DISSEMINATION OF GUIDELINES TO PATIENTS AND THE PUBLIC

DISSEMINATION OF CLINICAL PRACTICE GUIDELINES TO PATIENTS AND THE PUBLIC

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ABSTRACT

People are seeking health information from a wide variety of sources. The comprehensive information in clinical practice guidelines (CPGs) represents an excellent source of evidence based information which should be communicated to this audience. Currently, there is little research about how to write a version of a CPG that would be easily accessible to people and more information is needed to identify barriers and supports, and potential solutions to disseminate CPGs to this audience (i.e. patients and the public).

This thesis represents a body of research consisting of four scientific papers with an overarching objective to understand and explore how CPGs and recommendations primarily developed and written for health care professionals can be disseminated to patients and the public. A CPG was developed using the rigorous methods of the GRADE approach; a randomised controlled trial was conducted to evaluate a format to disseminate synthesised evidence to patients and the public; a systematic review of the literature with a thematic and narrative synthesis of patient and public attitudes towards and awareness of CPGs was performed; and a qualitative description and content analysis of a sample of patients versions of CPGs was conducted. The studies found that people are interested in patient versions of CPGs for a variety of purposes, such as for decision making, as a tool to prepare for consultations with health care providers, and as advice for self-care management. However, barriers to their use may

include lack of personalisation of information, negative attitudes towards

guidelines as ways to restrict and control access to care, and lack of understanding

of the recommendations and the evidence. A format to disseminate the evidence

from a guideline is proposed, but future research should focus on strategies to

personalise the information, to overcome the negative attitudes towards

guidelines, and to communicate the recommendations and the evidence informing

the recommendations.

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LIST OF ABBREVIATIONS

AAN	American Academy of Neurology
AIS	adenocarcinoma in situ
ASCUS	atypical squamous cells of undetermined significance
CAM	complementary and alternative medicines
CASP	Critical Appraisal Skills Programme
CI	confidence interval
CIN	cervical intraepithelial neoplasia
CKC	cold knife conization
CPG	Clinical practice guideline
DECIDE	Developing and Evaluating Communication Strategies to support Informed Decision and practice based on Evidence
EBPI	Evidence Based Patient Information
ENTEREQ	Enhancing transparency in reporting the synthesis of qualitative research
ESMO	European Society for Medical Oncology
FICA	Flanders International Cooperation Agency
GAVI	Alliance Global Alliance for Vaccines and Immunisation
GDG	Guideline Development Group
GERD	Gastroesophageal Reflux Disease
G-I-N	Guidelines International Network
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HIV	human immunodeficiency virus
HPV	human papillomavirus
IARC	International Agency for Research on Cancer
INCa	Institut National du Cancer (France)
IPDAS	International Patient Decision Aid Standards
IQR	interquartile range
LEEP	loop electrosurgical excision procedure (also LLETZ)
LLETZ	large loop excision of the transformation zone (also LEEP)
MG	Methods Group
NIH	National Institutes of Health (USA)
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute (USA)
NGC	National Guideline Clearing House
NICE	National Institute for Health and Care Excellence
OMRU	Ottawa Model of Research Use
PAHO	Pan American Health Organization
Pap test	Papanicolaou test (cytology-based method for cervical cancer screening)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QUADAS	QUality Assessment for Diagnostic Accuracy Studies
RCT	randomised controlled trial
SIGN	Scottish Intercollegiate Guidelines Network
USPTF	United States Preventive Task Force
VNS	vagus nerve stimulation
VIA	visual inspection with acetic acid
WHO	World Health Organization

PREFACE

The work presented in this doctoral thesis includes a series of manuscripts which have been accepted, submitted for publication or prepared for submission. The manuscript in Chapter 2, World Health Organization Guidelines: Treatment of cervical intraepithelial neoplasia 2-3 and Screen and Treat strategies to prevent cervical cancer, will be submitted to the *International Journal of Gynecology and Obstetrics*. Chapter 3 manuscript, A promising summary to communicate evidence from systematic reviews to the public: A randomised controlled trial, is in press with the *Journal of Clinical Epidemiology*. The manuscript in Chapter 4, Patient and public attitudes to and awareness of clinical practice guidelines: a systematic review with thematic and narrative syntheses, was accepted for publication on 15 July 2014 in *BMC Health Services Research*. Chapter 5 manuscript, Dissemination of clinical practice guidelines: A content analysis of patient versions, will be submitted to *Health Expectations*.

The development of the clinical guidelines presented in Chapter 2 was a four year project with the World Health Organisation and led by my supervisor, Dr. Holger Schünemann. I coordinated and conducted a series of systematic reviews, developed and presented evidence summaries to the guideline panel, and after the development of the recommendations by the panel, we wrote the recommendations with input from the panel. I drafted the manuscript and incorporated feedback from the co-authors. Chapter 4 was a joint review to which Ms. Kirsty Loudon and I contributed equally. I developed the protocol with the

co-authors, and screened and abstracted data from the studies. I analysed the data and wrote the review with Ms. Loudon, and I incorporated comments from co-authors. I conceived of and conducted the work in Chapters 3 and 5, and drafted those manuscripts and incorporated feedback from the co-authors.

CHAPTER 1

INTRODUCTION

INTRODUCTION

People are seeking health information from a wide variety of sources. While physicians are a traditional source of health information, people are going beyond what they can learn from their physicians to seek information from other sources, including other health care professionals, family and friends, other individuals with similar health conditions, the media, and from the Internet [1, 2]. In Canada, more than 80% of people access the Internet, and 67% of those individuals seek medical and health-related information [3]. Although new technologies are emerging, little seems to have changed about what type of information people seek and why. Individuals requiring health information typically seek it to understand the benefits and harms of tests and treatments, to assist with management of their health or of others in their care, and to provide reassurance about the diagnoses and treatments they receive [4, 5, 6].

Unfortunately, there have been concerns about the quality of health information via the Internet and through other sources. These concerns have over the past few years led to calls for health information that is based on evidence and the values and preferences of individuals making health care decisions. In 1999, Angela Coulter wrote an editorial in the *BMJ* arguing for "Evidence Based Patient Information (EBPI)" emphasising that patient information should be in accord with current evidence and be scientifically accurate [7]. In 2010, there was also work to establish criteria for EBPI with the premise that this information should

combine rigorously developed evidence with patient values and preferences [8]. Standards for the development of patient decision aids (tools which provide information about health care options to patients and help clarify their personal values to make health care decisions) require that decision aids be based on comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence [9]. Montori and colleagues in their description of the criteria in the International Patient Decision Aid Standards (IPDAS) further posit that this evidence should come from systematic reviews. It would appear that an ideal starting point for patient information should include systematic reviews of evidence, a consideration of patient values and preferences, and guidance for health care decisions

Clinical practice guidelines (CPGs) are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [p.8, 10]. CPGs provide guidance typically targeted to healthcare professionals through statements that describe what action is recommended under what health care circumstances. For example, the guideline for the screening of precancerous lesions for cervical cancer prevention provides guidance to health care professionals about what screening tests (the Human Papillomavirus test or the Papanicolaou test) should be provided to women 18 years or older [11]. Recommendations from high quality CPGs generally integrate information about benefits and harms of interventions with

other factors. In particular, CPGs using the GRADE approach and other high quality CPGs include a wealth of information: summary tables presenting the absolute effects of the benefits and harms of interventions along with the quality of the evidence; summaries of the evidence for resources; a summary of patient values and preferences; issues around feasibility and equity; explanations and remarks for how each of these factors were considered; and finally clearly written recommendations for action [12]. The comprehensive information in CPGs represents an excellent source of evidence based information which could be disseminated to individuals seeking health information. However, CPGs may not be appropriately written for them.

How can the unique information from CPGs therefore be made more useful and accessible to people seeking health information? We can look to knowledge translation and research use models to provide frameworks to explore how to disseminate the information from CPGs to patients. The Knowledge to Action model includes two cycles: knowledge creation and action [13]. The process of knowledge creation involves (1) knowledge inquiry, (2) knowledge synthesis, and (3) knowledge tools or products. CPGs are typically a knowledge tool for professionals and grounded in questions or a need for a change in practice in the health care professional community. However, as indicated in the definition above, CPGs should also provide information to facilitate decision-making by

patients. This could involve the *de novo* development of tools tailored for patients based on CPGs.

The Ottawa Model of Research Use (OMRU) provides another useful model that outlines potential contextual barriers and supports to the use of information from CPGs by patients, clinicians or other policy makers [14]. Graham and Logan explain that the barriers and supports to the use of information may be related to the evidence based innovation, the characteristics of the potential adopters, and attributes of the practice environment. Within each of these factors, they describe specific aspects which should be determined:

1. Evidence based innovation: How the innovation was developed (e.g. a trustworthy process) and its attributes (e.g. understandable language) may affect its uptake.
2. Potential adopters: Uptake may depend on whether adopters are aware of the innovation; whether they have positive or negative attitudes towards the innovation, or the knowledge or skills to use the information; and how it fits in with their current practice.
3. Practice environment: The culture (e.g. open to decision making), the structure of an organisation, and other uncontrolled events may influence use of the information.

Despite the fact that CPGs have been produced for many years, as an evidence based innovation, there continues to be ongoing research into how CPGs should be rigorously developed and written to improve uptake by health care professionals, policy makers, and programme managers [15, 16]. However, there is little research about how to write a version of a CPG that would be accessible to people seeking health information. With respect to the characteristics of these people, the adopters, there is already some research that people may perceive guidelines as rigid and inflexible, and feel that guidelines could potentially interfere with the quality of care physicians provide [17]. In another study, from the Canadian Task Force on Preventive Health Care, people wanted information about the evidence used to support recommendations and in a format they could easily understand [18]. It is also unclear at this point, what role or purpose CPGs could play in their daily lives, i.e., their 'practice environment.' Therefore, more information is needed to identify these barriers and supports and potential solutions to disseminate CPGs to this audience.

This thesis represents a body of research consisting of four scientific papers with an overarching objective to understand and explore how CPGs and recommendations primarily developed and written for health care professionals can be disseminated to individuals seeking health information. In this thesis, I refer to 'patients and the public' or 'consumers' or 'people' and these terms are used synonymously and without distinction to refer to people in general who are

seeking health information for their own care or for the care of others, and people who may in the future need health information.

Chapter 2 is a guideline for the prevention of cervical cancer produced by the World Health Organisation. This paper represents four years of my experiences working with guideline panels to understand and facilitate the production and presentation of guidelines to health care professionals and programme managers. The document provides a brief background to the health problem; describes the methods used to develop the guidelines, in this case using the GRADE approach; a clear separated list of recommendations; and a summary of the gaps in the literature.

The recommendations are expressed according to current standards and thinking about how to present recommendations. There is a statement about the strength of the recommendation and the quality of evidence, and remarks or considerations when applying the recommendation in practice are included. There is also a distinction between the recommendation and the evidence used to support that recommendation.

The guideline also provides a layered approach to the presentation of information. It is linked to a detailed summary of the evidence and a summary of other factors which were considered by the guideline panel, such as values and preferences,

resources and feasibility issues. There is a link to more detailed information found in tables, called GRADE evidence profiles or summary of findings tables, which present the evidence for the benefits and harms of screening and treatment. The presentation of the evidence in the guideline is based on research about how to present and communicate evidence to health care professionals and programme managers. While working with the guideline panel, and producing and writing this guideline, I gained an understanding of the importance of communicating the recommendations and evidence primarily to health care professionals. The guideline, itself, is an example of a trustworthy 'evidence-based innovation' but it may need to be tailored for the public.

Chapter 3 addresses how to present evidence to patients and the public. It is a published randomised controlled trial (RCT) that evaluated two strategies to communicate evidence from systematic reviews to patients and the public. The RCT follows from a qualitative research study in which we first explored different formats of plain language summaries with patients and the public through user-testing [19]. Based on the results of that qualitative study, we developed a new format, and we compared this new format to the format currently used in Cochrane systematic reviews in a randomised controlled trial with 143 participants across five countries. More specifically, we evaluated methods to improve understanding of the effects of an intervention using absolute numbers

and the quality of the evidence for those effects (which had not been previously evaluated).

However, guidelines include not just a synthesis of evidence but also recommendations within a larger guideline document. Our initial work on the presentation of evidence from systematic reviews led us to believe that few people understand what a systematic review is. Similarly, there is literature questioning whether people are aware of CPGs or patient versions of CPGs, and more importantly questions about how guidelines or, in particular, the recommendations are perceived. We therefore conducted a systematic review of studies that explored patient and public attitudes and awareness of clinical practice guidelines. We used a thematic analysis to summarise themes from that literature. **Chapter 4** presents the systematic review.

The systematic review identified potential barriers and supports to the uptake of CPGs and the patient versions by patients and the public. These barriers fell into the factors identified in the OMRU. For example, some people thought CPGs may not be trustworthy or be a list of rules. Some had negative attitudes towards guidelines believing that CPGs could limit their decision-making about their treatment options, and may not be applicable to their own situations. Others thought that patient versions of CPGs could fit into their own situations by providing information about how to manage their own care or a tool when

speaking with their health care providers, and could potentially help them make decisions if the right information was provided. It was thought that these factors would likely have an impact on how a patient version should be written and presented. We therefore sought to understand if, and how, currently published patient versions of CPGs address these barriers and supports. **Chapter 5** consists of a directed content analysis of a sample of patient versions of CPGs. These results are compared and contrasted with the results we found in the systematic review presented in Chapter 4 and areas for future research are identified.

The manuscripts in this thesis are based on a variety of study designs which involved the application of different methods of analysis and interpretation. In Chapter 2, we conducted a series of systematic reviews of RCTs and non-randomised studies for treatment interventions and diagnostic studies, and used "up-to-date" guideline development methods to produce the guidelines. In Chapter 3, I conducted an RCT on the Internet, and we analysed the data using the chi-square test, the t-test or the Mann-Whitney U test. In Chapter 4, we again performed a systematic review, but in this review we used a thematic analysis of qualitative and quantitative studies, as well as a narrative synthesis of data. In Chapter 5, we analysed the patient versions using a directed content analysis. Additional details of the methods in each paper are included within the body of each chapter and my role in the development and conduct for each study described in the unique papers is outlined in the preface to each chapter.

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CHAPTER 2

WORLD HEALTH ORGANIZATION GUIDELINES: TREATMENT OF

CERVICAL INTRAEPITHELIAL NEOPLASIA 2-3 AND SCREEN AND

TREAT STRATEGIES TO PREVENT CERVICAL CANCER

PREFACE TO CHAPTER 2

This chapter presents clinical practice guidelines that were developed with the

World Health Organization (WHO) from 2011 to 2013. The complete guidelines

have been published on the WHO website at

http://www.who.int/reproductivehealth/publications/cancers/treatment_CIN_2-

3/en/ and http://www.who.int/reproductivehealth/publications/cancers/

screening_and_treatment_of_precancerous_lesions/en/index.html. This

manuscript will be submitted to the International Journal of Gynecology and

Obstetrics. A team led by Dr. Holger Schünemann was contracted by WHO to

develop the guidelines, including all steps of the guideline process. Dr. Reem

Mustafa and I were the coordinators on this large project and had overlapping

responsibilities. From our team, I attended the meeting with the guideline panel to

develop the draft questions and outcomes to address in the guidelines. I surveyed

the panel and analysed the results to finalise the questions and outcomes. I

developed the protocols for the systematic reviews for the treatment questions

with feedback from the team and guideline panel. I developed the searches for all

questions. I oversaw the systematic reviews of treatment questions; and along

with other team members screened and abstracted data from the studies, analysed

the data, assessed the quality of the evidence, and created summary tables of the

findings (GRADE Evidence Profiles). Dr. Mustafa and I created tables to

facilitate the process during the guideline panel meeting to move from Evidence

to Recommendations. We both presented these tables in the guideline panel

meeting. I drafted this manuscript and incorporated feedback from the co-authors.

Dr. Schünemann provided methodological and conceptual support throughout the

project. Dr. Nathalie Broutet coordinated the administration of the project at

WHO and provided critical review of the manuscript and reports. All other

authors were members of the guideline panel and provided feedback into the

design and interpretation of the systematic reviews, and developed the

recommendations. All authors provided feedback and final approval of the

manuscript.

World Health Organization Guidelines: Treatment of cervical intraepithelial

neoplasia 2-3 and Screen and Treat strategies to prevent cervical cancer

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Keywords: cervical intraepithelial neoplasia, cervical cancer, guidelines, recommendations, screen, treat

Synopsis (24 words): Recommendations for treatment of cervical intraepithelial neoplasia, and screen and treat strategies for cervical cancer prevention were developed and approved by World Health Organisation.

Type of article: Special communication

Word count: 5452

Abstract: (word count <200)

Background

It is estimated that 1-2% of women develop cervical intraepithelial neoplasia grade 2-3 (CIN 2-3) annually, and women living with HIV have a higher incidence (10%). If left untreated, CIN 2-3 can progress to cervical cancer. WHO committed to producing updated guidelines for strategies to screen and treat precancerous cervical lesions and for treatment of histologically confirmed CIN 2-3.

Methods and Results

These guidelines were developed using the World Health Organization (WHO) handbook for guideline development. A panel consisting of healthcare providers with experience in screening and treating CIN, pathologists, researchers in cervical cancer prevention and treatment, programme directors, health educators, epidemiologists, public health officers, nurses and methodologists developed these guidelines. Systematic reviews of randomised controlled trials and observational studies were conducted for 16 recommendations. Evidence tables and Evidence to Recommendation tables were prepared using the GRADE approach, presented to the panel and recommendations made.

Conclusions

WHO recommendations for screen and treat strategies to prevent cervical cancer and for treatment of histologically confirmed CIN are presented. While these recommendations are based on the best available evidence, high quality evidence

was not available. Such evidence is needed, in particular for screen and treat

strategies that are relevant to low- and middle-income countries.

Introduction

Cervical intraepithelial neoplasia (CIN) is a premalignant lesion that is diagnosed by histology in 3 stages: CIN 1, CIN 2, and CIN 3. If left untreated, CIN 2 or 3 (CIN 2-3) can progress to cervical cancer. It is estimated that approximately 1-2% of women have CIN 2-3 each year, and this rate is reportedly higher in HIV positive women at around 10% [1-5]. Standard practice for diagnosing CIN is to perform a colposcopic visual exam on screen-positive women, biopsy suspicious lesions, and then treat only when CIN 2-3 has been histologically confirmed. Widely used treatments include cryotherapy, loop electrosurgical excision procedure (LEEP, including large loop excision of the transformation zone - LLETZ, or cone biopsy with loop excision), and cold knife conisation (CKC).

An alternative approach to diagnose and treat CIN is to 'screen and treat' in which treatment decisions are based on the results of a screening test, instead of histologically confirmed CIN 2-3, and then treatment is provided soon, or ideally, immediately after a positive screening test. The goals of a 'screen and treat' strategy are to reduce the incidence of cervical cancer and related mortality with relatively few adverse events and to link screening with treatment making the process more convenient for women. The strategy includes a screening test or a sequence of tests, links to appropriate treatments for women who screen positive, and referral for treatment of women with invasive cervical cancer. Widely used screening tests include tests for the Human Papillomavirus (HPV), cytology

(Pap), and unaided visual inspection with acetic acid (VIA). There is some

uncertainty across national programmes about which tests to provide and what

treatment to provide for women who screen positive.

In 2004, the World Health Organisation (WHO) published a guide to assist

clinicians and programme managers to diagnose and treat CIN in order to prevent

and control cervical cancer entitled "Comprehensive Cervical Cancer Control: a

Guide to Essential Practice (C4-GEP)". Since then, new evidence for the effects

of treatments and screening tests for CIN has become available. Based on this

evidence, the WHO published updated recommendations for the use of

cryotherapy to treat CIN in 2010 [6,7]. WHO also committed to producing

recommendations for strategies to screen and treat precancerous cervical lesions

and recommendations for treatment of histologically confirmed CIN 2-3. We

report here on these guidelines, which provide two sets of recommendations:

recommendations for the use of cryotherapy, LEEP/LLETZ, and CKC to treat

histologically confirmed CIN 2-3; and recommendations for strategies to screen

and treat. For countries where a screen and treat programme, or treatment protocol

already exists, these recommendations were developed to assist decision makers

to determine a different screen and treat programme or treatment should be used.

For countries where a screening programme or treatment protocol does not

currently, these recommendations can be used to determine which screen and treat

programme or treatment protocol to implement. The target audiences for these

guidelines are primarily low and middle income countries.

Methods

In general, we followed the methods described in the *WHO handbook for*

guideline development [8].

Guideline Development Group

WHO selected a Guideline Development Group (GDG) which consisted of 18

members who provided expert clinical guidance and support throughout the

guideline development process. WHO also selected an External Review Group of

35 professionals including healthcare providers with experience in screening and

treating CIN, pathologists, researchers in cervical cancer prevention and

treatment, programme directors, health educators, epidemiologists, public health

officers, nurses and methodologists. The GDG worked with the Methods Group

(MG) from the MacGRADE Centre at McMaster University, a WHO

Collaborating Centre, with expertise in evidence synthesis and guideline

development processes.

Formulating questions and determining outcomes

In February 2011, the GDG met and identified screening and treatment questions,

and developed a list of outcomes to consider when making recommendations.

Then, by anonymous survey, the GDG prioritized the questions by clinical

relevance in practice. They agreed on eight screening questions with comparisons

between screen and treat strategies, and nine treatment questions for CIN 2-3 or

adenocarcinoma-in-situ (AIS). The GDG and the External Review Group, also by

anonymous survey, ranked potential outcomes on a scale from 1 (not at all

important in decision making) to 7 (very important). Outcomes ranked as 4

(important) or higher were included in the systematic reviews (see Table 1).

[Insert Table 1]

Systematic review of the evidence, evidence profiles and grading the evidence
The MG conducted systematic reviews of the diagnostic accuracy of tests and the

effects of treatment following the methods of the Cochrane Collaboration [9]. The

full reviews are published in this issue [10,11]. Briefly, the MG searched

MEDLINE and EMBASE up to February 2012 for treatments and for screening

strategies related to HPV compared to VIA, and VIA compared to cytology, and

from January 2010 to November 2011 to update a review currently being

conducted for HPV compared to cytology [12]. The search for adverse events of

treatments was updated to July 2012 and the search for colposcopy was updated to

September 2012. Two members of the MG independently screened abstracts and

full text of relevant articles, and abstracted data from randomised (RCTs), non-

randomised controlled trials, and observational studies which included non-

pregnant women 18 years or older who had not been previously treated for CIN or AIS, and who were of known or unknown HIV status.

