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# BMJ Open

## Towards developing a guideline to inform policy on foetal alcohol spectrum disorder: A study protocol

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1 Towards developing a guideline to inform policy on foetal alcohol spectrum disorder: A  
2 study protocol

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13 **Key Words:** Foetus Alcohol Spectrum Disorder, Alcohol, Birth defects, Guidelines,  
14 Policies,

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56 22 **ABSTRACT**  
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9 23 **Introduction:** Maternal alcohol consumption during pregnancy results in mental and  
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11 24 physical birth defects in individuals. These birth defects are usually described as Foetal  
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13 25 Alcohol Spectrum Disorder (FASD). With an estimated of 183- 259 per 1000 children born  
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15 26 with FASD, South Africa is identified to have the highest prevalence of FASD in the world.  
16  
17 27 Nevertheless, there is a lack of relevant policies, guidelines, and interventions addressing the  
18  
19 28 issues around FASD. This protocol outlines a proposed process for developing a guideline to  
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21 29 inform policies on FASD.  
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24 30 **Methods and Analysis:** This process will have three phases. In phase one, we plan to  
25  
26 31 conduct a document review of available policies on the prevention, treatment, and  
27  
28 32 management of FASD and update the existing systematic review on FASD interventions. The  
29  
30 33 aim of the two reviews is to explore the availability and content of existing policies and  
31  
32 34 interventions on FASD. In addition, we will conduct an exploratory qualitative research to  
33  
34 35 obtain the perspectives of various stakeholders including the Department of Education, the  
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36 36 Department of Health and Social Development of the existing or possible guidelines and  
37  
38 37 policies for the management of FASD and available interventions and services. In phase two,  
39  
40 38 we will aggregate the findings of the previous phase to develop a prototype guideline. In  
41  
42 39 phase three, using the developed prototype, we will apply the Delphi approach with experts  
43  
44 40 on FASD, soliciting their opinions on the nature and content of the proposed guidelines for  
45  
46 41 policies. The information gathered will be used to modify the prototype to formulate a policy  
47  
48 42 guideline on FASD. Data will be analysed using thematic analysis and narrative synthesis.  
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51 43 **Ethics and Dissemination:** Ethical clearance has been obtained from the ethics  
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53 44 committee of the University and governmental departments. The findings will be  
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3 45 disseminated through publications and the guideline will be submitted to relevant  
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5 46 departments.  
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### 10 48 **Strengths and limitations of this study**

- 13 49 • It proposed multiple sources for data collection.
- 15 50 • It proposed proven methodology such as Delphi technique to develop the guideline.
- 17 51 • This study will not include people with FASD.
- 19 52 • This study is expected to influence policy nationally, however, it will be conducted in  
21 53 only one province out of nine provinces.  
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## 67 **Introduction**

68 Foetal alcohol spectrum disorders (FASDs) refer to an array of birth disorders produced by  
69 foetal exposure to alcohol during pregnancy. The word “foetal alcohol syndrome” was not  
70 used until 1973. This was when the negative effects were medically recognized [1, 2]. The  
71 word “fetal alcohol spectrum disorder” not was used until 2002 at a conference organized by  
72 the United States of America (USA) National Organization on Fetal Alcohol Syndrome  
73 (NOFAS). The new term was used to describe the range of outcomes that may occur as a  
74 result of prenatal alcohol exposure [3]. (FASDs) include foetal alcohol syndrome (FAS),  
75 partial FAS, alcohol-related neurodevelopment disorders (ARND) and alcohol-related birth  
76 defects (ARBD). FAS is identified as the most serious anomalies among FASDs [4].

77

78 FASD leads to primary and secondary disabilities. Primary disabilities are those that the child  
79 is born with [5], resulting in damages to the brain domains that are responsible for physical  
80 motor skills, sensory processing skills, cognition, communication skills, academic  
81 achievement, memory skills, executive functioning and abstract reasoning, attention deficit/  
82 hyperactivity, and adaptive skills [6, 7]. It can also result in physical abnormalities such as  
83 ante- and post-natal growth retardation, eye and ear malformations, mouth and jaw  
84 deformation, skeletal defects, organ pathology, sensory deficits, and impaired immune system  
85 [4]. Secondary disabilities relate to those disabilities that developed because of lack of timely  
86 and appropriate interventions to primary disabilities. These include: fatigue, frustration,  
87 anxiety, fearfulness, rigid, resistant, argumentative behavior, becoming overwhelmed, shut  
88 down (withdrawn), a poor self-concept, feelings of failure, low self-esteem, isolation, acting  
89 out, aggression, family and/or school problems, depression and other mental health problems,

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3 90 trouble with the law, drug and alcohol problems, problems with employment, and  
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5 91 homelessness [4, 8].  
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8 92 Studies conducted in United States of America (USA), South Africa, Canada and Australia  
9  
10 93 have identified various maternal risk factor for FASD. These include demographic factors  
11  
12 94 (socioeconomic status, employment status, educational status, marital status, religion, living  
13  
14 95 area, income and age), psychiatric and neuropsychological factors (psychiatric comorbidity,  
15  
16 96 identified stressful, physical aggression and sexual abuse), family and socials (family  
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18 97 lifestyle, drinking habit, alcohol use, illegal drugs use and tobacco use) and pattern of alcohol  
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20 98 consumption [9].  
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24  
25 100 The prevalence reported in the literature for FAS/FASD were conducted in certain regions of  
26  
27 101 various countries. Therefore, there is no national prevalence of FAS /FASD anywhere in the  
28  
29 102 world [10].The prevalence of foetal alcohol spectrum disorders vary from one country to  
30  
31 103 another, in the USA and Western Europe, it is assumed to be between 2% to 5% and FAS  
32  
33 104 ranges from 0.2 to 9 per 1000 live births [11]. Zelner and Koren [12] estimated the  
34  
35 105 prevalence of FAS and FASD at 1 to 3 and 9 per 1000 live births respectively in Canada. In  
36  
37 106 Italy, a study estimated the prevalence rate of 3.7 to 7.4 and 20.3 to 40.5 per 1000 births for  
38  
39 107 FAS and FASD respectively [13]. In South Africa, a study conducted in four rural  
40  
41 108 communities reported highest prevalence rate ever recorded in any part of the world. It was  
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43 109 estimated to be 93-128 per 1000 children for FAS and 183 to 259 per 1000 children for  
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45 110 FASD [14].  
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51 112 Prevention, care and support for persons affected by FAS and other alcohol-related disorders  
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53 113 are not being implemented, particular in developing countries. Evidence shows that only in  
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55 114 developed countries like Sweden and Canada that provide universal health care (health care  
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3 115 for all), that are making effort to recognise and accommodate the needs of women with an  
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5 116 alcohol problem and their children. Active and coordinated efforts towards addressing  
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7 117 alcoholism in women and their children were not evident in other parts of the world including  
8  
9 118 South Africa [15]. Furthermore, only the USA and France have been successful to have  
10  
11 119 Alcohol Labelling Act as part of their federal law [15]. Nevertheless, no country has  
12  
13 120 successfully implemented restrictions on public advertising of alcohol beverages in print  
14  
15 121 media, radio and television, and no medical school has introduced courses on FASD in any  
16  
17 122 part of the world [15].  
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## 22 124 **Background**

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25 125 South Africa is reported to have escalating levels of alcohol consumption [16], particularly in  
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27 126 the informal settlements in the Northern and Western Cape Provinces [17–21]. The  
28  
29 127 prevalence of alcohol use among pregnant women in the Cape Metropole, Western Cape  
30  
31 128 Province of South Africa is estimated at 19.6% and in poor communities of the Western and  
32  
33 129 Northern Cape provinces of South Africa, FASD (FAS/PFAS) is endemic [22–24]. Maternal  
34  
35 130 alcohol drinking during pregnancy, especially in rural and informal settlements, has made  
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37 131 FASD a huge problem in South Africa.  
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42 132  
43 133 Generally, FASD is relatively unknown among health professionals and has not been given  
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45 134 adequate consideration in policies, programmes, and interventions [25]. This is probably  
46  
47 135 because FASD is not yet formalized as a medical diagnosis, even though it is now over 40  
48  
49 136 years that it was first diagnosed [25]. In spite of this, efforts have been made to recognize  
50  
51 137 FASD as a public health problem. Because FASD is preventable, there have been efforts to  
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53 138 advocate for the implementation of various prevention programme and strategies for its  
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55 139 prevention. These strategies advocated for include adequately resourced alcohol control  
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3 140 services, support for pregnant women, and a sustainable commitment from communities,  
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5 141 service providers and the government in addressing alcohol-related health and psychological  
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7 142 problems [26, 27]. For these strategies to be effective and sustainable, a governing policy and  
8  
9 143 coordinated efforts are required.

10  
11 144 Globally, there is inadequate policy and guidelines for the management and prevention of  
12  
13 145 FASD. A review on FASD in Africa reported gaps in policy and service implementation [28].  
14  
15 146 In South Africa, only two of the national policy documents namely, the National Human  
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17 147 Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth  
18  
19 148 Defects and Disabilities (2001) and the National Drug Master Plan (2007) scanned during a  
20  
21 149 situation analysis by Rendall-Mkosi et al. used the term FAS and none of them mentioned  
22  
23 150 FASD [29]. In addition, the South African Guidelines for Maternity Care (2002) only  
24  
25 151 specifies that maternal alcohol, as well as tobacco and other substances, use behaviours  
26  
27 152 should be taken into consideration when taking a medical history of a woman [29]. This  
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29 153 reflects the extent to which issues related to FASD are being considered in policy.  
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35 155 Furthermore, current national hospital-based birth defects surveillance system developed by  
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37 156 the National Department of Health excludes FASD [29]. This surveillance system mainly  
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39 157 considers birth defects that can be clinically diagnosed at birth or few days after birth, which  
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41 158 can only be identified if a woman is hospitalised after birth. The exclusion of FASD in the  
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43 159 birth defects surveillance system is believed to be as a result of the difficulty in diagnosing  
44  
45 160 FASD at birth as most of its features are rarely manifested at birth and it requires a  
46  
47 161 multidisciplinary team to arrive at a definitive diagnosis [29]. The above gap speaks to the  
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49 162 need to develop relevant policies and guidelines to identify FASD and in order to guide  
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51 163 strategic implementation of appropriate interventions to address FASD in South Africa.  
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3 165 In 2001, the Western Cape Provincial executive council acknowledged FAS as a provincial  
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5 166 health priority for the years 2001 and 2002 [30, 31]. This led to the establishment of the  
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7 167 Western Cape Provincial FAS reference and working group (now called FASD task team).  
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9 168 The FASD Task Team of South Africa comprises of members from the Department of health,  
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11 169 the Department of Social Services, the Department of Education, the Medical Research  
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13 170 Council, the University of Stellenbosch, the University of Cape Town, NGOs such as  
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15 171 Foundation for Alcohol Related Research (FARR), Dopstop and Pebbles project. It was  
16  
17 172 headed by the provincial Maternal, Child and Women's Health Deputy Director [30, 31]. The  
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19 173 aims of the FASD task team is to raise awareness on FASD, create strategies for prevention  
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21 174 and, share skills and information [30, 31]. The FASD task team has been successful in the  
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23 175 development of FAS training manual for professional, designed posters for awareness on  
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25 176 FASD, organizing public awareness on International FASD Days, organizing FASD training  
26  
27 177 workshop and, development of website and Facebook page on FASD [30, 31]. The above  
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29 178 development is an important and commendable step in developing the capacity to support  
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31 179 management of FASD at the provincial level. However, a multi-sectoral national FAS Task  
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33 180 Team is needed for a coordinated response is expected to address FASD in the South African  
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35 181 population. Strengthening the newly established National FAS Task Team by the Department  
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37 182 of Health, and the establishment of provincial level Task Teams nationally has been  
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39 183 advocated to ensure a pragmatic coordinated national response for FASD [29]. To this end,  
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41 184 we are proposing a national FASD guideline that will inform policy on coordinated and  
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43 185 multi-sectoral response to FASD in South Africa. In this protocol, we propose systematic  
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45 186 steps to developing a guideline to inform policy for FASD prevention and management.  
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## 52 **Research aim**

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3 189 The aim of this protocol is to propose a process for developing a guideline to inform the  
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5 190 development and improvement of policy on FASD.  
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### 13 193 **Research objectives**

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16 194 To achieve the aim, we developed the following objectives:  
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- 18  
19 195 • To review policies and their contents on FASD internationally and in South Africa;  
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21  
22 196 • To explore and describe the content of FASD policies from the perspective of policy  
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24 197 makers;  
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26  
27 198 • To provide update on the interventions on FASD internationally and in South Africa;  
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29  
30 199 • To explore and describe the perspectives of service providers involved in the  
31  
32 200 implementation of identified FASD intervention activities.  
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35 201 • To apply the Delphi technique to guide the development of guidelines for an integrated  
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37 202 policy on FASD for the South African context.  
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### 41 42 204 **Understanding policy guidelines**

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45 205 According to the World Health Organization, a guideline is a document that contains  
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47 206 recommendations on health interventions for clinical or public health [32, 33]. It is also  
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49 207 described as a document that makes evidence-based recommendations for averting and  
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51 208 treating certain conditions, improving health, managing medicines, planning of services for  
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53 209 the community, development of an intervention for enhancing population health and to  
54  
55 210 deliver social care for people [34]. Guidelines promote individualised and integrated care,  
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211 help service providers and recipients, and other stakeholders to make informed decisions and  
212 serve as a response to a condition that needs urgent attention [32–35]. In addition, a guideline  
213 is considered as a statement, recommendation or best practice created to give a framework for  
214 policy implementation [35]. As applies to this protocol, we considered a guideline as a  
215 document that contains recommendations that will inform the development of integrated  
216 policy on FASD.

