A Report of a Patient and Public Involvement Consultation Event with Children with Asthma and their Parents to Review a Proposal for a Primary Care Intervention around the September School Return

Steven Julious, Jennifer Lai, Jonathan Boote, Heather Elphick Henry Smithson

January 2011
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Report from the PLEASANT Team
Steven A. Julious, Jennifer Lai, Jonathan Boote, Heather Elphick
Henry Smithson

January 2011
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1. Introduction

Asthma episodes and deaths are known to be seasonal\(^1\). A number of reports have shown peaks in asthma episodes in school aged children associated with the return to school following the summer holiday \(^2\)\(^{-11}\). These studies mainly report hospital admissions although one study has reported peaks both in hospital admissions and primary care contacts\(^{10}\).

The main supporting research was on medical contacts obtained from the General Practice Research Database (GPRD)\(^{11}\) (the GPRD is a database of anonymised medical records). All medical contacts of school aged (5-16 years old) patients with a documented medical diagnosis of asthma were chosen from selected general practices together with age (within 2 years) and sex matched controls from the same practice from the years 1999 to 2005 (the code list for the diagnosis of asthma is available from the authors). This data set had over 75,000 asthmatic patients and matched controls. The data showed an excess peak in medical contacts by asthmatic children following the end of the summer vacation compared to the control group.

One hypothesis is that the peak is due to a viral challenge children with asthma receive upon returning back to school. In age sex matched non-asthmatic controls, a peak was also observed with the end of summer return back to school supporting this hypothesis. However, it was also shown that the peak in asthmatic children was in excess of what would be expected compared to the controls.

It could be argued that it is a good time to be an asthmatic in August. The pollen season is in the main over and school age children are not at school and so have less opportunity to pick up any bugs that are going through population. Many asthmatics who are taking regular inhaled steroids may come off their medication in August as they feel they are not necessary. This theory is supported by a drop in the prescribing of inhaled steroids – there are 25% less prescriptions in August compared to July and September\(^{12}\). This drop in prescriptions precedes the viral challenge of a return back to school.

A recommendation from the study was that children with asthma should be encouraged to maintain their medication prior to the start of the new school year and to ensure that have adequate levels of medication i.e. if they take inhaled steroids, to ensure their inhaler is not empty and that they have spare inhalers \(^{11}\).

We are thus planning a study to investigate whether an intervention of a letter from the GP encouraging children with asthma to maintain their medication can prevent the peak in medical contacts upon returning back to school.

To assist the team with the ongoing research we arranged an evening where we discussed the project with children with asthma and their parents to get feedback on the intervention and to find out about their experiences with asthma.
2. Methods

The patient and public involvement consultation event was held on 4th January 2011 at The Clinical Research Facility of Sheffield Teaching Hospital. Heather Elphick led the discussions with the children while Henry Smithson led the discussions with the parents. The field notes from these discussions are given in the Appendix.

3. Summary

The children had different personal experiences of their own asthma, in particular with respect to when their asthma is at its worst throughout the year. For all children, treatment of their asthma was through self efficacy although for some of the younger children we believe at least in part this would be supervised by the parents.

The children believed that the letter from their GP should be addressed to to their parents rather than to themselves They also believed that their parents would act on a letter sent in the interests of their child.

The parents’ group revealed a variety of asthma challenges experienced by their children but all thought this study would be valuable, acceptable and of interest. We discussed the study design and all agreed that a letter from their practice would be a useful reminder and not seen in any way as intrusive. The problem of using inhalers regularly was viewed as a useful outcome.

All the parents agreed to be contacted in the future with respect to this ongoing research project

4. Acknowledgement

This event was funded through an award from the NIHR Research Design Service for Yorkshire and the Humber. The application for this funding is included as an appendix in Section 6.3.

5. References


2. Storr J. and Lenney W. School holidays and admissions with asthma. Archives of Disease in Childhood 1989;64:103-7


Dear Parent,

Asthma can get worse when the summer holidays end resulting in a number of children and young people with asthma getting poorly around this time of year. This may be due to exposure to infections at the start of the new school year.

To keep well at this time of year, we would encourage you to make sure your child takes their asthma sprays as prescribed by your GP or practice nurse. If your child has stopped taking inhalers over the summer holidays please make sure they restart them at least 2 weeks before returning to school. If your inhalers are in short supply (or you are unsure as to which inhalers your child should be taking), please get in touch with the practice.

