

## Patients' views about taking a polypill to manage cardiovascular risk:

a qualitative study in primary care

### Abstract

#### Background

A 'polypill' containing a combination of antihypertensives and statins could prevent up to 80% of cardiovascular disease (CVD) events.

#### Aim

To investigate patients' opinions about the use of a polypill for CVD prevention.

#### Design and setting

Qualitative study of 17 patients from seven primary care practices in Birmingham, UK.

#### Method

Patients were recruited through purposive sampling to maximise variation of characteristics. Semi-structured interviews were conducted with responders. Results were analysed and reported using a qualitative description approach.

#### Results

Patients expressed concerns that polypill prescription for primary prevention simply on the basis of age was unnecessary and would lead to side effects, despite recognising potential benefits. For high-risk patients, or for secondary prevention, a polypill was deemed more acceptable, but was still felt to require regular monitoring of blood pressure and cholesterol.

#### Conclusion

Patients were sceptical about the role of a polypill as a 'blanket' approach. If a population strategy offering a polypill to all people over a certain age was to be implemented, it would need to be supported by patient education.

#### Keywords

blood pressure; cardiovascular disease; cholesterol; patients' views; polypill; prevention; primary care; risk factors.

### INTRODUCTION

Cardiovascular disease (CVD) is a leading cause of morbidity and mortality worldwide.<sup>1</sup> Pharmacological interventions aimed at lowering blood pressure and cholesterol can reduce the risk of CVD.<sup>2-4</sup> Conventionally, these drugs are given to people who have an indication, either by virtue of having 'hypertension' or because they are at raised cardiovascular risk.<sup>5</sup> An alternative strategy is to offer everyone over a specific age a daily 'polypill' containing proven medications to reduce cardiovascular risk.<sup>6</sup> Such a pill could also be used for patients with established CVD as it may improve adherence.<sup>7,8</sup> Wald and Law estimated that a polypill strategy could prevent 80% of strokes and 88% of ischaemic heart disease events, with a low risk of adverse effects.<sup>6</sup>

One of the major challenges of successfully implementing a polypill strategy is gaining acceptance from patients. Only one study, a quantitative survey, has been conducted on patients' attitudes to a polypill. It found that approximately 90% of patients in a Sri Lankan polypill trial would either 'definitely' or 'probably' take a polypill for primary prevention if proven to be effective in reducing CVD risk.<sup>9</sup> In terms of patients' attitudes towards combined pills in general, most see little clinical benefit in changing from an established, effective, and tolerable regimen to one that

is less flexible and may not reflect their current dosages, although some would be willing to try a combined pill if suggested by their doctor.<sup>10</sup> When it comes to statins, studies have shown patients have concerns regarding unwanted side effects, with many preferring to make lifestyle changes instead.<sup>11,12</sup> Similar attitudes are held towards antihypertensives,<sup>13-15</sup> although many patients will take them because of positive experiences with doctors, perceived benefits, and pragmatic reasons.<sup>16</sup>

Since there is very little information about what patients would think of a polypill, this article reports on an interview study that aimed to understand patient attitudes about the use of such a pill for CVD prevention.

### METHOD

#### Participants and sampling

Participants were purposively selected for interview from nine primary care practices in Birmingham that were taking part in a screening study assessing cardiovascular risk. Patients with an indication for cardiovascular risk-lowering treatment were sent the Beliefs about Medicines Questionnaire (BMQ)-General,<sup>17</sup> which is designed to measure attitudes to medicines in general: with higher scores indicating a greater belief that medicines are harmful and overused. Of 4520 patients sent the questionnaire, 2860 (63%) returned a

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### How this fits in

Trials have shown that a polypill can lead to important reductions in blood pressure and serum cholesterol, thereby reducing cardiovascular morbidity. One patient survey suggested high acceptability of a polypill for primary prevention, but there have been no detailed data on patients' attitudes. This first qualitative study of the attitude of patients towards a polypill found substantial resistance to all people over a specific age taking such a pill for the primary prevention of cardiovascular disease. Patients were particularly concerned about: taking a pill if it was not 'necessary'; side effects; inflexibility; and minimal monitoring.

completed BMQ-General. In order to sample responders with extreme views, as well as those who held moderate beliefs, and taking into account the fact that different studies categorise scores in various ways,<sup>18–20</sup> patients' scores were divided into tertiles so that scores of 8–15 were categorised as low, 16–22 as medium, and 23–40 as high.

