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What can we learn from parents about enhancing participation in pharmacovigilance?

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Direct patient reporting of adverse drug reactions to systematic pharmacovigilance systems can provide valuable information but public awareness of such schemes is low. Research to identify barriers to participation has focused on adult patient reporting and none has looked specifically at parents' experiences of reporting children's adverse drug reactions (ADRs). Parents may have distinctive perspectives on reporting ADRs in a child arising from their caring role.

WHAT THIS STUDY ADDS

- We identified previously unreported barriers to parental participation in systematic pharmacovigilance, including uncertainty about whether it was legitimate for lay people to submit a report. We also found novel motivators for parental reporting, which included the need to resolve feelings of guilt. Our findings indicate that pharmacovigilance agencies may need to go beyond simply raising public awareness and take steps to present their schemes in ways that empower and support lay people to report ADRs.

AIMS

To investigate parents' views and experiences of direct reporting of a suspected ADR in their child.

METHODS

We audio-recorded semi-structured qualitative interviews with parents of children with suspected ADRs. Our sample included parents with (n = 17) and without (n = 27) previous experience of submitting a Yellow Card.

RESULTS

Parents in both groups described poor awareness of the Yellow Card Scheme. Parents who had participated in the Yellow Card Scheme were generally happy to report their child's ADR via the Scheme and valued the opportunity to report concerns independently of health practitioners. They expressed motivations for reporting that have not previously been described linked to the parental role, including how registering a concern about a medicine helped to resolve uncomfortable feelings about their child's ADR. Parents who had not previously submitted a Yellow Card expressed uncertainty about the legitimacy of their involvement in reporting and doubts about the value of the information that they could provide.

CONCLUSION

Promoting wider participation in pharmacovigilance schemes will depend on raising public awareness. Additionally, our findings point to the need to empower lay people to submitting reports and to reassure them about the value of their reports.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for monitoring medicines in the UK. Collecting and analyzing reports of ADRs is central to the MHRA's work to monitor the safety of medicines, which they do by collecting spontaneous reports of suspected ADRs submitted via the Yellow Card Scheme [1]. The Yellow Card Scheme is designed to detect signals that may indicate a potential hazard with a medicine. The signals can trigger further investigations that may result in changes in prescribing recommendations or restrictions, or the removal of a medicine. Medical practitioners and dentists have been able to submit Yellow Cards for suspected ADRs since 1964, and the Scheme was extended to other health practitioners in the 1990s and 2000s. Submitting a Yellow Card for suspected ADRs in children is strongly recommended [2] given the frequent use of off label and unlicensed medicines in paediatrics [3]. However, reporting of ADRs also depends on the enthusiasm and commitment of individual practitioners. As such there is considerable variation in ADR reporting by practitioners and concerns about under-reporting [4–6].

Partly in response to concerns about under-reporting, the Yellow Card Scheme was extended to patients and their families in 2005 [1]. Patients have been found to provide more detailed reports of ADRs than health practitioners and to value the opportunity to contribute to pharmacovigilance [7–14]. This suggests there are benefits to promoting patient involvement in pharmacovigilance [8–12, 15–17] beyond responding to concerns that practitioners under-report ADRs [6]. A recent amendment to the EU pharmacovigilance directive sought to encourage greater reporting of ADRs by both patients and practitioners, to improve information given to patients about ADRs and to create a central European wide pharmacovigilance system [18–20]. The new directive aims to give patients a greater role in the monitoring and reporting ADRs.

Research supports the development of patient participation in pharmacovigilance, with UK patients being positive about the aims of the Yellow Card Scheme and finding it 'user friendly' [8, 15, 16]. However, public awareness and participation in the UK Yellow Card Scheme is low [8, 21, 22]. Adult patients who use the Scheme report altruistic motives, as do clinicians [7, 23]. Adult patients also report being motivated by the severity of the ADR, a need to share their experience, concerns that the ADR they experienced was not included on the medicine patient information leaflet and concerns about their own situation [23]. However, patient participation in reporting ADRs using Yellow Cards is low and patients who do report may be atypical. Research with patients who have experienced an ADR but have not reported it using a Yellow Card is limited. A recent study of non-reporting adult patients who had been hospitalized because of a suspected ADR indicated that they did not share the altruistic views of patients who had used the Yellow Card Scheme. Moreover, non-reporters considered the Yellow Card Scheme to be remote and impersonal and felt that using it was not their concern [22].

