

## Would primary health care professionals prescribe a polypill to manage cardiovascular risk? A qualitative interview study

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# Would primary health care professionals prescribe a polypill to manage cardiovascular risk? A qualitative interview study

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#### Abstract

## **Objectives**

A 'polypill' containing both blood pressure and cholesterol lowering drugs could prevent up to 80% of cardiovascular disease events. Since little is known about the attitudes of primary health care professionals to use of such a pill for cardiovascular disease prevention, this study aimed to investigate opinions.

## Design

Semi-structured interviews were conducted with participants. A qualitative description approach was used to analyse and report the results.

## Setting

Participants were recruited from nine primary care practices in Birmingham.

#### **Participants**

Sixteen health care professionals (11 primary care physicians and 5 practice nurses) were selected through purposive sampling to maximise variation of characteristics.

## **Outcome measures**

Outcome measures for this study were: the attitude of health care professionals towards the use of a polypill for primary and secondary cardiovascular disease prevention; their views on monitoring the drug; and the factors influencing their willingness to prescribe the medication.

#### **Results**

Health care professionals expressed considerable concern over using a polypill for primary prevention for all people over a specific age, although there was greater acceptance of its use for secondary prevention. Regularly monitoring patients taking the polypill was deemed essential. Evidence of effectiveness, patient risk level and potential medicalisation were key determinants in willingness to prescribe such a pill.

#### Conclusions

Primary health care professionals have significant concerns about the use of a polypill, particularly in the prevention of cardiovascular disease in people who are not regarded as being at 'high risk'. If a population based polypill strategy is to be successfully implemented, health care professionals will need to be convinced of the potential benefits of a drug based population approach to prevention.

## **Article summary**

#### Article focus

- A 'polypill' containing several blood pressure and cholesterol lowering drugs has
  large theoretical benefits in terms of reducing cardiovascular morbidity. Short term
  trials have demonstrated its efficacy.
- Although small scale surveys of physicians suggest that the use of the polypill may be
  acceptable to health care professionals, they have not provided detailed data on
  attitudes to the polypill.
- The aim of this study was to investigate the attitude of health care professionals to the use of a polypill for cardiovascular disease prevention.

## **Key messages**

- There was considerable resistance towards the use of a polypill for the prevention of cardiovascular disease in people not regarded as being at 'high risk'.
- Evidence of efficacy was judged important but potential medicalisation and an ongoing need for monitoring were significant issues for many health care professionals.
- If a population based polypill strategy is to be introduced, significant barriers from professionals will need to be overcome.

## Strengths and limitations of this study

 The study's qualitative approach allowed a detailed exploration of attitudes not possible in quantitative surveys.

Conversely, we cannot comment on how prevalent the views expressed in this study
are in the wider population of health care professionals.



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**Competing interests:** None declared.

**Contributors:** The study was designed by SKV, SMG, KF and JM. SKV conducted the interviews, analysed the data and drafted the paper. SKV, SMG and JM contributed to subsequent drafts. All authors critically revised the paper.

**Data sharing statement:** No additional data available.

## Introduction

Cardiovascular disease remains the major cause of morbidity and mortality worldwide.<sup>1</sup> There have been significant advances in the evidence base for cardiovascular disease prevention, particularly regarding pharmacological interventions aimed at lowering blood pressure<sup>2,3</sup> and cholesterol.<sup>4</sup> Guidelines recommend use of these agents for both secondary and primary prevention in people at raised cardiovascular risk. 5,6 However repeated surveys have shown many patients are not being treated as intensively as guidelines recommend.<sup>7,8</sup> Furthermore, the majority of cardiovascular events occur in people not at high risk using conventional risk calculators. Therefore, offering a 'polypill' to everyone over a particular age (for example 55) has been proposed. 10 This involves a single daily combined pill containing both blood pressure and cholesterol lowering agents at a fixed low dose (to reduce adverse effects) with minimal monitoring required, as opposed to titrating individual treatments to specific targets. The polypill may also have a role in people with known cardiovascular risk factors, since it may lead to better patient adherence. 11,12 Wald and Law<sup>10</sup> estimate adopting a polypill strategy could prevent 80% of strokes and 88% of ischaemic heart disease events, with low risk of adverse effects.

If used in the UK, it is likely that the polypill would largely be prescribed and monitored within primary care. Implementation would require considerable professional engagement but to date there has been limited research on the polypill's professional acceptability. Three small practitioner surveys have been conducted, but none in the UK. Holt<sup>13</sup> found from a survey of 17 New Zealand primary care physicians almost all were familiar with the polypill. They were keen on its simplicity and the likely increased compliance, but disliked the lack of flexibility of the components and doses. More recently, Soliman at el<sup>14</sup> surveyed

58 Sri Lankan physicians and discovered a high degree of acceptability of prescribing the polypill for primary prevention and even higher for secondary prevention. Viera et al's findings from a survey of 952 US physicians also revealed relatively high acceptance, but low agreement to minimal monitoring. Such surveys whilst useful in gauging high level opinion, cannot explore detailed issues around acceptability in any depth.

This paper reports on a study which used a qualitative description approach<sup>16,17</sup> to investigate UK health care professionals' i.e. primary care physicians' and practice nurses' attitude towards using the polypill for cardiovascular disease prevention and the drug's practicality for monitoring and prescribing.

## Method

## Participants and sampling

11 Birmingham primary care practices agreed to participate of 20 initially approached.

Practices were purposively selected to maximise variation in our sample. They were chosen to represent different sizes (number of full-time equivalent primary care physicians) as practice size is known to affect prescribing behaviour. Practices were also selected to reflect different levels of socio-economic deprivation (Indices of Multiple Deprivation (IMD) score of the practice area) since cardiovascular need tends to be higher in practices based in relatively deprived areas. The IMD score is a single deprivation score combining a number of indicators covering a range of economic, social and housing issues. Scores were divided into quartiles, one representing the least deprived areas and four the most. To contextualise this work, Birmingham consists of a population of about one million people including diverse ethnic groups with one-third from a non-white background.

The 56 primary care physicians and 22 practice nurses in the 11 practices were sent a postal questionnaire enquiring about their gender, ethnicity (2001 general census ethnic categories)<sup>23</sup> and year of qualification, together with a 'Beliefs about Medicines Questionnaire (BMQ)-General.<sup>24</sup> This includes two scales (General-Harm and General-Overuse) to measure respondents' attitudes to medicines in general. High scores indicate a greater belief that medicines are harmful and overused. This was used for sampling to ensure a range of views on general medication usage. Since we wanted respondents with extreme views and moderate beliefs and there appeared to be different ways to interpret scores,<sup>25-27</sup> we divided respondents' scores into tertiles, scores between 8-15 being categorised as low, 16-22 as medium and 23-34 as high.

58 (74%) health care professionals returned a completed BMQ-General. Respondents were sampled on these scores as well as a maximum variety of individual (occupation, gender, ethnicity, qualification year) and organisational (practice size, practice IMD score) characteristics to allow a diversity of responses to emerge. 50 health care professionals (41 primary care physicians and 9 practice nurses) were selected and approached by letter, and 16 (11 primary care physicians and 5 practice nurses) agreed to interview across 9 practices.

#### **Interviews**

Semi-structured interviews were used to elicit health care professionals views as they provide an opportunity for in-depth investigation of personal perspectives, detailed understanding and chance for clarification. The interview guide was developed through a discussion of the polypill and cardiovascular disease literature by research team members (SKV, SMG, KF and JM) and covered: health care professionals' understanding of the polypill; their attitude towards its use; and prescribing and monitoring the drug. Ethical approval to conduct the interviews was granted by the Birmingham, East, North and Solihull Research Ethics Committee (08/H1206/91). Signed informed consent was obtained before the interview. All interviews were carried out at the practices by one of the authors (SKV) from March to October 2009. Interviews lasted between 30-60 minutes, were audio recorded and transcribed verbatim.

## **Analysis**

All transcripts were checked against the recording for accuracy. As part of the process of respondent validation,<sup>29</sup> health care professionals were sent a copy of their transcript and a brief summary of the interview for comments. Only one additional comment was made.

Throughout the analytic process each transcript was compared with others to develop conceptualisations of the possible relations between various pieces of data and key areas.<sup>30</sup> Interviews continued until the authors (SKV, SMG and KF) agreed saturation had been achieved. Transcripts and field notes were read independently by the authors (SKV, SMG and KF) and the subthemes identified in each key area.<sup>16</sup> These were discussed by the multidisciplinary team of clinicians and non-clinicians and a thematic coding framework was developed to code each transcript systematically. Framework software was used to aid data organisation.<sup>31</sup>

#### Results

## **Participants**

There were similar numbers of men and women (table 1) but all practice nurses were female and most primary care physicians were male. Seven participants were from a minority ethnic group (3 Indian; 1 White Irish; 1 Chinese; and 2 other). Most gained their professional qualification between 1970 and 1989. Participants had a full range of attitudes towards medicines determined by their BMQ-General score, but the four respondents with more positive attitudes towards medicines were all practice nurses.

