

Application of the no-harm approach to informed consent among women with intellectual disabilities in Colombia

Aplicación del enfoque de acción sin daño en el consentimiento informado de mujeres con discapacidad intelectual en Colombia

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Abstract

This article analyzes the relevance of the “Action No Harm Approach” (ANHA; in Spanish, *Enfoque de Acción sin Daño*, EASD) in obtaining informed consent in reproductive decisions of women with intellectual disabilities, who also face multiple

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forms of vulnerability. From a bioethical perspective, it raises the need to guarantee respect for the autonomy and dignity of these women, avoiding paternalistic practices or interventions that, although well-intentioned, may have adverse effects. The methodological proposal is qualitative and structured around the categories of ANHA, informed consent, reproductive decisions, intellectual disability, and vulnerability. Through a review of literature and case law, the study seeks to identify the models used in practice to obtain consent, noting the need for reasonable adjustments. The ANHA allows for a rethinking of interventions so that they are context-sensitive and promote truly informed decisions, without imposing undue burdens or substituting the will of the women involved.

Keywords: action no harm, informed consent, reproductive decisions, women with mental disabilities.

1. Introduction

Making reproductive decisions is extremely important in people's lives, whether they choose to become parents or not. However, these decisions become more complex when it comes to women with intellectual disabilities. The doubts that arise range from autonomy in decision-making to support in obtaining informed consent for medical procedures in the reproductive sphere, whether this involves the use of contraceptives, voluntary termination of pregnancy, or sterilization.

Suppose that an elderly woman, a caregiver living in a rural area in a former conflict zone, goes to the justice system on behalf of her granddaughter, an adult woman with intellectual disabilities, against a health service provider for denying her tubal ligation, also known as the Pomeroy method. The difficulty surrounding the provision of the requested health service lies in the lack of clarity regarding how to obtain informed consent from the adult patient with intellectual

disabilities. Who, how, where, when, why, and in what manner a reproductive decision should be made in a case such as this is highly complex.

Difficult decisions are generally made individually, after reviewing one's own interests and values. However, when a difficult decision must be made for people who cannot represent their own interests and understand the future consequences of their actions, the role of support, assistance, measures, or intervention must be reviewed. Whatever their origin, these actions are inevitably part of a context of vulnerability.

Although the terms disability, woman, and poverty are not synonymous with victim, it is also relevant to point out that when associated as conditions of the same person, they make that person a potential victim of abuse of all kinds. Conditions of vulnerability not only coexist, but also interact with each other, producing unique and individualized contexts. In other words, it is not simply a matter of adding up factors of vulnerability, but of recognizing that when they occur simultaneously in the same person, the risk situation is not simply greater, but qualitatively different, and requires a more complex and sensitive analysis.

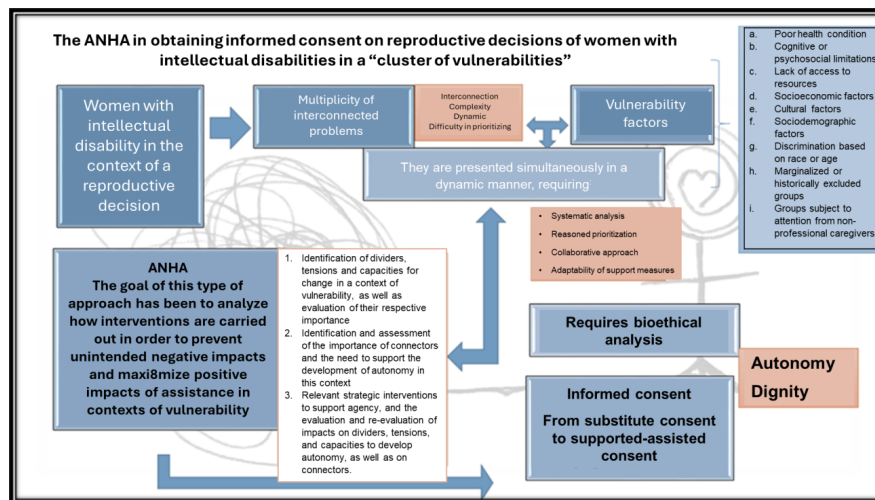
A woman with intellectual disabilities living in poverty is not necessarily a victim, but she is a potential victim due to her overexposure to vulnerability factors that, when combined, generate specific and cumulative forms of discrimination and disadvantage. Thus, when several conditions are present in a woman, she is subject to actions that seek to mitigate harm or guarantee her rights, but which may also exacerbate her vulnerability.

Some models of bioethical deliberation allow for the review of complex ethical dilemmas such as the one presented here, among the most notable are: the principled model (1), the deliberative model (2), the hermeneutic model (3), the narrative model (4,5), the casuistic model (6), the ethical model of responsibility (7), and the ethical model of virtues (8), to name but a few. However, these models do not account for the power of context, the multifactorial nature of vulnerability, or how, in certain cases, support or accompani-

ment in decision-making can intensify forms of vulnerability other than those intended to be addressed. For this reason, the ANHA approach, developed in the field of humanitarian aid, as shown in Figure 1, can offer useful methodological tools for analyzing and understanding support interventions in this type of scenario.