217

## 218 **Proposed methodology**

219 The development of the guideline will follow three phases: (1) Information gleaning, (2)  
220 development of prototype and (3) Delphi techniques and developing of guidelines (Figure 1).

221 The importance of involving proven methods, which are both inclusive and participatory, was  
222 considered as essential for developing a socially acceptable FASD guideline for South Africa.

223 **Figure 1:** A proposed methodological approach for the development of guidelines for FASD  
224 policy.

225

### 226 **Phase 1: Information gleaning**

227 In the first phase, we aim to obtain information from various sources to enable us to develop  
228 a prototype guideline. To this end, we plan to conduct a document review on FASD policies.

229 The documents review will consider policies developed internationally (with focus on South  
230 Africa) and the systematic review will focus on interventions globally and with focus on  
231 South Africa. In addition, we will identify relevant policy makers and service providers in the  
232 Departments of Health, Education and Social Development and engage with them through in-  
233 depth interviews and focus group discussions to obtain information on existing policies and  
234 interventions on FASD in South Africa. This phase will be conducted in the following steps.

235

**Step 1: Document review of policy on FASD globally and in South Africa**

The researchers will review available relevant documents such as policy documents and guidelines on FASD. The aim of this review is to explore the availability and content of existing guideline and policies on FASD. Government websites of low income, middle income and high-income countries, websites of various non-governmental organisations and databases will be searched for these documents. All the policies or guidelines that focused on any aspect of FASD will be included. The narrative analysis will be used to analyse the relevant documents identified. The information that will be obtained will inform the development of a prototype guideline. Following the document review, a systematic review will be undertaken.

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**STEP 2: Systematic review of interventions for FASD globally and in South Africa.**

The aim of the systematic review will be to systematically locate, appraise and synthesize intervention on FASD. The systematic review will consider the following review question: “What are the interventions that are available on FASD globally and in South Africa?” In conducting this review, the researchers will follow nine steps of a systematic review [36]. These steps include formulating review question, defining search strategy, establishing inclusion criteria and exclusion criteria, choosing a method for the review, conducting methodological quality and critical appraisal, extracting data, analyzing and synthesizing data, and writing a report.

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What are the interventions that are available on FASD globally and in South Africa? To answer this question, databases will be searched for articles discussing or evaluating

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3 260 interventions for the management of FASD. These databases include, Ebsco Host (Academic  
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5 261 Search Complete, ERIC, SoINDEX, Health Source: Nursing/Academic Edition, CINAHL  
6  
7 262 and PsycARTICLES), Science Direct, Springer Links, Wiley Online Library, JSTOR, and  
8  
9 263 SAGE Journals, LANCET, Pubmed, Cochrane Library, Sabinet, NEXUS and BioMed  
10  
11 264 Central Journal will be searched and retrieved for the period covering 1973 to 2016 using  
12  
13 265 intervention and FASD as search terms. Furthermore, the references of the retrieved article  
14  
15 266 will be used to search for more articles. The titles and abstracts of the articles will be  
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17 267 screened using inclusion/exclusion criteria and duplicates will be removed. After screening,  
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19 268 the remaining articles will be read and their methodological quality evaluated to establish  
20  
21 269 their inclusion in the systematic review. In addition, the included articles will be appraised  
22  
23 270 using a critical appraisal sheet. Narrative synthesis will be used for data analysis. Narrative  
24  
25 271 synthesis can be described as a descriptive written summary of included studies and their  
26  
27 272 findings [36]. The data extraction tool will consist of four distinctive sections namely: the  
28  
29 273 general description, a methodological appraisal, the content intervention, and the analysis of  
30  
31 274 the results. The information that will be obtained will inform the development of a prototype  
32  
33 275 guideline.  
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### 40 277 **STEP 3: Exploratory qualitative research**

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43 278 An explorative qualitative study will then be conducted. This is meant to allow the  
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45 279 perspectives of policy makers and service providers on policies and interventions for FASD  
46  
47 280 to be explored and described. Glenton, Lewin and Norris [37] reported that evidence from the  
48  
49 281 qualitative research can be used to develop the guideline. Policy makers and service providers  
50  
51 282 from the Department of Education, Department of Health and Department of Social  
52  
53 283 Development will be interviewed as part of the processes of developing guidelines that will  
54  
55 284 inform policy on FASD. A policy marker is defined as an administrator involved or supposed  
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3 285 to be involved in the area of policy formulation and programme monitoring on FASD and  
4  
5 286 related disabilities. A service provider is defined as a staff involved or supposed to be  
6  
7 287 involved in providing services and interventions on FASD and related disabilities. These  
8  
9 288 groups of individuals are deemed knowledgeable to provide relevant information for  
10  
11 289 developing the guidelines. Purposive sampling will be employed in selecting participants  
12  
13 290 based on the following criteria: policy makers with about five years' experience in policy on  
14  
15 291 FASD or related disabilities and service providers in primary health care, hospital, schools,  
16  
17 292 social development and NPOs with about five years of experience in providing interventions  
18  
19 293 and services to individuals with FASD. The researchers intend to sample three policy makers  
20  
21 294 from each department and conduct three focus group discussions in each department with an  
22  
23 295 average of 6-8 participants. In addition, for the focus group discussions, the researchers will  
24  
25 296 use service providers who are available in one facility as it may be difficult to combine two  
26  
27 297 facilities together. This is due to nature of their jobs and this was discovered during the  
28  
29 298 feasibility study. In addition, data saturation may also define the sample.  
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34  
35 300 The first set of data will be collected through in-depth interviews with policy makers using an  
36  
37 301 interview guide to explore the available policies and their contents on FASD. This could  
38  
39 302 provide information based on the perspectives of the policy makers. The second set of data  
40  
41 303 will be collected through focus group discussions with selected service providers using a  
42  
43 304 discussion schedule to explore available interventions, services and policies in practice.  
44  
45 305 Focus group discussions can give rich information and contributions from participants as they  
46  
47 306 contribute in moderated discussions. An audio recorder will be used to capture information  
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49 307 from the participants, notes will also be taken during the interview and the interview  
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51 308 recordings will be transcribed for data analysis. The rigour in the qualitative study which is  
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3 309 trustworthiness will be established through credibility, transferability, dependability,  
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5 310 conformability and reflexivity [38].  
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9 312 The data will be analysed using thematic content analysis technique [39]. The researchers  
10  
11 313 will use Creswell's data analysis spiral [40]. This process involves reading and memoing,  
12  
13 314 then, describe, classify, and interpret the data according to themes and the categories, and  
14  
15 315 finally visualize and represent the themes and categories. An independent coder will also be  
16  
17 316 used to ensure trustworthiness.  
18

### 19 20 317 **Phase 2: Development of prototype**

21  
22 318 In the second phase, we will aggregate the information from data collected in phase one and  
23  
24 319 two to develop a prototype guideline. In this phase, information obtained from document  
25  
26 320 review, systematic review, and in-depth and focus group interviews will be used to develop a  
27  
28 321 prototype guideline for FASD policy. This will involve conflating the information to draft a  
29  
30 322 prototype. The researchers will engage and agree on consensus interpretations of the findings  
31  
32 323 of the previous phases and these will then be used to develop the prototype guideline. The  
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34 324 researchers adopted this approach because it has been applicable in the guideline  
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36 325 development process as applied by other researchers in developing guidelines for various  
37  
38 326 issues [41–43].  
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### 43 44 328 **Phase 3: Delphi techniques and developing of guidelines**

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46 329 In the third phase, we will identify the relevant policy makers and health service providers  
47  
48 330 and key health policy advocates and engaged with them through a Delphi technique to  
49  
50 331 modify the prototype to develop obtain a refined guideline. These individuals will be mixed.  
51  
52 332 That is, part of them may be those that have been participated in the qualitative research. This  
53  
54 333 is because anecdotal information has it that these policy makers are not many and it may be  
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3 334 impossible to get a different set of participants. The process of guideline development is  
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5 335 expected to be evolving, and the researchers have included plans to follow through a  
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7 336 thorough process and procedures as resource and time would permit to get a consensus on  
8  
9 337 aspects of the policy. The use of the Delphi approach is recommended by WHO Handbook  
10  
11 338 for guideline development [32, 33, 37].  
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16 340 The Delphi technique is a structured communication technique initially developed as a  
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18 341 systematic, interactive forecasting method, which relies on a panel of experts [44]. There is  
19  
20 342 no agreement on sample size. It is common for these experts to answer questionnaires in two  
21  
22 343 or more rounds [45]. The researcher gives an anonymous summary of the experts' predictions  
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24 344 from the previous round, and the reasons they provided for their judgments. Experts are  
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26 345 encouraged to revise, subsequently, their earlier answers in the light of the replies of other  
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28 346 members of their panels. This process narrows the wide range of answers and converges the  
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30 347 group answers towards correct or an agreed answer [46]. However, the process is stopped  
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32 348 after a predefined stop criterion and the mean or median scores of the final rounds determine  
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34 349 the results [44]. In this study, the developed prototype will be used to engage in Delphi  
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36 350 technique with experts on FASD in order to develop the proposed guidelines. The researchers  
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38 351 will start by identifying the experts and contacting them to explain the research. The  
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40 352 researchers will then purposefully select 10 experts using the following criteria: Top  
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42 353 management decision makers; policy makers; FASD service providers and FASD researchers  
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44 354 with about 5years of experience relevant to FASD policies, services, intervention or research  
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46 355 [47]. These experts will be contacted through email, as well as a telephone for them to  
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48 356 contribute to the development of the guideline.  
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3 358 The researchers will use the prototype with these experts soliciting their opinions on what  
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5 359 should be included or excluded in the proposed guidelines for policies. The data generated  
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7 360 will be analysed and these will be used to modify the prototype, which will be used as an  
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9 361 instrument for the second round. The experts will be asked to review the items summarised  
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11 362 by the researchers based on the information provided in round one and they will be asked to  
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13 363 rate or rank- order items to establish priorities among items and to reach consensus. The  
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15 364 outcome will be presented to the experts. The information generated in the second round will  
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17 365 then be analysed and the information gathered will be used to refine the prototype to obtain  
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19 366 the guidelines.  
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## 25 368 **Discussion**

