

Ethical Challenges in Contemporary FASD Research and Practice

A Global Health Perspective

NINA DI PIETRO, JANTINA DE VRIES, ANGELINA PAOLOZZA, DOROTHY REID, JAMES N. REYNOLDS, AMY SALMON, MARSHA WILSON, DAN J. STEIN, and JUDY ILLES

Abstract: Fetal alcohol spectrum disorder (FASD) is increasingly recognized as a growing public health issue worldwide. Although more research is needed on both the diagnosis and treatment of FASD, and a broader and more culturally diverse range of services are needed to support those who suffer from FASD and their families, both research and practice for FASD raise significant ethical issues. In response, from the point of view of both research and clinical neuroethics, we provide a framework that emphasizes the need to maximize benefits and minimize harm, promote justice, and foster respect for persons within a global context.

Keywords: fetal alcohol spectrum disorder (FASD); clinical neuroethics; global public health

Introduction

The harmful use of alcohol, especially among pregnant women and women of childbearing age, is considered to be one of the main risk factors for poor health globally.¹ Alcohol exposure in pregnancy may cause damage to the central nervous system of the fetus as well as other systems and organs, including permanent physical defects and cognitive impairments leading to behavioral, emotional, and learning problems. Collectively known under the umbrella term of fetal alcohol spectrum disorder (FASD), these impairments are increasingly being recognized for the public health concerns they represent worldwide.²

More research is needed on both the diagnosis and treatment of FASD, and a broader and more culturally diverse range of services are needed to support those who suffer from FASD and their families. However, research and practice in this area also raise a number of ethical issues. For research initiatives that seek to determine FASD prevalence or improve diagnostic capacity, limited healthcare resources may represent an ethical challenge insofar as appropriate services may not be available to provide follow-up care. When considering services, it is noteworthy that stakeholders may be reluctant to undergo diagnostic assessments or seek treatment in the face of real or perceived social and legal risks, such as the stigmatization of patients and families, loss of child custody for mothers, or harm to family relationships.³

Funding for this work was provided by a grant from NeuroDevNet, Inc., a Network of Centres of Excellence program of the Canadian government. The authors thank Green College for in-kind support. Dr. Stein receives support from the Medical Research Council of South Africa. Judy Illes is Canada Research Chair in Neuroethics.

Here, we highlight ethical challenges in FASD research and practice, drawing on our experience in working among a number of culturally diverse groups living in low-resource settings within the global north (e.g., Canada and the United States) and global south (e.g., Ghana and South Africa). We provide an evidence-based ethical framework that emphasizes the need to maximize benefits and minimize harm, promote justice, and foster respect for persons within a global context.⁴

Duty and Responsibility

Developing Culturally Appropriate Paradigms

No conversation or action about duty and responsibility for the FASD context can take place in the absence of respect for the perspectives and needs of stakeholders who come from different communities and religious backgrounds, and who may have differing beliefs about autonomy, decision-making, safety and risk, wellness, and illness. At the same time, while recognizing the need for culturally informed approaches, it is important to acknowledge that deeply rooted rituals and beliefs, including drinking circles, may be harmful to an individual's health outcomes. Thus, among priorities for responsive action is the implementation of socially acceptable and culturally meaningful standards of care that promote continuity of care, bring access to sustainable services that enable and encourage compliance to both short- and long-term treatment, and provide reasonable trade-offs between the benefits and costs of ever-advancing diagnostic and prognostic tools. Research and clinical practice focused on FASD entail ethical issues, given that, particularly in the global north, reporting mothers may result in criminalization and further threaten trust in a cascade of already tenuous events and relationships. Community-based methods and interventions are key to ensure the success of any programmatic strategy borne out of the moral duty to protect vulnerable children and women.