Patients were included to reflect the variety of sociodemographic, individual, and practice characteristics (Table 1) to allow a diverse range of responses to emerge. Fifty-nine responders were selected and approached by letter to participate in the interview study.

### Interviews

Semi-structured interviews were used to explore patients' attitudes because this method allows an in-depth investigation of personal opinions and an opportunity for clarification.<sup>21</sup> Interviews were conducted at least 12 months after administering the BMQ-General, thereby minimising the possibility that the questionnaire may have influenced patients' responses during the interview. The interview guide was developed by the authors through a discussion of the literature surrounding polypills, combined pills, statins, and antihypertensives. During this process, the individual views of the multidisciplinary team (clinicians and non-clinicians) on the topic area were discussed, with the aim of ensuring that a wide range of viewpoints emerged, and were deliberated and challenged prior to interviews.<sup>22</sup>

The interviewer first asked participants about their understanding of blood pressure and cholesterol in order to contextualise the polypill. The topic guide then explored views on current treatment and attitude towards a polypill. Since the polypill did not exist in

the UK at the time of the interviews, the interviewer explained during each interview that it was a combined pill containing four drugs used to lower blood pressure and cholesterol. The interview guide was modified iteratively after each interview as new topics emerged.

Before each interview, signed informed consent was obtained from participants. All interviews were conducted by one of the authors in patients' homes between February and July 2010. Interviews lasted up to 60 minutes, were audiorecorded and transcribed verbatim.

### Analysis

Each transcript was checked against the recording for accuracy. As part of the process of responder validation,<sup>23</sup> participants were sent a copy of their transcript and a brief summary of the interview for comment: none were made.

Using the two main areas of the topic guide as a framework, interview transcripts were analysed using a constant comparative approach,<sup>24</sup> whereby throughout the analytic process each transcript was contrasted with others in order to develop an understanding of the possible associations between various pieces of data. Three of the authors read the transcripts and field notes independently and the main themes were identified. Interviews ceased when it was agreed that no new themes were emerging and saturation had been reached. Themes were discussed to develop a thematic coding framework and used to code each transcript systematically. There was general agreement between the three authors in identification of themes and coding of data. Any discrepancies were discussed and an agreement negotiated. Where an agreement could not be established, this was discussed with the rest of the authors until a consensus was reached. Framework software (version 1.1. 2009) was used to help organise the data.

### RESULTS

Seventeen patients participated, reflecting a broad range of characteristics from seven practices (Table 1).

In terms of views on current treatment, two themes relating to satisfaction with current medication and monitoring arose. For attitudes towards a polypill, three themes emerged: two relating to primary/secondary prevention and a third to monitoring. The number of responders discussing each theme is reported (denominator 17 participants) to facilitate comparison of comments and contextualise the findings.<sup>25</sup> A comparison of the themes

Table 1. Patient characteristics

Patient	Practice	Sex		Ethnicity	Age, years				Medications, n			Treatment with hypotensives and/or statins)	BMQ-General score				Practice size			IMD quartiles			
		Male	Female		50-59	60-69	70-79	≥80	0	1-4	≥5		No	Low (8-15)	Medium (16-22)	High (23-40)	Small <sup>a</sup>	Medium <sup>b</sup>	Large <sup>c</sup>	1	2	3	4
1		✓		White						✓		✓						✓					
2		✓		White					✓	✓		✓											
3			✓	White							✓	✓											
4		✓		White					✓	✓		✓											
5		✓		White					✓	✓		✓											
6		✓		White					✓	✓		✓											
7		✓		White					✓	✓		✓											
8		✓		White					✓	✓		✓											
9		✓		White					✓	✓		✓											
10			✓	White					✓	✓		✓						✓					
11		✓		White							✓	✓											
12		✓		White					✓			✓											
13		✓		White								✓											
14			✓	White							✓	✓						✓					
15			✓	White							✓	✓						✓					
16			✓	White							✓	✓						✓					
17			✓	White							✓	✓						✓					

<sup>a</sup> 1-2 full-time equivalent primary care physicians; <sup>b</sup> 3-4 full-time equivalent primary care physicians; <sup>c</sup> ≥5 full-time equivalent primary care physicians. IMD = Indices of multiple deprivation.

did not reveal any relationship between patient characteristics and their views on a polypill in managing cardiovascular risk.

