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Το Περιοδικό "ΒΙΟΗΘΙΚΑ"

Το Περιοδικό "ΒΙΟΗΘΙΚΑ" αποτελεί ηλεκτρονική έκδοση της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής. Τα θεματικά του ενδιαφέροντα καλύπτουν όλο το φάσμα της σύγχρονης βιοηθικής και τεχνοηθικής. Για τον λόγο αυτό, καλούμε όχι μόνο καθιερωμένους αλλά κυρίως νέους επιστήμονες να στείλουν τις συμβολές τους.

Σκοπός του Περιοδικού είναι η ενημέρωση και η ανταλλαγή απόψεων και γνώσεων μεταξύ των επιστημόνων όλων των κλάδων με ιδιαίτερο θεωρητικό ή πρακτικό ενδιαφέρον για θέματα που αφορούν στη Βιοηθική αλλά και τα ηθικά ζητήματα της τεχνολογίας. Για την επίτευξη αυτού του σκοπού, στο Περιοδικό δημοσιεύονται, στην ελληνική ή στις κύριες ευρωπαϊκές γλώσσες, εργασίες που αποτελούν Άρθρα Σύνταξης, Πρωτότυπες Εργασίες και Ανασκοπήσεις.

Οι Πρωτότυπες Εργασίες και οι Ανασκοπήσεις διαβιβάζονται ανώνυμα σε διεπιστημονική ομάδα τριών κριτών, οι οποίοι τις αξιολογούν. Μόνο όσες εργασίες λάβουν οριστική έγκριση από τους κριτές δημοσιεύονται στο Περιοδικό. Επισημαίνεται ότι οι απόψεις στα κείμενα εκφράζουν μόνο τους συγγραφείς.

Αναλυτικές πληροφορίες για το Περιοδικό "ΒΙΟΗΘΙΚΑ" θα βρείτε στην ιστοσελίδα του Εθνικού Κέντρου Τεκμηρίωσης (ΠΕΡΙΟΔΙΚΟ Bioethica).

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Μάρτιος 2025 • Τόμος 11 • Τεύχος 1

ΠΕΡΙΕΧΟΜΕΝΑ

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Βιοηθικής & Τεχνοηθικής

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Ηλεκτρονικό Περιοδικό της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής

March 2025 • Volume 11 • Issue 1

CONTENTS

Ελληνική Δημοκρατία
Εθνική Επιτροπή
Βιοηθικής & Τεχνοηθικής

ΒΙΟΗΘΙΚΑ

Ηλεκτρονικό Περιοδικό της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής

Άρθρο Σύνταξης - Editorial

Άρθρο Σύνταξης

Βιοηθική: ένας αναστοχασμός

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Λέξεις κλειδιά: Βιοηθική, αξία της ανθρώπινης ζωής, ανθρώπινη αξιοπρέπεια.

Bioethics: a reflection

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Keywords: Bioethics, value of human life, human dgnity.

Υπάρχουν στιγμές που πρέπει να αναστοχάζεται κανείς τους λόγους για τους οποίους η βιοηθική έχει νόημα. Σε εποχές που η τεχνολογία έχει επιτρέψει μια ευρύτατη διαχείριση της ζωής ως φυσικού φαινομένου, είναι ανάγκη κάποτε να κάνουμε «πίσω» για να σκεφτούμε αν αυτή η διαχείριση πρέπει να έχει κάποια όρια. Πολύ περισσότερο, αυτό πρέπει να γίνεται όταν μιλάμε για τη διαχείριση της ανθρώπινης ζωής.

Γιατί, η ανθρώπινη ζωή αναγνωρίζεται ως η σημαντικότερη αξία σε μια δημοκρατική κοινωνία. Το βλέπουμε, πρώτα, στα προγραμματικά κείμενα του διεθνούς δικαίου, του δικαίου της Ευρωπαϊκής Ένωσης, αλλά και στα εθνικά συντάγματα, όταν μιλούν για την «αξία του ανθρώπου», την «ανθρώπινη αξιοπρέπεια», την «προτεραιότητα του ανθρώπινου όντος», το «δικαίωμα στη ζωή», με απόλυτο τρόπο, χωρίς επιφυλάξεις. Το διαπιστώνουμε όμως και σαν κοινή παραδοχή των πιο διαφορετικών συστημάτων της σύγχρονης ηθικής, με εξαίρεση ορισμένες ριζοσπαστικές απόψεις «βαθιάς οικολογίας», που αναγνωρίζουν ίση αξία σε άλλα φυσικά όντα, έμβια ή μη.

Η έκταση της αναγνώρισης αυτής της αξίας δημιουργεί σήμερα ερωτηματικά, καθώς η τεχνολογία ανιχνεύει, αποκαλύπτει, αλλά και διαμορφώνει δομικά στοιχεία της ανθρώπινης ζωής, φτάνοντας να θέτει υπό έλεγχο βιολογικές διαδικασίες, όπως π.χ. η αναπαραγωγή ή ακόμη και ο θάνατος. Κρίσιμα ερωτήματα διαρκώς ανακύπτουν: Είναι σε κάθε περίπτωση ηθικά αποδεκτή η επιλογή εμβρύου για λόγους «αρνητικής ευγονικής»; Είναι πάντοτε απαράδεκτη η επιλογή εμβρύου με βάση επιθυμητά σε εμάς χαρακτηριστικά; Είναι επιτρεπτό να δημιουργούμε όσα εξωσωματικά έμβρυα θέλουμε, για να έχουμε επιτυχία στην υποβοηθούμενη αναπαραγωγή; Είναι αποδεκτή ηθικά η πρακτική της «μείωσης» κυοφορούμενων εμβρύων; Μπορεί η υποβοήθηση σε αυτοκτονία, ή διακοπή της τεχνητής υποστήριξης της ζωής, ή η ευθανασία να θεωρηθεί «ωφέλεια» για τον ασθενή, ώστε ο θεράπων να μην παραβιάζει την ιπποκρατική αρχή «ωφελέειν ή μη βλάπτειν»; Και ακόμη: Είναι ηθικά θεμιτή η τροποποίηση γονιδίων σε έμβρυα ή πρόσωπα, με σκοπό επιθυμητά φαινοτυπικά χαρακτηριστικά, που δεν σχετίζονται με την εκδήλωση ασθενειών; Είναι δικαιολογημένη η δημιουργία ανθρώπινων εμβρυικών μορφών, με περιορισμένο αναπτυξιακό δυναμικό, ώστε να διευκολύνεται η έρευνα; Ή, μπορούμε να αποδεχθούμε τη δημιουργία υβριδίων με μίξη ανθρώπινου και ζωικού γενετικού υλικού μήπως καταφέρουμε να εξασφαλίσουμε έτσι μια εναλλακτική πηγή ιστών και οργάνων για μεταμοσχεύσεις;

Σε κάποια από τα παραπάνω ερωτήματα έχουν δοθεί απαντήσεις από τη νομοθεσία, ωστόσο αυτό δεν λέει πολλά. Η σταθερότητα των νόμων δοκιμάζεται ανέκαθεν σε τέτοια θέματα, όσο η εξέλιξη της τεχνολογίας -που κατά κανόνα υποστηρίζεται από ισχυρά συμφέροντα της ιδιωτικής οικονομίας- πιέζει για την επαναξιολόγηση των σχετικών ρυθμίσεων. Αυτή η διαρκής επαναξιολόγηση ισοδυναμεί όμως με μια κατάσταση διαπραγμάτευσης αξιών: πόσο λοιπόν είμαστε διατεθειμένοι να διαπραγματευόμαστε την αξία της ανθρώπινης ζωής; Είναι ασφαλώς θεμιτό να αναλύουμε τη ζωή σε ένα σύνολο βιοχημικών δομών και αντιδράσεων, υπό τον όρο όμως ότι δεν τη βλέπουμε σαν «αναλώσιμο» αντικείμενο, σαν απλό μέσο για να αναπτύξουμε τεχνολογία ή να προσελκύσουμε επενδύσεις. Γιατί, αν περάσουμε αυτή την «κόκκινη γραμμή», όλοι μπορεί να γίνουμε αναλώσιμοι για οποιουσδήποτε σκοπούς.

Ένα υπόρρητο μήνυμα από τα Τέμπη είναι ακριβώς αυτό: ότι η αξία κάθε ανθρώπου είναι αδιαπραγμάτευτη. Αυτό σημαίνει, σε ό,τι μας αφορά στη βιοηθική, ότι η ανθρώπινη ζωή δεν σταθμίζεται με οποιαδήποτε άλλη αξία, είτε ατομική είτε συλλογική, ακόμη και αν αυτή είναι η πρόοδος της επιστήμης και της τεχνολογίας ή η ευημερία του συνόλου. Ότι, γι' αυτό -όπως μας διδάσκει το βουβό αλλά πάνδημο μήνυμα- όλες μας οι δυνάμεις πρέπει να επιστρατεύονται για να προλάβουμε την βλάβη ή την καταστροφή της ανθρώπινης ζωής. Και ότι -αν δεν την προλάβουμε- πρέπει να επαναβεβαιώνουμε την αξία της, πρώτα δείχνοντας τον πρέποντα σεβασμό στους νεκρούς και έπειτα επιβάλλοντας με κάθε τρόπο τη δικαιοσύνη που αξίζουν.

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Βιοηθικής & Τεχνοηθικής

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Πρωτότυπες Εργασίες - Original Articles

Πρωτότυπη Εργασία

Το βέλτιστο συμφέρον του τέκνου στις διαδικασίες απόκτησης παιδιών από ομόφυλα ζευγάρια

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Περίληψη

Η Διεθνής Σύμβαση για τα Δικαιώματα του Παιδιού καθορίζει ότι το βέλτιστο συμφέρον του παιδιού πρέπει να είναι η πρωταρχική προτεραιότητα σε όλες τις αποφάσεις που το αφορούν. Ένα από τα βασικά σημεία της Σύμβασης είναι η αρχή της μη διάκρισης, η οποία διασφαλίζει ότι τα παιδιά δεν υφίστανται διακρίσεις λόγω του σεξουαλικού προσανατολισμού των γονέων τους. Τα κράτη πρέπει να διασφαλίσουν ότι τα παιδιά των ομόφυλων οικογενειών έχουν ίση μεταχείριση με τα παιδιά των ετεροφυλόφιλων οικογενειών, θεσπίζοντας νομοθεσία που προστατεύει τα δικαιώματά τους. Η αναγνώριση και η προστασία των δικαιωμάτων αυτών των παιδιών συμβάλλει στη δημιουργία μιας κοινωνίας χωρίς διακρίσεις και προκαταλήψεις. Σχετικά με τα δικαιώματα των εμβρύων, οι νόμοι διαφέρουν ανά χώρα ως προς την αναγνώριση της προσωπικότητάς τους. Η προστασία των εμβρύων δεν πρέπει να υπερτερεί των δικαιωμάτων των γυναικών. Το έμβρυο προστατεύεται έμμεσα μέσω της μητέρας του, χωρίς να θεωρείται πλήρες άτομο. Το κριτήριο της βιωσιμότητας είναι σημαντικό, καθώς προσδιορίζει την ικανότητα του εμβρύου να ζήσει αυτόνομα, χωρίς να αποκτά πλήρη νομική προστασία ως άτομο.

Λέξεις κλειδιά: βέλτιστο συμφέρον του παιδιού, οικογενειακή ισότητα, νομική προστασία.

The best interests of the child in same-sex couples' procedures for obtaining children

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Abstract

The International Convention on the Rights of the Child mandates that the best interests of the child should be the primary consideration in all decisions affecting them. A key principle of the Convention is non-discrimination, ensuring that children are not discriminated against based on their parents' sexual orientation. States must ensure that children of same-sex families receive equal treatment to those of heterosexual families by enacting legislation that protects their rights. Recognizing and safeguarding the rights of these children contributes to creating a society free from discrimination and prejudice. Regarding the rights of embryos, laws vary by country concerning the recognition of their personhood. Embryo protection should not override women's rights. The embryo is indirectly protected through the mother and is not considered a full person. The viability criterion is significant as it determines the embryo's ability to live independently without granting it full legal protection as a person.

Keywords: best interests of the child, family equality, legal protection.

Η αξιολόγηση του βέλτιστου συμφέροντος του τέκνου

Η αρχή του βέλτιστου συμφέροντος του τέκνου είναι μια πολύ γενική, δυναμική έννοια που περιλαμβάνει διάφορα ζητήματα που εξελίσσονται συνεχώς. Είναι ένα υποκειμενικό δικαίωμα που εφαρμόζεται σε κάθε λήψη αποφάσεων σχετικά με ένα παιδί, μια ερμηνευτική νομική αρχή και ένας διαδικαστικός κανόνας.[1] Πρέπει να είναι προσαρμόσιμο στις ανάγκες κάθε παιδιού και στην εξέλιξη της γνώσης για την ανάπτυξη του παιδιού. Αν και συναντάται σε πολλά διεθνή κείμενα, γενικά αναγνωρίζεται ότι η βασική διάταξη είναι το άρθρο 3 (1) της Διεθνούς Σύμβασης για τα Δικαιώματα του Παιδιού.[2] Με τη Σύμβαση, η οποία τέθηκε σε ισχύ το 1990, η διεθνής κοινότητα δημιούργησε το πρώτο νομικά δεσμευτικό διεθνές μέσο που αποσκοπούσε στην προστασία των παιδιών και ενσωμάτωσε ένα πλήρες φάσμα ανθρωπίνων δικαιωμάτων – πολιτικών, πολιτιστικών, οικονομικών και κοινωνικών δικαιωμάτων. Όμως, για πρώτη φορά, η αρχή του βέλτιστου συμφέροντος του παιδιού χρησιμοποιήθηκε το 1959, στη Διακήρυξη των Δικαιωμάτων των Παιδιών.[3] Το άρθρο 2[4] ορίζει ότι η αρχή αυτή πρέπει να λαμβάνεται *paramount* υπόψη κατά τη θέσπιση νόμων που σχετίζονται με τα παιδιά. Το *paramount* υποδηλώνει ότι το παιδί πρέπει να είναι ο μόνος καθοριστικός παράγοντας στις αποφάσεις και τη νομική προσέγγιση. Ωστόσο, λόγω του νομικού της καθεστώτος, η Διακήρυξη δεν ήταν σε θέση να δεσμεύσει τα κράτη να συμμορφωθούν με τις υποχρεώσεις.

Διαφορετικά από τη Διακήρυξη του 1959, η αρχή του βέλτιστου συμφέροντος του παιδιού στη Σύμβαση δεν αναφέρεται ως *paramount*, αλλά ως *primary* εκτίμηση,[5] όπως αναφέρεται στο άρθρο 3. Ο όρος *primary* υποδηλώνει ότι υπάρχουν και άλλοι παράγοντες που μπορούν επίσης να συμβάλουν στη θέσπιση νόμων ή στη διαδικασία λήψης αποφάσεων που αφορούν τα παιδιά.

Είναι σημαντικό να διευκρινιστεί η διαφορά μεταξύ *paramountcy* και *primacy*. Μια εκτίμηση που είναι *paramount* υπερέχει και υπερτερεί όλων των άλλων εκτιμήσεων. Στην πραγματικότητα, είναι μια μοναδική εκτίμηση που είναι καθοριστική για ένα αποτέλεσμα.

Μια εκτίμηση που είναι *primary* είναι η κύρια εκτίμηση, αυτή που είναι πρώτη στη σειρά

[1] «Κάθε φορά που πρόκειται να ληφθεί μια απόφαση που θα επηρεάσει ένα συγκεκριμένο παιδί, μια καθορισμένη ομάδα παιδιών ή παιδιά γενικά, η διαδικασία λήψης αποφάσεων πρέπει να περιλαμβάνει αξιολόγηση του πιθανού αντίκτυπου (θετικού ή αρνητικού) της απόφασης στο συγκεκριμένο παιδί ή παιδιά. Η αξιολόγηση και ο καθορισμός του βέλτιστου συμφέροντος του παιδιού απαιτούν διαδικαστικές εγγυήσεις. Επιπλέον, η αιτιολόγηση μιας απόφασης πρέπει να δείχνει ότι το δικαίωμα έχει ληφθεί ρητά υπόψη. Εν προκειμένω, τα συμβαλλόμενα κράτη εξηγούν πώς έγινε σεβαστό το δικαίωμα στην απόφαση, δηλαδή τι θεωρείται ότι είναι προς το συμφέρον του παιδιού, σε ποια κριτήρια βασίζεται· και πώς τα συμφέροντα του παιδιού έχουν σταθμιστεί έναντι άλλων εκτιμήσεων, είτε πρόκειται για γενικά θέματα πολιτικής είτε για μεμονωμένες περιπτώσεις». General comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1) (note 133), para. 6 (c).

[2] The United Nations Convention on the Rights of the Child, 1990.

[3] UNICEF, Handbook: Geneva, Implementation Handbook for the Convention on the Rights of the Child, third edition, p. 35.

[4] The Declaration of the Rights of the Child, 1959.

[5] Το πρώτο σχέδιο αυτού του άρθρου αναπαρήγαγε την ίδια διατύπωση με τη Διακήρυξη του 1959, αλλά ορισμένες αντιπροσωπείες ήταν αυτού. Ένα εναλλακτικό σχέδιο υποβλήθηκε το 1980 και ο όρος αντικαταστάθηκε με την primary εκτίμηση.

μεταξύ πολλών. Όμως, παρόλο που καμία εκτίμηση δεν υπερβαίνει την *primary* εκτίμηση, μπορεί να υπάρχουν άλλες ίσες εκτιμήσεις. Επιπλέον, μια κύρια εκτίμηση δεν υπερέχει ακόμη και αν υπερτερεί όλων των άλλων εκτιμήσεων. Μια *primary* εκτίμηση δεν είναι μοναδική καθοριστική για ένα αποτέλεσμα. Επομένως, η διαφορά έγκειται στην απόλυτη επικράτηση της υπεροχής και στη σημασία, αλλά όχι στην αποκλειστική εκτίμηση της υπεροχής.[6]

Η μόνη περίπτωση, όπου η ιδέα *paramountcy* αναφέρεται ρητά στη Σύμβαση, είναι σε περιπτώσεις υιοθεσίας όπως αναφέρεται στο άρθρο 21. Επομένως, σε γενικές γραμμές, τα κράτη θα πρέπει να θεωρούν το βέλτιστο συμφέρον του παιδιού ως *primary* εκτίμηση στις διαδικασίες λήψης αποφάσεων. Ωστόσο, στην υιοθεσία, η αρχή πρέπει να έχει *paramount* εκτίμηση και θα πρέπει να καθορίζεται κατά περίπτωση. Είναι εξαιρετικά σημαντικό, κατά τη λήψη αποφάσεων, οι ειδικοί που εμπλέκονται σε υποθέσεις υιοθεσίας να κάνουν μια δίκαιη και αμερόληπτη αξιολόγηση κατά περίπτωση και να μην αναπαράγουν και να ενισχύουν τις εκτεταμένες διακρίσεις σε βάρος των ομόφυλων γονέων.

Μεγάλη κριτική έχει γίνει στην ιδέα της αρχής ως *paramount*. Η εξουσία *paramount* έγκειται στη φαινομενική της ουδετερότητα και δικαιοσύνη, αλλά μπορεί να χρησιμοποιηθεί για να δικαιολογήσει οποιαδήποτε απόφαση. Για παράδειγμα, οι δικαστές θα αποφάσιζαν κατά της μη παραδοσιακής υιοθεσίας, όπως από έναν μόνο και κατάλληλα ικανό ομοφυλόφιλο για υιοθεσία, στο όνομα της *paramount* εκτίμησης του βέλτιστου συμφέροντος του παιδιού. Η ιδέα επιτρέπει στους πολιτικούς και νομοθέτες να προτείνουν νομοσχέδια και δημόσιες πολιτικές που κρύβουν μια πολιτική, ιδεολογική ή ηθική πρόθεση με αναφορά σε *paramountcy* των παιδιών. Θα μπορούσε κανείς να υποστηρίξει ότι τα δικαιώματα του γονέα απειλούνται από τις ανάγκες των παιδιών. Τα προβλήματα με την εφαρμογή της αρχής *paramountcy* έχουν τις ρίζες τους στην κενή ιδέα της – ενώ όλοι συμφωνούν ότι η ευημερία των παιδιών πρέπει να είναι *paramount* σημασίας, όλοι έχουν διαφορετικές απόψεις για το τι απαιτεί η ευημερία των παιδιών.

***Primary* εκτίμηση**

Τα συμβαλλόμενα κράτη πρέπει να ενσωματώσουν μια πλήρη και επίσημη διαδικασία αξιολόγησης και προσδιορισμού του βέλτιστου συμφέροντος του παιδιού σε όλες τις περιπτώσεις, στις οποίες μια απόφαση θα έχει σημαντικό αντίκτυπο σε ένα παιδί ή σε παιδιά. Σε αυτές τις περιπτώσεις, ενδείκνυται μεγαλύτερο επίπεδο προστασίας και λεπτομερείς διαδικασίες για να ληφθούν υπόψη τα βέλτιστα συμφέροντά τους.

Η έκφραση *primary εκτίμηση* αποδίδει στο βέλτιστο συμφέρον των παιδιών μια ισχυρότερη θέση σε σύγκριση με άλλες εκτιμήσεις. Αυτό δικαιολογείται με βάση την ειδική κατάσταση του παιδιού – εξάρτηση, ωριμότητα, νομικό καθεστώς και, συχνά, αφωνία και το γεγονός ότι εάν τα συμφέροντα των παιδιών δεν επισημαίνονται, τείνουν να παραβλέπονται. Ωστόσο, δεδομένου ότι το άρθρο 3 (1) καλύπτει ευρύ φάσμα καταστάσεων, η Επιτροπή ΟΗΕ για τα Δικαιώματα του Παιδιού αναγνωρίζει την ανάγκη για ευελιξία στην εφαρμογή του. Αφού αξιολογηθεί, το βέλτιστο συμφέρον του παιδιού ενδέχεται να έρχεται σε σύγκρουση με άλλα συμφέροντα ή δικαιώματα, για παράδειγμα, αυτά άλλων παιδιών, δημόσιων αρχών, γονέων, φροντιστών κ.λπ. Για την Επιτροπή, η εξισορρόπηση των αντικρουόμενων συμφερόντων μπορεί να λειτουργήσει μόνο σε αξιολόγηση κατά περίπτωση. Κατά την αναζήτηση του κατάλληλου συμβιβασμού, οι αρχές και οι υπεύθυνοι για την λήψη αποφάσεων πρέπει να σταθμίσουν τα δικαιώματα όλων των ενδιαφερομένων, λαμβάνοντας υπόψη ότι το βέλτιστο συμφέρον του παιδιού έχει υψηλή προτεραιότητα και δεν αποτελεί απλώς

[6] Archard, David William. Children, Family and the State. Routledge, 2003.

ένα από τα πολλά ζητήματα. Αυτό δεν μπορεί να ακυρωθεί όταν μια ενέργεια έχει αναμφισβήτητο αντίκτυπο στα ενδιαφερόμενα παιδιά.

