the preference of patients and pharmacists/pharmacist assistants for an electronic versus a printed PIL
- assess the ease of implementing the QR code by regulatory affairs pharmacists in the pharmaceutical industry

Chapter 2 Materials and study design

2.1 Ethical considerations

Approval to conduct the study was obtained from the University of Pretoria, Faculty of Health Sciences, Research Ethics Committee (444/2022, Appendix I). As this study entailed collecting data from patients in the Outpatient Department and pharmacists, including pharmacist assistants of Tshwane District Hospital, permission was obtained from the hospital's Chief Executive Officer (CEO) prior to the commencement of the study (Appendix II). The study was recorded with the Gauteng Department of Health.

To ensure patient privacy, no patient identifiers such as name or national identity number were captured. The participants volunteering to take part in the patient survey were required to provide informed consent. This was managed by the medical doctor supporting the data collection.(Appendix III). A participant information leaflet providing information about the study was provided (Appendix III).Given that this was not an intervention study, the risks were limited to not understanding the question fully. The principles of the Declaration of Helsinki were adhered to. Informed consent was also obtained from the participants taking part in the survey amongst pharmacists and pharmacists assistants as well as the focus group as a prerequisite for inclusion in the study (Appendix III). A participant information leaflet providing information about the study was provided (Appendix III).

2.2 Study design

A mixed method design involving two cross-sectional quantitative surveys and a qualitative focus group study was conducted. The surveys included assessing the patients, pharmacists and pharmacist assistants' willingness and ability to scan a QR code created for a commonly prescribed medicine, ease of reading and location of information on the ePIL as well as preference for the ePIL versus hardcopy PIL. A focus group study was conducted among regulatory affairs pharmacists to gauge their perception of the ease of implementation of the QR codes and the use thereof to access the PIL.

2.3 Study setting

Both surveys in this study were conducted at a public sector (state) hospital called Tshwane District Hospital which is also affiliated with the University of Pretoria as a teaching hospital. Tshwane District Hospital is a district referral hospital serving seven sub-districts, which serves almost 2 million people from both urban and rural areas. [75.] Patients who are not able to afford medical insurance or access private healthcare rely on public sector facilities such as the study site for treatment. Only 24% of the population in Gauteng can afford medical insurance (General Household survey, 2021), indicating that the majority, 76%, access public health facilities such as Tshwane District Hospital.[53]

The first survey was conducted at the Tshwane District Hospital among outpatients. The second survey was conducted at the Tshwane District Hospital pharmacy among pharmacists and pharmacist assistants. The qualitative focus group study was conducted among regulatory affairs pharmacists from both the innovative (i.e. companies supporting novel and new medicines) and generic (i.e. companies supporting second brands) industries.

2.4 Study population and sampling

2.4.1 Survey conducted among patients

The theoretical population was defined as the monthly average number of patients presenting at the Outpatient Department (OPD) of the Tshwane District Hospital. Based on email communication from the Clinical Manager's office of the Tshwane District Hospital, the OPD has approximately 1810 patient consultations per month. To ensure a 95% confidence interval with a 5% precision, the sample size was estimated at 333 patients.[76,77] A volunteer sampling method was used to select the patients who participated in the survey. This was accomplished by verifying the volunteers who matched the set of characteristics in the inclusion criteria. The data was collected between 1 November 2022 and 30 June 2023.

The inclusion criteria were patients older than 18 years and who spoke English as either a primary or second language, given that PILs are currently only in English and Afrikaans.[6] Exclusion criteria included patients younger than 18 years of age, those who did not have command of the English language and patients who were not willing to provide consent to participate in the study.

2.4.2 Survey conducted among pharmacists and pharmacist assistants

The inclusion criteria were that the pharmacists and pharmacist assistants needed to work at the Tshwane District Hospital. The exclusion criteria included pharmacists not yet fully qualified (i.e. community service/those completing their internship) and participants not willing or able to provide consent to participate in the study. Convenience sampling was used. Pharmacists and pharmacist assistants' present on the day took part in the survey. The sample size was 17. One survey had to be discarded due to duplication of results.

2.4.3 Focus group study conducted with regulatory affairs pharmacists

The focus group arm of the study was conducted among regulatory affairs pharmacists to gauge their perception of the ease of implementation of the QR codes and the use thereof to access the PIL. The focus group was limited to 18 regulatory pharmacists from both the innovative (i.e. companies supporting novel and new medicines) and generic (i.e. companies supporting second brands) industries. To eliminate bias and ensure confidentiality, the chair of the industry association's regulatory working groups was approached to refer members willing to participate in the study. Voluntary sampling was therefore used. These participants contacted the investigator directly, upon which informed consent was requested. The focus group was facilitated by the researcher and informed consent was received prior to the start of the focus group.

2.5 Data collection

2.5.1 Survey conducted among patients

The data collection instrument was a set questionnaire (Appendix IV).The questionnaire used to test the delivery of QR codes for patient information delivery at the Queen Victoria Hospital in the UK and that used to test patients' views on electronic patient information leaflets in Sweden were used as the basis for the data collection instrument.[45,46] Face and content validity was assessed by reviewing the questionnaire with subject matter experts. These included regulatory affairs pharmacists as well as a family physician consultant at Tshwane District Hospital. Their suggestions were taken into consideration, and the questions were amended to improve the questionnaire. The amended questionnaire was included in the protocol and approved by the MSc and Ethics committees. Data collected included demographics, age, English as primary/secondary language, schooling level, access to the Internet, possession of a mobile device, access to data, patient's awareness of a QR code, willingness to scan the QR code, whether assistance was needed to scan the QR code, and patient's current use of the PIL including a check on sections of the PIL that were read. To attain information on the latter, a QR code for a commonly prescribed medicine was generated, and patients were asked to scan it. Thereafter, the patient's ability to locate the information required was determined, as well as how easy it was to read and locate the information the patient was looking for on the ePIL. Lastly, the preference of the patient for a QR-coded PIL (i.e. ePIL) or hardcopy or both (i.e. 'ePIL+hardcopy') was determined. A hardcopy of the PIL was shown to the patient for comparability.

To prevent response bias and enforce reliability, no open-ended questions were included in the survey. Questions were either categorical, list or Likert scale. Participants' personal information was de-identified. Internal consistency was ensured by working in one Outpatient Department and using only one primary data collector.

Reliability was also ensured using as large a sample size as possible. Reliability of the data was tested using Cronbach's alpha coefficient, which measures internal consistency.

2.5.2 Survey conducted among pharmacists and pharmacist assistants

The data collection instrument was a set questionnaire (Appendix V) conducted in person by the investigator. Face and content validity was assured by reviewing the questionnaire with regulatory affairs pharmacists. Their suggestions were taken into consideration and the questions were amended to improve the questionnaire. The amended questionnaire was included in the protocol and approved by the MSc and Ethics committees. Data collected included participants' demographics, namely gender and age. The survey included a question to determine whether participants practiced patient counselling. A check was put in place to determine participants' awareness and understanding of a QR code as well as their ability to access the Internet and willingness to scan the QR code to access the ePIL. The ease of scanning the QR code and location of information on the PIL was also assessed, as well as the preference for a QR-coded PIL or hardcopy or both (i.e. 'ePIL+hardcopy'). Participants' personal information was de-identified.

Reliability of the data was tested using the Cronbach's alpha coefficient which measures internal consistency.

2.5.3 Focus group study conducted among regulatory affairs pharmacists

The focus group interview guideline presented in Appendix VI was used. The questions were administered via the Microsoft Teams platform. Responses were captured as notes using a standardised form described in the focus group interview guideline. The survey covered industry sector representation, ease of generating a QR code, ease of applying a QR code, preference of a QR code over the hard copy PIL and reasons for inclusion/non-inclusion of a QR code. There were 18 participants in the focus group study. Based on the participants availability, there were six participants on 14 March and twelve participants on 2 May 2023. On every question asked, each participant was asked to share their insights and observations.

2.6 Statistical analysis

The responses to the questionnaires were analysed using a Statistical Software Package developed for the Social Sciences (SPSS®; IBM SPSS statistics Version 29).

2.6.1 Survey conducted among patients

Demographic data were summarised using descriptive statistics such as frequency and percentage.