Promoting Responsibility in the Alcohol Industry

There is a clear role for the alcohol industry in raising public awareness of the risks associated with drinking during pregnancy and reducing the incidence of FASD. Experts in the field, professional bodies, FASD organizations, and government agencies have for long advocated for the labeling of alcoholic beverage containers with prominent warnings about the known teratogenic effects of alcohol. Unfortunately, in many countries, opportunities to effect changes have been lost. For example, Canada's Bill C-206 that would have required clear warning labels on alcoholic beverages, failed at the committee level even though it had strong support in the House of Commons. Similarly, there have been delays in legislation on advertising in South Africa.⁵ In Australia and the United Kingdom, voluntary labeling of alcoholic beverage containers by the alcohol industry has been heavily criticized because either (1) the labels are considered to be weak, ambiguous messages designed to have minimal impact, or (2) only a relatively small fraction of containers actually contain any warning message.⁶ According to the Canada FASD Research Network, the first level of FASD prevention involves raising public awareness through campaigns and other broad strategies, which could include alcohol warning labels.⁷ However, few countries require that alcoholic beverage containers

contain messages about the specific risks of drinking during pregnancy. This may be a particular problem in low- and middle-income countries that do not have the infrastructure to develop or implement policies on this issue, and legislation is comparatively rare in these contexts. One key issue is whether it is possible for academic institutions to partner with the alcohol industry.⁸ Some scholars have argued that, given sufficient safeguards, the alcohol industry can potentially play a valuable role in informing communities about alcohol-related risks and in doing research on harm reduction. Others are less sanguine about this possibility.

Justice

Closing Gaps in FASD-Informed Services and Surveillance

There are significant disparities within and among countries in the global north and south regarding both the incidence and prevalence of FASD. Indeed, the incidence and prevalence of FASD are not conditions included in the current public health surveillance system of any country. At present, population-based studies of FASD tend to be limited to specific regions, whereas others take place opportunistically in areas where rates of FASD are believed to be particularly high. Without accurate and systematic collection of FASD surveillance data, it is difficult to plan health, social service, education, and related systems that anticipate and address the needs of individuals living with this disability. Epidemiological research may be useful in drawing attention to under-diagnosis and under-treatment, and those who participate in research on FASD may potentially benefit from the comprehensive assessments provided. Ideally, however, embedded in any surveillance system is a process for feedback to service delivery so that the knowledge obtained leads to improved quality of service delivery. Surveillance, particularly by external parties, that is not connected to an intervention service, may fail to implement the obtained knowledge and leave recipients with an identified problem but no capacity to respond. Consequently, it may do more harm than good. Ensuring that appropriate, ethical, evidence-based, and respectful approaches to screening and diagnosis for FASD are available is imperative to enhance the ability of all regions and countries to deliver services and systems that effectively meet the needs of affected individuals and families.

Balancing Costs and Benefits in International Research

Global mental health is a newly emergent discipline that is focused on closing the treatment gap and building relevant research capacity in low- and middle-income countries (LMICs). One key aspect of global mental health is international collaborative partnerships. Such partnerships aim to maximize opportunities for cross-learning and capacity building, while focusing on some of the most pressing mental health issues in LMICs. One example is the use of state-of-the-art neuroscience and imaging technology to investigate fetal alcohol syndrome in the Western Cape of South Africa. While promoting international collaborative partnerships, however, it is important to be aware of potential problems when collaborators have unequal resources and status. For example, research that uses LMIC populations may be perceived as providing answers to questions that are more relevant to high-income contexts than to local problems. Similarly, when such research is

perceived as not leading to improved training opportunities and healthcare in LMIC contexts, it may be criticized for reinforcing structural inequalities. On the other hand, international collaborative research has a real potential to increase awareness of local health issues, and to build local research capacity. A key question in promoting fairness relates to leadership, with strong arguments in favor of locating leadership opportunities in LMICs. Thus, international collaborative partnerships require self-reflection, ongoing communication, and recognition of both the value of and tensions inherent to such partnerships.