The objective of this article is therefore to analyze how the application of the ANHA approach contributes to obtaining informed consent on reproductive decisions in women with intellectual disabilities who are in vulnerable contexts, ensuring respect for their autonomy and dignity.

Figure 1. The ANHA



Source: prepared by the author.

2. The ANHA in the context of reproductive decisions by women with intellectual disabilities

ANHA is a widely used concept around the world, based on the experiences of humanitarian workers in addressing conflict contexts

without exacerbating them. The aim of this type of approach has been to analyze how the United Nations, NGOs, aid workers, mediators, and politicians carry out interventions to prevent unintended negative impacts and maximize the positive impacts of humanitarian aid (9).

In other words, this approach allows us to review how to design and implement humanitarian interventions that promote peace and reconciliation in conflict contexts, strengthening the capacity of local communities to build alternative conflict resolution systems and reduce their dependence on violence. This is in consideration of the fact that the way assistance interacts in conflict situations can lead to exacerbation or mitigation, making it important to identify the scenario in order to better control the impacts (10).

Thus, ANHA emerged in the context of humanitarian action, inspired by the ethical principle *primum non nocere*, based on the Hippocratic oath, which gave rise to the principle of non-maleficence (11).

However, this principle, was established under two precepts:

- a. That “do no harm” focuses equally on harm and benefit, i.e., it does not focus solely on the potential harm or negative effects of a humanitarian intervention but must also consider the good as a whole.
- b. That “no harm” cannot be used to justify inaction. Under the premise that the slightest possibility of harm or discomfort should not be caused, it is better to do nothing.

On the other hand, Wallace (12) builds on Anderson’s studies to develop six lessons on doing no harm in the context of humanitarian aid: i). Whenever an intervention of any kind enters a context, it becomes part of that context. ii). All contexts are characterized by dividers and connectors. iii). All interventions interact with both, either worsening or improving them. iv). Actions and behaviors have consequences, which create impacts. v). The details of interventions matter. vi). There are always options.

In this order, the principle of doing no harm within the ANHA is not limited to refraining from harm but implies above all the imperative to actively do good, in addition to preventing harm (13). Although this approach emerged in the context of humanitarian aid, it is applicable to other areas of intervention in contexts that are not necessarily characterized by violence (14), and the methodology used in the DSS approach can also become a valuable tool for understanding contexts of vulnerability. Table 1 shows the ANHA methodology, which includes at least the following stages:

Table 1. Context analysis (different from conflict analysis, which divides people and how their interests and objectives are connected)

Wallace	Anderson
Phase 1. Understand the context and setting of the conflict	<i>Stage 1 involves identifying the dividers, tensions, and capacities for war in a conflict context, as well as assessing their relative importance.</i>
Phase 2. Analyze the factors of division and sources of tension	Divisive factors “Things that people want to stop” These divisive factors can be ethnic, religious, political, economic, or social in nature, and are often exploited by violent actors to deepen divisions and perpetuate conflict. Divisive factors weaken local capacities for peace.
	<i>Stage 2 involves identifying and assessing the importance of connectors and capacities for peace in that context.</i>

	Connectors and local capacities for peace
Phase 3: Analyze cohesion factors or connectors and local capacities for peace	“Things to support” In the face of divisive forces, the proposal is to strengthen “local capacities for peace.” This involves developing the skills, resources, and structures necessary within communities so that they can manage their own conflicts in a peaceful and sustainable manner. In other words, it is about empowering communities to be the main actors in building their own peace.
Phase 4: Analyze the elements of the project	
Phase 5: Analyze the effects and impact of the project on the conflict scenario	<i>Stage 3. Identification of relevant characteristics of the aid agency and its program, and assessment and reassessment of impacts on dividers, tensions, and capacities for war, as well as on connectors and capacities for peace.</i>
Step 6: Identify options and/or alternatives for the project	
Stage 7: Check options and redesign project	

Source: based on (CDA, 2016; Wallace, 2016; Anderson, 1999).

However, the ANHA is particularly useful for the analysis of decision-making in contexts marked by conflict. Conflict is understood as a scenario in which two or more individuals or groups have opposing interests that generate disputes, disagreements, and situations of constant confrontation. In such cases, assistance or restoration measures often require the intervention of third parties, who act as mediators or facilitators in the search for solutions. Not all problematic scenarios requiring decision-making correspond to conflict contexts. Some should be understood as dilemmatic contexts, which

have a different logic. A dilemma is defined as a situation in which two possible solutions are faced, both acceptable but neither fully satisfactory (15).