To compare the benefits and harms of one screen and treat strategy to another, the MG developed and used a mathematical model. Typically, decisions about what tests and strategies to provide are determined by considering the sensitivity and specificity of the test. These data, however, do not address the downstream consequences of treatment or no treatment after women screen positive or negative, such as cervical cancer and related mortality, recurrence of CIN 2-3, adverse events of treatment (and overtreatment), resource use and feasibility. The model therefore includes data for CIN 2-3 prevalence, natural progression, the pooled diagnostic test accuracy for screening, and pooled treatment effects and complications for women of unknown and known HIV status. The predicted benefits and harms and also the quality of evidence using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) approach were summarised in evidence tables [13]. The quality of the evidence is assessed as high$\oplus\oplus\oplus\oplus$, moderate $\oplus\oplus\oplus\ominus$, low $\oplus\oplus\ominus\ominus$, or very low quality evidence $\oplus\ominus\ominus\ominus$. The MG also drafted tables to facilitate decision making for recommendations, Evidence to Recommendations Tables, which include a summary of the evidence, the quality of the evidence, relevant patient values and preferences, and resource implications and feasibility. The evidence

tables and Evidence to Recommendations Tables for these guidelines are available on the WHO website [14, 15].

Development of recommendations

On April 26-28, 2012, the GDG, External Review Group and MG met to discuss the recommendations. This meeting was chaired by a GDG member and a member of the MG. Members of the MG presented each Evidence Package and Evidence to Recommendation Table and the groups made the recommendations and identified key research gaps. The recommendations were then finalised by the GDG and approved by WHO. The recommendations are presented as 'strong' or 'conditional' according to the *WHO handbook for guidelines development* [6] (Table 2).

[insert Table 2]

Results

Treatment recommendations

A brief summary of the recommendations for the treatment of histologically

confirmed CIN 2-3 or AIS with cryotherapy, LEEP, or CKC are provided in Box

1. For decision makers, the full recommendations, including remarks and

evidence summaries, are freely available at the WHO website [14].

[insert Box 1]

Screen and treat recommendations

The full recommendations, including remarks and evidence summaries are

provided below. The evidence profiles (including references) and other

supplementary materials are freely available on the WHO website [14, 15].

Patient values and preferences

The GDG agreed with evidence presented from qualitative studies about patient

values and preferences [16-18]. This evidence suggests women may fear

screening and may have high anxiety related to colposcopy/treatment, and

experience greater burden with a second visit for treatment. However, once

women decide to be screened they find screening tests and immediate treatment

acceptable. Women also showed preference for more frequent screening and

active management as opposed to treatment when screened positive for CIN1. In

addition, evidence from controlled trials shows that women probably find

cryotherapy and LEEP acceptable treatments, and are satisfied with 'screen and treat' programmes [19].

Treatment for women who are screened positive

For all screen and treat recommendations, cryotherapy is the first choice of treatment for women who are screened positive and eligible for cryotherapy. For women not eligible for cryotherapy, LEEP is the alternative treatment.

Before treatment, ALL women who screen positive with any test (but especially with an HPV test) should be visually inspected with acetic acid to determine eligibility for cryotherapy and to rule out large lesions or suspected cervical cancer. VIA should be performed by a trained provider. Note that there is a distinction in these recommendations between a) using visual inspection with acetic acid to determine eligibility for treatment (i.e. Cryotherapy vs LEEP), and b) using VIA as a screening test to determine whether to treat or not to treat.

a) In the 'HPV' screen and treat strategy, women who are HPV negative are not treated. Women who are HPV positive will all be treated, and VIA is used to determine whether to treat with cryotherapy or LEEP.

b) In the 'HPV followed by VIA' strategy, women who are HPV negative are not treated. Women who are HPV positive receive VIA as a screening test. If a woman is HPV positive and VIA positive, she is treated but if a woman is HPV positive but VIA negative, she is not treated.

Screening intervals and follow-up

The recommendations below apply to women 30 years of age and older because of their higher risk of cervical cancer. However, the magnitude of the net benefit will differ between age groups and may extend to younger and older women depending on their baseline risk of CIN 2-3. For all women, priority should be given to screening women 30 to 49 for maximum coverage, rather than maximising the number of screening tests in a woman's lifetime. Screening should be started as soon as a sexually active woman or girl has tested positive for HIV.

For repeat screening, women who test negative on VIA or cytology should be rescreened within three to five years. If the woman's HIV status is either positive or unknown in areas of endemic HIV infection, screening should be repeated within three years. All women who have been treated for CIN should receive post-treatment follow-up at one year to ensure effectiveness of treatment.

Recommendation 1. The expert panel recommends against the use of CKC as treatment in a screen and treat strategy (strong recommendation, $\oplus\ominus\ominus\ominus$ evidence)

Remarks: The screen-and-treat strategies considered by the panel with CKC as treatment included an HPV test, VIA, or an HPV test followed by VIA as screening. Although the benefits were similar for CKC compared with

cryotherapy or LEEP for all screen-and-treat strategies, the harms were greater

with CKC. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: Low-quality evidence from

pooled observational studies showed that the recurrence of CIN after treatment

with CKC may be 3% less than the recurrence after cryotherapy or LEEP.

However, this difference did not lead to important differences in cervical cancer

incidence or related mortality (risk difference of 0.08%). In contrast, the incidence

of major bleeding requiring hospitalization or blood transfusions may be greater

(1/1000 treated with CKC versus 1/10 000 with cryotherapy or LEEP for most

screen-and-treat strategies) and the risk of premature delivery after treatment with

CKC may be greater than with cryotherapy or LEEP (Risk Ratio 3.41 versus

2.00). The increased risks of these complications apply to all treated women,

regardless of whether they were correctly or incorrectly classified as having

CIN2+ (i.e. including women with false-positive results who are treated

unnecessarily). These differences were similar to the benefits and harms found

when modelled for women of HIV-positive status.

Recommendation 2. Where resources permit, the expert panel suggests a
strategy of screen with an HPV test and treat with cryotherapy (or LEEP
when not eligible for cryotherapy) over a strategy of screen with VIA and

treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

In resource-constrained settings, where screening with an HPV test is not feasible, the expert panel suggests a strategy of screen with VIA and treat with cryotherapy (or LEEP when not eligible) over a strategy of screen with an HPV test and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

Remarks: The benefits of screen-and-treat with an HPV test or VIA, compared to no screening, outweighed the harms, but the reductions in cancer and related mortality were greater with an HPV test when compared to VIA. The availability of HPV testing is resource-dependent and, therefore, the expert panel suggests that an HPV test over VIA be provided where it is available, affordable, implementable, and sustainable over time.

Summary of the evidence from systematic reviews: Low-quality to very-low-quality evidence showed that there may be fewer CIN2+ recurrences with the screen-and-treat strategy using an HPV test (3/1000 fewer), as well as fewer cervical cancers (1/10 000 fewer) and fewer deaths (6/100 000 fewer) than with a strategy using VIA for screening. These differences result from fewer missed cases of CIN2+ with the HPV test strategy compared with the VIA strategy (i.e. fewer false negatives). The difference in overtreatment may be relatively small

(157 000 cases with an HPV test versus 127 000 cases with VIA out of 1 000 000 women). The number of cancers found at first-time screening may be slightly greater with VIA (7/10 000 more). There may be little to no difference in complications, such as major bleeding or infections (e.g. 1/100 000 fewer with the VIA strategy). These results are similar to the benefits and harms found when modelled for women of HIV-positive status.

Recommendation 3. The expert panel suggests a strategy of screen with an HPV test and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

Remarks: The reductions in cancer and related mortality were slightly greater with an HPV test only compared to cytology followed by colposcopy. Although there may be overtreatment of populations with high HPV prevalence and consequently more harms, as well as fewer cancers seen at first-time screening with an HPV test, there are greater resources required in cytology programmes due to quality control, training, and waiting time. The addition of colposcopy also requires a second visit. However, in countries where an appropriate/high-quality screening strategy with cytology (referring women with ASCUS or greater results) followed by colposcopy already exists, either an HPV test or cytology followed by colposcopy could be used.

Summary of the evidence from systematic reviews: As there were few or no studies evaluating the diagnostic accuracy of cytology followed by colposcopy compared to an HPV test, the effects of the sequence of tests were calculated by combining diagnostic data from cytology and colposcopy, resulting in lower-quality evidence. For the strategy of cytology followed by colposcopy (with or without biopsy), we analysed data for two scenarios: (1) Women who screened positive on cytology underwent colposcopy only (i.e. treatment was based on colposcopic impression); and (2) Women who screened positive on cytology underwent colposcopy, and then women with positive colposcopy results were biopsied (i.e. treatment was based on the biopsy result). Evidence showed that there may be fewer CIN2+ recurrences with the HPV test strategy (3/1000 fewer), as well as fewer cervical cancers (1/10 000 fewer) and fewer deaths (6/100 000 fewer) than with cytology followed by colposcopy. These differences result from fewer missed cases of CIN2+ with the HPV test strategy (i.e. fewer false negatives). Overtreatment, however, may be slightly greater with an HPV test when compared with cytology followed by colposcopy without biopsy (7/100 more women) or with biopsy when indicated (10/100 more women). This may result in slightly more complications with the HPV test strategy. The number of cancers detected at first-time screening may be slightly greater with the cytology followed by colposcopy strategy (1/1000 more).

Recommendation 4. The expert panel recommends a strategy of screen with VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (strong recommendation, ⊕⊖⊖⊖quality evidence)

Remarks: The benefits and harms of the two screen-and-treat strategies are similar, but there are fewer harms with cytology followed by colposcopy with biopsy when indicated. Despite overtreatment with VIA and fewer cancers detected at first-time screening, more resources are required for cytology programmes with colposcopy (with or without biopsy) due to quality control, training, and waiting time, as well as a second visit. The recommendation for VIA over cytology followed by colposcopy can be applied in countries that are currently considering either strategy or countries that currently have both strategies available. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: As there were few to no studies evaluating the diagnostic accuracy of cytology followed by colposcopy compared to VIA, the effects of the sequence of tests were calculated by combining diagnostic data from cytology and colposcopy, resulting in lower-quality evidence. For the strategy of cytology followed by colposcopy (with or without biopsy), we analysed data for two scenarios: (1) Women who screened

positive on cytology underwent colposcopy only (i.e. treatment was based on colposcopic impression); and (2) Women who screened positive on cytology underwent colposcopy, and then women with positive colposcopy results were biopsied (i.e. treatment was based on the biopsy result). Evidence showed that there may be little or no difference in CIN2+ recurrence, cervical cancers, and related mortality between the strategies. Overtreatment, however, may be slightly greater with VIA compared to cytology followed by colposcopy without biopsy (11/100 more women) or with biopsy when indicated (18/100 more women). This may result in slightly greater harm with the VIA strategy. The number of cancers detected at first-time screening may be slightly greater with the cytology followed by colposcopy strategy (2/1000 more) compared with the VIA strategy.

Recommendation 5. The expert panel suggests a strategy of screen with an HPV test and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with an HPV test followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, $\oplus\ominus\ominus\ominus$ evidence)
Remarks: The reductions in cancer and related mortality with either strategy outweigh the harms and costs of no screening, and were similar between the two strategies. Although overtreatment and, consequently, harms are reduced with the addition of colposcopy (with or without biopsy), there are more resource implications with colposcopy due to increased training of providers, quality

control, waiting time, and the potential for more women to be lost to follow-up.

The addition of colposcopy to an HPV test would also require a second visit. In

countries without an existing screening strategy, an HPV test followed by

colposcopy is not recommended. This recommendation applies to women

regardless of HIV status.

Summary of the evidence from systematic reviews: As there were few or no

studies evaluating the diagnostic accuracy of an HPV test followed by

colposcopy, the effects of the sequence of tests were calculated by combining

diagnostic data from the individual tests, resulting in lower-quality evidence. For

the strategy of an HPV test followed by colposcopy (with or without biopsy), we

analysed data for two scenarios: (1) Women who screened positive on HPV

testing underwent colposcopy only (i.e. treatment was based on colposcopic

impression); and (2) Women who screened positive on HPV testing underwent

colposcopy, and then women with positive colposcopy results were biopsied (i.e.

treatment was based on the biopsy result). Evidence showed that there may be

little to no difference in CIN2+ recurrence, cervical cancers, and related mortality

between the strategies. Overtreatment, however, may be slightly greater with an

HPV test only compared with an HPV test followed by colposcopy without

biopsy (5/100 more women) or with biopsy when indicated (12/100 more

women). This may result in slightly greater harm with an HPV-test-only strategy.

The number of cancers detected at first-time screening may be slightly greater

with an HPV test followed by colposcopy strategy (1/1000 more) than with an HPV test only.

Recommendation 6. The expert panel suggests either a strategy of screen with an HPV test followed by VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) or a strategy of screen with an HPV test and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, $\oplus\ominus\ominus\ominus$ evidence)

Remarks: The reductions in cancer and related mortality were greater with an HPV test used as a single screening test than with an HPV test followed by VIA, and this reduction was even greater in women of HIV-positive status. However, there may be overtreatment, and thus potentially greater harms with screen-and-treat when using an HPV test as a single test. There is also some uncertainty about the effects of an HPV test followed by VIA and how VIA performs after a positive HPV test because there was no direct evidence about this strategy. There is also the potential for additional resources that are required to refer women for VIA testing after a positive HPV test, the need for a second visit to perform VIA, and increased training to perform both tests. For these reasons, the recommendation is for either an HPV test followed by VIA or an HPV test only, and it is conditional. Given that benefits are more pronounced compared to harm in women of HIV-positive status when using an HPV test only, programmes may

elect to treat based on HPV testing only, especially in this group. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: As there were no studies evaluating the diagnostic accuracy of an HPV test followed by VIA, the effects were calculated by combining diagnostic data from an HPV test only with data for VIA only, resulting in lower-quality evidence. This evidence showed that there may be slightly greater CIN2+ recurrences with an HPV test followed by VIA (4/1000 more), as well as more cervical cancers (1/10 000 more) and more deaths (7/100 000 more) than with an HPV test only. The difference was due to a slightly higher rate of missed cases of CIN 2+ with an HPV test followed by VIA than with an HPV test only (6/1000 more). The number of cancers detected at first-time screening may be slightly greater with an HPV test followed by VIA (7/10 000 more), and there may be fewer women treated unnecessarily (1/10 fewer) due to the lower false-positive rate with an HPV test followed by VIA. If fewer women are treated unnecessarily, this may result in lower resource use and fewer complications with an HPV test followed by VIA.

However, these results were more pronounced when modelled for women living with HIV. There may be greater differences in benefits and harms. The evidence for women with HIV showed that there is likely to be an even greater rate of CIN2+ recurrences with an HPV test followed by VIA (22/1000 more), as well as

more cervical cancers (17/10 000 more) and more deaths (12/100 000 more) than

with HPV only. However, there may be fewer women treated unnecessarily (1/10

fewer) when using the screening strategy of an HPV test followed by VIA,

resulting in fewer resources for unnecessary treatment and fewer complications.

Recommendation 7. The expert panel suggests a strategy of screen with an HPV test followed by VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with VIA and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

Remarks: The reductions in cancer and related mortality with an HPV test

followed by VIA or with VIA alone outweighed the harms. However, the harms

may be greater when using VIA only, which is likely due to overtreatment.

Although, a slightly larger number of cancers may be detected on initial screen

with VIA only. This recommendation is conditional due to the uncertain costs of

providing the sequence of two tests (HPV test followed by VIA) over the single

VIA test. In countries where an HPV test is not available, we suggest screening

with VIA only. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: As there were no studies

evaluating the diagnostic accuracy of an HPV test followed by VIA, the effects

were calculated by combining diagnostic data from an HPV test only with data for VIA only, resulting in lower-quality evidence. This evidence showed little to no difference in CIN2+ recurrence, cervical cancer, and related mortality between a screen-and-treat strategy using an HPV test followed by VIA and a strategy using VIA only. This was likely due to the relatively small differences in the number of missed cases of CIN2+ between the two strategies. Although, the number of cancers detected at first-time screening may be slightly greater with VIA only (7/10 000 more), there may be more women treated unnecessarily (1/10 more) due to higher false-positive rates with VIA only (incurring higher resource use for overtreatment). Overtreatment may also result in greater complications with VIA only. These results are similar to the benefits and harms found when modelled for women of HIV-positive status.

Recommendation 8. The expert panel suggests a strategy of screen with an HPV test followed by VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with cytology followed by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)
Remarks: The benefits of the two screen-and-treat strategies are similar. However, there may be higher resources required in cytology programmes due to quality

control, training, and waiting time. The addition of colposcopy requires a second visit. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: As there were few to no studies evaluating the diagnostic accuracy of cytology followed by colposcopy compared to an HPV test followed by VIA, the effects of the sequence of tests were calculated by combining diagnostic data, resulting in lower-quality evidence. For the strategy of cytology followed by colposcopy (with or without biopsy), we analysed data for two scenarios: (1) Women who screened positive on cytology underwent colposcopy only (i.e. treatment was based on colposcopic impression); and (2) Women who screened positive on cytology underwent colposcopy, and then women with positive colposcopy results were biopsied (i.e. treatment was based on the biopsy result). Evidence showed that there may be little to no difference in CIN2+ recurrence, cervical cancers, and related mortality between the strategies. There may also be little to no difference in overtreatment between the strategies. The number of cancers detected at first-time screening may be slightly greater with the cytology followed by colposcopy strategy (2/1000 more).

Recommendation 9. The expert panel suggests a strategy of screen with an HPV test followed by VIA and treat with cryotherapy (or LEEP when not eligible for cryotherapy) over a strategy of screen with an HPV test followed

by colposcopy (with or without biopsy) and treat with cryotherapy (or LEEP when not eligible) (conditional recommendation, ⊕⊖⊖⊖ evidence)

Remarks: The reductions in cancer and related mortality of screen-and-treat with an HPV test followed by colposcopy (with or without biopsy) may be slightly greater compared to an HPV test followed by VIA. The panel agreed that the benefits of either strategy outweigh the harms and costs; however, the difference in costs between the strategies is uncertain. There may be more resource implications with colposcopy due to increased training of providers, quality control, waiting time, and the potential for more women to be lost to follow-up. It is also unclear whether women would perceive a difference between VIA or colposcopy; however, a biopsy during colposcopy may be less acceptable than VIA. This recommendation applies to women regardless of HIV status.

Summary of the evidence from systematic reviews: As there were few or no studies evaluating the diagnostic accuracy of both screening strategies, the effects of the strategies were calculated by combining diagnostic data from the individual tests, resulting in lower-quality evidence. For the strategy of an HPV test followed by colposcopy (with or without biopsy), we analysed data for two scenarios: (1) Women who screened positive on HPV testing underwent colposcopy only (i.e. treatment was based on colposcopic impression); and (2) Women who screened positive on HPV testing underwent colposcopy, and then women with positive colposcopy results were biopsied (i.e. treatment was based on the biopsy result).

Evidence showed that there may be fewer CIN2+ recurrences with the HPV test followed by colposcopy without biopsy (3/1000 fewer) and with biopsy (4/1000 fewer), as well as fewer cervical cancers (1/10 000 fewer with or without biopsy) and fewer deaths (6/100 000 fewer, with or without biopsy) than with an HPV test followed by VIA. These differences result from fewer missed cases of CIN2+ with the HPV test followed by colposcopy strategy when compared to an HPV test followed by VIA strategy (i.e. fewer false negatives). Overtreatment, however, may be greater with an HPV test followed by colposcopy without biopsy than with an HPV test followed by VIA (7/100 more women). There may be little to no difference between the strategies in the number of cancers detected at first-time screening.

Discussion

This guideline presents recommendations for the treatment of histologically confirmed CIN 2-3 and screen and treat strategies to prevent cervical cancer. The recommendations are based on a rigorous process using the GRADE approach and on rigorous systematic reviews of the literature [10,11,12]. We identified, however, few randomised controlled trials and observational studies which were at low risk of bias and directly applicable to the interventions, the population, and population important outcomes.

Ideally, the evidence for screen and treat questions should come from trials in which women are randomly allocated to receive one screen and treat strategy or another strategy, and then all screened women are followed and patient-important health outcomes, such as CIN recurrence, cervical cancer and complications of treatment are measured. However, there were no studies conducted in this way which compared the strategies covered in this set of guidelines, and therefore the panel used a decision analysis model to inform the recommendations for screen and treat strategies. In particular, it was essential to use the model to assess a sequence of tests, such as HPV followed by VIA or cytology followed by colposcopy.

There is some concern for the use of cytology programmes in areas where health systems are not robust, where resources are limited or quality assurance is not maintained. Cytology programmes have been and remain difficult to establish in low and middle income settings; quality assurance to ensure accurate and reproducible results in cytology programmes requires greater human and financial resources than other strategies; and, as cytology results are not available quickly, there is greater risk of loss to follow-up which reduces the benefits of cytology based programmes. Cytology followed by colposcopy with or without biopsy was not shown in this review of the literature to exceed other strategies. Adding a screening test, such as HPV, before cytology was not investigated in this evidence review, nor modelled for these recommendations, as the expert panel did not rank

an exploration of this algorithm highly enough for it to be among the questions addressed as part of the process of preparing these guidelines. Once studies become available that provide rigorous comparisons between, for example, HPV followed by cytology to HPV followed by VIA (or vice versa) then these could be the focus of new evidence-based recommendations.

With regard to the population included in the studies and to which these recommendations apply, there is little research which distinguishes the effects in women from 20 to 35 years of age, and women older than 50 years; women of known or unknown HIV status; nor research about intervals for follow-up after treatment. Data was also unclear about the natural progression and regression of CIN 2-3 across women of many age groups, and also for women living with HIV. For many of the outcomes, in particular for fertility and reproductive outcomes, and the detection of sexually transmitted diseases or the detection of cervical cancer in the case of screening strategies, there was also little to no data.