Αντίθετα, στην περίπτωση της υιοθεσίας, αυτή η εξισορρόπηση αντικρουόμενων συμφερόντων δεν χρειάζεται. Στο άρθρο 21, ενισχύεται περαιτέρω η αρχή του βέλτιστου συμφέροντος. «Δεν είναι απλώς να είναι *primary* εκτίμηση», αλλά «η *paramount* εκτίμηση». Επομένως, είναι ο καθοριστικός παράγοντας.[7,8]

Το Ευρωπαϊκό Δικαστήριο Ανθρωπίνων Δικαιωμάτων (ΕΔΔΑ) έχει ασχοληθεί με τις υποθέσεις υιοθεσίας, ωστόσο κάποιες από αυτές, ιδιαίτερα αυτές που αφορούν ομοφυλόφιλους προσφεύγοντες, δεν είναι σύμφωνες με το διεθνές δίκαιο, κατά το οποίο, το βέλτιστο συμφέρον του παιδιού πρέπει να λαμβάνεται *paramount* υπόψη σε υποθέσεις τέτοιου είδους. Πιο συγκεκριμένα, το Δικαστήριο λαμβάνει *paramount* υπόψη όσον αφορά το συμφέρον του παιδιού όταν ασχολείται με ετεροφυλόφιλους προσφεύγοντες (Keegan v. Ireland, Wagner and J.M.W.L v. Luxembourg, Kearns v. France, Harroudj v. France). Όμως, όταν οι προσφεύγοντες είναι ομοφυλόφιλοι, το Δικαστήριο δεν αναφέρεται σε *paramount* εκτίμηση σε κάθε υπόθεση.

Μια άλλη σχετική διαπίστωση είναι ότι το Δικαστήριο αποφασίζει ομόφωνα σε όλες τις υποθέσεις που σχετίζονται με το αντίθετο φύλο, αλλά στις υποθέσεις με τους ομοφυλόφιλους το Δικαστήριο δεν αποφασίζει ομόφωνα και παρουσιάζει αντίθετες απόψεις (EB v. France, Gas Dubois v. France, Fretté v. France, X and others v. Austria).

Το αποτέλεσμα δείχνει ότι το Δικαστήριο είναι διχασμένο και ο σεξουαλικός προσανατολισμός μπορεί να βρίσκεται στο επίκεντρο της μικρής σημασίας που δίνεται σε *paramountcy* του βέλτιστου συμφέροντος του παιδιού. Το συμπέρασμα είναι ότι η ευημερία του παιδιού, σε περιπτώσεις υιοθεσίας από γκέι ή λεσβίες, ελάχιστα λαμβάνεται υπόψη. Αντί για το βέλτιστο συμφέρον του παιδιού, το Δικαστήριο επικεντρώνεται στον σεξουαλικό προσανατολισμό των προσφευγόντων και στην αναγνώριση των δικαιωμάτων των σεξουαλικών μειονοτήτων στην Ευρώπη. Το Δικαστήριο στηρίζεται στην ύπαρξη ευρωπαϊκής συναίνεσης για να αποφύγει τη λήψη αποφάσεων για συγκεκριμένα ζητήματα που είναι αμφιλεγόμενα μεταξύ των ευρωπαϊκών χωρών. Η συναίνεση αυτή καθίσταται κρίσιμη στην απόφαση του Δικαστηρίου μαζί με μια άλλη έννοια – το περιθώριο εκτίμησης (the margin of appreciation).

Εφαρμογή της αρχής του βέλτιστου συμφέροντος του παιδιού σε οικογένειες ομόφυλων ζευγαριών

Το συμφέρον του παιδιού είναι μια σύνθετη αρχή χωρίς προκαθορισμένη απάντηση πώς πρέπει να το εφαρμόσουμε. Η διάταξη έχει ευρεία εφαρμογή σε περιπτώσεις που εξετάζονται τα δικαιώματα των παιδιών. Αυτό σημαίνει ότι η αρχή πρέπει να λαμβάνεται υπόψη σε συνδυασμό με κάθε άλλο δικαίωμα της Σύμβασης. Η ευρεία εφαρμογή απαιτεί από τα σχετικά όργανα να λαμβάνουν υπόψη τις ειδικές περιστάσεις σε κάθε περίπτωση και συνεπώς τα συμφέροντα κάθε παιδιού ξεχωριστά. Ως εκ τούτου, το συμφέρον του παιδιού εξαρτάται από την κατά περίπτωση ανάλυση. Παράγοντες που συνήθως αξιολογούνται κατά τον καθορισμό του βέλτιστου συμφέροντος του παιδιού είναι, μεταξύ άλλων: ηλικία, φύλο, αναπηρίες, ωριμότητα, οικογενειακή κατάσταση, σεξουαλικός προσανατολισμός, θρησκεία, προσωπικότητα, συναισθηματική φροντίδα, ασφάλεια και υγεία. Η ευέλικτη προσέγγιση επιτρέπει μια ζωντανή ερμηνεία όπου μπορούν να ληφθούν υπόψη οι νέες εξελίξεις των παιδιών. Δυστυχώς, οι ευέλικτες ερμηνείες μπορούν επίσης να δημιουργήσουν προβλήματα, να δικαιολογήσουν παράνομες πράξεις, όπως οι ρατσιστικές πολιτικές.

[7] Committee on the Rights of the Children. General comment No. 14 (2013), **op.cit**., παρ. 20, 37-40.
[8]UNICEF, Handbook**, op.cit**.

Ένας άλλος σημαντικός παράγοντας για τον καθορισμό του τι είναι προς το συμφέρον του παιδιού είναι το χρονικό σημείο στο οποίο λαμβάνεται η απόφαση. Για παράδειγμα, η αξιολόγηση του κατά πόσο είναι προς το συμφέρον ενός παιδιού να μεγαλώσει σε μια οικογένεια του ίδιου φύλου είναι πιθανό να είναι μια πολύ διαφορετική άσκηση το 2024 από ό,τι ήταν το 1980. Αυτό οφείλεται στο ότι οι κοινωνικές στάσεις απέναντι στις οικογένειες του ίδιου φύλου και τα νομικά πλαίσια που διέπουν τέτοιες οικογένειες έχουν εξελιχθεί σημαντικά τα τελευταία χρόνια, με αποτέλεσμα το στίγμα στο οποίο φοβόταν ότι θα εκτεθούν τέτοια παιδιά έχει, σε πολλούς πολιτισμούς, σε μεγάλο βαθμό εξαφανιστεί. Τι είναι προς το βέλτιστο συμφέρον ενός παιδιού θα ποικίλλει ανάλογα με τη χρονική περίοδο και την κουλτούρα στην οποία μεγαλώνει ένα παιδί.

Αυτό που είναι το βέλτιστο συμφέρον του παιδιού στο πλαίσιο οικογενειών του ίδιου φύλου είναι σχετικό σε δύο διακριτές χρονικές στιγμές.[9] Το πρώτο είναι όταν ένα ζευγάρι ομοφυλόφιλων ή ένα άτομο, επιθυμεί να κάνει οικογένεια. Η συζήτηση σχετικά με το εάν πρέπει να επιτρέπεται στα άτομα του ιδίου φύλου η πρόσβαση σε υπηρεσίες αναπαραγωγής ή να επιτρέπεται να υιοθετούν ή να αναθρέψουν ένα παιδί προκειμένου να δημιουργήσουν την επιθυμητή τους οικογένεια, συχνά επικεντρώνεται στο βέλτιστο συμφέρον του παιδιού. Υπό αυτές τις συνθήκες, η αρχή του βέλτιστου συμφέροντος του παιδιού λειτουργεί ως κατώτατο όριο για να καθοριστεί εάν τέτοιες οικογενειακές δομές πρέπει να εγκριθούν.

Το δεύτερο χρονικό σημείο κατά το οποίο είναι σημαντικό το συμφέρον του παιδιού είναι όταν υπάρχει ήδη οικογένεια ομοφυλόφιλων και το θέμα είναι πώς θα πρέπει να αντιμετωπίζεται το παιδί ή τα παιδιά του ίδιου φύλου από το νόμο και την κοινωνία. Ο νόμος σε πολλές δικαιοδοσίες αντιμετωπίζει τα παιδιά με γονείς του ίδιου φύλου διαφορετικά από τα παιδιά με ετεροφυλόφιλους γονείς. Αυτή η νομική διαφοροποίηση οδηγεί ορισμένα μέλη της κοινωνίας να αισθάνονται ότι και αυτά δικαιούνται να κάνουν διακρίσεις σε βάρος παιδιών με γονείς του ίδιου φύλου. Η μεταχείριση των παιδιών σε οικογένειες ομοφυλόφιλων με άνισο τρόπο σε σύγκριση με τα παιδιά των λεγόμενων συμβατικών οικογενειών σαφώς δεν είναι προς το συμφέρον τέτοιων παιδιών.

Οι τομείς του δικαίου που μπορούν να επηρεάσουν αρνητικά το συμφέρον του παιδιού σε οικογένειες ομοφυλόφιλων: (i) απουσία νομικής αναγνώρισης της οικογένειας ενός παιδιού· και (ii) διακρίσεις λόγω του σεξουαλικού προσανατολισμού των γονέων ενός παιδιού.

Αυτό οφείλεται στο γεγονός ότι δεν υπάρχει νομοθεσία που να αναγνωρίζει τις ομόφυλες οικογένειες και δεν απαγορεύει τις διακρίσεις σε βάρος των παιδιών με βάση τον σεξουαλικό προσανατολισμό των γονέων τους.

Απουσία νομικής αναγνώρισης της οικογένειας ενός παιδιού

Το Προοίμιο της Διεθνούς Σύμβασης για τα Δικαιώματα του Παιδιού αναγνωρίζει ότι η οικογένεια είναι «το φυσικό περιβάλλον για την ανάπτυξη και την ευημερία» των παιδιών και πρέπει να τους παρέχεται κάθε απαραίτητη προστασία και βοήθεια. Δεδομένης της σημασίας που δίνεται στις οικογένειες, όχι μόνο από την Σύμβαση αλλά και από την κοινωνία γενικότερα, είναι επιτακτική ανάγκη όλες οι οικογένειες να λαμβάνουν νομική αναγνώριση και προστασία. Ωστόσο, όταν πρόκειται για οικογένειες ομοφυλόφιλων, υπάρχουν δύο διαφορετικοί τρόποι με τους οποίους η νομική αναγνώριση μπορεί και συχνά αποκρύπτεται – δηλαδή, νομική αναγνώριση της σχέσης του γονέα και νομική αναγνώριση των σχέσεων του παιδιού και με τους δύο γονείς.

[9] Gerber, P. The Best Interests of Children in Same-sex Families. Law in Context 2010, 28(1), 28-42. σ. 6

Ο γάμος είναι ένας θεσμός μέσω του οποίου η κοινωνία αναγνωρίζει και υποστηρίζει ζευγάρια και οικογένειες και είναι μια μορφή δημόσιας αναγνώρισης και σεβασμού των προσωπικών δεσμών. Μόνο 35 χώρες[10] σε όλο τον κόσμο επιτρέπουν επί του παρόντος σε ομόφυλα ζευγάρια να παντρεύονται. Τα παιδιά των οποίων οι γονείς του ίδιου φύλου δεν απολαμβάνουν την αναγνώριση και την υποστήριξη που συνοδεύει ο γάμος μπορεί να υποστούν ψυχολογική βλάβη ως αποτέλεσμα της απαγόρευσης του γάμου των γονέων τους. Το να μην επιτρέπεται σε ζευγάρια του ίδιου φύλου να παντρευτούν σημαίνει ότι στα παιδιά που μπορεί να έχουν, υφίστανται δυνητικά ανισότητες, αναξιοπρέπεια και ανασφάλειες που μπορεί να προκύψουν από το να είναι μέλη μιας οικογένειας που δεν έχει νόμιμα κυρωθεί.[11]

Εξίσου σημαντική με τη νομική αναγνώριση της σχέσης του γονέα είναι και η νομική αναγνώριση της σχέσης του παιδιού και με τους δύο γονείς. Σε πολλές δικαιοδοσίες σε όλο τον κόσμο, τα παιδιά που μεγαλώνουν σε οικογένειες ομοφυλόφιλων είναι νομικά ξένα για έναν από τους γονείς τους. Για παράδειγμα, ένα ζευγάρι λεσβιών μπορεί να συλλάβει ένα παιδί μέσω της πρόσβασης σε θεραπεία γονιμότητας, ωστόσο σε πολλές χώρες δεν υπάρχει νομική αναγνώριση της μη βιολογικής μητέρας ως γονέα. Πολύ συχνά, οι εγχώριοι νόμοι αποτυγχάνουν να αναγνωρίσουν οποιονδήποτε δεσμό μεταξύ του παιδιού και του γονέα που δεν γεννήθηκε και της συναισθηματικής, ψυχολογικής και οικονομικής υποστήριξης που παρέχει η μη βιολογική μητέρα. Αυτό είναι αντίθετο με το άρθρο 8 της Σύμβασης, το οποίο προβλέπει ότι τα συμβαλλόμενα κράτη αναλαμβάνουν να σέβονται το δικαίωμα του παιδιού να διατηρεί την ταυτότητά του και τις οικογενειακές του σχέσεις. Το να αρνηθεί κανείς να αναγνωρίσει τη σχέση ενός παιδιού με τον γονέα του σημαίνει άρνηση της ταυτότητάς του καθώς και των οικογενειακών του σχέσεων. Τα κράτη έχουν θετική υποχρέωση να λαμβάνουν ενεργά και να αναγνωρίζουν νομικά στοιχεία σχετικά με την ταυτότητα των γονέων του παιδιού – gestational, γενετική και κοινωνική, και να τα καταγράφουν με τρόπο που να διασφαλίζει τη διατήρηση των οικογενειακών σχέσεων του παιδιού.

Έχει διαπιστωθεί από μια μελέτη[12] που διεξήχθη στην Αυστραλία ότι η μη νομική αναγνώριση του γονέα ενός παιδιού ως γονέα του δεν είναι προς το συμφέρον του παιδιού. Τα παιδιά που συμμετείχαν περιγράφοντας τη μη αναγνώριση της οικογένειάς τους χρησιμοποίησαν λέξεις όπως «λύπη», «θλίψη», «θυμός», «άγχος»

[10] Marriage Equality Around the World. https://www.hrc.org/resources/marriage-equality-around-the-world

[11] «Ο πολιτικός γάμος είναι ένα νομικό καθεστώς που προάγει υγιείς οικογένειες παρέχοντας ένα ισχυρό σύνολο δικαιωμάτων, προνομίων και προστασιών που δεν μπορούν να επιτευχθούν με άλλα μέσα. Ο πολιτικός γάμος μπορεί να συμβάλει στην ενίσχυση της οικονομικής και νομικής ασφάλειας, της ψυχοκοινωνικής σταθερότητας και της αυξημένης αίσθησης κοινωνικής αποδοχής και υποστήριξης. Η νομική αναγνώριση ενός συζύγου μπορεί να αυξήσει την ικανότητα των ενήλικων ζευγαριών να παρέχουν και να φροντίζουν ο ένας τον άλλον και να καλλιεργεί ένα περιβάλλον φροντίδας και ασφάλειας για τα παιδιά τους. Τα παιδιά που ανατρέφονται από πολιτικά έγγαμους γονείς επωφελούνται από το νομικό καθεστώς που παρέχεται στους γονείς τους». Pawelski JG, Perrin EC, Foy JM, Allen CE, Crawford JE, Del Monte M, Kaufman M, Klein JD, Smith K, Springer S, Tanner JL, Vickers DL. The effects of marriage, civil union, and domestic partnership laws on the health and well-being of children. Pediatrics. 2006 Jul;118(1):349-64.

[12] Conceiving the Family: Lesbian Mothers' Decisions, Experiences and Well-being, and the Current Legal, Public Policy and Discursive Context project.

και «ανησυχία». Ως απόρροια αυτού, η νομική αναγνώριση γονέων, που δεν τους γέννησαν, περιεγράφηκε από τους συμμετέχοντες στην έρευνα ως «τεράστια», «μαζική», «κεντρική», «θεμελιώδης», «φανταστική», «απερίγραπτη», «συντριπτική» και «απίστευτα σημαντική».[13]

Η μη αναγνώριση του ρόλου και της θέσης της μη βιολογικής μητέρας ισοδυναμεί με μη αναγνώριση της πραγματικότητας της οικογενειακής δομής του παιδιού. Αυτό με τη σειρά του ενισχύει το κοινωνικό στίγμα που βιώνουν οι ομόφυλοι γονείς και τα παιδιά τους.[14] Πολλά παιδιά ομόφυλων γονέων, όπως και οι γονείς τους, βιώνουν διακρίσεις και στιγματισμό.[15] Σχεδόν τα μισά από τα παιδιά ομόφυλων γονέων έχουν βιώσει κάποια μορφή διάκρισης ή ομοφοβίας, πειράγματος, εκφοβισμού ή υποτιμητική γλώσσα σε σχέση με την οικογένειά τους, σωματική και σεξουαλική βία, από συνομηλίκους ή δασκάλους.[16]

Η έλλειψη αναγνώρισης ορισμένων οικογενειακών δομών και των σχέσεων γονέα-παιδιού μέσα σε αυτές έχει σημαντικές προεκτάσεις για τα παιδιά αυτών των οικογενειών. Η νομική αναγνώριση των γονέων γεννά ένα σύνολο δικαιωμάτων και υποχρεώσεων βάσει του νόμου που εξυπηρετούν την προστασία και τη διατήρηση των παιδιών. Τα παιδιά στα οποία δεν αναγνωρίζεται η σχέση του γονέα τους μπορεί να έχουν λιγότερα δικαιώματα από άλλα παιδιά στην κοινότητα. Για παράδειγμα, ο ομοφυλόφιλος γονέας μπορεί να μην έχει την εξουσία να λαμβάνει αποφάσεις σχετικά με την ιατρική περίθαλψη του παιδιού, συμπεριλαμβανομένης της αφαίρεσης ιστού και των μεταγγίσεων αίματος· να ορίσει διαθήκη κηδεμόνα για το παιδί· να κινήσει νομικές διαδικασίες για λογαριασμό του παιδιού· να λαμβάνει αποφάσεις ή να εκπληρώνει νομικές υποχρεώσεις σχετικά με τη σχολική φοίτηση ή την απασχόληση των παιδιών· να έχει το δικαίωμα να συμμετέχει σε ακροάσεις για την προστασία των παιδιών· ή να έχει το δικαίωμα να παρευρίσκετε εάν το παιδί ανακρίνεται από την αστυνομία. Επιπλέον, το παιδί μπορεί να μην είναι σε θέση να διεκδικήσει την περιουσία του συνγονέα εάν δεν έχει γίνει επαρκής πρόβλεψη σε διαθήκη.[17]

[13] Short, L (2007) '"It Makes the World of Difference": Benefits for Children of Lesbian Parents of Having their Parents Legally Recognised as their Parents' 3(1) Gay and Lesbian Issues and Psychology Review 5. σ. 10-11.

[14] Απόσπασμα από την ένορκη βεβαίωση ενός 12χρονου παιδιού, που κατατέθηκε σε μια καναδική υπόθεση: «Απλώς θέλω και οι δύο μαμάδες μου να αναγνωρίζονται ως μαμάδες μου. Οι περισσότεροι από τους φίλους μου δεν χρειάστηκε να σκεφτούν τέτοια πράγματα - θεωρούν δεδομένο ότι οι γονείς τους αναγνωρίζονται νομικά ως γονείς τους. Θα ήθελα η οικογένειά μου να αναγνωρίζεται με τον ίδιο τρόπο όπως κάθε άλλη οικογένεια, να μην αντιμετωπίζεται διαφορετικά επειδή και οι δύο γονείς μου είναι γυναίκες. … Θα βοηθούσε αν η κυβέρνηση και ο νόμος αναγνώριζαν ότι έχω δύο μαμάδες. Θα βοηθούσε περισσότερους ανθρώπους να καταλάβουν. Θα έκανε τη ζωή μου πιο εύκολη. Θέλω η οικογένειά μου να γίνει αποδεκτή και να συμπεριληφθεί, όπως και η οικογένεια όλων των άλλων» (MDR v Ontario (Deputy Registrar General), 2006).

[15] Mazrekaj, D., Jin, Y. Mental health of children with gender and sexual minority parents: a review and future directions. Humanit Soc Sci Commun 2023, 10: 509.
Alday-Mondaca C, Lay-Lisboa S. The Impact of Internalized Stigma on LGBT Parenting and the Importance of Health Care Structures: A Qualitative Study. Int J Environ Res Public Health. 2021 May 18;18(10):5373.

[16] Goldberg AE, Garcia R. Community Characteristics, Victimization, and Psychological Adjustment Among School-Aged Adopted Children With Lesbian, Gay, and Heterosexual Parents. Front Psychol. 2020 Mar 10;11:372.

[17] Allan, Sonia, Recognition of Same-Sex Parenting in Australia: South Australia, the Final Frontier? (September 29, 2011). Alternative Law Journal 2010, Vol. 35, No. 4. σ. 229.

Προκειμένου να συμμορφωθούν με την Διεθνή Σύμβαση για τα Δικαιώματα του Παιδιού – ιδίως, το άρθρο 3 (βέλτιστο συμφέρον) και το άρθρο 8 (σεβασμός της ταυτότητας και των οικογενειακών σχέσεων) – τα κράτη πρέπει να αναγνωρίζουν νομικά και τους δύο γονείς σε μια οικογένεια του ιδίου φύλου. Υπάρχουν διαφορετικά μοντέλα για το πώς μπορεί να επιτευχθεί αυτό. Για παράδειγμα, στην Αυστραλία αναγνωρίζεται η μη βιολογική μητέρα ενός παιδιού που συνελήφθη από ένα ζευγάρι του ίδιου φύλου ως γονέα[18] και προβλέπεται ότι το παιδί θα φέρει το όνομά της στο πιστοποιητικό γέννησης του.[1920] Το 2008, Family Law Act 1975 τροποποιήθηκε για να αναγνωρίσει και τις δύο μητέρες σε λεσβιακή σχέση ως νόμιμους γονείς ενός παιδιού που γεννήθηκε μέσω ART.[21] Για να διασφαλιστεί αυτό το καθεστώς, η μη βιολογική μητέρα πρέπει να έχει συναινέσει στη διαδικασία και να έχει ζήσει με τη μητέρα του τοκετού ως ζευγάρι σε γνήσια οικιακή βάση όταν πραγματοποιήθηκε. Σε αυτές τις περιπτώσεις, ο δότης σπέρματος δεν θα θεωρείται νόμιμος γονέας. Ωστόσο, σε ορισμένες πολιτείες η νομοθεσία διαφέρει για τους ομοφυλόφιλους άνδρες που επιλέγουν να κάνουν παιδί μέσω αλτρουιστικής παρένθετης μητρότητας. Σε αυτή την περίπτωση, η παρένθετη μητέρα θα θεωρείται νόμιμος γονέας εάν το ζευγάρι δεν: υιοθετεί το παιδί, ή υποβάλλει αίτηση για τη μεταβίβαση της γονικής μέριμνας από αυτήν στους εαυτούς τους σύμφωνα με το Family Law Act 1975. Εάν η αίτηση δεν εγκριθεί, το ζευγάρι μπορεί να ζητήσει εντολές γονικής μέριμνας (parenting orders) ή να υποβάλει αίτηση για υιοθεσία.

Οι Ηνωμένες Πολιτείες έχουν υιοθετήσει μια διαφορετική προσέγγιση, με πολλές Πολιτείες να επιτρέπουν σε μια μη βιολογική μητέρα να υποβάλει αίτηση για υιοθεσία από δεύτερο γονέα (second-parent adoption). Αυτή η διαδικασία επιτρέπει στη μη βιολογική μητέρα να υιοθετήσει ένα παιδί χωρίς η βιολογική μητέρα να υποχρεωθεί να εγκαταλείψει τα γονικά της δικαιώματα (κάτι που συμβαίνει στις υιοθεσίες που δεν ανήκουν στον δεύτερο γονέα).