Unlike conflict, a dilemma focuses on a single person who must decide between two or more available options, each with both positive and negative consequences. These options reflect a value whose solution is not satisfactory for all of that person's rights; thus, rights come into tension, and a resolution inevitably leaves some aspect without a completely fair or adequate response.

The difficulties in making dilemmatic decisions are exacerbated when they arise at the boundary with conflicts; for example, when a person cannot express a moral dilemma for themselves and also faces conflicting interests. This happens in cases such as decision-making by women with intellectual disabilities and in situations of vulnerability.

In these cases, others need to intervene to provide support or assistance, which is consistent with one of the rules for treating people autonomously: "when asked, help others make important decisions" (16). This is because the context in which they operate makes a difference, due to the multifactorial socio-relational status of vulnerability, which is equally relevant for the assessment of their normative authority (17), as shown in Table 2.

Similarly, these are cases in which it is not only the specific vulnerability that must be addressed, but multiple vulnerabilities found in the same person, over which they rarely have any control because they arise from external dynamics.

Table 2. Context analysis in the ANHA approach

1. Understand the context	<p>Swarm of vulnerabilities</p> <p>Vulnerability factors:</p> <ol style="list-style-type: none"> Poor health conditions Cognitive or psychosocial limitations Lack of access to key resources Pressing socio-economic factors Limiting sociodemographic factors Age-related dependency Historically marginalized or excluded groups Forced displacement Subjects under the care of caregivers who are not trained in caregiving 	<p>They cannot be addressed in isolation when they are present in the same person, as one decision can have collateral effects or be connected to others.</p> <p>Characteristics:</p> <ul style="list-style-type: none"> • Interconnection • Complexity • Dynamics • Difficulty in prioritizing • They are present simultaneously <p>Requires the following to be performed:</p> <ul style="list-style-type: none"> - Systematic analysis: How are the vulnerability factors connected? What are their causes, origins, consequences, relationships, and effects? - Rational prioritization: Within the framework of prudence, which vulnerability factor, when resolved, facilitates the treatment of other factors? - Collaborative approach: How do families, the State, society, entities, and professionals work together to care for people with multiple vulnerabilities?
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2. Understanding the identification and evaluation of the importance of connectors and capabilities	Divisors	Help, Support, Reset Measure, or Intervention	Connectors
	Things you want to stop	Making a reproductive decision	Things you want to support
	Systems and institutions	Integration of cognitive, emotional, and motivational information Knowledge alone is not enough	Systems and institutions
	Attitudes and actions	Why? Where? What? When? How?	Attitudes and actions
	Values and interests		Values and interests
	Experiences		Experiences
	Symbols		Symbols
		All aid should reduce tensions and strengthen capacities (competence for autonomy).	

<p>3. identifying relevant characteristics of the aid agency and its program, and assessing and reassessing impacts on dividers, tensions, and capacities.</p>	<p><i>“Nothing about us without us”</i> No support that affects a right can be taken away from its beneficiary behind their back (trust).</p> <p><i>“I don’t understand, but you do”</i> Just because someone doesn’t understand the consequences of a decision doesn’t mean that those who support it don’t have to understand them on their behalf. (empathy)</p> <p><i>“It’s not enough to think about what’s good”</i> All assistance must take into account every factor of vulnerability so as not to exacerbate harm (responsibility)</p> <p><i>“It is always the right time to do what is right”</i> It is always better to act to improve conditions of vulnerability than to do nothing (action)</p> <p><i>Do not use “no harm” as an excuse to lie</i> Not doing harm cannot be used as an excuse for lying; people deserve to be treated with truth (truthfulness)</p> <p><i>Those who help or support “choose the good, not a good.”</i> The purpose of help or support is not to judge those who are supported. Although there may be a perception that their intervention is not being done well, it is always framed within the context of doing good, that is, seeking to choose the good (no recrimination).</p>
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Source: prepared by the author, based on Anderson and Wallace’s ANHA framework.

3. Practical implications of ANHA in obtaining informed consent

As mentioned above, the main objective of the ANHA is to prevent unintended negative consequences for the individuals, communities, or groups being supported. When this approach is applied to women with intellectual disabilities in the context of a reproductive decision,

where other factors of vulnerability may converge at the same time as their disability, the practical implications are profound.

This approach invites us to recognize that even well-intentioned actions can have adverse effects if the contextual conditions, the multiple dimensions of vulnerability, and the decision-making capacity of the women involved are not adequately considered.

Thus, applying the ANHA to these types of decisions not only involves preventing further harm, but also requires actively promoting scenarios that guarantee autonomy, dignity, and reproductive justice for women. This application must consider the following elements in all cases:

a. *Understanding intellectual disability as a vulnerability factor*

Intellectual disability is an intellectual development disorder, within the spectrum of neurodevelopmental disorders, defined since 2022 as “a disability characterized by significant limitations in both intellectual functioning and adaptive behavior, encompassing many social and daily life skills.” This disability originates before the age of 22 (18). ID has three diagnostic criteria: i). Impairments in intellectual functions, ii). Impairments in adaptive behavior, iii). Onset of intellectual and adaptive impairments during the developmental period. The DSM-5 TR (2022)¹ (19) proposes a classification of intellectual development disorders based on severity, measured according to adaptive functioning, as this determines the level of support required, distinguishing between: mild, moderate, severe, and profound.