These recommendations are based on the best available evidence for benefits and harms, patient values and preferences, resources and feasibility. The recommendations are currently being widely disseminated across WHO regional offices through this publication, through the WHO website and in the updated manual for use by programme managers and health care professionals: Comprehensive Cervical Cancer Control: a Guide to Essential Practice (C4-GEP).

As new evidence about treatments and strategies, as well as new screening tests become available, WHO will continue to update these guidelines.

Author contributions

All authors contributed to the concept, design, interpretation of data, and revision of the guidelines, and provided final approval. NS, RM, and HS were also responsible for the acquisition and analysis of the data. In addition, the WHO Steering Committee interpreted the data and, along with the External Review Group, provided revisions and final approval for the recommendations. NB is a staff member of WHO; the views of this author expressed in this publication do not necessarily represent the decisions, policy, or views of WHO.

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Conflicts of interest

Conflicts of Interest statements are available on the WHO website within the

original guideline documents.

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Boxes and tables

Box 1: Recommendations for the treatment of histologically confirmed cervical intraepithelial neoplasia 2-3 and adenocarcinoma-in-situ (AIS) in women of unknown or known HIV status

For women with histologically confirmed CIN2+ disease, regardless of HIV status		
Strong recommendation	**The expert panel recommends:**	
	1. use cryotherapy over no treatment	⊕⊖⊖⊖ very low quality evidence
	2. use large loop excision of the transformation zone (LEEP) over no treatment	⊕⊕⊖⊖ low quality evidence
	3. use cold knife conization (CKC) over no treatment	⊕⊖⊖⊖ very low quality evidence
Conditional recommendation	**The expert panel suggests:**	
	4. use either cryotherapy or LEEP in women for whom either cryotherapy or LEEP is appropriate to use and available	⊕⊖⊖⊖ very low quality evidence
Strong recommendation	**The expert panel recommends:**	
	5. use cryotherapy over CKC in women for whom either cryotherapy or CKC is appropriate to use	⊕⊖⊖⊖ very low quality evidence
	6. use LEEP over CKC in women in whom either LEEP or CKC is appropriate to use	⊕⊖⊖⊖ very low quality evidence
For women with histologically confirmed AIS disease, regardless of HIV status		
Conditional recommendation	**The expert panel suggests:**	
	7. use CKC over LEEP	⊕⊖⊖⊖ very low quality evidence

Table 1: Outcomes for treatment and screen and treat strategies identified as important to making recommendations (in order of importance)

Treatment outcomes	Screen and Treat outcomes
1. Residual/recurrent CIN 2-3 (after 6, 12 months and 24 months) 2. Damage to other organs/other surgery required – such as injury to bladder or urethra 3. Major Bleeding (requires hospitalization/blood transfusion) 4. Maternal death 5. HPV negative (after 6, 12 and 24 months) 6. Major infections (requiring hospital admission and antibiotics) 7. Premature delivery 8. Fetal/neonatal spontaneous abortions 9. Pelvic Inflammatory Disease 10. Infertility 11. Minor bleeding (requires packing or suturing)	1. Mortality from cervical cancer 2. Cervical cancer Incidence 3. Detected CIN 2,3 4. Major Infections (requiring hospital admission and antibiotics, e.g. PID) 5. Maternal bleeding 6. Premature delivery 7. Fertility 8. Identification of STIs (benefit) 9. Minor infections (requiring outpatient treatment only)

TABLE 2. Judgement and interpretation of strong and conditional recommendations

	Strong recommendation "we recommend…"	Conditional recommendation "we suggest…"
Judgement by guideline panel	It is clear to the panel that the net desirable consequences of a strategy outweighed the consequences of the alternative strategy	It is less clear to the panel whether the net desirable consequences of a strategy outweighed the alternative strategy
Implications for patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	The majority of individuals in this situation would want the suggested course of action, but many would not.
Implications for clinicians	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Clinicians should recognize that different choices will be appropriate for each individual and that clinicians must help each individual arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful to help individuals make decisions consistent with their values and preferences.
Implications for policy makers	The recommendation can be adopted as policy in most situations.	Policy-making will require substantial debate and involvement of various stakeholders.

CHAPTER 3

**A PROMISING SUMMARY TO COMMUNICATE EVIDENCE FROM
SYSTEMATIC REVIEWS TO THE PUBLIC: A RANDOMISED
CONTROLLED TRIAL**

PREFACE TO CHAPTER 3

This chapter is in press in the *Journal of Clinical Epidemiology*. It is an open

access article under the CC BY-NC-ND license

(http://creativecommons.org/licenses/by-nc-nd/3.0/) and the authors are able to

copy and redistribute the material in any medium or format. It describes a

randomised controlled trial comparing the effects of a new plain language

summary to the current summary used to communicate evidence from systematic

reviews to patients and the public. This work was conducted from 2009 to 2014.

This work was part of a larger project - of which I contributed to the conception -

to explore how to communicate the results of systematic reviews to patients and

the public. I developed the protocol for this study in consultation with Drs.

Schünemann and Glenton. I designed and created the questionnaire, recruited and

randomised participants, managed the data, assisted with the statistical analysis,

interpreted the data, drafted the manuscript and incorporated feedback from the

co-authors. Dr. Zhou conducted the statistical analysis. All authors assisted with

the recruitment of patients and provided feedback on the design of the study and

the draft of the manuscript. In addition, Drs. Schunemann and Glenton provided

critical review of the manuscript and interpretation of the analyses.

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A promising summary to communicate evidence from systematic reviews to the public: A randomised controlled trial

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Abstract

Objective: To evaluate a new format of a summary which presents research from synthesised evidence to patients and the public.

Study design and setting: We conducted a randomised controlled trial in 143 members of the public from five countries (Canada, Norway, Spain, Argentina and Italy). Participants received either a new summary format (a plain language summary, PLS) or the current format used in Cochrane systematic reviews. The new PLS presents information about the condition and intervention, a narrative summary of results, and a table of results with absolute numbers for effects of the intervention and quality of the evidence using GRADE.

Results: With the new PLS, more participants understood the benefits and harms and quality of evidence (53% versus 18%, *P*<0.001); more answered each of the five questions correctly (P≤0.001 for four questions); and they answered more questions correctly, median 3 (interquartile range 1,4) versus 1 (0,1), P<0.001. Better understanding was independent of education level. More participants found information in the new PLS reliable, easy to find, easy to understand and presented in a way that helped make decisions. Overall, participants preferred the new PLS.

Conclusion: This new PLS format for patients and the public is a promising tool to translate evidence from synthesised research**.**

Clinicaltrials.gov NCT01939925

Running title: Communicating evidence to the public: RCT

Word count: 3350

What is new?

- Members of the public preferred the new plain language summary format which presents research evidence from systematic reviews in two ways: narratively and in a table showing absolute effects and the quality of the evidence using the approach of Grading of Recommendations Assessment, Development, and Evaluation (GRADE).

- The new format also improved comprehension over the format currently used in Cochrane systematic reviews, and was perceived as just as easy to understand as the current format which does not include numbers or quality of evidence.

- Providing patients and the public with quantitative results from evidence in systematic reviews, along with an indication of the confidence in those results, may improve comprehension and help with patient decision making.

- These findings can be used to inform organisations who aim to provide patients and the public with information about the effects of treatments.

Introduction

The public is increasingly demanding to better understand health information in order to manage their health.[1] While there is a plethora of evidence about the benefits and harms of a multitude of treatments for many conditions, this information is typically not written in a way that optimises understanding, accessibility and usability for patients and the public. Much research has focused on the specifics of how to communicate benefits and harms of treatments, such as whether to present the effects in relative or absolute terms or both [2], whether to present rates or proportions or "1-in-X formats" [3], and also whether or not data should be presented in tables.[2, 4, 5] The challenge is pulling together what we have learned from that research into one template or format to summarise and communicate evidence to patients and the public. In 2010, we developed a new format for a plain language summary (PLS) for patients which summarised the results of a Cochrane systematic review about the effects of a treatment.[6] We conducted user-testing in 34 patients/members of the public and explored issues around quantitative and qualitative presentations of benefits and harms, as well as confidence intervals and tables. We found that participants preferred the effects of treatments presented in words, supplemented with numbers in a table, and that they largely ignored the confidence intervals. Previous research had also indicated that not only do patients want to know how many people will improve or be harmed when receiving a treatment, but they also want to know how 'sure ' those numbers are, i.e. the quality of the evidence informing those numbers [6, 7].

Therefore, we additionally experimented with how to present effects of treatments with the quality of the evidence.

This distinction between the effect of a treatment and the confidence in that effect has received more attention with the use of the GRADE approach in systematic reviews and guidelines. The GRADE approach to assess and present the quality of evidence for the effects of an intervention is used by over 70 organisations and is a standard component of Cochrane systematic reviews.[8] GRADE distinguishes between the magnitude of the effects and the confidence or certainty in those effects (i.e. quality of evidence) when presenting information about benefits and harms. An example to illustrate this distinction is the figure used in GRADE where a meteorologist reports the weather saying "I figure there's a 40% chance of showers, and a 10% chance we know what we're talking about." [9] The first part is about the size of the effect, the 40% chance of rain, and the second part, the 10%, is about the quality of the evidence or confidence in that effect. GRADE advocates for the use of this information by decision makers, and has developed tables to communicate this information to decision makers. Randomised controlled trials have shown that clinicians and guideline panels find these tables and the information easy to understand, accessible and helpful when making decisions.[10, 11] However trials testing different presentations of benefits and harms with the quality of the evidence with patients and the public, and their understanding of these two concepts together are limited.

We conducted this randomised controlled trial to compare a new format of a patient summary of evidence from a systematic review to the current narrative format. The new format is based on the user-testing we previously conducted. [6] It consists of two key parts (see Figure 1). The first part is a narrative summary of the evidence which is divided into three sections: an introduction to the concept of a systematic review; background information about the condition and treatment; and information using standardised qualitative statements about the magnitude of the effect and the quality of the evidence for important outcomes (e.g. "Vitamin C *probably* decreases how long a cold lasts by a *few* hours"). The second part of the summary is a table that presents the same outcomes and the same qualitative statements about the effect, but also the numerical results. The absolute effects and confidence intervals are presented in natural frequencies, and information about the quality of the evidence for each outcome are presented as symbols and words.

We evaluated if the new presentation improves understanding about the benefits and harms of an intervention and the confidence in those effects, if it improves the accessibility of the information, and if it is preferred over other versions by patients and the public. To ensure broad representation of members of the public we took a global approach by enlisting the help of the network of Cochrane groups across disease areas and regions to recruit participants.

Methods

Study design

We conducted this randomised controlled trial via the Internet in August 2009 in

five countries (Canada, Norway, Spain, Argentina and Italy). Members of the

Cochrane Collaboration recruited members of the public and patients in their

country to view the results of a Cochrane systematic review in one of two formats

of a PLS: one using the new format or one using the current format. Formats were

randomly allocated using block randomisation. While reading the summary about

a health care intervention and its effects, participants answered questions using an

on-line questionnaire to assess their understanding (primary outcome), their

satisfaction with the PLS, the ease of understanding, and the accessibility of the

findings of the review. Participants then viewed the alternate format (to which

they were not initially allocated, i.e. the new format if they were randomized to

the current format and vice versa) and were asked which of the two formats they

preferred. Participants did not receive incentives to participate in the study and

consent was provided when answering the on-line questionnaire. Each entity

obtained the necessary ethical approval from their institutions or national ethics

committees.

Participants

Four Cochrane groups (the Cochrane Musculoskeletal group in Canada; the

Norwegian branch of the Nordic Cochrane Centre in Norway; the Iberoamerican

Cochrane Centre in Argentina and Spain; and the Italian Cochrane Centre in collaboration with the PartecipaSalute [12]) recruited patients and the public who were 16 years and older. Methods of recruitment included a message on Cochrane group websites, and an email invitation disseminated through local consumer groups and forwarded via local patient, researcher and health professional networks. The message requested expression of willingness to participate in the study and was confirmed by the local investigator.

Randomisation

Eligible patients and members of the public who were willing to participate were centrally randomized to the new or current format of a PLS by a staff member at the Department of Clinical Epidemiology and Biostatistics at McMaster University who was unaware of participants' demographics or other characteristics. The randomisation sequence was generated using block-randomisation with 40 permuted blocks of four generated on http://www.randomization.com. An email was sent by the local investigator to the participant with a link to the SurveyMonkey questionnaire and PLS format to which the participant had been allocated. Participants were not made aware of which PLS was the current or new format.

Intervention and comparator

The new format of the PLS is based on research and development work over the past 15 years and was finalised following semi-structured interviews and user-testing with 34 members of the public.[6] Important differences between the new format and the currently used format in Cochrane systematic reviews are shown in Table 1. The new format has a more structured presentation using a question and answer approach and communicates information about benefits and harms with reference to both the magnitude of effect and the quality of evidence. This information is presented separately in tables as numbers and symbols and in standardised qualitative statements [6]. Thus, readers can use the qualitative statements, the tables or both to understand the information.

[insert Table 1]

Two formats of a PLS were created for this trial. The information in the PLS was derived from a systematic review of a common topic: Vitamin C for preventing and treating the common cold [13]. One investigator created the new format based on the user testing, and also revised the current PLS from the review to include similar background information and language, but maintained the current format. Both versions were then reviewed by the other investigators, and revised accordingly (see Figures 1 and 2). The PLS were first written in English and then translated into Norwegian, Spanish and Italian by the respective investigators, as our goal was to test the format as opposed to comprehension of the English. We

provided each PLS and the questionnaire online (in the respective language) using

Survey Monkey (www.surveymonkey.com).

Outcomes

The primary outcome was the proportion of people who correctly understood the

benefits and harms of the intervention and quality of evidence. The questions

were similar to questions used in randomised controlled trials for the public,

clinicians and health care researchers to evaluate presentation of health

information.[4, 10] Participants answered five multiple-choice questions, each

with five response options (see Table 3 for the specific questions marked with an

asterisk *). The proportion of people who correctly answered a question was

averaged over the five questions and then compared between formats.

Secondary outcomes included the proportion of people who correctly understood

each of the five questions; the overall number of correct answers for these five

questions; comprehension of the purpose of the summary; usability; ease of

understanding; accessibility; and preference for one format over the other.

Questions about purpose and producer of the summary were multiple-choice

questions with three options. Usability, accessibility (i.e. the extent to which the

main findings are easy to find, to understand and to use by someone making a

decision) and preference outcome measures were also based on questions

previously used in a randomised controlled trial in clinicians and health care

researchers.[10] Usability and accessibility were framed as positive questions and were measured on a seven-point Likert scale: 1 (strongly disagree) to 7 (strongly agree). Preference was measured after the participants evaluated the format to which they had been first allocated and viewed the alternate format. Preference was measured on a seven-point scale with a strong preference for one format at each end. We also collected demographic information including age, language spoken and read, education, and frequency searching the Internet for health information. The complete questionnaire is available in Appendix 1.

Sample size calculation

We calculated the sample size based on the main outcome of the study: proportion of people who understood the benefits and harms of the intervention averaged over all five questions. We used alpha of 0.05 and 90% power to detect a difference of 40% in the average proportion of people who correctly answered the questions. We used data from two studies by Schwartz, Woloshin and colleagues to determine the difference of 40%, a size of effect that we also deemed important for this study.[4, 5] In those studies, 80% of the people who received a summary of information in a table with event rates answered questions correctly compared to 20 to 40% of those who did not receive this information. We estimated that, at a minimum, 32 people in each arm needed to complete the survey in English and a total of 32 people in each arm for all other languages combined to allow analysis by language (English versus other languages).

Analysis

Analysis was conducted by a statistician who was blinded to the PLS format tested after importing data from Survey Monkey into SPSS Version 11. To analyse descriptive variables, we calculated proportions fix. We used the chi-square test to compare differences in proportions and the t-test or the Mann-Whitney U test for the means or medians comparison using 2-sided tests and considered $p < 0.05$ as statistically significant. We also conducted a generalized linear regression model adjusting for education level, language and Internet experience for the primary outcome.

Results

In total, 193 people from five countries agreed to participate. Given the two-step approach of initial invitation and second contact for randomization, 154 of 193 people began the survey and 143 (74%) completed the study: 74 exposed to the new format first and 69 to the current format first (see Figure 3 for study flow). The majority of participants were female (73%) and between the ages of 26 and 65 (76%) with diverse levels of education, from 30% who held a high school diploma or less to 33% who held a university degree. Participants also had a broad range of experience seeking health information on the Internet, from greater than once per week to less than a couple times a year. Overall, demographic characteristics were similar across groups (see Table 2). Of the 143 respondents,

79 received the English version of the PLS. Language was not a significant variable in the linear regression, and therefore, we present results for the two groups combined.

[insert Table 2]

Understanding of benefits, harms and quality of evidence

More participants who received the new format of the PLS correctly answered the comprehension questions than those who received the current format (53% versus 18%, P<0.001). This difference was statistically significant even after adjusting for education level, language and Internet experience (P <0.001). The linear regression, however, showed that education level was a significant factor in overall understanding of both formats. The analyses for each question showed that in four out of the five questions the differences in the proportion of people who answered the questions correctly were statistically significant (see Table 3). With the exception of the question about the meaning of the qualitative statements and understanding risk, the differences in the proportions with correct answers were greater than 40%. However, the number of participants who correctly answered each comprehension question with the new format did not exceed 65%. In addition, the median number of questions answered correctly out of the five questions was significantly higher in participants who received the new PLS compared with the current PLS (3 (interquartile range (IQ) 1, 4) versus 1 (IQ 0, 1), P <0.001).

[insert Table 3]

Comprehension of the purpose of the summary

A larger proportion of respondents who received the current PLS understood that the summary was not about one large study, but overall this understanding was fairly low and not significantly different (45% versus 32%, $P = 0.17$). On the contrary, most respondents understood that the new PLS was produced by the Cochrane Collaboration (89%); significantly more than with the current PLS (67%, $P < 0.001$).

Accessibility of the findings and usability

More participants exposed to the new PLS responded that the information was reliable; easy to find; easy to understand; presented in a way to help make a decision; and presented the most important effects. All comparisons were statistically significant except for the ease of understanding (see Figure 4).

Preference

Across both study arms, we found a greater preference for the new format over the current PLS (median 3 ["somewhat prefer"], IQ 1 and 6), although participants generally preferred the format to which they were exposed first.

Discussion

The development and testing of the PLS over the last 15 years has provided important information and feedback about a potentially useful format to present health evidence to the public and patients. In this randomised controlled trial, we have shown that the new format of the PLS improves understanding of benefits and harms, is accessible and usable, and preferred by most participants across several countries. Understanding not only about the effects of the interventions but also the quality of evidence was greater when communicated in qualitative statements, as well as in numbers and symbols. Contrary to concerns about whether patients or the public would be able to understand such detailed information about effects of interventions, our findings support communication of those elements. Indeed, our results showed that far fewer participants who were provided with the narrative format answered questions correctly about the benefits and harms, the primary outcome of our study. We also found that respondents found information about benefits and harms more easily and thought the information was accessible and usable with the new format. These findings and results of previous research should encourage organisations communicating evidence from synthesised research to provide detailed information about effects and quality of evidence narratively using a standardized language and in a table.[4-6, 14, 15]

This study, albeit relatively small, found no difference in the effects of the new format across different languages, across education levels or experience using the Internet. It provides evidence that the new PLS format may be preferred by a broad range of patients and the public, including people in different countries and education levels. Results from this trial also confirm our findings from our qualitative work which found that participants liked summaries divided into headings in a question and answer format and liked the flow of information in our new format. [6]

This study has several strengths including its randomised design and the careful developmental work that preceded this new format for PLS. [4-6, 14, 15] Conducting the trial in several languages and settings is another strength. However, our study has limitations. Of the 193 participants who initially agreed to participate in the study, 143 completed the study. However, we did not observe a large difference in completion rates in the two arms of the trial. We also did not engage respondents in real-life decisions. Instead, we chose a common topic, Vitamin C for the common cold, to ensure that respondents could relate to the health care information and we felt that many people not only understood the topic, but had likely thought about the use of vitamin supplements to prevent and treat a common cold in the past or were presently thinking about it. Although we recruited participants from several countries, respondents came primarily from high-income and middle-income countries, and it is unclear how the results of this

study apply to patients or the public from low income countries. Furthermore, recruitment through consumer and personal networks at the various Cochrane groups may have led to selection of people with a special interest in health information. However, the participants had a broad range of educational backgrounds and, given their interest in health information, would indeed be representative of those seeking such information.

It may also be argued that we gave an unfair advantage to people who received the new format, as we asked respondents the specific number of people who experienced an outcome, and provided quantitative information in the new format but not in the current format. We use the same argument put forth by Schwartz and Woloshin [5]. These authors described that decisions following narrative provision of information are based on implicit assumptions about the magnitude of the effect. Therefore, it is critical to evaluate if these assumptions are correct. In our study, in fact, we found that respondents were incorrectly estimating the size of the effect after reading the narrative summary in the current format.

Despite our careful development work and improved presentation of the PLS, only up to 65% of participants answered most comprehension questions correctly. It is unclear why this occurred and it indicates that more work should be conducted to explore the best ways to communicate information, such as whether to present absolute effects as natural frequencies or as percentages.[2, 4] We also

presented quantitative information with confidence intervals, and it is not clear whether the confidence intervals were helpful or distracting. In addition, this work is one of the first studies to explore the communication of the effects of an intervention and the quality of the evidence. In another study we found that patients preferred knowing about the underlying quality of evidence related to intervention effects [7]. In our study, understanding was improved with the new PLS, but fewer than 50% of the participants answered the questions about quality of evidence correctly. Certainly there is room for improvement and this will be explored in a project by the GRADE working group in which additional user-testing and randomised controlled trials about communication of evidence and recommendations from guidelines will be conducted with patients and the public (www.decide-collaboration.eu).

In summary, we created a new format to translate synthesised evidence from a Cochrane systematic review into a plain language summary in multiple languages, and found that the public preferred this new format over the current format, found the information more easily, and thought the information was accessible and usable. These results could encourage knowledge translation specialists, guideline developers, editors, and researchers from many organisations, such as health technology assessment agencies, and the Cochrane Collaboration to consider the use of this format to communicate results of systematic reviews to the public.

Authors' contributions

NS, CG, HS developed the protocol, wrote the first draft of the paper and revised.