### Views on current treatment

#### *Satisfaction with current medication.*

Although patients in the study had an indication for cardiovascular risk-lowering treatment, most ( $n = 11$ ) did not perceive themselves to be at significant risk of developing problems because they believed their blood pressure and cholesterol were being well controlled through current medication and lifestyle:

*'... my blood pressure has never been that high so no, I don't feel I'm at risk anymore than obviously everybody could be.'* (P17)

*'I don't think that I'm at risk because I think the doctor keeps it [blood pressure and cholesterol] fairly well under control.'* (P10)

Others ( $n = 6$ ) did not express the same degree of confidence and considered themselves to be vulnerable to complications:

*'I certainly do. I'm at risk, especially as I've been diagnosed with type 2 diabetes and suffering with blood pressure ... I think I'm an ideal candidate for an early exit.'* (P8)

Just over half of participants ( $n = 9$ ) who were taking antihypertensives and statins were pleased to be on medication: they believed it was controlling their condition and preventing the onset of disease:

*'Relieved to be on medication to be honest, because I've always had a bit of a problem with my blood pressure ... the tablets are doing a good job, so yeah it's good.'* (P9)

*'I'm alright with taking them ... it keeps me active, keeps me healthy and I don't have problems as such.'* (P15)

Others ( $n = 8$ ) were not so positive: they resented being on long-term medication, were sceptical of its effectiveness, and had concerns regarding side effects:

*'I don't think this medication they're pumping into you really does work all the time.'* (P3)

*'I'm very sceptical about statins ... and my arms and joints were aching ... I wouldn't be sceptical at all if I didn't feel side effects.'* (P4)

Consequently, at the time of the

interviews, two patients had stopped taking their medication without consulting their primary care physician: this may also be a reflection of their level of communication and relationship with their healthcare provider. The interviewer encouraged these patients to discuss their decision with their primary care physician.

**Current monitoring.** For most responders ( $n = 13$ ), having their blood pressure and cholesterol monitored at their practice reassured them that their medication and lifestyle were appropriate:

*'When you've been monitored and know you're okay, it's like a pat on the back, reassurance ... it gives you an indication of your health and longevity of life which we all want.'* (P13)

*'I am reassured because then I know that I'm eating properly ... and I don't have to increase the tablets.'* (P15)

A minority ( $n = 4$ ) did not share this view: they were unconvinced of the accuracy of the readings. On further exploration, this group appeared disillusioned with their primary care workers, believing them to be disinterested in their patients:

*'I'm a bit of a non-believer I suppose about how good these doctors are. They just give you a number you want to hear or it depends on how interested they are.'* (P3)

Patients who reported feeling reassured expressed greater confidence and trust in them. Patients' relationships with their primary care provider seemed to be central to their feelings of reassurance.

#### **Attitude towards the polypill**

Patients discussed their attitude towards using a polypill for primary and secondary prevention and monitoring while taking the medication.

**Primary prevention.** Most interviewees ( $n = 14$ ) had serious reservations about using a polypill for primary prevention. They considered it unnecessary in the absence of hypertension and hypercholesterolaemia. They also thought a polypill had the potential to cause problems such as side effects, hypotension, and encouraging people to become complacent about leading a healthy lifestyle. Furthermore, they expressed a general lack of confidence in preventive medicine, often referring to the frequent changes in guidance on taking aspirin:

potentially causing them to lose trust in their healthcare providers. Consequently, most ( $n = 10$ ) thought a polypill should only be given to those at high risk of developing CVD:

*'Well, you don't treat something that doesn't exist do you? If you've got somebody whose blood pressure is normal and you're giving them something which is going to reduce it, it's dangerous.'* (P1)

*'They're all foreign bodies that you're taking ... they can create other problems ... it can cause side effects.'* (P3)

*'If people think that a tablet saves them having fruit or taking exercise or changing their drinking habits, it can create more problems than it's worth.'* (P2)

*'... some time ago the idea that you took aspirin on a regular basis would prevent heart disease is now discovered to cause serious problems. So I would be a bit uneasy about a blanket approach to the polypill.'* (P5)