Exploration of the particular motivations of parents for using the Yellow Card Scheme and the barriers they encounter in doing so is important for several reasons. Previous research has focused primarily on adult patients [5, 7–10, 13–17, 21–23], yet the need for parental confidence in pharmacovigilance is particularly pressing in relation to children's medicines due to the widespread use of unlicensed medicines in children [24, 25] and public concern about the safety of children's medicines [26–32]. Also, the perspectives of parents may differ from those of other lay users of pharmacovigilance schemes, because of parents' distinctive caring and protective role [33, 34]. Parents can be concerned by their lack of control when managing a child's illness [34] and are helped by explicit communication with practitioners about their child [33], so they may have unique concerns about the Yellow Card Scheme or how their reports are used [11, 35]. While it is important to investigate the experiences of parents who have used the Yellow Card Scheme, it is also important to understand the views of parents who have not previously used the Scheme. Public participation in the Yellow Card Scheme is low and limited to certain groups [8, 21, 22] so understanding the views of parents of children who have experienced ADRs, but have not submitted Yellow Cards, may help inform strategies to promote wider participation in the Scheme.

We therefore conducted this study, ADRIC-QUAL, to investigate the experiences and views of parents of children who had experienced a suspected ADR. We took a qualitative approach to avoid pre-defining parents' views in this little researched area and to describe what considerations parents themselves regarded as important in directly reporting children's ADRs.

Method

Sample and setting

Our maximum variation sample aimed to access parents of children with a diversity of suspected ADRs in terms of severity, type of medicine, the child's underlying condition, and include parents who did not have experience of the Yellow Card Scheme as well as those who did [36]. We accessed the parents who had experience of the Yellow Card Scheme via the MHRA, who sent letters to parents across the UK who had submitted a Yellow Card on behalf of a child (aged 16 years or under) between April 2009 and October 2010. Letters invited parents to return a reply slip to the ADRIC-QUAL researchers. We term this subset 'YC parents'. Most YC parents who responded to the invitation in the first 6 months of the study had submitted Yellow Cards reporting reactions to vaccines. Thereafter, to maxi-

mize sample diversity the MHRA only sent study invitations to parents who reported suspected ADRs that were unrelated to vaccines.

We sampled parents who did not have experience of the Yellow Card Scheme via two observational studies (ADRIC 1 and 2) of the nature and prevalence of suspected ADRs in a tertiary paediatric hospital in North West England. These studies were conducted within the Adverse Drug Reactions in Children (ADRIC) Programme [37]. ADRIC 1 identified suspected ADRs among patients requiring an unplanned hospital admission and ADRIC 2 identified suspected ADRs among inpatients for 48 h or more. For ADRIC 1 and 2, a suspected ADR was defined as an '*appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dose regimen, or withdrawal of the product*' [38] and which was not related to a medical error or deliberate overdose. We termed this subset 'ADRIC parents'. These parents were eligible for ADRIC-QUAL if they could be approached about the study before hospital discharge, the family were not experiencing pronounced distress and there were no child protection concerns.

Procedure

YC parents who returned a reply slip were contacted by ADRIC-QUAL researchers who explained the study further and arranged an interview. For ADRIC parents, treating clinicians initially introduced ADRIC-QUAL and the researchers approached interested parents to explain the study and arrange an interview. YC parents were interviewed over the telephone whereas ADRIC parents were interviewed face-to-face.

