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Doctors' understanding of individualisation of drug treatments: A qualitative interview study

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ABSTRACT

Objective

To explore doctors' understanding of individualisation of drug treatments, and identify the methods used to achieve individualisation.

Design

In this exploratory study, we used in-depth qualitative interviews with doctors to gain insight into their understanding of the term 'individualised treatments' and the methods that they use to achieve individualised treatments.

Participants

Sixteen General Practitioners (GPs) in six rural and 10 urban practices and four hospital consultants were recruited.

Setting

Doctors from primary and secondary care in South West of England.

Results

Understanding of individualisation varied between doctors, and initial descriptions of individualisation were not always consistent with examples given. Understandings of, and methods used to achieve individualised treatment were frequently discussed in relation to making drug treatment decisions. Few doctors spoke of using tools to support patients to individualise their own treatments after the consultation.

Conclusion

Despite its widespread use, variation in doctors' understanding of the term individualisation highlights the need for it to be defined. Efforts are needed to develop effective tools to support patients to manage their treatments after consultations. Such a tool would offer a structured approach to support patients to self-manage their condition.

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ARTICLE SUMMARY

Article focus

- To explore doctors' understanding of individualisation of drug treatments
- To identify the methods used to achieve individualisation

Key messages

- There is a lack of consensus about whether individualised treatments are doctor-led, evidence based treatments, or treatments that are prescribed after consideration of patients' priorities.
- Doctors' stated definitions of individualisation were not always congruent with the examples they provided.
- Doctors rarely referred to patients' use of their medication after the consultation.

Strengths and limitations

- The use of qualitative methods generated a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two
- Strategies were used to enhance the trustworthiness of the data including multiple coders, respondent validation and triangulation of findings with the existing literature
- However, use of opportunity sampling may have resulted in a self-selected sample

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INTRODUCTION

Self-management is the foundation of chronic disease management. However, self-management is not straight forward. Policy initiatives advocate that treatments are tailored, personalised or individualised to patients' needs[[1]] and that patients are supported to self-manage their conditions[[2]]. However, terms such as individualisation and personalisation are regularly used to refer to a number of things[[3]]. It is often unclear as to whether individualised treatments are individualised to patients' medical needs or their personal needs[[3]]; which may or may not be complementary.

Successful pharmacological management of disease requires appropriate drug prescribing by doctors and appropriate drug utilisation by patients. This involves (at least) three processes. First is the interaction between the doctor and the patient within the medical consultation. The task here is to make a correct diagnosis and select appropriate treatments. Next is the doctor's prescription of appropriate drugs to treat the individual patient if necessary. The third process is the patient's use of the drug in the context of their lives. This process is not linear; interactions between doctors and patients will occur both before and after the prescription has been written and further interactions between patients and doctors are likely to occur during follow-up consultations. Treatments may be individualised at any stage.

Evidence based guidelines are available to support doctors to select appropriate drugs for individual patients. However, there remains a degree of uncertainty regarding the effectiveness of certain pharmacological treatments for individual patients[[4]]. Results of randomised controlled trials cannot always be accurately applied to individual patients[[5, 6]]. Individual variation in the severity of the condition, presence of co-morbidity, genetic profile, polypharmacy, and psychosocial factors all influence the effectiveness of the treatment and the potential risk of adverse drug reactions[[5]]. For individuals with multiple conditions, on multiple medications, or with a new or rare condition, guidelines are often unsuitable or unavailable[[7]]. A large body of research promotes models of interaction or decision making such as patient centred care[[8]] and shared decision making[[9]]. These are recommended by academics and policy makers as potential solutions in which patients' views and priorities are explored and treatment decisions are negotiated[[1, 11]]. Despite recommendations, these 'solutions' are not routinely used in clinical practice[[11, 12]], and there is very little consensus about what these terms entail or how they should be implemented[[12-14]].

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Previous qualitative research has explored how healthcare providers make individualised treatment decisions in the face of competing priorities[15-17]. That research highlights the variation in the strategies doctors employ to make treatment decisions in such situations[15, 17]. Doctors vary in their use of evidence and how they resolve the tensions that are inherent in using evidence alone (i.e., without consideration of patients' preferences). When faced with complex patients, doctors approach decisions with caution and uncertainty[17-19].

Should a drug be prescribed, the third process is the patients' use of the drug after the consultation. In a synthesis of qualitative studies of medication taking, Pound et al found that patients' use of medication is influenced by their judgements about the relative risks and benefits of using medications, the likelihood and impact of adverse effects, and the acceptability of the treatment regime in their lives[20]. Pound et al found evidence to suggest that patients are often motivated to minimise their use of medication - to reduce the dose of medication whilst still achieving some gain or to make the regime more acceptable or cost effective[20]. Patients actively sought answers to questions they had about their medication, for example, by modifying their treatment regimes by stopping or lowering the dose of medication to test its effectiveness (lay testing); only taking medication when symptomatic (symptomatic use of medication); only taking medication or taking more medication to offset lifestyle factors such as drinking alcohol (strategic use of medication) and replacement of medication with non pharmacological treatments. Thus, many patients carry out their own individualisation according to their own criteria.

This project aims to explore doctors' understanding of the term 'individualised treatments' and the methods that they employ to achieve individualised treatments.

METHODS

Design

In this exploratory study, we used in-depth qualitative interviews[21] with doctors to explore their understanding and clinical practice.

Sampling and data collection

We used opportunity sampling to recruit doctors to the study. We emailed information about the study to practices on the Devon Primary Care Incentive Scheme register, and asked interested doctors to make contact and arrange a time and place for the interview to take place.

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Our topic guide was based on a review of the literature and our own clinical experience. We used open ended questions to explore doctors' understanding of individualisation and the methods or strategies that they employ to deal with situations that require individualised treatment. In order to obtain detailed accounts, doctors were encouraged to provide examples whenever possible. All participants provided written consent prior to taking part.

Ethical approval was obtained from the Peninsula College of Medicine and Dentistry ethics committee.

Data analysis

Interviews were audio recorded, anonymised and transcribed verbatim. We analysed the data using a thematic approach[[22]]. Two researchers independently read transcripts and noted down core themes that were identified. We met regularly to discuss themes and to develop a preliminary list of codes. As coding progressed, we drew on the existing literature to refine this list and to group related themes together[[23]].

We then developed a chart for each theme[[23]], and copied any interview data that was related to each theme into the relevant chart. To enhance rigour[[24]], two authors carried out this process independently. We resolved discrepancies via discussion[[25]]. We then used the charts to identify narratives within cases and diversity between cases[[26]]. Divergent cases were discussed and included in the thematic analysis[[26]].

A summary of the findings were sent to all doctors along with an invitation to offer any comments.

RESULTS

One author collected data between February and July 2012 from sixteen General Practitioners (GPs) (six rural and ten urban practices) and four hospital consultants from clinical practices in Devon. Seven doctors were female. Interviews were held at a location to suit the doctors (mainly the doctor's place of work). Interviews lasted between twenty and sixty minutes.

The data are presented under two main headings. Firstly we identified two sub-themes relating to doctors' understanding: evidence based medicine and doctor-led prescribing, and individualising treatments around patient factors. Secondly we identified two sub-themes under the heading methods used to individualise treatments: methods used to make treatment decisions during the consultation, and methods to support patients after the consultation.

Understanding of individualised treatment

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Doctors' understanding of individualisation ranged from evidence based, medically focused, doctor-led care to prescribing drug treatments tailored to the patients' wishes. Whilst all but two doctors were able to describe their understanding of individualisation when asked, these answers did not always match the examples they provided. Doctors frequently discussed individualisation in relation to two of the processes involved in the prescription and use of pharmacological treatment - selecting appropriate drugs to treat the individual patient, and the interaction with the patient in the medical consultation. Doctors paid less attention to patients' use of treatments post consultation.

Evidence based medicine and doctor-led prescribing

At one end of the spectrum, individualisation was considered to be synonymous with evidence based practice. Focussing on the doctors' task of selecting appropriate drugs to treat the individual patient, one doctor described how the process of matching patients with guidelines resulted in all treatments being individualised:

> "I suppose when I did discuss it recently with my colleague the point he made was all treatments are individualised and it's, perhaps you're looking at it from a different perspective, because we look at it from the individual that comes in and then try and match a guideline to them or guidance, so everything you do is individualised anyway." (014)

Importantly, when asked about their understanding of individualised treatment, no doctor referred to doctor-led prescribing specifically. However, it was implicit in their examples that in certain situations (i.e., if the doctor thought that the patient really could benefit from treatment), they considered a doctor-led style of prescribing to be individualised.

> "Well again, it's a case of looking at what is right for that particular patient at that particular time, and, I, I, because the patient was at high risk of stroke, then I did really try to push the treatment." (004)

> "You know, because I think if, somebody might be very against a drug, but if I've seen it work really effectively in the past, I suppose I feel, I wouldn't force them to take it, if I force them to take it they won't take it anyway, but I suppose I feel if I can find a way round it that would encourage them just to give it a go, sometimes it's worth it." (019)

Individualising treatments around patient factors

Doctors described individualised treatments as drug treatments that had been selected after consideration of patient factors (such as patient circumstances). Frequently, this meant adapting or going against guideline recommendations. Some doctors described individualised treatments as

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treatments that had been tailored to suit the patients' medical needs (e.g., when treating patients with co-morbidities):

> "Well it's always checking on individual preferences, but the biggest factor is co-morbidity, that's what makes me step outside the box as it were." (012)

For other doctors, individualised treatments were treatments that had been adapted to suit patients' social circumstances:

> "So, I've got someone who lives out the back of beyond, no transport, they might be less keen to have something that requires frequent monitoring... We have a lot of shift workers round here so that can be quite an issue, um, shifts will often change from week to week... complete nightmare controlling anything like that because they're sometimes asleep when they're supposed to be taking their pills. So they can be tricky." (017)

For some, individualised treatment required the patient to be involved in treatment decisions; with treatments being individualised around what the patient is prepared to do. These doctors considered patients' preferences to be more important than their own views and preferences. In particular, the two geriatricians in our sample were conscious that the patients' preferences are perhaps more important than achieving optimal control of their conditions:

> "Because most of the patients that we see have reached what statistically would be regarded as their life expectancy. So there is, we can't in anyway force our opinions on them. We have to go with the fact that they have made this value judgement as to what is the right thing for them... And we just have to accept that they've made the right judgement for them. Which is not necessarily the right judgement for us. But as long as we feel that they are fully informed, or as informed as they can be, then we just accept what decisions they make on their behalf." (001)

> "Maybe that's easier in geriatrics where we know lots of what we do comes at a price, we know 10% of hospital admissions that we do are from drug side effects. So maybe we feel a bit more relaxed about it." (013)

For others, individualising treatment in accordance with what the patient was prepared to do simply meant accepting that the patient had declined treatment:

> "And I'm quite happy to agree to differ, if they want to decline treatment, I'd write down declined treatment. I think it's important to come back to, not just see it as

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> something that they've done wrong, but it's fine for them to do that, and I don't have a problem with them not taking that treatment." (006)

Methods used to individualise treatments

Doctors described the methods they used to achieve individualisation. Again, doctors focused on the methods used to select appropriate drugs to treat individuals and interactions with the patients during the consultation. Few doctors spoke of methods to support the patient to use treatments after the consultation when drug taking actually occurs.