*'Anybody that has high blood pressure or high cholesterol then yes I think it's a good idea, but not for everybody over a certain age.'* (P10)

*'It would be ridiculous to put people who weren't at high risk on a tablet because you're medicalising people.'* (P17)

However, a minority ( $n = 3$ ) were positive about administering a polypill for primary prevention at a population level because they believed it could prevent CVD, thereby saving the NHS money:

*'It's a very good idea as prevention is better than cure.'* (P6)

*'I think anything that prevents a disease rather than waiting for people to develop it is superb. It reduces heart attacks and perhaps frees up money to be spent on other things.'* (P13)

**Secondary prevention.** All interviewees ( $n = 17$ ) were optimistic about the use of a polypill for secondary prevention. This was largely due to the actual pill itself in terms of being more convenient and practical to take, patients being less likely to forget to take their medication, and less packaging. Several ( $n = 9$ ) also highlighted the potential cost savings of a polypill for patients and the NHS:

*'I think the polypill would be superb — anything that can cut down on the vast amount of tablets that people have to take would be superb to be honest.'* (P2)

*'People are less likely to forget to take it [a polypill] if it's only one tablet.'* (P5)

*'I should imagine it would be more cost-effective for the NHS.'* (P8)

Despite their confidence, many ( $n = 14$ ) also expressed concerns. Most of these were again to do with the actual medication itself in terms of its inflexibility since the ingredients and doses cannot be adjusted; the possible side effects; the potentially large size of the pill; and forgetting to take a polypill, in which case all cardiovascular medication for that day would be missed:

*'A lot of people have got high blood pressure and they are all on different tablets on different doses ... so I don't see how you can have one tablet to cure all.'* (P9)

*'... if they forget to take the polypill it means they've forgotten to take all of their tablets. Whereas now if you forget to take a tablet, it's far less dangerous than if you forget to take all your tablets.'* (P11)

**Monitoring.** Most participants ( $n = 11$ ) were sceptical about whether using a polypill should reduce monitoring. They believed monitoring was required to give them an indication of whether the medication was effective or causing side effects. They also recognised that blood pressure and cholesterol values tend to change with age, which can only be detected through regular monitoring. It was highlighted that most medications (including the ingredients proposed for a polypill) are monitored and patients therefore questioned why it should be any different for a polypill:

*'How do you know it [a polypill] is of benefit if it's not monitored? What if it's detrimental to my health? If the polypill is a combination of items which I am currently monitored for, then why wouldn't I be monitored for a polypill? It doesn't make sense.'* (P4)

*'I think that's dangerous ... because people vary through time ... so it would need to be checked in time.'* (P11)

Some interviewees ( $n = 4$ ) were receptive of minimal monitoring if the research and their primary care physician deemed it appropriate. They also welcomed fewer visits

to their practice. Others ( $n = 2$ ) were mixed in their opinions: although sceptical, they said they could be convinced by the evidence and their primary care physician's advice. This suggested the relationship with healthcare professionals played a key role in patients' attitudes towards minimal monitoring:

*'Minimal monitoring sounds good ... I put my faith in what doctors say, and if they said "well, you don't need to be monitored, just take this and you'll be okay" ... then I'd be quite happy to do that.'* (P12)

*'I wouldn't like no monitoring, but then again if that's what my doctor said was right, I'm inclined to go with whatever she says anyway.'* (P10)

## DISCUSSION

### Summary

There was a low degree of acceptability of a polypill for primary prevention. This was largely due to concerns around taking a pill that was not 'necessary' for everyone and potential problems such as side effects. However, the role of a polypill for high-risk patients was considered more legitimate. Although there was greater willingness to consider a polypill for secondary prevention, there were similar reservations about side effects but also about its inflexibility. Most were sceptical of minimal monitoring, perceiving regular monitoring as necessary to check for effectiveness and side effects, as well as providing reassurance.

### Strengths and limitations

A particular strength of the study is that all interviews were conducted by a single researcher, thus ensuring consistency. Although the aim of qualitative research is not to be generalisable,<sup>26</sup> the study had a representative sample of patients aged  $\geq 50$  years, and across sex, ethnicity, and general attitudes towards medicines. Participants were spread evenly in terms of their beliefs about medicines (Table 1), so it is unlikely that negative attitudes towards a polypill were due to selection effects. The sample size was also appropriate and sufficient to achieve saturation.<sup>27</sup>

Lower-risk or younger patients might have offered different responses. For example, younger patients may have been more accepting of minimal monitoring because it would involve less interference in their daily lives. Similarly, patients with experience of taking a polypill may have different views informed by that experience whereas the attitudes of included participants were about a hypothetical treatment.

