

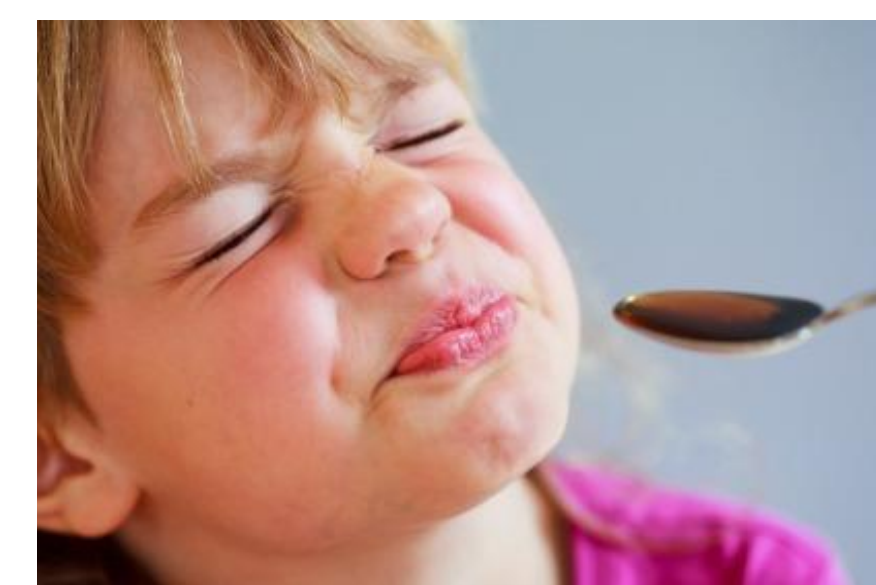
Parent acceptability of different forms of oral hydrocortisone

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AIM

Hydrocortisone is used in Congenital Adrenal Hyperplasia (CAH) as long-term replacement therapy. Patient acceptability and ease of administration are vital as treatment is life-long [1]. Prior to introduction of a licensed immediate-release granule formulation (Alkindi®) in Alder Hey in April 2019, off-label or unlicensed use of oral hydrocortisone preparations was widespread.

This work aimed to explore acceptability of oral hydrocortisone preparations in the real-world setting. This included the reasons for discontinuation, if more than one formulation had been used.

METHOD

This work was registered as a clinical audit in April 2021 (No.6367).

An e-survey was developed by a multi-disciplinary team using Microsoft Forms. With permission, this included the validated Pediatric Oral Medicines Acceptability Questionnaire for caregivers (POMAQ-C). Data were collected anonymously.

Most questions utilised Likert rating scales, with 5 being positive and 1 being negative. Formulations with a score of 3 or above were considered acceptable. The form was piloted with one family, then parents were contacted by the clinical team and if happy to take part, a member of the project team contacted them with the survey link details.

- **Inclusion criteria:** Patients with CAH, aged 6 months to 17 years (inclusive) taking an oral form of hydrocortisone.
- **Exclusion criteria:** non-English speaking, non-classical CAH.

RESULTS

Data were collected between 01.02.2022 and 01.05.2023.

38 eligible patients were identified; 9 families were unable to be contacted. 18 of the 29 remaining families completed the e-survey (response rate: 62%). Patients were aged 1 to 17 years (mean 8.1, median 7, IQR 7); 13 were female (72%).

Families obtained their hydrocortisone supply from their GP (56%) or a combination of their GP and hospital (33%).

Hydrocortisone formulations taken at the time the e-survey was completed are shown in Figure 1. 7 out of 18 (39%) families reported changing formulation(s). Reasons for this are shown in Table 1 and described below. Parent-reported mean overall acceptability scores are shown in Table 2.

It was difficult in the past to get the hydrocortisone liquid because the pharmacy had to order it in a special way. (Parent of 12 year old)

If we'd broken the bottle we would have been without medication for 5 days as this is how long it took from putting the request in and the medicine being available at the pharmacy. (Parent of 10 year old)

Some of the brands are very, very small tablets without break marks in them. I've tried breaking by hand and using a pill cutter but they shatter and we lose a number of tablets each month to this. Even when we do manage to break them (especially when quartering) the quarters are not necessarily the same size therefore the dose is just an estimate. This is a huge worry to me. (Parent of 10 year old)

Liquid hydrocortisone is much easier to administer. (Parent of 1 year old)

The powder form in the capsules (granules) was difficult to give to a baby. (Parent of 1 year old)

The pharmacy would give me one 300ml bottle of the medication which needed to be kept refrigerated. This was no good for us on days out when medication would need to be carried round and go back and forth to school. (Parent of 10 year old)