Crosstabulation was permutated to summarise the responses to observed categorical (nominal/ordinal) data in frequency and percentages. This included:

- reading the PIL with gender and schooling level
- patients' willingness and ability to scan the QR code presented
- ease of scanning the QR code in the patient population
- access to technology (i.e. access to the Internet, device and data) and knowledge of QR codes with gender

Pearson's Chi-square test (X^2) test of independence was used to determine if there was a significant relationship between two nominal (categorical) variables. Contingency tables were completed to display the data where each row represents a category for one variable and each column represents a category for another variable. The following variables were compared:

- knowledge of QR codes, access to technology, willingness, ability to scan the QR code *and* age groups
- ease of scanning the QR code *and* age groups
- schooling level, having previously scanned a QR code *and* assistance needed to scan the QR code
- ease of reading and locating the information on the ePIL *and* the scanned QR code in the patient population
- reading the PIL, age, gender, scanning the QR code *and* PIL format preference in the patient population

In all cases, a *p*-value <0.05 was considered statistically significant. The measure of association was conveyed using the contingency coefficient (*C*). The interpretation of the contingency coefficients is given as "0" as zero association, "<0.10" as weak association, "0.11-0.30" as moderate association, ">0.31" as strong association and "1" as perfect association.[78]

Reliability was assessed using Cronbach's alpha for the different sections of the survey, utilising questions that were categorical, list or Likert scale. A Cronbach's alpha value of > 0.60 indicates the data is reliable and demonstrates internal consistency.[79]

2.6.2 Survey conducted among pharmacists and pharmacist assistants

Descriptive statistics were used to summarise the response observed for categorical (nominal/ordinal) data as a frequency and percentage.

Crosstabulation was permutated to summarise the responses to observed categorical (nominal/ordinal) data in frequency and percentages. This included:

- patient counselling, knowledge of QR codes and access to technology, willingness, ability to scan the QR code, PIL format preference *and* age groups
- patient counselling, knowledge of QR codes, access to technology, willingness, ability to scan the QR code, PIL format preference *and* gender

Based on the small sample size, Fisher' exact test was used to determine if there was a significant relationship between two nominal (categorical) variables. Contingency tables were completed to display the data where each row represents a category for one variable and each column represents a category for another variable. The following variables were compared:

- Age, gender, scanned QR code and PIL format preference
- Ease of reading the ePIL, locating the information, use of ePIL to counsel patients and scanned QR code

In all cases, p <0.05 was considered statistically significant. The measure of association was given using the contingency coefficient (C) to determine the strength of the relationship.

Reliability was assessed using Cronbach's alpha for the different sections of the survey, utilising questions that were categorical, list or Likert scale. A Cronbach's alpha value of > 0.60 indicates the data is reliable and demonstrates internal consistency.[79]

2.6.3 Focus group survey conducted with regulatory affairs pharmacists

The responses were grouped into five categories/themes, which was evident from the discussion. The themes focused on familiarity, current usage, preference, technology debate and the creation of QR codes.

Chapter 3 Results and discussion

3.1 Survey conducted among patients

3.1.1 Demographics

The total number of responses was 333; however, the response of three participants had to be excluded due to these participants indicating more than one answer, the response been viewed as a 'spoilt questionnaire', N = 330. The age spectrum of the patients ranged from 18 to 85 years. The largest number of participants were in the 26-to-55-year age group (Table 1). The largest portion of the study population was female (Table 1). All participants either indicated English as primary (Table 1; 19%) or secondary language (Table 1; 81%). The ratio of female patients to male patients with a secondary education was 2:1, whilst the ratio of female patients to male patients with a tertiary education was 3:1 (Table 1). Of the 330 participants, 94% had, at minimum a grade 7 (i.e. secondary school) level of schooling (Table 1) aligned with 90% of South Africans older than 20 with a grade 7 or a higher level of education (General Household Survey, 2021).[53] Therefore, it is expected that the participants should have a literacy level (i.e. ability to read and write) enabling them to read the PIL.[53]

Table 1: Descriptive statistics of demographics in the patient sample.

Variable			**Frequency *N*=330 (per cent of *N*)**
Gender	Male		95 (28.7)
	Female		233 (70.6)
	Other		2 (0.6)
Age group (years)	19–25		36 (11)
	26–55		221 (67)
	56–85		73 (22)
Schooling level	Primary	Male	6 (1.8)
		Female	11 (3.3)
		Other	0 (0.0)
	Secondary	Male	48 (14.5)
		Female	95 (28.8)
		Other	1 (0.3)
	Tertiary	Male	40 (12.1)
		Female	127 (38.4)

Variable			Frequency *N*=330 (per cent of *N*)
		Other	1 (0.3)
	None	Male	1 (0.3)
		Female	0 (0.0)
		Other	0 (0.0)
English language schooling level	Primary		63 (19)
	Secondary		267 (81)

3.1.2 Reading of the current PIL in the medicine pack

Based on the survey results, 74% of participants indicated that they read the current PIL in the medicine pack. Of the patients who participated in the current study, 81% were not interested in reading the PIL in its entirety, but rather only certain sections (Table 2). This aligns with Sless's summary of "Common characteristics of a PIL reader."[51] The top three sections read by the participants were "possible side effects", "how to use the medicine", and "what the medicine is used for." It was interesting to note that 10% more female patients read the PIL compared to males, and they were mostly interested in reading the side effects section (Table 2). These results align with the fact that in South Africa, care of the family is highly gendered and women more than men are expected to provide care, including looking after the health of the family.[78] These results could also be related to the larger percentage of females having secondary and tertiary education compared to males who participated in the study. A slightly higher percentage of participants with tertiary and secondary education read the PIL compared to those with primary schooling (Table 2). None of the participants with primary school education felt it important to read the entire PIL, whilst only 15% with secondary education and 24% with tertiary education considered it important. Overall, only 19% of the participants read the entire PIL, indicating due consideration to be given to the improvement of health literacy on medication use. Health literacy may be a more accurate measure than literacy to determine a patient's ability to understand their disease and the use of medication. Health literacy involves knowledge and understanding of health information, medical conditions and treatment thereof.[54] This may be accomplished through changes in policy and regulation to allow for the promotion of educational materials related to schedule 2 and above prescription medicines to patients.[6,59,60] An update to the SAHPRA PIL format in current guidelines will make it simpler and also improve health literacy of medications in patients with low levels of schooling.[7] To

quote from Coleman, “This failure to communicate health information in its simplest and easiest-to-understand form unjustly favors people who have more education and higher health literacy levels.”[63]

The literature review indicated that the length of the PIL (electronic or printed) results in most people not reading it in its entirety but rather seeking to read certain sections only, which is the case in this study.[47,48,51,52] By design, the ePIL conveniently allows the patient to speedily locate the section of interest.[5,14] Regulators and stakeholders can agree on key principles such as language, standard texts, and sections to be included in the ePIL to enhance readability and align with patient needs.[14,16,17,47,48,51,52,64]

Table 2: Crosstabulation between variables related to reading the PIL and gender as well as schooling level.

Variable	Gender			***N*=330 (per cent of *N*)**
	Male n_i=95 (per cent of n_i)	**Female n_i=233 (per cent of n_i)**	**Other n_i=2 (per cent of n_i)**	
Read the PIL	64 (67.4)	177 (76)	2 (100.0)	243 (73.6)
What the medicine is used for	50 (52.6)	126 (54.1)	2 (100.0)	178 (53.9)
What you need to know before you take the medicine	23 (24.2)	68 (29.2)	1 (50.0)	92 (27.9)
How to use the medicine	52 (54.7)	150 (64.4)	1 (50.0)	203 (61.5)
Possible side effects	56 (58.9)	165 (70.8)	2 (100.0)	223 (67.6)
How to store the medicine	20 (21.1)	57 (24.5)	1 (50.0)	78 (23.6)
I want to know everything written on the PIL	13 (13.7)	48 (20.6)	1 (50.0)	62 (18.8)
Variable	**Schooling level**			***N*=330 (percent of *N*)**
	Primary n_i=17 (per cent of n_i)	**Secondary n_i=144 (per cent of n_i)**	**Tertiary n_i=168 (per cent of n_i)**	**None n_i=1 (percent of n_i)**
Read the PIL	12 (70.5)	104 (72.2)	127 (75.6)	0	243 (73.6)
What the medicine is used for	8 (47.1)	75 (52.1)	95 (56.5)	0	178 (53.9)
What you need to know before you take the medicine	5 (29.4)	31 (21.5)	56 (33.3)	0	92 (27.9)
How to use the medicine	9 (52.9)	88 (61.1)	106 (63.1)	0	203 (61.5)
Possible side effects	9 (52.9)	94 (65.3)	120 (71.4)	0	223 (67.6)
How to store the medicine	2 (11.8)	25 (17.4)	51 (30.1)	0	78 (23.6)
I want to know everything written on the PIL	0 (0)	22 (15.3)	40 (23.8)	0	62 (18.8)
Assistance needed to scan the QR code	14 (82.3)	79 (54.8)	56 (33.3)	1 (100)	152 (46.1)