The researchers (JA, HH and ES) conducted semi-structured interviews with parents using a conversational approach to ensure that the pace, sequencing and duration of the interviews was shaped by the participants. To achieve comparability across interviews, researchers used topic guides that contained a core set of prompts about parents' experience of their child's ADR and their views of the Yellow Card Scheme. However, we tailored the topic guides as appropriate for the two subsets of parents. For YC parents we included prompts about how parents had found out about the Yellow Card Scheme and their motivation, experience and expectations of submitting a Yellow Card. For ADRIC parents, we included prompts to explore parents' awareness, beliefs and perceptions of the Yellow Card Scheme and whether they would consider using it to report suspected ADRs. All interviews were audio-recorded transcribed and anonymized. Transcripts included indicators of hesitation, repetition, dysfluency and sub-verbal vocalizations. An NHS Research Ethics Committee (08/H1002/7) approved the study and all participants gave informed written consent.

Qualitative data analysis was interpretive and informed by the constant comparative method [39–41]. JA led the analysis, reading transcripts several times to identify emerging themes and develop analytic categories. We developed these themes by comparing within and between transcripts throughout data collection in an iterative process and sampling continued until theoretical saturation was achieved [39–42]. BY and MT supported this process by reading a sample of the transcripts and 'testing' and developing the analysis by periodically discussing the transcripts. We followed several procedures to ensure the quality of analysis, including respondent validation whereby we discussed the emerging analysis with later participants, and by attending to deviant cases [40, 41]. We scrutinized the quality of the developing analysis according to its coherence and potential to influence practice and policy, a process that was assisted by discussion of the analysis among all authors. This investigator triangulation, with authors from different disciplinary backgrounds, including paediatrics, pharmacology, psychology and health research, also helped to ensure the relevance of the analysis.

We provide data extracts in the body of the text to illustrate our findings and further extracts in Tables 2, 3 and 4 to evidence our interpretations of the data [39]. Extracts are coded as Yellow Card (YC) and ADRIC (A). Explanatory text is indicated by [text] and omitted text by [. . .].

Results

We conducted audio-recorded interviews with the parents of 44 children (41 mothers, four fathers). Of the 54 YC parents who were sent invitation letters by the MHRA, 21 returned reply slips indicating an interest in participating and we audio-recorded interviews with 17 parents. One YC family could not be contacted after consenting and a further three interviews were excluded from the analysis due to recording equipment failure. Of the 27 ADRIC families who participated, 10 were recruited via ADRIC 1 and 17 via ADRIC 2. A total of 21 ADRIC 2 families had been approached to participate. Those who declined cited their child's repeated hospital admissions as the reason. Data on the number of ADRIC 1 families approached are not available.

Approximately half the parents were interviewed about their daughter's ADR and half about their son's. Interviews lasted approximately 60 min (range 20–100 min) Three ADRIC parents were interviewed in private rooms in the hospital and the remainder were interviewed in their homes. All YC parents were in their homes when telephone interviews were conducted. Table 1 shows YC and ADRIC participants' characteristics Table 1. The Index of Multiple Deprivation scores of YC parents indicated significantly less deprivation among this group than the ADRIC parents (Mann–Whitney *U*-test; $Z = -3.920$; $P < 0.001$).

Table 1
Participant characteristics

Characteristics	ADRIC	YC
Mean (range) child age at interview in years and months	8 years 2 months (1 month–16 years 4 months)	11 years 7 months (1year 3 months–17 years 3 months)
Mean (range) weeks between ADR onset and ADRIC-QUAL interview	5 (2–15 weeks)	5 (4–56 weeks)
Number of parents not self-identified as White-British	0	1
Median (inter-quartile range) Ranked Index of Multiple Deprivation*	12 522 (2028–19 844)	29 795 (20 562 –31 473)†
Children with ADRs linked to a vaccine	2	9

*Calculated using Lower Super Output Area 2007 ranked score data, whereby lower scores indicate greater deprivation. †Three families from Wales are excluded due to incompatibility of English and Welsh Index of Multiple Deprivation scores.

Awareness of the Yellow Card Scheme

More than half of parents who sent in a Yellow Card remarked that they had found out about the Yellow Card Scheme through their training or work as a health practitioner '*The only reason I knew about it was because of the course that I'd done*' (YC7), or through friends or relatives who were health practitioners (Table 2). YC parents often commented that members of the general public who had little personal or informal contact with health professionals were unlikely to know about the Yellow Card Scheme and only a small number of these parents reported finding out about the Scheme via publically available sources such as the Internet or MHRA publicity materials. Only one parent had been told about the Yellow Card Scheme by the health practitioner caring for their child.

