



Is it time to re-imagine product information for human medicines?

A preview of initial findings from patient and
healthcare professional engagement

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Kent Surrey Sussex Academic Health Science Network, Unity Insights and the UK National Innovation Centre for Innovation for Ageing (Newcastle University), working with and partially funded by Pfizer. The discussions laid out in this report are based on data generated within the study. These data are preliminary and while under review do not express the views and opinions of Pfizer Inc.

FOREWORD

On behalf of Kent Surrey Sussex Academic Health Science Network and Pfizer, we are delighted to share preliminary findings from our co-design work with the NHS, regarding written information that comes with prescription medicine – specifically, the product information for human medicines which includes the summary of product characteristics, labelling and package leaflet that comes with each package of medicine.

As trained clinicians ourselves, we know despite prescriber and pharmacists’ best efforts to convey medicines information in a clear way, patients are not always emotionally or physically able to take on board the information required to take their medication correctly. For instance, a patient may be recovering from surgery, or may just have received a life-changing diagnosis. The purpose of prescribing is to improve health, but there are a lot of factors that can get in the way of this happening. The interaction between HCP and citizen is only one of these factors. Benefitting from prescribed medication depends on the relationship and trust between the people involved, where else individual members of the public get their information from (family, peers, other health professionals, the internet), how many other medications the person must take, and how the

medicines are perceived to make them feel. To keep patients safe, regulators and pharmaceutical manufacturers provide product information covering their most important instructions on how to take medicines correctly, but a key finding of this report is that few people look at this information systematically.

The things that drive Health inequality also impact patients’ abilities to understand written information. Patients come from diverse socioeconomic

backgrounds and have varying levels of literacy. Some may come from different cultures and speak different languages. Others may be facing physical challenges such as limited sight or mobility, or mental health challenges such as dementia, learning disabilities or even anxiety and stress. They may be finding it challenging to balance taking multiple medicines. Even when these factors are not in play, the chaotic lives many people live can make prioritising time to read information leaflets even more

difficult. In today’s information age how many people would read a leaflet on changing a fuse when they can be guided by a 90 second YouTube clip? So how can we help all patients to get the most benefit with the least risk from their medicines? How can everyone receiving a prescription access, understand and gain benefit from medicines information? We start by looking at the current product information and label regulatory paradigm. This report contains high level findings from a survey of over 2000 patients from across England, along with data from interviews and focus groups with patients and healthcare professionals. We will review these initial findings with key stakeholders, prior to publishing a detailed report and analysis with recommendations later this year.

With this work, we have set out to provide an evidence base regarding the needs and preferences of patients and healthcare professionals. We hope this is useful not only for policy makers

and regulators, but also for industry and the NHS, all working towards the same goal of optimising patient experience and use of medicines, whilst at the same time improving outcomes. Failing to access drug information cannot be blamed for all sub-optimal therapeutic benefit from prescribed drugs, but co-designing enhanced solutions with the public, care professionals and regulators may bring greater benefits in the relationship between health and care and the public. These benefits could transfer to

other areas of need, like public health and prevention. A prize worth trying for as we emerge from a pandemic with record levels of unmet health need.

We would like to thank our partners Unity Insights, the National Innovation Centre for Ageing (NICA, at Newcastle University), and Sussex and Surrey Healthcare NHS Trust.

Without their valuable input and support this would not have been possible.

A study on functional health literacy levels across England reports that 42% of working-age adults are unable to understand and make use of everyday health information.²

Patients forget between 40-80% of medical information provided by their healthcare practitioner as soon as they leave the clinical setting; furthermore, almost half of the information remembered is incorrect.¹



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1. RPC Kessels. Patients’ memory for medical information. J R Soc Med 2003; 96: 219-222.
2. Public Health England report on Local action on health inequalities: Improving health literacy to reduce health inequalities; Sep 2015.