Αν και το αποτέλεσμα και των δύο μοντέλων είναι το ίδιο –δηλαδή, η μη βιολογική μητέρα αναγνωρίζεται νομικά ως γονέας του παιδιού – οι διαδικασίες είναι πολύ διαφορετικές. Η υιοθεσία από δεύτερο γονέα είναι μια πολύ πιο επαχθής διαδικασία από την απλή εγγραφή της μη βιολογικής μητέρας που στο πιστοποιητικό γέννησης ενός παιδιού. Αυτό συμβαίνει επειδή η διαδικασία υιοθεσίας εμπλέκει τους γονείς σε μια μακρά διαδικασία που καταλήγει στην εμφάνιση των διαδίκων ενώπιον δικαστηρίου, με τον δικαστή να έχει την τελική εξουσία να εγκρίνει ή να μην εγκρίνει την υιοθεσία. Σαφώς, είναι προτιμότερο ο μη βιολογικός γονέας ενός παιδιού να αναγνωρίζεται νομικά χωρίς να χρειάζεται να ζητήσει την έγκριση των δικαστηρίων.

Από τα παραπάνω προκύπτει ότι τα βέλτιστα συμφέροντα ενός παιδιού που μεγαλώνει σε οικογένεια του ίδιου φύλου εξυπηρετούνται καλύτερα με τη διασφάλιση ότι η οικογένεια του παιδιού γίνεται σεβαστή και αναγνωρίζεται στα μάτια του νόμου. Αυτό απαιτεί από το κράτος να αναγνωρίσει δύο διαφορετικά, αλλά συγγενικά δικαιώματα – συγκεκριμένα, το δικαίωμα των γονέων του ίδιου φύλου ενός παιδιού να παντρεύονται και το δικαίωμα ενός παιδιού να αναγνωρίζεται νομικά η σχέση του με τον μη βιολογικό γονέα του.

[18]Art. 13 of the Status of Children Act 1974 (Vic). https://www.legislation.vic.gov.au/in-force/acts/status-children-act-1974/044

[19] 17A of the Births, Deaths and Marriages Registration Act 1996 (Vic). https://www.legislation.vic.gov.au/in-force/acts/births-deaths-and-marriages-registration-act-1996/039

[20] 5DA Rule relating to parentage - female de facto partners. https://legislation.nt.gov.au/en/Legislation/STATUS-OF-CHILDREN-ACT-1978

[21] Η Τεχνολογία Υποβοηθούμενης Αναπαραγωγής.

Διακρίσεις λόγω του σεξουαλικού προσανατολισμού των γονέων ενός παιδιού

Μια θεμελιώδης αρχή που στηρίζει όλα τα δικαιώματα που διατυπώνονται στη Διεθνή Σύμβαση για τα Δικαιώματα του Παιδιού είναι η μη διάκριση. Το «other status» του άρθρου 2 περιλαμβάνει αναπηρία, ηλικία, οικογενειακή ή οικογενειακή κατάσταση και σεξουαλικό προσανατολισμό. Επομένως το άρθρο 2 μπορεί να έχει ως αποτέλεσμα την απαγόρευση των διακρίσεων σε βάρος των παιδιών με βάση τα χαρακτηριστικά ή τις ιδιότητες ενός γονέα, και αυτό περιλαμβάνει τον σεξουαλικό τους προσανατολισμό.[22] Συνεπώς, ένα κράτος πρέπει να προστατεύει τα άτομα τόσο από άμεσες όσο και από έμμεσες διακρίσεις.[23] Άμεση διάκριση συμβαίνει όταν ένα άτομο τυγχάνει λιγότερο ευνοϊκής μεταχείρισης από ένα άλλο άτομο σε παρόμοια κατάσταση για έναν λόγο που σχετίζεται με έναν απαγορευμένο λόγο. Έμμεση διάκριση συμβαίνει όταν ένας νόμος, μια πολιτική ή μια πρακτική φαίνεται ουδέτερη εκ πρώτης όψεως, αλλά στην πραγματικότητα έχει δυσανάλογο αντίκτυπο στην άσκηση ενός δικαιώματος από ένα άτομο βάσει απαγορευμένου λόγου διάκρισης. Για παράδειγμα, ένας νόμος που προβλέπει ότι ένα παιδί μπορεί να αξιώσει αποζημίωση για το θάνατο ενός γονέα εισάγει έμμεσα διακρίσεις σε βάρος ενός παιδιού του οποίου ο μη βιολογικός γονέας σκοτώθηκε, εάν το παιδί αυτό βρίσκεται σε δικαιοδοσία που δεν αναγνωρίζει οικογένειες ομοφυλόφιλων. Ομοίως, ένα πρόγραμμα ασφάλισης υγείας που χρηματοδοτείται από τον εργοδότη που καλύπτει τα παιδιά ενός εργαζομένου θα εισάγει έμμεσα διακρίσεις σε βάρος ενός παιδιού που δεν αναγνωρίζεται νομικά ως τέκνο του μη βιολογικού γονέα, αποκλείοντας αυτό το παιδί από το σύστημα.

Υπάρχουν και άλλοι τομείς όπου μπορεί να προκύψουν έμμεσες διακρίσεις κατά των παιδιών με βάση τον σεξουαλικό προσανατολισμό των γονέων ενός παιδιού, συμπεριλαμβανομένων των κληρονομικών δικαιωμάτων, της μεταναστευτικής νομοθεσίας, της αβεβαιότητας ως προς την επιμέλεια σε περίπτωση θανάτου του βιολογικού γονέα, των φορολογικών και κρατικών παροχών και ζητήματα που σχετίζονται με την υποστήριξη και την επιμέλεια/επίσκεψη των παιδιών εάν οι γονείς του παιδιού χωρίσουν. Προκειμένου να συμμορφωθούν με την εντολή μη διάκρισης στη Σύμβαση, τα κράτη πρέπει να θεσπίσουν νομοθεσία που να διασφαλίζει ότι τα δικαιώματα και τα οφέλη[24] που προκύπτουν στα παιδιά των παντρεμένων ζευγαριών θα προκύψουν και στα παιδιά των ομόφυλων οικογενειών όπου οι γονείς απαγορεύεται νομικά να παντρευτούν. Οι διακρίσεις σε βάρος των παιδιών με βάση τον σεξουαλικό προσανατολισμό των γονέων τους δεν περιορίζονται σε οικονομικά ζητήματα. Μία από τις επιπτώσεις των νόμων που επιβάλλουν τις διακρίσεις είναι ότι στέλνουν ένα μήνυμα στην κοινωνία ότι οι διακρίσεις είναι επιτρεπτές.

Η πιθανότητα διάκρισης δεν μπορεί να χρησιμοποιηθεί ως θεμιτό επιχείρημα για τον περιορισμό της απόλαυσης των δικαιωμάτων των ατόμων. Αυτό τονίστηκε από το Διαμερικανικό Δικαστήριο Ανθρωπίνων Δικαιωμάτων

[22] UNICEF Position Paper: Eliminating Discrimination Against Children and Parents Based on Sexual Orientation and/or Gender Identity.

[23] General comment No. 20: Non-discrimination in economic, social and cultural rights (art. 2, para. 2, of the International Covenant on Economic, Social and Cultural Rights).

[24] General comment No. 14 (2013) **op.cit**., παρ. 41.

(IACHR) όταν δήλωσε ξεκάθαρα στην υπόθεση Atala v. Chile[25] ότι δυνητικό κοινωνικό στίγμα λόγω του σεξουαλικού προσανατολισμού της μητέρας ή του πατέρα δεν μπορεί να θεωρηθεί βάσιμη βλάβη (valid harm) για τους σκοπούς του προσδιορισμού του συμφέροντος του παιδιού. Εάν οι δικαστές που κρίνουν τέτοιες υποθέσεις επιβεβαιώσουν την ύπαρξη κοινωνικών διακρίσεων, είναι εντελώς απαράδεκτο να νομιμοποιηθεί αυτή η διάκριση με το επιχείρημα της προστασίας του βέλτιστου συμφέροντος του παιδιού.

Οι νόμοι που αναγνωρίζουν ότι όλα τα παιδιά πρέπει να έχουν ίση μεταχείριση, ανεξάρτητα από τον σεξουαλικό προσανατολισμό των γονέων τους, είναι ουσιαστικής σημασίας για τη δημιουργία μιας κοινωνίας απαλλαγμένης από διακρίσεις και προκαταλήψεις κατά των παιδιών που μεγαλώνουν σε οικογένειες ομοφυλόφιλων. Η αποτυχία να διασφαλιστεί ότι υπάρχει ένα τέτοιο νομοθετικό πλαίσιο αφήνει τα παιδιά των ομόφυλων οικογενειών σε ευάλωτη κατάσταση δυνητικά εκτεθειμένα σε πρακτικές που εισάγουν διακρίσεις από μέλη μιας κοινωνίας που αισθάνονται δικαιολογημένα να το κάνουν, επειδή ο νόμος επιβάλλει τέτοια συμπεριφορά.[26] Απαιτείται σημαντική νομοθετική μεταρρύθμιση σε πολλές δικαιοδοσίες σε όλο τον κόσμο, προκειμένου να διασφαλιστεί ότι η κοινωνία ως σύνολο σέβεται και προωθεί τα δικαιώματα και την ευημερία των παιδιών που μεγαλώνουν σε οικογένειες ομοφυλόφιλων.

Το βέλτιστο συμφέρον του εμβρύου

Δεν υπάρχει νομική υποστήριξη για να θεωρηθεί ότι τα κράτη έχουν υποχρέωση να μεταχειρίζονται τα αγέννητα έμβρυα ως πρόσωπα βάσει του νόμου.

Οι εθνικοί νόμοι στις διάφορες χώρες παρουσιάζουν σημαντικές διαφορές όσον αφορά το ζήτημα της έναρξης της ζωής και τον ορισμό της προσωπικότητας.[27] Κάθε φορά που οι δικαιοδοσίες ή τα διεθνή κείμενα θεσπίζουν κανόνες για την προστασία του ανθρώπινου εμβρύου, αποδέχονται ότι η προστασία του είναι απαραίτητη, αλλά απέχουν να μπουν στη συζήτηση για το ηθικό και νομικό καθεστώς του. *The Working Party on the Protection of the Human Embryo and Foetus by the Steering Committee on Bioethics*, στην έκθεση του 2003, κατέληξε στο συμπέρασμα ότι ο ορισμός της κατάστασης του εμβρύου παραμένει ένας τομέας όπου συναντώνται θεμελιώδεις διαφορές, με βάση ισχυρά επιχειρήματα. Αυτές οι διαφορές αποτελούν σε μεγάλο βαθμό τη βάση των περισσότερων αποκλίσεων σχετικά με τα άλλα ζητήματα που σχετίζονται με την προστασία του εμβρύου in vitro.[28] Παραδείγματος χάριν, ο πολυπολιτισμικός χαρακτήρας της ΕΕ δυσκολεύει τα θεσμικά της όργανα να συμφωνήσουν στο φιλοσοφικό και ηθι-

25 https://www.corteidh.or.cr/docs/casos/articulos/seriec_239_ing.pdf
Η Ατάλα είχε χάσει την επιμέλεια των κορών της λόγω της ομοφυλοφιλίας της, αλλά η IACHR ακύρωσε την απόφαση του δικαστηρίου της Χιλής και διαπίστωσε παραβίαση της ιδιωτικής της ζωής.

26 Parliamentary Assembly. Report | Doc. 14620 | 21 September 2018. Private and family life: achieving equality regardless of sexual orientation.

27 EGE Opinion n°12 - Ethical aspects of research involving the use of human embryo in the context of the 5th framework programme.

28 The Protection of The Human Embryo in Vitro. Report by the Working Party on the Protection of the Human Embryo and Fetus (CDBI-CO-GT3). https://www.coe.int/t/dg3/healthbioethic/activities/04_human_embryo_and_foetus_en/CDBI-CO-GT3(2003)13E.pdf

κό ζήτημα κατά τη θέσπιση κανόνων για την έρευνα που επηρεάζει το έμβρυο.[29]

Σε αντίθεση με το άρθρο 4 της Αμερικανικής Σύμβασης για τα Ανθρώπινα Δικαιώματα, το οποίο προβλέπει ότι το δικαίωμα στη ζωή πρέπει να προστατεύεται γενικά, από τη στιγμή της σύλληψης,[30] το άρθρο 2 της Σύμβασης σιωπά ως προς τους χρονικούς περιορισμούς του δικαιώματος στη ζωή και, ειδικότερα, δεν ορίζει «όλοι» («toute personne») των οποίων η ζωή προστατεύεται από τη Σύμβαση[31]. Το Δικαστήριο, λαμβάνοντας υπόψη την απουσία ευρωπαϊκής συναίνεσης σχετικά με τον επιστημονικό και νομικό ορισμό της αρχής της ζωής, έκρινε ότι το ζήτημα του πότε αρχίζει το δικαίωμα στη ζωή εμπίπτει στο περιθώριο εκτίμησης που γενικά θεωρεί ότι τα κράτη πρέπει να απολαμβάνουν αυτή τη σφαίρα.[32] Στην υπόθεση Vo v. France, όπου η προσφεύγουσα χρειάστηκε να υποβληθεί σε θεραπευτική άμβλωση ως αποτέλεσμα ιατρικής αμέλειας, το Δικαστήριο έκρινε περιττό να εξετάσει εάν ο απότομος τερματισμός της εγκυμοσύνης της προσφεύγουσα εμπίπτει στο πεδίο εφαρμογής του άρθρου 2, δεδομένου ότι, ακόμη και αν υποτεθεί ότι η διάταξη αυτή ίσχυε, δεν υπήρξε παράλειψη εκ μέρους του εναγόμενου κράτους να συμμορφωθεί με τις απαιτήσεις που αφορούν τη διατήρηση της ζωής στον τομέα της δημόσιας υγείας.[33] Στην υπόθεση Evans v. the United Kingdom, όπου η προσφεύγουσα παραπονέθηκε ότι η βρετανική νομοθεσία εξουσιοδότησε τον πρώην σύντροφό της να αποσύρει τη συναίνεση του για την αποθήκευση και τη χρήση από κοινού δημιουργηθέντων εμβρύων, το Δικαστήριο διαπίστωσε ότι, σύμφωνα με το αγγλικό δίκαιο, ένα έμβρυο δεν έχει ανεξάρτητα δικαιώματα ή συμφέροντα και δεν μπορούσαν να διεκδικήσουν – ή να έχουν διεκδικήσει για λογαριασμό του – δικαίωμα στη ζωή σύμφωνα με το άρθρο 2 και ότι επομένως τα εν λόγω έμβρυα δεν είχαν δικαίωμα στη ζωή κατά την έννοια του άρθρου 2.[34]

Το Ευρωπαϊκό Δικαστήριο Ανθρωπίνων Δικαιωμάτων έχει την τάση να αποφεύγει να καταλήξει σε συμπέρασμα σχετικά με το δικαίωμα στη ζωή του αγέννητου παιδιού. Η προσέγγιση ενώπιον της υπόθεσης Vo v. France ήταν να αρνηθεί «να αποκλείσει κατηγορηματικά την πιθανή εφαρμογή του άρθρου 2 στο αγέννητο έμβρυο», αλλά ταυτόχρονα να αρνηθεί να εκχωρήσει «απόλυτο δικαίωμα στη ζωή για το έμβρυο…[ως αποτέλεσμα] σιωπηρών περιορισμών για την προστασία της ζωής και της υγείας της εγκύου». Το ΕΔΔΑ δήλωσε ότι η προηγούμενη νομολογία του έχει ενημερωθεί από μια σαφή επιθυμία εξισορρόπησης και αυτό φαίνεται πράγματι να ισχύει.

Τα δικαστήρια δεν φαίνεται να είναι καλά προετοιμασμένα για την επίλυση τέτοιας φύσης ζητημάτων που είναι τόσο αμφιλεγόμενα. Για παράδειγμα, η Ευρωπαϊκή Επιτροπή των Ανθρωπίνων Δικαιωμάτων υιοθέτησε μια πολύ προσεκτική στάση στο θέμα της κατάστασης του εμβρύου, διότι αυτό θα συνεπαγόταν λήψη απόφασης για ζητήματα άμβλωσης και άλλων ανα-

[29] *Ibidem.*

[30] Το Διαμερικανικό Δικαστήριο Ανθρωπίνων Δικαιωμάτων, με τη σειρά του, καταλήγει στο συμπέρασμα ότι δεν είναι παραδεκτό χορηγεί την ιδιότητα του ατόμου στο έμβρυο. Summary Newsletter of the Judgments issued by the Inter American Court1 during its 97th Regular Period of Sessions, p. 17-18.

[31] Vo v. France, par. 75.

[32] **Idem**, par. 82.

[33] **Idem**, par. 85. Παρόμοια προσέγγιση Mehmet Şentürk and Bekir Şentürk v. Turkey, par. 109.

[34] Evans v. the United Kingdom, par. 54-56.

παραγωγικών δικαιωμάτων.[35] Απέφυγε να αποφασίσει εάν ένα αγέννητο παιδί πρέπει να θεωρείται «ζωή» κατά την έννοια του άρθρου 2 της ΕΣΔΑ, το οποίο δεν επεκτείνει ρητά το δικαίωμα ζωής στο αγέννητο παιδί. Η λογική συνέπεια ότι αν ένα έμβρυο δεν είναι άτομο, δεν μπορεί να έχει το βέλτιστο συμφέρον.

Η άποψη ότι τα αγέννητα έμβρυα είναι πρόσωπα που προστατεύονται από το άρθρο 2 θα ήταν ασυμβίβαστη με τη νομολογία του ευρωπαϊκού συστήματος ανθρωπίνων δικαιωμάτων, τους νόμους και τη νομολογία των συμβαλλόμενων μερών, τα διεθνή και περιφερειακά πρότυπα και τη νομολογία των εθνικών δικαστηρίων σε όλο τον κόσμο. Επιπλέον, η επέκταση των δικαιωμάτων του εμβρύου θα είχε σοβαρές επιπτώσεις για τα ανθρώπινα δικαιώματα των γυναικών στην ιδιωτική ζωή, τη ζωή και την ασφάλεια του ατόμου και τη μη διάκριση.

Η αναγνώριση της ιδιότητας του εμβρύου ως προσώπου βάσει του νόμου θα έρχονταν σε αντίθεση με τη νομολογία του ευρωπαϊκού συστήματος ανθρωπίνων δικαιωμάτων, συμπεριλαμβανομένου του ΕΔΔΑ.[36] Στην υπόθεση Paton v. U.K., ένας σύζυγος στον οποίο είχε αρνηθεί την έκδοση διαταγής για να εμποδίσει την έγκυο γυναίκα του να τερματίσει την εγκυμοσύνη της ισχυρίστηκε ότι παραβιάστηκε το δικαίωμα του εμβρύου στο Άρθρο 2 στη ζωή. Κρίθηκε ότι το δικαίωμα του εμβρύου στη ζωή δεν υπερτερούσε των συμφερόντων της εγκύου επειδή η χρήση της λέξης «όλοι» στο Άρθρο 2 και σε άλλα σημεία της Σύμβασης δεν περιλάμβανε τα έμβρυα. Στην Boso v. Italy, το Δικαστήριο δεν διαπίστωσε παραβίαση του άρθρου 2, σημειώνοντας ότι η εν λόγω άμβλωση έγινε σύμφωνα με την ιταλική νομοθεσία, η οποία επιτυγχάνει μια δίκαιη ισορροπία μεταξύ του συμφέροντος της γυναίκας και του συμφέροντος του κράτους για την προστασία του εμβρύου.

Η έννομη τάξη αναγνωρίζει την ύπαρξη του εμβρύου ως έννομου περιουσιακού στοιχείου που απαιτεί έννομη προστασία και όχι ως δικαιούχου, αφού αν δεν συνέβαινε η προστασία του εμβρύου θα έπρεπε να εξισωθεί με την προστασία της μητέρας. Προκειμένου να αναγνωριστεί το έμβρυο ως κάτοχος συνταγματικού δικαιώματος, δεν θα ήταν καθοριστικό να εμπλέκεται σε ένα πρόσωπο, η απλή καταγωγή από τον άνθρωπο, καθώς αυτή η άποψη μπορεί εύκολα να οδηγήσει σε παρεξηγήσεις. Το άτομο είναι δικαιούχος λόγω της συμμετοχής του και της αποφασιστικότητάς του από τις κοινωνικές σχέσεις, το έμβρυο δεν μπορεί να συμπεριληφθεί σε αυτές και επομένως δεν προστατεύεται ως δικαιούχος. Ωστόσο, μέσω αυτών των κοινωνικών σχέσεων η ζωή του αγέννητου παιδιού προστατεύεται ως αντικείμενο δικαιώματος, ενσωματώνει το δικαίωμα της μητέρας σε οικογένεια, αυτοδιάθεση, ελεύθερη ανάπτυξη προσωπικότητας. Το άτομο είναι η επίσημη, τελική, φυσική και αποτελεσματική αιτία και αρχή για την ανάπτυξη και λειτουργία των σταδίων της ανθρώπινης υλικής και ανθρώπινης ψυχικής κατάστασης. Τέλος, το άτομο είναι το κοινωνικό και λογικό

[35] EComHR, Bruggemann and Scheuten v. Federal Republic of Germany, app. no. No. 6959/75 (1981) 3 EHRR 244, par. 60.

[36] Το ΕΔΔΑ και η Ευρωπαϊκή Επιτροπή Ανθρωπίνων Δικαιωμάτων (the European Commission on Human Rights (EComHR)) αποφάσισαν, σε μια σειρά υποθέσεων που αφορούν την άμβλωση, ότι «ακόμη και αν υποτεθεί ότι» το έμβρυο προστατεύεται από το άρθρο 2, οποιοδήποτε τέτοιο δικαίωμα πρέπει να περιορίζεται σύμφωνα με τα δικαιώματα των μητέρα. Αυτό επαναδιατυπώθηκε στην Vo v. France, αλλά βοήθησε ελάχιστα καθώς, σε εκείνη την περίπτωση τα συμφέροντα τόσο της μητέρας όσο και του παιδιού συνέπιπταν.

άτομο που διεκδικεί φυσικά προσωπικότητα για τον εαυτό του και που τη μεταδίδει σε άλλους ανθρώπους. Με άλλα λόγια, η προσωπικότητα δεν συνεπάγεται μόνο την ύπαρξη μιας παθητικής ικανότητας να αποκτά συνείδηση και λογική, αλλά μάλλον μια ενεργητική ικανότητα να προκαλεί στον εαυτό της την ίδια την ύπαρξη και την ανάπτυξη των ατομικών της δυνατοτήτων, σωματικών και ψυχικών.[37] Επειδή λοιπόν η ύπαρξη του εμβρύου δεν είναι ούτε ανεξάρτητη ούτε πληροί τις παραπάνω προϋποθέσεις, προστατεύεται έμμεσα μέσω της μητέρας του. Είναι μια δυνητική ζωή[38] που δεν μπορεί να θεωρηθεί ίση με τις ζωές ατόμων που έχουν ήδη γεννηθεί και συμμετέχουν στην κοινωνία, επομένως η προστασία που του παρέχεται είναι έμμεσα συνταγματική αλλά όχι απόλυτη.