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27 369 The essence of the proposed guideline is to inform policy development on foetal alcohol  
28  
29 370 spectrum disorder. A guideline as earlier described in this protocol is a document that  
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31 371 contains recommendations on health interventions for clinical or public health [32, 33]. It  
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33 372 makes evidence-based recommendations for averting and treating certain conditions,  
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35 373 improving health, managing medicines, planning of services for the community, development  
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37 374 of an intervention for enhancing population health and to deliver social care for people [34].  
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39 375 In addition, it promotes individualised and integrated care, help service providers and  
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41 376 recipients, and other stakeholders to make informed decisions. Furthermore, it serves as a  
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43 377 response to a condition that needs urgent attention [32–35], and a statement, recommendation  
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45 378 or best practice created to give a framework for policy implementation [35].  
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51 380 During the feasibility study of this research, it was gathered by the researcher from a non-  
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53 381 governmental organisation (foetal alcohol related research) a leading organisation in  
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55 382 conducting prevalence studies and rolling out prevention programme on FASD. The Chief  
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3 383 Executive Officer said that there are no guidelines and policies are limited to facilitate  
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5 384 effective interventions on FASD. It was also gathered from the administrators of various  
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7 385 departments of government in the Western Cape Province that alcohol drinking is a huge  
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9 386 problem and FASD is one of the negative outcomes. These administrators pointed out that  
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11 387 various efforts have been made, ranging from awareness programme to funding of NGOs to  
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13 388 response to FASD, but these efforts are not being coordinated because there are no specific  
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15 389 guidelines or polices on FASD. Service providers were also consulted, they highlighted that  
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17 390 there are no specific services offered to people living with FASD. They mentioned that there  
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19 391 are no specific guidelines to guide services and interventions though they sometimes refer an  
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21 392 individual for proper diagnosis if they present signs of FASD. They also provide health  
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23 393 education on alcohol to pregnant women. However, this is not specifically targeting at FASD.  
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25 394 These gaps necessitate the conduct of this proposed research for the development of guideline  
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27 395 that will enhance the development of coordinated policy on FASD.  
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33 397 In developing the guideline protocol, the researchers adapted WHO Handbook for guideline  
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35 398 development [32, 33, 37]. The reason for adaptation is that some parts of the process are not  
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37 399 feasible and some are beyond the scope of this project. The process includes WHO  
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39 400 department decides to produce a guideline; discussion of required elements with Guideline  
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41 401 Review Committee (GRC) secretariat; planning, scoping, needs assessment; Guideline  
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43 402 Development Group (GDG) formation; key question formulation (PICO questions); planning  
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45 403 clearance submission; Guideline Review Committee (GRC) approval for development;  
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47 404 evidence retrieval / systematic review; evidence quality assessment / GRADE; development  
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49 405 of recommendations; Writing, external review, editing; director's executive clearance; final  
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51 406 GRC approval; ADG executive clearance; layout, proofread, publish; dissemination,  
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53 407 implementation, evaluation; and updating [32, 33, 37].  
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5 409 The strength of using this process is that it has been used to develop various guidelines for  
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7 410 interventions to combat diseases and improve services. The recommendations from the  
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9 411 guidelines are rooted in a comprehensive and objective assessment of the available evidence  
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11 412 and a clear pathway on how recommendations are generated by whom and on what. The  
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13 413 demerit of this process is that it requires a lot of resources, time and experts. The limitation of  
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15 414 this study might be that the researcher will not include the individuals with FASD and their  
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17 415 families directly in the study. Another limitation is that the study is restricted to the Western  
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19 416 Cape region of South Africa, which might affect the generalizability of the study findings.

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24 418 It has been reported that there are no guidelines for determining consensus, sample size and  
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26 419 sampling techniques when using the Delphi approach. This because these aspects of the  
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28 420 Delphi technique require a lot of time and participants' commitment, consequently, dropout is  
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30 421 likely to happen, which leads to low response rate and a delay in data analysis between  
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32 422 rounds [48, 49]. To mitigate the impact of the potential challenges, the researchers decided to  
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34 423 adapt the sample size of to a manageable number to favour in-depth engagement and  
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36 424 discursive approach with fewer experts, rather than having a large sample of experts with less  
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38 425 engagement with the guideline development process.

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## 41 42 43 44 427 **Conclusion**

45  
46 428 This protocol proposes a systematic procedure to develop a guideline that will inform the  
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48 429 development and improvement of policy on FASD. This study will, enhance coordinated  
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50 430 management of alcohol-related disorders, improve services to individuals with FASD,  
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52 431 facilitates the development or improvement of guidelines, and policies.

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3 433 **Declarations**  
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6 434 **Ethics approval and consent to participate**  
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8 435 Ethical research requires the protection of all participants in the study. This study will be in  
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10 436 accordance with the ethical guidelines and principals prescribed by the University of the  
11  
12 437 Western Cape. Ethical clearance has been obtained from the University of the Western Cape  
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14 438 Senate Higher Degree Committee and permission has been being requested by the  
15  
16 439 stakeholders from different organizations and governmental departments. Consent will be  
17  
18 440 obtained from all the participants.  
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25 442 **Consent for publication**  
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27 443 Not applicable  
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30 444  
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32 445 **Availability of data and material**  
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34 446 Not applicable  
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40 448 **Competing interests**  
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46 450 The authors declare that there is no competing interest.  
47  
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5 **455 Authors' contributions**

6  
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8 456 BOA and AMB conceived and conceptualised the study and the paper. BOA designed and  
9  
10 457 wrote the first draft of the manuscript. FCM redesigned the manuscript, contributed to the  
11  
12 458 development of the paper and provided comments to improve the manuscript. KJO  
13  
14 459 contributed to the development of the paper and provided comments to improve the  
15  
16 460 manuscript. All authors read and approved the final manuscript

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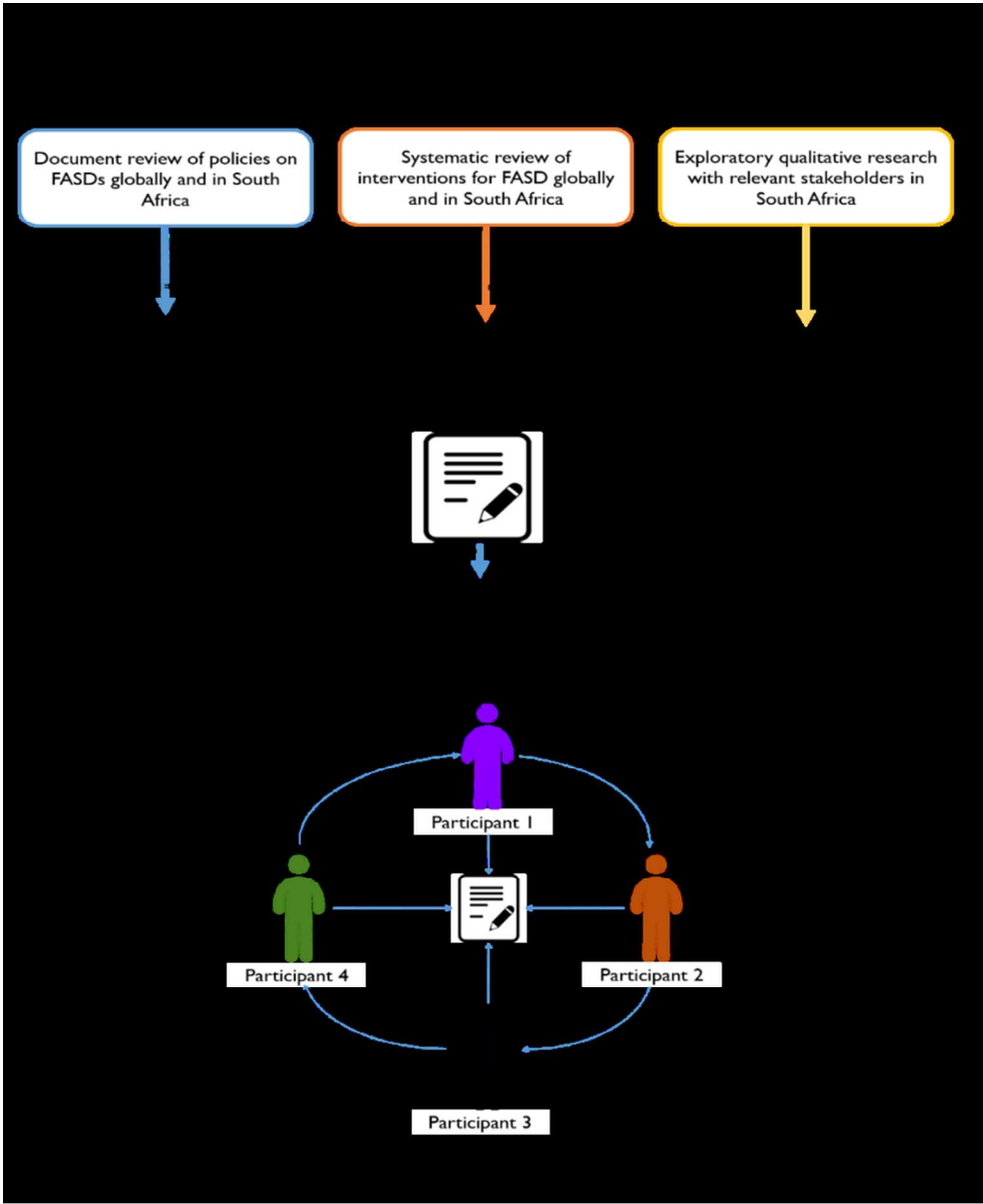
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42 604

## 605 **Figures**

606 **Figure 1:** A proposed methodological approach for the development of guidelines for FASD  
607 policy.

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# BMJ Open

## A Modified Delphi study towards developing a guideline to inform policy on Foetal Alcohol Spectrum Disorder in South Africa: A study protocol

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1 A Modified Delphi study towards developing a guideline to inform policy on Foetal Alcohol

2 Spectrum Disorder in South Africa: A study protocol

3

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13 **Key Words:** Foetus Alcohol Spectrum Disorder, Alcohol, Birth defects, Guidelines,  
14 Policies,

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67 **ABSTRACT**  
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10 **Introduction:** Maternal alcohol consumption during pregnancy can result in mental and  
11  
12 physical birth defects in individuals. These birth defects are usually described as Foetal  
13  
14 Alcohol Spectrum Disorder (FASD). With an estimated of 183- 259 per 1000 children born  
15  
16 with FASD, South Africa is identified to have the highest prevalence of FASD in the world.  
17  
18 Nevertheless, there is a lack of relevant policies, guidelines, and interventions addressing the  
19  
20 issues around FASD. This protocol outlines a proposed process for developing a guideline to  
21  
22 inform policies on FASD.  
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24

25 **Methods and Analysis:** This process will have three phases. Phase one will be carried  
26  
27 out in three steps; we plan to conduct a document review of available policies on the  
28  
29 prevention, and management of FASD and update the existing systematic review on FASD  
30  
31 interventions. The aim of the two reviews is to explore the availability and content of existing  
32  
33 policies and global interventions on FASD. In addition, we will conduct two exploratory  
34  
35 qualitative studies to obtain the perspectives of various stakeholders on the existing or  
36  
37 possible guidelines and policies for the management of FASD and available interventions and  
38  
39 services. In phase two, we will aggregate the findings of the previous phase to develop a  
40  
41 prototype guideline. In phase three, using the developed prototype, we will apply the Delphi  
42  
43 approach with experts on FASD, soliciting their opinions on the nature and content of the  
44  
45 proposed guidelines for policies. The information gathered will be used to modify the  
46  
47 prototype to formulate a policy guideline on FASD. Data will be analysed using thematic  
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49 analysis and narrative synthesis.  
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3 43 **Ethics and Dissemination:** Ethical clearance has been obtained from the ethics  
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5 44 committee of the University and governmental departments. The findings will be  
6  
7 45 disseminated through publications and the guideline will be submitted to relevant  
8  
9 46 departments.  
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### 13 14 15 48 **Strengths and limitations of this study**

- 16  
17 49 • The study proposes the use of multiple sources for data collection toward developing  
18  
19 50 a guideline to inform policy on Foetal Alcohol Syndrome Disorders.  
20  
21  
22 51 • It also proposes a proven methodology – The Delphi technique to develop the  
23  
24 52 guideline.  
25  
26 53 • A potential limitation to the study is that the study will not include people with  
27  
28 54 FASD;  
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30  
31 55 • This study is expected to inform policy on FASD nationally; however, it will be  
32  
33 56 conducted in only one province out of nine provinces of South Africa.  
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20 **Introduction**

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23 72 Foetal alcohol spectrum disorders (FASDs) refer to an array of birth disorders produced by  
24  
25 73 foetal exposure to alcohol during pregnancy. FASDs include foetal alcohol syndrome (FAS),  
26  
27 74 partial FAS, alcohol-related neurodevelopment disorders (ARND) and alcohol-related birth  
28  
29 75 defects (ARBD). FAS is identified as the most serious anomalies among FASDs [1]. The  
30  
31 76 word “foetal alcohol syndrome” was first used in 1973. This was when the negative effects  
32  
33 77 were medically recognized [2, 3]. The word “fetal alcohol spectrum disorder” was not used  
34  
35 78 until 2002 at a conference organized by the United States of America (USA) National  
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37 79 Organization on Fetal Alcohol Syndrome (NOFAS). The new term was used to describe the  
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39 80 range of outcomes that may occur as a result of prenatal alcohol exposure [4].  
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82 FASD may lead to primary and secondary disabilities. Primary disabilities are those that the  
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84 child is born with [5], resulting in damages to the brain domains that are responsible for  
85  
86 physical motor skills, sensory processing skills, cognition, communication skills, academic  
achievement, memory skills, executive functioning and abstract reasoning, attention, and  
adaptive skills [6, 7]. It can also result in physical abnormalities such as ante- and post-natal

