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Oral Rehydration Salts in Packages:
Difficult to open, Difficult to Dissolve.

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Introduction:

In the course of implementing the National Control of Diarrheal Diseases Project we noticed difficulty in opening both the aluminum foil packages of "Oralyte" the Unicef-sponsored product, and the Egyptian version made by C.I.D. firm (called "Mahlul Moalget El Gafaff," "Solution for treatment of Diarrhea, "or "M.M.G."). In many instances one had to use ones teeth, in which case spillage of powder occurred, or scissors. Since scissors are not always at hand in poorer homes the package itself may be an obstacle to use. We also noticed that M.M.G. when added to water yielded pellet - like clumps of powder difficult to bring into solution without vigorous, prolonged stirring. Besides presenting another barrier to easy use by the mother, this quality could lead to incorrect salt sugar concentrations. Therefore, We decided to test opening and dissolution more quantitatively.

Methods:

We compared Oralyte, M.M.G. and "Rehydran". The latter is C.I.D. Firm's commercial product with the same formula as Oralyte and M.M.G. but packaged to produce one fifth liter instead of one liter. Instead of aluminum foil Rehydran is packed in a stiff paper envelop with an aluminum liner inside.

a. Opening the Package

Ten mothers were recruited in sequence at a large MCH center, Each, separately, was asked to open an Oralyte, a Rehydran, and a MMG packages. A stopwatch timed them from the moment they took pack in hand until it was sufficiently open to pour into a glass or liter container. The sequence in which packages were handed to the mother was systematically varied. We also recorded what actions the mother took to open the packages, and if there was any spillage.

b. Dissolving the Powders

We used one batch of Oralyte, made by Gmbh in 1978; Rehydran and MMG, C.I.D. products, came from single batches made in 1982.

Each mother was asked to dissolve the powders in the appropriate-sized container using a large spoon to stir with. The time from entry of the powder into the container to disappearance of visible powder was recorded. Since speed and strength of stirring varied from mother to mother we conducted another set of time-trials with one of the authors (NH) stirring the solution vigorously. MMG, Rehydran and several batches of Oralyte were tested this way.

Standard t-tests were used to compare results statistically.

c. Mothers' Opinions

Mothers were asked to comment on their experiences with the packages in an open ended interview.

Results:

a. Opening the Package

Table I shows the time, in seconds, each mother took to open packages. Oralyte and M.M.G. were nearly equivalent (average time 25 and 19 seconds, respectively) but Rehydran took half the time to open (10 seconds), a difference significant at the 0.05 level. In 17/20 instances mothers had to use their teeth to open Oralyte or MMG after some struggle with the packages, whereas only one mother used teeth to open Rehydran. Little or no spillage of powder occurred as all mothers knew to shake the contents down before opening; had they not known to do so considerable loss of powder would have occurred.

Only a small, statistically insignificant, "training effect" was seen: the time to open Oralyte or MMG, when offered first was 25.4 ± 14.8 SD seconds; The time to open either when offered later in sequence was 18.6 ± 16.1 SD seconds.

b. Dissolving the Powders

In the mothers hands the different powder took considerable time to dissolve (in seconds):

| | | |
|----------|------------------|----|
| Oralyte | 38.7 ± 17 | SD |
| Rehydran | 68.8 ± 33.8 | SD |
| M.M.G. | 154.5 ± 80.4 | SD |

Differences between Oralyte and Rehydran, between MMG. and Rehydran, and between Oralyte and MMG. were statistically significant. In 8/10 MMG, 4/10 Rehydran and 1/10 Oralyte we noted clumping of the powder into pellets upon contact with water. It did not matter (in time) whether water was added to powder or powder to water.

When the tests were conducted by one person stirring vigorously the results were improved for Rehydran only (in seconds):

| | | |
|----------------|-----------------|----|
| Oralyte (N=9) | 37.4 ± 8.9 | SD |
| Rehydran (N=8) | 38.8 ± 13.6 | SD |
| M.M.G. (N=6) | 96.7 ± 24.7 | SD |

Differences between M.M.G. and the other powders were highly significant ($p < 0.001$). Slow solution times were due entirely to pellets resisting breakup. On inspection of the powders we noted Oralyte was finely but discretely granular while M.M.G. and Rehydran had the consistency of fine powdered sugar. The powders of the latter two

tended to adhere to a surface more than the Oralyte .

The Oralyte, despite its faster dissolving time, produced an opaque solution (letters could be recognized but not read through a glass) with what appeared to be a micro-suspension (non - dissolving, only a slight tendency to settle) either of the powder ingredients or some contaminant. We therefore tested several batches of Oralyte from different years and manufacturers.