Methods used to make treatment decisions during the consultation

Doctors described using a range of resources to select appropriate drugs to treat individual patients. These included evidence, clinical experience, colleague support, and the patients' views or circumstance. Use of resources was dependent on doctors' understanding of individualisation, but influenced by the patient and the situation. All doctors described using evidence to make treatment decisions. However, views about the role of the evidence varied between doctors:

> "EBM is only one of many strategies, and, it's like you've got a tool box you know? And the tool that you use every time is you yourself. And you need, and you can learn to do that better. I'm very interested in that. And then occasionally you'll pull EBM out as well. But not, you know, not very often. Honestly, I would think I probably, as a first tool that you pull out, it would probably be once or twice a day." (010)

It was widely acknowledged that text book scenarios were rare. One general practitioner reported that most of his patients had complex social needs, and both the geriatricians in our sample reported that nearly all of their patients had multiple conditions. These complex patients could not be treated only using evidence based guidelines[[7]]. Treatment decisions for patients with complex needs were made based on their own or their colleagues' clinical experience:

> "Often we send messages to each other. I share a list with another GP colleague, and we share difficult patients, and discuss how are we going to get Mr so and so to do X, Y and Z?" (014)

To treat patients with complex needs, doctors often made treatment decisions for the patient, using strategies like polypharmacy to deal with side-effects of treatments, and accepting that not all conditions can be optimally managed:

> "Q: Ok, so when you've got a patient who comes in and has a range of medical conditions, and you know if you treat all of them it's going to lead to interactions?

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> A: The regimens for each of these conditions, A, B and C are reasonably well sorted because they're common conditions, common drugs, usually sorted. So he has arthritis, diabetes and epilepsy. That's a nice juicy mix, and fairly common. By and large you will get away with this polypharmacy." (008)

To involve the patient in the treatment decisions, doctors reported using techniques such as providing the patient with the information needed to make an informed choice, suggesting treatment and outcome options, and giving the patient time to think about their priorities:

> "And then we can provide them with alternatives like 'well this will cure that but this could affect your kidneys. This might not have as big an effect on that but it would preserve the kidneys and could leave you a little bit short of breath. Of those two which would you rather have? The risk of feeling completely healthy, but potentially shorter life, or having some symptoms but a longer life?' And working with those decisions." (001)

Whilst one doctor aimed to prescribe treatments in accordance with patients' interests, he accepted that this could not be an everyday occurrence:

> "I'll be honest; I don't do it all the time, so I don't want to pretend I'm perfect at this. I think the clearest one that I've got is a bloke in his late 50s with Parkinsons who'd retired, but the thing that kept him going was that he could go to the swimming pool every morning... So we opted for a patch for him... You slap it on once a day and it gives you 24 hour coverage so he could put it on the night before and he'd be switched on in the morning, he wasn't waiting for a tablet to kick in and make him work. And it worked beautifully for him... but after a few months he got skin reactions and we had to stop it and find something else, but that really felt like we had really picked a drug around him and his interests and what was keeping him going." (013)

Interviewees also reported situations in which a more directive approach was considered to be necessary. This included situations in which patients' goals were deemed unrealistic, or when the doctor thought that the patient really should be using some form of treatment. In such situations, doctors reported using techniques in order to convince or persuade the patient to follow recommendations. In some cases, attempts were made to encourage the patient to see the medical imperative for treatment:

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> "They don't want to take any tablets, you say 'well you probably will die in 5 years time at the most without these things. If you take these things it might prolong your life, by this that or the other.'" (007)

For some doctors, the assumption appeared to be that the patient was in some way misinformed. Therefore, attempts were made to educate the patient:

> "Most of the time you can explain to people why they ought to be taking something and hopefully they might come round to thinking that that's the best thing to do. Sometimes people might have different ideas and won't take anything or certainly won't take what you suggest but I think most of the time you can explain to people why or what the evidence is or what the consensus is. And most of the time if people understand it they'll take it." (022)

If initial treatment decisions were not acceptable to the patient, attempts were made to change or simplify the regime or to prescribe alternative treatments:

> "You just say 'well let's try something else.' The nice thing is, there's always, or very often there's always alternatives that are either as good or, uh, you know, in the same league." (014)

Methods used to support patients after the consultation

In most interviews, individualisation was described in the context of making treatment decisions during the consultation. Few doctors spoke of methods to support patients to test and refine their treatment in the context of their own life. To support patients after the consultation, doctors reported using techniques such as reminders and instructions. This ranged from standardised dossette boxes or text messaging services, to writings and drawings on prescription labels. Crucially, the aim of such strategies was to help the patient use their medications as prescribed:

> "Q: Do you use any strategies to support the patients outside the consultation?
>
> A: Um, not enough. It's something I often think about that I should be doing more. So I do drawings and write things on bits of scrap paper, about if there is a complicated medication, or a list of things to do, or if people are older, forgetful" (006)

A minority of doctors described using strategies to help patients modify treatment regimes to suit their lives. One geriatrician described how he used techniques such as separating

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drugs into those that have to be taken (to treat the condition) and those that do not have to be taken (to treat the symptoms):

> "I tend to rearrange them so into treatments and symptoms... And if you group them like that, then if they get half way through the tablets, providing they've taken their treatment tablets, the symptom control, if they don't take it they're going to feel lousy, but the balance between taking a tablet or not taking a tablet, it's not going to make any difference to their longer term health." (001)

Another geriatrician described a process of trial and error, in which drugs were used for a period of time and then modified by the doctor if necessary:

> "I think as well, because we tell patients for a lot of these drugs let's try this and see if it works, if it's not working we'll stop it. It allows patients to come back and say it's not working rather than come back and feel that they're on it." (013)

Only one general practitioner actively encouraged patients to modify their treatments to achieve individualised doses. This doctor described reluctance on behalf of some patients to do so:

> "So actually, for an awful lot of drugs, I do this all the time. I say balance up your, you know yourself when you're getting the side effects. Titrate the medication until you're just below the level at which you get the side effects and fiddle around with it... And then sometimes the patient's say, 'ohh, but it says once a day and bla bla bla.'" (007)

The hospital consultants in our sample reported used diaries and graph paper to either assess the effectiveness of treatments and treatment doses, or to encourage patients to respond to worsening symptoms:

> "So, it's just a piece of paper really with days of the week and what their Parkinsons is like. But Parkinsons you swing from being on, when you can move around, to being off, when you're frozen and stuck. So if we're trying to give a drug to reduce the amount of time people are off , we'll often give them a diary so you can graphically see whether it's worked or not." (013)

> "Well they all get the graph paper. And it's "If it goes above this line, phone us and we'll see you in clinic straight away. Or, if it goes above this line increase your tablets. Or do this that or the other." And it's what we tell them to do when it reaches that point that varies by patients." (001)

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3 The question of whether or not patients needed to be encouraged to monitor symptoms
4 was contested. Some doctors were of the opinion that patients should not be encouraged
5 to monitor their symptoms or side-effects of their treatments:
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8 > "I quite often don't tell people about the side effects of tablets, which is against
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10 > our, against all the modern day teachings that you must tell people of the risks.
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12 > Well I often don't. Because there's a lot of evidence for this, there's a type of
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14 > patient that if you tell them there is a possibility that they'll get headaches, they'll
15 > get headaches." (002)
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17 Others felt that patients should be told what potential side effects they should look out for:
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19 > "Explain to them the possibility that one thing might affect another and what to
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21 > look out for. So if there are going to be interactions, what they, what they need to
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23 > be um, coming back with um, if certain symptoms present. You know if you get this,
24 > come back, because that's a side effect we need to know about." (016)
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26 However, even with clear instructions, mistakes could happen:
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28 > "We've had that with a patient who used, you know, he had the line [indicating safe
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30 > blood pressure readings], he went way below the line, kept on going without
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32 > bothering to phone anyone, and six weeks later he was in hospital with renal
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34 > failure. And we gave him pretty clear instructions. He decided to ignore them... It
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36 > worked; he just didn't follow the instructions. But you can't do anything about that.
37 > Patients are entitled to do what they want." (001)
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39 There was wide acceptance that, in the end, the final treatment decision was down to the
40 patient. In certain situations, no treatment could be the best option:
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42 > "You know, you say, 'this is what's going on, you tried them we've looked at
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44 > physiotherapy, we've looked at other alternatives, are your symptoms
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46 > manageable? Are the treatments worse than the condition, and if they are, then
47 > maybe you need to learn to live with the condition." (017)
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49 ## DISCUSSION
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51 ### Main findings and comparisons with other studies
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53 This paper presents a range of understandings of the meaning of individualised drug treatment.
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55 Overall, there was a lack of consensus about whether individualised treatment was treatment that
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57 was tailored to patients' priorities or treatment that was doctor-led, and followed evidence based
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guidelines. Furthermore, there was a lack of congruence between doctors' stated definition of individualisation and the examples they provided. Doctors frequently spoke of methods to support interactions during consultations, the first of the processes referred to in the introduction of this paper. However, despite the findings of Pound et al[20], doctors in our study infrequently mentioned patients' use of their medications outside the consultations.

The main strength of this study is the use of qualitative methods to generate a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two. We used strategies to enhance the trustworthiness of our study, including multiple coders and respondent validation. We triangulated our findings with the existing literature, and asked participants to comment on our findings[28]. Our study was based on a sample of hospital consultants and general practitioners from the South West of England. That doctors were only recruited from this area could limit the transferability of the results, although participants had both trained and practised beyond this region. Whilst we report that the four hospital consultants appeared to be more willing than general practitioners to individualise treatments after the consultation, this is based on a small number of participants. Further research is needed to explore differences in individualisation between different clinical areas as this may highlight situations clinical areas in which individualisation is commonly achieved, and situations in which individualisation is not appropriate. We acknowledge that our use of opportunity sampling may have resulted in a self-selected sample. However, our results demonstrate the lack of consensus about what individualisation of drug treatments means to participating doctors, suggesting that there is no shared understanding of what the term means. The lack of consistency between respondents' definitions of individualisation and the examples they gave suggests that there may also be inconsistency between their explanations and their clinical practice.