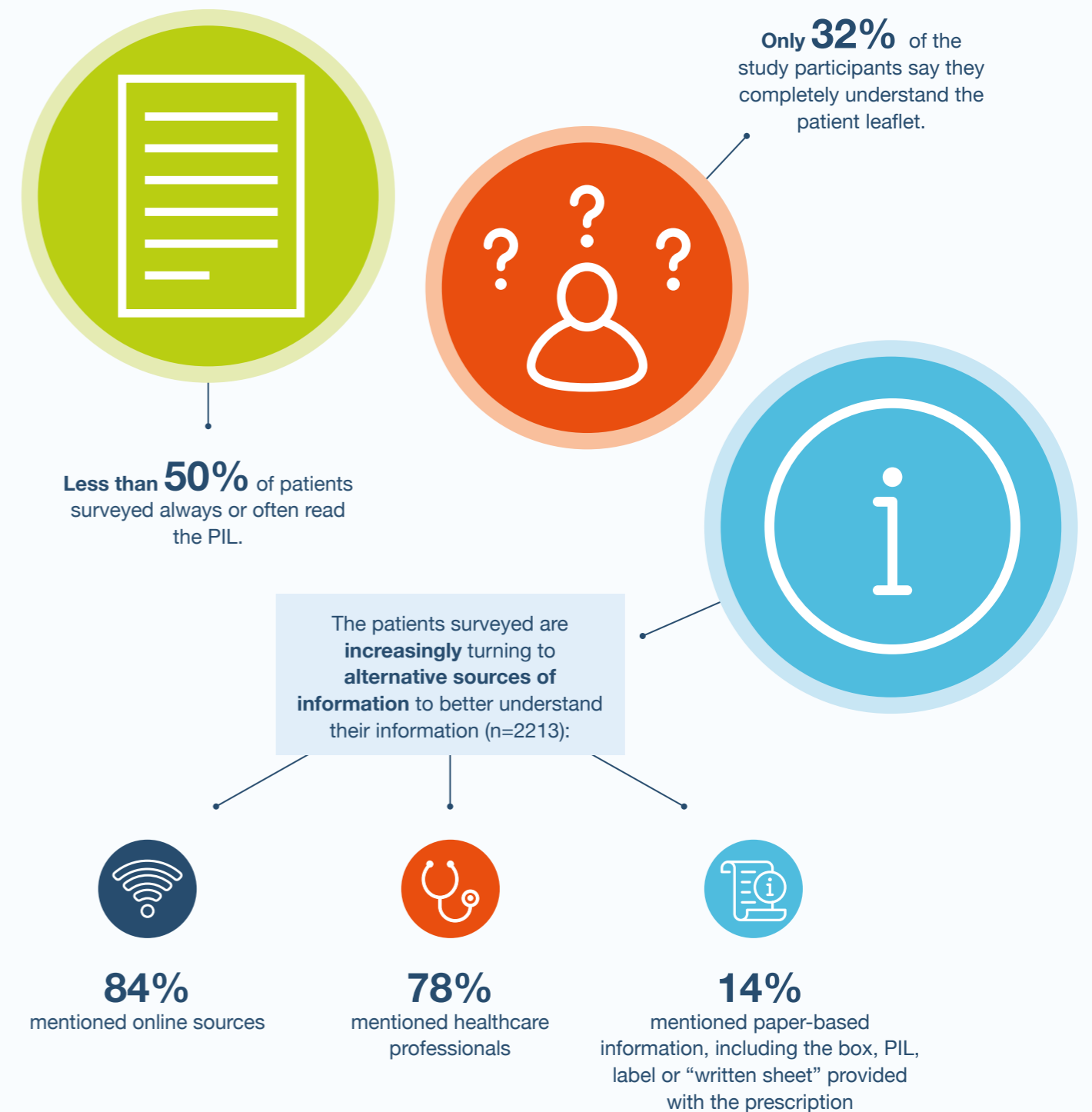
SUMMARY OF STUDY PERCEIVED CURRENT STATE AND EMERGING THEMES

Preliminary results show that study participants feel the following:

- The product information format and label regulatory paradigm has not changed substantially for decades.
- Not all patients are relying on the product information provided with their medicines and may not be revisiting this information on receiving their repeat prescription – meaning they may be missing out on vital product information updates.
- The survey and interviews and focus groups with Healthcare Professionals (HCPs) indicates that the HCPs appear to see product information as a collection of facts that fulfils a statutory requirement first and foremost, rather than giving patients the relevant information in a way that is accessible and understandable and addresses their anxieties about taking the medication.
- At the same time, many patients interviewed appear to feel that they lack access to clear, relevant, trusted information - personalised to meet their individual needs at the right time and in the right format.
- This is especially important for seldom heard groups, who may experience physical barriers such as sensory loss, language or cognitive barriers, or who may experience embarrassment, stigma and shame. As one patient interviewed said, “the information provided is not good enough, but clinicians don’t like patients finding information on the internet.”
- HCPs interviewed broadly recognized that there is not one size that fits all here and that the provision of information in the future will need to be in a whole variety of formats, and available on multiple platforms. Policymakers, industry and many of the HCPs interviewed noted the value of the interoperable medicines information standard, which could provide the opportunity to innovate in terms of the ways medication and patient information can be accessed and shared.
- Over the coming months, we will bring NHS patients and HCPs together with regulators, policymakers and industry partners to review the evidence collected, and to articulate a vision and a roadmap for a future product information paradigm. This will also examine concerns about the environmental impact of paper labels, and the potential for introducing more carbon-friendly alternatives.

Preliminary results show that study participants feel the following:

The study indicates that patients are not relying on the product information provided with the medicine, and instead increasingly are turning to online information sources, in addition to trusted clinical advice.



INTRODUCTION

“The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented.”

Medicines and Healthcare Products Regulatory Agency³

Medicines labelling and packaging are designed to keep patients safe. Regulators work together with pharmaceutical manufacturers to put into place “routine risk minimisation measures” for every medicinal product, including a standardised summary of product characteristics, the package label and the paper patient information leaflet (‘PIL’) that comes with each package of medicine.