The discussion raised by cases in which it is effectively recognized that the state of intellectual disability is of such magnitude that it prevents the right holder from unequivocally expressing a

¹ DMS TR 20022 has sought to simplify some terms for better understanding and communication. For example, “intellectual disability” has been renamed “intellectual developmental disorder” to better reflect the nature of the disorder and highlight its relationship to intellectual development.

decision about the disposition of her body, either to receive medical treatment or surgical intervention with the aim of preventing pregnancy, i.e., a permanent method of contraception. This is a momentous and, in this case, dilemmatic decision, given the implications of the decision to have children or not in people's life plans, which are based on their autonomy and free development of their personality, and, on the other hand, the conditions in which the new member of the family can develop, with the care that is desired and that a woman with a severe disability is unlikely to be able to provide, there is a debate that is not easy to mediate.

When intellectual disability affects an individual's decision-making capacity, it is very difficult to obtain informed consent from the patient, which poses an obstacle for health service providers or professionals, often forcing family members or caregivers to make the decision.

If the woman does not have full cognitive abilities that allow her to understand the decision-making process, i.e., attention, perception, motor skills, social cognition, executive functions, language, and memory (20), it is extremely difficult to obtain valid informed consent from her. This does not mean that health professionals in the health service provider network are exempt from taking all the necessary steps to obtain consent, which involves following the technical guidelines for the implementation of informed consent for people with disabilities, within the framework of sexual and reproductive rights (21).

As established by the slogan "Nothing about us without us" used by the movement for the independent living of persons with disabilities (22), which expresses the idea that no decision affecting persons with disabilities should be made without their full participation or behind their backs, it is important to note that recognition of their autonomy is not synonymous with their capacity, which must be respected in all decisions that affect them.

Medical recognition and assessment of the state, level, or degree of disability is a determining factor in establishing the extent to

which a person can understand a reproductive decision, from which the path to follow for possible clinical intervention is derived.

It must be understood that any intervention in the body requires consent, and in the clinical field, this consent must be sufficiently informed, with the following characteristics: voluntariness, disclosure or full information, and decision-making capacity. Among the skills involved in decision-making capacity, it should be noted that, as in the human cognitive process, the person must be in a situation that allows them to understand, appreciate, reason, and express their choice freely.

b. *Understanding the context of women with intellectual disabilities in reproductive decision-making from a normative perspective*

The context analysis must consult reproductive rights and their jurisprudential development in the category of women with intellectual disabilities. In Colombia, several provisions and jurisprudential pronouncements² have recognized the reproductive rights of women and, in particular, how this right must be guaranteed to women with disabilities, which will be discussed later. The first thing to note is that sterilization without the consent of women with disabilities is unconstitutional. However, it is recognized that women with disabilities

² The Constitutional Court, in ruling T-199 of May 25, 2025, with Judge Diana Fajardo Rivera presiding, in a historic decision defending women's autonomy in reproductive decision-making in situations of disability, raised the following legal issue to be resolved in a specific case: (i) Do an ESE and an EPS violate the rights to health, informed consent, legal capacity, a life free of violence, and the reproductive rights of a woman of legal age with intellectual, psychosocial (mental), and multiple disabilities by ordering a surgical contraception procedure? In this case, it was established that Verónica, as a woman with intellectual and psychosocial disabilities, has the right to exercise her sexual and reproductive rights fully and autonomously, on an equal basis with other persons. To this end, she can count on reasonable accommodation and support for decision-making, without her disability justifying others making decisions for her. Denying this autonomy constitutes a form of discrimination, contrary to the Constitution, case law, and the international commitments of the Colombian State.

need to be supported in their reproductive decisions in a respectful manner and with appropriate mechanisms to ensure that their autonomy is protected.

Table 3 shows the regulatory framework to be reviewed regarding the sexual and reproductive rights of persons with disabilities in Colombia, which includes, among other provisions, the following:

Table 3. Regulatory framework for sexual and reproductive rights of persons with disabilities in Colombia