Ensuring Clinical Utility

There are few formal guidelines that provide ethics guidance on disclosing an FASD diagnosis to a family member or child, and the clinical utility of the diagnosis will vary on a case-by-case basis. Clinicians must (1) determine the potential harms and benefits of disclosure, (2) communicate the diagnosis in a manner that reduces the likelihood of harm and maximizes the potential benefits, and (3) only disclose if the potential benefits outweigh the potential harms.⁹ The determination of potential harms and benefits will be heavily influenced by cultural, economic, and political contexts. Thus, the development of any formalized guidance must take into account the unique situational context of the child not only in the present but also, to the extent possible, over time. Such considerations are applicable in both the north and the south but, given the differences in resources available, may be realized in different ways in these different contexts.

Respect for Persons

Developing Culturally Appropriate and FASD-Informed Consent Practices

Informed consent is required for participation in research and disclosure of information for anyone considered to be legally competent. Researchers must assess individual cognitive functioning prior to seeking consent to participate in research.¹⁰ Many individuals with FASD meet the criteria for competence but have cognitive impairments that may significantly impact their ability to accurately predict outcomes and make informed decisions. Adults with FASD are often susceptible to influence. FASD researchers must be diligent in providing the information required for informed consent in as understandable and neutral a manner as possible to avoid placing undue influence—including remuneration for participation—on potential subjects. The onus is on the researcher to be aware of and effectively communicate both intended and possible unintended consequences for the individual. It is essential that researchers also be self-aware of their social biases and the lens through which they are operating.¹¹ Best practice in FASD research would suggest employing the use of an interpreter who understands the relevant cultural context and is able to present the potential consequences of participation in plain language. Community engagement is also key and, again, applicable in both the north and the south.

Elucidating and Mitigating Sources of Stigma

Despite the evidence in favor of early diagnosis, active surveillance in the absence of support for families and children with FASD potentially places them at risk of

stigmatization and harm. Reports suggest that stigma and lack of access to culturally appropriate and gender-specific services for women with alcohol-related problems remain international concerns and are particularly problematic in LMICs.¹² Yet only a small body of qualitative work examines the experiences of stigma by those affected by FASD and how it impacts their lives.¹³ Furthermore, knowledge gaps exist in relation to the beliefs endorsed by the public about mothers and children affected by FASD, especially in the global south. In North American contexts, the interpretation of FASD risk is often framed as either a health issue or a moral failure, in which the rights of the mother and the rights of the fetus are juxtaposed.¹⁴ Such competing rights discourses have been shown to have a negative impact on women and families and suggest that strengths-based models of practice and policy focused on supporting the mother–child dyad may yield better outcomes.¹⁵ Meanwhile, young women in South Africa who experience pregnancy before the age of 20 are more likely to experience stigma in relation to moral judgments about adolescent sex when trying to obtain contraceptives from medical professionals, rather than in relation to harmful binge-drinking practices.¹⁶ Given that alcohol use, including harmful binge-drinking practices, is common among adolescents in South Africa,¹⁷ strategies that prioritize non-stigmatizing access to effective contraceptives may be needed for FASD prevention programs.

Conclusion

The preceding discussion has outlined the following research priorities for addressing key ethical challenges in global FASD research and practice:

- 1) Duty and responsibility
 - Developing culturally appropriate practices that foster socially acceptable standards of care, improve health, and promote access to sustainable services in communities.
 - Encouraging academic/industry partnerships to promote responsibility in the alcohol industry through research on harm reduction and public outreach initiatives that work to inform communities about alcohol-related risks.
- 2) Justice
 - Closing gaps in FASD-informed services through systematic collection of FASD surveillance data, including feedback mechanisms to service providers so that the knowledge obtained directly impacts services provided in communities.
- 3) Respect for persons
 - Developing FASD-informed consent practices that recognize relevant cultural/medical contexts and effectively communicate the potential consequences of screening or diagnosis outcomes.
 - Elucidating and mitigating sources of stigma through ongoing research on the lived experiences of individuals, families, and communities affected by FASD.

The perception that FASD is brought about only by a woman's choice is a major barrier to global prevention efforts. Current understandings about the root causes

of FASD recognize the complex familial, cultural, and social contexts that impact the drinking behavior of women, pregnant or otherwise.