NS, ESN, TR, AC, LM and JPP conducted the study. SR, ESN, TR, AC, LM,

JPP and QZ provided feedback for protocol and paper. QZ, NS and HS conducted

statistical analyses.

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Tables

Table 1: New and current format of plain language summaries of Cochrane

systematic reviews

New Format	Current format
Qualitative and quantitative description of text (absolute effects and natural frequencies provided)	Qualitative description of effects
Quantitative results provided in a table	
Quality of the evidence according to GRADE provided in a table	No criteria for how to describe the quality of the evidence
Headings for question and answer format	Paragraph of text
Flow of information follows principles of linguistic frameworks (e.g. progressive movements from introduction to 'bottom line')	No criteria for flow of information

Table 2: Characteristics of participants

Characteristic	New format (n=74)	Current format (n=69)
Women, %	74	72
Age, %		
<25	20	23
26 to 35	15	16
36 to 45	23	25
46 to 55	22	22
56 to 65	16	13
>66	4	1
Education, %		
Some high school	15	17
High school	11	17
Some college or university	11	10
College diploma	34	19
University degree (s)	30	36
Seeks health information on Internet		
>once per week	24	25
once per week	16	17
once per month	23	20
couple times a year	20	19
<couple times a year	16	19
Health care professional, %	18	9
English speaking, n (%)	41 (55)	38 (55)

Table 3: Percentage of participants with correct answer

Concept	Question	New FORMAT	Current FORMAT	Difference	P value
Overall understanding (mean, standard deviation)	All five questions marked with * below	53% (31)	18% (17)	35%	<0.001**
Understanding of quality of evidence	In people at high risk of catching a cold (such as people in extreme cold conditions), what is more certain?*	43%	2%	41%	<0.001
Understanding of quality of evidence and risk (qualitative statements)	In an ordinary population (such as people at normal risk) will vitamin C decrease the chance of catching a cold?*	47%	40%	7%	0.42
Ability to quantify risk (dichotomous outcome)	How many people at normal risk (such as in an ordinary population) will catch a cold if they take vitamin C?*	64%	17%	47%	<0.001
Understanding of risk	When people take 8 grams or high doses of vitamin C as soon as a cold starts, they will....benefit?*	45%	19%	26%	0.001

Concept	Question	New FORMAT	Current FORMAT	Difference	P value
Ability to quantify risk (continuous outcome)	In people at normal risk of catching a cold (or in an ordinary population), how many fewer hours will their cold last if they took vitamin C regularly before the cold even started?*	65%	10%	55%	<0.001
Comprehension of purpose of summary	This summary is about the results of a large study. (correct answer: No)	32%	45%	-13%	0.17
Ability to identify producer of review	Who produced this summary? (correct answer: Researchers of the Cochrane Collaboration)	89%	67%	22%	0.001

* The five questions included in the primary outcome of overall understanding and understanding of benefits and harms and quality of evidence.
** Analysis adjusted for education level, language and Internet experience P<0.001.

Figure 1: New format of plain language summary

The effect of Vitamin C on the common cold

Douglas RM, Hemilä H, Chalker E, Treacy B. Vitamin C for preventing and treating the common cold. *Cochrane Database of Systematic Reviews*
Date: Issue 3, 2007

Plain Language Summary of a Cochrane Review

A review of the research of the effect of vitamin C on the common cold was conducted by researchers in the Cochrane Collaboration. After searching for all relevant studies, they found 30 studies. Their findings are summarised below.

What is the common cold and why take Vitamin C?

Symptoms of the common cold are well-known and can include runny nose, sore throat, fever and headache. Most adults, who are at *normal risk*, will have two to three colds a year that last about 3 to 4 days. People who are at *high risk*, for example, adults doing intense physical activity or working outside in sub-arctic conditions, have more than 3 colds a year that last about 6 days.

The common cold is caused by a virus and cannot be cured by antibiotics. Since it cannot be cured, much research has been done to find ways to prevent colds or reduce symptoms. The effect of taking more vitamin C than in a normal diet has been researched for over 60 years. Most countries recommend about 40 to 90 mg of vitamin C a day. The 30 studies in this review tested vitamin C supplements (usually pills) at 1000 to 2000 mg (1 to 2 grams) a day.

What the research says

There are two types of findings from the studies: the end results and the quality of those end results. To determine quality, they consider many factors, such as how well a study was done, who funded it, and how many people were in it. The higher the quality of the evidence, the more certain we can be about the end results and what will happen. Below we describe what will happen when taking vitamin C. When the effect is more certain (or from high quality evidence), the word *will* is used. When it's moderate quality, *probably*, is used, and *may* is used for low quality. When there is very low quality evidence or no evidence, the effect *is not known*. The word *slightly* means that there is a small effect.

Taking 1 to 2 grams of vitamin C per day for about 12 weeks regularly to prevent a cold

In people at normal risk, vitamin C
- will not decrease the chance of catching a cold
- will decrease how long a cold lasts by a few hours
- will not lead to side effects

In people at high risk, vitamin C
- may decrease the chance of catching a cold
- probably decreases how long the cold lasts by a few hours
- will not lead to side effects

Taking 1 to 2 grams of vitamin C per day as soon as a cold starts
- probably will not decrease how long the cold lasts

84

The effect on children and the effect of mega-doses of Vitamin C (4 to 8 grams per day), are not known.

What happens to people who take vitamin C

This table provides more detail about what happens to people who take vitamin C. These numbers are based on the results of the research, when available. The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.

What happens	Not taking Vitamin C	Taking Vitamin C (1 to 2 g per day)	Quality of evidence
Probably will not decrease how long the cold lasts if vitamin C taken as soon as the cold starts	The cold lasts **84 hours or 3 ½ days**	The cold lasts **2 fewer hours** (9 fewer to 4 more hours) *	⊕⊕⊕◯ Moderate
Will decrease how long the cold lasts if vitamin C taken before the cold	People at normal risk		⊕⊕⊕⊕ High
	The cold lasts **84 hours or 3 ½ days**	The cold lasts **7 fewer hours** (3 to 11 fewer hours)	
Probably decreases how long the cold lasts if vitamin C taken before the cold	People at high risk		⊕⊕⊕◯ Moderate
	The cold lasts **134 hours or 6 days**	The cold lasts **19 fewer hours** (8 to 30 fewer hours)	
Will not decrease the chance of catching a cold	People at normal risk		⊕⊕⊕⊕ High
	50 per 100 people	**49 per 100 people** (48 to 50 per 100)	
May decrease the chance of catching a cold	People at high risk		⊕⊕◯◯ Low
	70 per 100 people	**35 per 100 people** (27 to 46 per 100)	
Will not lead to more side effects	**6 per 100 people**	**6 per 100 people**	⊕⊕⊕⊕ High

Quality of evidence: The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.
*The numbers in brackets show the range where the actual effect may be.

Figure 2: Current format of the plain language summary

The effect of Vitamin C on the common cold
Douglas RM, Hemilä H, Chalker E, Treacy B. Vitamin C for preventing and treating the common cold. Cochrane Database of Systematic Reviews 2007, Issue 3.

Plain Language Summary of a Cochrane Review
Symptoms of the common cold are well-known and can include runny nose, sore throat, fever and headache. It is a major cause of visits to a doctor in Western countries and of absenteeism from work and school. The common cold is caused by a virus and cannot be cured by antibiotics. Since it cannot be cured, much research has been done to find ways to prevent colds or reduce symptoms. The effect of taking more vitamin C than in a normal diet has been researched for over 60 years. Most countries recommend about 40 to 90 mg of vitamin C a day. The 30 studies in this review tested vitamin C supplements (usually pills) at 1000 to 2000 mg (1 to 2 grams) a day.

Thirty studies involving 11,350 participants suggest that taking vitamin C regularly has no effect on catching a cold in the ordinary population. It reduced how long the cold lasted and severity of the symptoms slightly, although the effect was so small its usefulness is doubtful. Nevertheless, in six studies in people exposed to short periods of extreme physical or cold stress or both (including marathon runners and skiers) vitamin C reduced the common cold risk by half.

Studies of high doses of vitamin C (starting when the cold starts), showed no consistent effect on either the length of the cold or severity of symptoms. However, there were only a few studies testing this and their quality was variable. One large trial reported equivocal benefit from 8 g of vitamin C at the start of a cold, and two trials in which vitamin C was taken for 5 days reported benefit. More trials testing vitamin C to treat a cold are necessary to settle the question, especially in children.
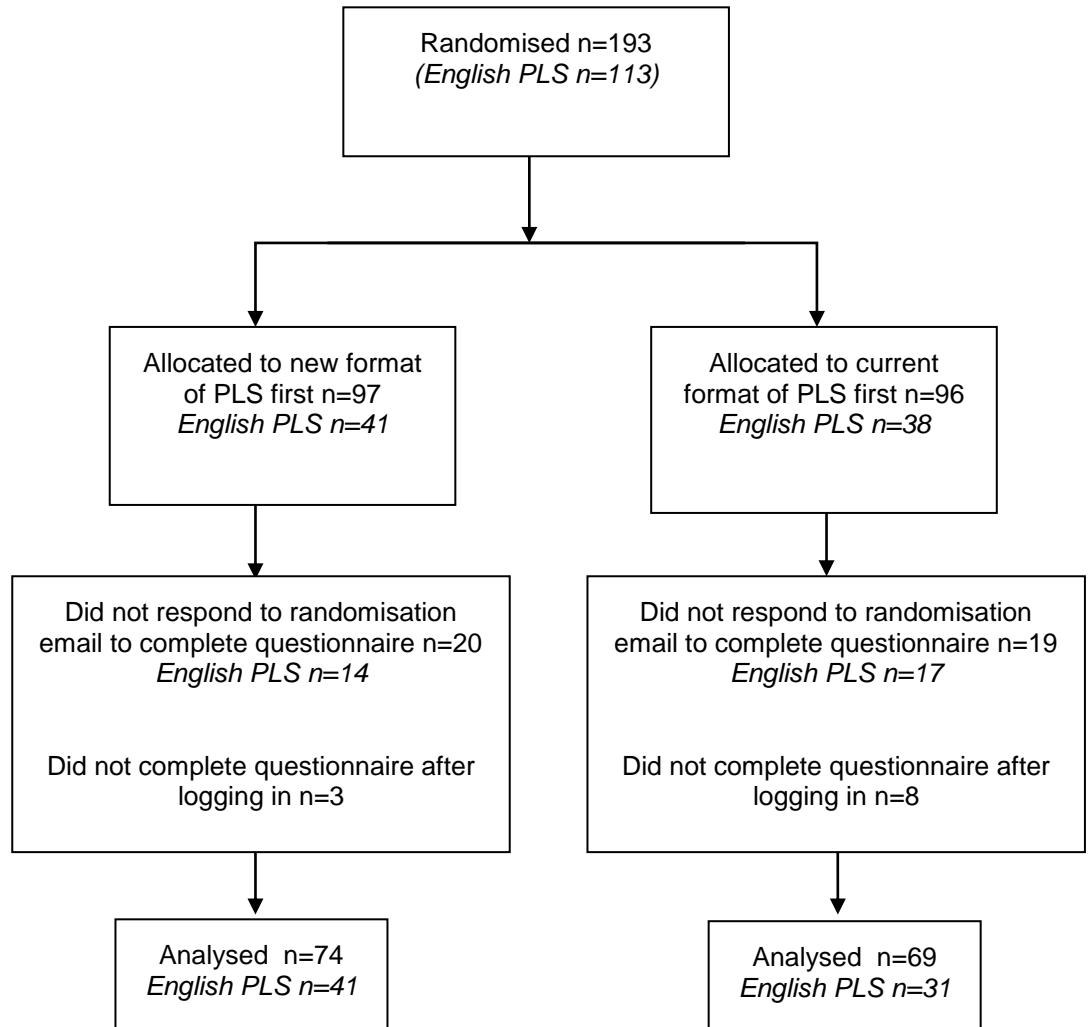
Figure 3: Participant flow diagram

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                    ┌─────────────────────────┐
                    │   Randomised n=193      │
                    │   (English PLS n=113)   │
                    └───────────┬─────────────┘
                                │
              ┌─────────────────┴──────────────────┐
              │                                    │
┌─────────────────────────┐          ┌─────────────────────────┐
│  Allocated to new format │          │   Allocated to current   │
│   of PLS first n=97      │          │  format of PLS first n=96 │
│   English PLS n=41       │          │    English PLS n=38      │
└───────────┬─────────────┘          └───────────┬─────────────┘
            │                                     │
┌───────────────────────────────┐   ┌───────────────────────────────┐
│ Did not respond to randomisation│   │ Did not respond to randomisation│
│ email to complete questionnaire │   │ email to complete questionnaire │
│ n=20                            │   │ n=19                            │
│ English PLS n=14                │   │ English PLS n=17                │
│                                 │   │                                 │
│ Did not complete questionnaire  │   │ Did not complete questionnaire  │
│ after logging in n=3            │   │ after logging in n=8            │
└───────────────┬─────────────────┘  └───────────────┬─────────────────┘
                │                                     │
      ┌───────────────────┐              ┌───────────────────┐
      │ Analysed  n=74    │              │ Analysed  n=69    │
      │ English PLS n=41  │              │ English PLS n=31  │
      └───────────────────┘              └───────────────────┘
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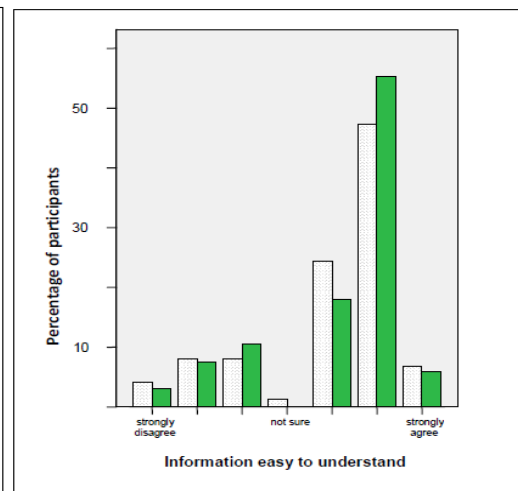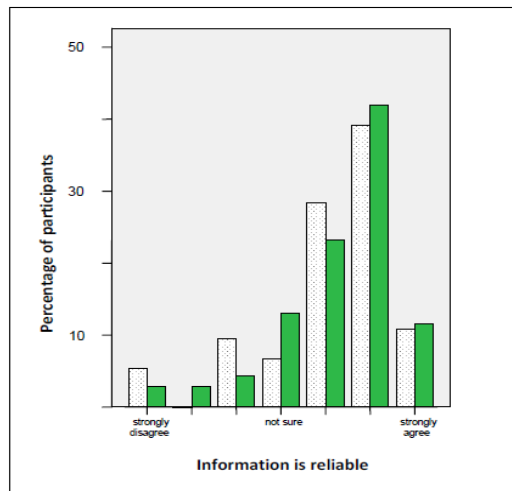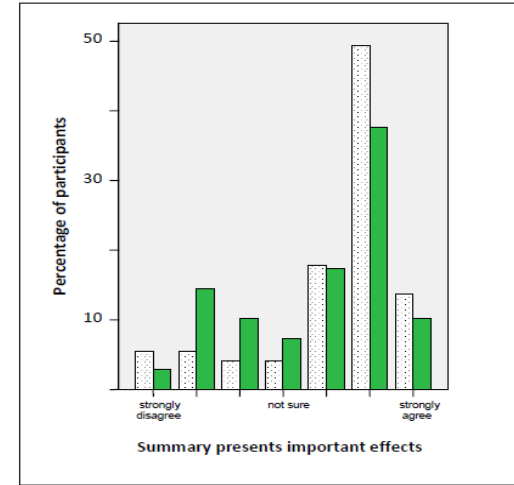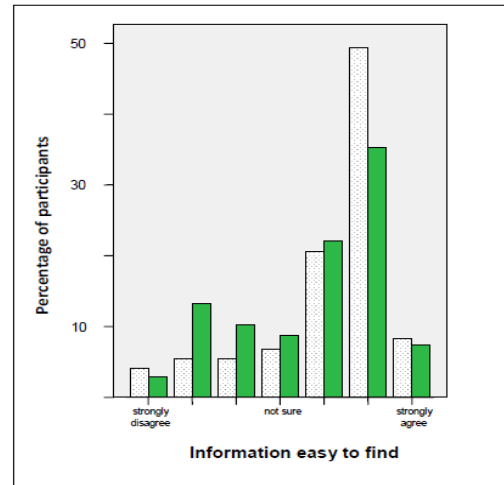
Figure 4: Assessment of usability and accessibility by new or current format

Figure 4: Assessment of usability and accessibility by new or current format

New format

Current format
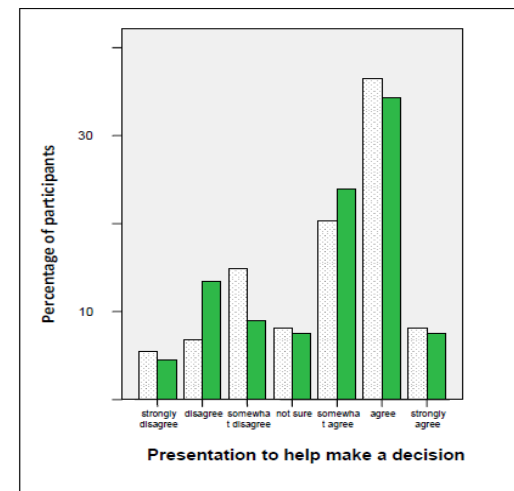
Appendix 1: Questionnaire

I am...

○ Female

○ Male

I am...

○ Less than 25 years old

○ Between 26 and 35

○ Between 36 and 45

○ Between 46 and 55

○ Between 56 and 65

○ Between 66 and 75

○ Over 75 years old

I have...

○ Some high school education

○ A high school education

○ Some college or university

○ A college diploma

○ A university degree

○ A post graduate degree

I am/was a health researcher or health care professional

○ Yes

○ No

I have read a Cochrane review or a Cochrane Plain Language Summary before this survey.

○ Yes

○ No

○ I'm not sure

The language I feel more comfortable speaking and reading is...

○ English

○ French

○ Spanish

○ Italian

○ German

○ Norwegian

○ Other (please specify)

I look for health information on the internet...

○ more than once a week

○ once a week

○ once a month

○ a couple of times a year

○ less than a couple of time a year

○ never

This summary is about the results of a large study.

○ Yes

○ No

○ I'm not sure

Who produced this summary?

○ The author of the large study

○ Researchers of the Cochrane Collaboration

○ I'm not sure

Please indicate how much you disagree or agree with the following statement.

	I strongly disagree	I disagree	I somewhat disagree	Not sure	I somewhat agree	I agree	I strongly agree
The information is reliable.	○	○	○	○	○	○	○

Please indicate how much you agree or disagree with the following.

	I strongly disagree	I disagree	I somewhat disagree	Not sure	I somewhat agree	I agree	I strongly agree
The summary presents the most important effects of vitamin C for the common cold.	○	○	○	○	○	○	○
It was easy to find the information about the effects.	○	○	○	○	○	○	○
It was easy to understand the information.	○	○	○	○	○	○	○
The information is presented in a way that would help me make a decision.	○	○	○	○	○	○	○

Overall, how would you rate the accessibility of the main findings of this review? By "accessibility" we mean the extent to which the main findings are easy to find, to understand and to use by someone making a decision.

	Very inaccessible	Inaccessible	Not sure	Accessible	Very accessible
Overall accessibility of the findings of the review.	○	○	○	○	○

In people at high risk of catching a cold (such as people in extreme cold conditions), what is more certain?

○ Vitamin C decreases the chance of catching a cold.

○ Vitamin C decreases how long a cold lasts (or the length of cold)

○ Vitamin C does not lead to more side effects

○ Mega doses (4 to 8 mg) decreases how long a cold lasts

○ All of the above are just as certain

In an ordinary population (such as people at normal risk) will vitamin C decrease the chance of catching a cold?

○ it will not

○ it may not

○ it probably will not

○ it will

○ it may

How many people at normal risk (such as in an ordinary population) will catch a cold if they take vitamin C?

○ 5 per 100 people or around that number

○ 10 per 100 people or around that number

○ 35 per 100 people or around that number

○ 49 per 100 people or around that number

○ 70 or more per 100 people or around that number

When people take 8 grams or high doses of vitamin C as soon as a cold starts,

○ they will probably see a benefit

○ they will see a benefit

○ they will not see a benefit

○ they will probably not see a benefit

○ the benefits are not known

In people at normal risk of catching a cold (or in an ordinary population), how many fewer hours will their cold last if they took vitamin C regularly before the cold even started?

○ 2 fewer hours or around that much

○ 7 fewer hours or around that much

○ 15 fewer hours or around that much

○ 19 fewer hours or around that much

○ 24 fewer hours or around that much

Comparing the plain language summary you evaluated to the one above, which one do you prefer?

	I strongly prefer the one I evaluated	I prefer the one I evaluated	I somewhat prefer the one I evaluated	I'm not sure which one I prefer	I somewhat prefer this one	I prefer this one	I strongly prefer this one
Which one do you prefer?	○	○	○	○	○	○	○

CHAPTER 4

PATIENT AND PUBLIC ATTITUDES TO AND AWARENESS OF

CLINICAL PRACTICE GUIDELINES: A SYSTEMATIC REVIEW AND

THEMATIC ANALYSIS

PREFACE TO CHAPTER 4

This paper presents a systematic review of patient and public attitudes to and awareness of clinical practice guidelines. This work was conducted from 2012 to 2014. It was accepted on 15 July 2014 in *BMC Health Services Research*. This journal is an open access journal in which authors retain copyright of the materials, and can grant any third party the right to use reproduce and disseminate the article (Creative Commons Attribution License, http://creativecommons.org/licenses/by/2.0).

Both Ms. Loudon and I contributed equally to this work. All authors contributed to the conception of the review, the protocol and search strategy, and screened titles and abstracts. Ms. Loudon and I also screened the full text of the studies, abstracted data from the studies, assessed the studies, and analysed and interpreted the results. We equally contributed to the writing of the manuscript and the revisions in response to feedback from the authors. Dr. Treweek also provided critical review of the interpretation of the data and the manuscript.