Table 2 shows the results. Only the GMBH product from several 1977 and 1978 batches gave the opaque solution. All others, whether new or old, caked or granular, rapidly produced a water-clear solution. The fastest dissolving Oralyte, that from KBI of 1982, dissolved twice as fast as Rehydran of the same year, a difference that is statistically significant ($p < 0.01$)

c. Mothers' Opinions

All mothers commented approvingly upon packages that were either easy to open (N=7), quick or easy to dissolve (N=5). One had wanted to give up the effort of opening, several had to be urged to continue stirring. Three mothers noted that speed of opening and/or solution would be beneficial to the sick child; five indicated a preference for the smaller package (Rehydran) because the fluid was more apt to stay fresh (that is, to be used up more quickly).

Seven of the 10 mothers were illiterate but no obvious differences in any of the measurements were related to literacy.

Discussion

A package that is difficult to open or a powder difficult to dissolve are likely to be barriers to use or re-use of ORT . In Honduras (Academy of Educational Development Washington, D.C., personal communication) nurses who had no scissors to open a UNICEF-like package, and too embarrassed to say so, refused to teach mothers about Oral Rehydration until a slit was placed at one edge of the package to facilitate opening.

Powders not dissolving easily--due in this case no doubt to excessive fineness leading to increased surface tension - is equally frustrating, and perhaps hazardous, certainly unattractive. It is noted that even different batches of UNICEF'S Oralyte have different solubility

characteristics, the fastest dissolving being finely but discretely granular producing a clear solution.

We recommend research into packaging that make each package easy to open. Standard specifications for powder characteristics leading to rapid dissolution need to be developed for and followed by any company making a national product.

Summary

Difficulties in opening ORS packages and in bringing the powders quickly into clear solution were demonstrated for several varieties of Oral Rehydration Salts Packages available in Egypt. Mothers, as testers of these packages, expressed clear preference for a package easy to open, and for a powder readily dissolved. If the package is hard to open or the powder hard to dissolve, mothers (and health workers) may be discouraged from the use of ORT.

Table 1
Time (In Seconds) Required To Open Packet
Sufficiently To Pour Out

| Test Pack: Position In Sequence: <u>Mothers</u> | Oralyte (GmbH. 1978) | | | (CID) Rehydran, 1982 | | | (CID) MMG, 1982 | | |
|---|----------------------|-------|-------|-------------------------|-------|------|--------------------|-------|-------|
| | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| 1 | 6.15 | | | | 3.83 | | | | |
| 2 | | | 12.01 | 4.73 | | | | 35.17 | 5.81 |
| 3 | | 6.5 | | | | 3.39 | 11.76 | | |
| 4 | 50.21 | | | | | 6.67 | | 32.48 | |
| 5 | | 21.6 | | 11.18 | | | | | 7.49 |
| 6 | 28.27 | | | | | 7.58 | | 10.35 | |
| 7 | | 52.49 | | | | 35.4 | 20.94 | | |
| 8 | 22.23 | | 36.44 | 10.65 | 11.59 | | | 11.1 | 12.38 |
| 9 | | 9.8 | | | | 7.46 | 46.73 | | |
| 10 | | | | | | | | | |
| AV. | 26.7 | 22.5 | 24.2 | 8.9 | 7.7 | 10.8 | 22.1 | 22.3 | 8.6 |

Overall Averages

Oralyte 24.6 ± 17.2 SD
 Rehydran 10.3 ± 9.3 SD
 MMG 19.4 ± 14.0 SD

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Table 2
Solubility Characteristics of Different
Batches of Oralyte (Unicef)

| <u>Manufacturer</u> | <u>Manufacturing Date</u> | <u>Batch No.</u> | <u>Time (seconds)</u> | <u>Comment</u> |
|------------------------------------|---------------------------|------------------|-----------------------|---|
| Gmbh (W. German) | 02/08/78 | 28586 | 29.97 | Cloudy, turbid solution |
| " | " | " | 23.64 | " |
| " | 18/05/78 | 28582 | 23.34 | " |
| " | 21/12/77 | 26575 | 22.14 | " |
| " | 17/05/78 | 28581 | 44.18 | " |
| | | | av. 28.7 ± 9.2SD | |
| Nutrichem Gmbh Geymonat (Italy) | 1982 2/ 9/79 | 7 | 19.90 19.05 | Clear solution Yellow Cake, Clear, Yellow solution. |
| KBI (W. German) | 23/07/80 | 221 | 17.81 | Clear solution. |
| " | 21/05/80 | 155 | 21.82 | " |
| " | 15/05/81 | 553 | 18.65 | " |
| " | " | " | 21.16 | " |
| " | " | " | 16.54 | " |
| | | | av. 19.20 ± 2.2SD | |

* All powders are very finely granular.
 ** Turbidity tends to settle after 60 minutes.
 + Difference between Gmbh Batches and K.B.I. batches borderline statistically significant, $0.1 > p < 0.05$