Convention on the Rights of Persons with Disabilities (2016). Adopted by Law 1346 of 2009, “Approving the Convention on the Rights of Persons with Disabilities,” adopted by the United Nations General Assembly on December 13, 2006. Specifically, Articles 12 and 25.
Statutory Law 1618 of 2013: “Establishing provisions to guarantee the full exercise of the rights of persons with disabilities.”
Statutory Law 1751 of 2015: “Regulating the fundamental right to health and establishing other provisions.”
Law 762 of 2002: “Approving the Inter-American Convention on the Elimination of All Forms of Discrimination against Persons with Disabilities, signed in Guatemala City, Guatemala, on June 7, 1999.”
Decree 3973 of 2005: “Enacting the Inter-American Convention on the Elimination of All Forms of Discrimination against Persons with Disabilities, signed in Guatemala City, Guatemala, on June 7, 1999.”
Law 1306 of 2009: “Establishing rules for the protection of persons with mental disabilities and establishing the <i>Legal Representation Regime for Emancipated Incapacitated Persons</i> .” Partially regulated by National Decree 600 of 2012. In accordance with Law 762 of 2002 and Law 1346 of 2009. Articles 1 to 48 were repealed by Article 61 of Law 1996 of 2019.
Law 1412 of 2010: “Authorizing and promoting free vasectomy and tubal ligation as a means of promoting responsible parenthood.”
Decree 0600 of 2012: “Partially regulating Law 1306 of 2009 and issuing provisions regarding endorsements or guarantees.”
Resolution 2003 of 2014 MinSalud: Defining the procedures and conditions for the registration of Health Service Providers and the authorization of health services.

Resolution 1904 of 2017 MinSalud: “Whereby the regulations are adopted in compliance with the eleventh order of ruling T-573 of 2016 of the Constitutional Court and other provisions are issued.”
Law 1996 of 2019: “Establishing the regime for the exercise of legal capacity by persons with disabilities of legal age.”
Amendment of Law 1564 of 2012, General Code of Procedure. Establishes the regime for the exercise of legal capacity by people with disabilities of legal age.
Case law framework of the Constitutional Court of Colombia on reproductive rights of women with disabilities
Judgment T-850/2002 , dated October 10, 2002. M.P. Rodrigo Escobar Gil.
Judgment T-248 of 2003 , dated March 21, 2003. M.P. Eduardo Montealegre Lynett.
Judgment T-492 of 2006 dated June 29, 2006. M.P. Marco Gerardo Monroy Cabra.
Judgment T-1019 of 2006 , dated December 1, 2006, Judge Jaime Córdoba Triviño.
Judgment T-063 of 2012 , dated February 9, 2012, M.P. Gabriel Eduardo Mendoza Martelo.
Judgment C-131 of 2014 , dated March 11, 2014. M.P. Mauricio González Cuervo.
Judgment T-740 of 2014 , dated October 3, 2014. Presiding Judge: Luis Ernesto Vargas Silva.
Judgment C-182 of 2016 , dated April 13, 2016, M.P. Gloria Stella Ortiz Delgado.
Judgment T-573 of 2016 , dated October 19, 2016, Presiding Judge Luis Ernesto Vargas Silva.
Judgment T-690 of 2016 , dated December 7, 2016. M.P. Alberto Rojas Ríos.
Judgment T-665 of 2017 by M.P. Gloria Stella Ortiz Delgado.
Judgment T-231 of 2019 , dated May 28, 2019. M.P. Cristina Pardo Schlesinger.
Judgment T-199 of 2025, May 25, M.P. Diana Fajardo Rivera

Source: prepared by the author.

As a result, Colombian constitutional law and jurisprudence have developed a solid framework that guarantees the sexual and reproductive rights of women with disabilities. The prohibition of sterilization without the free and informed consent of the person concerned, always presuming their legal capacity, has been established as a general rule. Only in exceptional cases —and after meeting rigorous requirements— can substitute consent be authorized, which requires the existence of a profound and severe disability, proven risk to life, proven inability of the person to consent in the present or future, and prior judicial authorization.

Currently, there is a call for the duty to provide reasonable accommodation and decision-making support as part of the transition to a social model of disability (23,24), in line with international human rights standards. Consequently, informed consent in these cases must be advanced, promoted, and facilitated through technical and educational means and by professionals to ensure respect for the self-determination of all women, including those with intellectual disabilities.

In this context, Law 23 of 1981, which establishes standards for medical ethics in Colombia, refers to doctor-patient relationships in Articles 14 and 15 and warns of the need for consent to perform the various medical and surgical treatments that may be required, as follows:

Article 14. The physician shall not perform surgery on minors, persons who are unconscious or mentally incapacitated without the prior authorization of their parents, guardians, or relatives, unless the urgency of the case requires immediate intervention.

Article 15. The physician shall not expose his or her patient to unjustified risks. He or she shall request the patient's consent to apply any medical or surgical treatment that he or she considers essential and that may affect the patient physically or psychologically, except in cases where this is not possible, and shall explain the consequences to the patient or those responsible for him or her in advance.

From the regulations and case law outlined above, at least four models of informed consent can be established in Colombia, as can be seen in Table 4, for cases of reproductive decision-making by women with intellectual disabilities, as follows: general informed consent in reproductive matters, assisted, qualified, and substitute.