Note that values represent patients who answered ‘yes’

3.1.3. Patients' willingness and ability to scan the QR code presented

The patient survey indicated that 85% were willing to scan the QR code, 80% were able to scan the QR code (Table 3), and 81% found it very easy/easy/okay to scan the QR code (Table 3). These results are similar to the findings in a related study at the Queen Victoria Hospital in the UK, where participants who were able to scan the QR code (96%) also found it easy to scan the QR code (Table 3).[45] However, the overall result for scanning the QR code in Tshwane district was determined to be 16% lower than the study conducted in the UK, indicating a possible lag in the adoption of the technology in Tshwane, leading to participant unfamiliarity.[44,50]

Table 3: Patients' willingness, ability and ease in scanning the QR code presented.

Variable	***N*=330 (per cent of *N*)**
Willingness to scan the QR code	281 (85.1)
Ability to scan the QR code	265 (80.3)
Ease of scanning the QR code:	
1 - Very easy	50.3
2 - Easy	27.3
3 - Okay	3.0
4 - Hard	14.8
5 - Very hard	4.5

Note that the values represent patients who answered 'yes'

3.1.4 Factors influencing the willingness and ability to scan the QR code

3.1.4.1 Access to technology

This study was conducted at a public sector (state) hospital. Patients who are not able to afford medical insurance or access private healthcare rely on public sector facilities such as the study site for treatment. Only 24% of the population in Gauteng can afford medical insurance (General Household survey, 2021), indicating that the majority, 76%, access public health facilities.[53] Tshwane District Hospital is a district referral hospital serving seven sub-districts, which serves almost 2 million people from both urban and rural areas.[75] Despite many of the patients not being able to afford medical insurance, 87% had access to the Internet, 91% had access to a mobile device, and 89% had access to data. Furthermore, 62% knew what a QR

code was, and 58% had scanned a QR code before (Table 4). As such, patients in the state sector should not be underestimated in terms of access to technology and knowledge of the Internet, including familiarity with QR codes. This observation is consistent with published data, which demonstrated that 98% of users in South Africa used a smartphone to access the Internet.[43]

A similar percentage of male and female patients had access to the Internet, access to a device and data (Table 4). Also, the percentage of male versus female patients willing to scan the QR code was similar. It was noted that 6% more female participants required assistance to scan the QR code (Table 4). Only 1% of the cohort defined themselves as “other”, and due to the low number, no conclusions can be drawn from the 1% (Table 1).

Table 4: Crosstabulation between variables related to access to technology and gender.

Variable	Gender			*N*=330 (per cent of *N*)
	Male n_i=95 (per cent of n_i)	Female n_i=233 (per cent of n_i)	Other n_i=2 (per cent of n_i)	
Do you know what a QR code is?	60 (63.2)	144 (61.8)	2 (100.0)	206 (62.4)
Have you ever scanned a QR code before?	55 (57.9)	134 (58.0)	2 (100.0)	191 (57.9)
Are you able to access the Internet?	79 (83.2)	206 (88.4)	2 (100.0)	287 (87.0)
Do you have access to a device?	87 (91.6)	211 (90.6)	2 (100.0)	300 (91.0)
Do you have access to data?	82 (86.3)	210 (90.1)	2 (100.0)	294 (89.1)
Are you willing to scan the QR code?	77 (81.0)	202 (86.7)	2 (100.0)	281 (85.1)
Are you able to scan the QR code?	69 (72.6)	194 (83.3)	2 (100.0)	265 (80.3)
Did you need assistance scanning the QR code?	40 (42.1)	112 (48.0)	0 (0.0)	152 (46.0)

Note that values represent patients who answered ‘yes’

3.1.4.2 Age and ability to scan the QR code

An association between the age group of the patients and knowledge of the QR code as well as access to technology, was found (Table 5). A higher percentage of patients, 72% in the age group of 19–25 and 68% in the age group 26–55, respectively, indicated that they knew what a QR code was compared to 41% from the 56–85-year age group. This implies that age had a highly significant relation (p <0.001) with knowledge of the QR code (X^2 = 18.43, df=2) and a moderate strength of association (C=0.230). In addition, patients in the 56–85-year age group

were less likely to have access to the Internet, 69% (Table 5), compared to those in other age groups (>90%). The measure of association was *C*=0.285, which is highly significant (*p*<0.001). Similarly, age and having access to a device and data had a significant relation (*p* <0.001) and measures of association of *C*=0.282, *C*=0.292 respectively (Table 5). The lower access of 23–30% to the internet, device and data for the older age group versus the other two age groups appears to correlate with the 30% difference in this group's willingness to scan the QR code presented compared to the other two groups (Table 5).

As per Table 6, 56% of the age group between 56 and 85 were able to scan the QR code, compared to >86% for the other two age groups. A strong contingency coefficient of *C*=0.318 and high significance (*p* <0.001) was noted. The digital divide between younger versus older patients is supported, as a higher percentage of older patients (75%) required assistance to scan the QR code compared to the other two age groups (28% and 39% for the 19–25 and 26–55-year age groups, respectively). The latter implies that younger patients are more familiar and early adopters of technology such as smartphone use for banking apps, online purchase of items, accessing the internet etc., versus the older patients who may not be familiar with the technology, hesitant to adopt the technology based on lack of trust and privacy issues.[21,37-40.] This was also seen in studies carried out in the United States, Dublin and India, where age differences in the knowledge and usage of QR codes were tested amongst various age groups.[47,48,50] There were significant age-related differences in awareness, knowledge and usage of QR codes between the age groups.[48] The differences were attributed to lower rates of smartphone usage by older adults, low familiarity due to the novelty of the technology, reduced access to smartphones and difficulty in using the technology.[48-50]

Overall, 46% of the population needed assistance to scan the QR code (Table 4), which is more than double the number of patients needing assistance in the study carried out at Queen Victoria Hospital in the UK. Once again, this indicates a possible lag in the adoption of the technology in Tshwane, leading to unfamiliarity with the QR code and finding it hard to scan (Table 4).[45,49,50]

There was a significant association between the younger age groups finding it easy to scan the QR code versus the older age group of 56–85 years (X^2=49.32, df=8, *p* < 0.001). The strength

of association was at *C*=0.361 (Table 6). For the age groups 19–25 and 26–55 years, 69% and 55%, respectively, indicated that they found it very easy to scan the QR code. Contrary, in the 56–85-years age group, only 26% of participants found it very easy to scan the QR code, with a high percentage in this age group indicating it was hard compared to the other two age groups.

Table 5: Chi-square values and contingency coefficients between variables related to access to technology and age groups.

Variable	Age (years)			X^2-value	C-value
	19–25 n_i=36 (per cent of n_i)	26–55 n_i=221 (per cent of n_i)	56–85 n_i=73 (per cent of n_i)		
Do you know what a QR code is?	26 (72.2)	150 (67.9)	30 (41.1)	18.43***	0.230
Have you ever scanned a QR code before?	26 (72.2)	147 (66.5)	18 (24.7)	42.85***	0.339
Are you able to access the internet?	35 (97.2)	202 (91.4)	50 (68.5)	29.16***	0.285
Do you have access to a device?	36 (100.0)	209 (94.6)	55 (75.3)	28.89***	0.282
Do you have access to data?	34 (94.4)	208 (94.1)	52 (71.2)	30.76***	0.292
Are you willing to scan the QR code?	34 (94.4)	201 (90.9)	46 (63.0)	36.63***	0.316
Are you able to scan the QR code?	35 (97.2)	189 (85.5)	41 (56.2)	37.21***	0.318
Did you need assistance scanning the QR code?	10 (27.8)	87 (39.4)	55 (75.3)	34.02***	0.306

Note that values represent patients who answered 'yes'
C: Contingency coefficient
***Correlation is significant at the 0.01 level (2-tailed)

Table 6: Chi-square values and contingency coefficients between ease of scanning the QR code and age groups.