Only two ADRIC parents had heard of a Yellow Card before we interviewed them and both were nurses. None of the ADRIC or YC parents knew for certain whether the practitioners caring for their child had submitted a Yellow Card reporting his/her suspected ADR: '*I don't know if one was filled in or not*' (A20), but remarked that they would appreciate being informed if a practitioner had done so: '*I would like to be informed*' (A14).

Motivations, views and experiences of parents who submitted Yellow Cards

YC parents described multiple motivations for submitting a Yellow Card (Table 3). Most emphasised how they wanted to help prevent other children experiencing the sorts of ADRs that their child had suffered. They also hoped that their report would contribute to a wider review process: '*if they look into things, and [. . .] if there is too many incidents, they might have to re-look at the tablet or re-label the information leaflet* (YC7). Parents did not usually think their reports would directly help their own child: '*I didn't think it would help me at all. I didn't have any expectation for us*' (YC10) and none of the parents that we interviewed wanted a medicine to be withdrawn from the market solely because of the difficulties their child had experienced. Linked to these altruistic motivations, YC parents also described a sense, albeit nebulous, of '*achieving something positive from that experience rather than just sort of happening*' (YC14). YC parents who had professional knowledge of the Yellow Card Scheme added that they were motivated to submit a report by a sense of professional integrity or obligation. Those who were not health practitioners expressed a preference for reports about suspected ADRs to come from health practitioners rather than themselves: '*I wished it* [Yellow Card] *had come from the doctor first*' (YC10).

Some YC parents seemed to understand that a certain number of reports would be needed in order to trigger action by the MHRA and were confident that their reports had potential to contribute to drug safety '*if enough people say something about this then something should and probably will get done*' (YC16). Others were unsure about what happened to the data after they had submitted it: '*I don't understand, you know, what happens to these reports really*' (YC2). Most parents did not report expecting to receive feedback from the MHRA in response to their Yellow Card: '*I didn't expect to hear anything further to be fair*' (YC14) but those who had received a response from the MHRA were pleased they had '*What I'm delighted about is the response – it makes you feel very pleased, glad that I followed it up*' (YC3)

Linked to their sense of responsibility for their child's wellbeing, some YC parents emphasized that they wanted to be involved in managing their child's care and in making sure that concerns about their child's medicines had been recorded in some way. Many YC parents emphasized how the health practitioners they consulted had not taken their concerns about their child's ADRs seriously. In this context, the opportunity the Yellow Card Scheme offered parents a welcome opportunity to voice their concerns about medicines in a way that was not filtered or influenced by practitioners: '*I felt very pleased that I could actually complete the Yellow Card and, erm, and actually take- take control of it really and let someone know regardless of what the doctor thought*' (YC8). Another parent spoke of how submitting a Yellow Card provided a form of redress: '*It's kind of restorative justice in a way*' (YC6). Other parents felt a sense of guilt about what had happened to their child and spoke of how submitting a Yellow Card helped to resolve these feelings: '*It felt that I might have failed* [my child] *so that's what I am doing it all for, really, to try and offload that information*' (YC10).

To explore potential practical barriers to completing Yellow Cards, we asked YC parents about their experience of filling them in (Table 4). Parents were generally positive about their experience and found the Yellow Cards straightforward to complete: '*It was very easy to do. Very,*

Table 2

How parents found out about the Yellow Card Scheme

Over half the parents heard about the Yellow Card through connections with the medical or pharmaceutical profession:
'I'd heard of the system and grown up within the sort of hospital environment, wasn't a big surprise that it was there, it was just a surprise that I could fill it out as a member of the public.' (YC14)
'I spoke to my sister who happens to have worked in a medical profession for twenty-five years: she told me about the yellow form.' (YC3)
'I'm a pharmacist.' (YC16)
Parents who heard about the Scheme from other sources did so fortuitously:
'I think I was waiting for a prescription and I just picked up a leaflet.' (YC1)
'through getting a solicitor's advice, someone finally gave me the number for the MHRA, which I didn't even know existed.' (YC5)
'It was an article in the newspaper. This mother of a child who'd had serious side-effects from the jab, erm, – she'd mentioned that she registered the concern on this Yellow Card system.' (YC9)