Table 4. Types of informed consent used in reproductive decision-making by women with intellectual disabilities in Colombia

Informed consent: general regulatory concept

Resolution 2003 of 2014 defined informed consent as: "...the free, voluntary, and conscious acceptance by a patient or user, expressed in the full exercise of their faculties, after receiving adequate information, for a healthcare procedure to be carried out."

For the purposes of the regulation on medical records, it is the document that is drawn up after acceptance under the conditions described. If the patient is not in full possession of their faculties, acceptance of the medical act must be given by a family member, close relative, or responsible representative of the patient.

Constitutional Court Ruling C-182-2016.

Informed consent must be (i) free, that is, it must be voluntary and without any undue interference or coercion, (ii) informed, in the sense that the information provided must be sufficient, that is, timely, complete, accessible, reliable, and informal, and in some cases, (iii) qualified, a criterion under which the degree of information that must be provided to the patient in order to make their decision is directly related to the complexity of the procedure and, therefore, a greater degree of capacity to exercise consent is required, in which cases formalities may also be required for such consent to be valid, such as that it be given in writing. In addition, it requires that the individual be able to understand independently and sufficiently the implications of the medical intervention on their body. Failing this, third parties may exceptionally give such consent, as will be discussed below.

Constitutional Court Ruling C-233-2021: established that informed consent must be free, informed, and unequivocal, indicating that individuals may not only express it when necessary, but that it may also be given in advance.

Informed Consent

Essential requirements in the field of access to information on reproductive matters according to the Inter-American Commission on Human Rights

The Inter-American Commission on Human Rights, specifically in the area of access to information on reproductive matters, has stated that informed consent consists of three essential requirements:

- (iv) that health professionals provide the necessary information on the nature, benefits, and risks of the treatment, as well as alternatives to the treatment;
- (v) consider the needs of the person and ensure the patient's understanding of that information; and
- (vi) that the patient's decision is voluntary. Thus, informed consent must guarantee a voluntary and sufficiently informed decision, which protects the patient's right to participate in medical decisions and, in turn, imposes obligations on health service providers.

Assisted informed consent

Assisted informed consent is understood to be obtained when it is not possible to ascertain the will of the person with a disability, after determining reasonable supports and adjustments. In these cases, support people who demonstrate a relationship of trust with the person with a disability and the treating health personnel will be called upon to jointly assist in decision-making regarding health care and the signing of the informed consent form. This fact must be recorded in the medical record with information on the decision made (25).

It is important to note that assisted informed consent, unlike substitute informed consent, requires the participation of the person with a disability and that they are also present when decisions are made regarding the health intervention they will receive.

- Rulings T 1019 of 2006, T-740 of 2014, C-182 of 2016, T-690 of 2016, T573-2016, T-665 of 2017.

Qualified informed consent

Constitutional case law has established that, depending on the extraordinary, invasive, or risky nature of a medical intervention, qualified informed consent may be required.

In other words, the more qualified the informed consent must be, “the greater the patient’s competence to decide must be and the clearer it must appear.” This shows that the exercise of patient autonomy, far from being an absolute concept, “depends on the very nature of the healthcare intervention.”

This type of consent requires greater clarity regarding the patient’s competence and more detailed information from the healthcare professional. Likewise, its formalization may involve additional requirements, such as written proof of the patient’s wishes and, in certain cases, the reiteration of consent after a period of reflection, especially in the case of prolonged treatments. These elements reinforce the idea that patient autonomy is a graduated concept, subject to the context and complexity of the medical procedure.

- Rulings C 182-2016, T-850 of 2002.

Substitute informed consent

Substitute informed consent occurs when a person is unable to express their wishes and has not done so in advance through an advance directive. In such cases, their family members and closest associates may help to interpret the person’s wishes and preferences (26).

Substitute consent is exceptional and only applies in cases where the person is unable to express their free and informed will after all necessary support has been provided.

Consequently, constitutional case law has determined that in cases where individuals lack sufficient awareness to authorize medical treatment for their own health and to recognize the reality surrounding them, such as in the case of “persons with profound mental disabilities or limitations or minors who, due to their young age, are totally dependent on their parents for survival,” third parties, through what is known as substitute consent, may endorse the medical procedures required by them in order to protect their life, health, and physical integrity. This type of consent is restricted and applies on a case-by-case basis, given its particular nature. It is exceptional and only applies in cases where the person is unable to express their will after all support has been provided to enable them to do so

Substitute consent is based on Articles 14 and 15 of Law 23 of 1981.

- Rulings T 248 of 2003, T 492 of 2006, T 063 of 2012, C 131 of 2014, C 182-2012, C-231 of 2019.

Source: prepared by the author.

