Management of Patient Adherence to Medications: Protocol for a Survey of Doctors, Pharmacists and Nurses in Europe

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Article summary

Article focus

- A protocol for a cross-sectional survey of health care professionals in Europe to examine the perceptions, beliefs and behaviours of health care professionals- doctors, pharmacists and nurses- about patient medication adherence.
- The questionnaire used in the survey of health care professionals is described in detail.

Key messages

- There is an acute need for evidence regarding healthcare professionals' beliefs, perceptions, and behaviour with regard to patient non-adherence to medicines.
- This protocol describes a study to address this need.
- The results of this study could guide health care professionals as they support patients with medicine taking in their day-to-day clinical practice.

Strengths and limitations of this study

- The survey is the largest cross-national survey of health care professional's approach to medication adherence.
- Reliance on self-report data may raise concerns regarding the validity of the findings.

Introduction

Chronic diseases are a major source of disability and death worldwide (1). One way of managing chronic diseases is by taking medicines. In order for these medicines to work in the way they are intended, they need to be taken in the way they were prescribed. Taking prescribed medicines irregularly or not at all is often referred to as non-adherence (2). It is widely recognised that many patients do not take prescribed medication as advised and the World Health Organisation (2) reports that only around 50% of the general population in developed countries are adherent to treatment for chronic diseases. Poor adherence can have a negative impact on both the potential clinical benefits of treatment (3) and the cost-effectiveness of medicines (4, 5). From the patients' point of view, non-adherence can also have positive consequences. For example, patients who fail to take their medicines as prescribed avoid the potential unpleasant side effects of their medicines. Patients may also benefit from a perception of autonomy and personal agency through non-adherence. Health care professionals have a role to play in providing support to patients in order to ensure that if the patient agrees to take the medicine, it is taken in a way that will maximise its benefit.

Several studies (6) report on the use and effectiveness of various interventions to improve patient adherence to medicines. The effectiveness of adherence interventions, however, needs to be looked at in a broader context which includes the role of health care professionals. Improving the ability of healthcare professionals to properly assess the risk of non-adherence and deliver interventions aimed at reducing non-adherence, may lead to more effective support offered to patients taking prescribed medicines. In the past, the focus of

research in the field of adherence has been largely on the patients' role. In order to gain a fuller understanding of the problem and address the gap in the current knowledge, this study, which is taking place in several countries across Europe, looks at the perceptions, beliefs and behaviours of health care professionals - doctors, nurses and pharmacists- with regards to patient medication adherence. Knowledge of the nature, extent and variability of the practices of health care professionals to support medication adherence could inform future service design, health care professional education, policy and research.

This study is part of a larger project on patient medication adherence funded by the European Commission called the 'ABC (**A**scertaining **B**arriers for **C**ompliance) Project'- www.abcproject.eu. The overall goal of the ABC project is to produce evidence-based policy recommendations for improving patient adherence and by so doing, to promote safer, more effective and cost-effective medicines use in Europe.

Methods and Analysis

Design

This paper describes the protocol and questionnaire used in a cross-sectional survey of health care professionals in Europe. A quantitative self-report questionnaire has been designed specifically for this study. The questionnaire is administered online using the survey tool provided by SurveyMonkey. SurveyMonkey has been successfully used in published research involving surveys of health professionals and its use is described in detail by Dobrow and colleagues (7). For a survey such as this with widespread geographical coverage, use of the internet should aid the logistics of survey administration.

Aim

The aim of this study is to ascertain how health care professionals- doctors, pharmacists and nurses- across Europe assess and support patient adherence to prescribed medication for long-term conditions; with secondary aims of assessing country to country and professional variations.

Objectives

The objectives of this study are to examine health care professionals' perceptions of the extent of non-adherence, to determine health care professionals' beliefs about adherence and non-adherence as well as the behaviours of health care professionals to support patients with taking medicines and their perceptions about the effectiveness of those actions. The study will also consider the perceived barriers to supporting adherence as well as training received for managing non-adherence as reported by health care professionals.

Study population

The study is being conducted in several countries across Europe including Austria, Belgium, France, Greece, The Netherlands, Germany, Poland, Portugal, Switzerland, Hungary, Italy and England. The survey is focused on primary care and community based doctors, pharmacists and nurses. These professional groups have been selected because of their involvement in the care of adults who are prescribed medicines for chronic and acute conditions.

Inclusion criteria

Healthcare professionals who satisfy the following criteria are eligible for inclusion in the survey:

a. They are currently employed as medical doctors, nurses or pharmacists
b. They work mainly with adults
c. They work mainly in the community or primary care
d. They work either in a private or public health care system (or both)
e. They are qualified and registered to practice
f. They consent to take part in the survey

Exclusion criteria

Healthcare professionals are not eligible to participate in the survey if:

a. They are student doctors, nurses or pharmacists
b. They work only in paediatrics (i.e. do not work with adults at all)
c. They work mainly in secondary care
d. Lack of consent from the healthcare professional or his/her decision to quit the study at any stage and for any reason.