Yours sincerely

<Name of Doctor>
6.2. Field Notes from the Public Patient Involvement Consultation

6.2.1. Qualitative discussion with Children with Asthma

Field Notes by Jennifer Lai

Present: five asthmatic children; four = female, one = male. Children were seven to fourteen years of age.

Dr Heather Elphick led the group’s discussion. The group discussion began with introductions and Heather clarified why the meeting was taking place.

The children were asked what type of inhalers they used and whether they used other medication to control their asthma. All five children used blue inhalers; two used brown inhalers, two used a purple inhaler and one used an orange. Spacers were left at home. One child reported taking oral medication night and day. All inhaler use was self administered hinting towards a sense of autonomy in their treatment and control of their condition. Children were asked whether they stopped using their inhalers at any point in the year or whether they noticed a pattern in their inhaler use. None reported not using their inhaler at any point in the year. One child reported using their brown inhaler less in the summer.

The following discussion was structured by a series of questions. These questions were written on cards enclosed in envelopes. The order of discussion began one child selected a card, the child read the question on the card then all children would feedback with their answers. The following questions and feedback were reported:

1. How does your asthma affect your sleep?
   - All the children reported sleep disturbance as a result of their asthma
   - Symptoms included cough and breathlessness. Once it starts cannot stop it and need an inhaler
   - Interrupted sleep worse when children are unwell with another condition
   - Rippling effects: Children reported that it can take a long time to return to sleep and this affected their school work because of tiredness

2. What is your favourite activity outside of school and how is this affected by your asthma?
   - Following activities were reported: ice skating, football, cycling, running
   - Asthma inhibited their ability to carry out these activities, following triggers or factors observed
     - Cold environment, “cold air gets into your lungs”
o Out of breath easily
o They can miss their breaks or dinner time due to their asthma
o Need to control their asthma so can take part

- Children were asked whether they played musical instruments or sang as a hobby. One child reported singing but that their ability to do so was hindered by asthma.

3. Which month is your asthma at its best?

The children answered in reference to seasons, two children reported that winter, one child reported spring whilst the remaining two children reported that the summer was a better time with their asthma.

4. How does you asthma affect your family, brothers and sisters, parents, carers etc?

- Majority of the children reported a negative effect on the parents and siblings as a result of their asthma
- If siblings are asthmatic, one child’s asthma attack can trigger an attack in the other child by coughing
- One child reported having to stay with their grandparents when poorly
- Mum (parent) has to take time off work to take child to hospital if asthma is severe
- One child reported staying in her room if her asthmatic condition worsen, reason being they tried to reduce the spreading of her germs to her other people
- Parents, siblings and friends at school worry
- Parents, siblings and friends are supportive, they have to offer reassurance when child has an attack
- One child reported no effect on their siblings but if their asthma worsen to a point where they could not control it, their parents had to take them to hospital
- No children mentioned waking up other siblings at night as a result of their asthma

5. How does your asthma affect what you do at school?

- PE, exercise
- At play or break time, children have to take extra precaution when they go outside. If it is cold, they have to wrap up warm to prevent an attack
- Time off school
- Need to carry their inhalers with them
• School work could be affected two to three times a week by tiredness because asthma symptoms kept the child awake at night
• Teachers do not understand their condition
• No children were at the age were they took exams

6. Which month is your asthma at its worst?

• August; related to increased exercise in warmer season
• Summer; hay fever, also when gets hot
• August to January; cold weather
• November to February; more people are unwell
• More people unwell after school return, bugs spread more when children return to school
• People unwell when they return from holiday abroad. This was thought to be related to the change in climate/weather

The final discussion point was in reference to the letter the study intends to send out to families with children who have asthma. Comments were requested from the children with regards to who the letter should be addressed to and some of the wording of the letter.

The children agreed that the letter should be addressed to their parent not the child. Even to as old as 16 for a child it was felt should be addressed to the parent. The personalisation of the letter was not agreed upon; one child noted that it matter not whether the letter was personalised or not, parents with a child who has asthma will have a point to read the letter – it is in their child’s interest.

6.2.2. Qualitative discussion with Parents of Children with Asthma

Field Notes by Jonathan Boote

• Henry spent some time at the beginning of the event setting the scene, and explaining why it is important for researchers to obtain the views and experiences of patients and the public when planning any piece of research, and why it important to obtain the parent/child viewpoint when planning this specific piece of research to help reduce child asthma exacerbations at the start of the school year. Henry explained the thinking behind the research idea; namely that the most common time for children with asthma to experience problems is at the start of the school year in September, but that the reasons
underlying this is unclear. It could be the exposure to coughs and viruses after the end of the summer holiday. Another theory is that in the summer, when it is warm, children experience less trouble with their asthma and they are less likely to be using their brown inhalers twice a day, and then, towards the end of the summer holiday children, parents, doctors and nurses forget to ensure that the child has enough brown inhalers in time for when they start school in September.