Table 3

Parents' motivation for submitting a Yellow Card

Parents cited altruistic reasons for submitting a Yellow Card:
'If children have it, and they can have experiences like my daughter, I don't want other children to go through it.' (YC7)
'I know other children who are on the medication, and I'd hate anyone else to go through what we've been through'. (YC2)
Parents also cited emotional and psychological reasons including needing to feel that their concerns had been acknowledged, recognized and recorded:
'I felt a bit cross that he [GP] didn't take it [ADR] seriously.' (YC8)
'It's [the Yellow Card] good for people who have had a bad experience, to get their point over. We were pleased [with our experience]. But if you had a bad experience you could [voice] your opinion, couldn't you?' (A5)
Contributing towards potential change:
'It's recorded [. . .] then you can find out how many have reacted to it in that way. Surely that's going to help the next generation? They'll know how to change it.' (YC10)
'I was hoping that they- that someone would alert the drug company, erm, and also that, erm, the NHS, the- the government would be aware.' (YC8)
Sense of professional responsibility and obligation:
'I knew it was the drug and I knew it's a new one and you should fill it in when it's a new product on the market. I knew I should do, because it was a new drug.' (YC13)

Table 4

Parents who submitted a Yellow Card were positive about their experience

'I thought, "what a marvellous thing, this is good" it seemed really up at the medical level.' (YC10)
'It was very good actually 'cause being able to look online and being able to report, erm, the symptoms online.' (YC8)
'I thought it was very simple I don't remember having any problems.' (YC16)
Parents occasionally experienced minor technical problems but usually found these were quickly resolved:
'I thought it was quite technical, some of the bits. I wasn't sure whether my – I seem to ask – if repeating the same thing – and whether that was going to be the right information in the right bit -otherwise it was fine.' (YC10)
'I tried twice and filled in all the information and everything and for some reason it didn't quite get through, so I had to then ring and, erm, speak to somebody about it. But it was fine, it was really straight forward, and they were very helpful.' (YC7)

very easy and straightforward' (YC5). Parents valued free text space on the Yellow Card as this allowed them to describe symptoms and behaviours in their own words: *'I use terms like meltdown and tantrum really kind of colloquial – the free space kind of helped to actually describe what I thought was going on* (YC16).

Views and experiences of parents who had not submitted Yellow Cards

Most ADRIC parents knew nothing of the Yellow Card Scheme prior to participating in this study. When we explained the Yellow Card Scheme to them during the interviews, like the YC parents, ADRIC parents were generally positive about the Scheme. All but one said they would consider using the Yellow Card Scheme in future:*'Now that I know about it, yeah, I would do. I'll tell my friends about this actually'* (A23). One parent was initially concerned about the potential for the Scheme to be misused: *'it's just going to open floodgates for people who are not going to be happy [. . .] And I think health and safety is [. . .] it's just going to the extreme now'* (A18), but her viewpoint changed after the interviewer had explained the Scheme and its purpose in more detail.

While many ADRIC parents were positive about the Yellow Card Scheme and said that they would consider using it in the future, none indicated that they would like to complete a Yellow Card for the particular ADR that we had discussed during the interview. Parents' reluctance may be potentially linked to their experiences of their child's ADR. Like the YC parents, many ADRIC parents had been dissatisfied with how health practitioners had communicated about their child's ADR, but ADRIC parents also described confusion and uncertainty about roles and responsibilities for recording and reporting a suspected ADR in their child. Some assumed this was a practitioner's role:'[I] *just assume the doctor would sort it out*' (A14), or expected that practitioners would submit Yellow Cards as a matter of course: *'I would more than likely think that the doctors would do it [. . .] if the child has had a reaction they would automatically'* (A13). Others implied that practitioners might disapprove of parents who submitted Yellow Cards and regard such parents as stepping beyond their role:'*they might think that you are trying to do their job for them*' (A20).