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3 87 growth retardation, eye and ear malformations, mouth and jaw deformation, skeletal defects,  
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5 88 organ pathology, sensory deficits, and impaired immune system [1].  
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11 90 Secondary disabilities relate to those disabilities that developed because of lack of timely and  
12  
13 91 appropriate interventions to primary disabilities. These include: fatigue, frustration, anxiety,  
14  
15 92 fearfulness, rigid, resistant, argumentative behavior, becoming overwhelmed, shut down  
16  
17 93 (withdrawn), a poor self-concept, feelings of failure, low self-esteem, isolation, acting out,  
18  
19 94 aggression, family and/or school problems, depression and other mental health problems,  
20  
21 95 trouble with the law, drug and alcohol problems, problems with employment, and  
22  
23 96 homelessness [1, 8].  
24  
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26  
27 97 A systematic review conducted to identify maternal risk factor for FASD that showed the  
28  
29 98 demographic (socioeconomic status, employment status, educational status, marital status,  
30  
31 99 religion, living area, income and age), psychiatric and neuropsychological (psychiatric  
32  
33 100 comorbidity, identified stressful, physical aggression and sexual abuse) played significant  
34  
35 101 roles [9]. The review also showed that family, social (family lifestyle, drinking habit, alcohol  
36  
37 102 use, illegal drugs use and tobacco use) and pattern of alcohol consumption could predispose  
38  
39 103 of woman to having babies with FASDs [9].  
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43  
44 105 In South Africa (SA), the national prevalence of FASD ranges from 29 to 290 per 1 000 live  
45  
46 106 births [10]. The prevalence of FASD has also been reported in various regions such as in the  
47  
48 107 Northern and Western Cape Provinces. The focus on these two regions is related to the high  
49  
50 108 prevalence of FASD. In the Northern Cape Province, an estimated 88 per 1,000 of first grade  
51  
52 109 pupils were reported to have FASD in 2008 [11]. In 2015, although the prevalence had  
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54 110 dropped at 63.9 per 1,000 in grade one pupils, the prevalence was still relatively high [12]. In  
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3 111 the Western Cape Province, the prevalence of FASD among primary school pupils was  
4  
5 112 estimated at 89.2/1,000 in 2007[13]. By 2013, the prevalence of FASD among first grade  
6  
7 113 pupils had doubled (135.1 to 207.5 per 1,000) [14]. In 2015, the prevalence of FASD among  
8  
9 114 first grade pupils recorded another increase (170 to 233 per 1,000) in the Western Cape [15].

115

116 Prevention, care and support for persons affected by FAS and other alcohol-related disorders  
117 are not being implemented, particular in developing countries [16]. Peadon et al. and Reid et  
118 al. [17, 18] reported the lack of good quality study studies and limited strong evidence for  
119 specific interventions in managing FASD. The authors, therefore, advocated for interventions  
120 targeting the specific clinical and neuropsychological deficits usually seen in individuals with  
121 FASD.

122

## 123 **Background**

124 South Africa is reported to have escalating levels of alcohol consumption [19], particularly in  
125 the informal settlements in the Northern and Western Cape Provinces [20–24]. The  
126 prevalence of alcohol use among pregnant women in the Cape Metropole, Western Cape  
127 Province of South Africa is estimated at 19.6% and in poor communities of the Western and  
128 Northern Cape provinces of South Africa, FASD (FAS/PFAS) is endemic [13, 25]. Maternal  
129 alcohol drinking during pregnancy, especially in rural and informal settlements, has led  
130 FASD becoming an increasing concern in South Africa.

131

132 Generally, FASD is relatively unknown among health professionals and has not been given  
133 adequate consideration in policies, programmes, and interventions [26]. This is probably  
134 because FASD is not yet formalised as a medical diagnosis, even though it is now over 40  
135 years that it was first diagnosed [26]. In spite of this, efforts toward developing guidelines for

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3 136 the diagnoses [27, 28] and management [29] of FASD have been taken toward formalising  
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5 137 FASD as a public health problem. Because FASD is preventable, there have been efforts to  
6  
7 138 advocate for the implementation of various prevention programme and strategies for its  
8  
9 139 prevention. These strategies advocated for include adequately resourced alcohol control  
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11 140 services, support for pregnant women, and a sustainable commitment from communities,  
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13 141 service providers and the government in addressing alcohol-related health and psychological  
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15 142 problems [30, 31]. For these strategies to be effective and sustainable, a governing policy and  
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17 143 coordinated efforts are required.  
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22 145 Globally, there is inadequate policy and guidelines for the management and prevention of  
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24 146 FASD. A review on FASD in Africa reported gaps in policy and service implementation [32].  
25  
26 147 In South Africa, only two of the national policy documents namely, the National Human  
27  
28 148 Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth  
29  
30 149 Defects and Disabilities (2001) and the National Drug Master Plan (2007) scanned during a  
31  
32 150 situation analysis by Rendall-Mkosi et al. [33] used the term FAS and none of them  
33  
34 151 mentioned FASD . In addition, the South African Guidelines for Maternity Care (2002) only  
35  
36 152 specifies that maternal alcohol, as well as tobacco and other substances use behaviours should  
37  
38 153 be taken into consideration when taking a medical history of a woman [33]. This reflects the  
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40 154 extent to which issues related to FASD are being considered in policy.  
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46 156 Furthermore, current national hospital-based birth defects surveillance system developed by  
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48 157 the National Department of Health excludes FASD [33]. This surveillance system mainly  
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50 158 considers birth defects that can be clinically diagnosed at birth or few days after birth; which  
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52 159 can only be identified if a woman is hospitalised after birth. The exclusion of FASD in the  
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54 160 birth defects surveillance system is believed to be as a result of the difficulty in diagnosing  
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3 161 FASD at birth as most of its features are rarely manifested at birth and it requires a  
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5 162 multidisciplinary team to arrive at a definitive diagnosis [33]. The above gap speaks to the  
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7 163 need to develop relevant policies and guidelines to identify FASD and in order to guide  
8  
9 164 strategic implementation of appropriate interventions to address FASD in South Africa.

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13 166 In 2001, the Western Cape Provincial executive council acknowledged FAS as a provincial  
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15 167 health priority for the years 2001 and 2002 [34, 35]. This led to the establishment of the  
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17 168 Western Cape Provincial FAS reference and working group (now called FASD task team).  
18  
19 169 The FASD Task Team of South Africa comprises of members from the Department of health,  
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21 170 the Department of Social Services, the Department of Education, the Medical Research  
22  
23 171 Council, the University of Stellenbosch, the University of Cape Town, NGOs such as  
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25 172 Foundation for Alcohol Related Research (FARR), Dopstop and Pebbles project. It was  
26  
27 173 headed by the provincial Maternal, Child and Women's Health Deputy Director [34, 35]. The  
28  
29 174 aims of the FASD task team is to raise awareness on FASD, create strategies for prevention  
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31 175 and, share skills and information [34, 35].

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37 177 The FASD task team has been successful in the development of FAS training manual for  
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39 178 health care workers, educators, school psychologists, social workers and other professionals  
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41 179 working with individuals with FASD, their families and caregivers. In addition, the FASD  
42  
43 180 task team has designed posters for creating awareness on FASD, organising special events to  
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45 181 improve public awareness on International FASD Days, organising FASD training workshop  
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47 182 and, the development of a website and Facebook page on FASD [34, 35].

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52 184 The above development is an important and commendable step in developing the capacity to  
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54 185 support the prevention and management of FASD at the provincial level. Nevertheless, a

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3 186 coordinated effort to facilitate the prevention and management of FASD at the national level  
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5 187 is required. To this end, we are proposing a national FASD guideline that will inform policy  
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7 188 on coordinated and multi-sectoral response to FASD in South Africa. In this protocol, we  
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9 189 propose systematic steps toward developing a guideline to inform policy for FASD  
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11 190 prevention and management.  
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## 15 16 192 **Research objectives**

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19 193 To achieve the aim, we developed the following objectives:

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22 194 • To review policies and their contents on FASD internationally and in South Africa;  
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25 195 • To explore and describe the content of FASD policies from the perspective of policy  
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27 196 makers;  
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30 197 • To provide update on the interventions on FASD internationally and in South Africa;  
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32  
33 198 • To explore and describe the perspectives of service providers involved in the  
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35 199 implementation of identified FASD intervention activities.  
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38 200 • To apply the Delphi technique to guide the development of guidelines for an integrated  
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40 201 policy on FASD for the South African context.  
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## 44 45 203 **Understanding policy guidelines**

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47 204 According to the World Health Organization, a guideline is a document that contains  
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49 205 recommendations on health interventions for clinical or public health [36, 37]. It is also  
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51 206 described as a document that makes evidence-based recommendations for averting and  
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53 207 treating certain conditions, improving health, managing medicines, planning of services for  
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55 208 the community, development of an intervention for enhancing population health and to  
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3 209 deliver social care for people [38]. Guidelines promote individualised and integrated care,  
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5 210 help service providers and recipients, and other stakeholders to make informed decisions and  
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7 211 serve as a response to a condition that needs urgent attention [36–39]. Therefore, a guideline  
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9 212 is considered as a set of systematically developed statements, recommendation or best  
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11 213 practice to give a framework for policy implementation [39]. As applies to this protocol, we  
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13 214 considered a guideline as a document that contains recommendations that will inform the  
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15 215 development of integrated policy on FASD.  
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## 20 217 **Proposed methodology**

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23 218 The development of the guideline will follow three phases: (1) Information gleaning, (2)  
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25 219 development of prototype and (3) Delphi techniques and developing of guidelines (Figure 1).

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28 220 The importance of involving proven methods, which are both inclusive and participatory, was  
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30 221 considered as essential for developing a socially acceptable FASD guideline for South Africa.

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33 222 **Figure 1:** A proposed methodological approach for the development of guidelines for FASD  
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35 223 policy.

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### 38 39 225 **Phase 1: Information gleaning**

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41 226 In the first phase, we aim to obtain information from various sources to enable us to develop  
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43 227 a prototype guideline. To this end, we plan to conduct a document review on FASD policies.

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45 228 The documents review will consider policies developed internationally (with focus on South  
46  
47 229 Africa) and the systematic review will focus on interventions globally and with focus on  
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49 230 South Africa. In addition, we will identify relevant policy makers and service providers in the  
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51 231 Departments of Health, Education and Social Development and engage with them through in-  
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3 232 depth interviews and focus group discussions to obtain information on existing policies and  
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5 233 interventions on FASD in South Africa. This phase will be conducted in the following steps.

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9 235 **Step 1: Document review of policy on FASD globally and in South Africa**

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11 236 The researchers will review available relevant documents such as policy documents and  
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13 237 guidelines on FASD. The aim of this review is to explore the availability and content of  
14  
15 238 existing guideline and polices on FASD. Government websites of low income, middle  
16  
17 239 income and high-income countries, websites of various non-governmental organisations and  
18  
19 240 databases will be searched for these documents. All the policies or guidelines that focused on  
20  
21 241 any aspect of FASD will be included. The narrative analysis will be used to analyse the  
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23 242 relevant documents identified. The information that will be obtained will inform the  
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25 243 development of a prototype guideline. Following the document review, a systematic review  
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27 244 will be undertaken.