#### **Key areas**

To facilitate comparison of comments and contextualise subthemes, these are presented within each of the three key areas: attitude towards the polypill; opinions on monitoring; and views on prescribing. The number of respondents discussing each subtheme is reported (denominator 16 participants).<sup>32</sup> Interview extracts representative of each subtheme are shown in tables 2-4. Comparison of the subthemes did not reveal any relationship between health care professionals' characteristics and their views on the polypill in managing cardiovascular risk.

#### Attitude towards the polypill (table 2)

Health care professionals discussed their attitude towards the polypill in terms of what they already knew and understood about it, and their thoughts about using the medication for primary and secondary prevention.

#### Knowledge and understanding of the polypill

The majority of respondents (11) understood the polypill would be used for cardiovascular disease prevention, whether for primary or secondary prevention or indeed both, and that it would contain multiple ingredients. Beyond this, their knowledge appeared limited. Most (10) were uncertain about how they might use it, and what drugs at what doses would be in it. Some (3) mentioned their knowledge was based on what they had read in journals or seen in the media.

#### Use of the polypill for primary prevention

All interviewees (16) expressed concern about using the polypill for primary prevention for everyone over a specific age. Most concerns were regarding: potential side-effects; difficulty in identifying the ingredient(s) causing side-effects; and the built-in inability to titrate the ingredients and dose. Other concerns raised were: unnecessary medicalisation of healthy people; lack of evidence demonstrating effectiveness; and the potential negative impact on health related behaviour, possibly leading to complacency about leading a healthy lifestyle.

Despite apprehension, half of health care professionals (8) recognised the possible advantages of administering a polypill to everyone over a specific age: mainly the potential to reduce the risk of developing cardiovascular disease at a population level. Hence a number (5) were receptive towards a population approach, although the majority (10) thought the polypill should only be given to those with cardiovascular disease risk factors.

## Use of the polypill for secondary prevention

Of those interviewees (8) who discussed using the polypill for secondary prevention, most (6) appeared positive believing it would be more practical for patients to take thereby

improving compliance. However, a minority (2) questioned its value for secondary prevention as it would merely be a combined replacement of current cardiovascular disease medication.

#### Monitoring patients taking the polypill (table 3)

Health care professionals reflected upon both regular and minimal monitoring of patients taking the polypill.

## Regular monitoring of patients

Almost all participants (15) felt it was essential to regularly monitor patients taking the polypill to: check the medication was both safe and effective, especially as it is a new drug; screen for and encourage patient compliance; and because of the perception that most prescribed medications require some degree of monitoring. Only one respondent felt regular monitoring was unnecessary otherwise the polypill would become unfeasible, although he highlighted the dose would need to be considered safe enough.

#### Minimal monitoring of patients

The idea of minimal monitoring of patients taking the polypill caused major unease amongst most health care professionals (11), with two claiming such a strategy to be negligent.

Several (7) claimed they would need to see evidence that minimal monitoring was deemed appropriate before they could be convinced to adopt this practice. Others (4) argued they would monitor patients regularly even if the advice was that it was unnecessary.

#### Prescribing the polypill (table 4)

Although all health care professionals (16) would consider prescribing the polypill, there appeared to be several factors influencing their willingness. These could be divided into four groups relating to: their personal values; features of the drug; external issues; and patient factors.

#### Personal factors

For many respondents (10), personal beliefs regarding unnecessary medicalisation meant they would not prescribe the polypill without an indication in addition to age alone.

## Drug factors

There were three important factors about the polypill that were deemed to have an influence on whether or not health care professionals would prescribe it: cost; monitoring; and titration. According to just under half (7) if the polypill was cost-effective for both patients and the National Health Service, they would be more likely to prescribe. However, others (5) stated cost would have no bearing on their decision if the outcome was beneficial. Some respondents (6) claimed they would be more willing to prescribe the polypill if they could monitor patients. Quite a few (6) had concerns over the inability to titrate it which meant they were reluctant about prescribing.

## External factors

Two external factors, evidence and guidance from the Department of Health (DoH), seemed to impact on participants' decision to prescribe the polypill. Most (13) claimed the evidence demonstrating the polypill to be safe, effective and beneficial would be a major determinant in their judgement. Two said if the DoH endorsed its prescribing, they would then do so.

#### Patient factors

There were several patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications) and one socio-demographic factor (age) that influenced health care professionals views regarding potential prescription of the polypill.

Most (10) claimed they would be more willing to prescribe the medication as a preventative measure for people with risk factors. Many (9) also believed their willingness would be influenced by the patient's choice to take the medication. A number of participants (7) mentioned they would not offer the polypill to patients who had experienced previous side-effects from the individual ingredients. Several (6) believed they would prescribe the polypill for patients on treatment for existing cardiovascular disease as a replacement for practical reasons. Others (4) thought they would avoid medicating these patients with the polypill since they require titrated dosages. Where patients had problems complying with multiple medications, some respondents (4) said they would be more likely to prescribe the polypill. A few (4) also suggested they would be less keen to offer the polypill to patients with complex medical conditions or who were on certain medications due to possible contra-indications.

In terms of age, the majority of interviewees (10) did not believe in prescribing the polypill to everyone over 50 years for primary prevention unless there were risk factors. However, several (5) claimed they would be willing to offer the medication to this population regardless of their risk level, as long as the evidence demonstrated it to be safe and effective. In fact, one health care professional thought the age limit should be as low as 40 years for men. Some (4) said they would be happy to prescribe the polypill for the elderly as

it would be more practical for them to take, whereas others (2) maintained they would



## Discussion

## **Summary of main findings**

Health care professionals were sceptical about the role of a polypill. A major concern was they did not feel the evidence base for a polypill had been established. They were particularly reluctant to prescribe on the basis of age and felt ongoing monitoring of blood pressure and cholesterol would be required. The inability to titrate dose in the polypill was seen as a further disadvantage. There was greater willingness to consider its use for secondary prevention, but with the same provisos about wanting to continue monitoring and with concerns about inability to adjust dose.

## Comparison with existing literature

As with a previous survey study,<sup>14</sup> we found health care professionals were more accepting of a polypill for secondary prevention perhaps because for those with existing cardiovascular disease there is a greater perceived need for medication. However, we discovered a lower level of acceptance for primary prevention, with more concerns regarding the pill itself. This may reflect typically slower uptake of new drugs by primary care physicians in the UK compared to other countries,<sup>33</sup> with many describing themselves as 'cautious' or 'conservative' in their prescribing behaviour.<sup>34</sup>

In our study, health care professionals disliked the concept of minimal monitoring of patients taking the polypill, a finding consistent with earlier studies. <sup>14,15</sup> This reflects current practice where patients are monitored for a number of reasons, including side-effects, effectiveness and compliance. Nevertheless, current National Institute for Health and

Clinical Excellence guidelines on lipid lowering therapy for primary prevention do not recommend monitoring, <sup>6</sup> so attitudes may change.

## Strengths and limitations

A study strength is that all interviews were carried out by a single researcher thereby ensuring consistency.<sup>35</sup> The researcher was non-medical, and health care professionals' responses may have been different if the researcher had been a clinician.

The study's qualitative approach allowed an in-depth exploration of attitudes not possible in quantitative surveys. Conversely, we are not able to comment on how prevalent the views expressed in this study are in the wider population of primary health care professionals.

Also, what respondents suggested they would do is not necessarily what they would actually do in reality.

Although the aim of qualitative research is not to be generalisable, <sup>36</sup> we did have a representative sample of respondents across gender and ethnicity. Our sample size was also sufficient to achieve saturation.<sup>37</sup>

## **Implications**

This study suggests despite potential acceptance of use of a polypill for secondary prevention, health care professionals remain concerned monitoring should continue. With regard to primary prevention, there was considerable resistance to a population strategy offering the polypill to everyone over a certain age. This reflected both a concern about the lack of empirical evidence of the polypill's effectiveness and safety, and a concern regarding medicalisation. If a polypill is to be used in this way, it is likely health care professionals

would need to be convinced about the potential benefits of a drug based population approach to prevention.

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**COMPETING INTERESTS: None** 

**CONTRIBUTORSHIP**: The study was designed by SKV, SMG, KF and JM. SKV conducted the interviews, analysed the data and drafted the paper. SKV, SMG and JM contributed to subsequent drafts. All authors critically revised the paper.

**DATA SHARING**: No additional data available.

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Table 1: Health care professional characteristics

#### Knowledge and understanding of the polypill

Would be used for cardiovascular disease prevention

"[The polypill is]...hoping to reduce heart attacks and heart disease and stroke and things like that really...regardless of whether or not they have hypertension or ischemic heart disease at the time." (Primary care physician 4)

Uncertainty over aspects of polypill

"...you're only going to put these people on primary prevention if they're at risk, aren't you? It's not for everybody is it?"

(Primary care physician 10)

Knowledge based on journals and media

"...I don't know what the thinking behind the use of it is other than what I've read in the national press." (Primary care physician 8)

#### Use of the polypill for primary prevention

Concerns regarding actual polypill

"...one would intellectually feel that if you put five pills in a pill, or four pills in a pill, more people are gonna react to it than if you've got one pill." (Primary care physician 3)

"I think you need titration, individual titration of different medications for individual people...so I can't imagine that one pill will work for everybody." (Practice nurse 3)

Unnecessary medicalisation

"...its [the polypill] just another medication that you'd be committing the person to really...I just think it's unnecessary. I think we should be teaching people, well people, how to keep themselves well without offering them preventive things, in the way of medication that is." (Practice nurse 1)

Lack of evidence demonstrating effectiveness

"...if you've got evidence that it works, then it would be easy for me to support. No, the evidence doesn't exist."