From the above, it can be concluded that case law shows a tendency toward support, assistance, or reasonable accommodations that allow women with intellectual disabilities to make assisted decisions and only in exceptional cases, when it becomes impossible to make an individual decision, should substitute consent be used. This is because it is understood that each person requires a specific and individual analysis, since disability is not the same in all cases, and therefore assistance, support, or interventions cannot be exhaustive.

c. *Contextual analysis should investigate vulnerability factors additional to intellectual disability – clusters of vulnerability*

Vulnerability, first of all, as part of the human condition, makes us all equal. However, it is recognized that some people require enhanced protection, either because of their environment or their own internal circumstances or limited capacities, which require differential, positive, and progressive treatment to protect them. In this sense, vulnerability is perceived as a warning sign that some people need special attention.

According to Ten, vulnerability exists when at least three components are present (27): a) exposure: there must be external stresses or disturbances that generate potentially harmful threats as a result of the relationship between humans and their natural and social environment; b) sensitivity: such as susceptibility to harm; and c) adaptive capacity or response capacity. Of these, a) corresponds to external factors and b) and c) to internal factors.

In general, women with intellectual disabilities also face other situations of vulnerability, which must be considered and addressed comprehensively in any form of support, assistance, or intervention provided to them.

Hence, the expression “vulnerability clusters” is used in this article to refer to the fact that some individuals or groups, due to certain social factors in which they operate, are at greater risk of harm, abuse, and exploitation in contexts where they must make important decisions related to their lives, health, or fundamental rights, and

therefore require enhanced protection to prevent their combined conditions of vulnerability from turning them into victims. Some of the factors of vulnerability include the following: a) Poor health conditions, b) Cognitive or psychosocial limitations, c). Lack of access to key resources, d) Pressing socioeconomic factors, e) Limiting sociodemographic factors, f) Dependence due to age, g) Historically marginalized or excluded groups, h) Forced displacement, i) Subject to care by caregivers who are not trained in caregiving.

In the case described above involving the grandmother and her granddaughter, several vulnerability factors converge. On the one hand, the grandmother is a woman with an intellectual disability, living in precarious socioeconomic conditions, dependent on the care of another elderly woman, in a rural area affected by armed conflict, where access to health and education services is limited for her specific needs. This is what could be called a “swarm of vulnerabilities,” which exposes women to disadvantage or fragility in the face of external or internal threats that can affect their well-being, rights, or access to essential resources.

Therefore, in analyzing the case, the assistance, support, or measures deemed prudent to take must consider the context so that the best interests of her rights are prioritized, in order not to make her situation more difficult and, on the contrary, to try to improve her current situation. The ANHA provides a better methodological approach to decision-making.

Some authors within the framework of social justice theories (28) have warned that a new perspective on vulnerability must be considered, criticizing traditional definitions that understand it as a fixed condition. They propose a dynamic and contextual approach, conceptualizing vulnerability in “layers” (29). These layers can overlap and manifest themselves in different ways depending on the context and individual circumstances in which the subjects operate, such as in the case of women in environments that limit their reproductive rights.

Thus, vulnerability is not a permanent label, but a variable condition that can be altered and adjusted. The layered approach to vul-

nerability aims to avoid stereotypes and labels, allowing for a more relational and adaptable understanding of vulnerability that reflects the complexities of each particular case.

However, unlike the *layers of vulnerability* approach, the term *swarms of vulnerability* present the idea that multiple factors exist at the same time which, although interconnected, do not always depend on each other and are in disorder, so that addressing one factor does not necessarily overcome it without exacerbating another. whereas layers suggest linear connections between each other, representing an order for addressing simultaneous problems.

On the other hand, layers are addressed as negative conditions that prevent something, as a simple divider and tensioner, while the “*swarm*” raises the idea of addressing the context that surrounds the subject, not only as an individual element that can be overcome, but also requiring an understanding that there are factors that may never be overcome because there is no individual power to do so, as overcoming them depends on others.

In summary, any assistance, support, measure, or intervention implemented to obtain informed consent from a woman with intellectual disabilities in the context of her reproductive rights must not only consult the principles of autonomy and non-maleficence, but must also give special consideration, and even priority, to the principle of beneficence, in which at least the following must be fulfilled:

1. Comply with the ethical requirement of “do no intentional harm.” In this case, it is necessary to establish what the harm is, which in these cases can range from:
 - a) That the woman is unable to have children as a result of a surgical procedure that she cannot understand and to which she may not be able to give informed individual consent (sterilization decided by third parties – *principle of prevention*, which establishes that it is better to act preventively to avoid risks that could compromise a person’s safety, well-being, or rights, rather than reacting once the harm has already occurred (30).

- b) That a person who is unable to understand a reproductive decision may become pregnant with the possibility of giving birth to a sick child and the impossibility of providing appropriate care and attention for herself and the child, as she cannot take care of herself in various aspects of her life (*precautionary principle* applicable when there are indications that an action could cause serious or irreversible harm, but there is no complete scientific certainty about the magnitude or probability of the risk. This principle implies that, in the absence of certainty, preventive measures should be taken to avoid possible harm, even if it has not yet been conclusively proven that harm will occur) (31,32). All in all, caution is human behavior that aims to avoid harm.
- 2. Prevent harm.
- 3. Remove or destroy the damage.
- 4. Maximize benefits and minimize possible damage.
- 5. Promote the good through positive actions of care and well-being.