Despite this, there are clear signs that the product information may not be fulfilling their stated intention. The World Health Organisation estimates that between 30-50% of patients do not take medicines according to prescription instructions.⁴ In the UK, ten days after starting a new medicine for a long-term

condition, one third of people are not taking it as advised on the pack, often intentionally so. Six in ten feel they have an unmet need for information and support 10 days after prescribing.⁵

This report investigates the current medicines product information paradigm and whether it can be enhanced to more positively influence both patient experience of and concordance with prescription medication. As healthcare shifts to digital solutions, it also explores if an opportunity exists to improve how this information might be provided in the future with the aim of increasing its value to patients and healthcare professionals. A full report will be published later in 2022.

What types of medicine could be addressed via improved product information and health literacy?

Several reviews presented by Howard et al. (2007) found that four groups of medicines account for more than 50% of the medicines groups associated with preventable medicines-related hospital admissions: antiplatelets, diuretics, nonsteroidal anti-inflammatory medicines and anticoagulants. Concentrating interventions on these medicines groups could reduce appreciably the number of preventable medicine-related admissions to hospital from primary care. Furthermore, Howard’s review of five studies found that the median proportion of preventable medicine-related admissions associated with prescribing problems was 30.6% (range 11.1–41.8), with adherence problems 33.3% (range 20.9–41.7) and with monitoring problems 22.2% (range 0–31.3).⁶

3. MHRA (2020). *Best practice guidance on the labelling and packaging of medicines*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/946705/Best_practice_guidance_labelling_and_packaging_of_medicines.pdf

4. World Health Organization. (2003). *Adherence to long-term therapies : evidence for action / [edited by Eduardo Sabaté]*. World Health Organization. <https://apps.who.int/iris/handle/10665/42682>. Quoted in <https://www.nice.org.uk/guidance/ng51/chapter/introduction>:

5. N Barber, J Parsons, S Clifford, R Darracott, R Horne. *Patients’ problems with new medication for chronic conditions*. *Qual Saf Health Care* 2004; 13: 172-175. doi: 10.1136/qshc.2003.005926

6. Howard RL, Avery AJ, Slavenburg S, et al. *Which drugs cause preventable admissions to hospital? A systematic review*. *Br J Clin Pharmacol*. 2007;63(2):136-147. doi:10.1111/j.1365-2125.2006.02698.x

APPROACH

Working together, Kent Surrey Sussex Academic Health Science Network, Unity Insights, the National Innovation Centre for Ageing at Newcastle University, and Surrey and Sussex NHS Trust brought together a number of streams of information, including a preliminary evidence search⁷ and data scan, 1:1 interviews, focus groups, and an online questionnaire advertised via social media. **In total we engaged:**



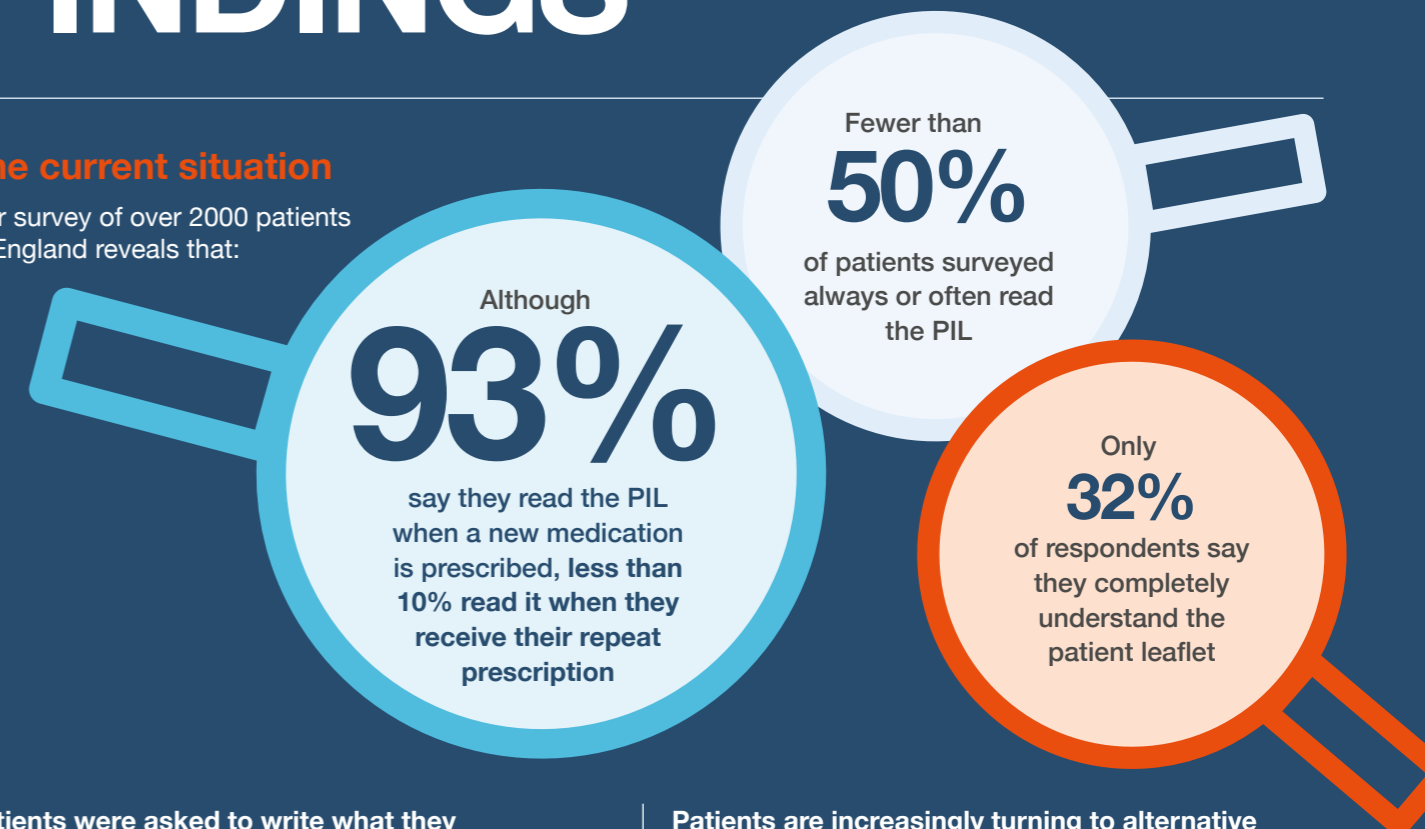
See Annex for further information. Detailed analysis is currently under way. In the meantime, we outline our preliminary findings below, so that we may test them with stakeholders and gain consensus on recommendations and next steps as part of the final report to be published later in 2022.