(Primary care physician 8)

Negative impact on patient lifestyle

"...it may very well give people a false sense of security...they'll continue to eat and drink too much, and smoke too much and take the polypill...it may make no difference whatsoever to them." (Primary care physician 4)

May reduce cardiovascular disease risk

"...the possibilities are that it might reduce a populations' risk of heart disease and stroke." (Primary care physician 11)

"You would reach a population that you wouldn't otherwise reach, then you're broadening the service you're providing and reducing cardiovascular risk." (Primary care physician 8)

Should only be for those with risk factors

"It [the polypill] should only be for those at risk of a cardiovascular attack...especially if there's any history of cardiovascular disease in the family." (Primary care physician 2)

#### Use of the polypill for secondary prevention

Practical for patients

"...it just saves taking lots of tablets often: I think compliance probably would be better." (Practice nurse 5)

Lack of purpose

"...secondary prevention: I'm not so sure about because we are supposed to be treating these patients anyway...so there is a question really about...well the purpose really." (Primary care physician 11)

Table 2: Attitude towards the Polypill

#### Regular monitoring of patients

To check it is safe and effective

"...how will you know it's actually being effective in terms of reducing blood pressure if it's not monitored?" (Practice nurse 3)

"...you need to see the side-effects...by monitoring. You need to see whether they are developing anything else as well."

(Primary care physician 7)

To screen for and encourage compliance

"...just to reassure [patients] that yes it is working, because I think some people might stop taking it and then not bother coming back, and then you've got problems with non-compliance again." (Practice nurse 5)

Medications are normally monitored

"...if someone's on a drug then historically they are monitored...not to monitor would be difficult." (Practice nurse 4)

Polypill is only feasible with no monitoring

"I think the polypill is only feasible if there is no monitoring associated with it...it's probably only feasible if the dose is considered safe enough not to be monitored." (Primary care physician 11)

#### Minimal monitoring of patients

Cause for concern

"That as a GP does not sit comfortably...if you're prescribing medication you have an ethical and a moral obligation to monitor this person." (Primary care physician 10)

"You don't give people medicines without seeing what it's going to do: that's pure negligent..." (Primary care physician 1)

Need to see the evidence

"So if the evidence was you don't have to monitor a polypill then I would say fine...but you've got to give me the evidence that that's an okay way to behave before I would consider that..." (Primary care physician 8)

Would still monitor

"...if the advice was saying not to monitor I'd still want to...for the patients sake and my sake." (Primary care physician 6)

#### Table 3: Monitoring patients taking the Polypill

## **Personal factors**

"...it's not my ethos to medicate well people to prevent the normal ageing process..." (Primary care physician 8)

"I just don't believe that there's a pill for every ill...later in life you are probably going to develop some problems with your blood pressure and maybe your cholesterol levels won't stay the same...I think you really have to live with them, you can't expect to be taking a tablet for every little change that's happening in your body." (Practice nurse 1)

## Drug factors (cost, monitoring, titration)

- "...if it's researched based, it's shown to have fantastic results, it's cost effective...yes I would prescribe it." (Practice nurse 2)
- "...I would be happy prescribing it if I could watch people carefully for a while and see how they feel about it." (Practice nurse 3)
- "...unless there are different doses of combinations of polypills, just giving one to somebody might not necessarily be the right one for that person." (Primary care physician 10)

#### External factors (evidence, guidance)

"...I would be happy [to prescribe the polypill], provided I've got enough data to go on...I think everything hinges on that actually." (Primary care physician 7)

"If our PCT and the Department of Health feel it's a good thing, then yes I would prescribe it." (Practice nurse 2)

## Patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications, age)

- "...patients would have to be selected on the basis of their family history...if the family history contains ischaemic heart disease then they're the ones we should be picking first." (Primary care physician 4)
- "I think we should give patients options. I don't think we should be saying "oh that is the one". It's very much a personal choice for the patient." (Primary care physician 5)

"Somebody who's had an adverse reaction to any of those things that are in it [the polypill], I honestly wouldn't prescribe it, just like you wouldn't prescribe that drug to them." (Primary care physician 2)

"Secondary prevention patients – if we're going to combine some of the medications that they're already on into a polypill so they're taking fewer tablets...they might be interested." (Primary care physician 1)

"...it very much depends on the type of patient...some people will probably just be happier to take one pill rather than a couple...people who have a problem with compliance...it would be the right one for them..." (Primary care physician 5)

"...I don't know if it is contraindicated with people with certain conditions or people who are on certain medications like warfarin for instance...that could be a barrier." (Practice nurse 2)

"If they haven't got any risk factors for cardiovascular disease, I don't think everybody over the age of 50 should be taking it. I don't think I'll agree to that." (Primary care physician 5)

"...[the polypill] couldn't just be handed out to everybody over the age of 50, unless the studies and research suggested that there were no adverse effects and anyone could take the drug...even if they didn't have hypertension." (Practice nurse 4)

Table 4: Prescribing the Polypill

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## Would primary health care professionals prescribe a polypill to manage cardiovascular risk? A qualitative interview study

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# Would primary health care professionals prescribe a polypill to manage cardiovascular risk? A qualitative interview study

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#### Abstract

## **Objectives**

A 'polypill' containing both blood pressure and cholesterol lowering drugs could prevent up to 80% of cardiovascular disease events. Since little is known about the attitudes of primary health care professionals to use of such a pill for cardiovascular disease prevention, this study aimed to investigate opinions.

## Design

Semi-structured interviews were conducted with participants. A qualitative description approach was used to analyse and report the results.

## Setting

Participants were recruited from nine primary care practices in Birmingham.

## **Participants**

Sixteen health care professionals (11 primary care physicians and 5 practice nurses) were selected through purposive sampling to maximise variation of characteristics.

#### **Outcome measures**

Outcome measures for this study were: the attitude of health care professionals towards the use of a polypill for primary and secondary cardiovascular disease prevention; their views on monitoring the drug; and the factors influencing their willingness to prescribe the medication.

#### **Results**

Health care professionals expressed considerable concern over using a polypill for primary prevention for all people over a specific age, although there was greater acceptance of its use for secondary prevention. Regularly monitoring patients taking the polypill was deemed essential. Evidence of effectiveness, patient risk level and potential medicalisation were key determinants in willingness to prescribe such a pill.

#### Conclusions

Primary health care professionals have significant concerns about the use of a polypill, particularly in the prevention of cardiovascular disease in people who are not regarded as being at 'high risk'. If a population based polypill strategy is to be successfully implemented, health care professionals will need to be convinced of the potential benefits of a drug based population approach to prevention.

## **Article summary**

#### **Article focus**

- A 'polypill' containing several blood pressure and cholesterol lowering drugs has
  large theoretical benefits in terms of reducing cardiovascular morbidity. Short term
  trials have demonstrated its efficacy.
- Although small scale surveys of physicians suggest that the use of the polypill may be
  acceptable to health care professionals, they have not provided detailed data on
  attitudes to the polypill.
- The aim of this study was to investigate the attitude of health care professionals to the use of a polypill for cardiovascular disease prevention.

## **Key messages**

- There was considerable resistance towards the use of a polypill for the prevention of cardiovascular disease in people not regarded as being at 'high risk'.
- Evidence of efficacy was judged important but potential medicalisation and an ongoing need for monitoring were significant issues for many health care professionals.
- If a population based polypill strategy is to be introduced, significant barriers from professionals will need to be overcome.

## Strengths and limitations of this study

 The study's qualitative approach allowed a detailed exploration of attitudes not possible in quantitative surveys. Conversely, we cannot comment on how prevalent the views expressed in this study
are in the wider population of health care professionals.



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**Competing interests:** None declared.

**Contributors:** The study was designed by SKV, SMG, KF and JM. SKV conducted the interviews, analysed the data and drafted the paper. SKV, SMG and JM contributed to subsequent drafts. All authors critically revised the paper.

Data sharing statement: No additional data available.

#### Introduction

Cardiovascular disease remains the major cause of morbidity and mortality worldwide.<sup>1</sup> There have been significant advances in the evidence base for cardiovascular disease prevention, particularly regarding pharmacological interventions aimed at lowering blood pressure<sup>2,3</sup> and cholesterol.<sup>4</sup> Guidelines recommend use of these agents for both secondary and primary prevention in people at raised cardiovascular risk. 5,6 However repeated surveys have shown many patients are not being treated as intensively as guidelines recommend.<sup>7-9</sup> Furthermore, the majority of cardiovascular events occur in people not at high risk using conventional risk calculators. <sup>10</sup> Therefore, offering a 'polypill' to everyone over a particular age (for example 55) has been proposed. 11 The original idea involved a six component pill (three blood pressure lowering agents; cholesterol lowering agent; folate; and aspirin), but due to question marks over the efficacy of folate and the appropriateness of aspirin use for primary prevention, this now typically involves a single daily combined pill containing just blood pressure and cholesterol lowering agents. Since the idea was first raised, the evidence base for the potential role of a polypill has grown. There is more evidence that the effect of blood pressure lowering on cardiovascular risk is independent of baseline blood pressure, 12 and that reduction of LDL cholesterol is beneficial in those at low risk of vascular disease. 13 Meta-analysis of early trials show that polypills do indeed lower blood pressure and serum cholesterol levels.<sup>14</sup>

The polypill may also have a role in people with known cardiovascular risk factors, since it may lead to better patient adherence. Wald and Law estimate adopting a polypill strategy could prevent 80% of strokes and 88% of ischaemic heart disease events, with low risk of adverse effects.

if used in the UK, it is likely that the polypill would largely be prescribed and monitored within primary care. Implementation would require considerable professional engagement but to date there has been limited research on the polypill's professional acceptability.