Ένα ζήτημα αν το έμβρυο έχει την προστασία του δικαιώματος στη ζωή είναι αυτό της βιωσιμότητάς του. Δεν υπάρχει αμφιβολία ότι το γονιμοποιημένο ωάριο της επόμενης ημέρας είναι επίσης κάτοχος του δικαιώματος όπως και το σχηματισμένο έμβρυο των τελευταίων μηνών της εγκυμοσύνης. Ωστόσο, το γεγονός ότι επιτρέπεται να καταστραφεί από το χάπι της επόμενης ημέρας δείχνει ακριβώς αυτό το όριο, ότι πριν το έμβρυο γίνει βιώσιμο από μόνο του, δεν μπορεί να θεωρηθεί ως υποκείμενο δικαιωμάτων. Είναι γενικά αποδεκτό ότι ένα έμβρυο 28 εβδομάδων που δεν χρειάζεται ανάνηψη είναι βιώσιμο. Ωστόσο, σύμφωνα με τον ΠΟΥ, η βιωσιμότητα του εμβρύου είναι δυνατή μετά από 20 εβδομάδες εμβρυϊκής ζωής (22 εβδομάδες αμηνόρροιας).[39]

Τα συμφέροντα του εμβρύου στη ζωή με την αναγνώριση του κριτηρίου της βιωσιμότητας δεν πρέπει σε καμία περίπτωση να θεωρηθεί ότι υπερισχύουν ή ακόμη και ότι δεσμεύουν τα δικαιώματα της μητέρας στην απόλυτη προστασία της ζωής και της υγείας της. Είναι αποδεκτό ότι η νομική κατανομή του δικαιώματος του εμβρύου στη ζωή περιορίζεται σταδιακά στα τελευταία στάδια της εμβρυϊκής ζωής σε σχέση με την ανάπτυξη του εμβρύου κατά την έναρξη της εγκυμοσύνης. Εφόσον το έμβρυο αποκτά την ικανότητα για αυτόνομη ύπαρξη, δικαιούται σταδιακά ανάλογη νομική και ηθική προστασία. Το κριτήριο της βιωσιμότητας του εμβρύου είναι σημαντικό, επειδή τη στιγμή της βιωσιμότητας του εμβρύου, ο εγκέφαλός του έχει αναπτυχθεί αρκετά ώστε να είναι πλέον διαθέσιμη μια βασική ικανότητα να το αισθάνεται, ώστε να μπορεί να υποστηριχθεί ότι το έμβρυο έχει τα δικά του συμφέροντα να υπάρχει. Αλλά αυτό δεν σημαίνει ότι από αυτό το σημείο και μετά αναγνωρίζεται ως πρόσωπο με αντίστοιχη υποχρέωση προστασίας του από το Δημόσιο. Δεύτερον, επειδή πριν από το σημείο της βιωσιμότητας του εμβρύου, οι έγκυες γυναίκες έχουν ένα ευρύ περιθώριο να αποφασίσουν αν θα συνεχίσουν ή θα διακόψουν την εγκυμοσύνη τους.

Εάν το έμβρυο δεν θεωρείται άτομο, δεν είναι παιδί που μπορεί να έχει δικαιώματα που προβλέπονται στη Διεθνή Σύμβαση για τα Δικαιώματα του Παιδιού. Κατά συνέπεια, το άρθρο

[37] Barry L. R. Medical Ethics: essays on abortion and euthanasia, American University Studies. 1989.

[38] Η προσωπικότητα του εμβρύου, ως αγέννητου ατόμου, δεν είναι άμεσα εμφανής, αφού η ζωή σε τόσο πρώιμο στάδιο δεν εκδηλώνεται με λειτουργίες που εκδηλώνονται σε άτομα που έχουν ήδη γεννηθεί. Οι λειτουργίες που εκτελεί το έμβρυο είναι φυσικές και χαρακτηριστικές για άτομα που κινούνται προς την πλήρη ωριμότητα.

[39] P. Lefèvre, F. Beauthier, J.-P. Beauthier, Anthropology: Forensic Anthropology and Childhood, Editor(s): Jason Payne-James, Roger W. Byard, Encyclopedia of Forensic and Legal Medicine (Second Edition), Elsevier, 2016, Pages 183-188.

3, σύμφωνα με το οποίο το βέλτιστο συμφέρον του παιδιού τίθεται σε πρωταρχική σημασία, δεν μπορεί να εφαρμόζεται σε ζητήματα που προκύπτουν πριν από τη γέννηση παιδιού. Ωστόσο, ένας νομοθέτης μπορεί να φροντίσει για το βέλτιστο συμφέρον ενός παιδιού που δεν έχει ακόμη γεννηθεί, π.χ. του nasciturus, υιοθετώντας διατάξεις που ισχύουν για αυτό κατά την περίοδο κύησης, αν και η πραγματική τους ισχύς αρχίζει μετά τη γέννησή του – πρόκειται για το πλάσμα δικαίου. Ο νόμος προστατεύει τις δυνατότητες ζωής που αντιπροσωπεύει το έμβρυο, αλλά όχι ένα παιδί. Έτσι, το έμβρυο σε περίπτωση παρένθετης μητρότητας δεν έχει τα βέλτιστα συμφέροντα που θα πρέπει να προστατεύονται πριν από τη γέννηση.

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Πρωτότυπη Εργασία

Insects in Scientific Research: A Philosophical Examination through the Lens of the 3Rs

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Abstract

This essay examines the ethical implications of using insects in scientific research through the framework of the 3Rs—Replacement, Reduction, and Refinement. Historically, ethical considerations in research have focused on vertebrates, but increasing evidence suggests that insects may possess more complex cognitive and sensory capacities than previously thought, raising moral questions about their treatment.

The principle of Replacement is discussed in relation to alternative methods such as in silico models, in vitro systems, and biomimetics, which offer promising ways to reduce the reliance on live insects. However, these alternatives are not yet advanced enough to fully replicate the complexity of biological processes in insects. Reduction, which aims to minimize the number of animals used in research, requires more precise statistical techniques and better experimental design to balance ethical concerns with scientific rigor. Finally, Refinement emphasizes minimizing suffering and improving welfare, including the use of anesthesia and appropriate euthanasia techniques, although research into insect welfare and euthanasia methods remains limited.

Through an analysis of utilitarianism, deontological ethics, and virtue ethics, this essay argues that ethical considerations must extend to insects. Despite their differences from vertebrates, the 3Rs should guide insect research to reduce harm and promote responsible scientific inquiry.

Keywords: Insect research ethics, 3Rs (Replacement, Reduction, Refinement), Animal welfare, Sentience and suffering.

Τα έντομα στην επιστημονική έρευνα: μια φιλοσοφική προσέγγιση υπό το πρίσμα των 3Rs

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Περίληψη

Η παρούσα εργασία εξετάζει τις ηθικές προεκτάσεις της χρήσεως εντόμων στην επιστημονική έρευνα υπό το πρίσμα των 3Rs—Αντικατάσταση (Replacement), Μείωση (Reduction) και Βελτίωση (Refinement). Ενώ οι ηθικές συζητήσεις στην επιστημονική έρευνα έχουν επικεντρωθεί κυρίως στα σπονδυλωτά, όλο και περισσότερα δεδομένα δείχνουν ότι τα έντομα διαθέτουν πιο σύνθετες γνωστικές και αισθητηριακές ικανότητες από ό,τι θεωρούνταν μέχρι πρότινος. Επομένως, προκύπτουν σοβαρά ηθικά ζητήματα για την ορθή διαχείρισή τους στην έρευνα.
Η Αντικατάσταση (Replacement) εξετάζεται μέσα από εναλλακτικές μεθόδους, όπως μοντέλα in silico, συστήματα in vitro και βιομιμητική, που προσφέρουν λύσεις για τον περιορισμό της εξαρτήσεως από ζώντα έντομα. Εν τούτοις, οι μέθοδοι αυτοί δεν έχουν ακόμη εξελιχθεί προς την πλήρη αντικατάσταση των βιολογικών διεργασιών των εντόμων. Η Μείωση (Reduction) στοχεύει στον περιορισμό του αριθμού των εντόμων που χρησιμοποιούνται στην έρευνα, αξιοποιόντας βελτιωμένες στατιστικές τεχνικές και πειραματικό σχεδιασμό. Τέλος, η Βελτίωση (Refinement) επικεντρώνεται στην ελαχιστοποίηση του πόνου και στην ευζωία των εντόμων, όπως με τη χρήση αναισθησίας και κατάλληλων μεθόδων ευθανασίας, αν και η έρευνα στον τομέα αυτόν παραμένει περιορισμένη.
Μέσα από μια ανάλυση του ωφελιμισμού (utilitarianism), της δεοντολογικής ηθικής (deontological ethics) και της αρεταϊκής ηθικής (virtue ethics), η παρούσα μελέτη υποστηρίζει οτι οι ηθικές εκτιμήσεις πρέπει να επεκταθούν και στα έντομα. Παρ' όλο που διαφέρουν από τα σπονδυλωτά, η εφαρμογή των 3Rs μπορεί να περιορίσει την επιβάρυνση, και να συμβάλει σε μια πιο υπεύθυνη επιστημνική έρευνα.

Keywords: Ηθικὴ της έρευνας με έντομα, 3Rs (Αντικατάσταση, Μείωση, Βελτίωση), ευζωία ζώων, αισθαντικότητα και πόνος.

1. Introduction

In scientific research, the ethical treatment of animals has been governed by the principles of Replacement, Reduction, and Refinement (the 3Rs). These principles aim to minimize the use of animals and to mitigate harm where their use is necessary. However, most discussions about the ethical treatment of animals in research focus on vertebrates, often overlooking invertebrates, particularly insects.

As insect research expands, it is crucial to ask: Should insects be afforded the same ethical consideration as vertebrates under the 3Rs framework? This essay explores the ethics of using insects in scientific research and how the 3Rs can or should apply to them. Drawing on ethical theories like utilitarianism, deontology, and virtue ethics, this paper argues that while insects do not evoke the same moral urgency as vertebrates, the ethical considerations inherent in the 3Rs should extend to insect research. This extension requires a reevaluation of the 3Rs, acknowledging the unique biological and cognitive characteristics of insects. By examining Replacement, Reduction, and Refinement in the context of insects, this essay contributes to a growing debate on how to responsibly and ethically conduct research involving invertebrate species.

2. Historical and Scientific Background

The 3Rs framework was first proposed in 1959 by William Russell and Rex Burch in their book The Principles of Humane Experimental Technique.[1] It was introduced as a guideline for ethical scientific research, emphasizing the need to respect and minimize harm to animals used in experiments. The principles of Replacement, Reduction, and Refinement were created to help researchers make decisions that would reduce the ethical cost of using animals in experiments.

Russell and Burch originally defined these principles as follows:

- Replacement: "Any scientific method employing non-sentient material (*sic*) which may in the history of animal experimentation replace methods with use conscious living vertebrates."
- Reduction: A means of minimizing, other than by replacement, "the number of animals used to obtain information of a given amount and precision."
- Refinement: Measures leading to "a decrease in the incidence or severity of inhumane procedures applied to those animals which have to be used."

From the definition alone, it is clear that insects (and other invertebrates) appear to be classified as non-sentient material, and based on the principle of replacement, they are suggested as alternatives to vertebrate animals. Indeed, the authors themselves mention that non-sentient material includes higher plants, microorganisms, and the more degenerate metazoan endoparasites, in which the nervous and sensory systems are almost atrophied, while free-living metazoan invertebrates (such as insects) were

[1] Russell WMS, Burch RL. The principles of humane experimental technique. Universities Federation for Animal Welfare, Wheathampstead (UK), 1959. (as reprinted 1992).

arbitrarily excluded from subjects of humanitarian concern:[2]

> A more difficult question arises when we consider the free-living metazoan invertebrates. We have arbitrarily excluded them from consideration as objects of humanitarian concern. It remains to consider them in the light of possible substitutes for vertebrate subjects. Such a procedure may be called comparative substitution.

However, this arbitrary exclusion is not related to the possibility that they might feel pain but primarily to the lack of research on similarities with humans.

3. Insects in Research

Most animal research involves insects or other invertebrates, as they offer numerous advantages over vertebrates, such as a relatively short life cycle, high reproductive rates, simple anatomy, and the ease with which large numbers of individuals can be studied.[3] Additionally, their use is significantly more economical, as thousands of invertebrates can easily be housed in a small laboratory.[4] The availability of large numbers of insects allows for statistically robust experiments and replicable studies, which are crucial for scientific validity. Research on invertebrates concerns either their direct impact on humans, such as the destruction of crops or the transmission of diseases, or their use as models for research related to genetics or physiology.

The use of invertebrates as models for human genetics and diseases in laboratory research dates to the late 19th century. Geneticist William E. Castle was one of the first to publish studies based on invertebrates: he used the ascidian *Ciona intestinalis* as a research model and published his dissertation on the species in 1896. Castle was also the first to use insects in his research: he conducted a long series of experiments (1901–1906) on inbreeding and outbreeding in the fruit fly *Drosophila melanogaster* (Diptera, Drosophilidae), and together with Charles Woodworth, he received recognition from Thomas H. Morgan, who was awarded the Nobel Prize in 1933 for his discoveries concerning the role of chromosomes in heredity. Since then, the fly *D. melanogaster* has been the most widely used animal in genetic studies. Apart from its ease of reproduction and cultivation, the molecular biology of this species is relatively simple, and a vast variety of mutant and genetically modified flies have been developed.[5] The genetics of flies has been crucial to the study of development, the cell cycle, ethology, and neuroscience. The similarities in the basic biochemistry of all animals allow us to use flies as simple models to investigate the

[2] *idem.* p. 69.

[3] Jans K, Lüersen K, Rimbach G. *Drosophila melanogaster* as a Model Organism to Study Lithium and Boron Bioactivity. Int J Mol Sc 2021, 22:11710.

[4] Andre RG, Wirtz RA, Das YT. Insect Models for Biomedical Research. In: Woodhead AD (Ed) Non-mammalian Animal Models for Biomedical Research. CRC Press, Boca Raton, 1989:61-72.

[5] Dietzl G, Chen D, Schnorrer F, Su KC, Barinova Y, Fellner M, Gasser B, Kinsey K, Oppel S, Scheiblauer S, Couto A, Marra V, Keleman K, Dickson, BJ. A genome-wide transgenic RNAi library for conditional gene inactivation in *Drosophila*. Nature 2007, 448(7150):151-156.

genetics of various conditions, such as heart disease and neurodegenerative diseases.[6]

Apart from the fruit fly *D. melanogaster*, the greater wax moth *Galleria mellonella* (Lepidoptera, Pyralidae),[7] the silkworm *Bombyx mori* (Lepidoptera, Bombycidae),[8] and the red flour beetle *Tribolium castaneum* (Coleoptera, Tenebrioidae)[9] are used as laboratory animals in many studies. Other insects less frequently used as laboratory animals include the tobacco hornworm moth *Manduca sexta* (Lepidoptera, Sphingidae),[10] the seven-spotted ladybird *Coccinella septempunctata* (Coleoptera, Coccinellidae),[11] the yellow mealworm beetle *Tenebrio molitor* (Coleoptera, Tenebrionidae),[12] the scorpionfly *Panorpa cognata* (Mecoptera, Panorpidae),[13] as well as various species of mosquitoes and grasshoppers.[14] Their large numbers and the perception that they are less capable of suffering compared to vertebrates have made insects an ethically less controversial choice for research. However, this assumption raises important questions about their moral status and whether the 3Rs should apply equally to them.

4. Ethical Gaps in Considering Insects

Despite the growing use of insects in research, they are often excluded from the scope of most animal welfare regulations. The European Union, for instance, includes cephalopods like octopuses in its regulations for the protection of animals used for scientific purposes, but insects remain largely unprotected.[15] This gap presents an ethical challenge. While vertebrates are granted some form of moral consideration due to their capacity to suffer, insects are often excluded based on assumptions about their limited cognitive and emotional capabilities.

[6] Marsh JL, Thompson, LM. Can flies help humans treat neurodegenerative diseases? BioEssays 2004, 26(5):485-96, Bier E, Bodmer R. *Drosophila*, an emerging model for cardiac disease. Gene 2004, 342(1):1-11.

[7] Mikulak E, Gliniewicz A, Przygodzka M, Solecka J. *Galleria mellonella* L. as model organism used in biomedical and other Studies. Przeglad Epidemiologiczny 2018, 72:57-73.

[8] Meng X. Zhu F, Chen K. Silkworm: a promising model organism in Life Science. J Insect Sci 2017, 17: 97, Abdelli N, Peng L, Keping C. Silkworm, *Bombyx mori*, as an alternative model organism in toxicological research. Environ Sci Pollut R 2018, 25:35048-35054.

[9] Rösner J, Wellmeyer B, Merzendorfer H. *Tribolium castaneum*: a model for investigating the mode of action of insecticides and mechanisms of resistance. Curr Pharm Des 2020, 26:3554-3568.

[10] Gershman A, Romer TG, Fan Y, Razaghi R, Smith WA, Timp W. *De novo* genome assembly of the tobacco hornworm moth (*Manduca sexta*). G3 Genes|Genomes|Genetics 2020, 11:jkaa047

[11] Ren XY, Zhang LS, Han YH, An T, Liu Y, Li YY, Chen HY. Proteomic research on diapause-related proteins in the female ladybird, *Coccinella septempunctata* L. Bull of Entom Res Lond 2016, 106:168-174.

[12] de Carvalho NM, Teixeira F, Silva S, Madureira AR, Pintado ME. Potential prebiotic activity of *Tenebrio molitor* insect flour using an optimized *in vitro* gut microbiota model. Food Funct 2019, 10:3909-3922.

[13] Engqvis, L, Sauer KP. Influence of nutrition on courtship and mating in the scorpionfly *Panorpa cognata* (Mecoptera, Insecta). Ethology 2003, 109:911-928.

[14] Smith RC. The mosquito as a laboratory animal. Am Biol Teach 1962, 24(7): 513-516, Badman J, Harrison J, McGarry M. Grasshoppers in research and education: methods for maintenance and production. Lab Anim 2007, 36:27-31.

[15] EU (2010). Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. Official Journal of the European Union, L276, 33-78.

However, recent research suggests that insects may experience pain and discomfort in ways that are more complex than previously thought. At least some insects have nociceptors—cells that detect and transmit signals responsible for the sensation of pain.[16] In a study by Tracey *et al.* on *Drosophila* larvae, researchers observed that the larvae responded to the touch of a heated probe with a stereotypical rolling behavior, which was different from their response to a non-heated probe.[17] Insects can detect and respond to harmful or disturbing stimuli, reacting in ways that protect their physical integrity. This ability is called nociception.[18] Unlike the conscious experience of pain, defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, nociception is an involuntary rapid reflex that lacks the emotional response or sensation associated with pain and does not require subjective reactions.[19] Thus, it is possible to have nociception without the conscious sensation of pain.

Despite the existence of nociception in insects, there is disagreement among scientists about whether insects can consciously feel pain. Eisemann *et al.* argue that it is impossible to provide a definite answer since an organism's subjective experience cannot be compared directly to that of another being.[20] To hypothesize about subjective experiences in other organisms, researchers must rely on experimental and theoretical criteria,[21] often using arguments by analogy.[22] For instance, if a mammal shows a particular behavior in response to a painful stimulus, such as an electric shock, and we conclude that it feels pain, we might draw the same conclusion if an insect reacts similarly—assuming we accept or reject the analogy for both.[23] The most relevant criteria for this comparison come from neurophysiology and ethology.

There are several neurophysiological and behavioral signs that suggest invertebrates, and potentially insects, might feel pain. One such indication is the presence of natural opioids and analgesics in their nervous system. The presence of endogenous opiates in animals is strong evidence that they experience pain.[24] Natural opioids help regulate pain to reduce its intensity.[25]

[16] Eisemann CH, Jorgensen WK, Merritt DJ, Rice MJ, Cribb BW, Webb PD, Zalucki MP. Do insects feel pain? - A biological view. Experientia 1984, 40:164-167.
[17] Tracey J, Wilson RI, Laurent G, Benzer S. painless, a *Drosophila* gene essential for nociception. Cell 2003, 113(2):261-273.
[18] Kavaliers M. Evolutionary and comparative aspects of nociception. Brain Res Bull 1988, 21: 923-931, Smith JA. A question of pain in insects. ILAR J 1991, 33(1-2):25-32.
[19] Bateson P. Assessment of pain in animals. Anim Behav 1991, 42:827-839, Broom DM. Evolution of pain. In: Soulsby EJL, Morton D (eds.), Pain: Its Nature and Management in Man and Animals. Royal Society of Medicine International Congress Symposium Series, vol 246. Royal Society of Medicine, London 2001:17-25, Mather JA. Animal suffering: An invertebrate perspective. J Appl Anim Welf Sci 2001, 4:151-156.
[20] Eisemann, *op. cit.*
[21] Dennett D. Consciousness Explained. Little, Brown and Company, Boston 1991.
[22] Sherwin CM. Can Invertebrates Suffer? Or, How Robust is Argumentby-analogy? Anim Welf 2001, 10(supplement 1):103-118.
[23] Elwood RW, Barr S, Patterson L. Pain and Stress in Crustaceans? Appl Anim Behav Sci 2009, 118:128-136.
[24] Rollin BE. The Unheeded Cry: Animal Consciousness, Animal Pain, and Science. Iowa State University, Ames 1998:154.
[25] Elwood, *op. cit.*

Therefore, a question arises on whether insects have a moral status that justifies applying the 3Rs framework. The failure to address this issue reflects a bias in ethical thinking that favors animals closer to humans on the evolutionary scale, while potentially overlooking the ethical treatment of species that are more distantly related.

5. Philosophical Perspectives

5.1. Utilitarianism and Insect Research

Utilitarianism, a consequentialist theory founded by Jeremy Bentham and John Stuart Mill, holds that the rightness of an action is determined by its outcomes, specifically by the amount of pleasure or pain it generates. The use of insects in research is typically justified from a utilitarian perspective on the grounds that the benefits of scientific knowledge far outweigh the harm caused to the insects. However, utilitarianism also requires that we consider the suffering of all sentient beings, no matter how small. The question, then, is whether insects are capable of suffering to an extent that would make their use in research ethically problematic. If insects can suffer, even minimally, utilitarian ethics would demand that we reduce or refine their use in research to minimize harm.

At the same time, the benefits of using insects in research—such as advances in medicine, agriculture, and environmental science—are significant. For instance, research on *Drosophila* has led to breakthroughs in understanding genetic diseases.[26] A utilitarian might argue that the relatively small amount of harm inflicted on insects is justified by these substantial benefits to human and animal health.

5.2. Deontological Ethics and the Moral Duty Toward Insects

In contrast to utilitarianism, deontological ethics, particularly as articulated by Immanuel Kant, is concerned with the moral duties we have, independent of the consequences. Deontology holds that certain actions are inherently right or wrong, based on principles or rules, rather than outcomes. From this perspective, we might ask whether humans have a moral duty toward insects in research, regardless of the benefits that such research might produce.

Kant's categorical imperative suggests that we should treat all rational beings as ends in themselves, not merely as means to an end. Since insects are not rational beings by Kant's definition, one could argue that they fall outside the scope of this duty. However, the challenge here is whether rationality is the only criterion for moral consideration. Modern deontological perspectives have expanded Kantian ethics to include non-rational beings, arguing that moral duties extend beyond rational agents.[27] Some scholars propose that animals, including insects, should not be used merely as tools for human benefit if it leads to unnecessary suffering.[28]

[26] Bonini NM. A perspective on *Drosophila* genetics and its insight into human neurodegenerative disease. Front Mol Biosci 2022, 9:1060796.

[27] Wood AW, O'Neill O. Kant on Duties Regarding Non-rational Nature. Proc Aristot Soc Suppl Vol 1998, 72:189-228.

[28] Denis L. Kant's Conception of Duties Regarding Animals: Reconstruction and Reconsideration. Hist Philos Q 2000, 17:405-423, Camenzind S. Kantian Ethics and the Animal Turn. On the Contemporary Defence of Kant's Indirect Duty View. Animals 2021, 11:512.