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### Ethical approval

Ethical approval to conduct the interviews was granted by the Birmingham, East, North and Solihull Research Ethics Committee (08/H1206/91).

### Provenance

Freely submitted; externally peer reviewed.

### Competing interests

The authors have declared no competing interests.

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### Comparison with existing literature

Most patients did not perceive themselves as being at significant risk of developing problems associated with CVD despite having a high risk score or existing disease. Similar results were found in a European study where patients at high risk of developing CVD still perceived their risk as low.<sup>28</sup> It may be that because they are receiving treatment they regard their risk as lower. However, the findings are consistent with the theory that patients generally display 'unrealistic optimism', whereby they underestimate their personal vulnerability to health and life-threatening problems.<sup>29,30</sup>

Several patients expressed concerns regarding antihypertensives and statins but most continued to take them because of their perceived benefits: a finding consistent with previous research.<sup>11–16</sup> Therefore, even if patients are apprehensive about taking a polypill, they may balance this against the potential benefits and still decide to take it.

There was a low degree of acceptability of a polypill for primary prevention because of concerns about unnecessary drug taking and the potential for problems. It was believed a polypill should only be for those at high risk, which may have been informed by previous health education regarding treatment for individual risk factors found to be above a treatment threshold. Similar reluctance towards preventive medication for CVD was found in another study.<sup>31</sup> In contrast, Soliman *et al*'s<sup>9</sup> survey demonstrated high acceptability of a polypill for primary prevention, although this may be because these patients were at high risk and were taking the drug as part of a trial. It may also be a reflection of the different methodology used — survey versus in-depth interviews — as well as a very different healthcare setting and cultural perspective.

The acceptability of a polypill for secondary prevention was somewhat higher, although there were still reservations regarding its flexibility and possible side effects. This has been found to be a concern from patients about combined pills in general.<sup>10</sup> Therefore the move to a polypill for secondary prevention may be problematic if the new drug regimen does not mirror the old trusted one.

Most patients were sceptical about a reduction in monitoring and described feeling reassured when monitored. This may reflect the demographics of patients in the study: most were older, retired patients for whom monitoring did not interfere excessively with their daily lives and who

may have valued the social contact of the consultation, as well as the opportunity to discuss their concerns. It may also reflect current practice where patients receive regular monitoring for prescribed medication. To alter this standard would require considerable patient confidence in both evidence and healthcare provider.

### Implications for research and practice

This study has found potential acceptance of a polypill for secondary prevention as well as for primary prevention in high-risk groups. However, it also suggests that a population strategy offering a polypill to all people over a certain age is likely to meet considerable resistance. Patients, as for healthcare professionals in previous research, would need to be convinced of the potential benefits of a drug-based population approach.<sup>32</sup> The prescribing clinician is likely to be key if this is to happen.<sup>33</sup> However, healthcare professionals would need to be persuaded themselves before they can offer this to their patients.

Significant degrees of scepticism were expressed towards the minimal monitoring possible with a polypill, which may influence uptake and adherence. However, the suggestion by some patients that they could be convinced by their primary care physician means it is essential to foster a relationship of trust and communication in order for this to occur. Despite this, until a polypill becomes established and trusted it may be necessary to allow a degree of monitoring.

This research identified resistance from some patients to cardiovascular risk-lowering medicines in general, and not just to a polypill. Strategies such as providing medication-specific information at the time of initiating therapy, explaining the risk of disease recurrence, and building up a relationship of trust between clinician and patient are likely to be key, whether the goal is to encourage use of a polypill, or use of the separate medications.<sup>33</sup>

Attitudes towards a polypill may change as experience of using it grows, and as evidence accumulates that it is an effective strategy.<sup>34</sup> Therefore, future research should focus on people who have experience of taking such a pill. Currently, this is likely to be in the context of a randomised controlled trial.

In conclusion, implementation of a polypill strategy for all people over a certain age would need to overcome resistance from both patients and healthcare professionals alike.



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