Three small practitioner surveys have been conducted, but none in the UK. Holt<sup>17</sup> found from a survey of 17 New Zealand primary care physicians almost all were familiar with the polypill. They were keen on its simplicity and the likely increased compliance, but disliked the lack of flexibility of the components and doses. More recently, Soliman at el<sup>18</sup> surveyed 58 Sri Lankan physicians and discovered a high degree of acceptability of prescribing the polypill for primary prevention and even higher for secondary prevention. Viera et al's<sup>19</sup> findings from a survey of 952 US physicians also revealed relatively high acceptance, but low agreement to minimal monitoring. Such surveys whilst useful in gauging high level opinion, cannot explore detailed issues around acceptability in any depth.

The polypill has been used in a range of settings. This paper reports on a study in Birmingham, UK, which used a qualitative description approach<sup>20,21</sup> to investigate UK health care professionals' i.e. primary care physicians' and practice nurses' attitude towards using the polypill for cardiovascular disease prevention and the drug's practicality for monitoring and prescribing.

#### Method

# Participants and sampling

11 Birmingham primary care practices agreed to participate of 20 initially approached.

Practices were purposively selected to maximise variation in our sample. They were chosen to represent different sizes (number of full-time equivalent primary care physicians) as practice size is known to affect prescribing behaviour. Practices were also selected to reflect different levels of socio-economic deprivation (Indices of Multiple Deprivation (IMD) score of the practice area) since cardiovascular need tends to be higher in practices based in relatively deprived areas. The IMD score is a single deprivation score combining a number of indicators covering a range of economic, social and housing issues. Scores were divided into quartiles, one representing the least deprived areas and four the most. To contextualise this work, Birmingham consists of a population of about one million people including diverse ethnic groups with one-third from a non-white background.

The 56 primary care physicians and 22 practice nurses in the 11 practices were sent a postal questionnaire enquiring about their gender, ethnicity (2001 general census ethnic categories)<sup>27</sup> and year of qualification, together with a 'Beliefs about Medicines Questionnaire (BMQ)-General.<sup>28</sup> This includes two scales (General-Harm and General-Overuse) to measure respondents' attitudes to medicines in general. High scores indicate a greater belief that medicines are harmful and overused. This was used for sampling to ensure a range of views on general medication usage. Since we wanted respondents with extreme views and moderate beliefs and there appeared to be different ways to interpret scores, <sup>29-31</sup> we divided respondents' scores into tertiles, scores between 8-15 being categorised as low, 16-22 as medium and 23-34 as high.

58 (74%) health care professionals returned a completed BMQ-General. Respondents were sampled on these scores as well as a maximum variety of individual (occupation, gender, ethnicity, qualification year) and organisational (practice size, practice IMD score) characteristics to allow a diversity of responses to emerge. 50 health care professionals (41 primary care physicians and 9 practice nurses) were selected and approached by letter, and 16 (11 primary care physicians and 5 practice nurses) agreed to interview across 9 practices.

#### **Interviews**

Semi-structured interviews were used to elicit health care professionals views as they provide an opportunity for in-depth investigation of personal perspectives, detailed understanding and chance for clarification. The interview guide was developed through a discussion of the polypill and cardiovascular disease literature by research team members (SKV, SMG, KF and JM) and covered: health care professionals' understanding of the polypill; their attitude towards its use; and prescribing and monitoring the drug. Ethical approval to conduct the interviews was granted by the Birmingham, East, North and Solihull Research Ethics Committee (08/H1206/91). Signed informed consent was obtained before the interview. All interviews were carried out at the practices by one of the authors (SKV) from March to October 2009. Interviews lasted between 30-60 minutes, were audio recorded and transcribed verbatim.

#### **Analysis**

All transcripts were checked against the recording for accuracy. As part of the process of respondent validation,<sup>33</sup> health care professionals were sent a copy of their transcript and a brief summary of the interview for comments. Only one additional comment was made.

Although the advantages and disadvantages of this process have been documented,<sup>34</sup> since this is the first qualitative study on the polypill and it was a new concept for interviewees, it was felt important to do this.

Throughout the analytic process each transcript was compared with others to develop conceptualisations of the possible relations between various pieces of data and key areas.<sup>35</sup> Interviews continued until the authors (SKV, SMG and KF) agreed saturation had been achieved. Transcripts and field notes were read independently by the authors (SKV, SMG and KF) and the subthemes identified in each key area.<sup>20</sup> These were discussed by the multidisciplinary team of clinicians and non-clinicians and a thematic coding framework was developed to code each transcript systematically. Framework software was used to aid data organisation.<sup>36</sup>

#### Results

## **Participants**

There were similar numbers of men and women (table 1) but all practice nurses were female and most primary care physicians were male. Seven participants were from a minority ethnic group (3 Indian; 1 White Irish; 1 Chinese; and 2 other). Most gained their professional qualification between 1970 and 1989. Participants had a full range of attitudes towards medicines determined by their BMQ-General score, but the four respondents with more positive attitudes towards medicines were all practice nurses.

#### Key areas

To facilitate comparison of comments and contextualise subthemes, these are presented within each of the three key areas: attitude towards the polypill; opinions on monitoring; and views on prescribing. The number of respondents discussing each subtheme is reported (denominator 16 participants)<sup>37</sup> in order to contextualise the findings and facilitate a comparison between respondents. Interview extracts representative of each subtheme are shown in tables 2-4. Comparison of the subthemes did not reveal any relationship between health care professionals' characteristics and their views on the polypill in managing cardiovascular risk.

#### Attitude towards the polypill (table 2)

Health care professionals discussed their attitude towards the polypill in terms of what they already knew and understood about it, and their thoughts about using the medication for primary and secondary prevention.

#### Knowledge and understanding of the polypill

The majority of respondents (11) understood the polypill would be used for cardiovascular disease prevention, whether for primary or secondary prevention or indeed both, and that it would contain multiple ingredients. Beyond this, their knowledge appeared limited. Most (10) were uncertain about how they might use it, and what drugs at what doses would be in it. Some (3) mentioned their knowledge was based on what they had read in journals or seen in the media.

#### Use of the polypill for primary prevention

All interviewees (16) expressed concern about using the polypill for primary prevention for everyone over a specific age. Most concerns were regarding: potential side-effects; difficulty in identifying the ingredient(s) causing side-effects; and the built-in inability to titrate the ingredients and dose. Other concerns raised were: unnecessary medicalisation of healthy people; lack of evidence demonstrating effectiveness; and the potential negative impact on health related behaviour, possibly leading to complacency about leading a healthy lifestyle.

Despite apprehension, half of health care professionals (8) recognised the possible advantages of administering a polypill to everyone over a specific age: mainly the potential to reduce the risk of developing cardiovascular disease at a population level. Hence a number (5) were receptive towards a population approach, although the majority (10) thought the polypill should only be given to those with cardiovascular disease risk factors.

#### Use of the polypill for secondary prevention

Of those interviewees (8) who discussed using the polypill for secondary prevention, most (6) appeared positive believing it would be more practical for patients to take thereby improving compliance. However, a minority (2) questioned its value for secondary prevention as it would merely be a combined replacement of current cardiovascular disease medication.

# Monitoring patients taking the polypill (table 3)

Health care professionals reflected upon both regular and minimal monitoring of patients taking the polypill.

#### Regular monitoring of patients

Almost all participants (15) felt it was essential to regularly monitor patients taking the polypill to: check the medication was both safe and effective, especially as it is a new drug; screen for and encourage patient compliance; and because of the perception that most prescribed medications require some degree of monitoring. Only one respondent felt regular monitoring was unnecessary otherwise the polypill would become unfeasible, although he highlighted the dose would need to be considered safe enough.

#### Minimal monitoring of patients

The idea of minimal monitoring of patients taking the polypill caused major unease amongst most health care professionals (11), with two claiming such a strategy to be negligent.

Several (7) claimed they would need to see evidence that minimal monitoring was deemed appropriate before they could be convinced to adopt this practice. Others (4) argued they would monitor patients regularly even if the advice was that it was unnecessary.

#### Prescribing the polypill (table 4)

Although all health care professionals (16) would consider prescribing the polypill, there appeared to be several factors influencing their willingness. These could be divided into four groups relating to: their personal values; features of the drug; external issues; and patient factors.

#### Personal factors

For many respondents (10), personal beliefs regarding unnecessary medicalisation meant they would not prescribe the polypill without an indication in addition to age alone.