- Henry asked if the thinking behind the proposed research, outlined above, made sense to the parents present?

- The first parent to speak agreed with the idea that the issue could be related to going back to school in September and picking viruses up, from her own personal experiences. She gave the example of her daughter picking up cold viruses at school and becoming very poorly with her asthma and needing to go into hospital.

- Another parent made the point that exacerbations were caused by her child coming off her medication, and discussed the period when the child was being tested for asthma and being in and out of hospital, saying that during the summer, there seemed less need for the child to be taking her medication. The parent stated that when the child seemed well, she thought the child was okay, which makes you less focused as a parent on the underlying problem of asthma. She stated that weeks pass by sometimes without you thinking about it if the child is okay. You forget about the inhaler when the child seems well. You shouldn’t forget but you do forget. When you’re abroad on holiday and the child seems well, you can let it slip.

- Another parent likened asthma inhalers to antibiotics, stating that once you start to feel better, you tend not to take the full dosage, and the same applies to asthma inhalers.

- One parent stated that she is much more vigilant regarding her daughter’s asthma inhalers now, having seen her have a few very bad episodes. But she has noticed that there are times of the year when her daughter’s asthma is worse. But when the child is well, it is such a relief.

- Another parent commented that sometimes, their child says that they don’t need their brown inhaler.

- One parent stated that the winter is especially bad, saying that they have not had a Christmas and new year yet without having visited hospital until this year.

- Henry asked parents if there were other times of year apart from autumn when the parents noticed their children having exacerbations.
• One parent said that they notice a bad period around March/April/Easter time and it can last up to 4 months, and then during the Summer she is less bad

• Henry summed up this part of the discussion, saying that different children have different patterns of exacerbations and that there is not always a seasonal pattern to the triggers.

• One parent noted that exercise such as football could have an effect on asthma attacks. The parent makes sure that he asks his son to bring his spray when he plays football. But sometimes the child forgets to bring the inhaler with him. And if he doesn’t take it before a game, by half time he can’t breathe. The parent stated that they carry an inhaler in the car in case the child forgets.

• Henry summed up the various triggers of the children’s asthma as described by the parents as pollen and seasonal allergens, exercise and infections such as cold viruses. A further reason discussed by another parent was a damp, cold, mouldy house that they have recently moved out of. And this seems to have lessened the asthma.

• Some parents discussed the issue of central heating and dry air can induce wheezing and bring on the asthma

• Henry then moved the discussion on to the research project idea – the letter sent from a GP to remind the parent about stocking up on inhalers in time for the start of the new school year in September. Henry asked the parents if this letter idea would be suitable for all parents of asthmatic children or if this letter would be ignored by parents who didn’t think the start of the school year is an issue for triggering an exacerbation in their child’s asthma. Henry then read the letter out to the parents asking if the letter is written in the right language, and he also highlighted that the letter would be sent from the child’s GP rather than the hospital. Henry also asked if the letter should be sent to the parent (as it currently is written) or should it go to the child, or to both parent and child (either jointly addressed or as 2 separate letters in the same envelope).

• In response to Henry’s question about whether the parents thought the letter intrusive or helpful, one parent said it would definitely be helpful because she leaves some of her daughter’s inhalers at school. A second parent stated that she couldn’t believe that any parent would find the letter as it is currently written intrusive, and which would probably be interpreted as a friendly reminder. It was likened to other useful reminders sent out by different organisations such as the DVLA or the TV licensing office.

• One parent said that because parents do not necessarily take inhalers themselves, the reminder letter serves a useful purpose as parents often forget to ask their children if they are taking their inhalers.
• One parent thought the letter could be strengthened by saying that stocking up on inhalers now and making sure that the child is taking them could reduce problems/exacerbations coming up to wintertime.

• There was general agreement that the letter gave sufficient information and there was a discussion about whether or not the letter should be addressed to the parent and to the child. There was concern that if the letter was just addressed to the child who is a reluctant user of an inhaler, then the parent might not see the letter. So, the parents suggested that a compromise might be for a joint letter to be sent out, or a letter addressed to the child and a letter addressed to the parent in the same envelope.
6.3 Application to the NIHR Research Design Service for Yorkshire and the Humber

Application for the RDSYH Public Involvement in Grant Applications Funding Award

Email your completed application form to rds-yh@sheffield.ac.uk, stating ‘RDSYH Public Involvement Funding Award’ in the email subject window.