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Patient and public attitudes to and awareness of clinical practice guidelines:

a systematic review with thematic and narrative syntheses

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Abstract

Background: Clinical practice guidelines are typically written for healthcare providers but there is increasing interest in producing versions for the public, patients and carers. The main objective of this review is to identify and synthesise evidence of the public's attitudes towards clinical practice guidelines and evidence-based recommendations written for providers or the public, together with their awareness of guidelines.

Methods: We included quantitative and qualitative studies of any design reporting on public, patient (and their carers) attitudes and awareness of guidelines written for providers or patients/public. We searched electronic databases including MEDLINE, PSYCHINFO, ERIC, ASSIA and the Cochrane Library from 2000 to 2012. We also searched relevant websites, reviewed citations and contacted experts in the field. At least two authors independently screened, abstracted data and assessed the quality of studies. We conducted a thematic analysis of first and second order themes and performed a separate narrative synthesis of patient and public awareness of guidelines.

Results: We reviewed 5415 records and included 26 studies (10 qualitative studies, 13 cross sectional and 3 randomised controlled trials) involving 24 887 individuals. Studies were mostly good to fair quality. The thematic analysis resulted in four overarching themes: Applicability of guidelines; Purpose of guidelines for patient; Purpose of guidelines for health care system and physician; and Properties of guidelines. Overall, participants had mixed attitudes towards

guidelines; some participants found them empowering but many saw them as a way of rationing care. Patients were also concerned that the information may not apply to their own health care situations. Awareness of guidelines ranged from 0-79%, with greater awareness in participants surveyed on national guideline websites.

Conclusion: There are many factors, not only formatting, that may affect the uptake and use of guideline-derived material by the public. Producers need to make clear how the information is relevant to the reader and how it can be used to make healthcare improvements although there were problems with data quality. Awareness of guidelines is generally low and guideline producers cannot assume that the public has a more positive perception of their material than of alternative sources of health information.

Keywords

Clinical practice guidelines
Patient
Public
Attitudes
Awareness

Background

Clinical practice guidelines are systematically developed tools that present recommendations and research evidence to direct appropriate healthcare throughout the world. They are typically produced for health care providers but there is an increasing interest in developing derivative products for the public. A recent review of existing programmes for patient and public involvement in guidelines found that almost half of the reports indicated that patients were involved in the development of products specifically for patients and the public [1]. In addition, there are now many organisations producing patient versions of guidelines. In the UK, for example, the National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN) produce freely accessible patient versions. The Finnish Medical Society, Duodecim, publishes patient versions of national Current Care guidelines at and a comprehensive collection of guideline-based patient information in Duodecim's Health Library. Professional groups are also producing patient versions of their guidelines, for example, the Netherlands Association of Posttraumatic Dystrophy.

The research base for presentation and uptake of patient versions of guidelines is also growing. Much of the research draws on work about how to present evidence to patients in different formats – the GIN toolkit [2] for example - and how to develop decision aids from guidelines to promote the use and uptake of guidelines by patients and the public [3, 4]. However, we know that other factors play an

important role in the use of evidence and guidelines. Graham and Logan, for example, describe the characteristics of the patient as an important factor which could act as a barrier or facilitator to uptake [5]. These characteristics would include patient and public attitudes towards guidelines, and awareness of guidelines. The literature suggests, for example, that consumers may perceive guidelines negatively as a way to ration access to medications [6], a perception that would need to be addressed by material intended for the public.

The main objective of this review was to identify and synthesise evidence on the public's attitudes towards clinical practice guidelines (including related patient versions) and evidence-based recommendations, as well as on their awareness. This work is part of a larger project which focuses on the communication of guidelines to a variety of target audiences in the DECIDE project (Developing and Evaluating Communication Strategies to support Informed Decision and practice based on Evidence: http://www.decide-collaboration.eu) [7].

Methods

We conducted a synthesis of quantitative and qualitative studies similar to the approach used by Smith [8] and based on the methodology described by Dixon-Woods [9] and Munro [10]. We have reported this review using the guidance provided in the ENTREQ statement, an EQUATOR Network reporting guideline for the synthesis of qualitative research [11].

Inclusion and exclusion criteria

We included quantitative and qualitative studies of any design reporting on the attitudes and awareness of guidance or guidelines, both for health care providers and patients and the public (patient versions). Other inclusion and exclusion criteria are given in Table 1.

Identification of studies

We searched MEDLINE, MEDLINE In Process, PSYCHINFO, ERIC, ASSIA from 2000 to January 2012 using key terms for patients, guidelines or guidance, awareness, perception, attitudes, communication and information dissemination (see Additional file 1 for the search strategies for principal databases). We updated our MEDLINE search up to January 2013. We conducted a search for secondary research in The Cochrane Library, Guidelines International Network (G-I-N) conference abstracts, Picker institute, Health Talk Online, Health Foundation, World Health Organisation, King's Fund, Biomed Central, National Institutes of Health, NLM, AHQR, OpenDOAR, The Knowledge Network, NHS Evidence, TRIP database, Intute (up to January 2012), Google (including Google Scholar), Dogpile, and Health on the Net Foundation for documents published between 1999 and 2012. We also reviewed citations from key documents, authors and institutions (published between 1999 to 2012), and contacted experts in the field via emails to members of the DECIDE project, GRADE Working Group G-I-N and the Evidence Based Health discussion list (April 2012).

At least two authors independently screened each citation by title and abstract. We then retrieved the full text of all citations identified as potentially relevant by at least one investigator and two authors independently screened these full texts. Articles in English, Finnish, Norwegian, Spanish and German were included.

Data extraction

Two authors independently extracted data from the included studies using a form which was first piloted and revised accordingly. Extracted data included study design and methods, recruitment strategy, study setting, number of participants, characteristics of participants (including age, sex, ethnicity, socio-economic status, and education level of participants), details of the interventions used to communicate guideline information, and awareness of clinical practice guidelines. From each study, we used an inductive approach to identify first order themes (i.e. themes based on the participants' understanding reported by the authors) and second order themes (i.e. themes from the authors' interpretation of the findings) related to attitudes and awareness of clinical practice guidelines.

Quality assessment of studies

As there is no agreed tool to assess the reliability of studies for qualitative research, we used the CASP (Critical Appraisal Skills Programme) tools [10]. Two reviewers independently assessed the methodological quality of the included quantitative and qualitative studies using the relevant CASP tool [12, 13]. Studies

were rated as good, fair or poor by considering all of the factors, but in particular, whether the study used a qualitative methodology appropriately to address our objectives.

Data synthesis

Two reviewers compared the data extracted from all studies and resolved disagreements by discussion. We reported the awareness of guidelines for each study, and also a range across the studies, as we could not pool this data.

For the analysis of qualitative data, we based our analysis on approaches described by Smith [8], Dixon-Woods [9] and Munro [10] and conducted a thematic analysis [14]. Two reviewers first compared the themes extracted from each study to develop consensus. All themes (first and second order) were then compiled across the studies and the two reviewers organised the themes to develop categories of dominant themes with subthemes. Each paper was then recoded according to the categories of overarching and subthemes. This process was iterative with discussion between the two reviewers, and also involved consultation with the team. Quotes from the original studies were used to illustrate the themes.

Results

Selection of studies

We found 5415 unique records with the database search and five additional studies through other methods. We assessed 183 studies as potentially eligible and retrieved those in full text. After full-text screening, 26 studies, involving 24 887 individuals were included in the review (see Figure 1 for the PRISMA Diagram of flow of studies). Of the 26, 20 studies provided data for the thematic analysis and 17 studies provided data for the awareness of clinical practice guidelines.

Study characteristics

There were ten qualitative studies using focus groups or semi-structured interviews [6, 15-23]; thirteen cross sectional studies [24-36]; and three randomised controlled trials: [37-39].

Tables 2 and 3 provide the characteristics of the included studies. Overall the studies included diverse populations: Canadian office workers, female carers in Maryland, USA, Londoners attending drop-in centres in the UK for patients with mental health problems, visitors to a welfare centre in Seoul, women attending secondary care for menstrual abnormalities in Leicestershire, UK, and patients with Diabetes in Australia. The age of participants ranged from 30 to over 76 years, apart from one study on 11–15 year old adolescents [33]. Most studies

included both genders although some included only women because of the topic
(e.g. breast cancer).

The qualitative research studies were mostly good to fair quality (Tables 2 and 3).
Common reasons for fair quality were: lack of description or discussion about the
analyses of the qualitative data reported in primarily quantitative studies; the role
of the researcher and their relationship with the participants when conducting the
focus groups or interviews; and whether or not saturation of data was reached.
Most of the quantitative studies were also good to fair quality. Few included
information about pre-testing questionnaires, or had poor response rates and/or
high drop-out rates.

**Thematic analysis of the public's attitudes towards clinical practice
guidelines and evidence based recommendations**

The thematic analysis of the included studies resulted in four overarching themes
and sub-themes for the patient and public attitudes towards clinical practice
guidelines:

- **Applicability of guidelines:** Patient as individual**,** Applicability of
  information to themselves

- **Purpose of guidelines for patient:** Communicate with physician**;** Decision
  making**;** Self- management

- **Purpose of guidelines for health care system and physician:** Guidelines control care (restrict/offer, access, cost)**;** Guidelines as rules

- **Properties of guidelines:** Format issues**;** Trustworthiness**;** Evidence behind recommendations

Theme 1: Applicability of guidelines

Several studies reported that individuals expressed concern that guidelines may not personally help them and may not be applicable to their particular needs [6, 18, 23, 26, 27, 38]. Two studies highlighted that treatment decisions should be tailor made to the individual and therefore guidelines may not be appropriate [6, 18]. Although Julian [18] also indicated in a qualitative study of women with menstrual disorders that this may not be true for all patients and that:

> *Patients' perception of clinical guidelines was also influenced by whether they viewed menstrual disorders as being unique to the individual patient and requiring personal treatment or as a process in which women experience similar symptoms requiring similar treatment.*

Participants were inclined to trust their judgement based on their own unique experiences [6, 26] or advice from others in similar situations rather than trust guidelines [18]. For instance, while the majority of women in a survey knew the guideline recommendations were *not* to give solid food to infants before four months, almost half did give their child cereal before the age of four months and more than 40% reported that the advice of a friend or family member was

influential in this decision [26]. Participants also wanted to clearly see that

guidelines could apply to them. When asked about a set of physical activity

guidelines, participants indicated that they needed to identify with the guidelines

first before reading or applying them [23] and this often lead to comments that

personal stories should be included in guidelines to help people relate to the

information [22, 23]. However, guidelines were also seen as an affirmation of

patient experiences. In one study, women with menstrual disorders saw the

guidelines as a way of reducing the need to 'prove' that they really had a

menstrual problem because their individual needs were being identified in the

guidelines [18].

Theme 2: Purpose of guidelines for patient

Nine studies described the potential purpose of guidelines for patients and the

public and the role that guidelines have played to date [6, 15, 16, 19, 21, 22, 27,

31, 38]. Five studies reported that participants thought guidelines could be used as

a simple tool to provide health information and recommendations which could

lead to a better understanding of their health [15, 16, 21, 22, 38]. However,

surveys conducted by SIGN and NICE found that only 8% of respondents thought

guidelines were used to inform the public or dealt with advice for patients [30,

34]. Patients also indicated that they could use guidelines to plan which questions

they would ask their health care providers during the clinical encounter [6, 16, 19,

21, 22, 27, 31, 38]. Guidelines, however, were not only useful for talking to

doctors but they were also perceived as a tool that could be used independently, outside the consulting room. One study indicated that participants thought guidelines could help them make their own health care decisions [21] and in several studies, patients and the public identified guidelines as a source of information to manage their own care [15, 16, 21, 22, 38]. Breast cancer survivors felt guidelines could provide much needed recommendations regarding diet and physical activity [22]. Self- management was also important to diabetic patients who used guidelines to act as a good reminder for their own self-care [16]. Guidelines were not only considered useful for treatment but also for preventing disease [21]. Other studies reported that guidelines could also be used to ensure patients received the care to which they were entitled [20]; as a second opinion [21]; and as validation of their health problems [18].

There were however some concerns about the use of guidelines by patients. One study found that patients were worried that guidelines might impair the patient-doctor relationship by reducing confidence in the doctor and also through the potential to create conflict between patients and doctors [18]. Another study reported that patients felt that guidelines may take away decision-making from patients [6]. Finally there was concern about the trustworthiness of guidelines. In one study investigating the impact of recent modifications to an endocarditis guideline, if a patient's doctor did not approve of the guideline changes then patients would not follow it [27].

Theme 3: Purpose of guidelines for health care system and physician

Several studies indicated that patients thought guidelines had several purposes related to their care at a system level and the care provided by their health care providers [6, 16, 18, 20, 30, 34, 35, 38]. Overall, participants' feelings were mixed about whether guidelines affected their care positively or negatively.

In several studies, guidelines were seen as a way to keep health care providers up to date with current treatments [16, 18] and also as a way to ensure consistent and high quality care [30, 34]. The survey conducted by SIGN exploring the public's understanding of the purpose of guidelines indicated that 44% thought guidelines to be 'consistent best care/practice' [34]. In a similar survey conducted by NICE, 11% of participants thought that the main purposes of guidelines was 'Best care', and 8% thought NICE 'had something to do with fair access' [30]. In addition, 20/24 (84%) of SIGN participants and 246/553 (45%) NICE participants felt more confident in their or their relative's care and treatment as result of the relevant guideline being applied.

In contrast, many studies reported that participants thought guidelines may be rules that health professionals must follow rigidly [6, 18]. Consequently, participants indicated that guidelines could lead to inflexibility in care provided to individual patients [18]; rationing or denial of care [6, 18, 35]; or limited access to innovative care that patients need [6]. Squiers found that participants felt that the

breast screening guidelines may have been developed to restrict care or screening to particular groups, which can also lead to controversy if the guideline is misunderstood or controversial [35]. This viewpoint was also supported by the respondents to the NICE survey [30] with 11% believing cost effectiveness was one of the main purposes of guidelines.

Theme 4: Properties of guidelines

A strong theme emerged in several studies: patients and the public emphasised the importance of formatting when trying to understand the guidelines and adapting the guidelines to themselves, and in how they perceived the guidelines. It was important to participants that the guidelines should be perceived as trustworthy. Berry *et al* found that the simplistic format of the *Canada Physical Activity Guideline*, especially its use of cartoons, put people off [23] and that this undermined the guideline's trustworthiness:

> *When it came to participants' perceptions of [the guideline], they expressed a dislike for the cartoon-like format, which led some to actually question whether adults were the target audience and if the guide would be taken seriously.*

Because of the use of cartoons participants felt they could not identify with the messages being put forward by the guideline.

Several studies found that a guideline's usefulness was also related to whether it was engaging to read and could hold a person's interest. Berry found that most participants thought the presentation of the guideline was dull and lacked the 'glitz' that would encourage people to pick up and read the guidelines [23]. Participants did not like to be presented with too much information [17] and liked information to be organised in layers (in particular on the internet), with quick access to layers of recommendations and the ability to drill down to get more detailed information [21].

Participants in many studies indicated that they wanted to know what to do and therefore the language needed to be clear and unambiguous [17, 29, 39]. People preferred simple phrases like 'low in fat' rather than more nuanced phrasing 'balance your fat' [17], and language that was specific and clear-cut [29]. Michie *et al* [39] explored using 'behaviourally specific plain English' text, which had been amended using psychological theory to address potential barriers to implementing the guideline recommendations. This wording was perceived by patients and the public to lead "to stronger intentions to implement the guidelines, more positive attitudes towards them, and greater perceived behavioural control over using them" [39].

Two studies reported that variation in the quality of care, in research evidence and in treatment effectiveness, were genuinely new concepts for many people and it

was unclear if guidelines were based on evidence [6]. Participants were unfamiliar

with and sometimes confused by the terms 'medical evidence', 'quality

guidelines' and 'quality standards' [6]. Despite this confusion, several studies

reported that participants expressed a strong preference to be informed about the

quality of evidence (or certainty or uncertainty) that supports a recommendation

[37]. In particular, participants preferred to know about uncertainty relating to

outcomes of a treatment or test but were slightly more interested in knowing about

uncertainty relating to benefits than harms [37].

Narrative synthesis of patient and public awareness of guidelines

Seventeen studies focused on asking patients and the public about awareness of

clinical guidelines, including those written for the public or professionals [16, 17,

19, 20, 22-26, 28-34, 36].

Awareness that clinical guidelines exist ranged from 79% to 0%. The largest

numbers were found in the (824/1040) of respondents to a NICE survey [30]

(which respondents entered through the NICE website) and 64% (151/236)

(through the SIGN website) [34]. However, these results may represent awareness

of an already 'aware' group of people. The smallest numbers were from few or no

participants in focus groups when asked about their awareness of guidelines

and/or guideline producers [16, 17, 19, 20, 23].

Other studies asked patients and the public about awareness of a particular

guideline after implementing strategies to improve awareness [19, 23, 32, 33, 36].

Berry *et al* [23] and Spence *et al* [36], focused on *Canada's Physical Activity*

Guide to Healthy Living. Mitchell and White focused on the National Health and

Medical Research Council colorectal cancer guidelines [19] and Nash *et al*

focused on national USA guidelines on managing cholesterol [32]. Whether or not

participants were aware of a particular guideline, rather than guidelines in general,

varied. Copeland *et al* found in a survey that 61% (78/128) of parents were aware

of illness exclusion guidelines from child care, though this was for any written

guideline on illness exclusion rather than a named guideline [25]. Spence *et al*

found that 20% (544/2719) of respondents to their survey were aware of

Canada's Physical Activity Guide to Healthy Living [36] while Roth and

Stamatakis found only around 11% of 1954 children aged 11-15 knew the key

NICE recommendation for physical activity in children [33]. When asked about

National Health and Medical Research Council colorectal cancer guidelines, none

of 33 people with colorectal cancer taking part in interviews were aware of them,

although all participants wanted a copy once they were made aware of them [19].

Keenan *et al* examined consumers' knowledge of the *1995 Dietary Guidelines for*

Americans using a telephone survey of 400 adults in two cities and found that

55% of people had never heard of a document containing the government's

dietary guidelines [29]. Of the 180 who knew it existed, 119 could not name it and

only one of those who gave a name identified the *Dietary Guidelines for Americans*. Hong [28]*,* found that 196/290 individuals interviewed about dietary guidance were not aware of the *Dietary Guidelines for Korean, a* sizeable minority (64/290) felt that dietary guidelines were unnecessary. Crocetti *et al* [26] surveyed 102 female caregivers at their child's 4 month well-child visit and found that 78% were aware of the guideline and the specific recommendation of when to begin feeding solids [26].

Miroballi surveyed 1399 people who had, or who were caring for someone with, cystic fibrosis about infection control guidelines from the Cystic Fibrosis Foundation in the USA [31]. Overall, 65% of respondents were aware of the guidelines but of these only 66% had discussed them with their care team.

Royak-Schaler ran four focus groups with 39 African American breast cancer survivors and found that participants wanted guidelines that could help them develop plans for follow-up and survivorship self-care [22]. This guidance was available, however participants were neither provided with it, nor aware of it.

Discussion

The principal aim of the review was to identify and summarise patient and public attitudes to clinical practice guidelines. We found 26 studies of fair to good quality from which four main themes emerged: Applicability of guidelines,

Purpose of guidelines for patient, Purpose of guidelines for health care system and physician, and Properties of guidelines. These themes represent patient and public attitudes to clinical practice guidelines which were written either specifically for health care providers or for patients and the public. We suggest that these themes may need to be incorporated into the design of patient versions of guidelines, to ensure their use.

For example, patients want to be seen as individuals with unique experiences and health care needs. The theme of Applicability to the individual, also known as 'Personalisation' or 'Affiliation', refers to the problems people have identifying with information and understanding the relevance to them, or what does it have to do with 'someone like me' [40]. Additional research is showing that conveying information is more than a question of whether patients understand the statistical risks (e.g. 3 out of 100 people were cured), but also how patients can use the information in their own situations [41]. Presenting personal stories of real people with the same health care needs may be one way to connect the reader to the information in guidelines, although there remains the question of how to select stories: should there be an attempt to provide balance, or should stories focus on the positive (or negative)? Perhaps guideline developers should pursue partnerships with patient organisations and popular 'patient story' websites such as healthtalkonline or PatientsLikeMe to provide direct access from patient stories to relevant guidelines-derived material. Alternatively, providing ways for readers

to tailor the information to themselves by using their own health information may help individuals apply guidelines to their own particular situation. Decision aids, which guide people through a decision while clarifying personal values, can be provided as supplementary resources linked to guidelines and can be semi-automated as demonstrated in the MAGIC guideline project for anti-antithrombotic therapy [42]. These guidelines, like others about Chronic Obstructive Pulmonary Disease, explicitly consider patient values and preferences when developing recommendations [43]; an approach the GRADE system has always considered when deciding the strength of a recommendation [44, 45]. This is of particular importance in versions of guidelines intended to be used directly by the public.

Patients and the public also saw guidelines as potentially serving many purposes, such as being sources of health information, as tools for making decisions, or as a resource to manage their own care. Many guidelines, however, do not typically include background information about the conditions or the interventions covered in the guideline. This means it could be challenging for guideline producers to then develop patient versions as a source of general health information and it may require producers to dedicate additional resources to look outside the guideline for that information, even if only to signpost readers towards those other sources of information.

It is clear though that guidelines are different from other sources of health information: guidelines include evidence-informed recommendations about what should or should not be provided or done, something that other sources of information do not generally do. Thus the recommendations should not be lost when producing patient versions since these are what make guideline-derived material unique. But while some guidelines lend themselves to helping patients with recommendations about self-management (e.g. test your blood sugar daily), this may not be straightforward for other guidelines. Guideline producers committed to providing patient versions will need to consider each guideline individually to determine the intended purpose of the patient version.

Patients and the public did not always see guidelines in a positive light; we found that many consider guidelines as a way to ration and deny access to care. Guideline producers may need to overcome this barrier directly in the text of patient versions - perhaps by providing the evidence behind a recommendation to show where the recommendation came from, or to simply be explicit in saying that the aim of guidelines is not to ration care but to provide care based on the best evidence currently available.

This review also found that public awareness of clinical guidelines is low, linked to the perception that clinical practice guidelines are only for health professionals and have little or no relevance for patients or the public. An increase in the

number of guideline producers developing patient and public versions of all or some of their guidelines may help to address this awareness issue. Guideline producers cannot assume that patients and the public will naturally go to their websites looking for high-quality information, or that they will ask health professionals about guidelines. The material will need to be easily picked-up by search engines, as well as being promoted to health professionals to hand to patients, before significant numbers of the public will be able to use it in their decision-making.