Ease of scanning the QR code	Age (years)			X^2 *C*-value
	19–25 n_i=36 (per cent of n_i)	26–55 n_i=221 (per cent of n_i)	56–85 n_i=73 (per cent of n_i)	
Very easy	25 (69.4)	122 (55.2)	19 (26.0)	$X^2 = 49.32^{***}$ *C*=0.361
Easy	9 (25.0)	61 (27.6)	20 (27.4)	
Okay	1 (2.8)	5 (2.3)	4 (5.5)	
Hard	1 (2.8)	22 (10)	28 (38.4)	
Very hard	0 (0.0)	11 (5.0)	2 (2.7)	

C: Contingency coefficient
***Correlation is significant at the 0.01 level (2-tailed)

3.1.4.3 Schooling level and ability to scan the QR code

There was a moderate, albeit significant, association between 'schooling level' and assistance required to scan the QR code (Table 7). Patients with no or only primary schooling level required more assistance than those who had secondary or tertiary education (Table 2). There was also a strong association between assistance required to scan the QR code and experience of previously scanning a QR code (Table 7), indicating patients who previously scanned a QR code would most probably not need assistance the second time around. This also indicates patients who have not scanned a QR code at all can be educated on how to scan the QR code as proposed by Wang[40] and Choudrie et al.[39] The dispensing pharmacists and pharmacist assistants, as per the Good Pharmacy Practice Guidelines, are required to counsel patients on the use of their medication.[61] In the event ePIL is introduced in South Africa, they are therefore ideally suited to educate the patient on how to scan the QR code or to print the PIL for the patient at the pharmacy as is the case in some countries such as Italy, United States and Australia for OTC products.[63,64] Section 22G of the Medicines Act 101 of 1965 in South Africa allows the pharmacist to charge an appropriate dispensing fee. The dispensing fee is related to the review of the patient prescription and promotion of health literacy through the provision of information and instructions to ensure the safe and effective use of a medicine. This regulation also points to the dispensing pharmacist being in the correct position to advise the patient on how to scan the QR code and locate the necessary information.[1] Pharmacies in the state sector may need to be provided with appropriate printers to facilitate the printing of PILs for a patient who may request it.[1] This may, in turn, initially add additional time to products initially dispensed to the patient as well as cost implications for printers at the pharmacy to allow printing of the PIL.

Table 7: Chi-square values and contingency coefficients between schooling level, having previously scanned a QR code and assistance required to scan the QR code.

Variable	Assistance needed to scan the QR code			X^2-value	C-value
	Schooling level	Total (n_i)	Frequency (per cent of n_i)		
Schooling level	None	4	3 (75)	24.61***	0.263
	Primary	17	14 (82.4)		
Schooling level	Secondary	144	79 (54.9)	24.61***	0.263
	Tertiary	165	56 (34.0)		
Have you ever scanned a QR code before?	Yes	191	50 (26.2)	72.15***	0.424

C: Contingency coefficient
*** Correlation is significant at the 0.01 level (2-tailed)

3.1.5 Ease of reading and locating the information on the ePIL

To increase patient compliance with their medication, the information contained in a PIL must be visible, read, understood and up to date.[47] The current study focused on 'ease of reading the ePIL' and 'locating the information needed on the ePIL' and not on understanding PIL content. A high percentage (>95%) of patients who scanned the QR code found it easy to read the ePIL (Table 8) as well as locate the information they sought on the ePIL (Table 8). Both variables showed strong contingency coefficients with patients who had scanned the QR code (Table 8). Reasons for ease of reading the ePIL may be related to the ability to increase text size, as pointed out by the FDA and EMA, and adjusting the brightness of the QR-linked PIL on their smartphone.[3,14,71] Based on current regulations of the Medicines Act 101 of 1965 in South Africa, font type and size on the printed PIL should be Helvetica 6 point.[6] This small text makes reading difficult, especially for people with poor vision. Age is related to vision changes.[72] It is common to require more light, larger font size and spectacles to read.[72] The position paper, "Electronic product information for human medicines in the EU" (EMA, 2019), goes further to state that the current paper PI does not serve all citizens equally, given the wide range of social and physical disabilities in society.[14] The position paper states that the ePI allows for the use of large fonts, high screen contrast for partially sighted users and audible formats for blind users and those with low literacy levels.[14] Several studies have also shown that one of the problems with the current PIL is the small font size, which makes it difficult to

find the information needed.[44,45,50,68] The EMA-HMA-EC collaboration (2020) indicates one of the key principles of the ePI will be "accessibility by design." The ePIL allows for an increase in front size, enhanced high-screen contrast, audible formats for blind users and can allow for videos.[14,46]

Table 8: Chi-square values and contingency coefficients between ease of reading and locating the information on the ePIL and the scanned QR code in the patient population.

Variable	Scanned the QR code n_i=265 (per cent of n_i)	X^2	C-value
Ease of reading the ePIL	257 (97.0)	114.16***	0.487
Did you find the information needed?	260 (98.1)	122.41***	0.521

C: Contingency coefficient
***Correlation is significant at the 0.01 level (2-tailed)

3.1.6 Patient preference of PIL format

There was a moderate association between participants who read the PIL or sections thereof and the PIL format preference (Table 9). Almost half the sample who had never read the PIL indicated that they liked the ePIL (Table 9). This is a positive finding, and it is believed that with the availability of the electronic format, the patients would in future read the ePIL. Should this be the case, such a change in behaviour could impact patient compliance positively.[73]

The association between participants' PIL format preference and age or gender was weak (Table 10). The highest percentage preference was for both 'ePIL+hardcopy' in all age groups, with the lowest percentage preference for the hardcopy PIL only. Irrespective of age, gender, or the ability to scan the QR code presented, there was a positive sentiment towards both the ePIL and 'ePIL+hardcopy' (Table 10). In contrast to the study carried out in Sweden, where only 17% preferred the ePIL. The limitation of this study was participants were only given the choice of paper or ePIL.[46]

The was no significant difference in PIL format preference between male and female patients at Tshwane (Table 9). The 34% female patients who preferred the ePIL was significantly lower

than the reported 69% at the Queen Victoria hospital in the UK.[45] However, the results cannot be compared directly since participants at Queen Victoria Hospital were only provided with two options, i.e. hardcopy or ePIL, compared to this study, which included an additional option of both 'ePIL+hardcopy.' Thus, looking at preference for hardcopy PIL only in both studies, showed a 13% increase in female patient preference at Tshwane for the hardcopy. This small difference could be related to the unfamiliarity with QR code technology as presented by the 62% of female patients who answered 'yes' to the question 'Do you know what a QR code is?' indicating the need for education on QR code technology amongst patients.[21,46,65]

There is an 80% positive sentiment towards ePILs, be it alone or together with a hardcopy (Table 10). Given this is the first survey making patients aware of the ePIL option, the high percentage preference for ePIL indicates movement towards electronic format will not be difficult if patients are educated on the QR code and navigation of the ePIL.[21,45,46,65] Patients could also be transitioned by providing both the ePIL and the hardcopy prior to full implementation of ePILs.[44] This dual system is supported by countries such as the EU, Canada and Brazil.[61] Industry groups, such as the Pharmaceutical Group of the European Union, also strongly support the ePI as a complementary tool to the current printed paper PI.[4,14,61] Bahrain, Kuwait, Oman and Qatar of the Gulf Cooperation Council issued circulars in July 2023 informing pharmaceutical companies to apply for QR codes for all registered medicines before the end of 2025, thereby enabling gradual move from paper leaflets to electronic leaflets by 2025.[67-70] Studies carried out in Sweden and the UK reported that patients preferred both ePILs and hardcopy PILs.[46,71,73,74] Whilst this transitional approach of having both the ePIL and hardcopy PIL seems like a rational compromise, there may be discrepancies between the ePIL and paper PIL at any given time given the speed an ePIL can be updated versus editing, review and printing of a paper PIL for incorporation in the medicine package.[64] It may, therefore, be important for the regulator to consider adding a statement to the PIL guideline, indicating the ePIL may be more up-to-date compared to the hardcopy PIL.[64] Whilst the dual system of ePIL and hardcopy PIL covers the transition period to a complete paperless medicine package, there will always be a percentage of patients preferring the hardcopy PIL as seen in the study (Table 10).