Sample size

The sample size is based on the estimation of the proportion of those participants who answer "never" to the primary outcome: 'I ask patients if they have missed any doses of their medication' in each country. Using the approach in Cochran (1977) (8) a sample size of 384 health care professionals in each country (128 people in each professional group) would enable estimation of this unknown proportion to within an absolute value of 5% with 95% confidence.

Recruitment of participants

A mixed-method approach has been used in order to recruit participants in each country. A random sample of health care professionals has been sought by sampling from registers of health care professional bodies or associations. Each health care professional that is selected from professional registers initially receives a letter inviting them to participate in the online survey and the project information sheet. The invitation letter has information about the survey as well as the web link which potential participants need in order to gain access to the survey. Reminder letters are then sent to the health care professionals three weeks and again five weeks after the initial contact.

News articles to promote awareness of the survey have also been sent to health care professional bodies and associations for circulation through the respective organisations' websites and newsletters. The news article has also been distributed to publications whose main audience is health care professionals. The news article contains information about the study as well as the web link which health care professionals need in order to access the survey.

All potential participants are given the same project information and gain access to the survey via the same web link.

Questionnaire development

There are relatively few research studies examining healthcare professional behaviour with regard to supporting patients with adherence to medication. Although it was not possible to identify any validated scales of healthcare

professional behaviour in this domain, two unvalidated but published questionnaires which had been used to measure adherence behaviour among hospital-based doctors (9) and cardiovascular nurses (10) were found. The ABC health care professional adherence questionnaire was informed by a combination of these scales (9,10), as well as recommendations for clinical practice from published adherence guidelines (2,6,11,12).

A sub-group of the ABC research team discussed, reviewed, and edited potential items considered for inclusion in the questionnaire. The themes covered are:

A. Perceptions of the extent of non-adherence to medication in patients
B. Beliefs about adherence to prescribed medication
C. Use of adherence enhancing interventions
D. Barriers to use of adherence enhancing interventions
E. Questions about training on adherence and use of guidelines for adherence management

Description of the questionnaire

The questionnaire was made up of eighty-six (86) items in total and divided into five sub-sections. Below is a brief description of each sub-section in the instrument.

A. Perceptions of the extent of patient non-adherence: This section contains a total of six questions split equally into two subsections. The first section asks about health care professionals' perception of non-adherence in all patients e.g. 'what percentage of **all** patients with a chronic condition/illness in your country do you think do not initiate

prescribed medication (that is, patients who do not take any of their prescribed medication)? The second section asks about their perceptions of non-adherence in their own patients e.g. what percentage of **your** patients with a chronic condition/illness in your country do you think do not initiate prescribed medication (that is, patients who do not take any of their prescribed medication)?

A five-point rating scale is provided for respondents to make their ratings, with response options of '0 -15%', '16 – 35%', '36 – 65%', '66 - 85%', and '86 – 100%'.

B. Beliefs about adherence to medicines: There are seven (7) items in this section. Participants are asked to indicate the extent to which they agree or disagree with each statement about patient adherence. For example, 'it is possible to improve patient adherence to medication'.

A five point rating scale is provided for participants to make their ratings, with options ranging from 'strongly disagree' to 'strongly agree' with intermediate labels of 'disagree', 'neither agree nor disagree' and 'agree'. The response category 'don't know' is also available to respondents.

C. Adherence enhancing interventions used by doctors, nurses and pharmacists: This section is made up of a total of fifty questions split into five sub-sections. These are:

(a) Assessment of adherence and its risk factors: There are eight (8) items in this sub-section. An example of an item in this section is: 'I use electronic monitoring devices to assess patient's level of adherence'. The primary outcome is included

in this sub-section. The wording for the question is: 'I ask patients if they have missed any doses of their medication'.

(b) Providing information for carers and patients: There are nine (9) items in this sub-section. An example of an item from this section is: 'I check that patients understand the information that I have given them'.

(c) Talking with patients about their medications: This sub-section is made up of a total of eighteen (18) items. An example of an item from this section is: 'I ask patients what level of involvement they would like in making decisions about their treatment'.

(d) Practical strategies to make medication taking easier: Eleven (11) items make up this sub-section. An example of an item from this section is: 'I help patients to tailor their medication regimen to their own lifestyle'.

(e) Involving others and services to support adherence. This sub-section consists of four (4) items in total. An example of an item from this section is: 'I refer patients to peer mentor programmes to support medication adherence'.

The response scale for the entire section on adherence enhancing interventions is adapted from Berben et al's survey of adherence practices by European cardiovascular nurses (10). The response options here are split into two. Respondents are first asked to indicate how often they use the intervention. A five-point rating scale is provided for participants to provide their frequency of use with

responses ranging from 'never' to 'all the time' and intermediate ratings of 'occasionally', 'sometimes' and 'frequently'. The response category 'not applicable' is made available to participants who do not use any of the interventions mentioned. Next, respondents are given the opportunity to indicate, for every intervention they use, how effective they think that intervention is. A three-point rating scale is provided; with responses ranging from 'not at all' to 'extremely' with an intermediate category 'somewhat'. The response category 'don't know' is provided for those who select the option 'not applicable' in column one.