⁷Evidence search: Review of initiatives and interventions to support medication adherence and health literacy, with a particular focus on product labelling and e-labelling Alison McLaren (September 2021). East Surrey Hospital, UK: Surrey and Sussex Library and Knowledge Services.

PRELIMINARY FINDINGS

The current situation

Our survey of over 2000 patients in England reveals that:



Patients were asked to write what they found most difficult when reading product information (n=2247; patients were able to enter more than one response):

- 58% cited themes concerning readability (e.g. font size, quantity, relevance of information provided)
- 13% cited themes concerning comprehension (e.g. technical language making it difficult to understand)
- 28% stated they had no difficulties with the PIL

Patients are increasingly turning to alternative sources of information to better understand their information (n=2213; patients were able to enter more than one response):

- 84% mentioned online sources
- 78% mentioned healthcare professionals
- 14% mentioned paper-based information, including the box, PIL, label or "written sheet" provided with the prescription

The survey contains inherent bias as the result of primarily being advertised on Facebook (in addition, 74 paper questionnaires were received). To address this bias, interviews and focus groups with 40 patients and 18 healthcare professionals were also undertaken. Preliminary analysis of these indicate that the participants feel the majority of patients may not be reading or completely understanding the product information. Study participants also felt that patients may not be relying on the product information and do not revisit the PIL on receiving their repeat prescription, despite the fact that updates can occur on a routine basis.

PRELIMINARY FINDINGS

Patient Focus Group Insights

Barriers to using and understanding medicines product information

A summary of common themes within patient interviews and focus groups is that patients appear to feel that they lack access to clear, relevant, trusted information - personalised to meet their individual needs at the right time and in the right format.