Table 9: Chi-square values and contingency coefficients between reading the PIL, age, gender, scanning the QR code and PIL format preference in the patient population.

Variable		PIL format preference			n_i	X^2	C-value
		ePIL (per cent of n_i)	Hardcopy (per cent of n_i)	ePIL+ Hardcopy (per cent of n_i)			
Read PIL	**Yes**	72 (29.7)	47 (19.3)	124 (51.0)	243	17.563***	0.223
	No	42 (48.3)	23 (26.4)	22 (25.3)	87		
Age (years)	**19–25**	13 (36.1)	5 (13.9)	18 (50.0)	36	28.34***	0.281
	26–55	88 (39.8)	34 (15.4)	99 (44.8)	221		
	56–85	13 (17.8)	31 (42.5)	29 (39.7)	73		
Gender	**Males**	36 (37.9)	27 (28.4)	32 (33.7)	95	11.06**	0.180
	Females	78 (33.5)	40 (17.2)	115 (49.3)	233		
	Other	2 (100.0)	0	0	2		
Scanned QR code		112 (42.3)	17 (6.4)	136 (51.3)	265	177.31***	0.591

C: Contingency coefficient
**Correlation is significant at the 0.05 level (2-tailed)
*** Correlation is significant at the 0.01 level (2-tailed).

Table 10: Patient Information Leaflet format preference of the patient population

Variable	***N*=330 (percent of *N*)**
ePIL	116 (35.2%)
Hardcopy	67 (20.3%)
ePIL + hardcopy	147 (44.5%)

3.1.7 Reliability of the patient data

The Cronbach's alpha for scale-level questions was >0.60, confirming the reliability of the data (Table 11).[79]

Table 11: Cronbach's alpha for scale-level questions

Questions related to	Cronbach's alpha
Reading the PIL	0.86
Access to technology	0.76
Ease of reading and locating the information on the ePIL	0.90

3.2 Survey conducted among pharmacists and pharmacist assistants

3.2.1 Demographics, patient counselling and knowledge of QR codes

The total number of participants was 17; however, one response had to be discarded as it was incomplete. In this study group, most participants were female and in the 26–55-year age group (Table 12).

Patient counselling was only performed by 69% of the pharmacists or pharmacist assistants. The main reasons chosen from the choices provided were 'insufficient time due to long patient queues' and 'the patient does not want to be counselled' (Table 12). This could be attributed to the number of scripts processed by the pharmacy in a day (i.e. 160–180 prescriptions based on the number of outpatients as well as clinics held), resulting in insufficient time to provide patient counselling. Furthermore, this would avoid patients needing to return to the pharmacy the next day to pick up their medicine if not being assisted on the day. Tshwane being a referral hospital supporting seven sub-districts of almost 2 million people from both urban and rural areas where two-thirds rely on the state for healthcare is indicative that patients do not have additional money for transport to return to the hospital the next day to pick up their medication.[75] A higher percentage of the 19–25 year age group had answered 'yes,' to performing patient counselling versus the 26–55 year age group. The 19–25-year age group, having recently

qualified, may be more passionate about patient counselling, whilst the older age group, having a better understanding of the hospital pharmacy and critical areas to ensure smooth day-to-day running of the pharmacy, may only be performing counselling when necessary.

Only 63% of the pharmacists and pharmacist assistants were aware of what a QR code was and 69% had access to the internet at the pharmacy (Table 12). The pharmacists and pharmacist assistants in the 19–25-year age group were more familiar with QR codes than the age group of 26–55 years (Table 12). The familiarity of QR codes was 17% lower in the 26–55-year age group compared to the patients in the same age group. This could be a result of not being exposed to the technology, given QR code usage only recently took off after the COVID-19 pandemic and was only recently adopted by countries for the delivery of health information.[35] It would be important to expose pharmacists and pharmacist assistants in the public sector to conferences and educational material on innovation in the pharmaceutical sector.[46,63,66]

Table 12: Crosstabulation of gender, knowledge of QR codes, access to technology, willingness and ability to scan the QR code, PIL format preference and age groups.

Variable		Age (years)		*N*=16 (per cent of *N*)
		19–25 n_i=6 (per cent of n_i)	26–55 n_i=10 (per cent of n_i)	
Gender	**Male**	1 (16.7)	6 (60.0)	7 (43.8)
	Female	5 (83.3)	3 (30.0)	8 (50.0)
	Other	0 (0.0)	1 (10.0)	1 (6.3)
Totals		6 (37.5)	10 (62.5%)	16 (100.0%)
Patient counselling and knowledge of QR codes				
Performance of patient counselling		5 (83.3)	6 (60.0)	11 (68.8)
Insufficient time to perform patient counselling due to long patient queues		2 (33.3)	4 (40.0)	6 (37.5)
The patient does not want to be counselled		1 (16.7)	3 (30.0)	4 (25.0)
Lack of facilities to perform counselling		1 (16.7)	1 (10.0)	2 (12.5)
I believe counselling will not change the patients' habits		1 (16.7)	1 (10.0)	2 (12.5)
Knowledge of QR codes		5 (83.3)	5 (50.0)	10 (62.5)
Scanned QR codes previously		3 (50.0)	4 (40.0)	7 (43.8)
Access to technology				
Access to the internet at the pharmacy		2 (33.3)	9 (90)	11 (68.8)
Device to scan		5 (83.3)	2 (20)	7 (43.8)

Variable	Age (years)		*N*=16 (per cent of *N*)
	19–25 n_i=6 (per cent of n_i)	26–55 n_i=10 (per cent of n_i)	
Willingness and ability to scan the QR code			
Willing to scan a QR code	3 (50.0)	6 (60.0)	9 (56.3)
Able to scan a QR Code	4 (67.0)	5 (50.0)	9 (56.3)
Assistance to scan QR code	1 (16.7)	1 (10.0)	2 (12.5)
Comfortable to scan QR code	4 (67.0)	6 (60.0)	10 (62.5)
Easy to read ePIL	4 (67.0)	5 (50.0)	9 (56.3)
Find info on ePIL	3 (50.0)	5 (50.0)	8 (50.0)
Use of ePIL to counsel	3 (50.0)	7 (70.0)	10 (62.5)
Preference ePIL/hardcopy/ePIL+hardcopy			
ePIL	2 (33.3)	3 (30.0)	5 (31.3)
Hardcopy	3 (50.0)	2 (20.0)	5 (31.3)
ePIL+hardcopy	1 (16.7)	5 (50.0)	6 (37.5)

Note that values represent patients who answered 'yes'

3.2.2 Access to technology, willingness and ability to scan the QR code

Only 44% of the participants reported previously scanning a QR code and having a device to perform scanning (Table 13). The responses were in stark contrast to the South Africa digital insights statistics report presented in 2023 and the ICASA report of 2022, where it was documented that 97% of the population accessed the internet with their smartphone.[41,42] Of the participants, 56% indicated 'willingness and ability to scan the QR code'. Twenty-one per cent more males than female pharmacist and pharmacist assistants were able to scan the QR code, with none of the male participants needing assistance to scan the QR code, compared to 13% of females requiring assistance to do so. More than half of the pharmacists and pharmacist assistants were able to scan the QR code presented in the survey using their mobile devices, with 86% finding it easy to read the ePIL. Only 63% were comfortable scanning the QR code, which could be related to privacy concerns. Community pharmacists in the European Union and Hong Kong confirmed the uniform resource locator (URL) of the ePI should be safe and secure, ensuring data protection and the privacy of the user is maintained.[4,62] Given the small sample size (N=16) and conducting the survey at a single medical facility, further studies are required to confirm the findings. Most staff did not require assistance scanning the QR code (Table 13). Associations such as the South African Association of Community Pharmacists

may need to consider training public sector pharmacists on QR codes, its use and how it can be used to speedily locate information needed by HCPs or patients.[62]

Table 13: Crosstabulation of pharmacist and pharmacist assistants with patient counselling, knowledge of QR codes, access to technology, willingness and ability to scan the QR code and PIL format preference and gender.