In this assessment, it must be considered that the obligation of the State through all its entities is related to the obligation to seek to “do good,” that is, to take measures to strengthen the rights of women with intellectual disabilities, provided that the following conditions are met (33): a) a threat of significant loss or damage to their rights. b) the necessary action and intervention by the State to prevent harm, loss, or impairment of an important right. c) recognition that, with the action and intervention of the State, the harm, loss, or impairment of an important right will likely be prevented.

- d. *The design of interventions with support measures must be focused on dignity and autonomy*

Once a systematic analysis of the context has been carried out, it is necessary to review that the intervention or support measures for

reproductive decision-making are carried out in a process that integrates cognitive, emotional, and motivational information.

Therefore, when obtaining informed consent, ways should be sought to reduce tensions and promote respect for the progressive autonomy of women with intellectual disabilities, avoiding imposed decisions or paternalistic practices and making reasonable adjustments as appropriate.

The International Convention on the Rights of Persons with Disabilities (34), Art. 2. Paragraph 4 establishes that “reasonable accommodation” means such appropriate modification and adjustment of services, facilities, or programs as may be needed in a particular case to ensure that persons with disabilities enjoy or exercise, on an equal basis with others, all human rights and fundamental freedoms.

Reasonable adjustments are currently seen as a new tool in anti-discrimination law which, although not exclusive to disability, allow for inclusive equality (35).

In relation to informed consent, these adjustments may include that all support must be adapted communicatively, in accordance with their cognitive abilities, using clear language, pictograms, or visual aids to facilitate understanding of medical information.

Depending on the case, accessible formats and the use of assent, understood as the verbal or nonverbal expression of will, should be provided. These measures seek to ensure respect for the autonomy and rights of people with disabilities in healthcare settings.

Among other considerations, any measures adopted involve reviewing policies, protocols, or services to ensure accessibility, inclusion, and reasonable accommodations.

It is no less important in cases of intellectual disability to involve families or caregivers in the process, as their role is important. However, the ANHA requires listening to and prioritizing the consent and perspective of women, even if they require support to express their will. In this way, processes of accompaniment and empowerment are generated, rather than replacement of decisions.

Women with intellectual disabilities face scenarios of constant social mistrust. Applying the ANHA approach means building ther-

apeutic or social bonds that restore their sense of trust and belonging, allowing them to be recognized as women who feel. In this order, all actions must be aligned with the Convention on the Rights of Persons with Disabilities, the intersectional gender approach, and frameworks such as the Social Model of Disability.

Conclusions

It is important to conclude on the importance of a bioethical approach that is sensitive to the realities faced by women with intellectual disabilities, especially in reproductive decision-making about their bodies, so that their well-being is always promoted without exacerbating factors of vulnerability associated with their context.

In this sense, the State, society represented by its doctors, among others, and the family, in joint responsibility, must guarantee that women with intellectual disabilities obtain informed consent in reproductive decisions, within the framework of respect for their autonomy and dignity, especially in highly vulnerable contexts.

The application of the ANHA offers a valuable framework for understanding how interventions should be designed so that they do not exacerbate existing vulnerabilities and, instead, promote women's well-being. This approach is proposed in consideration of the fact that traditional bioethical models do not always adequately address the multifactorial nature of vulnerabilities. Considering that traditional bioethical models, such as Beauchamp and Childress's principlism, utilitarian bioethics, and even the deliberative model, have been widely criticized for their individualistic, rational, universalist approach, which can mask existing power relations and be insensitive to cultural and relational diversity, revealing their limited capacity to address the complexity and multifactorial nature of the vulnerabilities affecting certain social groups, such as, in this case, women with intellectual disabilities.

These models tend to focus on ideal subjects —autonomous, informed, and fully rational— ignoring the intersections that can

occur simultaneously in a person, such as disability, gender, poverty, social exclusion, or others, which can lead to insufficient normative and ethical responses to real scenarios of structural inequality. Therefore, a more contextualized approach is needed that considers the intersection of various factors that simultaneously and in a difficult-to-overcome manner generate a *swarm of vulnerabilities*.

Thus, all support, assistance, measures, or interventions must be designed and evaluated based on the specific context in which they are carried out, recognizing that each situation may have different impacts on the women involved.

While it is always desirable to obtain informed consent that meets substantive and procedural requirements, where the expression of will is a true reflection of autonomy, in cases of intellectual disability in women in reproductive decisions, this is not easy. Therefore, in countries such as Colombia, models of qualified, assisted, and substitute informed consent have been reviewed. Evidenced by the incorporation of the Convention on the Rights of Persons with Disabilities, there is a tendency to obtain direct and assisted consent with reasonable support or adjustments that allow participation in decision-making about their own lives, through adequate accompaniment that respects their autonomy.

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