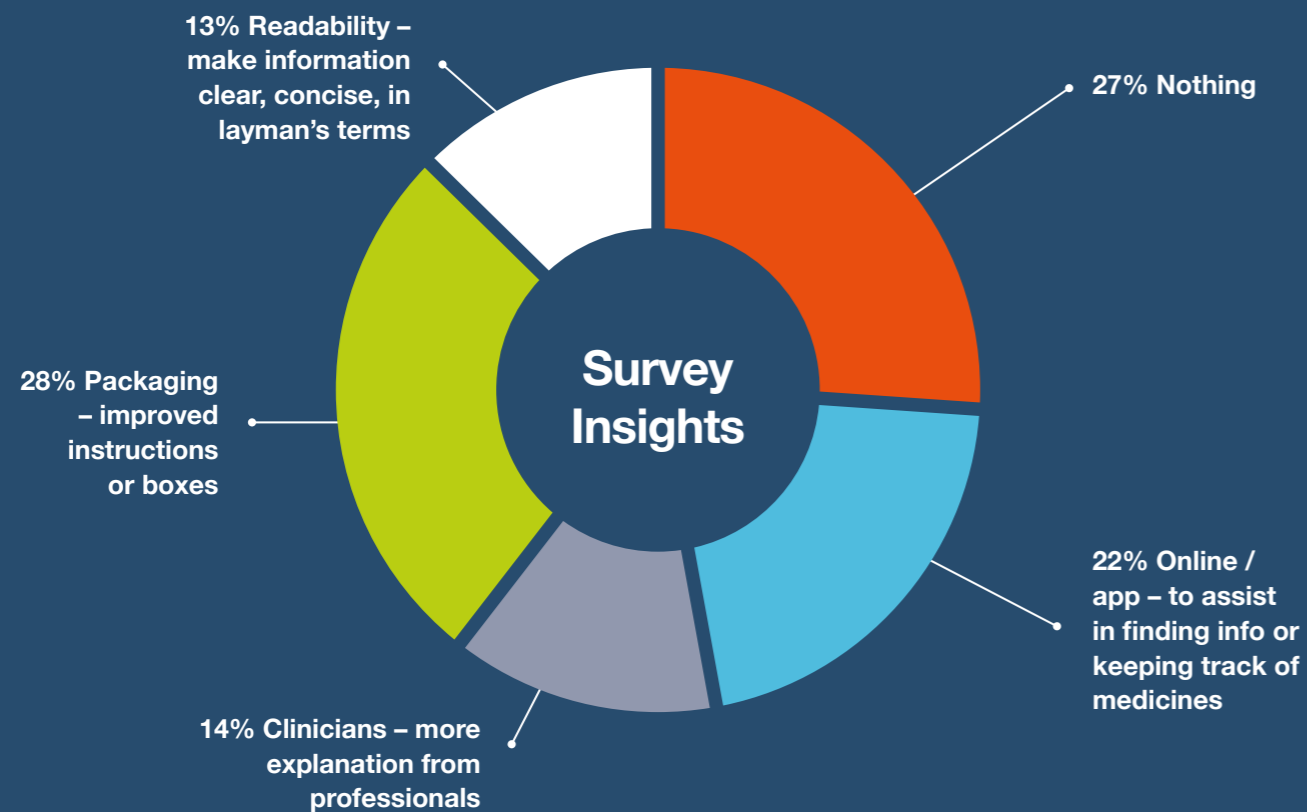
This is especially important for seldom heard groups, who may experience physical barriers such as sensory loss, language or cognitive barriers. Some may experience embarrassment, stigma and shame. A vicious cycle can form where patients struggle to articulate their lack of understanding or clarity about the kind of medications that they are taking, which in turn can lead to them having poor adherence, and they in turn can feel stigma acknowledging this.

A range of barriers to the effective use of the product information for human medicines were highlighted by patient focus group members.



THE FUTURE

When asked what would make it easier for patients to understand their medicines, help keep track, and take them correctly, top responses (n=2117) were:



Healthcare Professional Interview and Focus Group Insights

The potential exists for an enhanced medicines information paradigm which recognises that not all patients are the same and therefore patients require support and information in different ways. Overall, HCPs agreed that redesigned product information could be a powerful tool to support medicines access, understanding and adherence. Furthermore, as one consultant commented, "With the NHS desire for equality of access and improving outcomes and eliminating variation, a redesigned PIL could be a vehicle for tailoring information in a way that individual patients understand." But there are caveats. Whilst there appears to be broad belief that better medicines information and improved experience can lead to better concordance, more effective therapy and ultimately better outcomes, as one HCP interviewee points out, "this last causal step is philosophically accepted but will require further evidence."

HCPs interviewed broadly recognized that there is not one size that fits all here and that the provision of information in the future will need to be in a whole variety of forms, and available on multiple platforms.

Policymakers, industry and many of the HCPs interviewed noted the value of the interoperable medicines information standard, which could

provide the opportunity to innovate in terms of the ways medication and patient information can be accessed and shared.

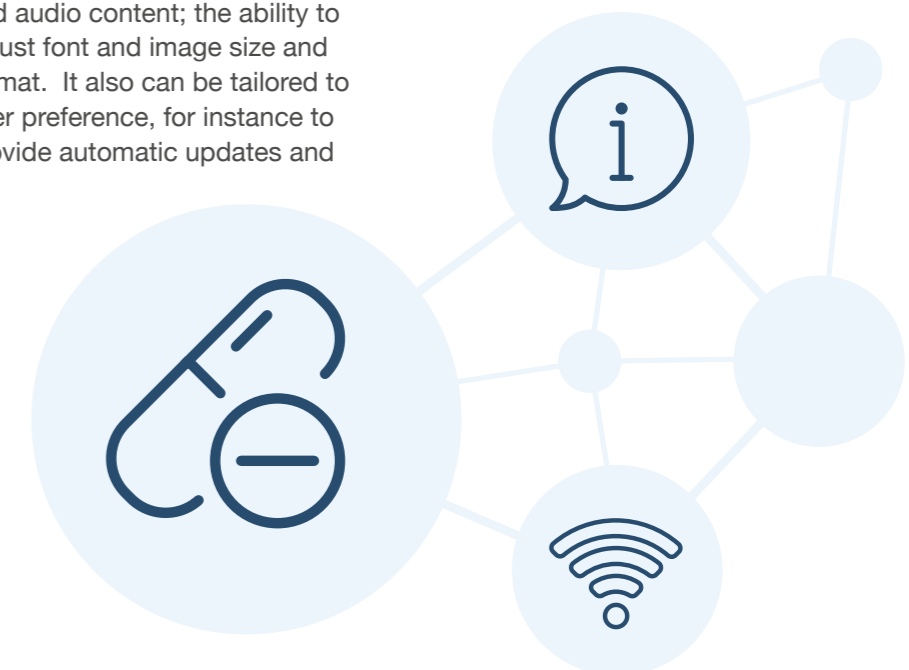
Given the increased pressures on budget and HCP time, models which rely primarily on HCP face to face discussion are not tenable moving forward. As one HCP interviewee commented, "The challenge, therefore, is to do more work with less people. The future looks to have technology and may perhaps make use of technology that simulates face to face solutions."