Variable	Gender			*N*=16 (per cent of *N*)
	Male $n_i = 7$ (per cent of n_i)	Female $n_i = 8$ (per cent of n_i)	Other $n_i = 1$ (per cent of n_i)	
Patient counselling and knowledge of QR codes				
Patient Counselling	4 (57.1)	6 (75.0)	1 (100.0)	11 (68.8)
Insufficient time to perform patient counselling due to long patient queues	3 (42.8)	2 (25.0)	1 (100.0)	6 (37.5)
The patient does not want to be counselled	3 (42.8)	1 (12.5)	0 (0.0)	4 (25.0)
Lack of facilities to perform counselling	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
I believe counselling will not change the patients' habits	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Knowledge of QR codes	5 (71.4)	5 (62.5)	0 (0.0)	10 (62.5)
Scanned QR codes previously	4 (57.1)	3 (37.5)	0 (0.0)	7 (43.8)
Access to technology				
Access to internet at the pharmacy	7 (100.0)	3 (37.5)	1 (100.0)	11 (68.8)
Device to scan	2 (28.5)	5 (62.5)	0 (0.0)	7 (43.8)
Willingness and ability to scan the QR code				
Willing to scan a QR code	6 (85.8)	2 (25.0)	1 (100.0)	9 (56.3)
Able to scan a QR Code	5 (71.4)	4 (50.0)	0 (0.0)	9 (56.3)
Assistance to scan QR code	0 (0)	1 (12.5)	1 (100.0)	2 (12.5)
Comfortable to scan QR code	6 (85.7)	4 (50.0)	0 (0.0)	10 (62.5)
Easy to read ePIL	6 (85.7)	3 (37.5)	0 (0.0)	9 (56.3)
Find info on ePIL	6 (85.7)	2 (25.0)	0 (0.0)	8 (50.0)
Use of ePIL to counsel	7 (100.0)	3 (37.5)	0 (0.0)	10 (62.5)
Preference ePIL/hardcopy/ePIL+hardcopy				
ePIL	4 (57.0)	1 (12.5)	0 (0.0)	5 (31.3)
Hardcopy	0 (0.0)	5 (62.5)	0 (0.0)	5 (31.3)
ePIL+hardcopy	3 (42.8)	2 (25.0)	1 (100.0)	6 (37.5)

Note that values represent patients who answered 'yes'

3.2.3 Pharmacist and pharmacist assistants preference, ease of reading the PIL and use of the QR-coded PIL for counselling

The Fisher's exact test showed there was a statically significant association between gender and PIL format preference (Table 14) none of the male pharmacists preferred the hardcopy PIL format only (Table 14). Preference for this group was for either the ePIL and 'ePIL+hardcopy' (Table 14). This finding is corroborated by the community pharmacists represented by PGEU,

who welcomed the electronic leaflet as complementary to the current paper copy.[4] This indicates the preference in South Africa for a dual system of ePILs and paper PILs similar to that adopted by the EU, Canada and Brazil.[4,64] There was no significant association between age and PIL format preference (Table 14).

There was a significant relationship between the 'ease of reading the ePIL' and the 'scanned QR code', as well as between the 'ability to locate the information on the ePIL' and the 'scanned QR code' (Table 15). Even though there was no association between pharmacy staff who 'scanned the QR code' and 'use of the ePIL to counsel patients,' more than 75% indicated they would scan the QR code to counsel the patients (Table 15).

Table 14: Fisher's exact test and contingency coefficients between age and gender and PIL format in pharmacists and pharmacist assistants.

Variable		PIL format preference			n_i	*p*-value	*C*-value
		ePIL (per cent of n_i)	Hardcopy (per cent of n_i)	ePIL + hardcopy (per cent of n_i)			
Age (years)	**19–25**	2 (33.3%)	3 (50.0%)	1 (16.7%)	6	*p*=0.3756	0.215
	26–55	3 (30.0%)	2 (20.0%)	5 (50.0%)	10		
Gender	**Males**	4 (57%)	0 (0.0%)	3 (42.9%)	7	*p*=0.0331	0.502
	Females	1 (12.5%)	5 (62.5%)	2 (25.0%)	8		
	Other	0	0	1 (100.0%)	1		
Scanned QR code		3 (33.3%)	2 (22.2%)	4 (44.4%)	9	*p*=0.8252	0.220

C: Contingency coefficient

Table 15: Fisher's exact test and contingency coefficients between age and gender and PIL format in pharmacists and pharmacist assistants.

Variable	Scanned QR code n_i=9 (per cent of n_i)	*p*-value	*C*-value
Ease of reading the ePIL	8 (88.9%)	*p*=0.0087	0.746
Did you find the information needed?	7 (77.8%)	*p*=0.0406	0.630
Use of ePIL to counsel patients	7 (77.8%)	*p*=0.3024	0.337

C: Contingency coefficient

3.2.4 Reliability of the pharmacy data

The Cronbach's alpha for scale-level questions was >0.60 confirming the reliability of the data (Table 16). [79]

Table 16: *Cronbach's alpha for scale-level questions*

Questions related to	Cronbach's alpha
Access to technology	0.75
Ease of reading and locating the information on the ePIL	0.94

3.3 Focus group study

The regulatory affairs pharmacist plays a critical role as the custodian responsible for the submission of the PIL to the regulator for approval. A key area in any medicine submission for registration is the PIL. This is reviewed by the regulator prior to medicine registration. Upon registration, the regulatory affairs pharmacist works with artwork management teams for the creation of the PIL commodity to be included in the medicine packaging. Any new indications as well as safety updates to a medicine, entail a variation of the PIL, which requires approval from the regulator.[1,6,7,8] In regions such as the EU, they take on the responsibility to submit the ePIL for approval based on the principles set out by EU CMDh.[65] The regulatory affairs pharmacist is in the driver's seat to ensure the conversion of the paper PIL to ePIL for patient access.[64] A focus group study was conducted among regulatory affairs pharmacists to gauge their perception of the ease of implementation of the QR codes and the use thereof to access the PIL.

3.3.1 Familiarity with the QR code

All participants were aware of QR codes and were able to quote examples of where they had used them. These included banking apps, restaurant menus, adverts, forms and pharmaceutical supply chain. This aligns with commercial tracking, entertainment, in-store

product labelling, and applications that are aimed at smartphones and other mobile devices provided by Atkinson[27], Chang[26] and Tiwari.[25]

Quotes from the focus group: theme 1: Familiarity with the QR code

"*QR codes are present for banking apps.*"
"*During COVID most restaurant implemented QR codes for their menus.*"
"Y*ou see lots of adverts with QR codes.*"
"A*pplication forms can now be access using a QR code.*"
"E*verything is going electronic.*"
"Used in supply chain for track and trace implementation."

3.3.2 Current usage of QR codes in the pharmaceutical industry

Some participants indicated that they had already used the QR code in practice, whilst others were able to quote examples of where it was used. Based on the feedback from participants, it was evident that QR codes are already being utilised for the provision of medical information, managing 'Dear Healthcare Professional letters' in the supply chain to track the product and prevent counterfeiting, and for easy access to PI and PIL on marketing material as well as current use by the OTC industry. The use of QR codes in the supply chain was aligned with the track and trace requirements in countries such as the EU, Ethiopia, Nigeria, South Africa and Zambia, which allows for tracking, tracing, product recall and preventing counterfeiting of medication.[29-34]

Quotes from focus group: theme 2: Current use of the QR code in the pharmaceutical industry

"*We are using it already for providing medical information and managing Dear HCP letters."*
"*It is a requirement for products on tender to include a 2D bar code in the supply chain to aid tracking of the product."*
"W*e are utilizing QR codes to capture the PI/PIL on marketing material*."
"Used in batch traceability to prevent counterfeiting."
"OTC industry in South Africa is using it for PI and PILs"

3.3.3 Regulatory Affairs Pharmacists' preference and advantages of using a QR code for PILs

Contrary to the dispensing staff and patients surveyed at Tshwane District Hospital, all regulatory affairs pharmacist participants preferred only the ePIL and mentioned the advantages for its use, which aligns with that already described: quick and easy access to product information, rapid update of new product safety information as it becomes available, readily accessible, ability to search label content, enhanced readability, improved production timelines, and a reduction in the use of paper[5,14,64,65,66] An additional advantage articulated by the regulatory affairs pharmacists included the use of QR codes to deliver ePILs for patient ready packs which are dispensed without a leaflet either in the public hospital or private pharmacy.