D. Barriers to the use of adherence management practices by healthcare professionals: This section contains thirteen questions. An example of an item from the list is: 'I have an excessive workload that prevents me from supporting patients with medicine adherence'. A four-point rating scale is provided for participants to indicate the extent to which the items listed act as barriers to their use of adherence promoting interventions. The options range from 'not at all' to 'very much' with intermediate options of 'slightly' and 'moderately'. The response option 'not applicable' is provided for those who do not consider an item to be relevant to their work setting.

E. A final set of three questions about previous training in medication adherence and use of adherence guidelines completes the questionnaire. The questions ask whether the health care professional has had any training in adherence management during pre-registration or post-registration training. Respondents are also asked

if they make use of any practitioner guidelines to manage patient adherence. The response options are 'yes' or 'no'.

Outcomes

Primary outcome

The primary outcome is the frequency of assessing the likelihood of non-adherence: This will be based on the response to the question "I ask patients if they have missed any doses of their medication."

Secondary outcomes

The following secondary outcomes will be reported:

- Perception of the extent of non-adherence: This measure is based on the participants' responses to a series of six questions that ask about their perceptions of the levels of non adherence in all patients versus their patients.
- Beliefs about adherence: This is based on an assessment of health care professionals' beliefs about patient adherence.
- Methods used to support patients with medication taking: This is a measure of health care professional's behaviour. Fifty items provide a measure of what health care professionals do to support patients with medicine taking.
- Barriers to the use of adherence enhancing practices: Participants are asked to indicate the extent to which the thirteen items listed act as barriers that limit their use of interventions to improve adherence.
- In addition, demographic information about the respondents will be collected, including health care setting (e.g. community setting, private or

state funded health care system), number of years since registration as a healthcare professional, gender, age and average length of consultations with patients about medicines.

Analysis

Analyses will be conducted by total sample, country, and professional group.

Analysis of primary outcome

For all countries, the number and proportion of participants with the primary outcome will be reported overall and in each country, as will 95% confidence intervals for the proportions. Comparisons between countries and professions will be performed using multilevel random models using the software MLwiN (http://www.cmm.bristol.ac.uk/MLwiN/) for both binary and ordered categories. The software has the advantage of dealing with missing values by using all available data on each individual and not by imputing missing values. Point estimates of the proportion of health care professionals who assess adherence in the entire sample (primary outcome) as well as in each country and each profession and their associated 95% confidence intervals will be obtained.

Analysis of secondary outcomes

For the entire sample and each group, the medians, modes, interquartile ranges and frequency distributions will be reported for each secondary outcome. 95% confidence intervals for the medians will be reported. Comparisons between and within countries and professions will be performed using multilevel models using all ordered categories and which will also include demographic and other

information on participants (see below). The following comparisons of outcomes will be performed:

- Comparisons between the participating countries
- Comparisons between each professional group
- Comparisons by country and profession

Description of samples

Characteristics of participants will be described for the sample as a whole, for each country, and for each profession. Participants will be described in terms of their health care setting, type of health care system, number of years since licensed to practice, average length of time consulting with patients about medicines, age, gender and country.

Ethics and dissemination

Consent

Respondents who accept the invitation to take part in the study, and use the link provided to access the survey web page, are taken to the survey introductory page. Here, the participants are provided with information about the project, anonymity of the survey findings, an outline of what participants are required to do and how long it will take to complete the questions, an assurance that every attempt will be made to ensure the confidentiality of the data and a statement indicating that participation is voluntary and that withdrawal from the survey is possible at any stage. Potential participants are asked to click on a link to confirm that they have read the participant information before proceeding. The act of

clicking on this link is considered consent to participate in the study. Access to the survey is denied unless this link is clicked.

Confidentiality

No personal information (such as names, addresses and professional licence numbers) will be collected from participants. The survey is completely anonymous and no IP addresses will be stored or downloaded.

Quality assurance

During the preparation of the study, quality has been ensured through the process of translation and back translation of research questionnaires. The questionnaire and the associated survey materials have been translated into the official language(s) for each participating country. The work-flow and quality management processes employed are certified to meet ISO 9001 Quality Management Standards. Forward translations have been performed by highly trained, approved and accredited translators who are native speakers of the target languages and fluent in English. Back translations have been performed by persons who are native English speakers and fluent in each target language. A third individual acts as a reviewer and highlights any discrepancies between the forward and back translations and resolves them by discussion with the translators. The respective national coordinators and their teams for each participating country also proofread each translated document and provide feedback on grammatical errors. They also provide contextual interpretation of the translations to ensure that they reflect the appropriate terminology used in each participating country. In addition to this, the online survey is piloted by at least five people in each country in

order to check its technical functionality and also to check for comprehensibility, and formatting errors.

Ethics approval

The study has obtained ethical approval from the NRES Committee North West-Liverpool East (REC Reference- 11/NW/0156).

Discussion

To our knowledge, this study is the largest survey of European health care professionals' medication adherence perceptions, beliefs and behaviours. It is expected that the results will inform our understanding of how health care professionals perceive medication non-adherence. This study will also provide some insight into how health care professionals respond to non-adherence to prescribed medication in their patients. By gaining a deeper understanding of health care professionals' perceptions and behaviour with regards to non-adherence in their patients, researchers will be able to design educational interventions and training for health care professionals that is evidence based and targeted at the training needs of health care professionals.