RESULTS

Figure 1: Formulation of Hydrocortisone being taken

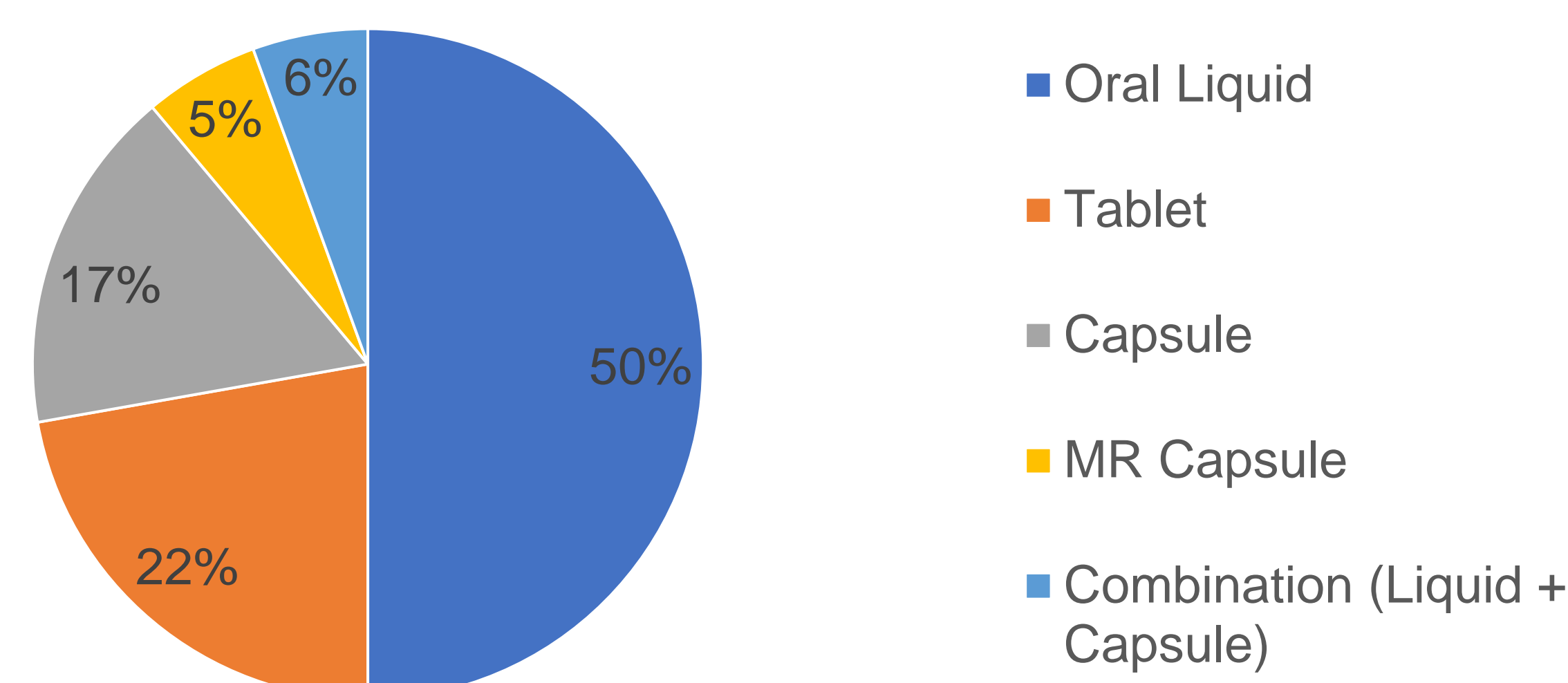


Table 1: Reasons for formulation change (more than one answer possible)

Reasons for change in formulation	Number of responses	Which formulation?
Difficult to obtain prescription	3	Liquid (2) Granules (1)
As advised by medical team	5	Granules (2) Liquid (2) Combination (1)
Difficult to give the medication to my child	3	Granules (3)

Table 2: Parent acceptability rating for Hydrocortisone formulations

	Mean acceptability score (n=18)				
	Liquid (n=9)	Tablet (n=4)	Granules (n=3)	Capsule (n=1)	Comb'n (n=1)
Acceptability from parent's perspective	4.4	4.5	4.7	5.0	3.0
Acceptability for their child	4.7	4.8	2.7	3.0	5.0

LIMITATIONS

The sample size was relatively small and the study conducted in a single hospital, which could limit generalizability of the findings.

CONCLUSION

Assessment of acceptability of medicines for children in a real-world setting is possible.

Parents described difficulties in obtaining, storing, and administering oral hydrocortisone, however, all rated their child's current hydrocortisone formulation as acceptable.

REFERENCES

1. Boulos N. Formulation matters: safe oral hydrocortisone use in children. The Pharmaceutical Journal. December 2021;No 7956;307(7956).
2. Turner-Bowker DM, An Haack K, Krohe M, et al. Development and content validation of the Pediatric Oral Medicines Acceptability Questionnaires (P-OMAQ): patient-reported and caregiver-reported outcome measures. Journal of Patient-Reported Outcomes. 2020;4(1).

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