



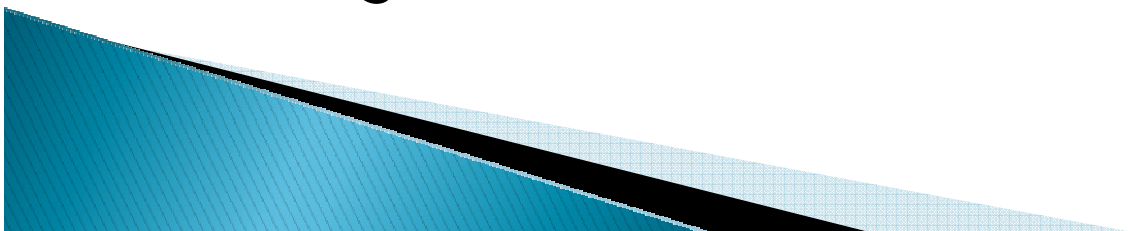
**Tablets are more acceptable and give fewer problems than syrups among young HIV-infected children in resource-limited settings in the ARROW trial.**

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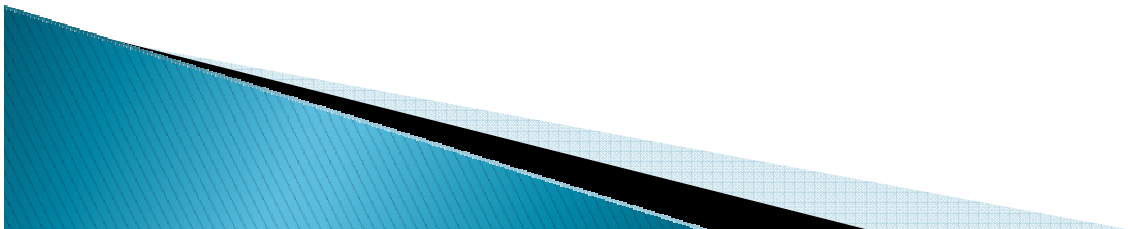
# INTRODUCTION

- ▶ The provision of anti-retrovirals (ARVs) for children is complicated by syrup formulations which in comparison to tablets are:
  - more expensive
  - harder to transport and store
  - more difficult for carers to administer
    - syrups require more accuracy in measurement
- ▶ Provided correct doses can be given, tablets are often more appropriate for children in resource-limited settings



# OBJECTIVE

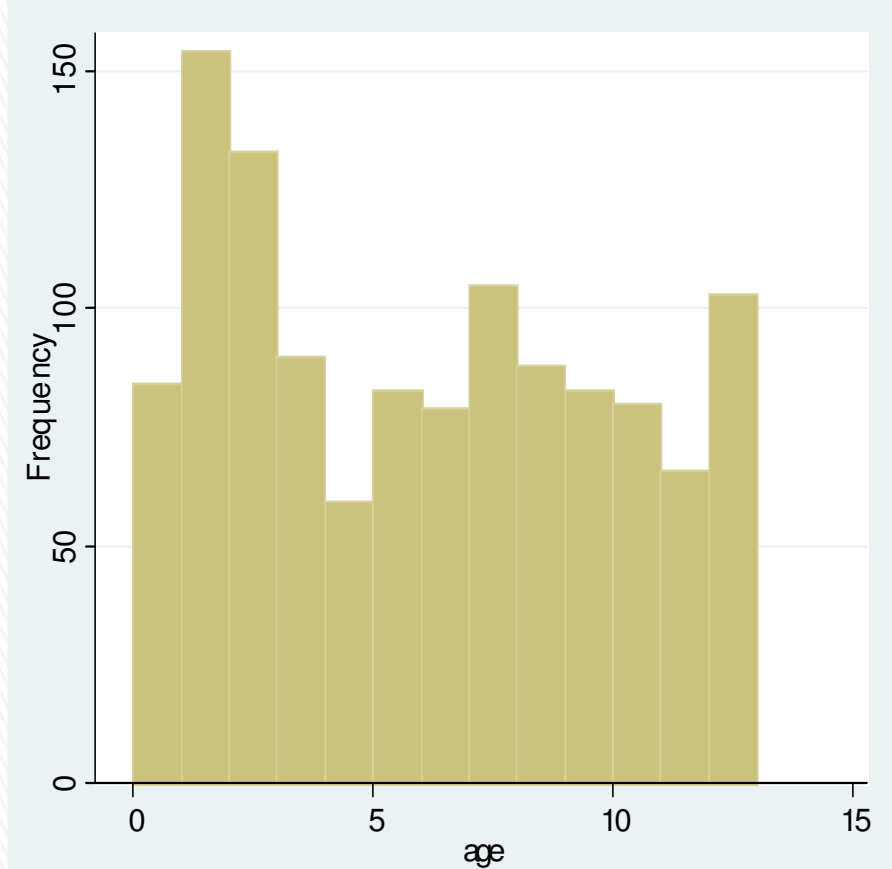
- ▶ In this sub-study we explored the acceptability of syrup and scored tablet ARVs dosed according to WHO weight bands among children substituting syrups with tablets