ADRIC parents were also reluctant to submit a Yellow Card on this occasion because they were uncertain about whether an ADR had occurred:'*I don't think they linked it to an adverse reaction at the time*' (A25) or they did not feel they or other members of the public were equipped to decide if an ADR had occurred:'*I'm not medical so I wouldn't know what a reaction would be*' (A18); *it* [the side-effect] *may not be from the drug, and* [a parent] *might think it is and go onto the internet and say that on a Yellow Card*' (A22).

Discussion

To our knowledge, this is the first study of how parents view the opportunity for them to directly report suspected ADRs in their child to the MHRA. All parents saw value in direct reporting and those who had submitted Yellow Cards were not discouraged by the Yellow Card Scheme's remoteness or the absence of feedback in response to their report. Parents also found the Yellow Card Scheme easy to use and in our sample of parents who had submitted Yellow Cards there was widespread satisfaction with the Scheme. However, our key findings come from the ADRIC parents, none of whom had previously submitted a Yellow Card. These parents were generally supportive of the aims of the Yellow Card Scheme after it had been explained, and although they were positive about using the Scheme in the future, they were reluctant to use the Scheme to report the ADR discussed in their interviews. Comparing the settings, roles and perceptions of the YC and ADRIC parents helps to shed light on these findings. The YC parents generally reported events that had happened in the community, and linked to their professional roles, many were confident about using the Scheme. In contrast, the children of ADRIC parents had received hospital care for their ADR or were hospital inpatients at the time the ADR occurred. As such, these parents either expected that it was the responsibility of the practitioners looking after their child to submit a Yellow Card, or they were uncertain about whether it was legitmate for parents to report the ADR. Moreover, only a few ADRIC parents had personal links to health practitioners or were themselves health practitioners.

Consistent with previous research on adult patient reporters [8, 21, 22], our findings indicated that awareness of the Yellow Card Scheme is limited. Of parents in our study who had submitted a Yellow Card, many worked as health practitioners or had personal contacts who did so. Of those who had not submitted a Yellow Card, only two had previously heard of the Yellow Card Scheme and both were nurses. This indicates that further work is needed to promote awareness of the Yellow Card Scheme.

Parents who submitted a Yellow Card reported multiple motivations. Altruistic motivations, such as a desire to contribute to the improving the safety of medicines at a population level, were particularly prominent in their accounts. This is similar to findings reported on other patient groups who have reported ADRs, to clinicians' motivations for submitting Yellow Cards [8, 15, 16] and it is also consistent with the goals of the MHRA [1]. However, self-reported altruism is difficult to distinguish from the self-presentational 'work' that most interviewees do to give socially acceptable accounts of themselves. Nevertheless, parents' descriptions of their motivations are consistent with other aspects of their accounts lending credibility to their reports of being altruistically motivated. For example, few parents expected their Yellow Card to benefit to their own child and unlike previous research with adult patient reporters, which indicated their desire for feedback following a report [16], most parents had little expectation of feedback.

Parents cited additional emotional and psychological motives for participating in the Yellow Card Scheme. In a context in which parents were dissatisfied with practitioners for not taking their concerns seriously, they reported being reassured, as others have also described [8, 15, 16], by the availability of an independent vehicle for 'officially' recording their child's ADR. Some experienced reporting as providing a form of redress. In this way, the Yellow Card Scheme empowered parents, allowing them to take action that seemed psychologically important following their child's ADR, even if it did not directly benefit their child. A few parents pointed to how submitting a Yellow Card had helped to resolve feelings of guilt about the medicines they had given or allowed their child to take, a motivation that has not been previously described and may be unique to parents and others who care for vulnerable patients.