Previous qualitative research has explored methods to support doctors during consultations[15-17]. In those studies, the focus was on strategies used by doctors to make individualised prescribing decisions within the medical consultation - where guidelines may not be appropriate. Similar to the doctors in our study, those in the study by Fried et al. had variable views about how treatment decisions for patients with complex conditions should be made. Use of evidence and strategies to balance the harms versus the benefits of guideline directed care varied between physicians. Doctors in both studies had differences of opinion regarding the role of the patient in treatment decisions. For some, treatment decisions should be doctor-led, with the doctor persuading the patient to use the treatment that they thought would be most appropriate. For others, patient involvement was an essential component of treatment decisions. A number of doctors reported that integrating patients' preferences into medical decisions was problematic if the treatment was essential. This was still a

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3 major concern for many doctors, despite research suggesting that patients' and doctors' priorities may be very different[27]. Pound et al found evidence to suggest that patients actively modify their medications in order to suit their lives[20]. However, there is a paucity of literature surrounding methods used to support patients during this third process. The few doctors in our study who spoke of methods to support patients outside the consultation described methods such as sorting drugs by their role (to treat or to cure), trial and error, and monitoring. These strategies are largely informal: drawings, or writings about the use of the medication on bits of paper. The limitations of such informal methods were acknowledged.

Our study highlights the variation in opinions about whether or not patients should be encouraged to adapt treatments after consultations. One doctor felt that patients did not want to adapt their treatments. Another doctor thought that encouraging patients to be aware of side-effects could actually contribute to side effects. Others were concerned that encouraging patients to monitor symptoms could lead to unnecessary stress. Only a small number of doctors (mainly from secondary care) thought that patients should be encouraged to individualise treatments after the consultation. However, as Pound et al., (2005) has shown, many patients will monitor their symptoms and side effects and make treatment adaptations as necessary – with or without the support of the doctor. Self-management of chronic disease requires patients to take multiple treatments and monitor their health over many years. Developing tools to support patients to modify treatments, and providing safe parameters for them to do so, may actually limit dangerous adaptations.

The findings reported here have important implications for research and practice. The focus of the doctors in this study was on the strategies and methods that they used to reach decisions within the consultation. Few doctors discussed methods to support patients to use drug treatments outside the consultation. Methods that were suggested were informal and unstructured, and doctors acknowledged that such methods may neither be supportive enough or measurable. Furthermore, doctors perceived a number of barriers to individualising treatments after the consultation; such as whether or not strategies could contribute to side-effects and cause unnecessary stress. Before policy recommendations concerning both individualisation and self-management can be achieved commissioners need to be clear about what they are advocating, thus, the concept of individualisation needs to be refined. Methods used to achieve individualisation may then be developed and piloted in different situations. Such methods should be appropriately structured to be supportive and their effects measurable. Given that some patients are already individualising treatments on their own, supporting patients to do so safely could improve patients' self-management practices.

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Competing interests

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Contributions and guarantor

All four authors had a substantial contribution to the conception and design of the research. The analysis and interpretation of the data was undertaken by Sarah Denford, with considerable input from Julia Frost, Nicky Britten and Paul Dieppe. The article was drafted by Sarah Denford, and revised by the remaining three authors. All four authors approved the final version of the article before publication. There were no other contributors that are not included as an author. Sarah Denford is the guarantor.

Data sharing

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Full dataset is available from the corresponding author at Sarah.denford@pms.ac.uk. Consent was not obtained but the presented data are anonymised and risk of identification is low.

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Doctors' understanding of individualisation of drug treatments: A qualitative interview study

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Doctors' understanding of individualisation of drug treatments: A qualitative interview study

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ABSTRACT

Objective

To explore doctors' understanding of individualisation of drug treatments, and identify the methods used to achieve individualisation.

Design

In this exploratory study, we used in-depth qualitative interviews with doctors to gain insight into their understanding of the term 'individualised treatments' and the methods that they use to achieve it.

Participants

Sixteen General Practitioners (GPs) in six rural and 10 urban practices, two geriatricians and two clinical academics were recruited.

Setting

Primary and secondary care in South West of England.

Results

Understanding of individualisation varied between doctors, and their initial descriptions of individualisation were not always consistent with subsequent examples of patients they had treated. Understandings of, and methods used to achieve individualised treatment were frequently discussed in relation to making drug treatment decisions. Few doctors spoke of using strategies to support patients to individualise their own treatments after the consultation.

Conclusion

Despite its widespread use, variation in doctors' understanding of the term individualisation highlights the need for it to be defined. Efforts are needed to develop effective methods that would offer a structured approach to support patients to manage their treatments after consultations.

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ARTICLE SUMMARY

Article focus

- To explore doctors' understanding of individualisation of drug treatments.
- To identify the methods used to achieve individualisation.

Key messages

- Doctors' understanding of individualised treatments ranged from treatments that are doctor-led and evidence based to treatments that are prescribed after consideration of patients' priorities.
- Doctors' stated definitions of individualisation were not always congruent with the examples they provided from their clinical practice.
- Doctors rarely referred to patients' use of their medication after the consultation.

Strengths and limitations

- The use of qualitative methods generated a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two.
- Strategies were used to enhance the trustworthiness of the data including multiple coders, respondent validation and triangulation of findings with the existing literature.
- However, use of opportunity sampling may have resulted in a self-selected sample.

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INTRODUCTION

Self-management is one of the foundations of chronic disease management; however, it is not straight forward. To facilitate self-management, policy makers advocate that treatments are tailored, personalised or individualised to patients' needs([1]) and that patients are supported to self-manage their conditions([2]). Despite this, terms such as individualisation and personalisation are regularly used to refer to a number of different things([3]). It is often unclear as to whether individualised treatments are individualised to patients' medical needs or their personal needs([3]); which may or may not be complementary.

Successful pharmacological management of chronic disease requires appropriate drug prescribing by doctors and appropriate drug utilisation by patients. This involves (at least) three processes. First there is the interaction between the doctor and the patient within the medical consultation: the task here is to make a correct diagnosis and select appropriate treatments. Next is the doctor's prescription of appropriate drugs and dosage schedules to treat the individual patient if necessary. The third process is the patient's use of the drug in the context of their lives. This process is not linear; interactions between doctors and patients will occur both before and after the prescription has been written and further interactions between patients and doctors are likely to occur during follow-up consultations. Treatments may be individualised at any stage.

Evidence based guidelines are available to support doctors to select appropriate drugs for individual people([4;5]). However, there remains a degree of uncertainty regarding the effectiveness of certain pharmacological treatments for individual patients([6]). Results of randomised controlled trials cannot always be accurately applied to different individuals in varying socio-demographic and medical contexts ([7;8]). Variation in the severity of the condition, presence of co-morbidity, genetic profile, polypharmacy, and psychosocial factors all influence the effectiveness of the treatment and the potential risk of adverse drug reactions([7]). For individuals with multiple conditions, on multiple medications, or with a new or rare condition, guidelines are often unsuitable or unavailable([9]). A large body of research promotes models of interaction or decision making such as patient centred care([10]) and shared decision making([11]). These are recommended by academics and policy makers as potential solutions in which patients' views and priorities are explored and treatment decisions are negotiated([12]). Despite recommendations, these 'solutions' are not

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routinely used in clinical practice([13]), and there is very little consensus about what these terms entail or how they should be implemented([13-15]).

Previous qualitative research has explored how healthcare providers make individualised treatment decisions in the face of competing priorities([16-18]). That research highlights the variation in the strategies doctors employ to make treatment decisions in such situations([16-18]). Doctors vary in their use of evidence and how they resolve the tensions that are inherent in using evidence alone (such as without consideration of patients' preferences). When faced with complex patients, doctors approach decisions with caution and uncertainty([16;19;20]).

Should a drug be prescribed, the third process is the patients' use of the drug after the consultation. In a synthesis of qualitative studies of medication taking, Pound et al found that patients' use of medication is influenced by their judgements about the relative risks and benefits of using medications, the likelihood and impact of adverse effects, and the acceptability of the treatment regime in their lives([21]). Pound et al also found evidence to suggest that patients are often motivated to minimise their use of medication - to reduce the dose of medication whilst still achieving some gain or to make the regime more acceptable or cost effective([21]). Patients actively sought answers to questions they had about their medication, for example, by stopping or lowering the dose of medication to test its effectiveness (lay testing); only taking medication when symptomatic (symptomatic use of medication); only taking medication or taking more medication to offset lifestyle factors such as drinking alcohol (strategic use of medication) and replacement of medication with non pharmacological treatments. Thus, many patients carry out their own individualisation according to their own criteria.

This project aims to explore doctors' understanding of the term 'individualised treatments' and the methods that they employ to achieve individualised treatments.

METHODS

Design

In this exploratory study, we used in-depth qualitative interviews([22]) with doctors to explore their understanding and clinical practice.

Sampling and data collection

We used opportunity sampling to recruit doctors to the study. We anticipated that individualisation would be particularly relevant to doctors who deal with patients who have a range of problems;

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therefore we decided to sample doctors who are generalists (such as general practitioners and geriatricians). Two clinical academics (who were also hospital consultants) from within the medical school took part in pilot interviews to help test the procedure and topic guide.

We then emailed information about the study to 55 practice managers from practices on the Devon Primary Care Incentive Scheme register (a register of primary care practices who have applied for support from the Primary Care Research Network for participation in research), and asked interested doctors to make contact and arrange a time and place for the interview to take place. Sixteen doctors from 12 primary care practices responded to the email and took part in the interview. Two geriatricians were also recruited using snowball sampling. Our initial topic guide was based on a review of the literature and our own clinical experience (an experienced nurse and rheumatologist are members of the team). Open ended questions were used to explore the following topics (i) understanding of individualisation (ii) examples of individualising treatments (iii) methods used when patients' preferences are incompatible with guideline recommendations (iv) methods used to support patients to use their medication outside consultations (v) methods used to individualise treatments for patients with multiple chronic conditions and (vi) when individualisation is and is not appropriate. Participants were also asked if there was anything else they thought was relevant to individualisation. On the basis of the two pilot interviews with local clinical academics, the topic guide was modified to make it clearer that we are interested in individualised drug (as opposed to talking or physical) treatments in patients with chronic (as opposed to acute) conditions. In order to obtain detailed accounts, doctors were encouraged to provide examples of patients they had seen whenever possible.