Quotes from focus group: theme 3: Regulatory affairs pharmacists' preference

"I would prefer the QR code versus 100 pieces of paper,"

"It will require a mind shift change on the part of the patient"

"There will always be those patients who prefer paper."

"*I would be delighted to only have an ePIL."*

"Pharmacy personal could offer the services to print the PIL for the patient wanting the paper PIL."

Quotes from focus group: theme 3: Advantages of using QR codes for PILs

"It is easy to use."

"Enables quick access to the PIL when needed as most people lose the PIL."

"Makes it easier to read the PIL as older people can increase the size of the text."

"*It is a more efficient way of managing 'Dear Doctor letters' as well as provision of updated product and safety information as well as medical information."*

"*It supports sustainability as it reduces the need to place a printed leaflet in the product pack."*

"It reduces paper wastage."

"*Allows for shared packs across many countries as the QR code can capture more than one language.*"

"*There are many products dispensed without a PIL particularly in the State sector, the QR coded PIL will be extremely beneficial here."*
"May help the hospital setting where medication is dispensed without the leaflet or patients not counselled on how to use the product."
"QR codes can be used by the pharmacy to provide an ePIL when breaking a pack to dispense to a patient as these packs do not come with a leaflet."

3.3.4 Debate over technology and the ability to scan the QR code

Half of the regulatory affairs pharmacists were concerned about the accessibility to a smartphone to scan the QR code for the ePIL by older patients who may not own one and those in rural areas. The regulatory affairs pharmacists also mentioned that a change in mind-shift on the part of the patient is required and that dispensing pharmacists should assist in educating the patient regarding scanning the QR code to access medicine information. Despite their concern, the patient survey indicated that 91% of patients had access to a device and 80% were able to scan the QR code (Table 4; page 45), implying that the reality is different. Furthermore, irrespective of age, gender or ability to scan the QR code presented, patients reflected a positive sentiment towards the ePIL, with 80% of the population preferring the ePIL or 'ePIL+hardcopy' (Table 10; page 52). The regulatory affairs pharmacists concerns over patients' accessibility to technology in rural areas may be valid; however, additional studies are required to confirm this.
Quotes from focus group: theme 4: Debate over technology and the older generation's ability to scan the QR code

"*What about older patients who may not have a smartphone to scan the QR code?*"
"*The dispensing pharmacist or family can teach them how to use their smartphone to scan the QR code. I showed my mum how to use her smartphone.*"
"W*e need to give patients credit and not to assume patients are ignorant or do not have a smartphone."*
"We need to consider patients in rural areas who may not have smartphones."

3.3.5 Implementing QR codes for PILs

Even though not all regulatory affairs pharmacists utilised QR codes in practice, there was unanimous agreement that it was a simple process and could not be more difficult than putting together a medicine application for registration.

Quotes from focus group: theme 5: Creation of QR codes

"*It is not tough to generate a QR Code."*

"I have not done it but if my colleagues say it is easy than it means once you show me, I will be able to manage this."

"I think if we can put a dossier together QR code generation should be a piece of cake."

"Companies may need global support."

"The readability may need to be checked."

Chapter 4 Conclusion

With the advancement in technology, more countries are implementing ePILs. By law, PILs are required to be included in the medicine pack. To benefit from a PIL, it must be up-to-date, visible, read and retained. The QR code is a smart way of ensuring the PIL is on the medicine pack. The PIL is critical to ensure the HCP and patient have the latest product information to enable informed decision-making, which includes but is not limited to dosage, usage, side effects, etc.

The regulatory affairs pharmacists supported the QR-coded PIL over paper PILs given the many advantages, which included enhancement of readability, quick access, searchability, management of safety and product information updates in real-time and added advantage of being present with the product at the point of dispensing for patient ready packs, where a leaflet is not included, increasing correct medication use and possibly patient compliance.

It was demonstrated that patients felt it important to read the PIL, however not in its entirety and patients who did not read the PIL previously were encouraged by the QR code to read the ePIL. Patients were familiar with a QR code and showed a positive sentiment toward the QR code for patient information delivery in the Tshwane district. The patient group aged 56–85-years had reduced access to technology and patients with only primary school or no education required assistance to scan the QR code, indicating that there is a role for the dispensing pharmacist to play in assisting and teaching the patient how to scan the QR code as well as locating the required information. Patients, as well as pharmacists and pharmacist assistants clearly saw the advantage of an ePIL, which included an increase in text size to enhance readability and ease of locating information needed. The pharmacists and pharmacists assistants who scanned the QR code also concurred that they would use the QR-coded PIL to counsel patients. Based on the results of this study, neither patients nor pharmacy staff are ready to completely transition to paperless medicine packs and would prefer a dual system including both a QR-coded PIL with a hardcopy PIL in the medicine pack.

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At this stage, the regulator in South Africa, SAHPRA, could consider updating regulations to allow for a dual system including both a QR-coded PIL as well as paper PIL in the medicine pack. The SAHPRA guidelines on PILs should also be updated to advise on the inclusion of a statement indicating the ePIL may be more up-to-date than the hardcopy PIL.

The complete transition to a paperless medicine pack is a possible consideration as a next phase, with a printed PIL available at the point of dispensing if required. SAHPRA and the South African Pharmacy Council, together with industry associations such as the South African Association of Community Pharmacists, have a key role to play in terms of providing patients with training on how to scan the QR-coded PIL and locate the information needed. This will aid in patient adoption of the innovative technology, facilitating the full role out of paperless PILs.

4.1 Limitations of the study and recommendations

The age bands used in this study were 19–25 years, 26–55 years and 56–85 years. These age bands are broad and there is an overlap in the generations. A better split between the age bands covering the four main generations and considering the inclusion criteria of 18 years and above could be Generation Z (19–22 years), Millennials (23–38 years), Generation X (39–54 years) and Baby Boomers (55–73 years).[78] Anyone over the age of 73 years can also be included in the Baby Boomer category. Splitting the age bands by the generations may be a better option to collate the data especially since the study reviews the use of new technology for patient information delivery. Future studies should include the four age groups to produce a more detailed review of the results.

The study conducted among pharmacists and pharmacist assistants was limited to 16 participants in only one hospital, whilst the study conducted amongst patients was limited to a tertiary hospital only. A study in a wider population, covering several hospitals, both at the academic and district level in both urban and rural areas, is necessary to draw conclusively on both pharmacy staff as well as patient knowledge of QR codes, use of a smartphone to scan the QR code and PIL format preference. The study should also consider pharmacists' willingness to educate patients on QR codes for patient information delivery and if pharmacists

would consider using the QR code for patient-dispensed packs with no PIL. A similar study can also be conducted among private sector pharmacies to better understand patients' and pharmacists' preference for patient information delivery through scanning of a QR code.

Additional studies on how to improve health literacy on medications are necessary to encourage patients to read the ePIL or PIL.

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Appendix I: Research Ethics Committee approval letter.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through June 30, 2025 and Expires 07/28/2026.

Faculty of Health Sciences **Research Ethics Committee**

15 September 2023

Approval Certificate
Annual Renewal

Dear Dr G Singh,

Ethics Reference No.: 444/2022 – Line 1
Title: Assessing the feasibility of quick response codes for patient information delivery in the Tshwane district

The **Annual Renewal** as supported by documents received between 2023-08-21 and 2023-09-13 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2023-09-13 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2024-09-15.
- Please remember to use your protocol number (444/2022) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

_____
On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4.60, Level 4, Tswelopele Building
University of Pretoria, Private Bag x323
Gezina 0031, South Africa
Tel +27 (0)12 356 3084
Email: deepeka.behari@up.ac.za
www.up.ac.za

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

Appendix II: CEO approval letter.

GAUTENG PROVINCE

Annexure 1

Declaration of intent from the hospital CEO

I give preliminary permission **Ms Githa Singh** to perform her research **on "Assessing the feasibility of quick response codes for patient information delivery in the Tshwane District Hospital.**

I know that the final approval will be from the Tshwane Regional Research Ethics Committee and that this is only to indicate that the hospital is willing to assist.

Other comments or conditions prescribed by the hospital CEO:
Once research is completed kindly send a copy to the hospital CEO so that the hospital can improve services based on research findings.