This study will also provide information on the interventions most frequently used by health care professionals and their perceptions of which interventions are most effective in managing non-adherence. It is anticipated that this will provide evidence-based knowledge of interventions which health care professionals have found to be effective at improving patient adherence. Health care professionals could use this information as a guide when making a decision about which interventions to make use of or to recommend to patients in order to improve adherence. Information on those interventions which are reported to

be less effective could help to channel the efforts of researchers towards finding ways to improve those interventions.

The Pan-European nature of this study will provide a comprehensive data set which will enable analysis of variability observed in health care professionals' beliefs and behaviours across twelve European nations. It is anticipated that this knowledge of the level of variability between professions in adherence-supporting behaviour, may provide a basis for promoting routine and continuous efforts to educate and modify the behaviour of health care professionals in order to enable them to fulfil their roles in supporting patients with medicine taking.

Authors' contributions

The principal investigator is WC. The ABC project coordinator is PK. All Authors took part in the development of the questionnaire. WC, CM, SH, SM and PJ took part in the design and development of the protocol. All authors have read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

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Table 1
Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

	Checklist for Reporting Results of Internet E-Surveys (CHERRIES)	
Item Category	***Checklist Item***	***Explanation***
Design		
	Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In â openâ surveys this is most likely.)
IRB (Institutional Review Board) approval and informed consent process		

	IRB approval	Mention whether the study has been approved by an IRB.
	Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?
	Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.
Development and pre-testing		
	Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.
Recruitment process and description of the sample having access to the questionnaire		
	Open survey versus closed survey	An â open surveyâ is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).
	Contact mode	Indicate whether or not the initial contact with the potential participants was made on the Internet. (Investigators may also send out questionnaires by mail and allow for Web-based data entry.)
	Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media (newspapers), or online (mailing lists â If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is

		important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.
Survey administration		
	Web/E-mail	State the type of e-survey (eg, one posted on a Web site, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?
	Context	Describe the Web site (for mailing list/newsgroup) in which the survey was posted. What is the Web site about, who is visiting it, what are visitors normally looking for? Discuss to what degree the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on a anti-immunization Web site will have different results from a Web survey conducted on a government Web site
	Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?
	Incentives	Were any incentives offered (eg, monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?
	Time/Date	In what timeframe were the data collected?
	Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.
	Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.
	Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.

	Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.
	Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if â yesâ , how (usually JAVAScript)? An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as â not applicableâ or â rather not sayâ , and selection of one response option should be enforced.
	Review step	State whether respondents were able to review and change their answers (eg, through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).
Response rates		
	Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.
	View rate (Ratio unique site visitors/unique survey visitors)	Requires counting unique site visitors (not page views!) divided by the number of unique visitors of the first page of the survey. It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.
	Participation rate (Ratio unique survey page visitors/agreed to participate)	Count the unique number of visitors who visit the first page of the survey (or the informed consents page, if present) divided by the number of people who filled in the first survey page (or agreed to participate). This can also be called â recruitmentâ rate.

	Completion rate (Ratio agreed to participate/finished survey)	The number of people agreeing to participate (or submitting the first survey page) divided by the number of people submitting the last questionnaire page. This is only relevant if there is a separate â informed consentâ page or if the survey goes over several pages. This is a measure for attrition. Note that â completionâ can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word â completeness rateâ .)
Preventing multiple entries from the same individual		
	Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?
	IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?
	Log file analysis	Indicate whether other techniques to

		analyze the log file for identification of multiple entries were used. If so, please describe.
	Registration	In â closedâ (non-open) surveys, users need to login first and it is easier to prevent duplicate entries from the same user. Describe how this was done. For example, was the survey never displayed a second time once the user had filled it in, or was the username stored together with the survey results and later eliminated? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?
Analysis		
	Handling of incomplete questionnaires	Were only completed questionnaires analyzed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analyzed?
	Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point, and describe how this point was determined.
	Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.

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- The questionnaire used in the survey of health care professionals is described in detail.

Key messages

- There is an acute need for evidence regarding healthcare professionals' beliefs, perceptions, and behaviour with regard to patient non-adherence to medicines.
- This protocol describes a study to address this need.
- The results of this study could guide health care professionals as they support patients with medicine taking in their day-to-day clinical practice.

Strengths and limitations of this study

- The survey is the largest cross-national survey of health care professional's approach to medication adherence.
- Reliance on self-report data may raise concerns regarding the validity of the findings.

ABSTRACT

Introduction

It is widely recognised that many patients do not take prescribed medicines as advised. Research in this field has commonly focused on the role of the patient in non-adherence, however, health care professionals can also have a major influence on patient behaviour in taking medicines. This study examines the perceptions, beliefs and behaviours of health care professionals - doctors, pharmacists and nurses - about patient medication adherence.