# METHODS (1)

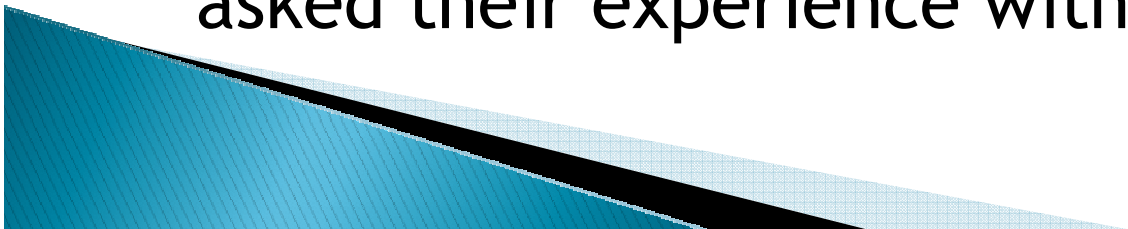
- ▶ In the ARROW trial, 1207 children were enrolled in Uganda / Zimbabwe during 2007/08
- ▶ At enrolment, 406 (34%) children received syrups of individual drugs (NNRTI + 2 or 3 of ZDV, ABC, 3TC)

Age of children at enrolment in Uganda and Zimbabwe



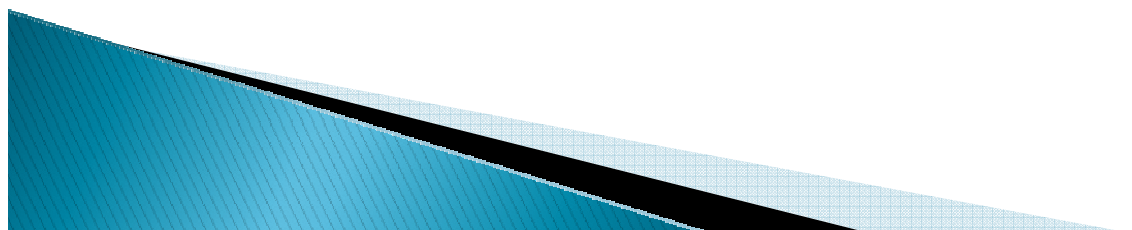
## METHODS (2)

- ▶ 236/406 (58%) substituted scored tablets (also individual drugs) between May 2008 and December 2009
- ▶ At substitution, baseline questionnaires were administered to carers to elicit their experience with syrups and expectations of tablets
- ▶ Eight weeks later follow-up questionnaires asked their experience with tablets



# RESULTS (1)

- ▶ 79% (186/236) questionnaires of children changing formulation were analysed
- ▶ 2.9 years (IQR 2.4,3.4) was median age of children at which formulation was changed





# RESULTS (2)

At baseline, 77% (144/186) carers reported problems while using syrups, because of:

- The number and weight of bottles of liquid
- Bottles of liquid being difficult to transport