To contextualise our study, the interviewer gave the following explanation at the beginning of the interview: "*Patients will vary in terms of the number of conditions they have, the amount of medications they take, and the severity of their condition(s). Patients will also have very different lifestyles, priorities, and beliefs about their condition(s) and treatments. We aim to explore the methods used by Healthcare providers to individualise treatments. We are aware that there is little consensus about what individualisation is, little guidance in the literature about how to do it, and that some doctors have developed their own approaches. We are interested in exploring the methods or strategies that are used by healthcare providers to tailor treatments to each individual patient.*" The interviewer started interviews by asking participants what they understood individualization to be, and to provide an example of a time during which they had individualized treatment with a patient. To avoid influencing participants' answers, we did not explicitly define individualisation. However, the interviewer later used prompts to encourage participants to discuss additional situations that could be considered to be amenable to individualisation (as per the topic

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3 guide). We anticipated that this would provide a detailed account of doctors' understanding of individualisation and the methods that they would use to achieve it within their understanding as well as the methods that they used to individualise treatments as others may see it.

All participants provided written consent prior to taking part. Ethical approval was obtained from the Peninsula College of Medicine and Dentistry ethics committee.

Data analysis

Interviews were audio recorded, anonymised and transcribed verbatim. We analysed the data using a thematic approach([23]). Two researchers independently read transcripts and noted down core codes that were identified. We met regularly to discuss codes and to develop a preliminary list of themes. As analysis progressed, we drew on the existing literature to refine this list and to group related themes together([24]).

We then developed a chart for each theme([24]), and copied any interview data that was related to each theme into the relevant chart. To enhance rigour([25]), two authors carried out this process independently. We resolved discrepancies via discussion([26]). We then used the charts to identify narratives within cases and diversity between cases([27]). Divergent cases were discussed and included in the thematic analysis([27]).

A summary of the findings were sent to all doctors along with an invitation to offer any comments.

RESULTS

One author (SD) collected data between February and July 2012 from sixteen General Practitioners (GPs) (six rural and ten urban practices) and two geriatricians from clinical practices in Devon. Data from the two clinical academics who took part in the pilot interviews was also included in the analysis. Seven doctors were female. Interviews were held at a location to suit the doctors (mainly at their place of work). The mean length of the interviews was 48 minutes (range 20-60 minutes). The data are presented under three main headings. First we identified two sub-themes relating to doctors' understanding: evidence based medicine and doctor-led prescribing, and individualising treatments around patient factors. Secondly we identified two sub-themes under the heading methods used to individualise treatments: methods used to make treatment decisions during the consultation, and methods to support patients after the consultation. Thirdly we identified dissonance between the rhetoric of individualisation and doctors' clinical reports of how they had dealt with some of their patients.

Understanding of individualised treatment

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Doctors' understanding of individualisation ranged from evidence based medically focused, doctor-led care, through to prescribing drug treatments tailored to the patients' wishes and beliefs. There was variation in the ease with which doctors spoke about individualisation. There were two doctors who could not articulate their understanding of individualisation, but who were still able to respond to prompts about how they would deal with situations that could be considered to be amenable to individualisation. Doctors frequently discussed individualisation in relation to two of the processes involved in the prescription and use of pharmacological treatment - selecting appropriate drugs to treat the individual patient, and the interaction with the patient in the medical consultation. Doctors paid less attention to patients' use of treatments post consultation.

Evidence based medicine and doctor-led prescribing

At one end of the spectrum, individualisation was considered to be synonymous with evidence based practice. Focussing on the doctors' task of selecting appropriate drugs to treat the individual patient, one doctor described how the process of matching patients with guidelines resulted in all treatments being individualised:

> "I suppose when I did discuss it recently with my colleague the point he made was all treatments are individualised and it's, perhaps you're looking at it from a different perspective, because we look at it from the individual that comes in and then try and match a guideline to them or guidance, so everything you do is individualised anyway." (Sophie, urban GP)

Importantly, when asked about their understanding of individualised treatment, no doctor referred to doctor-led prescribing specifically. However, it was implicit in their examples that in certain situations (such as if the doctor thought that the patient really could benefit from treatment), they considered a doctor-led style of prescribing to be individualised.

> "Well again, it's a case of looking at what is right for that particular patient at that particular time, and, I, I, because the patient was at high risk of stroke, then I did really try to push the treatment." (Jim, urban GP)

> "You know, because I think if, somebody might be very against a drug, but if I've seen it work really effectively in the past, I suppose I feel, I wouldn't force them to take it, if I force them to take it they won't take it anyway, but I suppose I feel if I can find a way round it that would encourage them just to give it a go, sometimes it's worth it." (Catherine, urban GP)

Individualising treatments around patient factors

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3 Doctors described individualised treatments as drug treatments that had been selected after
4 consideration of patient factors (such as patient circumstances). Frequently, this meant adapting or
5 going against guideline recommendations. Some doctors described individualised treatments as
6 treatments that had been tailored to suit the patients' medical needs (for example, when treating
7 patients with co-morbidities):

> "Well it's always checking on individual preferences, but the biggest factor is co-morbidity, that's what makes me step outside the box as it were." (Tom, urban GP)

For other doctors, individualised treatments were treatments that had been adapted to suit patients' social circumstances:

> "So, I've got someone who lives out the back of beyond, no transport, they might be less keen to have something that requires frequent monitoring... We have a lot of shift workers round here so that can be quite an issue, um, shifts will often change from week to week... complete nightmare controlling anything like that because they're sometimes asleep when they're supposed to be taking their pills. So they can be tricky." (Rachel, rural GP)

For some, individualised treatment required the patient to be involved in treatment decisions; with treatments being individualised around the patients' willingness to take a drug. These doctors considered patients' preferences to be more important than their own views and preferences. In particular, the two geriatricians in our sample were conscious that the patients' preferences are perhaps more important than achieving optimal control of their conditions:

> "Because most of the patients that we see have reached what statistically would be regarded as their life expectancy. So there is, we can't in anyway force our opinions on them. We have to go with the fact that they have made this value judgement as to what is the right thing for them... And we just have to accept that they've made the right judgement for them. Which is not necessarily the right judgement for us. But as long as we feel that they are fully informed, or as informed as they can be, then we just accept what decisions they make on their behalf." (Mark, geriatrician)

> "Maybe that's easier in geriatrics where we know lots of what we do comes at a price, we know 10% of hospital admissions that we do are from drug side effects. So maybe we feel a bit more relaxed about it." (William, geriatrician)

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For others, individualising treatment in accordance with the patients' willingness to take a drug simply meant accepting that the patient had declined treatment:

> "And I'm quite happy to agree to differ, if they want to decline treatment, I'd write down declined treatment. I think it's important to come back to, not just see it as something that they've done wrong, but it's fine for them to do that, and I don't have a problem with them not taking that treatment." (Marcus, urban GP)

Methods used to individualise treatments

Doctors described the methods they used to achieve individualisation. Again, doctors focused on the methods used to select appropriate drugs to treat individuals and interactions with the patients during the consultation. Few doctors spoke of methods to support the patient to use treatments after the consultation when drug taking actually occurs. *Methods used to make treatment decisions during the consultation*

Doctors described using a range of resources to select appropriate drugs to treat individual patients. These included evidence, clinical experience, colleague support, and the patients' views or circumstance. Use of resources was dependent on doctors' understanding of individualisation, but influenced by the patient and the situation. All doctors described using evidence to make treatment decisions. However, views about the role of the evidence varied between doctors:

> "EBM is only one of many strategies, and, it's like you've got a tool box you know? And the tool that you use every time is you yourself. And you need, and you can learn to do that better. I'm very interested in that. And then occasionally you'll pull EBM out as well. But not, you know, not very often. Honestly, I would think I probably, as a first tool that you pull out, it would probably be once or twice a day." (Andrew, urban GP)

It was widely acknowledged that "text book" scenarios were rare. One general practitioner reported that most of his patients had complex social needs, and both the geriatricians in our sample reported that nearly all of their patients had multiple conditions. These complex patients could not be treated only using evidence based guidelines([9]). Treatment decisions for patients with complex needs were made based on their own or their colleagues' clinical experience:

> "Often we send messages to each other. I share a list with another GP colleague, and we share difficult patients, and discuss how are we going to get Mr so and so to do X, Y and Z?" (Sophie, urban GP)

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3 To treat patients with complex needs, doctors often made treatment decisions for the patient, using strategies like polypharmacy to deal with side-effects of treatments, and accepting that not all conditions can be optimally managed:

> “Interviewer (I): Ok, so when you’ve got a patient who comes in and has a range of medical conditions, and you know if you treat all of them it’s going to lead to interactions?
>
> Respondent (R): The regimens for each of these conditions, A, B and C are reasonably well sorted because they’re common conditions, common drugs, usually sorted. So he has arthritis, diabetes and epilepsy. That’s a nice juicy mix, and fairly common. By and large you will get away with this polypharmacy.” (Mathew, urban GP)

To involve the patient in the treatment decisions, doctors reported using techniques such as providing the patient with the information needed to make an informed choice, suggesting treatment and outcome options, and giving the patient time to think about their priorities:

> “And then we can provide them with alternatives like ‘well this will cure that but this could affect your kidneys. This might not have as big an effect on that but it would preserve the kidneys and could leave you a little bit short of breath. Of those two which would you rather have? The risk of feeling completely healthy, but potentially shorter life, or having some symptoms but a longer life?’ And working with those decisions.” (Mark, geriatrician)

Whilst one doctor aimed to prescribe treatments in accordance with patients’ interests, he accepted that this could not be an everyday occurrence:

> “I’ll be honest; I don't do it all the time, so I don't want to pretend I’m perfect at this. I think the clearest one that I’ve got is a bloke in his late 50s with Parkinson’s who’d retired, but the thing that kept him going was that he could go to the swimming pool every morning... So we opted for a patch for him... You slap it on once a day and it gives you 24 hour coverage so he could put it on the night before and he’d be switched on in the morning, he wasn’t waiting for a tablet to kick in and make him work. And it worked beautifully for him... but after a few months he got skin reactions and we had to stop it and find something else, but that really felt like we had really picked a drug around him and his interests and what was keeping him going.” (William, geriatrician)

Interviewees also reported situations in which a more directive approach was considered to be necessary. This included situations in which patients’ goals were deemed unrealistic, or

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when the doctor thought that the patient really should be using some form of treatment. Doctors then reported using techniques in order to convince or persuade the patient to follow recommendations. In some cases, attempts were made to encourage the patient to see the medical imperative for treatment:

> "They don't want to take any tablets; you say 'well you probably will die in 5 years time at the most without these things. If you take these things it might prolong your life, by this that or the other.'" (Joe, urban GP)

For some doctors, the assumption appeared to be that the patient was in some way misinformed. Therefore, attempts were made to educate the patient:

> "Most of the time you can explain to people why they ought to be taking something and hopefully they might come round to thinking that that's the best thing to do. Sometimes people might have different ideas and won't take anything or certainly won't take what you suggest but I think most of the time you can explain to people why or what the evidence is or what the consensus is. And most of the time if people understand it they'll take it." (Lynn, rural GP)

If initial treatment decisions were not acceptable to the patient, attempts were made to change or simplify the regime or to prescribe alternative treatments:

> "You just say 'well let's try something else.' The nice thing is, there's always, or very often there's always alternatives that are either as good or, uh, you know, in the same league." (Sophie, urban GP)

Methods used to support patients after the consultation

In most interviews, individualisation was described in the context of making treatment decisions during the consultation. Few doctors spoke of methods to support patients to test and refine their treatment in the context of their own life. To support patients after the consultation, doctors reported using techniques such as reminders and instructions. This ranged from standardised monitored dosage system or text messaging services, to writings and drawings on prescription labels. Crucially, the aim of such strategies was to help the patient use their medications as prescribed:

> "I: Do you use any strategies to support the patients outside the consultation?
>
> R: Um, not enough. It's something I often think about that I should be doing more. So I do drawings and write things on bits of scrap paper, about if there is a

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complicated medication, or a list of things to do, or if people are older, forgetful" (Marcus, urban GP)

A minority of doctors described using strategies to help patients modify treatment regimes to suit their lives. One geriatrician described how he used techniques such as separating drugs into those that have to be taken (to treat the condition) and those that do not have to be taken (to treat the symptoms):

"I tend to rearrange them so into treatments and symptoms... And if you group them like that, then if they get half way through the tablets, providing they've taken their treatment tablets, the symptom control, if they don't take it they're going to feel lousy, but the balance between taking a tablet or not taking a tablet, it's not going to make any difference to their longer term health." (Mark, geriatrician)

Another geriatrician described a process of trial and error, in which drugs were used for a period of time and then modified by the doctor if necessary:

"I think as well, because we tell patients for a lot of these drugs let's try this and see if it works, if it's not working we'll stop it. It allows patients to come back and say it's not working rather than come back and feel that they're on it." (William, geriatrician)

Only one general practitioner actively encouraged patients to modify their treatments to achieve individualised doses. This doctor described reluctance on behalf of some patients to do so:

"So actually, for an awful lot of drugs, I do this all the time. I say balance up your, you know yourself when you're getting the side effects. Titrate the medication until you're just below the level at which you get the side effects and fiddle around with it... And then sometimes the patient's say, 'ohh, but it says once a day and bla bla bla.'" (Joe, urban GP)

The hospital consultants in our sample reported used diaries and graph paper to either assess the effectiveness of treatments and treatment doses, or to encourage patients to respond to worsening symptoms:

"So, it's just a piece of paper really with days of the week and what their Parkinson's is like. But Parkinson's you swing from being on, when you can move around, to being off, when you're frozen and stuck. So if we're trying to give a drug

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3 to reduce the amount of time people are off , we'll often give them a diary so you
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5 can graphically see whether it's worked or not." (William, geriatrician)
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7 "Well they all get the graph paper. And it's "If it goes above this line, phone us and
8
9 we'll see you in clinic straight away. Or, if it goes above this line increase your
10 tablets. Or do this that or the other." And it's what we tell them to do when it
11
12 reaches that point that varies by patients." (Mark, geriatrician)
13
14 The question of whether or not patients needed to be encouraged to monitor symptoms
15 was contested. Some doctors were of the opinion that patients should not be encouraged
16
17 to monitor their symptoms or side-effects of their treatments:
18
19 "I quite often don't tell people about the side effects of tablets, which is against
20
21 our, against all the modern day teachings that you must tell people of the risks.
22 Well I often don't. Because there's a lot of evidence for this, there's a type of
23
24 patient that if you tell them there is a possibility that they'll get headaches, they'll
25
26 get headaches." (John, clinical academic)
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28 Others felt that patients should be told what potential side effects they should look out for:
29
30 "Explain to them the possibility that one thing might affect another and what to
31 look out for. So if there are going to be interactions, what they, what they need to
32
33 be um, coming back with um, if certain symptoms present. You know if you get this,
34
35 come back, because that's a side effect we need to know about." (Becky, urban GP)
36
37 However, even with clear instructions, mistakes could happen:
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39 "We've had that with a patient who used, you know, he had the line [indicating safe
40 blood pressure readings], he went way below the line, kept on going without
41
42 bothering to phone anyone, and six weeks later he was in hospital with renal
43
44 failure. And we gave him pretty clear instructions. He decided to ignore them... It
45
46 worked; he just didn't follow the instructions. But you can't do anything about that.
47 Patients are entitled to do what they want." (Mark, geriatrician)
48
49 There was wide acceptance that, in the end, the final treatment decision was down to the
50
51 patient. In certain situations, no treatment could be the best option:
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53 "You know, you say, 'this is what's going on, you tried them we've looked at
54 physiotherapy, we've looked at other alternatives, are your symptoms
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56 manageable? Are the treatments worse than the condition, and if they are, then
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58 maybe you need to learn to live with the condition." (Rachel, rural GP)
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Dissonance between rhetoric and experience

Whilst all but two doctors were able to describe their understanding of individualisation when asked, these answers did not always match the examples they provided when talking about patients they had treated. For example, one doctor described individualisation as being:

> "All sorts of things. Everything from the persons' views or thoughts about - if you're talking about medicines - about drugs and what they want. But similarly that fits with their views of whether they like medicine, don't like medicine, what they want in terms of getting better." (Catherine, urban GP).

However, when this participant was asked how she would respond to a patient who did not want to use the treatment that she had prescribed, she responded:

> "There are even times when I'll say 'well actually I think this would be worth trying' even if they're not very keen. And I'll say to them 'how about you give it a go for two weeks and see how you feel.' You know, because I think somebody might be very against a drug, but if I've seen it work really effectively in the past, I suppose I feel, I wouldn't force them to take it, if I force them to take it they won't take it anyway, but I suppose I feel if I can find a way round it that would encourage them just to give it a go, sometimes it's worth it" (Catherine, urban GP).

This dissonance between rhetoric and experience was evident throughout the interviews. Whilst doctors appeared to think that individualising treatments around patients' preferences and world views into treatment decisions was of value, in practice this was not always considered to be the best strategy.

DISCUSSION

Main findings and comparisons with other studies

This paper presents a range of doctors' understandings of the meaning of individualised drug treatment. Individualised treatment was discussed in relation to both treatment that was tailored to patients' priorities, and treatment that was doctor-led and followed evidence based guidelines. Furthermore, there was a lack of congruence between doctors' stated definition of individualisation and the examples they provided from their practice. Doctors frequently spoke of methods to support interactions during consultations, the first of the processes referred to in the introduction of this paper. However, despite the findings of Pound et al([21]), doctors in our study infrequently mentioned patients' use of their medications outside the consultations.

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The main strength of this study is the use of qualitative methods to generate a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two. We used strategies to enhance the trustworthiness of our study, including multiple coders and respondent validation. We triangulated our findings with the existing literature, and asked participants to comment on our findings([28]). Participants who took part in pilot interviews stated that they could recognise our findings, and agreed that they were plausible.

Our study was based on a sample of hospital consultants and general practitioners from the South West of England. That doctors were only recruited from this area could limit the transferability of the results, although participants had both trained and practised beyond this region. We acknowledge that our use of opportunity sampling may have resulted in a self-selected sample. However, as we are interested in best practice, we were not overly concerned with recruiting only those with an interest in the study.

Previous qualitative research has explored methods to support doctors during consultations([16-18]). In those studies, the focus was on strategies used by doctors to make individualised prescribing decisions within the medical consultation - where guidelines may not be appropriate. Similar to the doctors in our study, those studied by Fried et al. had variable views about how treatment decisions for patients with complex conditions should be made. Use of evidence and strategies to balance the harms versus the benefits of guideline directed care varied between physicians.

Doctors in both of these studies had differences of opinion regarding the role of the patient in treatment decisions. For some, treatment decisions should be doctor-led, with the doctor persuading the patient to use the treatment that they thought would be most appropriate. For others, patient involvement was an essential component of treatment decisions. A number of doctors reported that integrating patients' preferences into medical decisions was problematic if the treatment was essential. This was still a major concern for many doctors, despite research suggesting that patients' and doctors' priorities may be very different([29]). This paternalism versus patient choice is an ongoing debate, and one that is widely discussed in the literature([15;30;31]). In the current paper, the dissonance between the rhetoric of individualisation and doctors' clinical behaviour appeared to stem from this issue, with the data revealing tensions between doctors desire to treat the patients' social needs, whilst simultaneously treating their medical needs.

Pound et al found evidence to suggest that patients actively modify their medications in order to suit their lives([21]). However, there is a paucity of literature surrounding methods used to support patients during this third process. The few doctors in our study who spoke of methods to support patients outside the consultation described methods such as sorting drugs by their role (to treat or

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to cure), trial and error, and monitoring. These strategies are largely informal: for example, drawings, or writing about the use of the medication on bits of paper. The limitations of such informal methods were acknowledged.

The lack of consideration of what goes on outside the consultation is particularly interesting and worrying. Pound et al., (2005) has shown that many patients will monitor their symptoms and side effects and make treatment adaptations as necessary – with or without the support of the doctor. Self-management of chronic disease requires patients to take multiple treatments and monitor their health over many years. Therefore, strategies to support patients to modify treatments, and providing safe parameters for them to do so, may actually limit patient driven amendments to treatments without professional support. However, our study highlights the variation in opinions about whether or not patients should be encouraged to adapt treatments after consultations. One doctor felt that patients did not want to adapt their treatments. Another doctor thought that encouraging patients to be aware of side-effects could actually contribute to side effects. Others were concerned that encouraging patients to monitor symptoms could lead to unnecessary stress. Only a small number of doctors thought that patients should be encouraged to individualise treatments after the consultation. In particular, the two geriatricians seemed to have a better understanding of, and a larger set of methods to support patients to individualise treatments after consultations than the general practitioners, thus suggesting that the findings might be related to medical subspecialty. Further research is needed to explore differences in individualisation between different clinical specialities, as this may highlight situations clinical areas in which individualisation is commonly achieved, and situations in which individualisation is not so appropriate.

The findings reported here have important implications for research and practice. The focus of this study was on the strategies and methods that doctors used to reach decisions within the consultation. Few doctors discussed methods to support patients to use drug treatments outside the consultation. Methods that were suggested were informal and unstructured, and doctors acknowledged that such methods may neither be supportive enough or measurable. Furthermore, doctors perceived a number of barriers to individualising treatments after the consultation; such as whether or not strategies could contribute to side-effects and cause unnecessary stress. Before policy recommendations concerning both individualisation and self-management can be achieved commissioners need to be clear about what they are advocating, thus, the concept of individualisation needs to be refined. Methods used to achieve individualisation may then be developed and piloted in different situations. Such methods should be appropriately structured to be supportive and their effects measurable. Given that some patients are already individualising

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treatments on their own, supporting patients to do so safely could improve patients' self-management practices.