Methods and Analysis

This paper describes the study protocol and online questionnaire used in a cross-sectional survey of health care professionals in Europe. The participating countries include Austria, Belgium, France, Greece, The Netherlands, Germany, Poland, Portugal, Switzerland, Hungary, Italy and England. The study population comprises primary care and community-based doctors, pharmacists and nurses involved in the care of adult patients taking prescribed medicines for chronic and acute illnesses.

Discussion

Knowledge of the nature, extent and variability of the practices of health care professionals to support medication adherence could inform future service design, health care professional education, policy and research.

Introduction

Chronic diseases are a major source of disability and death worldwide (1). One way of managing chronic diseases is by taking medicines. In order for these medicines to work in the way they are intended, they need to be taken in the way they were prescribed. Taking prescribed medicines irregularly or not at all is often referred to as non-adherence (2). It is widely recognised that many patients do not take prescribed medication as advised and the World Health Organisation (2) reports that only around 50% of the general population in developed countries are adherent to treatment for chronic diseases. Poor adherence can have a negative impact on both the potential clinical benefits of treatment (3) and the cost-effectiveness of medicines (4, 5). From the patients' point of view, non-adherence can also have positive consequences. For example, patients who fail to take their medicines as prescribed avoid the potential unpleasant side effects of their medicines. Patients may also benefit from a perception of autonomy and personal agency through non-adherence. Health care professionals have a role to play in providing support to patients in order to ensure that if the patient agrees to take the medicine, it is taken in a way that will maximise its benefit.

Several studies (6) report on the use and effectiveness of various interventions to improve patient adherence to medicines. The effectiveness of adherence interventions, however, needs to be looked at in a broader context which includes the role of health care professionals. Improving the ability of healthcare professionals to properly assess the risk of non-adherence and deliver interventions aimed at reducing non-adherence, may lead to more effective support offered to patients taking prescribed medicines. In the past, the focus of

research in the field of adherence has been largely on the patients' role. In order to gain a fuller understanding of the problem and address the gap in current knowledge, this study, which is taking place in several countries across Europe, looks at the perceptions, beliefs and behaviours of health care professionals - doctors, nurses and pharmacists- with regards to patient medication adherence. Knowledge of the nature, extent and variability of the practices of health care professionals to support medication adherence could inform future service design, health care professional education, policy and research.

This study is part of a larger project on patient medication adherence funded by the European Commission called the 'ABC (**A**scertaining **B**arriers for **C**ompliance) Project'- www.abcproject.eu. The overall goal of the ABC project is to produce evidence-based policy recommendations for improving patient adherence and by so doing, to promote safer, more effective and cost-effective medicines use in Europe.

Methods and Analysis

Design

This paper describes the protocol and questionnaire used in a cross-sectional survey of health care professionals in Europe. A quantitative self-report questionnaire has been designed specifically for this study. The questionnaire is administered online using the survey tool provided by SurveyMonkey. SurveyMonkey has been successfully used in published research involving surveys of health professionals and its use is described in detail by Dobrow and colleagues (7). For a survey such as this with widespread geographical coverage, use of the internet should aid the logistics of survey administration.

Aim

The aim of this study is to ascertain how health care professionals- doctors, pharmacists and nurses- across Europe assess and support patient adherence to prescribed medication for long-term conditions; with secondary aims of assessing national and professional variations in adherence support behaviour.

Objectives

The objectives of this study are to examine health care professionals' perceptions of the extent of non-adherence, to determine health care professionals' beliefs about adherence and non-adherence as well as the behaviours of health care professionals to support patients with taking medicines and their perceptions about the effectiveness of those actions. The study will also consider perceived barriers to supporting adherence as well as training received for managing non-adherence as reported by health care professionals.

Study population

The study is being conducted in several countries across Europe including Austria, Belgium, France, Greece, The Netherlands, Germany, Poland, Portugal, Switzerland, Hungary, Italy and England. The survey is focused on primary care and community based doctors, pharmacists and nurses. These professional groups have been selected because of their involvement in the care of adults who are prescribed medicines for chronic and acute conditions.

Inclusion criteria

Healthcare professionals who satisfy the following criteria are eligible for inclusion in the survey:

a. They are currently employed as medical doctors, nurses or pharmacists
b. They work mainly with adults
c. They work mainly in the community or primary care
d. They work either in a private or public health care system (or both)
e. They are qualified and registered to practice
f. They consent to take part in the survey

Exclusion criteria

Healthcare professionals are not eligible to participate in the survey if:

a. They are student doctors, nurses or pharmacists
b. They work only in paediatrics (i.e. do not work with adults at all)
c. They work mainly in secondary care
d. Lack of consent from the healthcare professional or his/her decision to quit the study at any stage and for any reason.

Sample size

The sample size is based on the estimation of the proportion of those participants who answer "never" to the primary outcome: 'I ask patients if they have missed any doses of their medication' in each country. Using the approach in Cochran (1977) (8) a sample size of 384 health care professionals in each country (128 people in each professional group) would enable estimation of this unknown proportion to within an absolute value of 5% with 95% confidence.