Methodological Limitations

The search was challenging as we could not filter our results by study design and our topic was broad (a problem also raised by others) [10]. However, we do not think we have missed any significant studies as we screened over 5000 citations and believe we have captured the most relevant studies for this review. We chose the widely used CASP tool to assess the quality of included studies, but we believe that it includes factors that may not be directly linked to the credibility of the results presented by the study (e.g. ethics approval). Therefore, studies scoring poorly on these factors may nevertheless have been higher quality which would further substantiate the results that we found. Regarding the degree of confidence we have in the synthesised results of this review, we have not provided an overall assessment. Although, there are methods to assess overall confidence in the quality of the evidence for reviews of interventions (e.g. GRADE), there is

currently no agreed system to undertake this for syntheses of qualitative evidence. We have instead indicated that most results came from studies of good to fair quality and that the themes from this review of the literature may be important to consider when developing patient versions of clinical practice guidelines.

Conclusions

Many guideline producers are producing patient versions of clinical practice guidelines. This review has found important factors, in addition to formatting issues, which may affect the uptake and use of these versions of guidelines by public, patients and carers. Guideline producers need to make clear how the information is relevant to the reader and how it can be used to make healthcare improvements. In addition, awareness of guidelines is generally low and guideline producers cannot assume that the public has a more positive perception of their material than of alternative sources of health information.

Research to develop and test a variety of methods to incorporate this information into patient versions of guidelines is currently being conducted in the DECIDE project (Developing and Evaluating Communication Strategies to support Informed Decisions and practice based on Evidence: http://www.decide-collaboration.eu). This project aims to improve the way guideline information is presented to a wide range of stakeholders, including the public, patients and their carers [7]. The intention is that by addressing the public's attitudes and awareness

of clinical practice guidelines when producing versions of guidelines intended for the public, these will be more useful in supporting evidence-informed healthcare decision.

List of abbreviations

CASP: Critical Appraisal Skills Programme

DECIDE: Developing and Evaluating Communication Strategies to support Informed Decision and practice based on Evidence

ENTEREQ: Enhancing transparency in reporting the synthesis of qualitative research

G-I-N: Guidelines International Network

GRADE: Grading of Recommendations Assessment, Development and Evaluation

NICE: National Institute for Health and Care Excellence

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

SIGN: Scottish Intercollegiate Guidelines Network

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors conceived of the review, screened studies, and read and approved the final manuscript. JH performed the searches. KL, MC and NS appraised the

studies and abstracted data. KL and NS interpreted the data and wrote the review; ST also wrote the review.

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Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Public, patient or carer beliefs, feelings, awareness, understanding, knowledge, attitudes, expectations and perceptions of clinical practice guidelines (and/or guidance).	Opinion pieces, editorials, narrative reviews and protocols. Public/patient involvement in guideline development.
User-testing of public/patient information tools derived from guidelines.	Public/patient-centred. communication/information not related to guidelines or evidence-based recommendations.
Readability/understandability of public/patient-targeted information materials derived from guidelines.	Public health campaigns.
Communicating research results to public/patients within the context of a guideline.	Procedure-specific information (e.g. details of surgical operations and their consequences).
Public/patient versions of guidelines	Informed consent for clinical trials.
Computer interpretable guidelines for public/patients.	Public understanding of science.
Knowledge translation tools for public/patients derived from guidelines.	
English, Finnish, Norwegian, Spanish and German articles.	

Table 2: Characteristics of studies and themes identified in thematic analysis of attitudes to clinical practice guidelines (19 included studies)

Author Year Study design Quality	Aim	Participants and study location	Key themes identified by reviewers
Akl 2007 RCT Fair	To evaluate the use of symbols and words to present information on the strength of recommendations	84 participants, 64.1% female, 48.6% graduate - part of community health education programme; USA	Evidence behind recommendations; format issues
Berry 2010 Qualitative study Good	To gain an understanding of public perceptions of Physical Activity guidelines put forward by a public health agency	22 participants in five focus groups, 18 to 70 years; Type II diabetes or cardiovascular disease; Canada	Patient as individual; format issues
Carman 2010 Qualitative study Fair	To determine how the concept of making health care decisions based on evidence of effectiveness could be translated into language that consumers would understand	34 consumers in 4 focus groups, 57 interviews and 1558 employees, 18-64; USA	Patient as individual; Guidelines control care; Guidelines as rules; Guidelines for physicians; Communicate with physician; Trustworthiness
Crocetti 2004 Cross sectional study Good	To determine awareness and knowledge of infant feeding guidelines	102 Primary female caregivers mean age 27 years; 34% African American; 64% completed high school; Maryland, USA	Patient as individual

Author Year Study design Quality	Aim	Participants and study location	Key themes identified by reviewers
Dykes 2004 Qualitative study Poor	To evaluate a tool to drive patient centred evidence based recommendations to facilitate guideline adherence	3 evaluators mean age 71 years, TV literate bedbound patients and carers (higher retirement income); Connecticut, USA	Self management; Format issues
Eaton 2011 RCT cluster randomised Good	To determine whether an intervention based on patient activation and a physician support tool was more effective than usual care to improve adherence to National Cholesterol Education Program guidelines (USA)	4105 patients; primary care; mean age 52 control/54 intervention; 96% white; 59% female, southeastern New England, USA.	Communicate with physician, decision making; Self management; Patient as individual. Format issues
Elad 2011 Cross sectional study Good	To gauge acceptance of 2007 American Heart Association guidelines on antibiotic prophylaxis after being notified about change by doctor	51 patients, 58 ± 17 yrs, 40% female with endocarditis; Israel.	Applicability of guideline information; Communicate with physician; Trustworthiness

Author Year Study design Quality	Aim	Participants and study location	Key themes identified by reviewers
Faruqi 2000 Qualitative study Poor	To determine views, how to put into practice and disseminate clinical management of diabetes mellitus guidelines	5-20 participants recruited through Diabetes Australia in four focus groups; Sydney, Australia	Self-management; Communicate with physician; Guidelines for physicians; Format issues
Geiger 2001 Qualitative study Poor	To determine awareness of dietary guidelines and test presentation formats	40 men and women (25-45; Missouri, USA	Guidelines for physicians; Guidelines control care; format issues
Julian 2010 Qualitative study Good	To determine knowledge and attitudes of women with menstrual disorders towards the use of evidence based clinical guidelines for their condition	24 women (22-54) attending secondary care; Leicestershire, England	Guidelines as rules; Guidelines control care; Guidelines for physicians; Patient as individual;
Keenan 2002 Cross sectional study Fair	To examine knowledge and understanding and factors that influence knowledge - media/nonmedia/age and education	400 adults over 18 years old, 51.8% college degree, 56% female; Minnesota, USA	Format issues
McFarlane 2011 Cross sectional study Fair	To determine public awareness of National Institute for Health and Care Excellence (NICE) guidelines and their implementation	1675 respondents (70% female, 61% (45-74 yrs old), 17% health care professionals); mostly England and Wales, UK	Guidelines for physicians; Guidelines control care

Author Year Study design Quality	Aim	Participants and study location	Key themes identified by reviewers
Michie 2005 RCT Poor	To evaluate knowledge of guideline and take up when using behaviourally specific language	84 mental health users; 41-50 years; 51% women; London, UK	Format issues
Miroballi 2012 Cross sectional study Fair	To determine awareness of infection control guidelines	1399 Cystic Fibrosis patients and their families, 38% patients, 62% family members; USA	Communicate with physician
Mitchell 2004 Qualitative study Fair	To determine knowledge of evidence based medicine and guidelines	33 patients with colorectal cancer and 9 carers, 43 to 86 years; 66% male, many had not completed highschool; Austin, Victoria, Australia	Communicate with physician
Owen-Smith 2010 Qualitative study Fair	To investigate patients' and healthcare providers' experiences of, and preferences for, implicit and explicit healthcare rationing	56 participants (31 patients, clinicians, healthcare managers); morbid obesity and breast cancer; Bristol, UK	Guidelines control care
Quintana 2010 Qualitative study Good	To explore how best to use the Internet to make evidence-based preventive health care guidelines available to physicians and consumers	39 participants (22 men, 17 women ,56% men), 35 to 65 years, experience using the Internet; Canada.	Format issues; self management; Trustworthiness; evidence behind recommendations; Communicate with physician; Decision making

Author Year Study design Quality	Aim	Participants and study location	Key themes identified by reviewers
Royak-Schaler 2008 Qualitative study Fair	To investigate patient-physician communication from the patient's perspective about guidelines	39, age 30-75 (mean age 55), 72% college education, breast cancer survivors, all African American; Baltimore, USA	Self-management; Communicate with physician
SIGN 2011 Cross sectional study Fair	To investigate public awareness of Scottish Intercollegiate Guidelines Network (SIGN) guidelines and their implementation	239 respondents (66 % female, 74% 45-74 yrs old, 61% had specific condition or disability); mostly Scotland, UK	Format issues; Evidence behind recommendations; Guidelines improve care; Guidelines for physicians
Squiers 2011 Cross sectional Good	To assess how knowledgeable women were about the new recommendations in mammography	1221 women, 40-74, who had never had breast cancer; USA	Format issues; Evidence behind recommendations; Guidelines control care

RCT: randomised controlled trial.

Table 3: Characteristics of studies and results for studies reporting awareness of clinical practice guidelines (17 included studies)

Author Year Study design Quality	Aim	Participants and study location	Awareness
Berry 2010 Qualitative study Good	To gain an understanding of public perceptions of Physical Activity guidelines put forward by a public health agency	22 paricipants in five focus groups, 18 to 70 years; Type II diabetes or cardiovascular disease; Canada	Lack of awareness
Cameron 2007 Cross sectional study Fair	To determine Awareness and Knowledge of Canadian Physical Activity Guide (CPAG) guidelines, prompted and unprompted	8892 adults aged 18 or older from Physical Activity Monitor; 52% female, 83% greater than high school education; Canada	4% aware of any guidelines for physical activity; 37% prompted aware of CPAG
Copeland 2005 Cross sectional study Fair	To determine awareness of written guidelines that define which conditions require exclusion from the Child Care Centre	128 parents picking up children at Day Care Centre, 91% female, 69% African American; Baltimore City, USA	61% aware of guideline
Crocetti 2004 Cross sectional study Good	To determine awareness and knowledge of infant feeding guidelines	102 Primary female caregivers mean age 27 years; 34% African American; 64% completed high school; Maryland, USA	77% aware of guideline
Faruqi 2000 Qualitative study Poor	To determine how to put into practice and disseminate clinical management of diabetes mellitus	5-20 participants recruited through Diabetes Australia in four focus groups; Sydney,	Lack of awareness

Author Year Study design Quality	Aim	Participants and study location	Awareness
	guidelines	Australia	
Geiger 2001 Qualitative study Fair	To determine awareness of dietary guidelines and test presentation formats	40 men and women (25-45; Missouri, USA	Lack of awareness
Hong 2007 Cross sectional study Poor	To determine awareness and knowledge of dietary guidelines	345 well people - 77% female; 46% <65 years. Randomly selected in one district Seoul urban population.	32.2% aware of dietery guidelines
Keenan 2002 Cross sectional study Fair	To examine knowledge and understanding and factors that influence knowledge - media/nonmedia/age and education	400 adults over 18 years old, 51.8% college degree, 56% female; Minnesota, USA	45% aware of dietary guidelines
Mitchell 2004 Qualitative study Fair	To examine knowledge of evidence based medicine and guidelines	33 patients with colorectal cancer and 9 carers; 43 to 86 yrs old; 66% male; many had not completed high school; Austin, Victoria, Australia	No awareness

Author Year Study design Quality	Aim	Participants and study location	Awareness
Miroballi 2012 Cross sectional study Fair	To determine awareness of Infection Control guidelines	1399 Cystic Fibrosis patients and their families; 38% patients, 62% family members in USA	65% aware of guidelines
Nash 2003 Cross sectional study Poor	To determine cholesterol guideline awareness	1163 adults, 56% female, >40 years; Canada	32% (94/290) aware of guideline
McFarlane 2011 Cross sectional study Fair	To determine public awareness of National Institute for Health and Care Excellence (NICE) guidelines and their implementation	1675 respondents (70% female, 61% (45-74 yrs old), 17% health care professionals); mostly England and Wales, UK	79% (824/1040) aware of guidelines
Owen-Smith 2010 Qualitative study Fair	To investigate patients' and healthcare providers' experiences of, and preferences for, implicit and explicit healthcare rationing	56 participants (31 patients, clinicians, healthcare managers); morbid obesity and breast cancer; Bristol, UK	Only 6/31 patients knew about NICE and what they did and 3 of these patients worked for health service.
Roth 2010 Cross sectional study Fair	To investigate knowledge of guidelines and if is this linked to following guidelines	1940 adolescents (11-15 yrs old); 49% female; England, UK	11% of children knew about the recommendations.
Royak-Schaler 2008 Qualitative study	To investigate patient-physician communication from the patient's perspective about	39 participants, 30-75 yrs old (mean age 55), 72% college education, breast cancer	Lack of awareness

Author Year Study design Quality	Aim	Participants and study location	Awareness
Fair	guidelines	survivors, all African American; Baltimore, USA	
SIGN 2011 Cross sectional study Fair	To investigate public awareness of Scottish Intercollegiate Guidelines Network (SIGN) guidelines and their implementation	239 respondents (66 % female, 74% 45-74 yrs old, 61% had specific condition or disability); mostly Scotland, UK	64% (151/236) aware of guidelines
Spence 2002 Cross sectional study Fair	To investigate awareness of Canada's Physical Guide to Healthy Active Living	2719 participants; 18-76+ years; Alberta, Canada	20% (544/2719) aware of guideline

Additional file 1: Search strategies for principal databases

OVID Medline (2000 to January 2012 - updated January 2013)
Medline in Process (2000 to January 2012)
1   exp Patients/
2   *Practice Guidelines as Topic/
3   *Guidelines as Topic/
4   (guideline* or guidance).tw.
5   or/2-4
6   exp Communication/
7   Comprehension/
8   Information Dissemination/mt [Methods]
9   Health Knowledge, Attitudes, Practice/
10   Attitude to Health/
11   Knowledge/
12   or/6-11
13   1 and 5 and 12
14   patient*.tw.
15   (public or "lay person" or "lay people" or citizen*).tw.
16   ("service user*" or consumer* or reader*).tw.
17   ("care-giver*" or "caregiver*" or carer*).tw.
18   (famil* or spouse* or relative* or partner* or parent*).tw.
19   or/14-18
20   (communicat* adj3 (guideline* or guidance)).tw.
21   (comprehen* adj3 (guideline* or guidance)).tw.
22   (present* adj3 (guideline* or guidance)).tw.
23   (disseminat* adj3 (guideline* or guidance)).tw.
24   ((understand* or understood) adj3 (guideline* or guidance)).tw.
25   ((belief* or believe) adj3 (guideline* or guidance)).tw.
26   (attitude* adj3 (guideline* or guidance)).tw.
27   (aware* adj3 (guideline* or guidance)).tw.
28   (knowledge adj3 (guideline* or guidance)).tw.
29   (expect* adj3 (guideline* or guidance)).tw.
30   ((perception* or perceive) adj3 (guideline* or guidance)).tw.
31   ((inform or informing) adj3 (guideline* or guidance)).tw.
32   (accept* adj3 (guideline* or guidance)).tw.
33   or/20-32
34   *Practice Guidelines as Topic/
35   *Guidelines as Topic/
36   (guideline* or guidance).tw.
37   34 or 35 or 36
38   19 and 33 and 37
39   13 or 38
40   limit 39 to yr="2000 -Current"

41   Animals/
42   Humans/
43   41 not (41 and 42)
44   40 not 43

OVID ERIC (2000 to January 2012)
1. exp Patients/
2. exp *Guidelines/
3. (guideline* or guidance).tw.
4. 2 or 3
5. exp Communications/
6. exp "communication (thought transfer)"/
7. exp Comprehension/
8. exp information dissemination/
9. exp Knowledge Level/
10. exp Health Education/
11. exp Attitudes/
12. exp Beliefs/
13. exp Expectation/
14. exp Perception/
15. or/5-14
16. 1 and 4 and 15
17. patient*.tw.
18. (public or "lay person" or "lay people" or citizen*).tw.
19. ("service user*" or consumer* or reader*).tw.
20. ("care-giver*" or "care giver*" or caregiver* or carer*).tw.
21. (famil* or spouse* or relative* or partner* or parent*).tw.
22. or/17-21
23. (communicat* adj3 (guideline* or guidance)).tw.
24. (comprehen* adj3 (guideline* or guidance)).tw.
25. (present* adj3 (guideline* or guidance)).tw.
26. (disseminat* adj3 (guideline* or guidance)).tw.
27. ((understand* or understood) adj3 (guideline* or guidance)).tw.
28. (accept* adj3 (guideline* or guidance)).tw.
29. ((belief* or believe) adj3 (guideline* or guidance)).tw.
30. (attitude* adj3 (guideline* or guidance)).tw.
31. (aware* adj3 (guideline* or guidance)).tw.
32. (knowledge adj3 (guideline* or guidance)).tw.
33. (expect* adj3 (guideline* or guidance)).tw.
34. ((perception* or perceive*) adj3 (guideline* or guidance)).tw.
35. ((inform* or informing) adj3 (guideline* or guidance)).tw.
36. or/23-35
37. exp Guidelines/
38. (guideline* or guidance).tw.

39. 37 or 38
40. 22 and 36 and 39
41. limit 40 to yr="2000 -Current"

EBSCO PsychInfo (2000 to January 2012)
S58   S15 or S57 Limiters - Publication Year from: 2000-2012
S57   S4 and S21 and S56
S56   S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or
S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or
S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53 or
S54 or S55
S55   TI informing W3 guidance OR AB informing W3 guidance
S54   TI informing W3 guideline* OR AB informing W3 guideline*
S53   TI inform* W3 guidance OR AB inform* W3 guidance
S52   TI inform* W3 guideline* OR AB inform* W3 guideline*
S51   TI perceive* W3 guidance OR AB perceive* W3 guidance
S50   TI perceive* W3 guideline* OR AB perceive* W3 guideline*
S49   TI perception* W3 guidance OR AB perception* W3 guidance
S48   TI perception* W3 guideline* OR AB perception* W3 guideline*
S47   TI expect* W3 guidance OR AB expect* W3 guidance
S46   TI expect* W3 guideline* OR AB expect* W3 guideline*
S45   TI knowledge W3 guidance OR AB knowledge W3 guidance
S44   TI knowledge W3 guideline* OR AB knowledge W3 guideline*
S43   TI aware* W3 guidance OR AB aware* W3 guidance
S42   TI aware* W3 guideline* OR AB aware* W3 guideline*
S41   TI attitude* W3 guidance OR AB attitude* W3 guidance
S40   TI attitude* W3 guideline* OR AB attitude* W3 guideline*
S39   TI believe W3 guidance OR AB believe W3 guidance
S38   TI believe W3 guideline* OR AB believe W3 guideline*
S37   TI belief* W3 guidance OR AB belief* W3 guidance
S36   TI belief* W3 guideline* OR AB belief* W3 guideline*
S35   TI understood W3 guidance OR AB understood W3 guidance
S34   TI understand* W3 guidance OR AB understand* W3 guidance
S33   TI understood W3 guideline* OR AB understood W3 guideline*
S32   TI understand* W3 guideline* OR AB understand* W3 guideline*
S31   TI accept* W3 guidance OR AB accept* W3 guidance
S30   TI accept* W3 guideline* OR AB accept* W3 guideline*
S29   TI disseminat* W3 guidance OR AB disseminat* W3 guidance
S28   TI disseminat* W3 guideline* OR AB disseminat* W3 guideline*
S27   TI present* W3 guidance OR AB present* W3 guidance
S26   TI present* W3 guideline* OR AB present* W3 guideline*
S25   TI comprehen* W3 guidance OR AB comprehen* W3 guidance
S24   TI comprehen* W3 guideline* OR AB comprehen* W3 guideline*
S23   TI communicat* W3 guidance OR AB communicat* W3 guidance

S22   TI communicat* W3 guideline* OR AB communicat* W3 guideline*
S21   S16 or S17 or S18 or S19 or S20
S20   TI (famil* or spouse* or relative* or partner* or parent*) OR AB (famil* or spouse* or relative* or partner* or parent*)
S19   TI ("care-giver*" or "care giver*" or caregiver* or carer*) OR AB ("care-giver*" or "care giver*" or caregiver* or carer*)
S18   TI ("service user" or consumer* or reader*) OR AB ("service user" or consumer* or reader*)
S17   TI (public or "lay person" or "lay people" or citizen*) OR AB (public or "lay person" or "lay people" or citizen*)
S16   TI patient* OR AB patient*
S15   S1 and S4 and S14
S14   S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13
S13   MM "Expectations"
S12   MM "Attitudes"
S11   MM "Awareness"
S10   MM "Consumer Attitudes"
S9   MM "Knowledge Level"
S8   MM "Health Knowledge"
S7   MM "Information Dissemination"
S6   MM "Comprehension"
S5   MM "Communication"
S4   S2 or S3
S3   TI (guideline* or guidance) OR AB (guideline* or guidance)
S2   MM "Treatment Guidelines"
S1   MM "Patients"

CHAPTER 5

DISSEMINATION OF CLINICAL PRACTICE GUIDELINES: A

CONTENT ANALYSIS OF PATIENT VERSIONS

PREFACE TO CHAPTER 5

This chapter is a manuscript that will be submitted to *Health Expectations*. It is a qualitative descriptive study of a sample of patient versions of CPGs, and the data was analysed using directed content analysis. This work was conducted in 2014.

I conceived the study and wrote the protocol. I received feedback about the protocol from the co-authors and revised it accordingly. I developed the data collection form with input from Gian Paolo Morgano (the second author). We both sampled the patient versions of the CPGs, and collected and analysed the data. I wrote the manuscript and incorporated feedback from all co-authors.

This study will be used to inform the patient and public stream of the DECIDE project (Developing and Evaluating Communication Strategies to support Informed Decision and practice based on Evidence: http://www.decide-collaboration.eu) funded by the European Community's Seventh Framework Programme (FP7/2007-2013).