This view might advocate for the application of the 3Rs, especially Refinement, even if insects are not rational agents. By refining experimental procedures, researchers could minimize harm and fulfill a moral duty to treat even non-rational beings with a certain level of respect. Therefore, from a deontological perspective, we could argue that humans have a duty to incorporate the 3Rs in research involving insects—not because insects have rights *per se*, but because it aligns with broader moral duties to avoid cruelty and respect the natural world.[29]

5.3. Virtue Ethics and the Moral Character of Researchers

Virtue ethics, derived from the philosophy of Aristotle, shifts the focus from rules and consequences to the character of the individual acting. According to virtue ethics, moral behavior is that which cultivates virtues such as compassion, temperance, and wisdom. The ethical use of animals in research, including insects, depends not just on the outcomes of research or abstract moral duties, but on the virtues or vices that researchers exhibit in their treatment of these creatures.

A researcher who embodies the virtue of compassion might question whether causing harm to insects in research is truly necessary, even if the insects' capacity for suffering is minimal. Compassionate researchers would be motivated to apply the 3Rs as a matter of moral character, not just because of external rules or consequences, but because they believe it is the right thing to do. They would seek to refine methods to avoid unnecessary harm and would be open to replacing insect models with non-animal alternatives where possible.

At the same time, a virtue ethicist would likely recognize that the role of research in improving human and animal welfare is itself virtuous.[30] The pursuit of knowledge and innovation, when done responsibly, contributes to the flourishing of humanity and other species. Therefore, a researcher who uses insects in a manner consistent with the 3Rs could be seen as balancing virtues—compassion for the insects and responsibility toward the broader human and ecological community.

In this sense, virtue ethics provides a holistic approach to the ethical challenges posed by insect research. It encourages researchers to reflect on their own moral character and to strive for excellence not just in scientific rigor, but in ethical sensitivity as well.

6. Applying the 3Rs to Insect Research

Having explored the philosophical frameworks, we turn to how the 3Rs can and should be applied to research involving insects. Each of the 3Rs presents unique challenges when considered in relation to insects, particularly given the differences in cognitive capacity and sentience between insects and vertebrates.

6.1. Replacement

The principle of Replacement encourages researchers to use non-animal models whenever possible. In the case of insect research, this principle raises the question of whether insects

[29] Camenzind, *op. cit.*

[30] Hursthouse R. Virtue Ethics and the Treatment of Animals. In: Beauchamp TL, Frey RG (eds.), The Oxford Handbook of Animal Ethics. Oxford Handbooks 2011; online edn, Oxford Academic.

can be replaced by non-sentient alternatives such as computer models, simulations, or *in vitro* systems. These alternatives not only address ethical concerns but also offer the potential for more refined and accurate scientific outcomes. However, while computer models and other non-animal methods are improving, they have not yet reached the level of complexity necessary to fully replace insects in the fields of genetic research, toxicology, and behavioral studies.

One of the most promising alternatives to using live insects in research is the development of *in silico* methods, which rely on computer simulations and mathematical models to study biological processes.[31] These methods offer several advantages, like predictive modeling based on existing data, simulating molecular and genetic processes at a high level of detail, but they also allow researchers to integrate and analyze large datasets from multiple sources, including genomic, transcriptomic, and proteomic data. Examples of *in silico* methods and computational models as alternatives to insects include *in silico* toxicology models,[32] computational models of insect nervous systems,[33] virtual fly models of *Drosophila* simulators for genetics research,[34] and metabolic and physiological modeling.[35] By reducing the reliance on live insects, these methods contribute to the ethical goal of minimizing harm to living beings. Despite their potential, *in silico* methods are not without limitations. Computational models are only as good as the data they are based on, and inaccuracies in the data can lead to flawed predictions. Moreover, some biological processes are too complex to be fully captured by current modeling techniques. Hence, while *in silico* methods offer a valuable alternative to insect research, they are often used in conjunction with *in vivo* experiments rather than as a complete replacement.

In vitro techniques involve studying biological processes outside of a living organism, typically in a controlled laboratory environment using cells, tissues, or biochemical systems. These techniques serve as ethical alternatives to *in vivo* studies in insects, adhering to the replacement principle. Examples include cell culture systems for studying various biological processes such as gene expression, metabolism, signal transduction, and viral replication,[36] tissue engineering and organotypic cultures, which are three-dimensional tissue models that closely replicate the structure and

[31] Madden JC, Enoch SJ, Paini A, Cronin MTD. A Review of *In Silico* Tools as Alternatives to Animal Testing: Principles, Resources and Applications. Altern Lab Anim 2020, 48(4):146-172.

[32] *ibidem.*

[33] Mosqueiro TS, Huerta R. Computational models to understand decision making and pattern recognition in the insect brain. Curr Opin Insec Sci 2014, 6:80-85.

[34] Cresiski RH. Two Virtual Labs to Study Genetic Inheritance in the Fruit Fly. J Microbiol Biol Educ 2013, 14(1):141-142.

[35] Hall RJ, Thorpe S, Thomas GH, Wood AJ. Simulating the evolutionary trajectories of metabolic pathways for insect symbionts in the genus *Sodalis*. Microb Genom 2020, 6(7):mgen000378, Cesur MF, Basile A, Patil KR, Çakır T. A new metabolic model of *Drosophila melanogaster* and the integrative analysis of Parkinson's disease. Life Sci Alliance 2023, 6(8):e202201695.

[36] Schneider I. Cell lines derived from late embryonic stages of *Drosophila melanogaster*. J Embryol Exp Morphol 1972, 27(2):353-365, He X, Lu L, Huang P, Yu B, Peng L, Zou L, Ren Y. Insect Cell-Based Models: Cell Line Establishment and Application in Insecticide Screening and Toxicology Research. Insects 2023,14(2):104.

function of whole organs,[37] and high-throughput screening (HTS), which allows researchers to rapidly test large numbers of chemical compounds or genetic modifications for their effects on insect cells or tissues, especially in the fields of drug discovery, pesticide development, and genetic research.[38] While *in vitro* techniques offer significant ethical and practical advantages, they also have limitations. The complexity of whole-organism interactions cannot always be replicated *in vitro*, and some physiological processes may require the context of a complete, living system to be fully understood.[39] Nevertheless, *in vitro* methods represent a valuable alternative to insect research, particularly in the early stages of scientific inquiry.

Another promising alternative to insect research is the use of non-animal models and biomimetics, where biological principles observed in insects are replicated using artificial or synthetic systems. Examples include the use of Artificial Neural Networks (ANNs) which can be used to simulate insect behavior, decision-making, and learning processes, like the navigational strategies of bees and the foraging behavior of ants,[40] robotics and biomimetics systems,[41] and synthetic biology and biohybrid systems, like biohybrid drones and engineered tissues.[42] Non-animal models and biomimetics offer a compelling alternative to traditional insect research. However, these approaches also have limitations, as they may not fully capture the complexity of living organisms. Nevertheless, they represent an innovative and ethically sound approach to studying insect-related phenomena.

6.2. Reduction

Reduction focuses on minimizing the number of animals used in research while still obtaining valid results. Insects, because of their small size and short life cycles, are often used in large numbers. Entire populations of insects can be easily manipulated or destroyed in a single experiment, raising questions about whether the principle of Reduction is being sufficiently applied. Despite their numerical abundance, applying Reduction to insect research is an ethical necessity, ensuring that experiments do not use more individuals than required while maintaining scientific integrity.

[37] Napoleão TH, Albuquerque LP, Santos ND, Nova IC, Lima TA, Paiva PM, Pontual EV. Insect midgut structures and molecules as targets of plant-derived protease inhibitors and lectins. Pest Manag Sci 2019, 75(5):1212-1222.

[38] Hughes TR, Marton MJ, Jones AR, Roberts CJ, Stoughton R, Armour CD, Bennett HA, Coffey E, Dai H, He YD, Kidd MJ, King AM, Meyer MR, Slade D, Lum PY, Stepaniants SB, Shoemaker DD, Gachotte D, Chakrabortty K, Simon J, Bard M, Friend SH. Functional discovery via a compendium of expression profiles. Cell 2000,102(1):109-26.

[39] Forestiero S. The historical nature of biological complexity and the ineffectiveness of the mathematical approach to it. Theory Biosci. 2022, 141(2):213-231.

[40] Knaden M, Graham P. The Sensory Ecology of Ant Navigation: From Natural Environments to Neural Mechanisms. Annu Rev Entomol 2016, 61(1):63-76.

[41] Fry SN. Experimental Approaches Toward a Functional Understanding of Insect Flight Control. In: Floreano D, Zufferey JC, Srinivasan MV, Ellington C (eds.) Flying Insects and Robots. Springer, Heidelberg Dordrecht London New York 2010:1-14.

[42] Lentink D, Dickinson MH. Biofluid dynamic scaling of flapping, spinning and translating fins and wings. J Exp Biol 2009, 212(16):2691-2704, Webster-Wood VA, Guix M, Xu NW, Behkam B, Sato H, Sarkar D, Sanchez S, Shimizu M, Parker KK. Biohybrid robots: recent progress, challenges, and perspectives. Bioinspir Biomim 2022, 18:015001.

To ethically apply Reduction to insect research, scientists must balance the need for large sample sizes with the ethical imperative to minimize harm. This might involve developing more precise statistical methods to reduce the number of insects used in experiments or improving experimental designs to gather the necessary data with fewer subjects. To adhere to the principle of Reduction, scientists must employ advanced statistical methods and experimental designs that allow them to achieve valid results with fewer subjects. For instance, power analysis, a statistical technique used to determine the minimum sample size required to detect an effect with a given degree of confidence,[43] could be used in insect research. This method can significantly reduce the number of insects used by ensuring that sample sizes are neither too large nor too small to produce meaningful results.

Another effective approach in Reduction is the use of pilot studies, which can provide critical preliminary data to guide full-scale experimental designs. Pilot studies allow researchers to estimate effect sizes, identify potential sources of variability, and optimize protocols before committing to large-scale trials.[44] By conducting small-scale preliminary experiments, researchers can refine their hypotheses, select the most effective methodologies, and determine the necessary sample sizes more accurately. This not only reduces unnecessary insect use but also enhances the overall efficiency of research, reducing costs and time investment. Recent discussions in the literature have underscored the importance of pilot studies in determining appropriate sample sizes and improving experimental design in animal research.[45]

At the same time, it is important to recognize that the biological characteristics of insects—such as their high reproductive rates—complicate the application of Reduction. Unlike vertebrates, whose individual lives might hold more significance from a moral perspective, insects are often viewed as part of a collective group. Nevertheless, ethical research demands that we apply Reduction wherever possible, even to species that reproduce quickly and exist in large numbers.

6.3. Refinement

Refinement seeks to minimize suffering and improve the welfare of animals used in research. In vertebrate studies, this principle is applied through better living conditions, the use of anesthesia or analgesia to reduce pain, and the implementation of humane endpoints in experiments. The ethical considerations surrounding insect research have traditionally been overlooked, but emerging evidence suggests that insects may have more complex responses to harmful stimuli than previously assumed.[46] This underscores the necessity of incorporating Refinement into insect research by

[43] Nakagawa S, Cuthill IC. Effect size, confidence interval and statistical significance: a practical guide for biologists. Biol Rev 2007, 82(4):591-605.

[44] Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials 2014, 5:264.

[45] Laws TR, Maishman TC. Considerations in the design of animal infection pilot studies. Front Cell Infect Microbiol 2022, 12:948464.

[46] Crump A, Gibbons M, Barrett M, Birch J, Chittka L. Is it time for insect researchers to consider their subjects' welfare? PLoS Biol 2023, 1;21(6):e3002138.

improving handling techniques, using appropriate anesthesia, and ensuring humane euthanasia where necessary.

Anesthesia is deemed essential for procedures requiring immobilization, such as microscopic examination and sampling, as well as for procedures that may cause pain or distress, including surgical interventions, electrophysiological studies, and magnetic resonance imaging (MRI).[47] It is important for researchers and technicians working with insects to be familiar with and able to use appropriate anesthesia techniques for each species. There is sufficient research and a variety of methods available for anesthetizing insects.[48] Carbon dioxide (CO_2) is the most popular agent to immobilize insects in entomological research, although multiple side effects and high mortality makes its use controversial, and a more progressive approach would be the use of a volatile anesthetic agent like isoflurane or sevoflurane.[49] However, species-specific responses must be considered, as different insects exhibit varying levels of resistance to hypoxia and chemical agents. For example, cockroaches (Blattodea) show remarkable tolerance to hypoxia and can survive prolonged oxygen deprivation.[50]

Since little is known about the needs of different species, understanding the physiology of each species is essential, such as maintaining fluid balance, as with all animal species.[51] Insects are small, with a large surface area relative to their body mass, making them prone to dehydration. The use of analgesics in invertebrates does not yet appear to be feasible; since they do not possess a central nervous system with a well-described cortex or similar structure, it is not clear whether they perceive pain and suffer emotional distress from it. For instance, although snails exhibit withdrawal and escape behaviors in response to mechanical, chemical, and electrical stimuli, the presence of an analgesic appears to diminish or slow these responses.[52] However, it remains uncertain whether this reduction is attributable to a sedative effect or the analgesic properties of the drug.[53] As an alternative, anesthesia is recommended for any procedures that may be painful or disrupt the insect's normal behavior.[54]

The practice of euthanasia in laboratory insects is not widely represented in existing protocols. With the exception of the UFAW handbook series, which has included information on invertebrate anesthesia and euthanasia since

[47] Cooper JE. Anesthesia, analgesia, and euthanasia of invertebrates. ILAR J 2011, 52(2):196-204.

[48] Lewbart GA (ed.) Invertebrate Medicine. (3rd ed). John Wiley & Sons inc, Hoboken 2022.

[49] Wahltinez SJ, Harms CA, Lewbart GA. Chapter 26 - Anesthesia and analgesia in invertebrates, In: Dyson MC, Jirkof P, Lofgren J, Nunamaker EA, Pang D (eds.) Anesthesia and Analgesia in Laboratory Animals (Third Edition), Academic Press, Cambridge 2023:647-671.

[50] Natalie G. Schimpf, Philip G. D. Matthews, Craig R. White, Cockroaches that exchange respiratory gases discontinuously survive food and water restriction, Evolution 2012, 66(2):597-604.

[51] Kirby R, Rudloff E. Fluid balance. In: Kirby R, Linklater A. (eds), Monitoring and Intervention for the Critically Ill Small Animal: The Rule of 20. John Wiley & Sons inc, Hoboken 2016:9-28.

[52] Kavaliers M, Hirst M. Tolerance to morphine-induced thermalresponse in terrestrial snail, *Cepaea nemoralis*. Neuropharmaology 1983, 22: 1321e1326, Kavaliers M, Hirst M, Teskey GC. A functional role for an opiate system in snail thermal behavior. Science 220 (4592):99e101.

[53] Wahltinez *et al.*, *op. cit.*

[54] Cooper, *op. cit.*

1967, including methods for the "*tranquilizing and killing insects and ticks*",[55] there are no specific guidelines. In the literature, extensive references to euthanasia methods are made by Lewbart, but most of these have not been sufficiently studied.[56] Bennie *et al.* proposed injection sites and doses for different orders of arthropods,[57] extending the Potassium chloride (KCl) technique of Battison *et al.* for euthanasia of the American lobster (*Homarus americanus*),[58] but this method is hard to use for small insects. However, information is available on certain characteristics of ectothermic animals (mainly reptiles and amphibians), such as severing the nervous tissue, which may relate to some invertebrates.[59] Other euthanasia methods that can be used are rapid decapitation - although insects have different nervous systems from vertebrates and decapitation alone may not always be sufficient to destroy neural functions[60] - and immersion in ethanol. For the euthanasia of arachnids, which are closely relatives to insects, Pizzi and Kennedy recommended immersion in 70% ethanol, dismissing the method of rapid freezing for these and other invertebrates, as the resulting tissue damage risks compromising histological examination.[61] In any case, euthanasia methods for insects have been insufficiently researched and require further investigation.

Another important issue that it has to be under Refinement is insects' welfare. Due to indications that insects may be capable of experiencing sensations, the precautionary principle should be invoked when designing legislation for the welfare and protection of insects, and it should be applied across the board. The precautionary principle was defined by Birch:[62]

> When there are threats of serious negative outcomes for the welfare of animals, the lack of complete scientific certainty regarding the sentience of those animals is not used as a reason to postpone economically feasible measures to prevent those outcomes.

Furthermore, legislation must be enacted to ensure the well-being of insects used in research. Good conditions relate to the housing and environmental conditions, their nutrition, and anything else that might affect their well-being. The questions that arise, of course, pertain to the very nature of insect living conditions and what might constitute 'well-being' for them. The lack of clarity regarding the presence of emotional

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[56] Lewbart, *op. cit.*
[57] Bennie NAC, Loaring CD, Bennie MMG, Trim SA. An effective method for terrestrial arthropod euthanasia. J Exp Biol 2012, 215(24):4237-4241.
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[62] Birch J. Animal sentience and the precautionary principle. Anim Sentience 2017, 16(1):1-15.

states in insects makes it difficult to know what actions should be taken to optimize their living conditions.[63] The International Platform of Insects for Food and Feed (IPIFF) suggests adopting Brambell's Five Freedoms as a basis for establishing good practices and proper treatment of farmed insects, provided these take into account the specific characteristics of insects.[64] Five Freedoms, as derive from Brambell's quote,[65] are: freedom from hunger and thirst, freedom from discomfort, freedom from pain, injury or disease, freedom to express normal behavior, and freedom from fear and distress.

Although the welfare of insects has not traditionally been a priority in research, applying Refinement to insect studies would represent an important ethical step forward.

7. Conclusion

Insects are increasingly used in scientific research, yet their moral and ethical status remains a matter of debate. Through the lens of the 3Rs—Replacement, Reduction, and Refinement—this essay has explored the ethical complexities of using insects in research, drawing on utilitarian, deontological, and virtue ethics perspectives. While insects may not possess the same cognitive and emotional capacities as vertebrates, emerging evidence suggests that they are capable of more complex experiences than previously assumed.

The ethical application of the 3Rs to insect research requires a nuanced understanding of both the scientific and philosophical dimensions of the issue. The 3Rs should extend to insects, even if the practical challenges differ from those faced in vertebrate research. By continuing to refine our ethical frameworks and scientific practices, we can ensure that research involving insects is conducted responsibly and humanely, in a manner that respects both the needs of science and the ethical imperative to reduce harm.

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[64] IPIFF, (2019). Ensuring High Standards of Animal Welfare in Insect Production. https://ipiff.org/wp-content/uploads/2019/02/Animal-Welfare-in-Insect-Production.pdf

[65] Brambell R. Report of the Technical Committee to Enquire into the Welfare of Animals kept under Intensive Livestock Husbandry Systems. Her Majesty's Stationary Office, London, 1965:13.

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Ανασκοπήσεις - Reviews

Pediatric Deep Brain Stimulation for Therapy and Neuroenhancement: Ethical, Clinical and Legal Dimensions

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Abstract

Deep Brain Stimulation (DBS) is traditionally applied in adults for the therapy of certain neurological and psychiatric disorders. Except for adults, it can also be implemented in children, but its applications in pediatrics are limited. A groundbreaking scenario regarding the future of DBS is its potential use beyond the restoration of human health, in the field of neuroenhancement. However, the new applications of DBS present serious ethical, clinical, and legal concerns, which are examined in this paper.

In the beginning, the applications of pediatric DBS are presented, along with the method's potential short- and long-term effects. Subsequently, the concept of "neuroenhancement", contrasted with "therapy", and the potential role of pediatric DBS in this domain are analyzed. Moving on to the ethical considerations of pediatric DBS, a wide range of topics are covered, involving safety issues, authenticity, decision-making, and social concerns. In the section on clinical dimensions, the importance of conducting relevant clinical trials as well as their challenges are elucidated. Afterward, as the legal framework of DBS devices is examined, regulations both for medical and non-medical devices are provided, depending on the specific DBS application. These discussions serve as a preparation for the proposal of recommendations, from an ethical, clinical, and legal perspective.

The overall purpose of this paper is to provide pathways for the alignment of scientific advancement with the welfare of children.

Keywords: pediatric DBS, therapy, neuroenhancement, ethics, clinical trials, regulations.

Παιδιατρική Εν τω Βάθει Εγκεφαλική Διέγερση για Θεραπεία και Ενίσχυση του Εγκεφάλου: Ηθικές, Κλινικές και Νομικές Διαστάσεις

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Περίληψη

Η εν τω βάθει εγκεφαλική διέγερση (DBS) εφαρμόζεται παραδοσιακά σε ενήλικες για τη θεραπεία ορισμένων νευρολογικών και ψυχιατρικών διαταραχών. Πέρα από τους ενήλικες, μπορεί επίσης να χρησιμοποιηθεί σε παιδιά, αλλά οι εφαρμογές της στην παιδιατρική είναι περιορισμένες. Ένα καινοτόμο σενάριο αναφορικά με το μέλλον της DBS είναι η εφαρμογή της πέρα από το κομμάτι της αποκατάστασης της ανθρώπινης υγείας, στον τομέα της ενίσχυσης του εγκεφάλου. Ωστόσο, οι καινούργιες εφαρμογές της DBS παρουσιάζουν σοβαρά ηθικά, κλινικά και νομικά ζητήματα, τα οποία εξετάζονται στην παρούσα εργασία.

Αρχικά, παρουσιάζονται οι εφαρμογές της παιδιατρικής DBS, μαζί με τις δυνητικές βραχυπρόθεσμες και μακροπρόθεσμες επιδράσεις της. Στη συνέχεια, αναλύεται ο έννοια της "ενίσχυσης του εγκεφάλου", σε αντιδιαστολή με τη "θεραπεία", και ο πιθανός ρόλος της παιδιατρικής DBS σε αυτόν τον τομέα. Προχωρώντας στα ηθικά ζητήματα της παιδιατρικής DBS, καλύπτεται μία ευρεία γκάμα θεμάτων, μεταξύ των οποίων είναι τα ζητήματα ασφάλειας, η αυθεντικότητα, η λήψη αποφάσεων και οι κοινωνικές ανησυχίες. Στην ενότητα των κλινικών διαστάσεων, επισημαίνεται η σημασία της διεξαγωγής σχετικών κλινικών δοκιμών, καθώς και οι προκλήσεις που αντιμετωπίζονται. Στη συνέχεια, εξετάζεται το νομικό πλαίσιο των συσκευών DBS, με την παράθεση κανονισμών τόσο για ιατρικές όσο και για μη ιατρικές συσκευές, ανάλογα με τη συγκεκριμένη εφαρμογή της DBS. Αυτές οι συζητήσεις αποτελούν προετοιμασία για την παρουσίαση συστάσεων, από ηθική, κλινική και νομική άποψη.

Ο απώτερος στόχος της εργασίας είναι να παρέχει μονοπάτια για την ευθυγράμμιση της επιστημονικής προόδου με την ευζωία των παιδιών.

Λέξεις κλειδιά: παιδιατρική DBS, θεραπεία, ενίσχυση εγκεφάλου, ηθική, κλινικές δοκιμές, κανονισμοί.