Recruitment of participants

A mixed-method approach will be used in order to recruit participants in each country. A random sample of health care professionals will be sought by sampling from registers of health care professional bodies or associations. The number of health care professionals sampled and invited to participate in the survey will be based on reported (9) response rates of health care professionals to online surveys of this nature. Each health care professional that is selected from professional registers will initially receive a letter inviting them to participate in the online survey and a project information sheet. The invitation letter will contain information about the survey as well as the web link which potential participants need in order to gain access to the survey. Reminder letters will then sent to the health care professionals three weeks and again five weeks after the initial contact.

News articles to promote awareness of the survey will also been sent to health care professional bodies and associations for circulation through the respective organisations' websites and newsletters. The news article will also be distributed to publications whose main audience is health care professionals. The news article will contain information about the study as well as the web link which health care professionals need in order to access the survey.

All potential participants will be given the same project information and gain access to the survey via the same web link.

Data collection commenced at the beginning of July, 2011. It is anticipated that data collection in all countries will cease at the end of March, 2012.

Questionnaire development

There are relatively few research studies examining healthcare professional behaviour with regard to supporting patients with adherence to medication. Although it was not possible to identify any validated scales of healthcare professional behaviour in this domain, two unvalidated but published questionnaires which had been used to measure adherence behaviour among hospital-based doctors (10) and cardiovascular nurses (11) were found. The ABC health care professional adherence questionnaire was informed by a combination of these scales (9,11), as well as recommendations for clinical practice from published adherence guidelines (2,6,12,13).

A sub-group of the ABC research team discussed, reviewed, and edited potential items considered for inclusion in the questionnaire. The themes covered are:

A. Perceptions of the extent of non-adherence to medication in patients
B. Beliefs about adherence to prescribed medication
C. Use of adherence enhancing interventions
D. Barriers to use of adherence enhancing interventions
E. Questions about training on adherence and use of guidelines for adherence management

Description of the questionnaire

The questionnaire was made up of eighty-six (86) items in total and divided into five sub-sections. Below is a brief description of each sub-section in the instrument.

A. Perceptions of the extent of patient non-adherence: This section contains a total of six questions split equally into two subsections. The first section asks about health care professionals' perception of non-adherence in all patients e.g. 'what percentage of **all** patients with a chronic condition/illness in your country do you think do not initiate prescribed medication (that is, patients who do not take any of their prescribed medication)? The second section asks about their perceptions of non-adherence in their own patients e.g. what percentage of **your** patients with a chronic condition/illness in your country do you think do not initiate prescribed medication (that is, patients who do not take any of their prescribed medication)?

   A five-point rating scale is provided for respondents to make their ratings, with response options of '0 -15%', '16 – 35%', '36 – 65%', '66 - 85%', and '86 – 100%'.

B. Beliefs about adherence to medicines: There are seven (7) items in this section. Participants are asked to indicate the extent to which they agree or disagree with each statement about patient adherence. For example, 'it is possible to improve patient adherence to medication'.

   A five point rating scale is provided for participants to make their ratings, with options ranging from 'strongly disagree' to 'strongly agree' with intermediate labels of 'disagree', 'neither agree nor disagree' and 'agree'. The response category 'don't know' is also available to respondents.

C. Adherence enhancing interventions used by doctors, nurses and pharmacists: This section is made up of a total of fifty questions split into five sub-sections. These are:

(a) Assessment of adherence and its risk factors: There are eight (8) items in this sub-section. An example of an item in this section is: 'I use electronic monitoring devices to assess patient's level of adherence'. The primary outcome is included in this sub-section. The wording for the question is: 'I ask patients if they have missed any doses of their medication'.

(b) Providing information for carers and patients: There are nine (9) items in this sub-section. An example of an item from this section is: 'I check that patients understand the information that I have given them'.

(c) Talking with patients about their medications: This sub-section is made up of a total of eighteen (18) items. An example of an item from this section is: 'I ask patients what level of involvement they would like in making decisions about their treatment'.

(d) Practical strategies to make medication taking easier: Eleven (11) items make up this sub-section. An example of an item from this section is: 'I help patients to tailor their medication regimen to their own lifestyle'.

(e) Involving others and services to support adherence. This sub-section consists of four (4) items in total. An example of an item

from this section is: 'I refer patients to peer mentor programmes to support medication adherence'.

The response scale for the entire section on adherence enhancing interventions is adapted from Berben et al's survey of adherence practices by European cardiovascular nurses (10). The response options here are split into two. Respondents are first asked to indicate how often they use the intervention. A five-point rating scale is provided for participants to provide their frequency of use with responses ranging from 'never' to 'all the time' and intermediate ratings of 'occasionally', 'sometimes' and 'frequently'. The response category 'not applicable' is made available to participants who do not use any of the interventions mentioned. Next, respondents are given the opportunity to indicate, for every intervention they use, how effective they think that intervention is. A three-point rating scale is provided; with responses ranging from 'not at all' to 'extremely' with an intermediate category 'somewhat'. The response category 'don't know' is provided for those who select the option 'not applicable' in column one.