What could the future look like?

Many HCP and patient interviewees favour a shift to 'dynamic' medicines electronic product information (ePI) that could empower patients with the right information, at the right time, in order to become more fully engaged in their own care. Dynamic ePI could allow for more flexible content presentation, for example translator, search and dictionary functions; additions of pictographs, videos and audio content; the ability to adjust font and image size and format. It also can be tailored to user preference, for instance to provide automatic updates and

alerts and to improve readability and comprehension. Many also stated that signposting and navigating people to tailored information will be commonplace in the future, as one HCP interviewed said, "So if you want it in pictures go here. If you want it in Gujarati, go here. If you want it in a reading age of six go here."

In the future, integration with electronic patient records (EPR) could support signposting patients and carers to content that best suits their individual health profile and comorbidities, health literacy levels, demographics, care giver support, and patient activation levels. Polypharmacy was a driver for many HCP interviewees, including the need for bespoke guidance for patients taking multiple medications - covering interactions, side effects and a schedule for taking the medicines safely. QR codes on packaging and/or labels were suggested by some patients and HCPs as a mechanism for enabling patient access to digital ePI.



Trusted medicines information



Medical information, tailored to patient needs (examples based directly on survey responses). Updated in real time.



Tracking and feedback loops to support patients and carers with understanding and adherence, and to feed back real world evidence to support research and development

Carbon Friendly Solutions?

Some HCPs interviewed mentioned the potential environmental benefits of removing paper labels altogether. This could reduce the amount of paper required to provide a paper PIL with every prescription. It could also potentially reduce packaging and distribution wastage costs, due to batch recalls updating medicines product information. According to the Sustainable Medicines Partnership roundtable report (2021), globally 100 billion paper leaflets are produced each year, requiring paper produced from 9 million trees and enough energy to fuel 50,000 homes for a year.⁸

At the same time there was consensus that paper labels will be needed for some parts of the population in the foreseeable future due to concerns for patient safety, although who would be responsible for the administration of printing out personalised printed labels would need to be resolved, given the current pressure on the pharmacy workforce and on funding. To support any policy decisions in the future, there is a need for research studies assessing the impact of removing the paper label on patients, carers, healthcare professionals, and of course, the environment. These need to be mindful of digital literacy and equitable access to information.

⁸Sustainable Medicines Partnership (2021). "Roadmapping the transition to digital medicines information." Available at: <https://www.yewmaker.com/news/dmi-roundtable-report>.

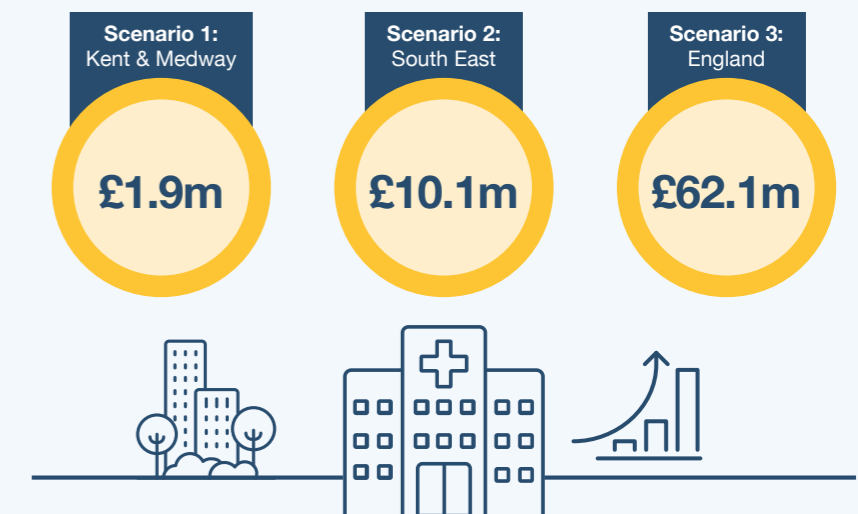
Modelling potential economic benefits

An ex-ante benefit appraisal was conducted to focus specifically on non-pharma NHS benefits, with a view to understand the NHS effect on service demand.