#### **Drug** factors

There were three important factors about the polypill that were deemed to have an influence on whether or not health care professionals would prescribe it: cost; monitoring; and titration. According to just under half (7) if the polypill was cost-effective for both patients and the National Health Service, they would be more likely to prescribe. However, others (5) stated cost would have no bearing on their decision if the outcome was beneficial. Some respondents (6) claimed they would be more willing to prescribe the polypill if they could monitor patients. Quite a few (6) had concerns over the inability to titrate it which meant they were reluctant about prescribing.

#### External factors

Two external factors, evidence and guidance from the Department of Health (DoH), seemed to impact on participants' decision to prescribe the polypill. Most (13) claimed the evidence

demonstrating the polypill to be safe, effective and beneficial would be a major determinant in their judgement. Two said if the DoH endorsed its prescribing, they would then do so.

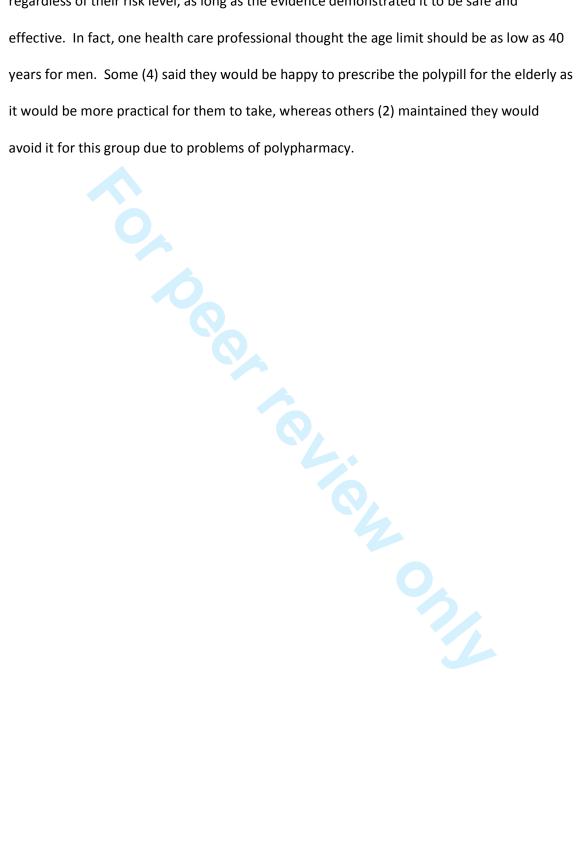
#### Patient factors

There were several patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications) and one socio-demographic factor (age) that influenced health care professionals views regarding potential prescription of the polypill.

Most (10) claimed they would be more willing to prescribe the medication as a preventative measure for people with risk factors. Many (9) also believed their willingness would be influenced by the patient's choice to take the medication. A number of participants (7) mentioned they would not offer the polypill to patients who had experienced previous side-effects from the individual ingredients. Several (6) believed they would prescribe the polypill for patients on treatment for existing cardiovascular disease as a replacement for practical reasons. Others (4) thought they would avoid medicating these patients with the polypill since they require titrated dosages. Where patients had problems complying with multiple medications, some respondents (4) said they would be more likely to prescribe the polypill. A few (4) also suggested they would be less keen to offer the polypill to patients with complex medical conditions or who were on certain medications due to possible contra-indications.

In terms of age, the majority of interviewees (10) did not believe in prescribing the polypill to everyone over 50 years for primary prevention unless there were risk factors. However, several (5) claimed they would be willing to offer the medication to this population

regardless of their risk level, as long as the evidence demonstrated it to be safe and effective. In fact, one health care professional thought the age limit should be as low as 40



#### Discussion

# **Summary of main findings**

Health care professionals were sceptical about the role of a polypill. A major concern was they did not feel the evidence base for a polypill had been established. They were particularly reluctant to prescribe on the basis of age and felt ongoing monitoring of blood pressure and cholesterol would be required. The inability to titrate dose in the polypill was seen as a further disadvantage. There was greater willingness to consider its use for secondary prevention, but with the same provisos about wanting to continue monitoring and with concerns about inability to adjust dose.

# Comparison with existing literature

As with a previous survey study, <sup>18</sup> we found health care professionals were more accepting of a polypill for secondary prevention perhaps because for those with existing cardiovascular disease there is a greater perceived need for medication. However, we discovered a lower level of acceptance for primary prevention, with more concerns regarding the pill itself. This may reflect typically slower uptake of new drugs by primary care physicians in the UK compared to other countries, <sup>38</sup> with many describing themselves as 'cautious' or 'conservative' in their prescribing behaviour. <sup>39</sup>

In our study, health care professionals disliked the concept of minimal monitoring of patients taking the polypill, a finding consistent with earlier studies. <sup>18,19</sup> This reflects current practice where patients are monitored for a number of reasons, including side-effects, effectiveness and compliance. Nevertheless, current National Institute for Health and

Clinical Excellence guidelines on lipid lowering therapy for primary prevention do not recommend monitoring, <sup>6</sup> so attitudes may change.

## **Strengths and limitations**

A study strength is that all interviews were carried out by a single researcher thereby ensuring consistency. <sup>40</sup> The researcher was non-medical, and health care professionals' responses may have been different if the researcher had been a clinician.

The study's qualitative approach allowed an in-depth exploration of attitudes not possible in quantitative surveys. Study participants were recruited from a single major city. Sixteen of the 50 approached were interviewed and we are not able to comment on how prevalent the views expressed in this study are in the wider population of primary health care professionals or those from other healthcare systems. Also, what respondents suggested they would do is not necessarily what they would actually do in reality.

Although the aim of qualitative research is not to be generalisable, <sup>41</sup> we did have a representative sample of respondents across gender and ethnicity. Our sample size was also sufficient to achieve saturation. <sup>42</sup>

#### **Implications**

This study suggests despite potential acceptance of use of a polypill for secondary prevention, health care professionals interviewed remained concerned that monitoring should continue. With regard to primary prevention, there was considerable resistance to a population strategy offering the polypill to everyone over a certain age. This reflected both a concern about the lack of empirical evidence of the polypill's effectiveness and safety, and a concern regarding medicalisation. If a polypill is to be used in this way, based on our

respondents views it is likely health care professionals would need to be convinced about



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Table 1: Health care professional characteristics

#### Knowledge and understanding of the polypill

Would be used for cardiovascular disease prevention

"[The polypill is]...hoping to reduce heart attacks and heart disease and stroke and things like that really...regardless of whether or not they have hypertension or ischemic heart disease at the time." (Primary care physician 4)

Uncertainty over aspects of polypill

"...you're only going to put these people on primary prevention if they're at risk, aren't you? It's not for everybody is it?"

(Primary care physician 10)

Knowledge based on journals and media

"...I don't know what the thinking behind the use of it is other than what I've read in the national press." (Primary care physician 8)

#### Use of the polypill for primary prevention

Concerns regarding actual polypill

"...one would intellectually feel that if you put five pills in a pill, or four pills in a pill, more people are gonna react to it than if you've got one pill." (Primary care physician 3)

"I think you need titration, individual titration of different medications for individual people...so I can't imagine that one pill will work for everybody." (Practice nurse 3)

Unnecessary medicalisation

"...its [the polypill] just another medication that you'd be committing the person to really...I just think it's unnecessary. I think we should be teaching people, well people, how to keep themselves well without offering them preventive things, in the way of medication that is." (Practice nurse 1)

Lack of evidence demonstrating effectiveness

"...if you've got evidence that it works, then it would be easy for me to support. No, the evidence doesn't exist."

(Primary care physician 8)

Negative impact on patient lifestyle

"...it may very well give people a false sense of security...they'll continue to eat and drink too much, and smoke too much and take the polypill...it may make no difference whatsoever to them." (Primary care physician 4)

May reduce cardiovascular disease risk

"...the possibilities are that it might reduce a populations' risk of heart disease and stroke." (Primary care physician 11)

"You would reach a population that you wouldn't otherwise reach, then you're broadening the service you're providing and reducing cardiovascular risk." (Primary care physician 8)

Should only be for those with risk factors

"It [the polypill] should only be for those at risk of a cardiovascular attack...especially if there's any history of cardiovascular disease in the family." (Primary care physician 2)

#### Use of the polypill for secondary prevention

Practical for patients

"...it just saves taking lots of tablets often: I think compliance probably would be better." (Practice nurse 5)

Lack of purpose

"...secondary prevention: I'm not so sure about because we are supposed to be treating these patients anyway...so there is a question really about...well the purpose really." (Primary care physician 11)

Table 2: Attitude towards the Polypill

#### Regular monitoring of patients

To check it is safe and effective

"...how will you know it's actually being effective in terms of reducing blood pressure if it's not monitored?" (Practice nurse 3)

"...you need to see the side-effects...by monitoring. You need to see whether they are developing anything else as well."