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33 246 **STEP 2: Systematic review of interventions for FASD globally and in South**  
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35 247 **Africa.**

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37 248 The purpose of the systematic review will be to update the current most recent systematic  
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39 249 review on FASD “Fetal Alcohol Spectrum Disorder Interventions across the Life Span” [18]  
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41 250 to include interventions for prevention. The aim of the systematic review will be to  
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43 251 systematically locate, appraise and synthesize intervention on FASD. The systematic review  
44  
45 252 will consider the following review question: “What are the prevention and management  
46  
47 253 interventions that are available on FASD globally and in South Africa?” In conducting this  
48  
49 254 review, the researchers will follow nine steps of a systematic review [36]. These steps include  
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51 255 formulating review question, defining search strategy, establishing inclusion criteria and  
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3 256 exclusion criteria, choosing a method for the review, conducting methodological quality and  
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5 257 critical appraisal, extracting data, analysing and synthesizing data, and writing a report.  
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9 259 What are the interventions that are available on FASD globally and in South Africa? To  
10  
11 260 answer this question, databases will be searched for articles discussing or evaluating  
12  
13 261 interventions for the management of FASD. These databases include, Ebsco Host (Academic  
14  
15 262 Search Complete, ERIC, SoINDEX, Health Source: Nursing/Academic Edition, CINAHL  
16  
17 263 and PsycARTICLES), Science Direct, Springer Links, Wiley Online Library, JSTOR, and  
18  
19 264 SAGE Journals, LANCET, Pubmed, Cochrane Library, Sabinet, NEXUS and BioMed  
20  
21 265 Central Journal will be searched and retrieved for the period covering 1973 to 2016 using  
22  
23 266 intervention and FASD as search terms. Furthermore, the references of the retrieved article  
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25 267 will be used to search for more articles. The titles and abstracts of the articles will be  
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27 268 screened using inclusion/exclusion criteria and duplicates will be removed. After screening,  
28  
29 269 the remaining articles will be read and their methodological quality evaluated to establish  
30  
31 270 their inclusion in the systematic review. In addition, the included articles will be appraised  
32  
33 271 using a critical appraisal sheet. Narrative synthesis will be used for data analysis. Narrative  
34  
35 272 synthesis can be described as a descriptive written summary of included studies and their  
36  
37 273 findings [40]. The data extraction tool will consist of four distinctive sections namely: the  
38  
39 274 general description, a methodological appraisal, the content intervention, and the analysis of  
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41 275 the results. The information that will be obtained will inform the development of a prototype  
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43 276 guideline.  
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### 51 278 **STEP 3: Exploratory qualitative research**

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54 279 Two exploratory qualitative studies will be conducted. The first qualitative study will be  
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56 280 aimed at exploring the availability of guidelines/policies for the prevention and management  
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3 281 of FASD within the South African health system and the need to develop a policy for the  
4  
5 282 prevention and management of FASD. This study will target the policy makers from three  
6  
7 283 relevant departments: Department of Education, Department of Health and Department of  
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9 284 Social Development. A policy maker is defined as an administrator involved or supposed to  
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11 285 be involved in the area of policy formulation and programme monitoring on FASD and  
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13 286 related disabilities.  
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18 288 The second qualitative study will be aimed at identifying existing interventions and  
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20 289 guideline/policy statements that are being used by the service providers for the prevention  
21  
22 290 and management of FASD. A service provider is defined as a staff involved or supposed to  
23  
24 291 be involved in providing services and interventions on FASD and related disabilities. These  
25  
26 292 include paediatricians, nurses, social workers, and occupational therapist. Policy makers and  
27  
28 293 service providers from the Department of Education, Department of Health and Department  
29  
30 294 of Social Development will be interviewed as part of the processes of developing guidelines  
31  
32 295 that will inform policy on FASD. These groups of individuals are deemed knowledgeable to  
33  
34 296 provide relevant information toward developing FASD guidelines.  
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38  
39 298 Purposive sampling will be employed in selecting participants based on the following criteria:  
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41 299 policy makers with about five years' experience in policy on FASD or related disabilities and  
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43 300 service providers in primary health care, hospital, schools, social development and NPOs  
44  
45 301 with about five years of experience in providing interventions and services to individuals  
46  
47 302 with FASD. The researchers intend to sample three policy makers from each department and  
48  
49 303 conduct three focus group discussions in each department with an average of 6-8 participants.  
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51 304 Data saturation will be used to determine the sample sizes in the two studies.  
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3 306 The first set of data will be collected through in-depth interviews with policy makers using an  
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5 307 interview guide to explore the available policies and their contents on FASD. This could  
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7 308 provide information based on the perspectives of the policy makers. The second set of data  
8  
9 309 will be collected through focus group discussions with selected service providers using a  
10  
11 310 discussion schedule to explore available interventions, services and policies in practice.  
12  
13 311 Focus group discussions can give rich information and contributions from participants as they  
14  
15 312 contribute in moderated discussions. An audio recorder will be used to capture information  
16  
17 313 from the participants. Notes will also be taken during the interview and the interview  
18  
19 314 recordings will be transcribed for data analysis. The rigour in the qualitative study, which is  
20  
21 315 trustworthiness will be established through credibility, transferability, dependability,  
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23 316 conformability and reflexivity [41].  
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29 318 The data will be analysed using thematic content analysis technique [42]. Both inductive –  
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31 319 making interpretations from the raw data – and deductive – using a framework – analytic  
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33 320 approaches will be used to analyses the data [43]. The framework will be developed from the  
34  
35 321 prevention and management aspects of FASD. The researchers will use Creswell’s data  
36  
37 322 analysis spiral [44]. This process involves reading and memoing, then, describe, classify, and  
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39 323 interpret the data according to themes and the categories, and finally visualize and represent  
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41 324 the themes and categories. An independent coder will also be used to ensure trustworthiness.  
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## 46 326 **Phase 2: Development of prototype**

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48 327 In the second phase, we will aggregate the information from data collected in phase one and  
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50 328 two to develop a prototype guideline. In this phase, information obtained from document  
51  
52 329 review, systematic review, and in-depth and focus group interviews will be used to develop a  
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54 330 prototype guideline for FASD policy. This will involve conflating the information to draft a  
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3 331 prototype. The researchers will engage and agree on consensus interpretations of the findings  
4  
5 332 of the previous phases and these will then be used to develop the prototype guideline. The  
6  
7 333 researchers adopted this approach because it has been applicable in the guideline  
8  
9 334 development process as applied by other researchers in developing guidelines for various  
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11 335 issues [45–47].  
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### 15 16 337 **Phase 3: Delphi techniques and developing of guidelines**

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18 338 In the third phase, we will identify the relevant policy makers and health service providers  
19  
20 339 and key health policy advocates and engaged with them through a Delphi technique to  
21  
22 340 modify the prototype to develop obtain a refined guideline. These individuals will be mixed.  
23  
24 341 That is, part of them may be those that have been participated in the qualitative research. This  
25  
26 342 is because anecdotal information has it that these policy makers are not many and it may be  
27  
28 343 impossible to get a different set of participants. The process of guideline development is  
29  
30 344 expected to be evolving, and the researchers have included plans to follow through a  
31  
32 345 thorough process and procedures as resource and time would permit to get a consensus on  
33  
34 346 aspects of the policy. The use of the Delphi approach is recommended by the World Health  
35  
36 347 Organization (WHO) Handbook for guideline development [36, 37, 48].  
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42 349 The Delphi technique is a structured communication technique initially developed as a  
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44 350 systematic, interactive forecasting method, which relies on a panel of experts [49]. There is  
45  
46 351 no agreement on sample size. It is common for these experts to answer questionnaires in two  
47  
48 352 or more rounds [50]. The researcher gives an anonymous summary of the experts' predictions  
49  
50 353 from the previous round, and the reasons they provided for their judgments. Experts are  
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52 354 encouraged to revise, subsequently, their earlier answers in the light of the replies of other  
53  
54 355 members of their panels. This process narrows the wide range of answers and converges the  
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3 356 group answers towards correct or an agreed answer [51]. However, the process is stopped  
4  
5 357 after a predefined stop criterion and the mean or median scores of the final rounds determine  
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7 358 the results [49].  
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9 359

10  
11 360 In this study, the developed prototype will be used to engage in Delphi technique with experts  
12  
13 361 on FASD in order to develop the proposed guidelines. The researchers will start by  
14  
15 362 identifying the experts and contacting them to explain the research. The researchers will then  
16  
17 363 purposefully select 30 experts using the following criteria: Top management decision makers;  
18  
19 364 policy makers; FASD service providers and FASD researchers with about five years of  
20  
21 365 experience relevant to FASD policies, services, intervention or research [52]. These experts  
22  
23 366 will be contacted through email, as well as a telephone for them to contribute to the  
24  
25 367 development of the guideline.  
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30  
31 369 The researchers will use the prototype with these experts soliciting their opinions on what  
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33 370 should be included or excluded in the proposed guidelines for policies. Descriptions of  
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35 371 prevention and management interventions identified in phase 1 will used to design Likert  
36  
37 372 statements to evaluate the perceptions of the experts on prevention modalities, screening  
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39 373 components, and management methods. Participants will be asked to rate their agreement  
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41 374 with each statement on a 5-point Likert scale, which will range from 'strongly agree' to  
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43 375 'strongly disagree', and a response option of 'no comment' will be provided to enable  
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45 376 participants to indicate that a statement was outside their area of expertise [53].  
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49  
50 378 The data generated will be analysed and these will be used to modify the prototype, which  
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52 379 will be used as an instrument for the second round. The experts will be asked to review the  
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54 380 items summarised by the researchers based on the information provided in round one and  
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3 381 they will be asked to rate or rank- order items to establish priorities among items and to reach  
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5 382 consensus. The outcome will be presented to the experts. The information generated in the  
6  
7 383 second round will then be analysed and the information gathered will be used to refine the  
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9 384 prototype to obtain the guidelines.  
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## 12 13 386 **Discussion**

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16 387 The essence of the proposed guideline is to inform policy development on foetal alcohol  
17  
18 388 spectrum disorder. While having informal discussions with the head of a non-governmental  
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20 389 organisation, a leading organisation in conducting prevalence studies and rolling out  
21  
22 390 prevention programme on FASD, we understood that guidelines and policies are limited to  
23  
24 391 facilitate effective interventions on FASD. The administrators of the departments of  
25  
26 392 Education, Health, and Social Development in the Western Cape Province also revealed that  
27  
28 393 alcohol drinking is a huge problem and FASD is one of the negative outcomes. These  
29  
30 394 administrators pointed out that various efforts have been made, ranging from awareness  
31  
32 395 programme to funding of NGOs to response to FASD, but these efforts are not being  
33  
34 396 coordinated because there are no specific guidelines or polices on FASD. Service providers  
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36 397 were also consulted, they highlighted that there are no specific services offered to people  
37  
38 398 living with FASD. They mentioned that there are no specific guidelines to guide services and  
39  
40 399 interventions though they sometimes refer an individual for proper diagnosis if they present  
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42 400 signs of FASD. They also provide health education on alcohol to pregnant women. However,  
43  
44 401 this is not specifically targeting at FASD. These gaps necessitate the conduct of this proposed  
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46 402 research for the development of guideline that will enhance the development of coordinated  
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48 403 policy on FASD.  
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3 405 In developing the guideline protocol, the researchers will adapt the WHO Handbook for  
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5 406 guideline development [36, 37, 48]. The reason for adaptation is that some parts of the  
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7 407 process are not feasible and some are beyond the scope of this project.