Introduction

DBS constitutes a neurosurgical procedure whose traditional role is the treatment of neurological and psychiatric disorders. Not only is it applied for the management of movement disorders in adults, including Parkinson's disease (PD), essential tremor, and dystonia, but currently it is also being investigated for psychiatric conditions like schizophrenia, depression, as well as anorexia nervosa.[1]

During the process, tiny electrodes are surgically implanted in specific regions of the brain. An Implantable Pulse Generator (IPG), which is placed in the area of the chest, is connected to the electrodes and modifies neuronal activity with the delivery of electrical pulses.[1,2]

In the last decades, DBS has been rapidly evolving, and its applications have immensely expanded. For example, the advent of techniques that facilitate the study of neural networks, like optogenetics, has contributed to the surge of DBS.[3]

A major update is the initiation of the method for underage patients. Pediatric populations can significantly benefit from the adjustability and the reversibility of the method. These special characteristics render DBS promising for the improvement of pediatric healthcare.[3]

In addition, an exciting scenario is the use of DBS for neuroenhancement purposes. This means that DBS has the potential to be applied in non-disordered children with the aim of augmenting their emotional, cognitive, and social capacities.[4]

This paper underscores the ethical, clinical, and legal concerns which arise from the use of pediatric DBS, in the context of therapy and neuroenhancement. These discussions will highlight the importance of ensuring the welfare of children as medicine and technology advance.

Materials and Methodology

Existing literature was thoroughly examined using the databases PubMed, Academia, and Google Scholar. Case studies, academic papers, and scholarly articles were extracted from these databases, focusing on the prospects of DBS for treatment and neuroenhancement. Furthermore, targeted Google searches were employed with the aim of gathering additional information. More specifically, by visiting technological and legal organizations' websites, information regarding the latest DBS approvals and relevant regulations was obtained. Used keywords included "pediatric DBS," "therapy," "neuroenhancement," "ethical considerations," "clinical trials", and "DBS approvals."

Therapeutic Application

1. Overview

Pediatric DBS can be a useful tool for the treatment of pediatric disorders characterized by a low remission rate over time, but clinical studies focusing on this topic are limited. Additionally, technological advancements, such as the development of smaller and longer-lasting batteries, as well as rechargeable systems, have made DBS more suitable for pediatric patients.[3,5]

In this section, the use of DBS for the treatment of pediatric dystonia, epilepsy, and obsessive-compulsive disorder (OCD) is presented. Subsequently, the short- and long-term effects of the procedure are elucidated, providing a basic grasp of the risks and benefits associated with pediatric DBS.

2. Dystonia

Dystonia constitutes "the most common indication of DBS" in underage patients. It is a neurological disorder characterized by uncontrollable movements and abnormal postures which are caused by prolonged muscle contractions. Therapeutic approaches for dystonia include botulinum toxin (BoNT) injections, dopaminergic medications, baclofen, and anticholinergic medications. Even though these methods have shown promise in some cases, they are not effective for all patients, and evidence supporting their efficacy is limited. With various etiologies and phenotypes, dystonia necessitates individualized approaches for its treatment. Thanks to its personalized nature, DBS is alleged to be effective for the condition.

Findings actually suggest that DBS is more successful when it comes to alleviating the symptoms of younger patients with genetic dystonias, rather than secondary dystonias, which arise from another underlying disorder, such as traumatic brain injury. Notably, DBS has received Humanitarian Device Exemption (HDE) from the U.S. Food and Drug Administration (FDA) for refractory dystonia in both adult and underage patients.[3,5,6]

3. Epilepsy

Neurological disorder epilepsy causes repetitive seizures, which are sudden bursts of abnormal electrical activity in the brain. The International League Against Epilepsy (ILAE) categorizes seizures into "focal (partial), generalized, and unknown types". Childhood absence epilepsy (CAE) is a type of genetic generalized epilepsy that affects children aged 2 to 13 years. While antiepileptic drugs (AEDs) and vagus nerve stimulation (VNS) are among the methods intended to manage epilepsy, their efficacy is often insufficient. Additionally, neurosurgical resection, while effective, is associated with inherent risks. DBS)appears to be a promising new solution for epilepsy. Initial studies suggest its potential to successfully treat seizures, although its mechanism is not fully understood. DBS has even received FDA approval for patients aged 18 and older who suffer from refractory focal epilepsy.[7,8,9,10]

4. OCD

Neuropsychiatric disorder OCD is characterized by "obsessional symptoms and compulsive acts that cause distress and interfere with daily activities." These unwanted and persistent symptoms typically appear during childhood or adolescence and constitute a source of discomfort and unease. The combination of behavioral therapy with medications like antipsychotics and selective serotonin reuptake inhibitors (SSRIs) is a standard approach for the management of OCD, but it is ineffective in a significant number of cases. Another alternative is stereotactic ablation, which is still under examination. Lately, healthcare professionals have shown growing interest in using DBS for OCD, but there is not sufficient evidence supporting its efficacy in pediatric populations. For this reason, the HDE granted by the FDA is restricted to adult OCD patients who do not respond to other treatments.[3,11,12]

5. Short- and Long-Term Effects of DBS

There is a wide variety of DBS effects due to the fact that the treatment is personalized and there are multiple variables affecting the process. The presence of both short- and long-term effects shows the importance of both pre- and post-operation surveillance. In addition, discussing DBS health outcomes prior to its implementation suggests ethical oversight and is essential for the protection of young patients' health.

In the context of short-term effects, patients' symptoms like respiratory distress and muscle spasms can be immediately alleviated, providing relief to the patient. At the same time, though, studies indicate that DBS poses multiple risks to patients' health, and children are particularly vulnerable to them in comparison with adults. Effects can be classified as reversible, when they can be resolved with additional interventions, or irreversible, which are considered to seriously impact children's health. The existence of reversible and irreversible effects raises ethical considerations that need to be meticulously taken into account when estimating the risk-benefit ratio of the procedure. Reversible effects are related to surgical risks, device-related complications, and neuropsychiatric effects. On the other side, irreversible effects can encompass severe surgical site infections at the site of the electrodes' implantation. When serious infections occur, the complete removal of the hardware might be needed.[1,3,5,6]

Managing DBS in the long term is quite challenging. Long-term follow-up studies have shown that, even though some patients may experience significant relief of their symptoms, in other cases, symptoms may gradually worsen. What is more, IPG's lifespan can vary greatly, depending on the condition of the patient, the type of the device, and its settings. The battery is then replaced

with a relatively simple surgical procedure that may pose additional risks to the individual's health. It can be inferred that underage patients are more vulnerable than adults because it is likely they will undergo more battery replacements throughout their lives.[3,6,13]

Neuroenhancement

1. "Therapy" vs "Enhancement"

In the present study of pediatric DBS, "therapy" and "enhancement" are two key terms that need to be clarified. It is important to remember that distinguishing these terms is vital, as this has practical effects.

According to the US President's Council on Bioethics, "therapy" is defined as "the use of biotechnical power to treat individuals with known diseases, disabilities, or impairments, in an attempt to restore them to a normal state of health and fitness." On the other hand, "enhancement" can be conceptualized as "the directed use of biotechnical power to alter, by direct intervention, not disease processes but the normal workings of the human body and psyche, to augment or improve their native capacities and performances."[14]

These definitions point out that "therapy" aims to restore the health of disordered individuals and seeks "improvement up to the species-typical level". On the contrary, "enhancement" strives for "improvement beyond species-typical functioning".[14,15]

The distinction between the two terms meets certain challenges that should be carefully examined. Firstly, clinicians' critical thinking abilities and experience are highly needed, as the concepts "typical" and "normal" can be diverse and subjective. In addition, because of the involvement of various normal factors like sleep deprivation and aging, sometimes it is hard to tell whether the individual is healthy or disordered.[14,15]

Distinguishing "therapy" from "enhancement" is crucial and has important practical implications. These implications are mainly related to the allocation of resources and the accessibility of these interventions.[15]

2. Definition and Methods

The term "neuroenhancement" can be described as "a variety of interventions and technologies aiming to improve human performance above the subject's normal performance." Neuroenhancement targets various domains, including attention, concentration, memory, perception, creativity, emotional regulation, and reasoning skills. Enhancing the individual's skills beyond the levels of "physiologically normal", it has the potential to optimize their mood, cognition, and sociality.[14,15,16,17]

There are diverse strategies that serve the role of neuroenhancement, and they can be divided into pharmacological and non-pharmacological ones. The prescription of drugs like benzodiazepines (BDZs), antidepressants (ADs), and antipsychotics is the most common approach for neuroenhancement and constitutes a pharmacological strategy.[17,18]

In the context of non-pharmacological strategies, behavioral interventions like meditation, formal education, and mnemonic strategies are included. Choosing the most appropriate intervention is determined by the targeted domain. For example, when it comes to improving memory, mnemonic strategies are preferred, while meditation is usually practiced for the improvement of attention. In addition, physical measures may be preferred, such as DBS and transcranial magnetic stimulation (TMS), which is non-invasive. Further novel non-pharmacological strategies are also being investigated, like implants of neural tissue derived from stem cells.[14,15,17]

3. Neuroenhancement in Education

Education in developed countries is a widely accessible form of non-physical and non-biomedical neuroenhancement. As Nelson Mandela once said, "Education is the most powerful weapon which you can use to change the world." It is of paramount importance because it equips and endows students with knowledge and skills that contribute to their character development and prepare them to become independent and active young citizens.

Apart from traditional teaching methods, in certain educational settings, other neuroenhancement strategies are deliberately applied to augment students' capacities. For example, in the context of diet, specific nutrients associated with improved brain activity are included in schools' meal programs.[17]

In addition, studies suggest that 1-3% of American and Canadian students use pharmacological neuroenhancers on a weekly basis. This method is becoming more and more popular among students, and an increase in the percentage is observed with the transition from high school to college. However, the use of certain drugs like Ritalin is limited to students suffering from cognitive disorders like Attention Deficit Hyperactivity Disorder (ADHD) .[18]

The consumption of vitamins, which are beneficial for the neurological development of the fetus, constitutes a widely preferred method among pregnant women. This practice can assist children with their studies in the long run.[17]

Furthermore, novel strategies, including DBS, are being considered to enhance student performance and, thus, maximize the results of traditional educational techniques. Nonetheless, the impact of DBS on educational settings remains unknown because its use for neuroenhancement purposes has not been thoroughly examined yet.

4. DBS for Neuroenhancement

The use of DBS for neuroenhancement is a very intriguing scenario. However, the development of this innovative application is confronted with challenges, mainly because of the unique nature of each individual. To facilitate the process, Neuralink and IMEC have invested in the development of new technologies.[4]

One interesting application of DBS could be the enhancement of memory beyond typical levels. This is considered feasible by targeting the medial temporal lobe (MTL) circuitry, which is related to memory. The technique has had success in epileptic patients, but it can also potentially extend to healthy children. This is a groundbreaking application, yet it raises an abundance of ethical concerns.[19]

A study was conducted to examine and compare the views of adaptive DBS researchers in the US regarding the implementation of DBS for the purpose of neuroenhancement. 61% of them expressed worries about the method's inherent risks, which are linked to its invasiveness. What is more, 43% found it unnatural and stated that they would remain opposed to the method, even if its risks were eradicated. It is also particularly interesting that some researchers drew parallels to plastic surgeries.[4]

The findings of this study highlight the importance of addressing the ethical issues of DBS when it is used for neuroenhancement. In case the method is applied in pediatric populations with the same purpose, greater attention is needed because of the additional concerns that emerge.

Ethical Considerations

1. Overview

DBS is associated with a wide variety of ethical issues, including safety, authenticity, decision-making, as well as social concerns. When examining the ethical considerations of pediatric DBS, the interplay of concerns related to neuroethics and child-specific issues is a major source of intricacies.

To be more specific, neuroethics is a subfield of bioethics that can be defined as "the study of the ethical, moral, social, and legal issues raised by our continually improving understanding of the brain, and by consequent improvements in our ability to monitor and influence brain function". In addition to neuroethics, pediatric DBS presents challenges that are unique to children because of their vulnerability and developmental stage.[15]

The potential of DBS for enhancement purposes gives us food for thought regarding the "goals of medicine". A main question that arises is whether pediatric DBS should extend beyond the restoration of human health. At this point, it is important to reflect on how the purposes of medicine ought to evolve, in

response to the new challenges that emerge.[15,20]

2. Safety Issues

2.1. Health Risks

As previously discussed, DBS can have unfavorable short- and long-term outcomes. However, health risks in children remain unclear, and evidence largely stems from studies involving adults. More years of investigation are required to unveil long-term effects in pediatric populations. This highlights the need for caution and thorough discussions with families about the practice's potential risks.[21,22]

It is also important to take into consideration that "children are not small adults". Adult-sized leads and batteries can possibly cause harm to underage individuals, such as skin erosion and higher infection rates in comparison to adults.[22]

Generally, estimating the risk-benefit ratio is quite challenging, especially in the case of considering DBS in non-disordered individuals for enhancement purposes. In therapeutic applications, the potential adverse effects are outweighed by the urgent need to address health issues. Consequently, the risk-benefit ratio appears to be more favorable in contrast to enhancement interventions. The disagreement on where specific brain functions are localized constitutes another root of confusion. Additionally, the fact that children's and adolescents' brains are not fully developed yet makes the prediction of the ratio even harder.[4,12,14]

2.2. Neurosecurity Threats

Despite its multiple benefits, DBS poses risks to children's well-being, which are linked to neurosecurity threats. "Brainjacking" is a novel term that has emerged in regard to this topic. The term refers to "the exercise of unauthorized control of another's electronic brain implant." In response to brainjacking, "neurosecurity"—the development of defense mechanisms against the breach of neurological implants—has evolved.[2,23]

There are several ways in which hackers could possibly exert influence, but for the time being, they remain mainly theoretical. Depending on their level of sophistication, attacks are either blind or targeted. They can be detrimental to health or even fatal, and this can cause distress not only to children but also to their families.[1,2]

Hackers can possibly cause harm by controlling different parameters, including voltage, frequency, and pulse width. They have the potential to provoke pain with excessive frequency, exacerbate symptoms with the impairment of the IPG, and even trigger emotional and behavioral changes, such as hypersexuality.[2,23]

Neurosecurity threats are expected to become a palpable threat in the near future, and considering them will be essential for the formation of the risk-benefit ratio.

3. Authenticity

3.1. Definition and Views

Philosopher Charles Guignon has defined the authentic self as "the constellation of feelings, needs, desires, capacities, aptitudes, dispositions, and creative abilities that make the person a unique individual."[24]

DBS is linked to authenticity concerns, and this is particularly worrying in the case of underage individuals, let alone adolescents, because they go through a transitional period where their identity is formed. DBS can interfere with children's character development and identity formation by provoking personality and emotional changes, including anxiety, mania, and increased libido. Additionally, it can potentially affect the perception of body image, but responses vary among individuals.[24]

From a philosophical point of view, there is a wide range of perceptions and approaches regarding personal identity. For instance, Platonic and Aristotelian philosophies support that it is an "ontological entity" that remains unchanged over time. On the contrary, according to social constructionist views, personal identity is continuously shaped through social interactions and cultural norms.

Transhumanist viewpoints advocate for the enhancement of human capabilities through technology, but bioconservative approaches are against it, as they prioritize the preservation of human nature. Moreover, the importance of self-perfection is illustrated in the "Ethics of Authenticity" by Charles Taylor. It is clear that viewpoints that support the optimization of human skills are in favor of DBS for neuroenhancement.[15,18]

When considering DBS for children, it is imperative to take into account the preservation of their authentic selves. However, the diversity of views surrounding this topic makes the process very complex. Careful consideration is needed to maximize positive outcomes and, simultaneously, protect children's identity, especially during this crucial period of their life.

3.2. Nature of Personal Accomplishments

Drawing upon authenticity, a debate focusing on the nature of personal achievements unfolds. A main argument against DBS for neuroenhancement purposes is that accomplishments are less meaningful due to the fact that they require less effort. When human skills are enhanced, there is a diminished sense of responsibility, and authenticity is undermined. On the other hand, natural accomplishments reflect the personal identity of the individual on the grounds that they stem from their dedication and commitment. In response to opponents, DBS supporters assert that augmenting cognitive abilities does not replace genuine effort but enhances its effectiveness instead. In fact, neuroenhancement is highly beneficial in terms of productivity and efficacy of work.[15]

The debate goes on as critics point out that, despite its benefits, DBS may negatively influence other domains that have not been targeted directly. The unintended consequences of DBS can potentially have a significant impact on education. For example, in the case of intentionally enhancing memory, the performance of students is bound to improve in subjects requiring memorization. At the expense of this improvement, there may be weaker performances in subjects where critical thinking and problem-solving skills are needed. Hence, neuroenhancement may imbalance the skills of students.[15]

4. Decision-making

4.1. Autonomy

According to philosopher Dan Brock, autonomy "involves the capacities of individuals to form, revise over time, and pursue a plan of life or conception of their good. It is a broad concept, applicable at both the levels of decision and of action."[2]

Given the challenges and probable risks of certain medical procedures, it is of utmost importance to strike a balance between the individual's autonomy and the clinician's medical duty. Even though the individual's preferences should always be taken into consideration, the clinician might need to take initiatives that are not in perfect alignment with the individual's wishes. This is important when it comes to ensuring safety and making decisions in the best interests of the individual. Practically, this is a way of respecting beneficence and non-maleficence.[20]

In the context of pediatric DBS, it is complicated to determine the extent to which children should participate in decision-making processes, as they constitute a vulnerable population with limited decision-making capacities. In many cases, especially when children have suffered serious cognitive damage, the engagement of guardians might also be needed, along with the intervention of healthcare professionals.[2]

Children's age and cognitive capacities can immensely influence the procedure. Generally, children who are more mature and at a higher intellectual level can understand to a greater degree the role of DBS and the nature of their condition. What is more, they are better at maintaining a dialogue with their parents and physicians, at communicating their ideas, and at expressing their desires and objections. For these reasons, their engagement in the process is higher. The same applies in the case of children with previous experiences of surgery, even if it was not related to DBS, as they are more familiar with the process.[22,25]

Overall, a number of factors are examined regarding the participation of children in decision-making. Preserving children's autonomy is paramount and necessitates thorough ethical introspection from the part of healthcare professionals. However, ensuring that children participate in decision-making may delay the treatment process and, hence, result in harm caused by the decline of their disease.[22]

4.2. Treatment Exhaustion

The concept of treatment exhaustion may further complicate decision-making. Alternative treatments are exhausted when they have been proven to have inadequate or even adverse results. A useful example is the case where baclofen therapy for pediatric dystonia is ineffective or causes harm to patients. In this instance, DBS may be seriously considered, even though it is associated with potential risks.[22]

Nevertheless, before DBS is applied, it is pivotal that the refractoriness and severity of the condition are assessed. Patient selection may be challenging because there might be disagreement when classifying a disease as refractory. Before labeling a patient as refractory, clinicians should also make sure that conventional treatments have been exhausted and that there are no gaps in the treatment of the patient.[12]

4.3. Parental Approach

Parents have the duty to make well-informed decisions in the best interest of their children. Through their open dialogue with clinicians, they receive comprehensive information as well as ethical guidance. Parents' participation in decision-making is a challenging task, which requires the assessment of the child's developmental stage and other available treatments.[22]

A major issue is that, because of their emotional attachment, parents might experience a variety of emotions, mainly associated with uncertainty and inadequacy. Parents' emotional state may impact their capacity to make responsible decisions and this necessitates their productive partnership with clinicians, who serve as gatekeepers thanks to their medical expertise.[22,26]

Despite the complexity of pediatric DBS, research indicates an overall willingness of parents to consider DBS as a therapeutic option for adolescents, especially when they have previous experiences with it. Nonetheless, more challenges may arise when parents consider DBS for neuroenhancement, because its nature is more uncertain, and taking into account societal norms would also be needed.[25]

5. Social Concerns

Issues related to justice, fairness, and equality come up when DBS is considered. A critical issue is the high cost of the technology, particularly when it is not offered under insurance coverage. This can widen the gap between the families who can afford DBS for their children and those who cannot. The negative impact of high expenses may be more noticeable among children who come from a lower socioeconomic background. This may perpetuate inequalities and reinforce the process of class stratification.[4,15]

On the other side, if DBS were available for every person, it would pose a serious threat to societal diversity. Especially in the case of neuroenhancement, universal access to DBS leads to increased homogenization, and this could disrupt the division of labor.[14]

In addition, stigmatization of children constitutes one of the most serious social implications of DBS. This is usually observed in terms of less studied and practiced applications of DBS due to the lack of societal familiarity with them. For instance, this is prevalent in psychiatric conditions and neuroenhancement practices.

In a study about the views of clinicians on DBS for OCD adolescents, a clinician expressed that stigmatization of patients happens "largely due to the history of psychosurgery and it being misused in the past." They also added that "there weren't clear guidelines for its use, and it was probably used in a lot of patients where it did more damage than good, so there is a lot of stigma surrounding psychosurgery."[12]

The debate revolving around prioritization principles further complicates matters. These principles advocate for the prioritization of children who are in greater medical need. This works to the detriment of healthy children, who, as a consequence, may have the urge to resort to the black market. This may upset the societal balance and intensify inequalities.[15]

Clinical Dimensions

Moving on to the clinical dimensions of pediatric DBS, findings regarding DBS effects on children are limited, so further clinical trials should be conducted. Pediatric clinical trials are of utmost importance on the grounds that they constitute a foundation for increasing our medical knowledge and enhancing the outcomes of pediatric patient care. Especially in the context of pediatric DBS, the role of research involving children is particularly important, as it can shed light on the risks and benefits of the method, its short- and long-term outcomes as well as its reversible and irreversible effects.

Nevertheless, conducting pediatric research is usually challenging and has encountered multiple oppositions. First and foremost, clinical trials in children are confronted with serious financial challenges. To be more specific, their costs are elevated because of the unique nature of children and their particular needs during clinical processes. Skilled personnel and adequate facilities are required and, thus, expenses considerably increase. Because of their high costs, pediatric clinical studies generally meet the reluctance of governments and the medical industry, in terms of their financial support. This highlights the need to resort to nongovernmental organizations for funding. Apart from the economic barriers, pediatric research is hindered by additional challenges, including the presence of stricter regulations in comparison to adult standards. Moreover, particularly in the case of DBS studies, there are major difficulties in recruiting underage participants. These are mainly associated with the limited number of eligible candidates, the method's invasive nature, the need for long-term surveillance, special ethical considerations that emerge, parental concerns, and the importance of interdisciplinary collaboration.[6,12,27]

Despite the above-mentioned adversities, the latest updates are favorable for the conduct of pediatric clinical studies, encompassing those focusing on DBS. Certain widely recognized organizations like the European Medicines Agency's Network of Pediatric Research, the US NICHD Pediatric Trial Network, and the World Health Organization (WHO) promote clinical studies in children, with the purpose of developing the field of pediatric healthcare on a global level.[27]

Legal Framework of DBS Devices

1. Medical device regulations

A medical device is defined by the FDA as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes".[28]

While in the US medical devices need to be FDA approved, in the EU they must obtain a Conformité Européenne (CE) Mark. To receive CE approval, they must adhere to European regulations like the Medical Devices Regulation (MDR).