MS M.G MOGASHOA
TSHWANE DISTRICT HOSPITAL
CEO

Ms Monene Mogashoa
Chief Executive Officer
Tshwane District Hospital
072 0944411

04/2012
Date

Appendix III: Participant information and informed consent

PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT

STUDY TITLE:

Assessing the feasibility of quick response codes for patient information delivery in the Tshwane district

Sponsor: …Department of Pharmacology, University of Pretoria**……**

Principal Investigators: …Githa Singh**……..**

Institution: …… University of Pretoria **……**

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

Daytime number/s: ……083 794 5518**……**

Afterhours number: ……083 794 5518**……...**

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

			:	
Date	**month**	**year**	**Time**	

Dear Prospective Participant

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a …**MSc**….. Degree purpose at the University of Pretoria. This information in this document is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to evaluate **the feasibility of the implementation of the quick response (QR) code of the patient information leaflet (PIL) in the Tshwane district**. By doing so we wish to learn more about your view **on implementation of a QR code for PILs.**
Definition of QR code:. . A QR code is ***a pattern of black and white squares that can be read by a smartphone***, allowing the phone user to get more information about something.

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS.

This study involves answering some questions and scanning of a QR Code using your mobile phone.

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no medical risks associated with the study.

5) POSSIBLE BENEFITS OF THIS STUDY

Although you may not benefit directly. The study results may help us to improve readability and understanding of the PIL.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If you have any questions concerning this study, you should contact:
Mrs Githa Singh. Cell: 083 794 5518

10) CONFIDENTIALITY

All information obtained during the course of this study will be regarded as confidential. All data and patient identifiers will be anonymised. The hard copies of all your records will be kept in a locked facility at the Department of Pharmacology, University of Pretoria.

11) CONSENT TO PARTICIPATE IN THIS STUDY

- I have also received, read and understood the above written information about the study.
- I have had adequate time to ask questions and I have no objections to participate in this study.
- I am aware that the information obtained in the study, including personal details, will be anonymously processed and presented in the reporting of results.
- I understand that I will not be penalized in any way should I wish to discontinue with the study and that withdrawal will not affect my further treatments.
- I am participating willingly.
- I have received a signed copy of this informed consent agreement.

_____	_____
Participant's name (Please print)	Date
_____	_____
Participant's signature	Date
_____	_____
Researcher's name (Please print)	Date
_____	_____
Researcher's signature	Date

Appendix IV: Patient data collection survey

Definitions:
Patient information leaflet: *A page supplied in the medicine box providing more information on the medicine*

QR code: *A QR code is* **a pattern of black and white squares that can be read by a smart phone***, allowing the phone user to get more information about something*

Device*: Cell phone or tablet with camera which can scan the QR Code*

1.

1.1	**Gender**	**Place tick/cross**
a	Male	
b	Female	
c	Other	
1.2	**AGE**	
a	19 - 25	
b	26 - 55	
c	56 - 85	
d	➢ 85	
1.3	**Is English your primary or secondary language**	
a	primary	
b	secondary	
1.4	**Schooling level**	
a	Primary	
b	Secondary	
c	Tertiary	
d	None	

2. Please tick or cross ‘Yes’ or ‘No’ (If No, skip question 3)

No.	Question	Yes	No
2.1	Do you currently read the patient information leaflet (PIL) that is included in the medicine packaging?	Yes	No

3. What are the key areas you read in the PIL? (please circle)

No.	Area of PIL you read	Please tick/cross
3.1	What the medicine is used for?	
3.2	What do you need to know before you take the medicine?	
3.3	How to use the medicine?	
3.4	Possible side effects	
3.5	How to store the medicine?	
3.6	I want to know everything written on the PIL	

4. The following questions are based on QR codes. Please tick or cross ‘Yes’ or ‘No’

No.	Question	Yes	No
4.1	Do you know what a QR code is?	Yes	No
4.2	Have you ever scanned a QR code before?	Yes	No
4.3	Are you able to access the internet?	Yes	No
4.4	Do you have access to a device?	Yes	No
4.5	Do you have access to data?	Yes	No
4.6	Are you willing to scan the QR code?	Yes	No

5.1. Are you able to scan the QR code below to obtain a patient information leaflet of a medication? Please tick or cross “Yes” or “No”

Yes	No

5.2. How did you find scanning the above QR code?

1 – very easy	2 – easy	3 – ok	4 – hard	5 – very hard

5.3. These questions relate to the QR code scanned. Please tick or cross ‘yes’ or “no”

No.	Question	Yes	No
5.3.1	Did you need assistance in scanning the QR code?	Yes	No
5.3.2	Do you find it easy to read the PIL accessed by scanning the QR code?	Yes	No
5.3.3	Did you find the information you needed?	Yes	No

5.4. After scanning the above QR code, would you prefer using the QR coded PIL or a printed PIL to access information for a medicine, or both?

	Please tick or cross
QR coded PIL	
Printed PIL	
Both	

Appendix V: Pharmacy data collection survey

Definitions:
Patient information leaflet: *A page supplied in the medicine box providing more information on the medicine*

QR code: A QR code is ***a pattern of black and white squares that can be read by a smart phone***, allowing the phone user to get more information about something

Device*: Cell phone or tablet with camera which can scan the QR Code.*

1.

1.1	Gender	Place tick/cross
a	Male	
b	Female	
c	Other	
1.2	**AGE**	
c	19 - 25	
d	26 - 55	
e	56 - 85	
f	➢ 85	

2.1. Do you currently perform patient counselling? (Please tick or cross 'Yes' or 'No')

Yes	No

2.2. If you have answered 'No' to question 2.1, please advise why patient counselling is not being done. (Please tick or cross 'Yes' or 'No')

		Yes	No
2.2.1	Insufficient time to perform counselling due to long patient cues.	Yes	No
2.2.2	The patient does not want to be counselled.	Yes	No
2.2.3	Lack of facilities to perform counselling.	Yes	No
2.2.4	I believe counselling will not change the patient's habits.	Yes	No

3. The following questions relate to QR codes. Please tick or cross 'Yes' or 'No'

No.	Question	Yes	No
3.1.	Do you know what a QR code is?	Yes	No
3.2.	Have you ever scanned a QR code?	Yes	No
3.3	Are you able to access the internet at the pharmacy?	Yes	No
3.4.	Do you have a device to scan a QR code?	Yes	No
3.5.	Are you willing to scan the QR code to access the PIL?	Yes	No

4.1. Are you able to scan the QR code below to obtain a patient information leaflet of a medication? Please tick or cross "Yes" or "No"

Yes	No

4.2. Please tick or cross 'Yes' or 'No'

No.	Question	Yes	No
4.2.1.	Did you need assistance in scanning the QR code?	Yes	No
4.2.2.	Are you comfortable scanning the QR code?	Yes	No
4.2.3.	Do you find it easy to read the PIL accessed by scanning?	Yes	No
4.2.4.	Are you able to easily find what you are looking for in the electronic leaflet?	Yes	No

5. After scanning the above QR code, would you prefer using the QR coded PIL or a printed PIL to access information for a medicine or both?

	Please tick or cross
QR coded PIL	
Printed PIL	
Both	

5.1. Based on the functionality of the QR code, would you scan it to counsel patients? (Please tick or cross 'Yes' or 'No')

Yes	No

Appendix VI : Focus group Interview guideline

(1) Welcome participants.

(2) Define the topic. Indicate how the results of the study will be used

(3) Ground rules

Indicate that there are no right or wrong answers only differing viewpoints and to respect each other's views. Request participants to switch off all mobile phones. As moderator guide the discussion and facilitate the discussion.

(4) Ask permission from the participants to record the meeting.

(5) Ask the questions

Use open ended questions. Avoid, "yes" or "no" questions. Indicate that both positive and negative views will be captured as they are both important. Start with an opening question (round robin) moving from an introductory question, followed by transition and key questions and closing with and ending question. The questions should go from general to specific.

(6) Use a standardised form to take notes such as:

Question no.	Question	Notes
1	How and when have you used QR codes?	
2	Tell me about positive experiences you have had with QR codes.	
3	Tell me about disappointments you have had with QR codes.	
4	In what way do you think QR codes can benefit the pharmaceutical industry?	
5	Have you used QR codes in practice and can you provide any examples?	
6	How would you feel if the PIL was to be replaced by a QR code?	
7	What would be the impact of replacing the PIL with a QR code?	

(7) Analyse the notes, group the themes of the discussion in categories.