Improving participation in pharmacovigilance

Our study provides valuable insight into to the perspectives of parents who had not used the Yellow Card Scheme but were 'eligible' to do so. As we note above, these parents

supported the aims of the Scheme but they were reluctant to use it to report the ADR that we interviewed them about. The reasons for their reluctance may help inform strategies to widen participation in pharmacovigilance. Their accounts indicate that attention needs to be given not just to raising awareness of the Yellow Card Scheme but also to improving potential users' understanding of the Scheme and empowering them to use it. These parents were concerned that because they lacked medical knowledge their reports would be inaccurate, or that the information they provided would be of little value. Emphasizing that reports from members of the public can make a valuable contribution to drug safety would help to overcome such barriers, as would emphasising that people do not need medical expertise or to be certain that a medicine definitely caused a reaction in order to submit a report. Some parents expected that their child's practitioners would report the ADR, yet practitioner participation in pharmacovigilance is poor [6]. Informing the public that their reports are an adjunct to practitioner reporting may help members of the public to understand the importance of their participation in pharmacovigilance. Parents also worried that their reports might be perceived as undermining practitioners. These concerns could be addressed by emphasizing that the Yellow Card Scheme is confidential and that information will not be shared with practitioners without a reporter's consent. Beyond this, health practitioners have a role in informing patients and carers about the Yellow Card Scheme and supporting them in submitting Yellow Cards. We did not have access to parents' Yellow Cards, or to data about how the MHRA used parents' reports so we are unable to comment on the value to the MHRA of the information parents provided. However, utilizing disease or medicine specific parent networks to publicise the Yellow Card Scheme, particularly those networks that support families of children receiving orphan medicines, could help to improve participation in the Scheme. This would be consistent with the MHRA's aim of generating useful signals.

Limitations

Our study had some limitations. The parents who submitted Yellow Cards represent a small minority of parents of children who experience ADRs. Most worked as, or had personal connections with, health practitioners. They were therefore more knowledgeable about medicines, the process of reporting ADRs and the reasoning behind reporting ADRs than the general population of parents. Previous studies of direct patient reporting within pharmacovigilance schemes share similar limitations, which arise from the limited public awareness of the Yellow Card Scheme. In this context, our sampling of parents who had a child with a suspected ADR but had not used the Yellow Card Scheme is particularly important. The views of such groups have rarely been investigated, yet they are crucial in identifying how public participation in pharmacovigilance may be promoted. Our use of both telephone and face-to-face interviews raises questions about the comparability of the data, and in particular, whether participants interviewed over the telephone were be more guarded than those interviewed face-to-face. However, in line with previous reports [43] we found no evidence that the medium for conducting the interviews influenced participants' accounts.

Recomendations

Parents who had used the Yellow Card Scheme found it straightforward and were satisfied with its aims and procedures. Parents who had not used the Yellow Card Scheme were uncertain about their role in reporting ADRs and many assumed that submitting a Yellow Card was the responsibility of practitioners. Despite this the Yellow Card Scheme was acceptable to parents. To extend participation in pharmacovigilance, agencies need to improve public awareness of their reporting schemes. This could be done generally, or targeted at those patient groups most likely to benefit from pharmacovigilance. While awareness of reporting schemes is important, our findings indicate that raising awareness will not be sufficient to improve public participation by itself. Agencies will need to go beyond raising awareness to present their schemes in ways that empower and support lay reporters. Based on our findings we recommend that agencies emphasize the following points when publicising their schemes among members of the public: i) the value of lay people's reports in promoting drug safety, ii) that reports will not be shared with practitioners without the reporter's permission and iii) that reports can be submitted even when there is uncertainty about whether a medicine caused a reaction. In the light of recent changes to EU policy about pharmacovigilance, our findings can inform Members States planning spontaneous reporting systems.

Competing Interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf and declare no support from any organization for the submitted work and no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years. RLS and MPi are members of the Commission on Human Medicines. MPi Chairs the Pharmacovigilance Expert Advisory Group, while RLS Chairs the Paediatric Medicines Expert Advisory Group. This paper presents independent research commissioned by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (RP-PG-0606-1170). The views expressed are solely those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. All other authors have indicated they have no competing interests relevant to this article to disclose.

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