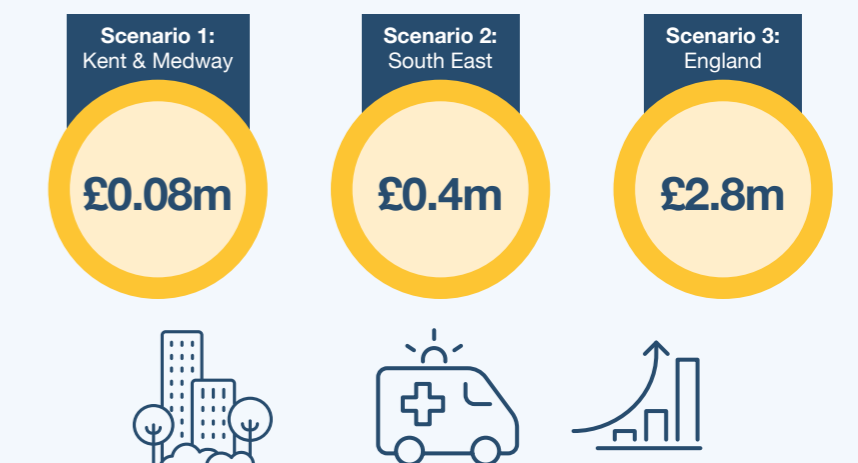
Assuming a 1 point patient activation point improvement as a result of better labelling, the following may be possible.

5-Year Total Cumulative Benefits (2022-2023) for a 1 point improvement in patient activation[#]

Reduction in hospital admissions due to adverse drug effects



Reduction in A&E visits due to adverse drug reactions.



[#]A single point increase in PAM score has been shown to correlate to a 2% decrease in hospitalisation and 2% increase in medication adherence (Advisory board, 2018. The High-Risk Patient Activation Equation.) See the following for more information on PAM scores: <https://www.england.nhs.uk/wp-content/uploads/2018/04/patient-activation-measure-quick-guide.pdf>.

NEXT STEPS

Over the coming months, we will bring patients and HCPs together with patient organisations, regulators, policymakers, academic and industry partners to review the evidence collected, and to start to articulate a vision and a roadmap for an enhanced product information paradigm. This will also examine concerns about the environmental impact of paper labels, and the potential for introducing more carbon-friendly alternatives.

A full report with analysis and recommendations will be published later in 2022.

ANNEX: APPROACH

The final report will be based on a number of streams of information that have been collected in a variety of different ways, including a preliminary evidence search⁸ and data scan, 1:1 interviews, focus groups, and an online questionnaire advertised via social media.

Table 1 provides an overview of patient and healthcare professional engagement. Results from this work continue to be analysed. Full results, including sentiment analysis where applicable, policy analysis and recommendations, will be published later in 2022.

⁸Evidence search: Review of initiatives and interventions to support medication adherence and health literacy, with a particular focus on product labelling and e-labelling Alison McLaren (September 2021). East Surrey Hospital, UK: Surrey and Sussex Library and Knowledge Services.

Table 1

Engagement Lead	Stakeholder Group	Response	Key perspectives captured
<ul style="list-style-type: none"> KSS AHSN / NIHR Applied Research Collaboration Kent, Surrey and Sussex (ARC KSS) 	<ul style="list-style-type: none"> Patient Representatives from Seldom Heard Groups 	<ul style="list-style-type: none"> 3 virtual Focus Groups, comprised of patient representatives (n=22) and a carer (n=1) 	<ul style="list-style-type: none"> Enduring mental health issues Learning disabilities Dementia Blind/visually impaired Homeless Care home In penal system Ethnic minority
<ul style="list-style-type: none"> UK National Innovation Centre for Ageing (NICA) and VOICE 	<ul style="list-style-type: none"> Patients 	<ul style="list-style-type: none"> 1:1 Interviews (n=11) Workshop exploring survey data in more detail (n=7) 	<ul style="list-style-type: none"> Purposive sample of NICA survey respondents and VOICE members (considering demographics, diversity, health literacy, tech literacy)
<ul style="list-style-type: none"> KSS AHSN Unity Insights NICA/VOICE Surrey and Sussex Healthcare NHS Trust (SASH) 	<ul style="list-style-type: none"> Patients 	<ul style="list-style-type: none"> NICA/Voice online questionnaire (n=207) KSS AHSN online SurveyMonkey questionnaire (advertised via Facebook) (n=1877)⁹ Paper questionnaire administered by SASH (n=74) 	<ul style="list-style-type: none"> Digital users 1366 unique post codes in urban and rural settings (99% in England) Aged 51 and over (51%) Female (77%) White (95%) Retired (77%) Higher education degree (40%) Mobility issues (35%) Dexterity issues (26%) Polypharmacy (45%)
<ul style="list-style-type: none"> KSS AHSN 	<ul style="list-style-type: none"> Healthcare professionals (HCPs) 	<ul style="list-style-type: none"> 1:1 Interviews (n=12) 2 Focus Groups (n=6) 	<ul style="list-style-type: none"> Community and hospital pharmacists and consultants General Practice Other HCPs
Final Interviews and Analysis yet to be completed			
<ul style="list-style-type: none"> KSS AHSN 	<ul style="list-style-type: none"> Senior Stakeholders – NHS, Central Government 	<ul style="list-style-type: none"> 1:1 Interviews (n=15) NHS England, plus <ul style="list-style-type: none"> NHS Digital Health Education England NHS England South East Region Integrated Care System AHSN Medicine Optimisation and Commercial 	<ul style="list-style-type: none"> Clinical and non-clinical leaders working within the NHS, Central Government and ALBs Policymakers Budget holders Education and training Medicines Optimisation leads Commercial/innovation leads Technologists
Total Sample	2158 patients (via questionnaire)		