- 8  
9 408 - The research team decides to produce a guideline for the prevention and management  
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11 409 of FASD based-on informal discussions with relevant stakeholders on the need of an  
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13 410 FASD policy;  
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15 411 - Discussion of required elements among the researchers planning, scoping, needs  
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17 412 assessment;  
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19 413 - Key question formulation (PICO questions);  
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21 414 - Planning clearance submission; University Ethics review committee approval for the  
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23 415 development; evidence retrieval / systematic review;  
24  
25 416 - Conducting the various studies, evidence quality assessment; development of  
26  
27 417 recommendations;  
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29 418 - Writing, external review, editing; final approval; proofread, publish; dissemination,  
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31 419 [36, 37, 48].  
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37 421 The strength of using this process is that it has been used to develop various guidelines for  
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39 422 interventions to combat diseases and improve services. The recommendations from the  
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41 423 guidelines are rooted in a comprehensive and objective assessment of the available evidence  
42  
43 424 and a clear pathway on how recommendations are generated by whom and on what. The  
44  
45 425 demerit of this process is that it requires a lot of resources, time and experts. The limitation of  
46  
47 426 this study might be that the researcher will not include the individuals with FASD and their  
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49 427 families directly in the study. Another limitation is that the study is restricted to the Western  
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51 428 Cape region of South Africa, which might affect the generalizability of the study findings.  
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3 430 It has been reported that there are no guidelines for determining consensus, sample size and  
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5 431 sampling techniques when using the Delphi approach. This because these aspects of the  
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7 432 Delphi technique require a lot of time and participants' commitment, consequently, dropout is  
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9 433 likely to happen, which leads to low response rate and a delay in data analysis between  
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11 434 rounds [54, 55]. To mitigate the impact of the potential challenges, the researchers decided to  
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13 435 adapt the sample size to a manageable number to favour in-depth engagement and discursive  
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15 436 approach with fewer experts, rather than having a large sample of experts with less  
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17 437 engagement with the guideline development process.  
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22 439 The finalised guideline will be distributed to all the participants in the study and to the  
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24 440 departments of Health, Education and Social Development as well as to the relevant NGOs  
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26 441 working on FASD. The guideline will also be published in a peer review journal to add to the  
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28 442 literature of FASD.  
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30 443

### 31 444 **Ethics and Dissemination**

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36 445 The approval for the study was obtained from the research ethics committee of the University  
37  
38 446 of the Western Cape (BM/16/4/4) and further approvals were obtained from the Western  
39  
40 447 Cape Department of Education (20161212-6937), Department of Health  
41  
42 448 (WC\_2016RP29\_862), and Social Development (12/1/2/4). Before the interviews and the  
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44 449 FGDs, the study aims and objectives we will explain to the potential participants and they  
45  
46 450 will be provided with an information sheet written in English explaining their roles. The  
47  
48 451 potential participants will be requested to sign a consent form if they agreed to participant in  
49  
50 452 the study. All participants for the interviews and FGDs will be asked to sign a consent form  
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52 453 All information obtained during the study will be kept strictly confidential in a computer with  
53  
54 454 password known only to the researchers in this study.  
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6 456 **Declarations**

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10 457 **Consent for publication**

11  
12 458 Not applicable  
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17 460 **Availability of data and material**

18  
19 461 Not applicable  
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21 462  
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24  
25 463 **Competing interests**

26  
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30  
31 465 The authors declare that there is no competing interest.  
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33  
34 466  
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36  
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41

42 469  
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44  
45 470 **Authors' contributions**

46  
47 471 BOA and AMB conceived and conceptualised the study and the paper. BOA designed and

48  
49 472 wrote the first draft of the manuscript. FCM redesigned the manuscript, contributed to the

50  
51 473 development of the paper and provided comments to improve the manuscript. KJO

52  
53 474 contributed to the development of the paper and provided comments to improve the

54  
55 475 manuscript. All authors read and approved the final manuscript  
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## 15 16 639 **Figures**

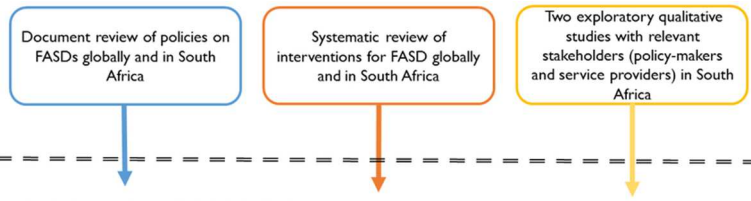
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19 640 **Figure 1:** A proposed methodological approach for the development of guidelines for FASD  
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**PHASE I: INFORMATION GLEANING**

Exploratory approaches will be employed to gather relevant information for the development of a prototype FASD guidelines



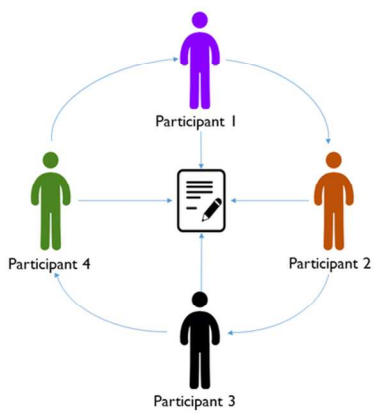
**PHASE II: PROTOTYPE DEVELOPMENT**

Information obtained from these three sources will be used to formulate a prototype guideline document



**PHASE III: REFINING THE PROTOTYPE**

The process of fine-tuning and refining the prototype guideline will involve repeating consultations with some key stakeholders in the Delphi approach



The outcome of the Delphi process is to obtain a more refined guideline that can inform policies for the management of FASDs

80x113mm (300 x 300 DPI)

# BMJ Open

## A Modified Delphi study towards developing a guideline to inform policy on Foetal Alcohol Spectrum Disorders in South Africa: A study protocol

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1 A Modified Delphi study towards developing a guideline to inform policy on Foetal Alcohol

2 Spectrum Disorders in South Africa: A study protocol

3

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13 **Key Words:** Foetus Alcohol Spectrum Disorder, Alcohol, Birth defects, Guidelines,  
14 Policies,

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67 **ABSTRACT**  
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10 **Introduction:** Maternal alcohol consumption during pregnancy can result in mental and  
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12 physical birth defects in individuals. These birth defects are usually described as Foetal  
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14 Alcohol Spectrum Disorders (FASDs). With an estimated 183- 259 per 1000 children born  
15  
16 with FASDs, South Africa is identified to have the highest prevalence of FASDs in the world.  
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18 Nevertheless, there is a lack of appropriate policies, guidelines, and interventions addressing  
19  
20 the issues around FASDs. This protocol outlines a proposed process for developing a  
21  
22 guideline to inform policies on FASDs.  
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26 **Methods and Analysis:** This process will have three phases. Phase one will be carried  
27  
28 out in three steps; we plan to conduct a document review of available policies on the  
29  
30 prevention, and management of FASDs and update the existing systematic review on FASDs  
31  
32 interventions. The aim of the two reviews is to explore the availability and content of existing  
33  
34 policies and global interventions on FASDs. In addition, we will conduct two exploratory  
35  
36 qualitative studies to obtain the perspectives of various stakeholders on the existing or  
37  
38 possible guidelines and policies for the management of FASDs and available interventions  
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40 and services. In phase two, we will aggregate the findings of the previous phase to develop a  
41  
42 prototype guideline. In phase three, using the developed prototype, we will apply the Delphi  
43  
44 approach with experts on FASDs, soliciting their opinions on the nature and content of the  
45  
46 proposed guidelines for policies. The information gathered will be used to modify the  
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48 prototype to formulate a policy guideline on FASDs. Data will be analysed using thematic  
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50 analysis and narrative synthesis.  
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3 43 **Ethics and Dissemination:** Ethical clearance has been obtained from the ethics  
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5 44 committee of the University and governmental departments. The findings will be  
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7 45 disseminated through publications and the guideline will be submitted to relevant  
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9 46 departments.  
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### 15 48 **Strengths and limitations of this study**

- 17 49 • The study proposes the use of multiple sources for data collection toward developing  
18 50 a guideline to inform policy on FASDs.
- 20 51 • It also proposes a proven methodology – The Delphi technique to develop the  
21 52 guideline.
- 23 53 • A potential limitation of the study is that the study will not include individuals with  
24 54 FASDs.
- 26 55 • This study is expected to inform policy on FASDs nationally; however, it will be  
27 56 conducted in only one Province out of nine Provinces of South Africa.  
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15 **Introduction**  
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17 Foetal alcohol spectrum disorders (FASDs) refer to an array of birth disorders related to  
18 foetal exposure to alcohol during pregnancy. FASDs are classified under four broad groups;  
19 foetal alcohol syndrome (FAS), partial FAS, alcohol-related neurodevelopment disorders  
20 (ARND) and alcohol-related birth defects (ARBD) [1]. Of these four groups, FAS is  
21 identified as having the most serious anomalies [2, 3].  
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30 FASDs may lead to primary and secondary disabilities [4]. Primary disabilities are those that  
31 the child is born with [5], usually associated with damages to the brain domains that are  
32 responsible for physical motor skills, sensory processing skills, cognition, communication  
33 skills, academic achievement, memory skills, executive functioning and abstract reasoning,  
34 attention and adaptive skills [6, 7]. The brain damages could also result in physical  
35 abnormalities such as ante- and post-natal growth retardation, eye and ear malformations,  
36 mouth and jaw deformation, skeletal defects, organ pathology, sensory deficits and impaired  
37 immune system [1].  
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50 Secondary disabilities relate to those disabilities that develop because of untimely and  
51 inappropriate interventions to primary disabilities – consequences of unaddressed primary  
52 disabilities. These include fatigue, frustration, anxiety, fearfulness, rigid, resistant,  
53 argumentative behaviour, becoming overwhelmed, shut down (withdrawn), a poor self-  
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3 89 concept, feelings of failure, low self-esteem, isolation, acting out, aggression, family and/or  
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5 90 school problems, depression and other mental health problems, trouble with the law, drug and  
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7 91 alcohol problems, problems with employment, and homelessness [8].  
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12 93 A systematic review conducted to identify maternal risk factors for FASDs showed that the  
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14 94 maternal demographic (socioeconomic status, employment status, educational status, marital  
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16 95 status, religion, living area, income, and age) and psychiatric - including neuropsychological  
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18 96 (psychiatric comorbidity, identified stressful, physical aggression, and sexual abuse) factors  
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20 97 play significant roles [9]. The review also showed that family, social (family lifestyle,  
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22 98 drinking habit, alcohol use, illegal drugs use, and tobacco use) and pattern of alcohol  
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24 99 consumption could predispose women to have babies with FASDs [9].  
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29 101 In South Africa, the national prevalence of FASD ranges from 29 to 290 per 1 000 live births  
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31 102 [10]. Some Provinces such as the Northern and Western Cape Provinces of South Africa have  
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33 103 particularly registered high FASDs prevalence. In the Northern Cape Province, an estimated  
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35 104 88 per 1,000 of first-grade pupils were reported to have FASDs in 2008 [11]. In 2015,  
36  
37 105 although the prevalence had dropped to 63.9 per 1,000, the prevalence was still relatively  
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39 106 high [12]. In the Western Cape Province, the prevalence of FASDs among primary school  
40  
41 107 pupils was estimated at 89.2 per 1,000 in 2007 [13]. By 2013, the prevalence of FASDs  
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43 108 among first-grade pupils had doubled (135.1 to 207.5 per 1,000) [14], and another increase  
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45 109 (170 to 233 per 1,000) was recorded in 2015 [15].  
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51 111 There is evidence that strategies designed to prevent FASDs and to care and support persons  
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53 112 affected by FASDs are not effectively implemented, particularly in developing countries [16].  
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55 113 Peadon et al. [17] and Reid et al. [18] also reported the lack of good quality studies and  
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3 114 limited strong evidence for specific interventions in managing FASDs. The authors,  
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5 115 therefore, advocated for interventions targeting the specific clinical and neuropsychological  
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7 116 deficits usually seen in individuals with FASDs.  
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## 11 118 **Background**

13  
14 119 South Africa is reportedly having escalating levels of alcohol consumption [19], particularly  
15  
16 120 in the informal settlements of the Northern and Western Cape Provinces [20–23]. The  
17  
18 121 prevalence of alcohol use among pregnant women in the Cape Metropole of the Western  
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20 122 Cape Province of South Africa is estimated at 19.6% and in poor communities of the Western  
21  
22 123 and Northern Cape provinces of South Africa, FASDs are endemic [13, 24]. Maternal alcohol  
23  
24 124 drinking during pregnancy, especially in rural and informal settlements, has led FASDs  
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26 125 becoming an increasing concern in South Africa.  
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30 127 Generally, FASDs are relatively unknown among health professionals and have not been  
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32 128 given adequate consideration in policies, programmes, and interventions [25]. This is  
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34 129 probably because FASDs remain unformalised medical diagnoses since they were first  
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36 130 identified and described 40 years earlier [25]. Despite the apparent lack of interest in FASDs,  
37  
38 131 efforts toward developing guidelines for the diagnoses [26, 27] and management [28] of  
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40 132 FASDs have been made, especially toward recognising FASDs as a public health problem.  
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42 133 Because FASDs are preventable, there have also been advocacy efforts for the  
43  
44 134 implementation of various prevention programmes. These advocacy strategies call for the  
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46 135 availability of adequately resourced alcohol control services, support for pregnant women,  
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48 136 and a sustainable commitment from communities, service providers, and the government in  
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50 137 addressing alcohol-related health and psychological problems [29, 30]. Nevertheless, for  
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3 138 these strategies to be effective and sustainable, a governing policy and coordinated efforts are  
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5 139 required.