D. Barriers to the use of adherence management practices by healthcare professionals: This section contains thirteen questions. An example of an item from the list is: 'I have an excessive workload that prevents me from supporting patients with medicine adherence'. A four-point rating scale is provided for participants to indicate the extent to which the items listed act as barriers to their use of adherence promoting interventions. The options range from 'not at all' to 'very much' with

intermediate options of 'slightly' and 'moderately'. The response option 'not applicable' is provided for those who do not consider an item to be relevant to their work setting.

E. A final set of three questions about previous training in medication adherence and use of adherence guidelines completes the questionnaire. The questions ask whether the health care professional has had any training in adherence management during pre-registration or post-registration training. Respondents are also asked if they make use of any practitioner guidelines to manage patient adherence. The response options are 'yes' or 'no'.

Outcomes

Primary outcome

The primary outcome is the frequency of assessing the likelihood of non-adherence: This will be based on the response to the question "I ask patients if they have missed any doses of their medication."

Secondary outcomes

The following secondary outcomes will be reported:

- Perception of the extent of non-adherence: This measure is based on the participants' responses to a series of six questions that ask about their perceptions of the levels of non adherence in all patients versus their patients.
- Beliefs about adherence: This is based on an assessment of health care professionals' beliefs about patient adherence.

- Methods used to support patients with medication taking: This is a measure of health care professional's behaviour. Fifty items provide a measure of what health care professionals do to support patients with medicine taking.
- Barriers to the use of adherence enhancing practices: Participants are asked to indicate the extent to which the thirteen items listed act as barriers that limit their use of interventions to improve adherence.
- In addition, demographic information about the respondents will be collected, including health care setting (e.g. community setting, private or state funded health care system), number of years since registration as a healthcare professional, gender, age and average length of consultations with patients about medicines.

Analysis

Analyses will be conducted by total sample, country, and professional group. No interim analysis is planned.

Analysis of primary outcome

For all countries, the number and proportion of participants with the primary outcome will be reported overall and in each country, as will 95% confidence intervals for the proportions. Comparisons between countries and professions will be performed using multilevel random models using the software MLwiN (http://www.cmm.bristol.ac.uk/MLwiN/) for both binary and ordered categories. The software has the advantage of dealing with missing values by using all available data on each individual and not by imputing missing values.

Point estimates of the proportion of health care professionals who assess adherence in the entire sample (primary outcome) as well as in each country and each profession and their associated 95% confidence intervals will be obtained.

Analysis of secondary outcomes

For the entire sample and each group, the medians, modes, interquartile ranges and frequency distributions will be reported for each secondary outcome. 95% confidence intervals for the medians will be reported. Comparisons between and within countries and professions will be performed using multilevel models using all ordered categories and which will also include demographic and other information on participants (see below). The following comparisons of outcomes will be performed:

- Comparisons between the participating countries
- Comparisons between each professional group
- Comparisons by country and profession

Description of samples

Characteristics of participants will be described for the sample as a whole, for each country, and for each profession. Participants will be described in terms of their health care setting, type of health care system, number of years since licensed to practice, average length of time consulting with patients about medicines, age, gender and country.

Data Handling

Only the research team at Keele University will have access to the data during the study. After the study is completed, Keele University will make available the relevant data to ABC project partners for analysis, as appropriate.

Ethics and dissemination

Consent

Respondents who accept the invitation to take part in the study, and use the link provided to access the survey web page, are taken to the survey introductory page. Here, the participants are provided with information about the project, anonymity of the survey findings, an outline of what participants are required to do and how long it will take to complete the questions, an assurance that every attempt will be made to ensure the confidentiality of the data and a statement indicating that participation is voluntary and that withdrawal from the survey is possible at any stage. Potential participants are asked to click on a link to confirm that they have read the participant information before proceeding. The act of clicking on this link is considered consent to participate in the study. Access to the survey is denied unless this link is clicked.

Confidentiality

No personal information (such as names, addresses and professional licence numbers) will be collected from participants. The survey is completely anonymous and no IP addresses will be stored or downloaded.

Quality assurance

During the preparation of the study, quality has been ensured through the process of translation and back translation of research questionnaires. The questionnaire and the associated survey materials have been translated into the official language(s) for each participating country. The work-flow and quality management processes employed are certified to meet ISO 9001 Quality Management Standards. Forward translations have been performed by highly trained, approved and accredited translators who are native speakers of the target languages and fluent in English. Back translations have been performed by persons who are native English speakers and fluent in each target language. A third individual acts as a reviewer and highlights any discrepancies between the forward and back translations and resolves them by discussion with the translators. The respective national coordinators and their teams for each participating country also proofread each translated document and provide feedback on grammatical errors. They also provide contextual interpretation of the translations to ensure that they reflect the appropriate terminology used in each participating country. In addition to this, the online survey is piloted by at least five people in each country in order to check its technical functionality and also to check for comprehensibility, and formatting errors.

The ABC research team at Keele University will have overall responsibility for the design, recruitment, management, analysis of data and interpretation of results as well as writing the report. The ABC Project partners (First Department of Family Medicine, Medical University of Lodz, Poland, Center for Health

Services and Nursing Research, Katholieke Universiteit, Belgium, Aardex Group, Switzerland, Bangor University, Wales) participated in the design of the study. ABC partners will manage recruitment and data collection in their respective countries and also contribute to the interpretation of the results and their dissemination. The ABC project partners share all decisions about research developments and outputs; determining decisions by vote if appropriate. The funder of the research, the FP7 programme of the European Commission is not involved in the design or interpretation of the study.