⁹The number of responses for the online Survey Monkey questionnaire far exceeded what the project team expected to receive. Whilst the response rate was fantastic and shows the power of social media the sheer quantity of responses meant that we were unable to go into the depth we wanted to with the qualitative analysis. Something else to consider is selection bias as in order for the respondents to participate in the questionnaire they must have access to the internet and have a facebook account.

Acknowledgements

Authors

This project is the result of a long-standing collaboration between the KSS AHSN and Pfizer teams, seeking to understand the patient, carer and healthcare professional perspective in relation to the information that comes with prescription medicines.

KSS AHSN: Melissa Ream, Fiona Craig, Gill Potts, Lisa James, Hinal Patel, Mike Baxter and Des Holden

KSS AHSN is one of the 15 AHSNs across England, established by NHS England in 2013 to improve health and generate economic growth by spreading innovation at pace and scale. KSS AHSN connect citizens, NHS and academic organisations, local authorities, the third sector and industry to facilitate change across whole health and social care economies. KSS AHSN provided in kind support for the project, co-ordinated the work of the partners listed below, and conducted the healthcare professional and senior stakeholder interviews.

Pfizer: Smita Robinson, Jim Silvey, Shimon Yoshida, Natalie Bohm

Pfizer is committed to relentless pursuit of breakthroughs that change patients' lives, and to innovating every day to make the world a healthier place. Pfizer provided funding and leadership for the project, as well as insights into the current and emerging labelling landscape.

With special thanks to:

The joint KSS AHSN and Pfizer team would like to thank the patients and healthcare professionals involved in this project for their time, input and insights. Their thoughts and words have enabled us to uncover our blind spots, challenge our assumptions, and begin to explore the problem from other perspectives. We look forward to publishing more of their insights, combined with further stakeholder interviews in the full report later this year.

We would also like to thank the following organisations for enabling the patient voice to shine through:

UK National Innovation Centre for Ageing (NICA): Lauren Zayya and Lynne Corner

NICA specialise in understanding people - harnessing their knowledge capital and ideas to channel the VOICE of the patient, their carers and loved ones. Their unique approach and data driven methodology is designed to unearth deep insights and generate actionable, patient-centric tools to shape decision-making. The NICA team conducted a survey, a series of one-on-one interviews and a group workshop with members of their VOICE community.

NIHR Applied Research Collaboration (ARC) KSS / KSS AHSN Implementation Leads: Sam Fraser, Rebecca Sharp, Becca Randell and Kath Sykes

The [NIHR ARC Kent Surrey Sussex](#) is one of 15 ARCs across England, part of a £135 million investment by the NIHR to improve the health and care of patients and the public. Many of the population that they serve experience issues around accessing timely, and adequate health and social care, and as a result health provision inequity and resultant health inequality is a significant problem in the KSS region. For this project the ARC team held focus groups with seldom heard patients, carers and representatives to better understand their unmet needs, galvanise their views and in turn help amplify their voices in an already noisy and overcrowded system.

Unity Insights: Justin Rowcliffe, Ian Mylon and Richard Lee-Wright

Unity Insights, a partner organisation to KSS AHSN, provides evidence-based services measuring the impact on patients, staff, and the wider system. The Unity Insights team supported an initial data scan to identify suitable metrics and sources of information to support this project, and data collection and analysis across the project. The team is currently conducting a semi-automated thematic analysis to identify high level notable themes, which will be contained in the full report when it is published.

In addition, Unity Insights conducted an ex-ante benefit appraisal to focus specifically on non-pharma NHS benefits, with a view to understand the NHS effect on service demand.

Surrey and Sussex Healthcare NHS Trust (SASH): Charlotte Rowbotham and Alison McClaren

The SASH Patient and Public Participation team coordinated the conducting of paper surveys by using hospital volunteers to reach out to patients from a number of areas, including wards and outpatients. They also used the Trust Council of Governors

to ask members of public in their constituents / neighbourhoods to complete the survey. Feedback from both governors and volunteers was that the surveys were well received and people were happy to engage.

Surrey and Sussex Healthcare Library and Knowledge Service (LKS) conducted an evidence search for the project, including a review of initiatives and interventions to support medication adherence and health literacy, with a particular focus on product labelling and e-labelling.





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