The FDA further employs a risk-based regulatory system that involves the classification of devices into Class I, II, and III

categories. DBS devices belong to the Class III category on the grounds that they constitute high-risk devices. They can significantly impact patients' health and, for this reason, the FDA needs to meticulously assess their probable risks and benefits. Analogous to the FDA, the EU MDR classifies medical devices into Class I, Class IIa, Class IIb, and Class III categories, and DBS devices fall under the Class III category.[28,29]

In the US, being Class III devices, DBS devices must also obtain Premarket Approval (PMA), before they can be distributed. In addition, they also need to pass through further safety measures before their market entry, as they must also receive an HDE approval, which is for devices that target rare conditions. Manufacturers have to provide data which support the safety of the device and prove that it does not expose patients to unreasonable risk. It is also worth noting that HDE approval does not have an equivalent in the EU. Furthermore, focusing on children, the Pediatric Medical Device Safety and Improvement Act governs the development and use of safe and biocompatible pediatric medical devices.[30,31,32]

Notably, both in the US and EU, manufacturers are also required to provide clear labeling of the device. In the context of pediatric DBS, provided information should involve device indications, potential hazards, warnings, precautions, proper implantation techniques, and directions for long-term management.[29,33]

Because of the restrictions regarding the approval of pediatric DBS devices, children may resort to medical DBS devices off-label. Off-label use refers to the usage of a medical device "outside of the approved instructions for use including indications" and has to be reported by manufacturers, following the General Safety and Performance Requirements (GSPR), as outlined by the MDR. In pediatric interventional cardiology, studies suggest that more than 60% of pediatric patients who receive therapeutic cardiac catheterization may be exposed to adult devices off-label. Were we to extend the implications of this finding, there is a high probability that children use adult DBS devices off-label, when they do not have legal access to pediatric DBS devices.[34,35]

2. Latest DBS approval

The Percept™ RC DBS system, launched by Medtronic, received CE and FDA approvals at the end of 2023 and the beginning of 2024, respectively. The device is groundbreaking, as it is "the only rechargeable DBS system with BrainSense™ sensing technology." Its standout features include its small size, great battery capacity, and potential for customized treatment, as it can effectively record brain signals. It shows promise for treating movement disorders like PD, dystonia, and essential tremor in adults, and it may also enhance pediatric treatment. Without doubt, it constitutes a significant innovation with numerous prospects that could profoundly impact the field of neurology in the future. Amaza Reitmeier, Vice President and General Manager for Medtronic Brain Modulation, stated, "We are transforming brain modulation through sensing-enabled DBS and will continue to drive therapy innovation with the goal of improving the lives of many more people with Medtronic DBS therapy."[36,37,38]

3. Non-medical device regulations

DBS devices for neuroenhancement are not treated as medical devices in the US, as they do not have an "explicit connection to a disease." Consequently, they are governed by regulations beyond those for traditional medical devices and are controlled by different regulatory bodies, including the Federal Communications Commission (FCC). In contrast, in the EU, the Medical Devices Regulation (MDR) may regulate "products without an intended medical purpose" in certain cases. Such devices are termed "Medical Devices without an Intended Use." Furthermore, the updated EU's MDR specifically addresses "equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields penetrating the cranium to modify neuronal activity in the brain." The EU's inclination to develop its own regulations regarding neuroenhancement devices, including DBS

devices, reflects its cautious approach. On the other hand, the US approach is less comprehensive.[16,39]

Conclusion and Recommendations

In conclusion, DBS holds promise for the treatment of various neurological and psychiatric disorders in pediatric populations. Beyond the realm of therapy, it could also potentially be applied for neuroenhancement purposes in order to optimize the capacities of children, especially in the area of education.

Nevertheless, the method is still in the research stages, both in children and adults, particularly in the fields of psychiatry and neuroenhancement. Research involving underage participants is limited and usually adult findings are adapted to pediatric cases.

The advancement of technology and medicine aims to provide an explanation of DBS mechanisms and contribute to the development of better operating and more effective models. Thus, it is expected that pediatric healthcare will improve and great progress in neurology and psychiatry will be achieved.

However, various issues, concerns, and limitations are related to pediatric DBS, on multiple levels. Based on my research, the following ethical, clinical, and legal recommendations are put forth:

1. Further relevant research should be conducted to reveal the effects of pediatric DBS, particularly the long-term ones. Greater interest must be expressed from the part of governments, the medical industry, and non-profit organizations for the financial support of such trials.
2. Interdisciplinary collaboration on a global scale is of vital importance for the development of the method. It includes productive interaction and communication among researchers, ethicists, and clinicians specializing in different fields like neurology and psychiatry.
3. Education is a must, not only for healthcare professionals but also for children and their families. Healthcare professionals should be educated in depth regarding the mechanisms of DBS and its legal as well as ethical concerns. They must also share their knowledge effectively with children and their families to ensure informed decision-making. The process of decision-making can also be facilitated by the development of clear decision aids (DAs).
4. The development of clear legal guidelines is imperative. Establishing regulations that are specific to pediatric DBS, and cover the field of neuroenhancement as well, is crucial.

Following these recommendations plays a significant role regarding the future of the domains where pediatric DBS can be applied. It is worth highlighting that, regardless of the extent to which pediatric DBS advances, its ethical, clinical, and legal considerations should not cease to be carefully explored.

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Ανασκόπηση

Artificial Intelligence (AI) in Palliative Care: Ethical Challenges

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Abstract

Palliative Care (PC), which has recently become a more prominent field in healthcare, focuses on providing patients quality of life, relief from pain and other symptoms of serious illnesses, regardless of the diagnosis or stage of the disease. Even though several studies have reported the development of Artificial Intelligence (AI) in medicine, AI in the field of PC is still in early progress. The application of AI technologies in PC raises many ethical challenges which this paper will attempt to highlight. To achieve this, a literature review was conducted, scientific studies were gathered and were critically examined. It was observed that current AI applications in PC include Mortality risk prediction, Data annotation and Morbidity prediction. Ethical dilemmas and the legal framework will be investigated to emphasize the rights of patients, as well as the responsibilities and obligations healthcare professionals carry. Furthermore, directions for trustworthy AI in PC will be proposed. Finally, since PC requires a close doctor-patient relationship, healthcare professionals should focus on developing AI algorithms that align with the patients' needs and the goals of PC.

Keywords: artificial intelligence, AI, deep learning, machine learning, palliative care, ethical challenges, ethics.

Η Τεχνητή Νοημοσύνη (ΤΝ) στην παροχή Παρηγορητικής Φροντίδας: Ηθικές προκλήσεις

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Περίληψη

Η Παρηγορητική Φροντίδα, η οποία τελευταία αναδεικνύεται ως πιο σημαντικός τομέας στην υγειονομική περίθαλψη, επικεντρώνεται στην παροχή ποιότητας ζωής και στην ανακούφιση από τον πόνο ή από άλλα συμπτώματα σοβαρών ασθενειών, ανεξαρτήτως διάγνωσης ή σταδίου της νόσου. Παρόλο που αρκετές μελέτες έχουν αναφέρει την ανάπτυξη της Τεχνητής Νοημοσύνης (ΤΝ) στην Ιατρική, η ΤΝ στον τομέα της Παρηγορητικής Φροντίδας βρίσκεται ακόμα σε πρώιμα στάδια. Η εφαρμογή τεχνολογιών ΤΝ στην Παρηγορητική Φροντίδα εγείρει πολλά ηθικά διλήμματα, τα οποία θα συζητηθούν μέσω αυτής της εργασίας. Για να επιτευχθεί αυτό, πραγματοποιήθηκε ανασκόπηση της βιβλιογραφίας, συγκεντρώθηκαν επιστημονικές μελέτες, οι οποίες εξετάστηκαν κριτικά. Παρατηρήθηκε ότι οι τρέχουσες εφαρμογές ΤΝ στην Παρηγορητική Φροντίδα περιλαμβάνουν την πρόβλεψη της θνητότητας, τον σχολιασμό δεδομένων και την πρόβλεψη νοσηροτήτων. Τα ηθικά διλήμματα και το νομικό πλαίσιο θα διερευνηθούν για να δοθεί έμφαση στα δικαιώματα των ασθενών, καθώς και στις ευθύνες και υποχρεώσεις των επαγγελματιών υγείας. Επιπλέον, θα προταθούν κατευθύνσεις για δημιουργία αξιόπιστης ΤΝ στην Παρηγορητική Φροντίδα. Τέλος, δεδομένου ότι η Παρηγορητική Φροντίδα απαιτεί στενή σχέση γιατρού-ασθενούς, οι επαγγελματίες υγείας θα πρέπει να επικεντρωθούν στην ανάπτυξη αλγορίθμων ΤΝ που να ευθυγραμμίζονται με τις ανάγκες των ασθενών και τους στόχους της Παρηγορητικής Φροντίδας.

Λέξεις κλειδιά: τεχνητή νοημοσύνη, ΤΝ, παρηγορητική φροντίδα, μηχανική μάθηση, ηθικές προκλήσεις, ηθική.

INTRODUCTION

Palliative Care (PC) is explicitly and inseparably linked to the human right to health. This can be easily understood from its purpose and definition. PC is an approach that improves the quality of life of patients, both adults and children, and their families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through the early identification, correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual.[1] Its main purpose is to offer a support system in order to help patients live as actively as possible until death. Despite the crucial importance of palliative care and its inseparable nature from human rights, it is not being successfully applied in the medical care of patients. According to WHO, each year, an estimated 56.8 million people are in need of palliative care. Worldwide, only about 14% of people who need palliative care currently receive it. The global need for palliative care will continue to grow as a result of the aging of populations and the rising burden of noncommunicable diseases and some communicable diseases. Regardless of the unmet need for palliative care, national health policies and systems often do not include palliative care at all and training on palliative care for health professionals is often limited or non-existent.

Within this context, the reality of Artificial Intelligence (AI) is unfolding, with its use spreading more and more in healthcare. The use of AI in medicine has stood at the center of interdisciplinary scientific research, political debate, and social activism. With the increasing availability of health-care data and the rapid progress in analytics techniques, AI has the potential to transform the health sector. It can offer health professionals the ability to reduce errors and costs of care, to increase their engagement with their patients, to enable research in clinical settings, to provide timely intervention, predictive analytics and as much informed patient care as possible.[2] All the above suggest that artificial intelligence could address the growing need for Palliative Care and potentially enhance its applications and benefits for patients. However, one should not overlook the considerations discussed in the health sector about the use of AI in medicine, and by extension in palliative care, but also the possible ways that this use could be harmful.[3,4]

To maintain a common understanding with readers regarding AI and its related terms, it is essential to clarify the main terms and concepts in medical AI used throughout this report. The historical definition of AI talks about a machine that is able to mimic human intelligence or even surpass it to perform a given task such as prediction or reasoning. However, dominant in healthcare is actually a subfield of AI called Machine Learning (ML) which uses methods that learn to perform given tasks, such as prediction or classification or tasks automation, based on existing data. Accordingly, a subfield of ML is Deep Learning (DL), which refers to the use of large Neural networks (NNs) and big data to better solve complex problems. It is important to note that DL and NN demand sufficiently large data samples, so when this condition cannot be applied other techniques are used such as decision trees or support vector machines.[5]

In this literature review it is considered important to highlight dilemmas that may be caused by AI applications in PC, such as Mortality Risk prediction, Data annotation, Morbidity prediction and Response prediction under PC settings. It should be noted that current literature does not adequately cover this problem and the ethical challenges that arise from these applications.

METHODS

The study aims to understand the areas of Palliative Care in which AI techniques have been implemented and to critically examine the ethical challenges that occur from this application. In order to examine the ethical challenges of AI use in PC, scientific studies were gathered from various databases and journals (PubMed, Google Scholar, ResearchGate, UpToDate etc.). Examples of AI applications in PC are provided and examined based on ethical dimensions and

values. The following keywords were used: artificial intelligence, AI, deep learning, machine learning, palliative care, ethical challenges, ethics

RESULTS

The relevant studies that were identified in the literature are briefly presented in Section A, whereas the studies referring to the ethical challenges are presented in Section B. A more extensive analysis of the ethical challenges that may occur through AI applications in PC is presented in Section C.

A. STUDIES REGARDING THE APPLICATION OF AI IN PALLIATIVE CARE

A1. Improving Palliative care with Deep Learning[6]

In this study, scientists described a method using DL and Electronic Health Record (EHR) data of patients, to predict all-cause 3-12 month mortality of patients as a proxy for those who could benefit from palliative care. The EHR data of admitted patients were automatically evaluated by an algorithm, which brings patients who are likely to benefit from palliative care services to the attention of the Palliative Care team. These predictions enable the Palliative Care team to take a proactive approach in reaching out to such patients, rather than relying on referrals from treating physicians, or conduct time consuming chart reviews of all patients. They used the following proxy problem statement: "Given a patient and a date, predict the mortality of that patient within 12 months from that date, using EHR data of that patient from the prior year". They were also separately interested in the model performance on a subproblem — the ability to predict mortality of patients who are currently admitted. This is because it is much easier for the palliative care staff to intervene with admitted patients. The model eventually was a little under-confident in its probability estimates. Although some patients did not pass away within 12 months from their prediction dates, they were often diagnosed with terminal illness and/or were high utilizers of healthcare services. They also demonstrated a novel method of generating explanations from complex deep learning models that helps build confidence of practitioners to act on the recommendations of the system.

A2. Machine Learning–based model to predict delirium in patients with advanced cancer treated with palliative care: a multicenter, patient–based registry cohort[7]

This study aimed to present a machine learning model that predicted delirium in patients in palliative care and to identify the significant features that influenced the model. The study dataset included 165 patients with delirium among 2314 patients with advanced cancer admitted to the acute palliative care unit. Seven machine learning models, including extreme gradient boosting, adaptive boosting, gradient boosting, light gradient boosting, logistic regression, support vector machine, and random forest, were evaluated. The study revealed that the combination of XBoost and RF delivered the most optimal performance. Additionally, they identified that sex was the primary contributor in predicting delirium, followed by a history of delirium, chemotherapy, smoking status, alcohol consumption, and living with family. Furthermore, the machine learning model was successfully deployed on a public website (http://ai-wm.khu.ac.kr/Delirium/) to provide public access to delirium prediction results in patients with advanced cancer. The plan is to securely store the user-entered information with their consent, facilitating a real-time learning process to enhance the machine learning model.

A3. Novel method for predicting nonvisible symptoms using machine learning in cancer palliative care[8]

This study aimed to create a model to predict non-visible symptoms from visible symptoms and basic patient characteristics using machine learning. They performed a retrospective clinical survey involving 213 patients with cancer (no children included) by

dividing the reported symptoms into two groups-visible and nonvisible symptoms. They used decision tree analysis as an analytical machine learning method. The machine learning model used patient background data and visible symptoms to predict nonvisible symptoms: pain, dyspnea, fatigue, drowsiness, anxiety, delirium, inadequate informed consent, and spiritual issues. Although the proposed application is unlikely to be an absolute replacement for palliative care specialists, it is expected to help improve the quality of palliative care provided by healthcare professionals. The results can help better assess and manage symptoms in patients with cancer.

A4. Development and Validation of a Deep Learning Algorithm for Mortality Prediction in Selecting Patients With Dementia for Earlier Palliative Care Interventions[9]

The aim of this study was to develop a deep learning algorithm using longitudinal electronic health records to predict mortality risk as a proxy indicator for identifying patients with dementia who may benefit from palliative care. This retrospective cohort study, used patient demographic information and topics generated from clinical notes, to conduct 6-month, 1-year, and 2-year mortality prediction models with recurrent neural networks. They chose the long short-term memory (LSTM) network, given LSTM's ability to model longitudinal EHR data, in conjunction with an appropriate gradient-based learning algorithm. The models were trained using a data set of 24.229 patients and validated using another data set of 2692 patients. The top-ranked latent topics associated with 6-month and 1- and 2-year mortality in patients with dementia include palliative and end-of-life care, cognitive function, delirium, testing of cholesterol levels, cancer, pain, use of health care services, arthritis, nutritional status, skin care, family meeting, shock, respiratory failure, and swallowing function. The model proved that clinical notes along with patient demographics are informative, and the deep learning neural network structure can successfully capture short- and long-range longitudinal patterns.

A5. Identifying Connectional Silence in Palliative Care Consultations: A Tandem Machine-Learning and Human Coding Method[10]

This study is a cross-sectional analysis of 354 audio-recorded inpatient palliative care consultation conversations to evaluate the reliability, efficiency and sensitivity of a tandem ML-HC (Machine Learning-Human Coding) approach to identify Connectional Silence. The codebook included three types of Connectional Silences: Emotional, Compassionate and Invitational. Connectional Silences were rare (5.5%) among all two-second or longer pauses in palliative care conversations. Tandem ML-HC demonstrated strong reliability. HC alone required 61% more time than the Tandem ML-HC method. No Connectional Silences were missed by the ML screening algorithm. According to the authors tandem ML-HC method meets the purpose for which it was created in serious illness conversations.

A6. Applications of Machine Learning in Palliative Care: A Systematic Review[11]

In this study they systematically searched for published research papers that used different kinds of machine learning in palliative care for different use cases. In total, 22 publications using ML for mortality prediction (n=15), data annotation (n=5), predicting morbidity under palliative therapy (n=1), and predicting response to palliative therapy (n=1) were included. The studies used a variety of different supervised and unsupervised models such as neural networks, (boosted) tree-based classifiers, support vector machines, and hierarchical clustering. This review found mortality prediction as the most frequent use case of ML in palliative care. According to the authors, in an ideal world, models that recommend patients for palliative care referral should not only predict mortality but also try to predict the time to clinical deterioration, which is usually the much more relevant event to determine when palliative

care is needed. In conclusion, machine learning in palliative care is mainly used to predict mortality, but recent publications indicated its potential for other innovative use cases such as data annotation and predicting complications.

A7. Improving palliative care with machine learning and routine data: a rapid review [version 2; peer review: 3 approved][12]

In this study they conducted a rapid review including peer-reviewed studies that used ML approaches on routine data to improve palliative care for adults. The specified outcomes were survival, quality of life (QoL), place of death, costs, and receipt of high-intensity treatment near the end of life. The database search identified 426 citations. One paper predicted six-month mortality, one paper predicted 12-month mortality and one paper cross-referenced predicted 12-month mortality with healthcare spending. ML-informed models outperformed logistic regression in predicting mortality where data inputs were relatively strong, but those using only basic administrative data had limited benefit from ML. Identifying poor prognosis does not appear effective in tackling high costs associated with serious illness. While ML can help to identify those at risk of adverse outcomes and inappropriate treatment, applications to policy and practice are formative. Future research must not only expand scope to other outcomes and longer timeframes, but also engage with individual preferences and ethical challenges of this emerging field. According to the authors, most important is to recognise that improving clinical decision-making will require more than simply improving the predictive power of mortality models.

B. STUDIES ABOUT ETHICAL CHALLENGES IN THE USE OF AI IN PC

After a brief review of the literature, it appears that there are not many references to the ethical dilemmas that may arise from the use of artificial intelligence in palliative care.

B1. Ethical challenges of artificial intelligence technology in palliative care[13]

This project aimed to identify the ethical challenges of AI in palliative care. Ethical challenges for AI in palliative care were identified and summarized into themes, using the four ethical principle framework (Autonomy, Beneficence, Non-maleficence, Justice). AI may limit individual autonomy to choose who has access to their data, where, how and for what purposes. It may not be possible for the individual to be fully aware of what is involved in the analysis (autonomy). The individual may not benefit directly; privacy for their data may need to be sacrificed to benefit wider society (Beneficence). AI may amplify pre-existing biases in the data set and/or in society (Non-maleficence). Resource poor areas and individuals and groups with limited data (e.g. homeless) are least likely to benefit from data driven medicine (Justice).

B2. Ethical Considerations Related to Using Machine Learning-Based Prediction of Mortality in the Pediatric Intensive Care Unit[14]

This study discusses ethical challenges associated with applying ML technology in pediatric intensive care unit (PICU) patients by considering the benefits and risks related to the technology and to care delivery, as well as organizational and legal issues. Pediatric patients differ from adults because children generally do not have legal control over their data or legal authority to give or withhold consent. Because data can be tracked across a longer proportion of their lives, the implications for privacy harms extend through the lifespan. Firstly, regarding technical considerations, ML relies on “learning” from comprehensive datasets. Lack of diversity or inaccuracy in datasets becomes reflected in predictions. Also, some prediction algorithms are so complex that one cannot determine how decisions are made (the “black box” phenomenon). This lack of transparency can lead to or contribute to mistrust and may affect clinician and patient acceptance and use of such technology if the models are not properly checked for their safety and effectiveness.

Secondly, regarding care delivery considerations, for the patients who are predicted to live, the perceived objectivity of ML could substantiate decisions about using high-risk or resource-, time-, and labor-intensive therapies. When decisions involve therapies with high side effect profiles impacting future quality of life, such as an organ or hematopoietic stem cell transplant, families and clinicians would be better informed to make such choices. One might argue that such models could reduce the decision-making burden on families who are now sometimes asked to contribute to life and death decisions about their child's care with limited data. However, mortality prediction models could also limit the advancement of medical knowledge and family engagement. If clinicians avoid therapies with unknown efficacy for patients predicted to die, we could lose opportunities to learn. Third, regarding organizational considerations, healthcare organizations may be interested in the financial impact of using ML. The initial cost for hospitals purchasing AI technology ranges from $75,000 to $120,000. Despite the importance of transparency, hospitals currently use many prediction models as part of "quality improvement efforts" without necessarily disclosing their use to patients. This practice reflects the blurry line between hospital operations and medical research. Fourth, regarding legal considerations, AI also introduces liability questions. Under current law, physicians may be liable for harm to patients if they follow AI recommendations to use nonstandard approaches to care delivery. Current law likely only shields physicians from liability when they follow the standard of care. However, if AI becomes part of the standard of care, physicians will likely avoid liability when following (even incorrect) AI recommendations and patient harm occurs.

C. ETHICAL CHALLENGES OF AI APPLICATIONS IN PALLIATIVE CARE

As the applications of AI in medicine keep rising and developing, they require compliance both with scientific and ethical rules, in order to produce benefit for the patients, notwithstanding safety and effectiveness of medical care. Palliative care is a sensitive field of AI as its applications directly impact the quality of life, the mental and physical distress or discomfort and the comfort care of patients[1]. With the intention of focusing on the ethical challenges that arise, the use of AI will be approached on the basis of fundamental human rights, which are defined by the EU charter of fundamental rights[4]. These rights include respect for human dignity, freedom of the individual, solidarity, equality, citizens' rights, justice, respect for democracy and the law. The parallels that unite these rights can be reflected by what has been described as an "anthropocentric approach". In addition, they are legally binding rights and they ensure the compliance of the AI applications with the law. This approach for AI applications is necessary to promote health for everyone and everywhere by accelerating the development and adoption of appropriate, accessible and affordable person-centric digital healthcare[15]. The following analysis will be based on a set of 5 principles (autonomy, beneficence, non-maleficence, justice, data privacy) that could conflict with applications of AI in palliative care.