(Primary care physician 7)

To screen for and encourage compliance

"...just to reassure [patients] that yes it is working, because I think some people might stop taking it and then not bother coming back, and then you've got problems with non-compliance again." (Practice nurse 5)

Medications are normally monitored

"...if someone's on a drug then historically they are monitored...not to monitor would be difficult." (Practice nurse 4)

Polypill is only feasible with no monitoring

"I think the polypill is only feasible if there is no monitoring associated with it...it's probably only feasible if the dose is considered safe enough not to be monitored." (Primary care physician 11)

#### Minimal monitoring of patients

Cause for concern

"That as a GP does not sit comfortably...if you're prescribing medication you have an ethical and a moral obligation to monitor this person." (Primary care physician 10)

"You don't give people medicines without seeing what it's going to do: that's pure negligent..." (Primary care physician 1)

Need to see the evidence

"So if the evidence was you don't have to monitor a polypill then I would say fine...but you've got to give me the evidence that that's an okay way to behave before I would consider that..." (Primary care physician 8)

Would still monitor

"...if the advice was saying not to monitor I'd still want to...for the patients sake and my sake." (Primary care physician 6)

#### Table 3: Monitoring patients taking the Polypill

#### **Personal factors**

"...it's not my ethos to medicate well people to prevent the normal ageing process..." (Primary care physician 8)

"I just don't believe that there's a pill for every ill...later in life you are probably going to develop some problems with your blood pressure and maybe your cholesterol levels won't stay the same...I think you really have to live with them, you can't expect to be taking a tablet for every little change that's happening in your body." (Practice nurse 1)

#### Drug factors (cost, monitoring, titration)

"...if it's researched based, it's shown to have fantastic results, it's cost effective...yes I would prescribe it." (Practice nurse 2)

"...I would be happy prescribing it if I could watch people carefully for a while and see how they feel about it." (Practice nurse 3)

"...unless there are different doses of combinations of polypills, just giving one to somebody might not necessarily be the right one for that person." (Primary care physician 10)

#### External factors (evidence, guidance)

"...I would be happy [to prescribe the polypill], provided I've got enough data to go on...I think everything hinges on that actually." (Primary care physician 7)

"If our PCT and the Department of Health feel it's a good thing, then yes I would prescribe it." (Practice nurse 2)

# Patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications, age)

"...patients would have to be selected on the basis of their family history...if the family history contains ischaemic heart disease then they're the ones we should be picking first." (Primary care physician 4)

"I think we should give patients options. I don't think we should be saying "oh that is the one". It's very much a personal choice for the patient." (Primary care physician 5)

"Somebody who's had an adverse reaction to any of those things that are in it [the polypill], I honestly wouldn't prescribe it, just like you wouldn't prescribe that drug to them." (Primary care physician 2)

"Secondary prevention patients – if we're going to combine some of the medications that they're already on into a polypill so they're taking fewer tablets...they might be interested." (Primary care physician 1)

"...it very much depends on the type of patient...some people will probably just be happier to take one pill rather than a couple...people who have a problem with compliance...it would be the right one for them..." (Primary care physician 5)

"...I don't know if it is contraindicated with people with certain conditions or people who are on certain medications like warfarin for instance...that could be a barrier." (Practice nurse 2)

"If they haven't got any risk factors for cardiovascular disease, I don't think everybody over the age of 50 should be taking it. I don't think I'll agree to that." (Primary care physician 5)

"...[the polypill] couldn't just be handed out to everybody over the age of 50, unless the studies and research suggested that there were no adverse effects and anyone could take the drug...even if they didn't have hypertension." (Practice nurse 4)

Table 4: Prescribing the Polypill

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# Would primary health care professionals prescribe a polypill to manage cardiovascular risk? A qualitative interview study

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#### Abstract

## **Objectives**

A 'polypill' containing both blood pressure and cholesterol lowering drugs could prevent up to 80% of cardiovascular disease events. Since little is known about the attitudes of primary health care professionals to use of such a pill for cardiovascular disease prevention, this study aimed to investigate opinions.

#### Design

Semi-structured interviews were conducted with participants. A qualitative description approach was used to analyse and report the results.

#### Setting

Participants were recruited from nine primary care practices in Birmingham.

# **Participants**

Sixteen health care professionals (11 primary care physicians and 5 practice nurses) were selected through purposive sampling to maximise variation of characteristics.

#### **Outcome measures**

Outcome measures for this study were: the attitude of health care professionals towards the use of a polypill for primary and secondary cardiovascular disease prevention; their views on monitoring the drug; and the factors influencing their willingness to prescribe the medication.

#### **Results**

Health care professionals expressed considerable concern over using a polypill for primary prevention for all people over a specific age, although there was greater acceptance of its use for secondary prevention. Regularly monitoring patients taking the polypill was deemed essential. Evidence of effectiveness, patient risk level and potential medicalisation were key determinants in willingness to prescribe such a pill.

#### Conclusions

Primary health care professionals have significant concerns about the use of a polypill, particularly in the prevention of cardiovascular disease in people who are not regarded as being at 'high risk'. If a population based polypill strategy is to be successfully implemented, health care professionals will need to be convinced of the potential benefits of a drug based population approach to prevention.

# **Article summary**

#### Article focus

- A 'polypill' containing several blood pressure and cholesterol lowering drugs has
  large theoretical benefits in terms of reducing cardiovascular morbidity. Short term
  trials have demonstrated its efficacy.
- Although small scale surveys of physicians suggest that the use of the polypill may be
  acceptable to health care professionals, they have not provided detailed data on
  attitudes to the polypill.
- The aim of this study was to investigate the attitude of health care professionals to the use of a polypill for cardiovascular disease prevention.

#### **Key messages**

- There was considerable resistance towards the use of a polypill for the prevention of cardiovascular disease in people not regarded as being at 'high risk'.
- Evidence of efficacy was judged important but potential medicalisation and an ongoing need for monitoring were significant issues for many health care professionals.
- If a population based polypill strategy is to be introduced, significant barriers from professionals will need to be overcome.

#### Strengths and limitations of this study

 The study's qualitative approach allowed a detailed exploration of attitudes not possible in quantitative surveys.

Conversely, we cannot comment on how prevalent the views expressed in this study
are in the wider population of health care professionals.



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**Competing interests:** None declared.

**Contributors:** The study was designed by SKV, SMG, KF and JM. SKV conducted the interviews, analysed the data and drafted the paper. SKV, SMG and JM contributed to subsequent drafts. All authors critically revised the paper.

**Data sharing statement:** No additional data available.

#### Introduction

Cardiovascular disease remains the major cause of morbidity and mortality worldwide.<sup>1</sup> There have been significant advances in the evidence base for cardiovascular disease prevention, particularly regarding pharmacological interventions aimed at lowering blood pressure<sup>2,3</sup> and cholesterol.<sup>4</sup> Guidelines recommend use of these agents for both secondary and primary prevention in people at raised cardiovascular risk.<sup>5,6</sup> However repeated surveys have shown many patients are not being treated as intensively as guidelines recommend. 7,8 7-9 Furthermore, the majority of cardiovascular events occur in people not at high risk using conventional risk calculators. 10 Therefore, offering a 'polypill' to everyone over a particular age (for example 55) has been proposed. 11 This involves a single daily combined pill containing both blood pressure and cholesterol lowering agents at a fixed low dose (to reduce adverse effects) with minimal monitoring required, as opposed to titrating individual treatments to specific targets.— The original idea involved a six component pill (three blood pressure lowering agents; cholesterol lowering agent; folate; and aspirin), but due to question marks over the efficacy of folate and the appropriateness of aspirin use for primary prevention, this now typically involves a single daily combined pill containing just blood pressure and cholesterol lowering agents. Since the idea was first raised, the evidence base for the potential role of a polypill has grown. There is more evidence that the effect of blood pressure lowering on cardiovascular risk is independent of baseline blood pressure, 12 and that reduction of LDL cholesterol is beneficial in those at low risk of vascular disease. 13 Meta-analysis of early trials show that polypills do indeed lower blood pressure and serum cholesterol levels. 14

The polypill may also have a role in people with known cardiovascular risk factors, since it may lead to better patient adherence. Wald and Law estimate adopting a polypill strategy could prevent 80% of strokes and 88% of ischaemic heart disease events, with low risk of adverse effects.

If used in the UK, it is likely that the polypill would largely be prescribed and monitored within primary care. Implementation would require considerable professional engagement but to date there has been limited research on the polypill's professional acceptability.

Three small practitioner surveys have been conducted, but none in the UK. Holt<sup>17</sup> found from a survey of 17 New Zealand primary care physicians almost all were familiar with the polypill. They were keen on its simplicity and the likely increased compliance, but disliked the lack of flexibility of the components and doses. More recently, Soliman at el<sup>18</sup> surveyed 58 Sri Lankan physicians and discovered a high degree of acceptability of prescribing the polypill for primary prevention and even higher for secondary prevention. Viera et al's<sup>19</sup> findings from a survey of 952 US physicians also revealed relatively high acceptance, but low agreement to minimal monitoring. Such surveys whilst useful in gauging high level opinion, cannot explore detailed issues around acceptability in any depth.

The polypill has been used in a range of settings. This paper reports on a study in Birmingham, UK, which used a qualitative description approach<sup>20,21</sup> to investigate UK health care professionals' i.e. primary care physicians' and practice nurses' attitude towards using the polypill for cardiovascular disease prevention and the drug's practicality for monitoring and prescribing.