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Contributions and guarantor

All four authors had a substantial contribution to the conception and design of the research. The analysis and interpretation of the data was undertaken by Sarah Denford, with considerable input from Julia Frost, Nicky Britten and Paul Dieppe. The article was drafted by Sarah Denford, and revised by the remaining three authors. All four authors approved the final version of the article

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before publication. There were no other contributors that are not included as an author. Sarah Denford is the guarantor.

Data sharing

Full dataset is available from the corresponding author at Sarah.denford@pms.ac.uk. Consent was not obtained but the presented data are anonymised and risk of identification is low.

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Doctors' understanding of individualisation of drug treatments: A qualitative interview study

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ABSTRACT

Objective

To explore doctors' understanding of individualisation of drug treatments, and identify the methods used to achieve individualisation.

Design

In this exploratory study, we used in-depth qualitative interviews with doctors to gain insight into their understanding of the term 'individualised treatments' and the methods that they use to achieve it. ~~individualised treatments.~~

Participants

Sixteen General Practitioners (GPs) in six rural and 10 urban practices, two geriatricians and two clinical academics ~~and four hospital consultants~~ were recruited.

Setting

~~Doctors from p~~Primary and secondary care in South West of England.

Results

Understanding of individualisation varied between doctors, and their initial descriptions of individualisation were not always consistent with subsequent ~~examples~~ examples of patients they had treated~~given~~. Understandings of, and methods used to achieve individualised treatment were frequently discussed in relation to making drug treatment decisions. Few doctors spoke of using ~~tools~~ strategies to support patients to individualise their own treatments after the consultation.

Conclusion

Despite its widespread use, variation in doctors' understanding of the term individualisation highlights the need for it to be defined. Efforts are needed to develop effective ~~tools~~ methods that would offer a structured approach to support patients to manage their treatments after consultations. ~~Such a tool would offer a structured approach to support patients to self-manage their condition.~~

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ARTICLE SUMMARY

Article focus

- To explore doctors' understanding of individualisation of drug treatments.
- To identify the methods used to achieve individualisation.

Key messages

- Doctors' understanding of individualised treatments ranged from ~~There is a lack of consensus about whether individualised~~ treatments that are doctor-led and~~,~~ evidence based ~~treatments, or~~ to treatments that are prescribed after consideration of patients' priorities.
- Doctors' stated definitions of individualisation were not always congruent with the examples they provided from their clinical practice.
- Doctors rarely referred to patients' use of their medication after the consultation.

Strengths and limitations

- The use of qualitative methods generated a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two.
- Strategies were used to enhance the trustworthiness of the data including multiple coders, respondent validation and triangulation of findings with the existing literature.
- However, use of opportunity sampling may have resulted in a self-selected sample.

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INTRODUCTION

Self-management is one of the foundations of chronic disease management; however, it is ~~self-management is~~ not straight forward. To facilitate self-management, p~~P~~olicy makers ~~initiatives~~ advocate that treatments are tailored, personalised or individualised to patients' needs([1]) and that patients are supported to self-manage their conditions([2]). Despite this, ~~However,~~ terms such as individualisation and personalisation are regularly used to refer to a number of different things([3]). It is often unclear as to whether individualised treatments are individualised to patients' medical needs or their personal needs([3]); which may or may not be complementary.

Successful pharmacological management of chronic ~~-~~disease requires appropriate drug prescribing by doctors and appropriate drug utilisation by patients. This involves (at least) three processes. First there is the interaction between the doctor and the patient within the medical consultation: the task here is to make a correct diagnosis and select appropriate treatments. Next is the doctor's prescription of appropriate drugs and dosage schedules to treat the individual patient if necessary. The third process is the patient's use of the drug in the context of their lives. This process is not linear; interactions between doctors and patients will occur both before and after the prescription has been written and further interactions between patients and doctors are likely to occur during follow-up consultations. Treatments may be individualised at any stage.

Evidence based guidelines are available to support doctors to select appropriate drugs for individual people([4;5]). However, there remains a degree of uncertainty regarding the effectiveness of certain pharmacological treatments for individual patients([6]). Results of randomised controlled trials cannot always be accurately applied to different individuals in varying socio-demographic and medical contexts ~~patients~~([7;8]). Variation in the severity of the condition, presence of co-morbidity, genetic profile, polypharmacy, and psychosocial factors all influence the effectiveness of the treatment and the potential risk of adverse drug reactions([7]). For individuals with multiple conditions, on multiple medications, or with a new or rare condition, guidelines are often unsuitable or unavailable([9]). A large body of research promotes models of interaction or decision making such as patient centred care([10]) and shared decision making([11]). These are recommended by academics and policy makers as potential solutions in which patients' views and priorities are explored and treatment decisions are negotiated([12]). Despite recommendations, these 'solutions' are not

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routinely used in clinical practice([13]), and there is very little consensus about what these terms entail or how they should be implemented([13-15]).

Previous qualitative research has explored how healthcare providers make individualised treatment decisions in the face of competing priorities([16-18]). That research highlights the variation in the strategies doctors employ to make treatment decisions in such situations([16-18]). Doctors vary in their use of evidence and how they resolve the tensions that are inherent in using evidence alone (~~i.e.,~~such as without consideration of patients' preferences). When faced with complex patients, doctors approach decisions with caution and uncertainty([16;19;20]).

Should a drug be prescribed, the third process is the patients' use of the drug after the consultation. In a synthesis of qualitative studies of medication taking, Pound et al found that patients' use of medication is influenced by their judgements about the relative risks and benefits of using medications, the likelihood and impact of adverse effects, and the acceptability of the treatment regime in their lives([21]). Pound et al also found evidence to suggest that patients are often motivated to minimise their use of medication - to reduce the dose of medication whilst still achieving some gain or to make the regime more acceptable or cost effective([21]). Patients actively sought answers to questions they had about their medication, for example, ~~by modifying their treatment regimes~~ by stopping or lowering the dose of medication to test its effectiveness (lay testing); only taking medication when symptomatic (symptomatic use of medication); only taking medication or taking more medication to offset lifestyle factors such as drinking alcohol (strategic use of medication) and replacement of medication with non pharmacological treatments. Thus, many patients carry out their own individualisation according to their own criteria.

This project aims to explore doctors' understanding of the term 'individualised treatments' and the methods that they employ to achieve individualised treatments.

METHODS

Design

In this exploratory study, we used in-depth qualitative interviews([22]) with doctors to explore their understanding and clinical practice.

Sampling and data collection

We used opportunity sampling to recruit doctors to the study. We anticipated that individualisation would be particularly relevant to doctors who deal with patients who have a range of problems;

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therefore we decided to sample doctors who are generalists (such as general practitioners and geriatricians). Two clinical academics (who were also hospital consultants) from within the medical school took part in pilot interviews to help test the procedure and topic guide.

We then emailed information about the study to 55 practice managers from practices on the Devon Primary Care Incentive Scheme -register (a register of primary care practices who have applied for support from the Primary Care Research Network for participation in research), and asked interested doctors -to make contact and arrange a time and place for the interview to take place. Sixteen doctors from 12 primary care practices responded to the email and took part in the interview. Two geriatricians were also recruited using snowball sampling. Our initial topic guide was based on a review of the literature and our own clinical experience (an experienced nurse and -rheumatologist are members of the team). ~~We used open ended questions to explore doctors' understanding of individualisation and the methods or strategies that they employ to deal with situations that require individualised treatment. In order to obtain detailed accounts, doctors were encouraged to provide examples whenever possible.~~ Open ended questions were used to explore the following topics (i) understanding of individualisation (ii) examples of individualising treatments (iii) methods used when patients' preferences are incompatible with guideline recommendations (iv) methods used to support patients to use their medication outside consultations (v) methods used to individualise treatments for patients with multiple chronic conditions and (vi) when individualisation is and is not appropriate. Participants were also asked if there was anything else they thought was relevant to individualisation. On the basis of the two pilot interviews with local clinical academics, the topic guide was modified to make it clearer that we are interested in individualised drug (as opposed to talking or physical) treatments in patients with chronic (as opposed to acute) conditions. In order to obtain detailed accounts, doctors were encouraged to provide examples of patients they had seen whenever possible.

To contextualise our study, the interviewer gave the following explanation at the beginning of the interview: "*Patients will vary in terms of the number of conditions they have, the amount of medications they take, and the severity of their condition(s). Patients will also have very different lifestyles, priorities, and beliefs about their condition(s) and treatments. We aim to explore the methods used by Healthcare providers to individualise treatments. We are aware that there is little consensus about what individualisation is, little guidance in the literature about how to do it, and that some doctors have developed their own approaches. We are interested in exploring the methods or strategies that are used by healthcare providers to tailor treatments to each individual patient.*" The interviewer started interviews by asking participants what they understood individualization to be, and to provide an example of a time during which they had individualized

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treatment with a patient. To avoid influencing participants' answers, we did not explicitly define individualisation. However, the interviewer later used prompts to encourage participants to discuss additional situations that could be considered to be amenable to individualisation (as per the topic guide). We anticipated that this would provide a detailed account of doctors' understanding of individualisation and the methods that they would use to achieve it within their understanding as well as the methods that they used to individualise treatments as others may see it.

All participants provided written consent prior to taking part. Ethical approval was obtained from the Peninsula College of Medicine and Dentistry ethics committee.

Data analysis

Interviews were audio recorded, anonymised and transcribed verbatim. We analysed the data using a thematic approach([23]). Two researchers independently read transcripts and noted down core codes~~themes~~ that were identified. We met regularly to discuss codes ~~themes~~ and to develop a preliminary list of themes~~codes~~. As analysis ~~coding~~ progressed, we drew on the existing literature to refine this list and to group related themes together([24]).

We then developed a chart for each theme([24]), and copied any interview data that was related to each theme into the relevant chart. To enhance rigour([25]), two authors carried out this process independently. We resolved discrepancies via discussion([26]). We then used the charts to identify narratives within cases and diversity between cases([27]). Divergent cases were discussed and included in the thematic analysis([27]).

A summary of the findings were sent to all doctors along with an invitation to offer any comments.