Dissemination of clinical practice guidelines: A content analysis of patient versions

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Dissemination of clinical practice guidelines: A content analysis of patient versions

Abstract

Background Clinical practice guidelines (CPGs) are typically written for health care professionals but are meant to assist patients with health care decisions. A number of guideline producers have started to develop patient versions of CPGs to reach this audience.

Objective To describe the content and purpose of current patient versions of CPGs and compare with the views of CPGs in the target audience.

Design A descriptive qualitative study with a directed content analysis of a sample of patient versions of CPGs published and freely available in English from 2012-2014.

Results We included 34 patient versions of CPGs from 17 guideline producers. Over half of patient versions were in dedicated patient sections of national/professional agency websites. There was essentially no information about how to manage care in the health care system. The most common purpose was to equip people with information about disease, tests or treatments, and recommendations, but few provided quantitative data about benefits and harms of treatments. Information about beliefs, values and preferences, accessibility, costs or feasibility of the interventions was rarely addressed. Very few provided

personal stories or scenarios to personalise the information. Three versions

described the strength of the recommendation or the level of evidence.

Conclusions This review provides the current landscape of patient versions of

CPGs, but results suggest that these versions might not address the needs of their

targeted audience. Research is needed about how to personalise information,

provide information about factors contributing to the recommendations, and

provide access.

Introduction

Clinical practice guidelines (CPGs) provide health care recommendations and are meant to facilitate health care decision-making not only by clinicians, but also by patients [1]. However, people, i.e. patients (including carers) and other members of the public, face the dilemma that CPGs have traditionally been developed to communicate information to clinicians. This is unfortunate as high quality CPGs ideally provide useful information which could be tailored to this audience, such as information about the effects of tests or treatments, the quality of that evidence, and clear recommendations which factor in patient values and preferences, resources, feasibility and other issues such as equity [2]. Guideline producers can build on the expanding evidence base about how to produce patient information from CPGs, but there may be other challenges inherent in guidelines. A recent review of the literature of patient and public attitudes to CPGs found that there may be unique factors to consider when communicating guidelines [3]. The review found that people may not always perceive guidelines positively. Some people thought CPGs could limit their decision making by providing rules about their treatment options, may not be trustworthy or credible, and may not be applicable to their own situations. Nevertheless, others thought that patient versions of CPGs could provide information about how to manage their own care, could be used as a tool when speaking with their health care providers, and could potentially help them make decisions if the right information was provided.

Recently, there has been more attention directed towards the development of decision aids directly from recommendations to help people participate in health care decisions [4,5]. In addition to decision aids, there is an opportunity to produce patient information based on CPGs which could play multiple roles. Dixon-Woods has identified a variety of purposes for patient information and organised them into two perspectives: materials for patient education, and materials for patient empowerment [6]. Traditionally, the predominant purpose was to provide information to educate people about their condition and treatments, to save time during consultations, and to enhance compliance with recommendations. Materials for patient empowerment build upon patient education, and also include information to assist people to consider their own experiences, preferences and resources to inform decisions [6]. A number of guideline producers are developing patient versions: SIGN (Scottish Intercollegiate Guidelines Network) has produced over 30 patient versions based on their CPGs and NICE (National Institute for Health and Care Excellence) has over 150 CPG patient versions available. A survey conducted by Kryworuchko and colleagues found that 42% of guideline producers are targeting patients with versions different from the CPGs [7], and a recent review of international programmes to involve patients and the public revealed that 18/71 of the organisations involve patients in the development of products for patients and the public based on CPGs [8].

Guideline producers now have the opportunity to learn from what is currently being developed and build on that knowledge base while considering the unique factors which may play a role in the use of guidelines by patients and the public. The purpose of this descriptive qualitative study is to describe the patient versions of CPGs currently available using directed content analysis. In addition, we specifically ask i) What are the stated and latent purposes of the patient versions? and, ii) How does the content compare with the patient and public views of CPGs? Based on our analysis, we describe the current landscape of patient versions and based on our findings make suggestions for future research.

Methods

Study design

We conducted a qualitative descriptive study with a directed content analysis of a sample of patient versions currently available from key institutions producing CPGs [9]. We described the characteristics of the patient versions, summarised and quantified the information provided, identified the purpose of the patient versions, and briefly described how recommendations and evidence are communicated.

Sample: Identification of patient versions

Because our overarching aim is to learn from guideline producers with experience currently producing patient versions, we conducted a search to identify patient

versions of CPGs published between 2012 and April 2014 by key institutions producing guidelines or recommendations. We defined a key institution as a national, public or professional organisation with a mandate to produce guidelines and which had produced at least six clinical guidelines since January 2012. To develop the list of key institutions, we reviewed the members' list of a large guideline network: the GRADE Working Group (an informal international group of people interested in methods for guideline development) with members of GRADE's DECIDE project (a co-funded project by the European Commission under the Seventh Framework Programme for Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence). To broaden our search for key institutions beyond this, we searched the International Guideline Library produced by the Guidelines International Network (GIN), the CMA Infobase (a database of guidelines from the Canadian Medical Association); the National Health and Medical Research Council Clinical Practice Guidelines Portal from Australia; and the NICE Evidence Search in the United Kingdom, for key institutions producing more than six guidelines between 2012 and 2014. We visited the websites of those institutions to determine if they had produced patient versions (see inclusion criteria below for a definition of patient version). We also searched the National Guideline Clearing House (NGC) using the advanced search and restricted to 2012-2014 and used the filter for 'only include guidelines that have/incorporate: patient resources' to find institutions

producing patient versions. One investigator screened through the institutions from the search using the a priori inclusion criteria.

Inclusion criteria

From each institution, we randomly sampled two patient versions produced between January 2012 and April 2014 by using the random function in Excel. We decided to include two patient versions after reviewing four patient versions from NICE and two from SIGN because we observed that the versions were quite similar within organisations. We included patient versions which were

- defined as a patient version/information by the organisation,

- based on a CPG or Recommendations for clinicians,

- produced by organisations which have dedicated resources or research to produce patient versions - indicated by more than four topic specific patient versions produced between 2012 and 2014,

- available publicly,

- published in English.

Data extraction

We took a directed (deductive) approach to content analysis as described by Hsieh and Shannon [10]. We developed a coding form and data abstraction sheet for manifest and latent content based on categories informed by the current literature around patient education materials and research into disseminating guidelines and

recommendations to practitioners [2,3,6,11]. Key components of the patient

versions were extracted: format of the patient versions (e.g. length, booklet), types

of information provided (background, tests or treatments, evidence,

recommendations, and additional information), the purpose of the patient

versions, and communication of recommendations and evidence (see

Supplementary Material 1 for the key components extracted and themes). We

used the work from Dixon-Woods [6] to develop a list of the purposes of patient

versions; we identified recommendations using the criteria outlined by Hussain

[11]; identified important factors unique to guideline recommendations, such as

patient values and preferences using the GRADE approach [2]; and used the

themes found in the systematic review of patient and public attitudes towards

CPGs (personalisation, credibility, purpose and format issues) [3]. The two

investigators piloted the form using four patient versions and revised accordingly.

Data was independently extracted by two investigators and/or verified by the

other. When new categories arose during data extraction, the investigators

discussed and agreed and re-extracted data from the documents.

Data analysis

Data were managed using an electronic database. The two investigators compared

the quantitative data abstracted for discrepancies and resolved disagreements. We

calculated frequency data as proportions of guidelines that included a component,

and calculated a median and interquartile range (IQR) for continuous data (e.g.

percent of document which was background information). For content related to the purpose of the documents, we created separate tables and compared our assessment of the presence or absence of a purpose. Disagreements were discussed between the two investigators until consensus was reached. We provided a qualitative description of the purpose of the patient versions, and illustrated the purpose through examples. Finally, we compared the content of the documents to the views of patients and the public about CPGs identified by our previous review of research about their attitudes and awareness of CPGs [3].

Results

Our search of the guideline databases and member lists found 38 key institutions that met our inclusion criteria, and 21 institutions from NGC using the 'patient' limits. Of these, 42 had not produced more than four patient versions between 2012-April 2014. We therefore included 17 organisations and sampled two patient versions from each for a total of 34 patient versions (see Table 1). A variety of medical topics were covered including cancer (breast, lung, prostate, esophageal, pancreatic and melanoma), women's health and reproduction, gastrointestinal conditions, diabetes and mental health. Most patient versions (24/34) primarily focused on guidelines about treatment, but many also covered diagnosis, screening and/or prevention. A summary of the characteristics of the patient versions is available in Table 2 and described below.

[insert table 1]

Location of patient versions

Over half of patient versions (20/34) were found in dedicated patient sections of national and professional agency websites (e.g. in sections 'For patients' or 'Patient Education') or linked directly from the professional version of the CPG (18%). A small number (4/34) were found on patient dedicated websites that were affiliated with the professional organisations. Almost half of the patient versions (16/34) were available on websites as a printed document only and 11/34 as web pages which were printable. Patient versions were called a variety of names by different organisations and were typically referred to simply as 'patient information'. Thirteen indicated that they were based on guidelines. For example, the European Society for Medical Oncology (ESMO) titles their versions as "Patient information based on ESMO Clinical Practice Guidelines," and the American Academy of Neurology (AAN) as "Summary of Evidence-based Guideline for PATIENTS and their FAMILIES."

[insert table 2]

Information provided in the patient versions

The documents provided a diversity of information about the disease, anatomy, risk factors, symptoms and incidence. However, few documents included

information about the prognosis of the disease or condition. Proportionately little information consisted of background (16%, IQR 12 to 23%) and there was essentially no information (0%, IQR 0 to 6%) provided about the health care system or how to navigate through the system with disease. In the documents that did provide health care system information, it typically described the health care team involved in care. A little over 1/3 of the documents did not include pictures, graphics or figures, but those that did often depicted the anatomy of the body affected by the condition or disease.

Many patient versions (27/34) referred to or linked directly to the professional versions of the guidelines. But only half included a description of what a guideline is or how the guideline was developed. When guidelines were described in the patient version, it was usually at the back of the document. While the use of evidence was mentioned in some documents in this section, the emphasis was on the 'experts' or committees of professionals and patient representatives who developed the guidelines. In fact, in 21 documents it was stated that patients were involved in the development or review of the material. The amount of information about guidelines varied from a single statement to multiple paragraphs. NICE wrote: 'NICE clinical guidelines advise the NHS [National Health Service] on caring for people with specific conditions or diseases and the treatments they should receive.' In contrast, the United States Preventive Task Force (USPSTF) patient summaries include information about methods, which covered what are

guidelines, how they are produced, and what grading system is used. In addition
to providing text within the document, SIGN also provided a link to a separate
patient information booklet about the development of guidelines.

The majority of patient versions provided links or contact information (such as
telephone numbers) for additional information and support, and typically at the
end of the document (though sometimes within the document). However, the
credibility of these links was sometimes compromised as some patient versions
also included a caveat about not being responsible for the content in those
recommended sites. The majority of patient versions also encouraged people to
talk to their health care provider for more information, but only five provided a
section for 'questions to ask your doctor.'

Credibility of the information

In addition to referring to or providing a link to the professional version or
providing the methods for development, the most common method used to convey
credibility was the use of the logo of the professional association (and if
applicable, the affiliated patient organisation). NICE and the Royal College of
Obstetrics and Gynaecology also referenced the Information Standard; SIGN
referenced Crystal Mark/Plain English Campaign; and the Canadian Paediatric
Society referenced the Health on the Net Code of Conduct.

[insert table 3]

Purpose of the patient versions

Twenty-one patient versions explicitly stated their purpose. All 21 aimed to educate or equip people with information. Eight stated an additional purpose: six stated that the goal was to empower people to obtain the 'best care'; one version about HIV and pregnancy was to provide information for self-care and to stay healthy; and another about overactive bladder was to empower patients to become more active by openly talking about the condition.

Our qualitative analysis of the purpose of the patient versions began with categories adapted from Dixon-Woods [6]. Although we did not find additional categories, we did refine categories. For example, we included 'entitlement of care' within 'navigating the health system,' and emphasised consideration of patient values and preferences within decision making. We did not find examples for some categories: persuasion for the use of specific interventions, to reassure or provide a second opinion, and to replace the healthcare consultation or counseling (see Table 3 for the list of purposes with examples).

Similar to the stated purpose of the patient versions, the most common purpose from our qualitative analysis was to provide education about or equip people with information about the disease, the tests or treatments, and the recommendations.

Even when the versions were short, the purpose was to still to provide information by directing people to more information and resources. Links to additional websites, telephone numbers, names of other organisations were provided whether for background information, treatment or test information, or for support. There was, however, little information about benefits and harms, and again most times people were advised to speak with their health care providers who should provide information about the risks and benefits of treatments instead: 'During your care and treatment, your healthcare team should give you information (including written information) about fertility problems and treatments to help you make informed decisions.' (NICE, Assessment and treatment for people with fertility problems). When this information was provided it was generally vague and very few patient versions provided quantitative data about how often benefits and harms would occur (Table 3). Although many versions indicated that the information could be used to make decisions and should be discussed with the health care provider to make decisions, it was often not accompanied by other information to assist with decision-making. Information about what beliefs, values or preferences have an impact on the decision, or information about the accessibility, costs or feasibility of the interventions were rarely addressed. When it was mentioned, for example in the patient version from NICE for Hyperphosphataemia in chronic kidney disease, specific information about the preferences that might play a role in the decision was not described; '...your

healthcare team will take into account which type you prefer, how easy they are to take, and other factors when deciding which is the most suitable for you.'

Most patient versions presented multiple options for tests and treatments, enhanced choice and did not appear to be about persuading people to use particular interventions. For example, both patient versions produced by the National Comprehensive Cancer Network not only provided a list and description of the treatments available for esophageal and pancreatic cancers, but also described and provided additional resources for information about complementary and alternative medicines (CAMs). Further, it was stated that 'If there was good proof that CAMs or other treatments cured cancer, they would be included in this booklet.' Even documents that presented information about one treatment noted that other options should be discussed with health care providers. The patient version from the AAN for Vagus Nerve Stimulation (VNS) advised readers to '…talk with your doctor about therapies for treating seizures. Be sure you understand all the options available, including VNS.' In contrast, the patient version describing what to expect after stillbirth, appeared to focus on options for seeing the baby or taking the baby home for a period but not on other options. For example, it stated: 'If you made the decision not to see your baby after the birth, and then change your mind, you can still ask to see your baby.'

As indicated previously, there was little information to help people understand or navigate the health care system. When this type of information was provided, it was limited and only identified the different types of health care providers and what type of care they provide. Nevertheless, many of the documents were organised in a typical care pathway to reflect a health care journey, starting with diagnosis, treatments, and follow-up care. The Managing Schizophrenia booklet produced by SIGN, also included information before diagnosis and what to do when first feeling unwell, and the Brain Injury Rehabilitation in Adults, also from SIGN, included information at the end of the document about returning home, and to work or study.

Few patient versions were clearly about empowering readers beyond providing information for decision making. There were some notable exceptions. Both patient versions from the National Comprehensive Cancer Network (NCCN) included a section describing two roles that patients could take in their treatment plan: 'Some patients want to be involved as little as possible. Others want to know everything and share decision making with their doctors.' NICE conveyed that the patient has power over their care using statements such as, 'You should have the opportunity to ask any questions you have…' and 'If you think that your treatment or care does not match this advice, talk to your healthcare team.' Other patient versions provided information for self-care, recognising symptoms and knowing what to do, and tips about what people could do at home to manage their

own care. The patient versions for Fibre and Diabetes, from the Canadian

Diabetes Association, and Gastroesophageal Reflux Disease (GERD), from the

University of Michigan Hospital and Health Centers, provided practical guidance

about what foods to eat to increase fibre in the diet while at home, and strategies

to prevent or reduce reflux. No patient versions were identified for the purpose of

replacing consultations or counseling, even those that provided self-care

strategies. However, while providing information could, in fact, be interpreted as

a replacement or a second opinion, almost all patient versions included a

statement advising readers that the information did not replace the advice of

health care providers. There was also no document that was prescriptive when

describing how to take medicines; compliance was not an explicit purpose.

Instead, reasons for why it was important to follow prescribed medications were

provided (see the example from the Canadian Diabetes Association in Table 3).

Other documents encouraged individuals to participate in the health care provider

consultation by advising readers that decisions should be made along with their

doctors. It was also explained which type of health care provider they would

encounter and their role in management (e.g. a radiologist or oncologist). In

addition, as indicated earlier, there were sections to help people plan for a

successful consultation with 'questions to ask your doctor.'

Some documents were also written to allay fears and address emotional issues.

There was acknowledgement of emotional concerns and issues for sensitive

topics, such as stillbirth, mental health issues and cancer (see Table 3). The patient version about what to expect after a still birth from Queensland Health, also provided information about how to deal with and tell family members and the National Comprehensive Care Network, Pancreatic Cancer, included a section about emotional challenges and relationships with family and friends. Emotional concerns were still covered in other topics which may not be perceived as particularly sensitive. The patient version from the Canadian Diabetes Association about starting insulin included text throughout the document recognising that the amount of information could be overwhelming and that starting insulin injections may be scary. The patient version for alopecia areata stated 'Patients who have difficulty with the psychosocial impact of losing their hair should speak to a healthcare provider about their feelings.' Some documents may have accomplished the opposite to allaying fears though. The patient version for the influenza vaccine from the Centers for Disease Control and Prevention provided a proportionately large amount information about adverse reactions, how to find help if adverse reactions occur, how to report adverse reactions, and how to be compensated for adverse reactions.

[insert table 4]

Personalisation of the information

Many patient versions (27/34) made attempts to personalise the information. The words 'you' or 'I' were often used to personalise within the text and in headings (e.g. 'What you need to know' or 'How much fibre do I need?'). Some documents personalised the information by providing background information about how the condition might affect feelings, and personal situations in life, in particular for sensitive topics such as mental health issues. The SIGN version for managing schizophrenia stated: 'Tiredness and a lack of energy are often described, and may mean you are doing a lot less than you used to (sometimes this may be due to the side effects of medication).' Very few provided personal stories or scenarios. One patient version featured an introduction from a representative of the NCCN, who wrote about her experience with pancreatic cancer and to advocate for more patient information. Five other documents provided brief information about how other people felt or managed in similar situations, e.g. 'You can resume sexual activities whenever it feels right for you...Some women feel like sex earlier than six weeks but many women want to wait even longer than this.' When used, the scenarios were very brief and usually as a section header, for example, 'I am HIV infected and pregnant. When should I start taking anti-HIV medications?' or 'I have epilepsy, and my current therapy is not helping me. How can I know if [vagus nerve stimulation] is right for me?' Another way to make the information more personally relevant was to include a section at the beginning of the document about to whom the information applies (11/34). One document for overactive bladder provided a tool for readers to identify their symptoms.

Presentation of recommendations and evidence

We collected data about whether recommendations were recognisable (an important factor in professional guidelines) using the four criteria set out by Hussain [11]. It was challenging to assess but we found that recommendations were recognisable using at least one of the four criteria. All guidelines used common words to communicate the recommendations such as 'your doctor should', 'your doctor may offer' which were easily recognisable. Other times it was difficult to determine if the statements were simply about what the treatment will be. For example, the guide from ESMO for melanoma listed the tests which would be used and it was not clear whether it was based on a recommendation. Specifically, it stated: 'Sentinel lymph node biopsy is a procedure performed for all stage I and stage II patients, except for patients whose tumors are 1 mm thick or less.' In most documents (25/34), recommendations were easily recognisable as they were separated out into a paragraph indicating what should be done and for whom. An equal number of patient versions did or did not include a heading or title to highlight the recommendations, sometimes this was more clear in some versions (e.g. the heading 'The Task Force Recommendations on Screening for Cervical Cancer: What Do They Mean?') than in others (e.g. the heading 'Tests you should not be offered'). Only the patient versions from the USPSTF, and one from the AAN, provided recommendations followed by a statement of the strength of the recommendation and/or the level of evidence. The USPSTF

versions were also the only ones to present the system for grading the

recommendations and the evidence. As indicated above, the evidence on which

the recommendations were based was rarely provided as quantitative data about

effects, and when described in words, interventions were often vaguely described

as 'effective' or 'helpful'.

Discussion

This study is the first to analyse the landscape of patient versions of CPGs

currently available to disseminate CPGs to this audience. We have been able to

learn from what others have produced and have gathered good examples to inform

the development of patient versions in the future. From our comprehensive search

of multiple databases of guidelines and using our selective criteria, we identified

17 key organisations that have expertise in producing patient versions of CPGs

and randomly sampled 34 patient versions. We conducted a content analysis

which was directed by themes about purpose and content important to patients

and the public. Based on this analysis, we identified some gaps in what is

provided and what patients and the public perceive as helpful in their health care,

and provide some suggestions for future work.

First, it is questionable whether patients would be able to find these patient

versions and identify whether it is credible advice. We found these patient

versions primarily through professional organisation websites, which were more

often than not, unavailable on patient websites. Furthermore, it would also likely be difficult for patients to find these versions using Internet search engines, as the versions were called a variety of names. For health care professionals, CPG databases and portals overcome this challenge, and perhaps a similar website or portal of patient versions by topic may be useful for patients and the public. However, once patients or the public find this information will they know that it is credible or consider evidence from guidelines as more trustworthy than other information? Guideline producers typically focus on the methods behind the development of guidelines, but the results from the review of qualitative research indicate that people do not necessarily want information about how guidelines are produced and instead look at simple clues about credibility, such as logos and whether CPGs came from national and professional sounding organisations [3]. While the majority of patient versions did include logos, few included much information about how the guidelines were produced. However, logos do not convey that these patient versions are providing recommendations that are based on a rigorous process. Recommendations and CPGs are quite unique from other patient material that should not provide this type of advice, and perhaps clarifying the credibility of the advice for what to do should be emphasised in patient versions of CPGs.

Second, the review of the literature of patient and public attitudes towards CPGs revealed that patients do want background information about their health

conditions and information about the evidence used to make the recommendations [3]. Background information was adequately provided in the patient versions, but the patient versions in this analysis had less specific information about benefits and harms and instead patients and the public were advised to speak to the doctor about that information. This seems contrary to the model of empowering individuals to find and use information without going through health care providers. Interestingly, many versions provided the direct link to the professional oriented CPGs and hypothetically individuals could find out more and read the evidence directly in those versions. However, there is a large body of evidence around the need to tailor the presentation of evidence to patients and the public to make it more user friendly, and therefore guideline producers may need to reconsider if and how evidence is provided in patient versions.

