

The rectal route of medicine administration for children: Let's get to the bottom of it!

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with the London Generation R Young Persons Advisory Group³

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Abstract

Aims: Research around paediatric rectal drug delivery has previously been based on views of parents and healthcare workers. The aim of this exploratory study was to gauge whether children and young adults in the UK were comfortable with the idea of rectal drug delivery.

Methods: Eleven children from a pre-existing patient and public advisory group were involved in the session. Rectal drug delivery was explained and group participants were asked a series of questions. Responses were discussed in a group and recorded individually.

Results: Of the group, 27% would consider the rectal route, while 64% said it depended on other options available. The primary concern focused on potential for abusive misuse by others. Participants thought this would be overcome if the child could self-administer, although there was also concern about the process of self-administration.

Conclusions: Not all children in the UK are against rectal drug delivery, but education is needed to teach children to self-administer medication in this way.

Key words

Patient and public involvement, rectal route, drug delivery, paediatrics

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Introduction

Rectal drug delivery has several advantages over other routes of administration, especially for paediatrics. It avoids taste and swallowability concerns often associated with oral delivery and does not require trained carers, unlike intravenous administration. Rectal drug delivery is not a new concept,[1] yet there are limited marketed rectal formulations available. Recent *in vitro* pharmaceutical development into rectal dosage forms including omeprazole,[2] doxycycline and amoxicillin [3] suppositories indicate that there may be more rectal formulations on the horizon. Further, artesunate suppositories have been shown to be clinically effective for the pre-treatment of severe malaria. [4]

There are also challenges to rectal drug delivery, a key one being patient barriers. The rectal route is generally not preferred by patients. A study into views of parents and health staff regarding rectal treatments for children in Laos found it was considered an ineffective and undesirable drug delivery route.[5] In the United Kingdom (UK), the rectal route is reportedly not favoured.[6, 7] This could be due to potential for discomfort and leakage, as well as a lack of awareness, misconceptions and limited precedent of use. There is a general lack of research into this route compared with other routes for gastrointestinal drug delivery, hindering innovations in rectal drug formulations and translations to commercial products. [8]

Historically, it has been assumed that acceptability of the rectal route amongst children is poor. However, no systematic, formal research has been conducted in children to support this view.[1] This patient and public involvement (PPI)

exercise aimed to gain an indication of whether children and young adults living in the UK were comfortable with the idea of rectal medicine delivery. By discussing the rectal route with a small cohort in this exploratory study, a secondary aim was to gather ideas about how the topic of rectal drug delivery could be approached in a manner in which children and young adults feel comfortable.

Methods

Children and young people from the Generation R London Young Persons Advisory Group (YPAG), a pre-existing patient and public focus group funded by the Biomedical Research Centre, Great Ormond Street Hospital (London, UK), were involved in the 45-minute session. First, rectal drug delivery was explained to the group. The potential for rectal antibiotic use in developing countries, where access to clean water and trained health professionals may be limited, was used as an example of when rectal drug delivery may be a good option, as this area was of particular interest to the authors. A general discussion ensued and the group had the opportunity to write down responses individually. Questions that were posed to the group included:

- Are you comfortable taking part in research that involves being asked questions about rectal drug delivery?
- How do you think we can best get a response from young people with this type of research?
- Did you know medicines could be given rectally?
- Have you been given medicine rectally?
- Would you consider taking a medicine rectally?
- What are your thoughts/concerns with rectal drug delivery?

At the end of the session, responses were collected and a short summary provided. Individuals had the opportunity to ask questions throughout the session.

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Results

Eleven individuals (2 males, 9 females) aged from eight to 18 years old took part in this focus session (median age=15 years). The two boys in the session did not participate in the group discussion, but recorded written responses in full. The older girls (15 years and over) were the most responsive, leading the group discussion.

A summary of responses around willingness to discuss and consider rectal drug delivery is presented in Table 1. Interestingly, only one individual would not consider taking medicine rectally, with the majority (64%) stating 'maybe', or 'not sure'. Comments surrounding their basis for this answer were primarily based on whether other options were available, duration and frequency of treatment.

YPAG members raised several concerns about rectal drug delivery, and discussed some ideas to help overcome these (Table 2). One of the primary concerns about this method of drug delivery focused on the potential for misuse and sexual abuse. To this end, the ability for children to self-administer a drug rectally was described as one of the key factors to acceptability and compliance. It was felt that a detailed explanation of how to do it would help. Ideas such as a demonstration doll or smartphone application (App) were suggested to help teach a child to administer the dose and break down psychological barriers, and YPAG members stressed the value of a healthcare professional being available to explain the process of self-

administration face-to-face. The group were surprised to learn that in some countries, such as France, rectal drug delivery was common, with one participant
125 saying that this knowledge made the idea more acceptable. It was raised that if the same discussion were to take place in other countries, then the main concern may not have focused on potential misuse and sexual abuse.