RESULTS

One author (SD) collected data between February and July 2012 from sixteen General Practitioners (GPs) (six rural and ten urban practices) and two geriatricians ~~four hospital consultants~~ from clinical practices in Devon. Data from the two clinical academics who took part in the pilot interviews was also included in the analysis. Seven doctors were female. Interviews were held at a location to suit the doctors (mainly at their place of work). The mean length of the interviews was 48 minutes (range 20-60 minutes). ~~Interviews lasted between twenty and sixty minutes.~~

The data are presented under three~~wo~~ main headings. First we identified two sub-themes relating to doctors' understanding: evidence based medicine and doctor-led prescribing, and individualising treatments around patient factors. Secondly we identified two sub-themes under the heading methods used to individualise treatments: methods used to make treatment decisions during the consultation, and methods to support patients after the consultation. Thirdly we identified

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dissonance between the rhetoric of individualisation and doctors' clinical reports of how they had dealt with some of their patients.

Understanding of individualised treatment

Doctors' understanding of individualisation ranged from evidence based medically focused, doctor-led care, through to prescribing drug treatments tailored to the patients' wishes and beliefs. There was variation in the ease with which doctors spoke about individualisation. There were two doctors who could not articulate their understanding of individualisation, but who were still able to respond to prompts about how they would deal with situations that could be considered to be amenable to individualisation. ~~Whilst all but two doctors were able to describe their understanding of individualisation when asked, these answers did not always match the examples they provided.~~ Doctors frequently discussed individualisation in relation to two of the processes involved in the prescription and use of pharmacological treatment - selecting appropriate drugs to treat the individual patient, and the interaction with the patient in the medical consultation. Doctors paid less attention to patients' use of treatments post consultation.

Evidence based medicine and doctor-led prescribing

At one end of the spectrum, individualisation was considered to be synonymous with evidence based practice. Focussing on the doctors' task of selecting appropriate drugs to treat the individual patient, one doctor described how the process of matching patients with guidelines resulted in all treatments being individualised:

> "I suppose when I did discuss it recently with my colleague the point he made was all treatments are individualised and it's, perhaps you're looking at it from a different perspective, because we look at it from the individual that comes in and then try and match a guideline to them or guidance, so everything you do is individualised anyway." (~~014~~Sophie, urban GP)

Importantly, when asked about their understanding of individualised treatment, no doctor referred to doctor-led prescribing specifically. However, it was implicit in their examples that in certain situations (~~i.e.,~~such as if the doctor thought that the patient really could benefit from treatment), they considered a doctor-led style of prescribing to be individualised.

> "Well again, it's a case of looking at what is right for that particular patient at that particular time, and, I, I, because the patient was at high risk of stroke, then I did really try to push the treatment." (~~004~~Jim, urban GP)

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> "You know, because I think if, somebody might be very against a drug, but if I've seen it work really effectively in the past, I suppose I feel, I wouldn't force them to take it, if I force them to take it they won't take it anyway, but I suppose I feel if I can find a way round it that would encourage them just to give it a go, sometimes it's worth it." (~~019~~Catherine, urban GP)

Individualising treatments around patient factors

Doctors described individualised treatments as drug treatments that had been selected after consideration of patient factors (such as patient circumstances). Frequently, this meant adapting or going against guideline recommendations. Some doctors described individualised treatments as treatments that had been tailored to suit the patients' medical needs (for example, ~~e.g.,~~ when treating patients with co-morbidities):

> "Well it's always checking on individual preferences, but the biggest factor is co-morbidity, that's what makes me step outside the box as it were." (~~012~~Tom, urban GP)

For other doctors, individualised treatments were treatments that had been adapted to suit patients' social circumstances:

> "So, I've got someone who lives out the back of beyond, no transport, they might be less keen to have something that requires frequent monitoring... We have a lot of shift workers round here so that can be quite an issue, um, shifts will often change from week to week... complete nightmare controlling anything like that because they're sometimes asleep when they're supposed to be taking their pills. So they can be tricky." (~~017~~Rachel, rural GP)

For some, individualised treatment required the patient to be involved in treatment decisions; with treatments being individualised around ~~what~~ the patients' willingness to take a drug ~~is prepared to do~~. These doctors considered patients' preferences to be more important than their own views and preferences. In particular, the two geriatricians in our sample were conscious that the patients' preferences are perhaps more important than achieving optimal control of their conditions:

> "Because most of the patients that we see have reached what statistically would be regarded as their life expectancy. So there is, we can't in anyway force our opinions on them. We have to go with the fact that they have made this value judgement as to what is the right thing for them... And we just have to accept that they've made the right judgement for them. Which is not necessarily the right

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> judgement for us. But as long as we feel that they are fully informed, or as informed as they can be, then we just accept what decisions they make on their behalf." (~~001~~Mark, geriatrician)

> "Maybe that's easier in geriatrics where we know lots of what we do comes at a price, we know 10% of hospital admissions that we do are from drug side effects. So maybe we feel a bit more relaxed about it." (~~013~~William, geriatrician)

For others, individualising treatment in accordance with ~~what~~ the patients' willingness to take a drug ~~was prepared to do~~ simply meant accepting that the patient had declined treatment:

> "And I'm quite happy to agree to differ, if they want to decline treatment, I'd write down declined treatment. I think it's important to come back to, not just see it as something that they've done wrong, but it's fine for them to do that, and I don't have a problem with them not taking that treatment." (~~006~~Marcus, urban GP)

Methods used to individualise treatments

Doctors described the methods they used to achieve individualisation. Again, doctors focused on the methods used to select appropriate drugs to treat individuals and interactions with the patients during the consultation. Few doctors spoke of methods to support the patient to use treatments after the consultation when drug taking actually occurs.

Methods used to make treatment decisions during the consultation

Doctors described using a range of resources to select appropriate drugs to treat individual patients. These included evidence, clinical experience, colleague support, and the patients' views or circumstance. Use of resources was dependent on doctors' understanding of individualisation, but influenced by the patient and the situation. All doctors described using evidence to make treatment decisions. However, views about the role of the evidence varied between doctors:

> "EBM is only one of many strategies, and, it's like you've got a tool box you know? And the tool that you use every time is you yourself. And you need, and you can learn to do that better. I'm very interested in that. And then occasionally you'll pull EBM out as well. But not, you know, not very often. Honestly, I would think I probably, as a first tool that you pull out, it would probably be once or twice a day." (~~010~~Andrew, urban GP)

It was widely acknowledged that "text book" scenarios were rare. One general practitioner reported that most of his patients had complex social needs, and both the geriatricians in our sample reported that nearly all of their patients had multiple conditions. These complex patients could not

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be treated only using evidence based guidelines([9]). Treatment decisions for patients with complex needs were made based on their own or their colleagues' clinical experience:

> "Often we send messages to each other. I share a list with another GP colleague, and we share difficult patients, and discuss how are we going to get Mr so and so to do X, Y and Z?" (014Sophie, urban GP)

To treat patients with complex needs, doctors often made treatment decisions for the patient, using strategies like polypharmacy to deal with side-effects of treatments, and accepting that not all conditions can be optimally managed:

> "Interviewer (I)Q: Ok, so when you've got a patient who comes in and has a range of medical conditions, and you know if you treat all of them it's going to lead to interactions?
>
> Respondent (R)A: The regimens for each of these conditions, A, B and C are reasonably well sorted because they're common conditions, common drugs, usually sorted. So he has arthritis, diabetes and epilepsy. That's a nice juicy mix, and fairly common. By and large you will get away with this polypharmacy." (008Mathew, urban GP)

To involve the patient in the treatment decisions, doctors reported using techniques such as providing the patient with the information needed to make an informed choice, suggesting treatment and outcome options, and giving the patient time to think about their priorities:

> "And then we can provide them with alternatives like 'well this will cure that but this could affect your kidneys. This might not have as big an effect on that but it would preserve the kidneys and could leave you a little bit short of breath. Of those two which would you rather have? The risk of feeling completely healthy, but potentially shorter life, or having some symptoms but a longer life?' And working with those decisions." (001Mark, geriatrician)

Whilst one doctor aimed to prescribe treatments in accordance with patients' interests, he accepted that this could not be an everyday occurrence:

> "I'll be honest; I don't do it all the time, so I don't want to pretend I'm perfect at this. I think the clearest one that I've got is a bloke in his late 50s with Parkinson'ss who'd retired, but the thing that kept him going was that he could go to the swimming pool every morning... So we opted for a patch for him... You slap it on once a day and it gives you 24 hour coverage so he could put it on the night before and he'd be switched on in the morning, he wasn't waiting for a tablet to kick in and make him work. And it worked beautifully for him... but after a few

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> months he got skin reactions and we had to stop it and find something else, but that really felt like we had really picked a drug around him and his interests and what was keeping him going." (~~013~~William, geriatrician)

Interviewees also reported situations in which a more directive approach was considered to be necessary. This included situations in which patients' goals were deemed unrealistic, or when the doctor thought that the patient really should be using some form of treatment. Doctors then reported using techniques in order to convince or persuade the patient to follow recommendations. In some cases, attempts were made to encourage the patient to see the medical imperative for treatment:

> "They don't want to take any tablets; you say 'well you probably will die in 5 years time at the most without these things. If you take these things it might prolong your life, by this that or the other.'" (~~007~~Joe, urban GP)

For some doctors, the assumption appeared to be that the patient was in some way misinformed. Therefore, attempts were made to educate the patient:

> "Most of the time you can explain to people why they ought to be taking something and hopefully they might come round to thinking that that's the best thing to do. Sometimes people might have different ideas and won't take anything or certainly won't take what you suggest but I think most of the time you can explain to people why or what the evidence is or what the consensus is. And most of the time if people understand it they'll take it." (~~022~~Lynn, rural GP)

If initial treatment decisions were not acceptable to the patient, attempts were made to change or simplify the regime or to prescribe alternative treatments:

> "You just say 'well let's try something else.' The nice thing is, there's always, or very often there's always alternatives that are either as good or, uh, you know, in the same league." (~~014~~Sophie, urban GP)

Methods used to support patients after the consultation

In most interviews, individualisation was described in the context of making treatment decisions during the consultation. Few doctors spoke of methods to support patients to test and refine their treatment in the context of their own life. To support patients after the consultation, doctors reported using techniques such as reminders and instructions. This ranged from standardised ~~dossette~~ monitored dosage system ~~boxes~~ or text messaging

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services, to writings and drawings on prescription labels. Crucially, the aim of such strategies was to help the patient use their medications as prescribed:

> "~~Q~~I: Do you use any strategies to support the patients outside the consultation?
>
> R~~A~~: Um, not enough. It's something I often think about that I should be doing more. So I do drawings and write things on bits of scrap paper, about if there is a complicated medication, or a list of things to do, or if people are older, forgetful" (~~006~~Marcus, urban GP)

A minority of doctors described using strategies to help patients modify treatment regimes to suit their lives. One geriatrician described how he used techniques such as separating drugs into those that have to be taken (to treat the condition) and those that do not have to be taken (to treat the symptoms):