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9 141 Globally, there is inadequate policy and guidelines for the management and prevention of  
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11 142 FASDs. A review on FASDs in Africa reported gaps in policy and service implementation  
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13 143 [31]. In South Africa, only two of the national policy documents namely, the National Human  
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15 144 Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth  
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17 145 Defects and Disabilities (2001) and the National Drug Master Plan (2007) mentioned the  
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19 146 term FAS and none mentioned FASD [32]. In addition, the South African Guidelines for  
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21 147 Maternity Care (2002) only suggests that maternal alcohol, tobacco, and other substances use  
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23 148 behaviours should be taken into consideration when taking a medical history of a pregnant  
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25 149 woman [32]. The limited occurrence of issues related to FASDs in policy documents offers a  
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27 150 reflection on the extent to which FASDs are (not) being considered in policy.  
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33 152 Current national hospital-based birth defects surveillance system developed by the National  
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35 153 Department of Health also excludes some FASDs [32]. This surveillance system mainly  
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37 154 considers birth defects that can be clinically diagnosed at birth or few days after birth, which  
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39 155 can only be identified during post-natal hospitalisation. The exclusion of some FASDs in the  
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41 156 birth defects surveillance system is because of the difficulty of diagnosing certain FASDs at  
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43 157 birth as most of their features are rarely manifested at birth. In addition, it requires a  
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45 158 multidisciplinary team to arrive at a definitive diagnosis of FASDs [32]. The above gaps  
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47 159 speak to the need to develop relevant policies and guidelines to identify FASDs and to guide  
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49 160 strategic implementation of appropriate interventions to address FASDs in South Africa.  
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3 162 In 2001, the Western Cape Provincial executive council acknowledged FASDs as a  
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5 163 provincial health priority for the years 2001 and 2002 [33, 34]. This led to the establishment  
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7 164 of the Western Cape Provincial FAS reference and working group (now called FASD task  
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9 165 team). The FASD Task Team of South Africa comprises of members from the Department of  
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11 166 Health, the Department of Social Services, the Department of Education, the Medical  
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13 167 Research Council, the University of Stellenbosch, the University of Cape Town, and Non-  
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15 168 profit organisations (NPOs) [Foundation for Alcohol Related Research (FARR), Dopstop,  
16  
17 169 and Pebbles project]. The task team is headed by the Provincial Maternal, Child and  
18  
19 170 Women's Health Deputy Director [33, 34]. The aims of the FASD task team is to raise  
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21 171 awareness on FASDs, create strategies for the prevention of FASDs, and share skills and  
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23 172 information [33, 34].  
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29 174 The FASD task team has been successful in developing FASDs training manuals for health  
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31 175 care workers, educators, school psychologists, social workers, and other professionals  
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33 176 working with individuals with FASDs, their families, and caregivers. In addition, the FASD  
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35 177 task team has designed posters for creating awareness on FASDs, organising special events to  
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37 178 improve public awareness on International FASDs days, organising FASDs training  
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39 179 workshops and, developing a website and Facebook page on FASD [33, 34].  
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44 181 The above development is an important and commendable step in developing the capacity to  
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46 182 support the prevention and management of FASDs at the provincial level. Nevertheless, a  
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48 183 coordinated effort to facilitate the prevention and management of FASDs at the national level  
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50 184 is required. To this end, we are proposing a national FASDs guideline that will inform policy  
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52 185 on coordinated and multi-sectoral response to FASDs in South Africa. In this protocol, we  
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186 propose a systematic approach toward developing a guideline to inform policy for the  
187 prevention and management FASDs in South Africa.

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## 189 **Research objectives**

190 To develop a guideline for the prevention and management of FASDs in South Africa, we  
191 aimed to achieve the following objectives:

- 192 • To review policies and their contents on FASDs in South Africa;
- 193 • To explore and describe the content of FASDs policies from the perspective of policy  
194 makers;
- 195 • To provide an update on the interventions on FASDs internationally and in South Africa;
- 196 • To explore and describe the perspectives of service providers involved in the  
197 implementation of identified FASDs intervention activities;
- 198 • To apply the Delphi technique to guide the development of guidelines for an integrated  
199 policy on FASDs for the South African context.

200

## 201 **Understanding policy guidelines**

202 According to the World Health Organization, a guideline is a document that contains  
203 recommendations for clinical or public health interventions [35, 36]. It is also described as a  
204 document that makes evidence-based recommendations for averting and treating certain  
205 conditions, improving health, managing medicines, planning of services for the community,  
206 development of an intervention for enhancing population health, and to deliver social care for  
207 people [37]. Thus, guidelines promote individualised and integrated care, help service  
208 providers and recipients, and other stakeholders to make informed decisions, and serve as a  
209 response to a condition that needs urgent attention [35–38]. Therefore, a guideline is

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3 210 considered as a set of systematically developed statements, recommendation or best practice  
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5 211 to give a framework for policy implementation [38]. As applies to this protocol, we  
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7 212 considered a guideline as a document that contains recommendations that will inform the  
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9 213 development of integrated policy on FASDs.  
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## 14 215 **Adopted Approach**

16 216 In developing the guideline for FASDs, we adopted the WHO's approach (steps) as stipulated  
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18 217 in the WHO's Handbook for guideline development [35, 36].

- 20  
21 218 1. We agreed to design a guideline for the prevention and management of FASDs based-  
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23 219 on informal discussions with relevant stakeholders on the need for a policy governing  
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25 220 the prevention and management efforts of FASDs;  
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27 221 2. We planned on scoping of the literature and conducting a needs assessment;  
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29 222 3. After gathering preliminary information, the team formulated key PICO questions  
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31 223 [39] Population – individuals with FASDs,  
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33 224 Intervention – a guideline to inform policy,  
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35 225 Comparison – (Not applicable) and  
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37 226 Outcomes – a guideline for the prevention and management of FASDs;  
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39 227 4. After agreeing on the need to design the guideline to inform policy on the prevention  
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41 228 and management of FASDs, the next step involved designing the project protocol  
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43 229 (which is reported in this paper);  
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45 230 5. The team applied for Ethics clearance for the project from the University of the  
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47 231 Western Cape – this has been obtained;  
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49 232 6. The next step will entail conducting the various studies and exercises outlined in this  
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51 233 protocol;  
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3 234 7. The team will develop and prepare the guideline to inform policy on FASDs based on  
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5 235 the findings of the various studies and the outcomes of the various exercises;  
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7 236 8. The team will disseminate the developed guideline through various channels  
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9 237 including having feedback meetings with the various stakeholders and sharing our  
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11 238 findings, publish the guideline in a peer-reviewed journal, present the findings in  
12  
13 239 journal club meeting organised at the provincial department of Health and at other  
14  
15 240 national and international conferences [35, 36].  
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19  
20 242 Some of the steps outlined in the WHO's handbook were adapted to our context. The reason  
21  
22 243 for the adaptation is that some parts of the process are not applicable to this study and other  
23  
24 244 parts are beyond the scope of this project.  
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## 28 29 246 **Proposed methodology**

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31  
32 247 The development of the guideline will follow three phases: (1) Information gleaning, (2)  
33  
34 248 development of prototype and (3) Delphi techniques and developing of guidelines (Figure 1).  
35  
36 249 The importance of involving proven methods, which are both inclusive and participatory, was  
37  
38 250 considered as essential for developing a socially acceptable FASDs guideline for South  
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40 251 Africa.  
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44  
45 253 **Figure 1:** A proposed methodological approach for the development of guidelines for FASDs  
46 254 policy.  
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### 49 50 256 **Phase 1: Information gleaning**

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53 257 In phase 1, three steps will be undertaken with the purpose of obtaining diverse information  
54  
55 258 to develop a prototype guideline. To this end, we plan to conduct a document review on  
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3 259 FASDs policies and a systematic review on FASDs interventions. The document review will  
4  
5 260 consider policies developed South Africa and the systematic review will focus on  
6  
7 261 interventions globally with a focus on South Africa. In addition, we will identify relevant  
8  
9 262 policy makers and service providers from the Departments of Health, Education, and Social  
10  
11 263 Development and engage with them through in-depth interviews and focus group discussions  
12  
13 264 to obtain information on existing policies and interventions on FASDs in South Africa. This  
14  
15 265 information-gleaning phase will be conducted in the following steps.  
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18 266

### 20 267 **Step 1: Document review of policy on FASD in South Africa**

22 268 The researchers will review available relevant documents such as policy documents and  
23  
24 269 guidelines on FASDs. The aim of this review is to explore the availability and content of  
25  
26 270 existing guidelines and policies on FASDs. Websites (government and NPOs) and databases  
27  
28 271 will be searched for these documents. All the policies or guidelines that focused on any  
29  
30 272 aspect of FASDs will be included. A narrative analysis will be used to analyse the relevant  
31  
32 273 documents identified. The information that will be obtained will inform the development of a  
33  
34 274 prototype guideline. Following the document review, a systematic review will be undertaken.  
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### 40 276 **STEP 2: Systematic review of interventions for FASDs globally and in** 41 277 **South Africa.**

43 278 The purpose of the systematic review will be to update the current most recent systematic  
44  
45 279 review on FASDs “Foetal Alcohol Spectrum Disorder Interventions across the Life Span”  
46  
47 280 [18] to include interventions for prevention. The aim of the systematic review will be to  
48  
49 281 systematically locate, appraise, and synthesise intervention on FASDs. The systematic review  
50  
51 282 will consider the following review question: “What are the prevention and management  
52  
53 283 interventions that are available on FASDs globally and in South Africa?” In conducting this  
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3 284 review, the researchers will follow nine steps of a systematic review [40]. These steps include  
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5 285 formulating review question, defining search strategy, establishing inclusion criteria and  
6  
7 286 exclusion criteria, choosing a method for the review, conducting methodological quality and  
8  
9 287 critical appraisal, extracting data, analysing and synthesizing data, and writing a report.  
10

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12  
13 289 What are the interventions that are available on FASDs globally and in South Africa? To  
14  
15 290 answer this question, databases will be searched for articles discussing or evaluating  
16  
17 291 interventions for the prevention and management of FASDs. These databases include, Ebsco  
18  
19 292 Host (Academic Search Complete, ERIC, SoINDEX, Health Source: Nursing/Academic  
20  
21 293 Edition, CINAHL and PsycARTICLES), Science Direct, Springer Links, Wiley Online  
22  
23 294 Library, JSTOR, and SAGE Journals, Pubmed, Cochrane Library, Sabinet, and NEXUS will  
24  
25 295 be searched and retrieved for the period covering 2007 to 2017 using intervention and FASDs  
26  
27 296 as search terms. Furthermore, the references of the retrieved article will be used to search for  
28  
29 297 more articles.  
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35 299 The titles and abstracts of the articles will be screened using inclusion/exclusion criteria and  
36  
37 300 duplicates will be removed. After screening, the articles that meet the inclusion criteria will  
38  
39 301 be read and their methodological quality evaluated. In addition, the included articles will be  
40  
41 302 appraised using a critical appraisal sheet. Narrative synthesis will be used for data analysis.  
42

43  
44 303 Narrative synthesis can be described as a descriptive written summary of included studies and  
45  
46 304 their findings [41]. The data extraction tool will consist of four distinct sections namely: the  
47  
48 305 general description, a methodological appraisal, the content intervention, and the analysis of  
49  
50 306 the results. While conducting and reporting the reviews, we will follow the guidelines for  
51  
52 307 systematic reviews.  
53

54 308

### 309 **STEP 3: Exploratory qualitative research**

310 Two exploratory qualitative studies will be conducted. The first qualitative study will explore  
311 the availability of guidelines/policies for the prevention and management of FASDs within  
312 the South African health system and the need to develop a policy for the prevention and  
313 management of FASDs. This study will target the policy makers (administrators involved in  
314 policy formulation and programme monitoring on FASDs and related disabilities) from three  
315 relevant departments: Department of Education, Department of Health, and Department of  
316 Social Development.

317

318 The second qualitative study will be aimed at identifying existing interventions and  
319 guideline/policy statements that are being used by the service providers (individuals involved  
320 in providing services and interventions on FASDs and related disabilities) for the prevention  
321 and management of FASDs. Relevant service providers include paediatricians, nurses, social  
322 workers, and occupational therapist. Policy makers and service providers from the  
323 Department of Education, Department of Health, and Department of Social Development will  
324 be interviewed as part of the processes of developing guidelines that will inform policy on  
325 FASDs. These groups of individuals are deemed knowledgeable to provide relevant  
326 information toward developing FASDs guidelines.