Canada has been a leader in promoting international efforts to develop broad-based policy initiatives and actions at different levels of government and society to prevent the global FASD crisis. In September 2013, the first international conference on the prevention of FASD was held in Edmonton, Alberta, and resulted in the development of an international charter on FASD prevention that was endorsed by more than 35 countries worldwide.¹⁸ Clearly, there is worldwide recognition and willingness to address this growing problem.

The ethical considerations that we highlighted above are intended to broaden the discussion and provide direction on critical next steps for international collaborations to ensure that the benefits of global FASD research are maximized. As international efforts and partnerships between global northern and southern countries grow, so must our commitment to become champions for this globally underserved and marginalized patient population.

Notes

1. World Health Organization. Global strategy to reduce the harmful use of alcohol [WHO website]; 2010; available at http://www.who.int/substance_abuse/msbalcstragegy.pdf (last accessed on 29 July 2015).
2. Popova S, Chambers C. Fetal alcohol spectrum disorders must be recognized globally as a large public health problem. *International Journal of Alcohol and Drug Research* 2014;3(1):1–3.
3. Bell E, Andrew G, Di Pietro N, Chudley AE, Reynolds JN, Racine E. It's a shame! Stigma against fetal alcohol spectrum disorder: Examining the ethical implications for public health practices and policies. *Public Health Ethics* 2015;8(2):1–13.
4. Stein DJ, Illes J. Beyond scientism and scepticism: An integrative approach to global mental health. *Frontiers in Neuroscience* 2015. doi:10.3389/fpsy.2015.00166.
5. Parry C, London L, Myers B. Delays in South Africa's plans to ban advertising. *Lancet* 2014; 383(9933):1972.
6. Mathews R, Thorn M, Giorgi C. Vested interests in addiction research and policy: Is the alcohol industry delaying government action on alcohol health warning labels in Australia? *Addiction* 2013;108:1889–96.
7. Thomas G, Cook JL, Poole N, Gonneau G. The effectiveness of alcohol warning labels for reducing drinking in pregnancy: A brief review [CanFASD website]; available at <http://www.canfasd.ca/wp-content/uploads/2014/01/Warning-Label-Issue-Brief-FINAL.pdf> (last accessed 29 July 2015).
8. Stein DJ. Academic-industry partnerships in alcohol and gambling: A continuum of benefits and harms. *Israel Journal of Psychiatry and Related Sciences* 2015;52:81–4.
9. Todorow M, Paris K, Fantus E. Ethical considerations when communicating a diagnosis of a fetal alcohol spectrum disorder to a child. *Journal of Population Therapeutics and Clinical Pharmacology* 2011;19(3):e361–8.
10. Taylor H. Helping people with learning disabilities exercise their right to autonomy. *Learn Disability Practice* 2014:32–7.
11. Nuwagaba E, Rule P. Navigating the ethical maze in disability research: Ethical contestations in an African context. *Disability and Society* 2015:255–69.
12. Wechsberg WM, Luseno W, Ellerson RM. Reaching women substance abusers in diverse settings: Stigma and access to treatment 30 years later. *Substance Use & Misuse* 2008;43(8–9):1277–9.
13. See note 3, Bell et al. 2015.
14. See note 3, Bell et al. 2015.
15. Poole N, Greaves L. Mother and child reunion: Achieving balance in policies affecting substance-using mothers and their children, 2009. In: Rutman D, Callahan M, Lundquist A, Jackson S, Field B, eds. *Substance Use and Pregnancy: Conceiving Women in the Policy-Making Process*. Vol. 112. Ottawa: Status of Women Canada; 2000.
16. Wood K, Jewkes R. Blood blockages and scolding nurses: Barriers to adolescent contraceptive use in South Africa. *Reproductive Health Matters* 2006;14:109–18.

Nina Di Pietro et al.

17. Parry C. Substance abuse in South Africa: Focusing on young persons. Prepared for the WHO/UNDCP Regional Consultation—Global Initiative on Primary Prevention of Substance Abuse Among Young People; 1998.
18. Jonsson E, Salmon A, Warren KR. The international charter on prevention of fetal alcohol spectrum disorder. *Lancet Global Health* 2014;2(3):e135–e137.