**AVERAGE NUMBER OF BOTTLES OF SYRUPS PER VISIT VERSUS AVERAGE BOTTLES OF TABLETS PER CHILD PER VISIT.**



Syrups

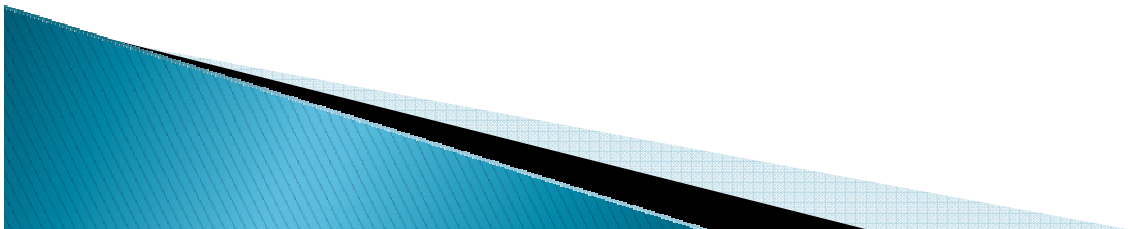


Tablets( scored)



## RESULTS (3)

- ▶ Most carers usually dissolved/crushed the scored tablets in liquid
- ▶ Specific difficulties with scored tablets were
  - expected by 53% (99/186) of carers
  - but reported after 8 weeks by only 27% (50/186)
- ▶ The difficulties were taste, swallowing and vomiting

