

# Measuring Prevention Impact: Outcomes in Clinical Trials

## Assessing the Effectiveness of Prevention Approaches for Fetal Alcohol Spectrum Disorders

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### Introduction

The selection of appropriate outcome measures is crucial when designing trials to assess the effectiveness of intervention approaches to FASD.

### Objectives

To describe the characteristics of outcome measures reported in trials assessing the effectiveness of prevention interventions for FASD.

### Methods

- Descriptive analysis of outcomes reported in 59 randomized controlled clinical trials (RCT) or controlled clinical trials (CCT) included in a systematic review of the effectiveness of universal, selective and indicated prevention strategies for FASD published between 1970 and February 2012
- All outcome measures reported in the individual trials were extracted and classified by type of prevention strategy and follow-up period as:
  - Immediate outcomes (short-term outcomes that pertain to knowledge, perceptions and attitudes towards prenatal alcohol use)
  - Intermediate outcomes: medium-term outcomes related to behavioural changes to reduce the risk of alcohol use during pregnancy (e.g., outcomes related to alcohol intake, alcohol abstinence and binge drinking)
  - Ultimate outcomes: long-term maternal and newborn/infant outcomes, psychosocial and family outcomes, and changes in the incidence of FASD

### Results

- A total of 39 outcomes were assessed in 19 studies on the effectiveness of universal FASD-prevention approaches (**Table 1**).
  - Overall, the studies mainly evaluated immediate outcomes, frequently related to knowledge and attitudes towards drinking alcohol during pregnancy (n = 15). Less frequently reported were intermediate outcomes related to behavioural changes, such as alcohol intake (n = 7). Most recently, outcomes related to changes in the incidence of FASD have been evaluated (n = 3).
- A total of 91 outcomes were reported in 30 studies that assessed the effectiveness of selective FASD-prevention approaches (**Table 2**).
  - Overall, intermediate outcomes related to changes in patterns of drinking behaviour during pregnancy (n = 46) and ultimate neonatal and infant-related outcomes (n = 18) were most frequently reported.
- A total of 38 outcomes were assessed in 10 studies on the effectiveness of indicated FASD-prevention approaches (**Table 3**).
- The studies mainly evaluated ultimate outcomes, neonatal and infant outcomes being the most frequently reported (n = 12).
- Less frequently reported were intermediate outcomes related to changes in alcohol intake (n = 8) and abstinence rates (n = 6).
- Immediate outcomes such as perceptions about alcohol use during pregnancy were rarely reported in the studies.

Table 1: Outcomes examined in studies on universal prevention approaches to FASD

Type of outcome		Number of outcomes assessed at different follow-up periods					Total number of outcomes
		≤ 3 months	> 3 months and ≤ 6 months	> 6 months and ≤ 9 months	> 9 months and ≤ 1 year	> 1 year	
Immediate	Knowledge about alcohol use during pregnancy/FASD	7	1	3	2	2	15
	Attitudes toward alcohol use during pregnancy	5	---	---	1	---	6
	Awareness of risk of alcohol use during pregnancy	---	1	---	---	1	2
	Perceptions about alcohol use during pregnancy	1	---	---	1	---	2
Intermediate	Alcohol intake	---	2	1	2	2	7
	Alcohol abstinence	---	---	---	---	1	1
	Binge drinking	---	---	---	---	1	1
Ultimate	Maternal outcomes	---	---	---	---	1	1
	Infant outcomes					1	1
	FASD outcomes	---	---	---	---	3	3
Total		13	4	4	6	12	39

Table 2: Outcomes examined in studies on selective prevention approaches to FASD

Type of outcome		Number of outcomes assessed at different follow-up periods					
		≤ 3 months	> 3 months and ≤ 6 months	> 6 months and ≤ 9 months	> 9 months and ≤ 1 year	> 1 year	Total number of outcomes
Immediate	Attitudes toward alcohol use during pregnancy	---	1	---	1	---	2
	Knowledge about alcohol use during pregnancy/ FASD	2	1	---	---	---	3
	Awareness of risk of alcohol use during pregnancy	---	---	---	1	---	1
	Perceptions about alcohol use during pregnancy	---	---	---	---	---	---
Intermediate	Alcohol intake	19	13	3	11	---	46
	Alcohol abstinence	2	---	1	1	---	4
	Binge drinking	1	1	1	1	---	4
	Alcohol-exposed pregnancy	1	2	1	---	---	4
Ultimate	Neonatal and infant outcomes	---	---	1	14	3	18
	FASD outcomes	---	---	---	2	---	2
	Legal outcomes	---	---	---	1	---	1
	Maternal outcomes	---	---	2	3	---	5
	Economic and health care utilization outcomes	---	---	---	1	---	1
	Family outcomes	---	---	---	---	---	---
Total		25	18	9	36	3	91

Table 3: Outcomes examined in studies in indicated prevention approaches to FASD

Type of outcome		Number of outcomes assessed at different follow-up periods					
		≤ 3 months	> 3 months and ≤ 6 months	> 6 months and ≤ 9 months	> 9 months and ≤ 1 year	> 1 year	Total number of outcomes
Immediate	Perceptions about alcohol use during pregnancy	---	1	---	---	---	1
	Attitudes toward alcohol use during pregnancy	---	---	---	---	---	---
	Awareness of risk of alcohol use during pregnancy	---	---	---	---	---	---
	Knowledge about alcohol use during pregnancy/FASD	---	---	---	---	---	---
Intermediate	Alcohol intake	---	---	---	7	1	8
	Alcohol abstinence	---	---	1	1	4	6
	Binge drinking	---	---	---	---	---	---
	Alcohol-exposed pregnancy	---	---	---	---	---	---
Ultimate	Neonatal and infant outcomes	---	---	---	7	5	12
	Maternal outcomes	---	---	---	1	3	4
	Economic and health care utilization outcomes	---	---	---	1	---	1
	Family/social outcomes	---	---	---	---	3	3
	FASD outcomes	---	---	---	2	1**	3
	Legal outcomes	---	---	---	---	---	---
Total		---	1	1	19	17	38

### Conclusions

- The majority of studies included in the review evaluated the effects of FASD-prevention interventions on intermediate outcomes, such as changes in maternal alcohol intake and abstinence rates during pregnancy.
- Studies assessing interventions that target low risk population tend to use immediate outcomes to assess effectiveness, whereas there is a shift to assessing ultimate outcomes for interventions that target the highest risk populations within indicated prevention approaches.
- The studies provided little information about how the interventions might ultimately affect the incidence of FASD.
- Outcome measures currently used in trials assessing the effectiveness of FASD interventions may not reflect endpoints that are meaningful for all key stakeholders, including pregnant women and their partners , the general public, health care professionals and others making policy decisions.
- There is a need to develop and use an agreed set of standardized outcome measures to enable meaningful comparisons across trials of FASD prevention.

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