> "I tend to rearrange them so into treatments and symptoms... And if you group them like that, then if they get half way through the tablets, providing they've taken their treatment tablets, the symptom control, if they don't take it they're going to feel lousy, but the balance between taking a tablet or not taking a tablet, it's not going to make any difference to their longer term health." (~~001~~Mark, geriatrician)

Another geriatrician described a process of trial and error, in which drugs were used for a period of time and then modified by the doctor if necessary:

> "I think as well, because we tell patients for a lot of these drugs let's try this and see if it works, if it's not working we'll stop it. It allows patients to come back and say it's not working rather than come back and feel that they're on it." (~~013~~William, geriatrician)

Only one general practitioner actively encouraged patients to modify their treatments to achieve individualised doses. This doctor described reluctance on behalf of some patients to do so:

> "So actually, for an awful lot of drugs, I do this all the time. I say balance up your, you know yourself when you're getting the side effects. Titrate the medication until you're just below the level at which you get the side effects and fiddle around with it... And then sometimes the patient's say, 'ohh, but it says once a day and bla bla bla.'" (~~007~~Joe, urban GP)

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The hospital consultants in our sample reported used diaries and graph paper to either assess the effectiveness of treatments and treatment doses, or to encourage patients to respond to worsening symptoms:

> "So, it's just a piece of paper really with days of the week and what their Parkinson's is like. But Parkinson's you swing from being on, when you can move around, to being off, when you're frozen and stuck. So if we're trying to give a drug to reduce the amount of time people are off , we'll often give them a diary so you can graphically see whether it's worked or not." (~~013~~William, geriatrician)

> "Well they all get the graph paper. And it's "If it goes above this line, phone us and we'll see you in clinic straight away. Or, if it goes above this line increase your tablets. Or do this that or the other." And it's what we tell them to do when it reaches that point that varies by patients." (~~001~~Mark, geriatrician)

The question of whether or not patients needed to be encouraged to monitor symptoms was contested. Some doctors were of the opinion that patients should not be encouraged to monitor their symptoms or side-effects of their treatments:

> "I quite often don't tell people about the side effects of tablets, which is against our, against all the modern day teachings that you must tell people of the risks. Well I often don't. Because there's a lot of evidence for this, there's a type of patient that if you tell them there is a possibility that they'll get headaches, they'll get headaches." (~~002~~John, clinical academic)

Others felt that patients should be told what potential side effects they should look out for:

> "Explain to them the possibility that one thing might affect another and what to look out for. So if there are going to be interactions, what they, what they need to be um, coming back with um, if certain symptoms present. You know if you get this, come back, because that's a side effect we need to know about." (~~016~~Becky, urban GP)

However, even with clear instructions, mistakes could happen:

> "We've had that with a patient who used, you know, he had the line [indicating safe blood pressure readings], he went way below the line, kept on going without bothering to phone anyone, and six weeks later he was in hospital with renal failure. And we gave him pretty clear instructions. He decided to ignore them... It

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> worked; he just didn't follow the instructions. But you can't do anything about that. Patients are entitled to do what they want." (~~001~~Mark, geriatrician)

There was wide acceptance that, in the end, the final treatment decision was down to the patient. In certain situations, no treatment could be the best option:

> "You know, you say, 'this is what's going on, you tried them we've looked at physiotherapy, we've looked at other alternatives, are your symptoms manageable? Are the treatments worse than the condition, and if they are, then maybe you need to learn to live with the condition." (~~017~~Rachel, rural GP)

Dissonance between rhetoric and experience

Whilst all but two doctors were able to describe their understanding of individualisation when asked, these answers did not always match the examples they provided when talking about patients they had treated. For example, one doctor described individualisation as being:

> "All sorts of things. Everything from the persons' views or thoughts about - if you're talking about medicines - about drugs and what they want. But similarly that fits with their views of whether they like medicine, don't like medicine, what they want in terms of getting better." (Catherine, urban GP).

However, when this participant was asked how she would respond to a patient who did not want to use the treatment that she had prescribed, she responded:

> "There are even times when I'll say 'well actually I think this would be worth trying' even if they're not very keen. And I'll say to them 'how about you give it a go for two weeks and see how you feel.' You know, because I think somebody might be very against a drug, but if I've seen it work really effectively in the past, I suppose I feel, I wouldn't force them to take it, if I force them to take it they won't take it anyway, but I suppose I feel if I can find a way round it that would encourage them just to give it a go, sometimes it's worth it" (Catherine, urban GP).

This dissonance between rhetoric and experience was evident throughout the interviews. Whilst doctors appeared to think that individualising treatments around patients' preferences and world views into treatment decisions was of value, in practice this was not always considered to be the best strategy.

DISCUSSION

Main findings and comparisons with other studies

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This paper presents a range of doctors' understandings of the meaning of individualised drug treatment. ~~Overall, there was a lack of consensus about whether i~~Individualised treatment was discussed in relation to both treatment that was tailored to patients' priorities, and treatment that was doctor-led and followed evidence based guidelines. Furthermore, there was a lack of congruence between doctors' stated definition of individualisation and the examples they provided from their practice. Doctors frequently spoke of methods to support interactions during consultations, the first of the processes referred to in the introduction of this paper. However, despite the findings of Pound et al([21]), doctors in our study infrequently mentioned patients' use of their medications outside the consultations.

The main strength of this study is the use of qualitative methods to generate a rich insight into doctors' understanding of individualisation, methods used to achieve individualisation, and the relationships between the two. We used strategies to enhance the trustworthiness of our study, including multiple coders and respondent validation. We triangulated our findings with the existing literature, and asked participants to comment on our findings([28]). Participants who took part in pilot interviews stated that they could recognise our findings, and agreed that they were plausible.

Our study was based on a sample of hospital consultants and general practitioners from the South West of England. That doctors were only recruited from this area could limit the transferability of the results, although participants had both trained and practised beyond this region. ~~Whilst we report that the four hospital consultants appeared to be more willing than general practitioners to individualise treatments after the consultation, this is based on a small number of participants. Further research is needed to explore differences in individualisation between different clinical specialities. This may highlight situations clinical areas in which individualisation is commonly achieved and situations in which individualisation is not so appropriate.~~ We acknowledge that our use of opportunity sampling may have resulted in a self-selected sample. ~~However, our results demonstrate the lack of consensus about what individualisation of drug treatments means to participating doctors, suggesting that there is no shared understanding of what the term means. The lack of consistency between respondents' definitions of individualisation and the examples they gave suggests that there may also be inconsistency between their explanations and their clinical practice.~~ However, as we are interested in best practice, we were not overly concerned with recruiting only those with an interest in the study.

Previous qualitative research has explored methods to support doctors during consultations([16-18]). In those studies, the focus was on strategies used by doctors to make individualised prescribing decisions within the medical consultation - where guidelines may not be appropriate. Similar to the doctors in our study, those studied ~~in the study~~ by Fried et al. had variable views about how

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treatment decisions for patients with complex conditions should be made. Use of evidence and strategies to balance the harms versus the benefits of guideline directed care varied between physicians.

Doctors in both of these studies had differences of opinion regarding the role of the patient in treatment decisions. For some, treatment decisions should be doctor-led, with the doctor persuading the patient to use the treatment that they thought would be most appropriate. For others, patient involvement was an essential component of treatment decisions. A number of doctors reported that integrating patients' preferences into medical decisions was problematic if the treatment was essential. This was still a major concern for many doctors, despite research suggesting that patients' and doctors' priorities may be very different([29]). This paternalism versus patient choice is an ongoing debate, and one that is widely discussed in the literature([15;30;31]). In the current paper, the dissonance between the rhetoric of individualisation and doctors' clinical behaviour appeared to stem from this issue, with the data revealing tensions between doctors desire to treat the patients' social needs, whilst simultaneously treating their medical needs.

Pound et al found evidence to suggest that patients actively modify their medications in order to suit their lives([21]). However, there is a paucity of literature surrounding methods used to support patients during this third process. The few doctors in our study who spoke of methods to support patients outside the consultation described methods such as sorting drugs by their role (to treat or to cure), trial and error, and monitoring. These strategies are largely informal: for example, drawings, or writing about the use of the medication on bits of paper. The limitations of such informal methods were acknowledged.

The lack of consideration of what goes on outside the consultation is particularly interesting and worrying. Pound et al., (2005) has shown that many patients will monitor their symptoms and side effects and make treatment adaptations as necessary – with or without the support of the doctor. Self-management of chronic disease requires patients to take multiple treatments and monitor their health over many years. Therefore, strategies to support patients to modify treatments, and providing safe parameters for them to do so, may actually limit patient driven amendments to treatments without professional support. However, our study highlights the variation in opinions about whether or not patients should be encouraged to adapt treatments after consultations. One doctor felt that patients did not want to adapt their treatments. Another doctor thought that encouraging patients to be aware of side-effects could actually contribute to side effects. Others were concerned that encouraging patients to monitor symptoms could lead to unnecessary stress. Only a small number of doctors ~~(mainly from secondary care)~~ thought that patients should be encouraged to individualise treatments after the consultation. In particular, the ~~-~~ two geriatricians

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seemed to have a better understanding of, and a larger set of methods to support patients to individualise treatments after consultations than the general practitioners, thus suggesting that the findings might be related to medical subspecialty. Further research is needed to explore differences in individualisation between different clinical specialities, as this may highlight situations clinical areas in which individualisation is commonly achieved, and situations in which individualisation is not so appropriate. ~~However, as Pound et al., (2005) has shown, many patients will monitor their symptoms and side effects and make treatment adaptations as necessary – with or without the support of the doctor. Self-management of chronic disease requires patients to take multiple treatments and monitor their health over many years. Developing tools to support patients to modify treatments, and providing safe parameters for them to do so, may actually limit dangerous adaptations.~~

The findings reported here have important implications for research and practice. The focus of ~~the doctors in~~ this study was on the strategies and methods that doctors ~~doctorsthey~~ used to reach decisions within the consultation. Few doctors discussed methods to support patients to use drug treatments outside the consultation. Methods that were suggested were informal and unstructured, and doctors acknowledged that such methods may neither be supportive enough or measurable. Furthermore, doctors perceived a number of barriers to individualising treatments after the consultation; such as whether or not strategies could contribute to side-effects and cause unnecessary stress. Before policy recommendations concerning both individualisation and self-management can be achieved commissioners need to be clear about what they are advocating, thus, the concept of individualisation needs to be refined. Methods used to achieve individualisation may then be developed and piloted in different situations. Such methods should be appropriately structured to be supportive and their effects measurable. Given that some patients are already individualising treatments on their own, supporting patients to do so safely could improve patients' self-management practices.

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