#### Method

#### Participants and sampling

11 Birmingham primary care practices agreed to participate of 20 initially approached.

Practices were purposively selected to maximise variation in our sample. They were chosen to represent different sizes (number of full-time equivalent primary care physicians) as practice size is known to affect prescribing behaviour. Practices were also selected to reflect different levels of socio-economic deprivation (Indices of Multiple Deprivation (IMD) score of the practice area) since cardiovascular need tends to be higher in practices based in relatively deprived areas. The IMD score is a single deprivation score combining a number of indicators covering a range of economic, social and housing issues. Scores were divided into quartiles, one representing the least deprived areas and four the most. To contextualise this work, Birmingham consists of a population of about one million people including diverse ethnic groups with one-third from a non-white background.

The 56 primary care physicians and 22 practice nurses in the 11 practices were sent a postal questionnaire enquiring about their gender, ethnicity (2001 general census ethnic categories)<sup>27</sup> and year of qualification, together with a 'Beliefs about Medicines Questionnaire (BMQ)-General.<sup>28</sup> This includes two scales (General-Harm and General-Overuse) to measure respondents' attitudes to medicines in general. High scores indicate a greater belief that medicines are harmful and overused. This was used for sampling to ensure a range of views on general medication usage. Since we wanted respondents with extreme views and moderate beliefs and there appeared to be different ways to interpret scores,<sup>29-31</sup> we divided respondents' scores into tertiles, scores between 8-15 being categorised as low, 16-22 as medium and 23-34 as high.

58 (74%) health care professionals returned a completed BMQ-General. Respondents were sampled on these scores as well as a maximum variety of individual (occupation, gender, ethnicity, qualification year) and organisational (practice size, practice IMD score) characteristics to allow a diversity of responses to emerge. 50 health care professionals (41 primary care physicians and 9 practice nurses) were selected and approached by letter, and 16 (11 primary care physicians and 5 practice nurses) agreed to interview across 9 practices.

#### **Interviews**

Semi-structured interviews were used to elicit health care professionals views as they provide an opportunity for in-depth investigation of personal perspectives, detailed understanding and chance for clarification. The interview guide was developed through a discussion of the polypill and cardiovascular disease literature by research team members (SKV, SMG, KF and JM) and covered: health care professionals' understanding of the polypill; their attitude towards its use; and prescribing and monitoring the drug. Ethical approval to conduct the interviews was granted by the Birmingham, East, North and Solihull Research Ethics Committee (08/H1206/91). Signed informed consent was obtained before the interview. All interviews were carried out at the practices by one of the authors (SKV) from March to October 2009. Interviews lasted between 30-60 minutes, were audio recorded and transcribed verbatim.

#### **Analysis**

All transcripts were checked against the recording for accuracy. As part of the process of respondent validation,<sup>33</sup> health care professionals were sent a copy of their transcript and a brief summary of the interview for comments. Only one additional comment was made.

Although the advantages and disadvantages of this process have been documented,<sup>34</sup> since this is the first qualitative study on the polypill and it was a new concept for interviewees, it was felt important to do this.

Throughout the analytic process each transcript was compared with others to develop conceptualisations of the possible relations between various pieces of data and key areas.<sup>35</sup> Interviews continued until the authors (SKV, SMG and KF) agreed saturation had been achieved. Transcripts and field notes were read independently by the authors (SKV, SMG and KF) and the subthemes identified in each key area.<sup>20</sup> These were discussed by the multidisciplinary team of clinicians and non-clinicians and a thematic coding framework was developed to code each transcript systematically. Framework software was used to aid data organisation.<sup>36</sup>

#### Results

# **Participants**

There were similar numbers of men and women (table 1) but all practice nurses were female and most primary care physicians were male. Seven participants were from a minority ethnic group (3 Indian; 1 White Irish; 1 Chinese; and 2 other). Most gained their professional qualification between 1970 and 1989. Participants had a full range of attitudes towards medicines determined by their BMQ-General score, but the four respondents with more positive attitudes towards medicines were all practice nurses.

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#### **Key areas**

To facilitate comparison of comments and contextualise subthemes, these are presented within each of the three key areas: attitude towards the polypill; opinions on monitoring; and views on prescribing. The number of respondents discussing each subtheme is reported (denominator 16 participants)-<sup>32</sup> 37 in order to contextualise the findings and facilitate a comparison between respondents. Interview extracts representative of each subtheme are shown in tables 2-4. Comparison of the subthemes did not reveal any relationship between health care professionals' characteristics and their views on the polypill in managing cardiovascular risk.

#### Attitude towards the polypill (table 2)

Health care professionals discussed their attitude towards the polypill in terms of what they already knew and understood about it, and their thoughts about using the medication for primary and secondary prevention.

## Knowledge and understanding of the polypill

The majority of respondents (11) understood the polypill would be used for cardiovascular disease prevention, whether for primary or secondary prevention or indeed both, and that it would contain multiple ingredients. Beyond this, their knowledge appeared limited. Most (10) were uncertain about how they might use it, and what drugs at what doses would be in it. Some (3) mentioned their knowledge was based on what they had read in journals or seen in the media.

## Use of the polypill for primary prevention

All interviewees (16) expressed concern about using the polypill for primary prevention for everyone over a specific age. Most concerns were regarding: potential side-effects; difficulty in identifying the ingredient(s) causing side-effects; and the built-in inability to titrate the ingredients and dose. Other concerns raised were: unnecessary medicalisation of healthy people; lack of evidence demonstrating effectiveness; and the potential negative impact on health related behaviour, possibly leading to complacency about leading a healthy lifestyle.

Despite apprehension, half of health care professionals (8) recognised the possible advantages of administering a polypill to everyone over a specific age: mainly the potential to reduce the risk of developing cardiovascular disease at a population level. Hence a number (5) were receptive towards a population approach, although the majority (10) thought the polypill should only be given to those with cardiovascular disease risk factors.

#### Use of the polypill for secondary prevention

Of those interviewees (8) who discussed using the polypill for secondary prevention, most (6) appeared positive believing it would be more practical for patients to take thereby improving compliance. However, a minority (2) questioned its value for secondary prevention as it would merely be a combined replacement of current cardiovascular disease medication.

# Monitoring patients taking the polypill (table 3)

Health care professionals reflected upon both regular and minimal monitoring of patients taking the polypill.

## Regular monitoring of patients

Almost all participants (15) felt it was essential to regularly monitor patients taking the polypill to: check the medication was both safe and effective, especially as it is a new drug; screen for and encourage patient compliance; and because of the perception that most prescribed medications require some degree of monitoring. Only one respondent felt regular monitoring was unnecessary otherwise the polypill would become unfeasible, although he highlighted the dose would need to be considered safe enough.

## Minimal monitoring of patients

The idea of minimal monitoring of patients taking the polypill caused major unease amongst most health care professionals (11), with two claiming such a strategy to be negligent.

Several (7) claimed they would need to see evidence that minimal monitoring was deemed appropriate before they could be convinced to adopt this practice. Others (4) argued they would monitor patients regularly even if the advice was that it was unnecessary.

# Prescribing the polypill (table 4)

Although all health care professionals (16) would consider prescribing the polypill, there appeared to be several factors influencing their willingness. These could be divided into four groups relating to: their personal values; features of the drug; external issues; and patient factors.

# Personal factors

For many respondents (10), personal beliefs regarding unnecessary medicalisation meant they would not prescribe the polypill without an indication in addition to age alone.

## **Drug** factors

There were three important factors about the polypill that were deemed to have an influence on whether or not health care professionals would prescribe it: cost; monitoring; and titration. According to just under half (7) if the polypill was cost-effective for both patients and the National Health Service, they would be more likely to prescribe. However, others (5) stated cost would have no bearing on their decision if the outcome was beneficial. Some respondents (6) claimed they would be more willing to prescribe the polypill if they could monitor patients. Quite a few (6) had concerns over the inability to titrate it which meant they were reluctant about prescribing.

## External factors

Two external factors, evidence and guidance from the Department of Health (DoH), seemed to impact on participants' decision to prescribe the polypill. Most (13) claimed the evidence

demonstrating the polypill to be safe, effective and beneficial would be a major determinant in their judgement. Two said if the DoH endorsed its prescribing, they would then do so.

## Patient factors

There were several patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications) and one socio-demographic factor (age) that influenced health care professionals views regarding potential prescription of the polypill.

Most (10) claimed they would be more willing to prescribe the medication as a preventative measure for people with risk factors. Many (9) also believed their willingness would be influenced by the patient's choice to take the medication. A number of participants (7) mentioned they would not offer the polypill to patients who had experienced previous side-effects from the individual ingredients. Several (6) believed they would prescribe the polypill for patients on treatment for existing cardiovascular disease as a replacement for practical reasons. Others (4) thought they would avoid medicating these patients with the polypill since they require titrated dosages. Where patients had problems complying with multiple medications, some respondents (4) said they would be more likely to prescribe the polypill. A few (4) also suggested they would be less keen to offer the polypill to patients with complex medical conditions or who were on certain medications due to possible contra-indications.