327

328 Purposive sampling will be employed in selecting participants. For the policy makers, we will  
329 include those individuals with about five years' experience in policy on FASDs or related  
330 disabilities. Similarly, service providers working in primary health care, hospital, schools,  
331 social development and NPOs with at least five years of experience in providing  
332 interventions and services to individuals with FASDs will be potential participants. The  
333 researchers intend to sample three policy makers from each department and conduct three

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3 334 focus group discussions in each department with an average of 6-8 participants. Data  
4  
5 335 saturation will be used to determine the sample sizes in the two qualitative studies.  
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9 337 In the first qualitative study, data will be collected through in-depth interviews with policy  
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11 338 makers using an interview guide. Open-ended questions will be used to start the interviews  
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13 339 and follow-up questions will be used to probe for additional explanations when required. The  
14  
15 340 study participants will be asked various questions on available policies on FASDs, the  
16  
17 341 coordination of FASDs interventions and relevant aspects of FASDs to inform the FASDs  
18  
19 342 guidelines. Each interview will last for about 30- 60 minutes and each interview will be  
20  
21 343 audio-recorded with the permission from the participants.  
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26 345 Data, in the second qualitative study, will be collected through focus group discussions with  
27  
28 346 selected service providers using a discussion schedule to explore available interventions,  
29  
30 347 services, and policies in practice. Focus groups use unstructured discussion subjects  
31  
32 348 involving small ranges of subjects (6-10). It is cost-effective and time-efficient and  
33  
34 349 participants are allowed to express their viewpoints in detail. Discussants are often motivated  
35  
36 350 to contribute more in the presence of their co-participants [42]. In addition, focus group  
37  
38 351 discussions can give rich information as discussants contribute in moderated discussions. An  
39  
40 352 audio recorder will be used to capture information from the discussants. Notes will also be  
41  
42 353 taken during the interview and the interview recordings will be transcribed for data analysis.  
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48 355 The data will be analysed using thematic content analysis technique [43]. Both inductive –  
49  
50 356 making interpretations of the raw data – and deductive – using a framework – analytic  
51  
52 357 approaches will be used to analyse the data [44]. The framework will be developed from the  
53  
54 358 prevention and management aspects of FASDs. The researchers will use Creswell's data  
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3 359 analysis spiral [45]. This process involves reading and memoing, then, describing,  
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5 360 classifying, and interpreting the data according to themes and categories, and finally  
6  
7 361 visualising and representing the themes and categories. An independent coder will also be  
8  
9 362 used to ensure trustworthiness.

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12  
13 364 The rigour in the qualitative studies, which is trustworthiness will be established through  
14  
15 365 credibility, transferability, dependability, conformability, and reflexivity [46]. In addition, the  
16  
17 366 reporting of the qualitative findings will follow the consolidated criteria for reporting  
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19 367 qualitative research (COREQ) [47].

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## 22 369 **Phase 2: Development of prototype**

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27 370 In the second phase, information obtained from the document review, systematic review and  
28  
29 371 in-depth and focus group interviews will be conflated to develop a prototype guideline for a  
30  
31 372 FASDs policy. The researchers will engage and agree on consensus interpretations of the  
32  
33 373 findings to develop the prototype guideline. We selected this approach because it has been  
34  
35 374 successfully applied in the guideline development process by other researchers in developing  
36  
37 375 guidelines for various issues [48–50].

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## 40 377 **Phase 3: Delphi techniques and developing of guidelines**

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44 378 In the third phase, we will apply the Delphi approach to refine the developed prototype. The  
45  
46 379 use of the Delphi approach is recommended by the World Health Organization (WHO)  
47  
48 380 Handbook for guideline development [35, 36]. The Delphi technique is a structured  
49  
50 381 communication technique initially developed as a systematic, interactive forecasting method,  
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52 382 which relies on a panel of experts [51]. It is common for experts to answer questionnaires in  
53  
54 383 two or more rounds [52]. The researcher gives an anonymous summary of the experts'

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3 384 predictions from the previous round, and the reasons they provided for their judgments.  
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5 385 Experts are encouraged to revise their earlier responses in the light of the replies of other  
6  
7 386 members in the forum. This process narrows the wide range of answers and converges the  
8  
9 387 group answers towards an agreed answer [53]. The process is stopped after a predefined stop  
10  
11 388 criterion and the mean or median scores of the final rounds determine the results [51].  
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15  
16 390 There is no agreement on the sample size of participants in the Delphi discussion forum. We  
17  
18 391 will identify relevant policy makers, health service providers and health policy advocates to  
19  
20 392 participate in a Delphi contribution forum to refine the prototype. Some of the Delphi  
21  
22 393 participants will include those who participated in any of the two qualitative studies. This is  
23  
24 394 because experts on FASDs issues are few and it may be challenging to get a complete set of  
25  
26 395 different participants.  
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30  
31 397 We will start by identifying the experts and contacting them to explain the research. We will  
32  
33 398 then purposefully select 30 experts using the following criteria: Top management decision  
34  
35 399 makers; policy makers; FASDs service providers and FASDs researchers with about five  
36  
37 400 years of experience relevant to FASDs policies, services, and intervention or research [54].  
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39 401 These experts will be contacted via email and telephone for their contributions.  
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44 403 The developed prototype will be used to engage in a Delphi technique with experts on  
45  
46 404 FASDs to develop the proposed guidelines. Descriptions of prevention and management  
47  
48 405 interventions identified in phase 1 will be used to design Likert statements to evaluate the  
49  
50 406 perceptions of the experts on prevention modalities, screening components, and management  
51  
52 407 methods. We will solicit their opinions on what should be included or excluded in the  
53  
54 408 proposed guidelines for policies. Participants will be asked to rate their agreement with each  
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3 409 statement on a 5-point Likert scale, which will range from ‘strongly agree’ to ‘strongly  
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5 410 disagree’, and a response option of ‘no comment’ will be provided to enable participants to  
6  
7 411 indicate that a statement was outside their area of expertise [55].  
8

9 412

10  
11 413 The data generated will be analysed and these will be used to modify the prototype, which  
12  
13 414 will be used as an instrument for the second round. The experts will be asked to review the  
14  
15 415 items summarised by the researchers based on the information provided in round one and  
16  
17 416 they will be asked to rate or rank - order items to establish priorities among items and to  
18  
19 417 reach consensus. The information generated in the second round will then be analysed to  
20  
21 418 refine the prototype to obtain the guidelines. The process of guideline development is  
22  
23 419 expected to be evolving, thus, we plan to follow a thorough process and procedures as  
24  
25 420 resource and time would permit.  
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28 421

## 30 422 **Patient and public involvement**

31  
32  
33 423 Patient and public will not be involved in the study. The findings of the study will be  
34  
35 424 disseminated to the study participants through emails.  
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## 40 426 **Discussion**

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43 427 The essence of the proposed guideline is to inform policy development on FASDs. While  
44  
45 428 having informal discussions with the head of a non-governmental organisation, a leading  
46  
47 429 organisation in conducting prevalence studies and rolling out prevention programme on  
48  
49 430 FASDs, we understood that focused guidelines and policies to facilitate effective  
50  
51 431 interventions on FASDs are non-existent. The administrators of the departments of  
52  
53 432 Education, Health, and Social Development in the Western Cape Province also revealed that  
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3 433 drinking alcohol remains a major concern and FASDs are among the negative outcomes of  
4  
5 434 irresponsible drinking practices.

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9 436 These administrators pointed out that various efforts have been made, ranging from  
10  
11 437 awareness programmes to funding of NGOs to response to FASDs, but these efforts are not  
12  
13 438 being coordinated because there are no specific guidelines or policies on FASDs. Service  
14  
15 439 providers consulted also raised the similar concerns. Nevertheless, the service provides  
16  
17 440 suggested that generic programmes are in place to provide health education on alcohol use  
18  
19 441 during pregnancy to pregnant women and that they would sometimes refer suspected cases of  
20  
21 442 FASDs for proper diagnosis. Of course, these practices are not specifically targeting the  
22  
23 443 problem of FASDs or addressing the issues around FASDs in an intended manner. The lack  
24  
25 444 of focused attention accorded to FASDs prompted the conception to develop guidelines that  
26  
27 445 will enhance the prevention and management of FASDs.

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32  
33 447 The strength of using the approach outlined in this protocol lies in the fact that it has been  
34  
35 448 successfully used to develop various guidelines for interventions to combat diseases and  
36  
37 449 improve services. In addition, the recommendations from the guidelines will be rooted in a  
38  
39 450 comprehensive and objective assessment of the available evidence and a clear pathway on  
40  
41 451 how recommendations are generated. The demerit of this process is that it requires a lot of  
42  
43 452 resources, time and expertise. The limitation of this study might be that the researchers will  
44  
45 453 not include the individuals with FASDs and their families directly in the study. Another  
46  
47 454 limitation is that the study is restricted to the Western Cape region of South Africa, which  
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49 455 might affect the generalizability of the study findings.

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3 457 It has been reported that there are no guidelines for determining consensus, sample size, and  
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5 458 sampling techniques when using the Delphi approach. This is because these aspects of the  
6  
7 459 Delphi technique require a lot of time and participants' commitment, consequently, dropout is  
8  
9 460 likely to happen, which leads to low response rate and a delay in data analysis between  
10  
11 461 rounds [56, 57]. To mitigate the impact of these potential challenges, the researchers have  
12  
13 462 decided to adapt the sample size to a manageable number to favour the in-depth engagement  
14  
15 463 and discursive approach with fewer experts, rather than having a large sample of experts with  
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17 464 less engagement with the guideline development process.  
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22 466 The finalised guideline will be distributed to all the participants in the study and to the  
23  
24 467 departments of Health, Education, and Social Development as well as to the relevant NGOs  
25  
26 468 working on FASDs. The guideline will also be published in a peer review journal to add to  
27  
28 469 the literature on FASDs.  
29

30 470

### 31 471 **Ethics and Dissemination**

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35  
36 472 The approval for the study was obtained from the research ethics committee of the University  
37  
38 473 of the Western Cape (BM/16/4/4) and further approvals were obtained from the Western  
39  
40 474 Cape Department of Education (20161212-6937), Department of Health  
41  
42 475 (WC\_2016RP29\_862), and Social Development (12/1/2/4). Before the interviews and the  
43  
44 476 FGDs, the study aims and objectives we will explain to the potential participants and they  
45  
46 477 will be provided with an information sheet written in English explaining their roles. The  
47  
48 478 potential participants will be requested to sign a consent form if they agreed to participant in  
49  
50 479 the study. All participants for the interviews and FGDs will be asked to sign a consent form  
51  
52 480 All information obtained during the study will be kept strictly confidential in a computer with  
53  
54 481 a password known only to the researchers in this study.  
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6 483 **Declarations**

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9  
10 484 **Consent for publication**

11  
12 485 Not applicable

13  
14 486

15  
16  
17 487 **Availability of data and material**

18  
19 488 Not applicable

20  
21 489

22  
23  
24  
25 490 **Competing interests**

26  
27  
28 491 The authors declare that there is no competing interest.

29  
30  
31 492

32  
33  
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38  
39 495

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41  
42 496 **Authors' contributions**

43  
44 497 BOA and AMB conceived and conceptualised the study and the paper. BOA designed and  
45  
46 498 wrote the first draft of the manuscript. FCM redesigned the manuscript, contributed to the  
47  
48 499 development of the paper and provided comments to improve the manuscript. KJO  
50  
51 500 contributed to the development of the paper and provided comments to improve the  
52  
53 501 manuscript. All authors read and approved the final manuscript

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19 665 **Figures**  
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22 666 **Figure 1:** A proposed methodological approach for the development of guidelines for FASDs  
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**PHASE I: INFORMATION GLEANING**

Exploratory approaches will be employed to gather relevant information for the development of a prototype FASD guidelines



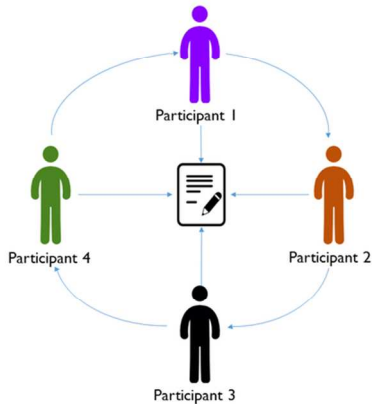
**PHASE II: PROTOTYPE DEVELOPMENT**

Information obtained from these three sources will be used to formulate a prototype guideline document



**PHASE III: REFINING THE PROTOTYPE**

The process of fine-tuning and refining the prototype guideline will involve repeating consultations with some key stakeholders in the Delphi approach



The outcome of the Delphi process is to obtain a more refined guideline that can inform policies for the management of FASDs

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