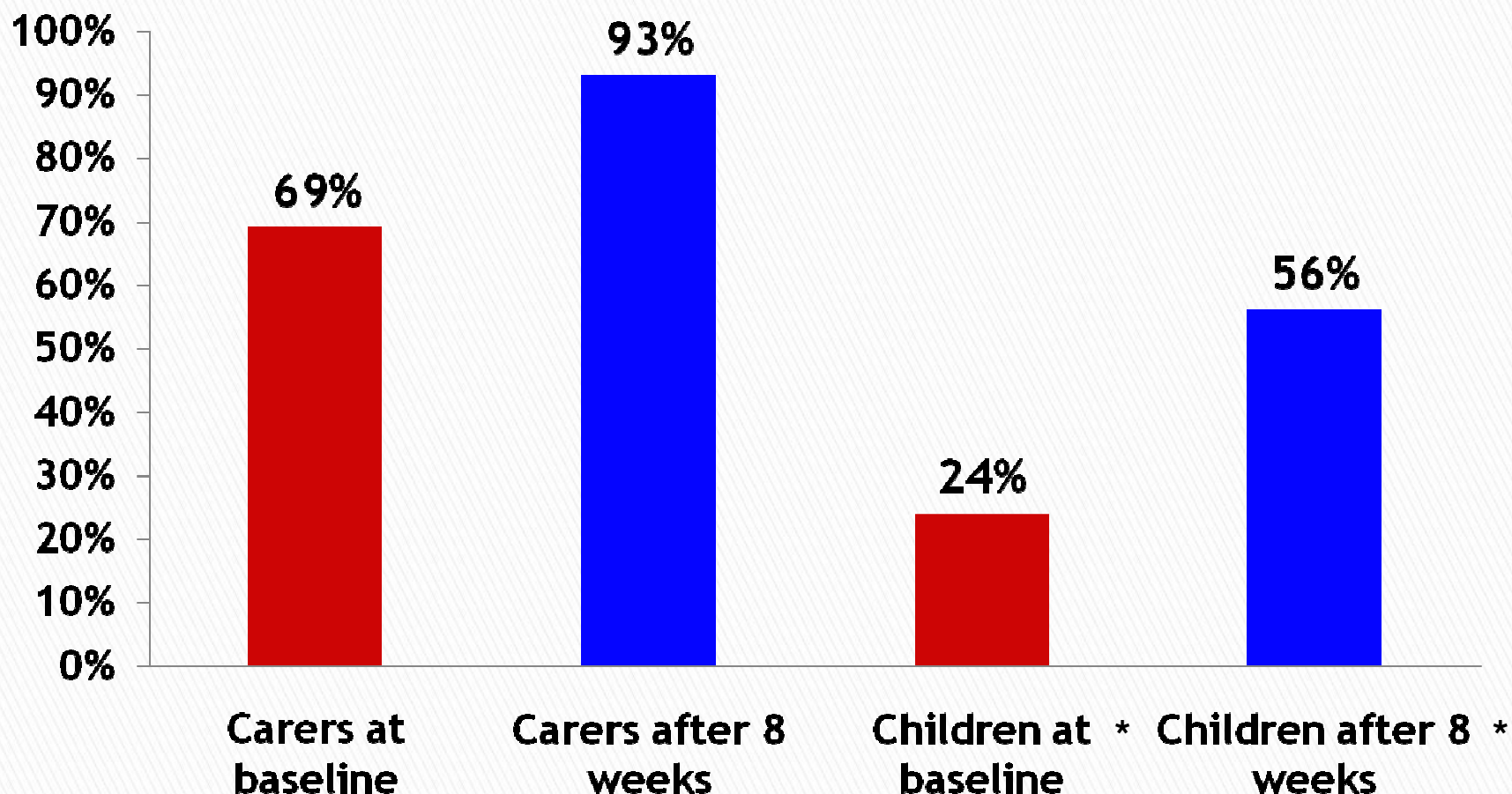






## RESULTS (4)

### OVERALL PREFERENCE FOR TABLETS

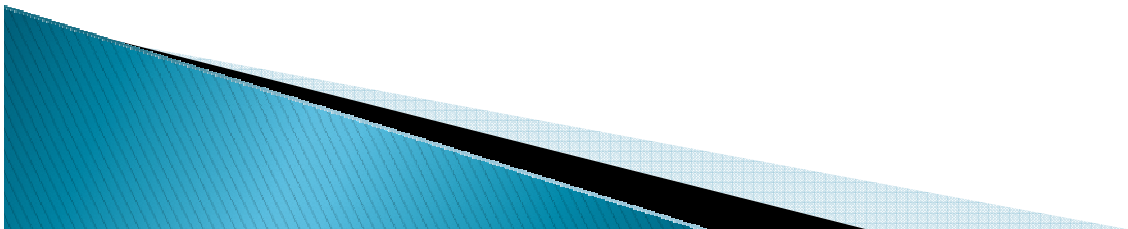


\*Parents/carers reported the children's preferences



# CONCLUSIONS

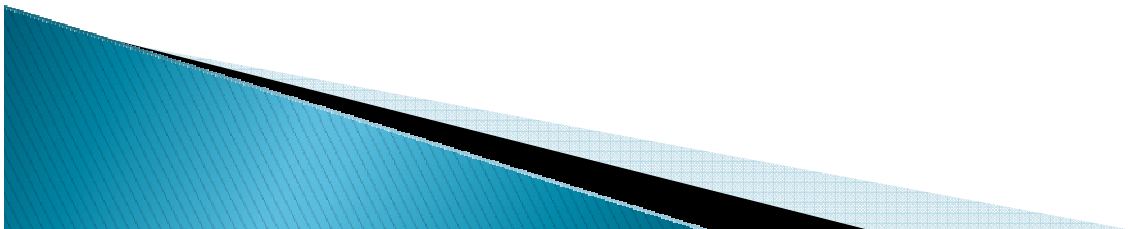
- Carers anticipated fewer difficulties using scored tablets than syrups, and experienced even fewer difficulties
- After 8 weeks use most carers reported that children preferred scored tablets; none had switched back to syrups





# IMPLICATIONS

- Scored tablets for young children cause few problems
- Most children and almost all their carers prefer scored tablets
- We are eliciting long term information after 24 weeks on tablets and will also evaluate the effect of acceptability on adherence





# ACKNOWLEDGEMENTS

- ▶ The children and their parents/carers
- ▶ The ARROW Trial teams at:
  - MRC/UVRI, Entebbe
  - Joint Clinical Research Centre, Kampala
  - Mulago Hospital, PIDC
  - UZ College of Health Sciences, Harare, Zimbabwe
  - MRC - CTU, London, UK
- ▶ The ARROW Trial Steering Committee, Data Monitoring Committee, Endpoint Review Committee
- ▶ ARROW funders: MRC UK, UK DfID
- ▶ GlaxoSmithKline (GSK) for trial drugs