Send the signed, hard copy of your completed application form to: Clare Clarke, The NIHR Research Design Service for Yorkshire and the Humber, The University of Sheffield, School of Health and Related Research (ScHARR), Ground Floor, Room G045, Regent Court, 30 Regent Street, Sheffield S1 4DA.

Please complete the form as fully as possible. The boxes given below for you to provide your answers are expandable, allowing you to write as much as you feel is necessary. Refer to the guidance notes or contact your public involvement advisor if you have any difficulties with answering the questions on this form.

1. Name and details of lead applicant for RDSYH Public Involvement in Grant Applications Funding Award

<table>
<thead>
<tr>
<th>Full name</th>
<th>Steven A. Julious</th>
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<tr>
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<td>Reader in Medical Statistics</td>
</tr>
<tr>
<td>Organisation</td>
<td>University of Sheffield</td>
</tr>
<tr>
<td>Work address</td>
<td>Medical Statistics Group, ScHARR University of Sheffield Regent Court, 30 Regent Street Sheffield</td>
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<tr>
<td>Postcode</td>
<td>S1 4DA</td>
</tr>
<tr>
<td>Telephone number</td>
<td>0114 222 0709</td>
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<tr>
<td>Email</td>
<td><a href="mailto:S.A.Julious@Sheffield.ac.uk">S.A.Julious@Sheffield.ac.uk</a></td>
</tr>
<tr>
<td>Self-employed?</td>
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2. Please give the details of co-applicants (if applicable). Copy and paste the table below as appropriate if there is more than one co-applicant

<table>
<thead>
<tr>
<th>Full name</th>
<th>Tjeerd van Staa</th>
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<tbody>
<tr>
<td>Job title</td>
<td>Head of Research GPRD</td>
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<td>Organisation</td>
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<tr>
<th>Full name</th>
<th>Heather Elphick</th>
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<tr>
<td>Job title</td>
<td>Consultant in Paediatric Respiratory Medicine</td>
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<tr>
<td>Organisation</td>
<td>Sheffield Children’s Hospital</td>
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<tr>
<td>Full name</td>
<td>Henry Smithson</td>
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<tr>
<td>Job title</td>
<td>Deputy Head of the Academic Unit of Primary Medical Care</td>
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<tr>
<td>Full name</td>
<td>Annie Wright</td>
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<tr>
<td>Job title</td>
<td>Paediatric Endocrinology Research Nurse</td>
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<tr>
<td>Full name</td>
<td>Cindy Cooper</td>
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<tr>
<td>Job title</td>
<td>Director of the Clinical Trials Research Unit (CTRU), ScHARR</td>
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<tr>
<td>Full name</td>
<td>Jonathan Boote</td>
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<tr>
<td>Job title</td>
<td>Research Fellow</td>
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<td>Organisation</td>
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<tbody>
<tr>
<td>Full name</td>
<td>Sarah Davis</td>
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<tr>
<td>Job title</td>
<td>Senior Lecturer in Health Economics</td>
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<tr>
<td>Organisation</td>
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<tr>
<td>Full name</td>
<td>Michelle Horspool</td>
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<tr>
<td>Job title</td>
<td>Research Fellow in the Clinical Trials Research Unit/ RDS, ScHARR and Locality Manager for PCRN EMSY</td>
</tr>
<tr>
<td>Organisation</td>
<td>University of Sheffield</td>
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3. Please provide an outline of the grant application that is being developed, including:

- Which specific type(s) of members of the public will be involved in developing the grant (e.g. a specific patient/service user/carer group, older people, children etc)
- How you intend to gain access to, and approach, members of the public to invite them to become involved
- How members of the public will be actively involved in developing the grant application, including an indication of the duration, location, and degree of complexity of all involvement activities
- How the involvement of members of the public in the development of the grant application will be evaluated
- How you intend to continue to actively involve members of the public should you be successful in winning the grant

Outline of the grant application that is being developed

Asthma episodes and deaths are known to be seasonal [1]. In particular a number of reports have shown peaks in asthma episodes in school aged children associated with the return to school following the summer holiday [2-10].