In terms of age, the majority of interviewees (10) did not believe in prescribing the polypill to everyone over 50 years for primary prevention unless there were risk factors. However, several (5) claimed they would be willing to offer the medication to this population

regardless of their risk level, as long as the evidence demonstrated it to be safe and effective. In fact, one health care professional thought the age limit should be as low as 40



## Discussion

# **Summary of main findings**

Health care professionals were sceptical about the role of a polypill. A major concern was they did not feel the evidence base for a polypill had been established. They were particularly reluctant to prescribe on the basis of age and felt ongoing monitoring of blood pressure and cholesterol would be required. The inability to titrate dose in the polypill was seen as a further disadvantage. There was greater willingness to consider its use for secondary prevention, but with the same provisos about wanting to continue monitoring and with concerns about inability to adjust dose.

# Comparison with existing literature

As with a previous survey study, <sup>18</sup> we found health care professionals were more accepting of a polypill for secondary prevention perhaps because for those with existing cardiovascular disease there is a greater perceived need for medication. However, we discovered a lower level of acceptance for primary prevention, with more concerns regarding the pill itself. This may reflect typically slower uptake of new drugs by primary care physicians in the UK compared to other countries, <sup>38</sup> with many describing themselves as 'cautious' or 'conservative' in their prescribing behaviour. <sup>39</sup>

In our study, health care professionals disliked the concept of minimal monitoring of patients taking the polypill, a finding consistent with earlier studies. <sup>18,19</sup> This reflects current practice where patients are monitored for a number of reasons, including side-effects, effectiveness and compliance. Nevertheless, current National Institute for Health and

Clinical Excellence guidelines on lipid lowering therapy for primary prevention do not recommend monitoring, <sup>6</sup> so attitudes may change.

# **Strengths and limitations**

A study strength is that all interviews were carried out by a single researcher thereby ensuring consistency. <sup>40</sup> The researcher was non-medical, and health care professionals' responses may have been different if the researcher had been a clinician.

The study's qualitative approach allowed an in-depth exploration of attitudes not possible in quantitative surveys. Study participants were recruited from a single major city. Sixteen of the 50 approached were interviewed Conversely, and we are not able to comment on how prevalent the views expressed in this study are in the wider population of primary health care professionals or those from other healthcare systems. Also, what respondents suggested they would do is not necessarily what they would actually do in reality.

Although the aim of qualitative research is not to be generalisable, <sup>41</sup> we did have a representative sample of respondents across gender and ethnicity. Our sample size was also sufficient to achieve saturation. <sup>42</sup>

## **Implications**

This study suggests despite potential acceptance of use of a polypill for secondary prevention, health care professionals <u>interviewed</u> remained concerned <u>that</u> monitoring should continue. With regard to primary prevention, there was considerable resistance to a population strategy offering the polypill to everyone over a certain age. This reflected both a concern about the lack of empirical evidence of the polypill's effectiveness and safety, and a concern regarding medicalisation. If a polypill is to be used in this way, <u>based on our</u>

respondents views it is likely health care professionals would need to be convinced about



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Table 1: Health care professional characteristics

#### Knowledge and understanding of the polypill

Would be used for cardiovascular disease prevention

"[The polypill is]...hoping to reduce heart attacks and heart disease and stroke and things like that really...regardless of whether or not they have hypertension or ischemic heart disease at the time." (Primary care physician 4)

Uncertainty over aspects of polypill

"...you're only going to put these people on primary prevention if they're at risk, aren't you? It's not for everybody is it?"

(Primary care physician 10)

Knowledge based on journals and media

"...I don't know what the thinking behind the use of it is other than what I've read in the national press." (Primary care physician 8)

#### Use of the polypill for primary prevention

Concerns regarding actual polypill

"...one would intellectually feel that if you put five pills in a pill, or four pills in a pill, more people are gonna react to it than if you've got one pill." (Primary care physician 3)

"I think you need titration, individual titration of different medications for individual people...so I can't imagine that one pill will work for everybody." (Practice nurse 3)

Unnecessary medicalisation

"...its [the polypill] just another medication that you'd be committing the person to really...I just think it's unnecessary. I think we should be teaching people, well people, how to keep themselves well without offering them preventive things, in the way of medication that is." (Practice nurse 1)

Lack of evidence demonstrating effectiveness

"...if you've got evidence that it works, then it would be easy for me to support. No, the evidence doesn't exist."

(Primary care physician 8)

Negative impact on patient lifestyle

"...it may very well give people a false sense of security...they'll continue to eat and drink too much, and smoke too much and take the polypill...it may make no difference whatsoever to them." (Primary care physician 4)

May reduce cardiovascular disease risk

"...the possibilities are that it might reduce a populations' risk of heart disease and stroke." (Primary care physician 11)

"You would reach a population that you wouldn't otherwise reach, then you're broadening the service you're providing and reducing cardiovascular risk." (Primary care physician 8)

Should only be for those with risk factors

"It [the polypill] should only be for those at risk of a cardiovascular attack...especially if there's any history of cardiovascular disease in the family." (Primary care physician 2)

## Use of the polypill for secondary prevention

Practical for patients

"...it just saves taking lots of tablets often: I think compliance probably would be better." (Practice nurse 5)

Lack of purpose

"...secondary prevention: I'm not so sure about because we are supposed to be treating these patients anyway...so there is a question really about...well the purpose really." (Primary care physician 11)

Table 2: Attitude towards the Polypill

#### Regular monitoring of patients

To check it is safe and effective

"...how will you know it's actually being effective in terms of reducing blood pressure if it's not monitored?" (Practice nurse 3)

"...you need to see the side-effects...by monitoring. You need to see whether they are developing anything else as well."

(Primary care physician 7)

To screen for and encourage compliance

"...just to reassure [patients] that yes it is working, because I think some people might stop taking it and then not bother coming back, and then you've got problems with non-compliance again." (Practice nurse 5)

Medications are normally monitored

"...if someone's on a drug then historically they are monitored...not to monitor would be difficult." (Practice nurse 4)

Polypill is only feasible with no monitoring

"I think the polypill is only feasible if there is no monitoring associated with it...it's probably only feasible if the dose is considered safe enough not to be monitored." (Primary care physician 11)

# Minimal monitoring of patients

Cause for concern

"That as a GP does not sit comfortably...if you're prescribing medication you have an ethical and a moral obligation to monitor this person." (Primary care physician 10)

"You don't give people medicines without seeing what it's going to do: that's pure negligent..." (Primary care physician 1)

Need to see the evidence

"So if the evidence was you don't have to monitor a polypill then I would say fine...but you've got to give me the evidence that that's an okay way to behave before I would consider that..." (Primary care physician 8)

Would still monitor

"...if the advice was saying not to monitor I'd still want to...for the patients sake and my sake." (Primary care physician 6)

## Table 3: Monitoring patients taking the Polypill

## **Personal factors**

"...it's not my ethos to medicate well people to prevent the normal ageing process..." (Primary care physician 8)

"I just don't believe that there's a pill for every ill...later in life you are probably going to develop some problems with your blood pressure and maybe your cholesterol levels won't stay the same...I think you really have to live with them, you can't expect to be taking a tablet for every little change that's happening in your body." (Practice nurse 1)

## Drug factors (cost, monitoring, titration)

"...if it's researched based, it's shown to have fantastic results, it's cost effective...yes I would prescribe it." (Practice nurse 2)

"...I would be happy prescribing it if I could watch people carefully for a while and see how they feel about it." (Practice nurse 3)

"...unless there are different doses of combinations of polypills, just giving one to somebody might not necessarily be the right one for that person." (Primary care physician 10)

#### External factors (evidence, guidance)

"...I would be happy [to prescribe the polypill], provided I've got enough data to go on...I think everything hinges on that actually." (Primary care physician 7)

"If our PCT and the Department of Health feel it's a good thing, then yes I would prescribe it." (Practice nurse 2)

# Patient factors (risk level, patient choice, previous side-effects, existing cardiovascular disease, compliance, other medical conditions/medications, age)

"...patients would have to be selected on the basis of their family history...if the family history contains ischaemic heart disease then they're the ones we should be picking first." (Primary care physician 4)

"I think we should give patients options. I don't think we should be saying "oh that is the one". It's very much a personal choice for the patient." (Primary care physician 5)

"Somebody who's had an adverse reaction to any of those things that are in it [the polypill], I honestly wouldn't prescribe it, just like you wouldn't prescribe that drug to them." (Primary care physician 2)

"Secondary prevention patients – if we're going to combine some of the medications that they're already on into a polypill so they're taking fewer tablets...they might be interested." (Primary care physician 1)

"...it very much depends on the type of patient...some people will probably just be happier to take one pill rather than a couple...people who have a problem with compliance...it would be the right one for them..." (Primary care physician 5)

"...I don't know if it is contraindicated with people with certain conditions or people who are on certain medications like warfarin for instance...that could be a barrier." (Practice nurse 2)

"If they haven't got any risk factors for cardiovascular disease, I don't think everybody over the age of 50 should be taking it. I don't think I'll agree to that." (Primary care physician 5)

"...[the polypill] couldn't just be handed out to everybody over the age of 50, unless the studies and research suggested that there were no adverse effects and anyone could take the drug...even if they didn't have hypertension." (Practice nurse 4)

Table 4: Prescribing the Polypill

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