Dissemination

The results will also be published in internal reports, in peer reviewed scientific journals as well as via conference presentations. The results of the study will also be available to the public on the ABC project website (www.ABCproject.eu) and via press releases in each of the participating countries.

Ethics approval

The study has ethical approval from the NRES Committee North West-Liverpool East (REC Reference- 11/NW/0156).

Discussion

To our knowledge, this study is the largest survey of European health care professionals' medication adherence perceptions, beliefs and behaviours. It is expected that the results will inform our understanding of how health care professionals perceive medication non-adherence. This study will also provide some insight into how health care professionals respond to non-adherence to

prescribed medication in their patients. By gaining a deeper understanding of health care professionals' perceptions and behaviour with regards to non-adherence in their patients, researchers will be able to design educational interventions and training for health care professionals that is evidence based and targeted at the training needs of health care professionals.

This study will also provide information on the interventions most frequently used by health care professionals and their perceptions of which interventions are most effective in managing non-adherence. It is anticipated that this will provide evidence-based knowledge of interventions which health care professionals have found to be effective at improving patient adherence. Health care professionals could use this information as a guide when making a decision about which interventions to make use of or to recommend to patients in order to improve adherence. Information on those interventions which are reported to be less effective could help to channel the efforts of researchers towards finding ways to improve those interventions.

The Pan-European nature of this study will provide a comprehensive data set which will enable analysis of variability observed in health care professionals' beliefs and behaviours across twelve European nations. It is anticipated that this knowledge of the level of variability between professions in adherence-supporting behaviour, may provide a basis for promoting routine and continuous efforts to educate and modify the behaviour of health care professionals in order to enable them to fulfil their roles in supporting patients with medicine taking.

Authors' contributions

The principal investigator is WC. The ABC project coordinator is PK. All Authors took part in the development of the questionnaire. WC, CM, SH, SM and PJ took part in the design and development of the protocol. All authors contributed to the writing of the final manuscript. WC and CM revised the manuscript with input and advice from all authors.

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Competing interests

The authors declare that they have no competing interests.

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Table 1
Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

	Checklist for Reporting Results of Internet E-Surveys (CHERRIES)	
Item Category	***Checklist Item***	***Explanation***
Design		
	Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In â openâ surveys this is most likely.)
IRB (Institutional Review Board) approval and informed consent process		

	IRB approval	Mention whether the study has been approved by an IRB.
	Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?
	Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.
Development and pre-testing		
	Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.
Recruitment process and description of the sample having access to the questionnaire		
	Open survey versus closed survey	An â open surveyâ is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).
	Contact mode	Indicate whether or not the initial contact with the potential participants was made on the Internet. (Investigators may also send out questionnaires by mail and allow for Web-based data entry.)
	Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media (newspapers), or online (mailing lists â If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is

		important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.
Survey administration		
	Web/E-mail	State the type of e-survey (eg, one posted on a Web site, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?
	Context	Describe the Web site (for mailing list/newsgroup) in which the survey was posted. What is the Web site about, who is visiting it, what are visitors normally looking for? Discuss to what degree the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on a anti-immunization Web site will have different results from a Web survey conducted on a government Web site
	Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?
	Incentives	Were any incentives offered (eg, monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?
	Time/Date	In what timeframe were the data collected?
	Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.
	Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.
	Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.

	Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.
	Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if â yesâ , how (usually JAVAScript)? An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as â not applicableâ or â rather not sayâ , and selection of one response option should be enforced.
	Review step	State whether respondents were able to review and change their answers (eg, through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).
Response rates		
	Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.
	View rate (Ratio unique site visitors/unique survey visitors)	Requires counting unique site visitors (not page views!) divided by the number of unique visitors of the first page of the survey. It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.
	Participation rate (Ratio unique survey page visitors/agreed to participate)	Count the unique number of visitors who visit the first page of the survey (or the informed consents page, if present) divided by the number of people who filled in the first survey page (or agreed to participate). This can also be called â recruitmentâ rate.

	Completion rate (Ratio agreed to participate/finished survey)	The number of people agreeing to participate (or submitting the first survey page) divided by the number of people submitting the last questionnaire page. This is only relevant if there is a separate â informed consentâ page or if the survey goes over several pages. This is a measure for attrition. Note that â completionâ can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word â completeness rateâ .)
Preventing multiple entries from the same individual		
	Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?
	IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?
	Log file analysis	Indicate whether other techniques to

		analyze the log file for identification of multiple entries were used. If so, please describe.
	Registration	In â closedâ (non-open) surveys, users need to login first and it is easier to prevent duplicate entries from the same user. Describe how this was done. For example, was the survey never displayed a second time once the user had filled it in, or was the username stored together with the survey results and later eliminated? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?
Analysis		
	Handling of incomplete questionnaires	Were only completed questionnaires analyzed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analyzed?
	Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point, and describe how this point was determined.
	Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.