The main supporting research for the proposed grant was on medical contacts obtained from the General Practice Research Database (GPRD) [12]. All medical contacts of school aged (5-16 years old) patients with a documented medical diagnosis of asthma were chosen from selected general practices together with age (within 2 years) and sex matched controls from the same practice from the years 1999 to 2005. The data showed an excess peak in medical contacts by asthmatic children following the end of the summer vacation compared to the control group.

One hypothesis is that the peak is due to a viral challenge they receive upon returning back to school. In age sex matched non-asthmatic controls, a peak was also observed with the end of summer return back to school supporting this hypothesis. However, it was also shown that the peak in asthmatic children was in excess of what would be expected compared to the controls.

It could be argued that it is a good time to be an asthmatic in August. The pollen season is in the main over and school age children are not at school and so have less opportunity to pick up any bugs that are going through population. Many asthmatics who are taking regular inhaled steroids may come off their medication in August as they feel they are not necessary. This theory is supported by a drop in the prescribing of inhaled steroids – there are 25% less prescriptions in August compared to July and September[12]. This drop in prescriptions precedes the viral challenge of a return back to school.

The aim of the grant being developed is to assess whether a letter to school age asthmatic children by their general practitioner prior to the start of the new school term to suggest they ensure their medication is up to date can reduce the September peak in medical contacts for school age asthmatic patients.
The type of patients and public to be involved in developing the grant and details of the involvement activity to be undertaken

We are seeking PPI funding from the RDSYH to hold a focus group of 6-7 parents and children with relevant clinical experience of asthma to comment on the intervention letter and choice of patient-centred outcome measures. The main primary outcomes at the moment are planned to be number of medical contacts and medical contacts due to asthma exacerbation. Feedback on the patient centred relevance of these will be sought. Another potential outcome measure for the study will be health related quality of life and parents and patients’ opinions as to choice and appropriateness of the instruments will be sought at the focus group meeting.

The focus group will be convened prior to the submission of the grant application as a single event, duration of up to 2 hours, facilitated by a member of the research team. The meeting will be held at Clinical Research Facility (CRF) at Sheffield Children’s Hospital. A summary of the findings will be made and used to inform the development of the grant application, in particular the justification of clinical outcomes for the grant.

How patients and the public will be identified and approached

Children with present or past experience of asthma will be identified from the population of the respiratory clinic at Sheffield Children’s Hospital, by Dr Heather Elphick and will be invited by letter to participate in the focus group, along with their parent(s). If insufficient volunteers are identified through this source, other patient/parent groups interested in research involvement may be identified through the PALS manager for Sheffield Children’s Hospital (Mrs Linda Towers) or through the Trust Foundation office (Mrs Jacqueline Mann).

How the involvement of patients and the public will be evaluated

An evaluation form will be developed by the research team and the children and their parents will be asked to complete this evaluation at the end of the focus group meeting. The form will ask participants to rate how important they found the research proposal being developed, how much influence they thought that they had at the meeting on the research, and how seriously they thought their contributions were being taken at the meeting.

How we will involve patients and the public in the research if the grant is successfully funded

If the grant is successful we will have two patient representatives on the trial steering group and we will involve these representatives in the interpretation of the findings and the communication of the study findings to relevant patient groups. Parents and children who attend the focus group at the project design stage will be asked if they would be willing to be members of the trial steering group.
References

2. Storr J. and Lenney W. School holidays and admissions with asthma. Archives of Disease in Childhood 1989;64:103-7

4. Please state to which NIHR funding scheme (or other scheme) the grant application is to be submitted. Please also include: (1) the submission deadline of the grant that you are developing (and for applications to the Research for Patient Benefit scheme, indicate to which Competition you are applying); (2) an estimate of the total amount of funding being sought

The grant will be submitted for the HTA Clinical Evaluation and Trials programme with a deadline of 1st February 2010. The grant will be in the region of £500,000
5. Please provide a breakdown, together with costings, of how the RDSYH Public Involvement in Grant Applications Funding Award will be spent (for example, venue, travel, subsistence, payments to members of the public)

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<td><strong>Total</strong></td>
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6. If applicable, please indicate other sources of contributory funding already obtained for the active involvement of members of the public in the development of the grant application. If more than one source of contributory funding has already been obtained, please copy and paste the table below as appropriate.

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DECLARATION (to be signed by the lead applicant for this award)

I confirm that to the best of my knowledge the information given on this form is correct. I understand that my name will be held on a database in accordance with the Data Protection Act, and that I may be asked to participate in future evaluations of this award scheme.

Signature…..Steven A. Julious…………………………………….

Date………30 September 2010…………………………………….