The ability to self-administer was a key factor in acceptance and the age at which
130 a child may be able to begin self-administration was discussed. In general, it was agreed that this would vary significantly between children, but that the age whereby a child began to look after their own personal hygiene (such as bathing and showering) could be used as an indicator. Similarities were drawn to using tampons, so it was thought that older children would have no problems with this
135 route. Some children also highlighted positive aspects of rectal drug delivery, for example 'I think it's good if you're scared of pills then you can take that' and 'it seems like a good idea for those who oppose injections etc'.

Discussion

140 Cultural factors impact acceptability of rectal drug administration.[1] In the UK, the rectal route is not favoured,[7] with one UK study rating the rectal route as more unpleasant than oral and parenteral routes.[6] Similarly, a more recent study based in the United States found that caregivers of children with epilepsy preferred intranasal midazolam to rectal diazepam for the management of acute
145 seizures.[9] However, the focus of these studies is on acceptability from parent's perspective, and one of the key concerns seems to be the premise that the rectal route is less effective. This issue was not considered by the YPAG. In liaising with

this group, concerns focused on giving other people access to a sensitive area and potential for misuse and sexual abuse. However, this issue was thought to be
150 minimised if children were equipped with the knowledge to self-administer the medication. This is promising as it indicates that children are willing to be educated. In the UK, this lack of knowledge may be in part due to the limited availability of rectal products. This is a catch-22 as people are less likely to accept the rectal route until they are familiar with it, but rectal products are unlikely to
155 become available until there is a sufficient market of people willing to take medicines in this way. The YPAG members suggested it could be helpful to raise awareness amongst the general public about this method of medicine self-administration through leaflets or other public health communicative tools, which could help address this catch-22.

160 Patient and public involvement requires consideration of health literacy. Health literacy is a broad and evolving concept, but can be defined as the competencies and skills required to interpret health information and concepts in order to make informed choices. [10] Therefore, it was considered vital to first give the group background information about rectal drug delivery including situations where it
165 might be useful. This encouraged the group to approach the concept with a level of health literacy on the subject that allowed for meaningful discussion. Further, it seemed to reduce any discomfort in talking about the rectal route with children and young adults.

On top of demonstrating that the topic does not have to be taboo and can be
170 discussed openly, this study provided insights into what children and young adults in UK thought about the use of rectal formulations. In doing so, the relevance of patient and public involvement in research was highlighted. However, there were

several limitations to this work. This was an exploratory study that involved an existing focus group of children and young people. The sample size was small, 175 which meant that the effect of age, gender, ethnicity and religion could not be ascertained. Observations could be used as a starting point for a larger study investigating the acceptability of the rectal route in the UK amongst children and young people. It would also be interesting to try to pinpoint what social, cultural, and historical factors actually contribute to acceptance of rectal administration in 180 other countries such as France as this is not known. It would be worthwhile to consider other factors that might impact the acceptability of medicines for rectal delivery such as volume, size and shape of the dosage form.

In summary, discussions with the YPAG indicated that not all children in the UK 185 seem to be against the rectal route as a mode of medicine delivery. However, education is needed to remove the taboo surrounding it and teach children to self-administer medication in this way. Invaluable insight was gained into the thought process of children with regards to this route and future research will benefit from the feedback provided. Further, the importance of involving children in research 190 such as this was highlighted. In this group, males appeared less comfortable in discussing rectal drug delivery than females and this would be worth exploring further. The next step would be to put this feedback into practice and approach a larger cohort of children to gain more widespread views on the acceptability of medicine delivery via the rectal route.

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260 Table 1 Summary of responses from the participants (n=11) regarding the rectal route for medicine administration.

Question	Response (% (n))		
	Yes	No	Maybe/ Not sure
Are you comfortable taking part in research that involves being asked questions about rectal drug delivery?	55(6)	0	45 (5)
Did you know medicines could be given rectally?	82 (9)	9 (1)	9 (1)
Have you been given medicine rectally?	9 (1)	82 (9)	9 (1)
Would you consider taking a medicine rectally?	27 (3)	9 (1)	64 (7)

265 Table 2 Summary of key concerns and ideas the focus group came up with to overcome them.

Concern	Ideas to overcome this concern
Potential for misuse and sexual abuse when giving someone access to that part of their body	<ul style="list-style-type: none"> • Self-administration
Physical size of the suppository	<ul style="list-style-type: none"> • Present children with some example suppositories, so they can see the dimensions
How to actually administer a drug rectally as it is a new concept	<ul style="list-style-type: none"> • Animated how-to video • Demonstration doll • Phone/gaming App
Someone else administering	<ul style="list-style-type: none"> • Equip children with the knowledge to administer themselves