Third, the main purpose of all of the patient versions of guidelines was to provide information or direct people to more information. This in itself is a form of empowerment by equipping patients with this information, but in the patient empowerment discourse used by Dixon-Woods [6], the patient versions would also provide information useful to making decisions. This would include providing not only information about benefits and harms but also information and guidance around incorporating values and preferences, feasibility or costs in some settings. We found that less than half of the patient versions included this type of information. Instead it appears that most documents are still reflecting the patient

education discourse that Dixon-Woods identified. In addition, few provided self-care advice, again limiting what people can do for themselves and their sense of control over their health care situation. It is not clear though whether the lack of self-care advice is because it was not communicated in the patient version or because recommendations for self-care were not provided in the original CPG. In contrast, some patient versions were not written as recommendations but primarily included information about how to apply a recommendation into one's personal life or unique situation, e.g. how to increase fibre in the diet or how to wean your baby. This perhaps could be a goal of patient versions: choose a recommendation, e.g. 25-50 g of fibre is recommended daily, and then provide practical information about how people can achieve it. Health care navigation was also not addressed in the patient versions. Again, this may be because few guidelines provide recommendations related to the health care system. However, in most circumstances, professional and national organisations make recommendations based on who provides the care and to whom, which could be included in the patient versions.

Fourth, the need for more personalised or applicable information has also been identified by patients and the public as important to interpreting health information [3,12]. In this analysis, we saw a variety of different methods used to personalise the information in patient versions. The use of 'you' or 'I' could help readers see how the information applies to them and was used often in these

versions. However, only one version included a personal story, and this was not really being used to personalise the information, but instead to convey how important it is to empower oneself with information. Some documents also personalised the information in small ways by framing the information under a brief personal scenario. Additional exploration of methods to personalise research information has been previously advocated through the use of personal stories and decision aids [12].

Our comments are based on the strengths of our analysis, but there are some limitations. Although two investigators extracted data and analysed the results, we were not reading the patient versions as people directly affected by the topic of the patient version. Our background is in evidence based medicine and guideline development and therefore our method is to critically appraise the information and evidence provided. We however were informed by the review of the literature of patient and public attitudes towards guidelines and the role of patient materials and used these works as our framework when analysing the patient versions. Although, our search for key institutions who produce patient versions of guidelines was comprehensive, we included English versions only and versions which were freely available. We know, in fact, that many international organisations are working in this area, such as the German Agency for Quality in Medicine and the Institute for Quality and Efficiency in Health Care, and other members of the GRADE Working Group. We also know that private

organisations, such as Kaiser Permanente in the United States and Duodecim in Finland provide patient information based on guidelines, but they are not publicly available. We are currently working with these groups and others under the umbrella of the GRADE/DECIDE project to contribute to this work and to conduct user-testing into new strategies to communicate CPGs to patients and the public.

Conclusions

This study presents the current landscape of patient versions of CPGs, and their content which may not be addressing the views of patients and the public. Future work in this area could focus on how to provide the content in order to personalise the information, empower people to manage their own care or navigate the health care system, or speak with their doctor, for example. More specifically, research is also needed into how to clearly communicate the recommendations, as well as the evidence, patient values and preferences, and other feasibility and accessibility issues feeding into those recommendations. Finally, it appears that it would likely be challenging for the public and patients to find recommendations and CPGs, and therefore an exploration of how they could access the credible wealth of information found in CPGs would be warranted.

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TABLES

Table 1: List of included key institutions

1. American Academy of Neurology
2. American College of Gastroenterology
3. American College of Physicians
4. American Society of Clinical Oncology
5. American Urological Association, Urology Care Foundation
6. Canadian Diabetes Association
7. Centers for Disease Control and Prevention
8. Canadian Paediatric Society
9. European Society for Medical Oncology
10. National Comprehensive Cancer Network
11. NICE
12. Queensland Clinical Guidelines
13. Royal College of Obstetricians and Gynaecologists
14. Scottish Intercollegiate Guidelines Network
15. University of Michigan Health System
16. UpToDate
17. US Preventive Services Task Force

Table 2: General characteristics of 34 patient versions

Characteristic	Number of documents
Main topic area	
Treatment	24
Diagnosis or screening	7
Prevention	3
Type of website	
National agency, professional section	2
National agency, patient section	10
Professional organisation, professional section	2
Professional organisation, patient section	10
Patient organisation affiliated with professional organisation	4
Patient organisation	0
Other	6
Format of document	
Booklet	6
Webpage	11
Printed documents	16
Brochure	1
Length (pages)	
1 to 3	18
4 to 9	7
10 to 20	1
21 or greater	8
Number of graphics	
0	13
1 to 5	13
6 or greater	8

Table 3: Information provided in 34 patient versions

Type of information provided	Number of documents (unless otherwise indicated)
Reference to Clinical Practice Guideline	
Citation	13
Citation and link	14
No reference	7
Information about guidelines (%)	
General description of guidelines	11
Methods to develop the specific recommendations	15
No information provided	17
Proportion of background information to topic area	16% (IQR 12, 23)
Proportion of Health care services information	0 (IQR 0, 6)
Information about benefits	27
Information about harms	19
Information about costs/resources related to interventions	5
Information about feasibility/accessibility related to interventions	18
Information about values/preferences related to the interventions	10
Recommendations used words	34
Recommendations used heading or title	16
Recommendations in paragraphs	25
Recommendations had statement of evidence/recommendation (level of evidence 2, recommendation A).	4

Table 4: Common purposes of patient versions of guidelines and examples

Purpose	Examples
To empower to become active participants in health care	Don't feel rushed to leave the hospital. Be sure all your questions are answered before you go home…You will develop a plan for follow-up care with your health care team before your baby leaves the hospital. *Canadian Paediatric Society, Bringing baby home from the hospital*
To understand and navigate the health system	People with breast cancer should talk with their doctors about a follow-up care plan and how to coordinate this care between the oncologist and their primary care or family doctor…The follow-up care may be provided by your oncologist or primary care doctor, as long as your primary care doctor has talked with your oncologist about appropriate follow-up care and the possible late effects. *American Society of Clinical Oncology, What to know: ASCO's Guideline on Follow-Up Care for Breast Cancer*
To educate and equip with information	For the mother, the risk of infection or a blood clot in the legs or lungs is greater with a cesarean delivery than with a vaginal delivery. All women who have a cesarean delivery, including women infected with HIV, should receive antibiotics to prevent infection. For the infant, the risk of temporary breathing difficulties may be greater with a cesarean delivery. *Centers for Disease Control and Prevention, HIV and Pregnancy*

There is also the general risk from overuse of antibiotics leading to strains of bacteria becoming resistant…Giving all carriers of GBS antibiotics would mean that a very large number of women at very low risk would receive treatment they do not need. *Royal College of Obstetricians and Gynaecologists, Group B Streptococcus infection in newborn babies* |
To aid in decision making	There's no single treatment right for everyone. Your healthcare professional may use one treatment alone, or several at the same time. You and your healthcare professional should talk about what you want from treatment and about each treatment choice. *American Urological Association, Overactive Bladder (OAB) Patient Guide*
To help with self-care	How can I reduce the pain of the tear after birth? The following are ways to reduce pain and swelling after having a baby: ›› Lie down on your back or on your side regularly to help reduce swelling in your perineum. *Queensland Health, Perineal tears during birth*
To prepare for health care consultation	Questions to ask about hyperphosphataemia in chronic kidney disease: These questions may help you discuss your condition or the treatments you have been offered with your healthcare team. *National Institute for*

	Health and Care Excellence, Hyperphosphataemia in chronic kidney disease
	Keep a Bladder Diary: Writing down when you make trips to the bathroom for a few days can help you and your healthcare professional understand your symptoms better. *American Urological Association , Overactive Bladder (OAB) Patient Guide*
To provide resources (e.g. more information)	Your health care provider can assist you to do many of these things and can direct you to other resources and organizations that will provide further assistance and ideas. *Queensland Health, What to expect after the stillbirth of your baby*
	Where can I find out more information? We hope you have found this booklet helpful. If you need more information, we have listed some national organisations that can offer information and support. Helplines, Breathing Space, 0800 838 587 *Scottish Intercollegiate Guidelines Network, Managing schizophrenia: A booklet for patients, carers and their families*
To enhance compliance to treatments	Regular checks give you important information about how your glucose levels vary during the day, how much insulin you need, and help you determine if you're on track managing your diabetes. Understanding and acting on the results of your blood glucose checks is the best way to keep your glucose levels in their target range. *Canadian Diabetes Association, Thinking of starting insulin?*
To allay fears or acknowledge emotions	Intense reactions are very common. Deep sadness, anxiety, fear, anger, guilt, helplessness and despair are just some of the many emotions you might experience. Grief is a reaction to loss. There is no right or wrong way to grieve. *Queensland Health, What to expect after the stillbirth of your baby*
	Feelings of anxiety and depression are common among patients with cancer. You may feel anxious before testing and while waiting for the results. *National Comprehensive Care Network, Pancreatic Cancer*
To enhance choice	They can be taken separately or in combination and your healthcare team will take into account which type you prefer, how easy they are to take, and other factors when deciding which is the most suitable for you. *NICE, Hyperphosphataemia in chronic kidney disease*

SUPPLEMENTARY MATERIAL S1

Data extraction form

Patient version title
Website link to patient version
Type of website
Patient version referred as?
date of patient version
Topic area
Length of document
Number of paragraphs in the text
Number of pictures/graphs/tables, etc in text
Format (e.g. brochure, booklet, decision aid, etc.)
OUTLINE OF CONTENT
Table of contents or outline of content?
CREDIBILITY
Reference to, link to, description of, original professional guideline
Was there a description of what guidelines are in general?
Was there a description of how the recommendations or guidelines were made?
Was there an attempt to convey credibility?
BACKGROUND INFORMATION (introductory information)
Was background information provided in a 'background' section?
What type of background information was provided?
Number of paragraphs in the text and graphics that were about background
Were definitions provided?
Was a link/reference/guidance/'talk to your doctor about background information' to find additional **BACKGROUND** information provided?
HEALTH SYSTEM INFORMATION
Was information provided about the health system or how to navigate the health system?
Number of paragraphs with information about health system or navigating health system
APPLICABILITY OR PERSONALISATION OF INFORMATION
Was the information personalised at any time? (how)
RECOMMENDATIONS
Were there recognisable recommendations? *(see below for more details about how to recognise)*
Were recommendations recognisable by the use words *such as you should, your provider should, your doctor may, it is appropriate for your doctor, etc.*
Were recommendations recognisable because a title or heading was used to separate out the section *e.g. Recommendations, what you can do, what your doctor should do, etc.*

Were recommendations recognisable because they were found in concise paragraphs *e.g. for people who are X, you should/may…, a sentence indicating action followed by explanation, etc.*
Were recommendations recognisable because there was a statement showing the level of evidence and strength of recommendation? *E.g. drug x may reduce these symptoms and could be used (level of evidence 2, recommendation A).*
Were the recommendations provided in a consistent way? *(e.g. all in similar format, we would not want to see recommendations presented in all different ways and therefore difficult for people to distinguish what is or what isn't a recommendation)*
EVIDENCE (RELATED TO RECOMMENDATIONS)
Were the benefits of the interventions described?
How was it described? *(words, numbers, words and numbers)*
Were graphics used? (pictures, graphs and charts, tables)
Were the risks of the interventions described?
How was it described? *(words, numbers, words and numbers)*
Were graphics used? (pictures, graphs and charts, tables)
OTHER INFORMATION RELATED TO RECOMMENDATIONS
Did it include information about costs related to the interventions?
Did it include information about feasibility/accessibility related to the interventions?
Did it include information about patient values and preferences related to the interventions?
Is background information about the treatment or test provided with the recommendation?
ADDITIONAL INFORMATION AND SUPPORT
Is there a specific section to provide additional information or support?
Is there a warning or caution about using the additional information?
PURPOSE
To empower (patients to become active participants in health care, patients are experts and know their own needs and preferences, patients can do some things to help themselves - self management recommendations,)
To aid with navigating health system
To describe risks and benefits of treatments (to educate), equip patients with information
To aid in decision making (encourage people to use the information to make a decision)
To help people self-manage their disease (see also to empower people to self-manage their disease)
To help with physician consultation, save time for the physician, to prepare person for consultation
To direct people to more information
To reassure/second opinion
To persuade patient to use the interventions, screening, etc. (could be a bad thing - and does not give the alternative options, but only 1 option)

Enhance compliance to treatments, etc. (tips of how to, consideration of challenges)
To allay fears (calm patients, reduce anxiety), acknowledge stress, help to deal with stress
Replace verbal consultations/counseling
To enhance choice (there are many choices, you have a choice, not all treatments are best, there are alternatives)
To help people consider beliefs, values, preferences in decisions, in health (explicit: you have different beliefs, such as…)

CHAPTER 6

CONCLUSIONS

CONCLUSIONS

This doctoral thesis describes four studies exploring the development of clinical practice guidelines (CPGs) and the dissemination of CPGs to patients and the public. The impetus for this thesis was the latent source of evidence-based information found in CPGs traditionally written for health care professionals that could meet the health care information needs of patients and the public. Although many organisations are producing plain language versions, these versions vary and it is unclear what is useful and accessible to people. Models for research use and uptake point to many factors affecting the use of information by different audiences, such as the characteristics of the evidence-based product (i.e. the CPG), the characteristics of the audience (i.e. patients and the public), and their environment. However, little research into these factors has been conducted or synthesised to inform the development of patient versions of CPGs.

The four studies in this doctoral thesis, when taken together, highlight both the potential barriers and supports to the development of patient versions of CPGs and provide a base from which strategies to disseminate CPGs to this audience can be developed, refined and tested. More specifically, the manuscripts can be used to inform guideline producers about the key information found in a CPG developed using rigorous methods; what key guideline institutions with experience producing patient versions are currently providing to patients and the public; what are the potential methods to present the evidence used in guidelines;

and what are the attitudes of patients and the public towards CPGs and patient versions.

Before embarking on the development of a patient version of a CPG, there should be a traditional (health professional oriented) CPG developed using rigorous methods. Chapter 2 presents a CPG produced using the GRADE approach, a process currently being used by over 80 organisations to produce CPGs. To produce this guideline, evidence for the effects of the interventions and for patient values and preferences were synthesised [1,2], and information about resources and other feasibility issues were collected and used by the guideline panel to make recommendations. The recommendations within this document are written as clear actionable messages with remarks that describe the factors considered by the guideline panel and why the recommendations were made. This guideline from the World Health Organisation (WHO) will inform programme managers and clinicians globally about the recommended tests and treatments to prevent cervical cancer. It includes a wealth of health information that would be valuable to people directly affected by the recommendations. However, this document has over 5000 words, with additional links to supporting information such as evidence tables, and written in a language for health care professionals. While it represents an important guideline that has the potential to affect care across the WHO member states and other jurisdictions, this document may not be accessible to others.

In fact, the systematic review of qualitative studies in Chapter 4 found a variety of barriers and potential supports for the use of CPGs by patients and the public. The review includes results from 20 qualitative and quantitative studies that explored patient and public attitudes to, and awareness of CPGs. It was conducted using rigorous methods: studies were found using a comprehensive search of the literature which likely did not miss important work in this area; and results were collected and synthesised by two independent investigators. However, the methods for the synthesis of information from qualitative research are less developed than methods for intervention reviews of randomised [3]. In particular, the tools to assess the quality of the studies and the quality of the overall evidence (or confidence in the effects) have not been agreed upon or validated yet. Therefore, conclusions could not be drawn about the true barriers and supports or the most significant. Nevertheless, the results from what can currently be called good to fair quality studies led to suggestions about what guideline producers might consider when developing patient versions.

The review found that patients and the public thought guidelines and patient versions could be used for a variety of purposes. One of which was for information about the benefits and harms of interventions. Chapter 3 of this doctoral thesis evaluated how this information could be communicated. Based on earlier qualitative work and reviews of the literature about how to communicate evidence to patients and the public, a new format was developed that summarised

the benefits and harms and the confidence in those effects both narratively and in a table including the numerical effects. The new format was tested in a randomised controlled trial. Over 143 members of the public from five countries were randomised to receive either the new format or a format that was currently being used. They were asked about their understanding and preferences, as well as about the accessibility of the different formats. Patients and the public found the new format easy to understand and accessible, and they preferred the new format over the old format. Understanding was also improved with the new format. Potentially guideline producers in the development of patient versions of CPGs could use this improved format. Indeed, the analysis of the patient versions in Chapter 5 indicated that this information is currently missing in patient versions; few organisations include numbers to describe benefits and harms, and instead use vague descriptive words.

While the new format for the summary of evidence for benefits and harms that we developed could be used, there are some limitations to the results and areas for future work and development. The new format that was tested in the RCT was based on a general topic of health and was not selected by the participants because it was important or of interest. The findings may have been different - in potentially either direction - if the topic was of critical interest, and future research could evaluate the new format in people who choose their topic of interest first. Although understanding was higher with the new format, few people

(<50%) understood the meaning behind the symbols or words about quality of evidence. More work to explore how to better communicate this certainty in the benefits and risks of a treatment could also inform how that information plays a role in decision making. In addition, at most only 65% of participants answered the questions about understanding correctly. Other studies testing how to communicate evidence of benefits and harms to patients and the public have also found less than optimal understanding [4,5,6]. This may be due to factors other than the simple translation of the effects narratively or quantitatively.

The review in Chapter 4 revealed that when people were asked about guidelines they thought that the information was impersonal or would not be applicable to them. This barrier to understanding has been previously considered, along with suggestions for solutions to contextualise the information, such as using personal stories or decision aids [7]. The study in Chapter 5 suggests that guideline producers of patient versions may be attempting to overcome this barrier to understanding as well. Chapter 5 is a qualitative descriptive study of a sample of 34 patient versions of CPGs produced by key guideline producers that have dedicated resources to create patient versions. Two investigators collected information from the patient versions and conducted a content analysis. Although the background of both investigators is in critical appraisal of evidence and would not represent the viewpoint of patients or the public per se, some conclusions could be drawn about the strategies being used by guideline producers who have

some experience disseminating patient versions. From this study, information was often personalised with the use of 'you' or 'I' throughout the text or with an introduction clearly stating to whom the information applied; but very few patient versions included personal stories/scenarios or decision aids. There may be an opportunity for future research to investigate how best to personalise the information, perhaps drawing on other disciplines in learning and multi-media. Related to the issue of personalisation, the review of qualitative research found that people thought they could use the guidelines to prepare for consultations with their doctor or to assist with self-care. Patient versions typically provided well marked sections about 'questions to ask the doctor' to prepare people for consultations. However, recommendations for self-care were less distinguishable, largely because it was difficult to determine whether advice about what 'you can do' was a recommendation; this was true for all recommendations regardless if it was for self-care or not.

In addition, Chapter 4 found that people may not perceive guidelines in a positive light, and thought that recommendations may restrict care, be too rigid, were rules for physicians, or were based on costs. The lack of clear recommendations and remarks about the basis of the recommendation (for example, based on patient values and preferences or the balance of benefits and harms, and not on resources), suggests that research should be conducted to determine and test the best wording for recommendations and the accompanying details for patients and

the public. It is likely that writing recommendations for patients and the public

could build upon the GRADE approach for writing recommendations for health

care professionals in that a recommendation is presented as a separate statement

with remarks describing why the recommendation was made and what factors can

be considered when applying the recommendation [8]. Collaborative work with

members of the DECIDE project (a co-funded project by the European

Commission under the Seventh Framework Programme for Developing and

Evaluating Communication Strategies to Support Informed Decisions and Practice

Based on Evidence) has led to a series of a variety of draft formats for

recommendations, one of which edited to incorporate work from this PhD thesis is

in Table 1. This format could be built upon in future research.

Table 1: An example of a recommendation for patient versions of CPGs
(Adapted from work of the DECIDE project)

 Weak recommendation

To prevent breaking your hip, you probably should wear hip protectors.

Who is this recommendation for?
For most, but not all elderly people living in a nursing home who do not have a high risk of breaking a hip, and are still up and walking.

What would following the recommendation mean for you?
People may consider whether the costs and discomfort of wearing a hip protector is worth the decrease in the small number of hip breaks. But if a break occurs there is pain, possible loss of the ability to walk, and a higher but small chance of death. If you do fall, wearing a hip protector will probably decrease your risk of a hip break slightly.

If you follow this recommendation, you will need to buy about 2 or 3 hip protectors so you can wash them. Someone may need to help you put them on. You will also need to wear the hip protector all day and usually at night.

In summary, a number of organisations produce patient versions of CPGs and research continues to grow in this area. This doctoral thesis adds to this body of research by exploring the barriers and supports to the dissemination of CPGs to patients and the public. It shows that people are interested in patient versions of CPGs for a variety of purposes, but strategies should be investigated to overcome negative attitudes towards CPGs, to personalise the information, and to communicate the recommendations and the evidence informing the recommendations. Table 2 provides a summary of the implications of this PhD thesis and next steps.

Table 2: Implications and next steps

Presentation of evidence in patient versions of CPGs (for example, for benefits and harms)	The new format for a summary of evidence developed in this work should be used within a patient version of a CPG to communicate the evidence about benefits and harms
	Future research, such as user testing, should test strategies to disseminate evidence along with the quality of the evidence, in particular in people who have a special interest in a topic
Presentation of recommendations in patient versions	Research into methods currently being used in patient versions to disseminate recommendations should be conducted. Interviews or focus groups could explore perceptions of recommendations, which can inform user testing and randomised controlled trials for effective methods
	How to disseminate recommendations, strong or weak recommendations, and the additional information in recommendations (including patient values and preferences, accessibility and resources) could be explored
Personalisation of information	Making information (e.g. research information) more personal and applicable to people was identified as important to use and understanding of patient versions
	Future research should explore effective ways to personalise health information, for example through a review of the literature, interviews or focus groups with patients and the public, and user testing
Purpose of patient versions of CPGs	Many purposes of patient versions were identified
	The development of patient versions to specifically prepare people for consultations with their health care providers could be explored

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