Firstly, it should be taken under consideration if the AI applications in PC maintain respect for human autonomy, which surrounds the idea that every human being should never be degraded, violated, or suppressed by new technologies such as AI systems. Briefly, end-users of those systems must have meaningful opportunities for choice over who accesses their data, where, when and for what purpose. Each patient or end-user must have their own voice and they should make decisions not only about their treatment but also the services they will receive[16]. This patients' right inevitably leads the health professionals to what is described as Transparency. Transparency and explainability are increasingly recognized as critical to ethical AI, leading the PC providers to fully inform the patients' or their caregivers of what is involved, meaning the goals, benefits and possible risks[15,17]. Without such information, a decision cannot be duly contested. An

explanation as to why a model has generated a particular output or decision is not always possible ("black box" phenomenon). This task is rather easy for clinicians since it raises the question of whether the patients will be able to understand the function of AI, how it will affect their treatment or their data privacy, keeping in mind the complexity of those systems. This difficulty should definitely not stand in the way of clinicians informing patients and families about the function-purpose-risks, since the trust between patients and clinicians would be shuttered.[12] The degree to which explicability is needed is highly dependent on the context and the severity of the consequences and risks that AI applications can produce. For example, the results from Mortality Risk Prediction can potentially affect clinical decisions according to PC treatment and influence the patients' psychological burden.[11] On the other hand AI models, that are used safely and with shared decision making, may provide more opportunities for patients to access PC or make decisions for their treatment.[13]

The following considerations are raised by the principle of Beneficence, which supports that AI applications should be designed and implemented for the common good to benefit humanity by some measure. Patient safety and quality of care are priorities when designing and implementing AI models in PC, hence its connected to PCs values and goals. The benefit for the patients must be emerged by all different "layers" of AI applications, which include the reliable and reproducible design, accuracy of performance, ecological validation, quality evaluation, proper implementation and training of clinicians. Such considerations could apply for patients whose data have been used to train AI algorithms. These patients may not benefit directly from these applications. Though, their data is used for the common good if the AI algorithm meets the rest of the criteria. For example, data has been used to identify the patients who are in need of PC, but not all patients are. This can lead to the fact that privacy of data might be sacrificed to benefit wider society. On the other hand, AI applications in PC can lead to improvements of provided healthcare and more access to evidence-based, updated Palliative Care.[13]

Furthermore, as far as the principle of Non-maleficence is concerned, AI systems should neither cause nor exacerbate any harm or affect humans negatively. This entails the protection of human dignity, as well as mental and physical integrity. AI systems and the environments in which they operate should be secure and protected. They should be technically robust while ensuring that they are not open to malicious use. An example of such consideration could be the ML-based model that predicts delirium in patients with cancer treated with PC.[7] This model is deployed on a public website to provide public access to its results while it uses the data to enhance the ML model and train it. It has to be clarified that the research team ensures security of data and proper information of patients. Vulnerable people should be given more attention and included in the development and deployment of AI systems. For example, there are studies and ML models, from those mentioned above, that exclude children from the input data. In the AI models that refer to PC there are either not enough models trained over childrens' data or children are not adequately represented in the data for training these AI models.[18] Particular attention should also be given to situations where AI systems are likely to cause or exacerbate negative effects due to power or information asymmetry, such as between employers and employees, businesses and consumers, or governments and citizens. Harm prevention also involves consideration of the natural environment and all living things.

In addition, the principle of Justice is concerned as far as the AI applications in PC, meaning that the development and implementation of AI systems should be done in a fair manner. The main factors that contribute to inequalities, inequities and injustice include sex/gender, age, ethnicity, income, education and geography[19]. The main problem that threatens societies following the development of AI is the social gap issue. In all countries around the world, with every development, discovery and invention, people

face greater social inequality and less social justice. Although AI improves the accessibility to more information about science and technology, it exacerbates social inequality with a greater gap between developing and advanced countries. These are also strengthened by the fact that almost all studies were conducted based on data from Western countries, mostly from the USA. Other countries included Canada, the UK, France, Denmark, Germany, Spain, and Australia. One study collected data from both North America and Asia, and another study included data from three European countries (Switzerland, Germany, and Italy). One study used data from nine Western countries. Two non-Western countries/regions appeared in the collection of studies: sub-Saharan Africa and India.[11] Consequently, resource poor areas and individuals or groups with limited data in PC are least likely to benefit from data driven medicine. Such systematic biases and missing data in training data sets (such as electronic health records (EHRs) and insurance claims) are likely to perpetuate existing health disparities and they contribute to the disparity in AI performance among different demographic groups. While some of these inequities are systemic due to socioeconomic differences and discrimination, human biases also play an important role. For example, in the United States, existing research has demonstrated that doctors do not take Black patients' complaints of pain as seriously nor do they respond to them as quickly as they do for their White counterparts.[20] Another example of common bias embedded in healthcare systems is gender-based discrimination. Once again, in the domain of pain management, studies have pointed to the increased invisibilisation of female patients when reporting pain[21]. Though, there is not enough research and data around the biases in Palliative Care settings. It is widely argued that the most common cause for unfairness in medical AI is the bias in the data used to train the machine learning models. Besides that, another dimension that AI systems should imply commitment to, is that justice entails the ability to contest and provides effective legal protection against decisions taken by the systems and by the people who operate them. In order to do this, the entity that is responsible for the decision should be identifiable and the decision-making processes should be explained. As far as the AI in PC settings is concerned, the so far applications of AI models are either for training algorithms or aiding clinicians as simple prognostic tools with none crucial decision-making responsibility.

Lastly, yet another concerning principle is that of Data Privacy. Informed consent is a crucial and integral part to the patient's experience in healthcare and it is linked to protection from harm, respect for autonomy and privacy protection. The risks that may arise from poor data privacy of patients could be using and sharing patients' data without informed consent, repurposing them without their knowledge, exposing data as a result of thefts or frauds and potential cyberattacks on AI models[4]. Not informing patients and families about these risks could result in loss of their trust in both their clinicians and the health care system[17]. Such an example is the use of EHR data in an AI algorithm that can detect possible patients who are in need of PC. Further considerations are born regarding children. Childrens' data exists and thus can be tracked across a longer proportion of their lives, which creates severe considerations and potential implications of privacy harms that extend through their lifespan.[14]

DISCUSSION

At first glance, while the need for PC has grown exponentially, current research about applications of AI in PC, even though not nonexistent, remain low compared to the actual needs for patients and caregivers[12]. The results suggest that there has been an effort of applying AI models in PC, most of which have been training models and some have been provided for public access. The use of AI in PC can be summarized as all cause 3-12 months Mortality risk prediction as a proxy for those who could benefit from PC, Morbidity prediction under PC (dementia, delirium, non visible symptoms) and Data annotation

(Identifying Connectional Silence in Palliative Care Consultations). The majority of research suggests that the AI models should not be used as an automated clinical decision, rather than a tool to make the workflow of a human more efficient. In any case, the clinician is always in the loop to make the decision after having a closer look at patients' history. In addition, most of ML models are accompanied with limitations such as low data heterogeneity with imbalance in the number of patients in each groups,[7,8,9] limited sample size datasets[7,8], use of assessments and tools that differ from clinical trials and might exclude confusing results[7]. Furthermore, while the timing of offering PC to a patient is certainly an important aspect that could benefit from AI, it is far from being the only one.[22] Every decision where the clinician has to weigh the benefits of an intervention and the consequences of performing it, could benefit from more precise predictions.

The limitations and ethical dilemmas are evidently challenging for both clinicians and researchers. The difficulty is accompanied by lack of regulations regarding AI applications in PC. The European Union (EU) has been at the forefront of medical AI innovation and has explicitly recognized the challenges AI presents for existing liability regimes. To provide legal certainty, the European Commission has proposed one of the first legal frameworks specific to AI, the *Artificial Intelligence Act*. This framework aims to promote the safe use of AI in high impact sectors, such as healthcare, while also strengthening technological innovation[23]. Research and implementation should be in accordance with general regulations regarding AI in healthcare and medicine. Most importantly, it is crucial to assess the risk of the AI application or development early in the design process. The Risk assessment should be performed according to the EU AI-ACT Risk Classification. It sets out four risk levels for AI systems: unacceptable, high, limited, and minimal (or no) risk. So far, AI applications in PC mainly concern models for mortality or comorbidities prediction. However, they do not contribute to the decision-making process but they are used as tools to support and assist clinical decisions, meaning that the clinician makes the final decision after critical examination. Therefore, the so far applied AI models in PC can be classified as minimal risk. As stated by the AI-ACT, minimal risk AI models do not have any restrictions or mandatory obligations. Nevertheless, it is suggested to follow general principles such as human oversight, non-discrimination and fairness. If these models functioned as decision-makers, the risk would be classified as limited or high. This is explained by the potential for significant damage if these models fail or are misused. For example, if decisions about who receives palliative care were determined solely by such models, many patients could be deprived of the care they need. Some examples of limited risk AI in PC could potentially be the use of deepfakes as patient data in order to create larger databases and better train algorithms, or the use of biometric systems to recognize emotions such as anxiety or fatigue to improve the provision of PC. AI-ACT states that AI systems of limited risk must be transparent, meaning any deepfakes should be donated as such and humans should be informed about their interaction with the AI. An example of high risk AI in PC could be the risk assessment by insurance companies of whether a candidate will need PC or not. AI systems in this risk-class must meet certain requirements in order to be put on the market and operate in the EU.[23]

The overall conclusion drawn from these facts is that risk assessment is of utmost and mandatory importance for the development of an AI model, both in the field of healthcare and specifically in PC. A helpful self-assessment checklist exists in the FUTURE-AI guidelines for trustworthy AI in medicine.[24] These guidelines are organized according to six principles (Fairness, Universality, Traceability, Usability, Robustness, Explainability) and comprise concrete recommendations and a self-assessment checklist to enable AI designers, developers, evaluators and regulators to develop

trustworthy and ethical AI solutions in medicine and healthcare.

It is certainly understood that the existence of a common axis is necessary for the development of algorithmic models and their application in PC, in order to have reproducible and repeatable results. For the time being, researchers should develop their models in accordance with National Regulations, such as the assessment checklist for trustworthy AI called ALTAI.[15] The checklist is structured along seven categories: 1) human agency and oversight, 2) technical robustness and safety, 3) privacy and data governance, 4) transparency, 5) diversity, non-discrimination and fairness, 6) environmental and societal well-being and 7) accountability.[15] Consequently, the ethical challenges are not insurmountable. Health care professionals have the capability and obligation to act in the best interest of the patients and to ensure that the use of AI meets safeguards for mitigating these ethical risks.

CONCLUSION

In summary, AI applications in palliative care are ushering in a new era for the field, though they are still in a premature stage of development. As mentioned, current applications include Mortality risk prediction, Data annotation and Morbidity prediction under PC settings. AI, ML and DL technologies are drastically advancing, offering healthcare greater possibilities, while becoming more and more popular every day. However, this potential is accompanied by significant ethical challenges that cannot be ignored. First and foremost, AI applications in PC must incorporate patient needs and ensure patients have control over their data and treatment decisions. In addition, transparency is crucial, requiring healthcare providers to fully inform patients about the goals, benefits, and risks of AI technologies. This should be accompanied by informed consent in order to maintain patients' trust and protect against potential risks. AI must be designed for the common good, prioritizing patient safety and quality care. Healthcare professionals must develop AI systems fairly, avoiding biases that exacerbate social inequalities. Legally, it is not yet clear how civil liability should apply to AI and who would be liable, due to ongoing debates about whether human or product liability should be applied. Nonetheless, AI systems should be developed in accordance with the ethics guidelines for trustworthy AI, presented by HLEG. Finally, it's important to mention that PC requires a close doctor-patient relationship, which means that AI should be used alongside traditional palliative care methods. AI in PC is not just about Mortality prediction, but also about developing algorithms that can identify patient needs and lead to beneficial interventions.

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A 2016 113(16):4296-301. *Available at*: https://doi.org/10.1073/pnas.1516047113
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23. European Union, AI Act: first regulation on artificial intelligence, European Parliament 2024. *Available at*: https://www.trail-ml.com/blog/eu-ai-act-how-risk-is-classified
24. International consensus guideline for trustworthy and deployable artificial intelligence in healthcare, FUTURE-AI 2024. *Available at*: https://future-ai.eu/

Ανασκόπηση

Best practices on informed consent procedures in sensitive areas of medical practice

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Abstract

The contribution focuses on best practices regarding informed consent procedures in sensitive areas of medical practice, specifically death with dignity. Initially, attention is given to defining key terms such as active euthanasia, assisted suicide, dignity, and psychological suffering. Subsequently, the paper analyzes the current situation in selected states, examining legislation, draft laws, jurisprudence, etc. Finally, a comparison of the legislation of individual states is provided.

Keywords: euthanasia; assisted suicide; dignified death;informed consent; health law.

Βέλτιστες πρακτικές σχετικά με τις διαδικασίες ενημερωμένης συναίνεσης σε ευαίσθητους τομείς της ιατρικής πρακτικής

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Περίληψη

Η μελέτη επικεντρώνεται στις βέλτιστες πρακτικές που αφορούν τις διαδικασίες ενημερωμένης συγκατάθεσης σε ευαίσθητους τομείς της ιατρικής πρακτικής, συγκεκριμένα ως προς αποφάσεις σχετικές με το τέλος της ζωής. Αρχικά, επιχειρείται ο ορισμός βασικών εννοιών, όπως ενεργητική ευθανασία, υποβοηθούμενη αυτοκτονία, αξιοπρέπεια και ψυχολογική οδύνη. Στη συνέχεια, αναλύεται η τρέχουσα κατάσταση σε επιλεγμένα κράτη, εξετάζοντας τη νομοθεσία, τα σχέδια νόμων, τη νομολογία κ.λπ. και επιχειρείται μια σύγκριση των διαφορετικών καθεστώτων στα κράτη αυτά.

Λέξεις κλειδιά: ευθανασία; υποβοηθούμενη αυτοκτονία; αξιοπρεπής θάνατος; ενημερωμένη συναίνεση; νόμος για την υγεία.

Introduction

The issues surrounding the dignified ending of life, its legalization, and regulation remain highly debated across states, encompassing legal, ethical, and moral considerations. When crafting laws on this sensitive topic, states aim to balance a patient's autonomy and dignity with protections for those in vulnerable situations. States introducing euthanasia or assisted suicide often focus on ensuring access while others emphasize palliative care and improving the quality of life, limiting death assistance to exceptional cases. Conversely, some prioritize patient autonomy and respect for end-of-life decisions. However, adopting such legislation raises numerous practical questions.

This thesis explores the topic of dignified death, providing insights into relevant legislation, court practices, and specific aspects of the debate. Drawing on valid laws, professional articles, literature, and jurisprudence, it aims to familiarize readers with the current legal landscape. Organized from general to specific, the text defines key terms before examining the legal frameworks and judicial practices in various states that regulate dignified death.

The research employs analytical and comparative methods. States were selected based on their approaches to end-of-life legal regulations. The study examines four European countries (Netherlands, Belgium, Luxembourg, Spain) permitting active euthanasia, alongside Canada. It also includes European states allowing assisted suicide (Germany, Austria) and those focusing on palliative care (France, Italy).

The thesis details the legal processes surrounding dignified death in these states, emphasizing patient requests, their requirements, and expectations. These findings are critically compared and evaluated. The research provides a comprehensive overview, analyzing euthanasia-friendly states, those permitting assisted suicide, and others with alternative approaches, ultimately offering a comparative perspective on the legislation and practices surrounding dignified death.

1. General starting points

1. 1 Definitions

Several terms are associated with the issue of dignified death, each with distinct meanings. For this article, certain terms need to be clearly defined, as distinguishing them is crucial for informed discussions and crafting legislation. States differ in their approaches to end-of-life choices, as not all permit active euthanasia. Switzerland, for instance, is well-known for its stance on death with dignity but allows only assisted suicide, not active euthanasia.

1. 1. 1 Autonomy of the will

The first concept that needs to be mentioned is the autonomy of the will. This is one of the fundamental legal principles, allowing individuals to choose their legally significant behaviors. Autonomy of the will can manifest at different levels, including the choice of whether to act, the selection of the act's recipient, and the determination of its content and form.[1]

1. 1. 2 Euthanasia

Štěpán defines euthanasia as an act or omission whose own goal is to shorten life, while the decisive motive is compassion for the sufferer.[2] According to the literature, euthanasia can be further divided into active and passive. Active euthanasia is „*an act in which a person other than the patient, at the*

[1] Oxford Reference. Autonomy. Available at: https://www.oxfordreference.com/display/10.1093/oi/authority.20110803095436282.

[2] School of Medicine University of Missouri. Euthanasia. Available at: https://medicine.missouri.edu/centers-institutes-labs/health-ethics/faq/euthanasia.

request of the patient, intentionally performs the final act leading to the end of the patient's life". Passive euthanasia is an act in which a person other than the patient withholds or withdraws life-sustaining treatment from the patient. [3]

1. 1. 3 Asisted suicide

Another term that requires clarification is assisted suicide. In this scenario, a patient intentionally ends their life but seeks the assistance of others in doing so. It's important to note that the patient must ultimately perform the decisive act themselves.[4]

1. 1. 4 Informed consent

Informed consent is a legal term that refers to a person's voluntary, informed, and usually written consent to a certain medical or research procedure, treatment, or participation in clinical research. This consent requires that the person be properly informed about all aspects of the procedure or treatment, including risks, benefits, alternatives, and possible side effects. Informed consent is an important legal and ethical principle in medicine and research to ensure that a patient or participant has the right to the information needed to make an informed decision about their health and treatment.[5]

1. 1. 5 Dignity

Dignity is defined as the state of being worthy of honor or respect. Human dignity refers to the concept that represents the inherent value of each individual. Every person should be treated with respect and no one should be discriminated against.[6] This is further related at the international level to the guarantees of rights contained in the Universal Declaration of Human Rights[7] (also known as „UDHR"), namely the guarantee of freedom, dignity and equality (Article 1 UDHR) etc. This is related to the mutual respect of the will of each individual. Furthermore, the prohibition of torture, cruel, inhuman and degrading treatment is guaranteed (Art. 5 UDHR). Human dignity, rather than a label for collective law, represents the ultimate source of all rights recognized, equal, and inalienable.[8]

[3] Garrard E; Wilkinson, S. Passive euthanasia. Journal of Medical Ethics, 2005, 31: 64-68. Available at: http://dx.doi.org/10.1136/jme.2003.005777.

[4] Picón-Jaimes YA, Lozada-Martinez ID, Orozco-Chinome JE, Montaña-Gómez LM, Bolaño-Romero MP, Moscote-Salazar LR, Janjua T, Rahman S. Euthanasia and assisted suicide: An in-depth review of relevant historical aspects. Elsevier, Annals of Medicine and Surgery. 2022, 75. Available at: https://www.sciencedirect.com/science/article/pii/S2049080122001406#section-cited-by.

[5] National Library of Medicine. Inform consent. Available at: https://www.ncbi.nlm.nih.gov/books/NBK430827/.

[6] Andorno R. Human Dignity and Human Rights. In: Henk AMJ ten Have (ed) Handbook of Global Bioethics. Springer Reference, 2014: 45-57. Available at: https://www.researchgate.net/profile/Francis-Masiye/publication/286484913_Toward_an_African_UbuntuologyuMunthuolo-gy_Bioethics_in_Malawi_in_the_Context_of_Globalization/links/5de52d1b4585159aa45c992c/Toward-an-African-Ubuntuology-uMunthuology-Bioethics-in-Malawi-in-the-Context-of-Globalization.pdf#page=68.

[7] United Nations. Universal Declaration of Human Rights. Available at: https://www.un.org/en/about-us/universal-declaration-of-human-rights.

[8] Andorno R. Human Dignity and Human Rights. In: Henk AMJ ten Have (ed) Handbook of Global Bioeth-

The concept of dignity in the field of bioethics and healthcare has undergone historical development. A significant historical milestone in this area is the Universal Declaration of Human Rights and the Nuremberg Code. After the events and horrifying experiments of the Second World War, it became essential to address human dignity and its associated rights at the international level. The Nuremberg Code is especially important as it is the first document to formally enshrine obligations such as informed consent. This marked a shift in the approach to the individual, emphasizing the importance of respecting their will and dignified treatment. This rule underscores the significance of the individual and their right to have their personality and will respected.[9]

Currently, the primary protected interests in the doctor-patient relationship are dignity and the autonomy of one's will. This marks a shift from earlier times when the focus was primarily on life and health, with less consideration given to individual dignity.[10]

1. 1. 6 Psychological suffering

Psychological suffering related to death with dignity refers to the emotional and mental pain caused or anticipated by the patient's illness or medical condition. This suffering can take various forms, including the subjective perception of life quality. In addition to feelings of loneliness, dependence on others, loss of autonomy, and discomfort, it may also encompass a sense of loss of social contacts.[11]

Firstly, it can involve psychological suffering resulting from physical pain. The patient may no longer have control over the physical pain, and even medication and palliative care may not offer sufficient relief. The prolonged experience of pain exhausts the patient, significantly impacting their mental health.

Furthermore, states of fear, uncertainty, and anxiety can also be included under the term psychological suffering. In such cases, the patient experiences distress due to a diagnosis with a progressive nature, certain to worsen in the future. After entering the terminal stage of the disease, the patient loses control over themselves. This can occur in cases of progressive malignant diseases where the patient may lose consciousness or in situations involving psychiatric degenerative diseases where the patient is no longer able to express

ics. Springer Reference, 2014: 49-50. Available at: https://www.researchgate.net/profile/Francis-Masiye/publication/286484913_Toward_an_African_UbuntuologyuMunthuolo-gy_Bioethics_in_Malawi_in_the_Context_of_Globalization/links/5de52d1b4585159aa45c992c/Toward-an-African-Ubuntuology-uMunthuology-Bioethics-in-Malawi-in-the-Context-of-Globalization.pdf#page=68.

[9] Shuster E. Fifty Years Later: The Significance of the Nuremberg Code. The New England Journal of Medicine, 1997, 337: 1436-1440 Available at: https://www.nejm.org/doi/full/10.1056/NEJM199711133372006?query=recirc_curatedRelated_article.

[10] UNC. Nuremberg Code Available at: https://research.unc.edu/human-research-ethics/resources/ccm3_019064/. And: Pellegrino ED. Some things ought never be done: moral absolutes in clinical ethics. Theoretical Medicine Bioethics, 2005, 26: 469-486. Available At: https://link.springer.com/article/10.1007/s11017-005-2201-2.

[11] Haekens A. Euthanasia for Unbearable Psychological Suffering. In: Devos T (ed) Euthanasia: Searching for the Full Story. Springer, 2021: 39-47. Available at: https://library.oapen.org/bitstream/handle/20.500.12657/48260/9783030567958.pdf?sequence=1#page=55.

their will. In these instances, patients may choose to express their will while they are still able to do so, and the procedure will be carried out in accordance with the expressed will once the condition arises.

Psychological suffering can also stem from a subjective perception of the situation as undignified. These are cases where, for example, the patient becomes paralyzed as a result of an accident. The patient is not brain-damaged, but their body is impaired. The patient cannot move, only talks, and is cared for by others. For some people, this situation is unacceptable, but there are cases where patients want to live.[12] In cases where a person's idea of living consists of an active life, the loss of movement and the inability to take care of oneself can be perceived as undignified, leading to psychological suffering.[13] Here, even though death does not pose an immediate threat, the person remains essentially trapped in their body.

From the perspective of expressing a valid will, it is crucial to carefully distinguish between psychological suffering and psychological illness. Psychological illness does not necessarily equate to psychological suffering for the patient. A patient may have a form of psychological illness that can be controlled with appropriate medication, allowing them to live life according to their subjective experience with dignity and reasonable autonomy.

However, physicians must be cautious with patients who seem capable of making decisions for themselves but whose choices might be influenced by a long-term transient condition. For instance, a patient may exhibit signs of psychological suffering for an extended period, which could be attributed to conditions like depression. In such cases, it is essential to explore all therapeutic options and ensure that the patient's condition genuinely cannot be changed, even if it has persisted for a relatively long time. The patient's situation must be static, lacking any prospect of improvement. The doctor should, therefore, rely on the diagnosis, follow proper procedures, and consider available treatment options rather than solely relying on the patient's subjective state, which can be challenging to ascertain, especially in the case of psychological illnesses.[14]

Last but not least, it should be mentioned that certain mental and psychiatric illnesses inherently prevent the ability to make a valid will. One example is mental disability.

2. Situation in individual states

2. 1 Netherlands

The Netherlands became the first country in the world to legalize euthanasia; until then, only a few states allowed assisted suicide. Currently, the Termination of life on request and assisted suicide law (also as „TLRaASL“)

[12] For example Paul Alexander. The Guardian. The man in the iron lung. Available at: https://www.theguardian.com/society/2020/may/26/last-iron-lung-paul-alexander-polio-coronavirus.

[13] For example Ramón Sampedro case. University of Minnesota, Human Rights Library. Manuela Sanlés Sanlés v. Spain. Available at: http://hrlibrary.umn.edu/undocs/html/1024-2001.html.

[14] Haekens A. Euthanasia for Unbearable Psychological Suffering. In: Devos T (ed) Euthanasia: Searching for the Full Story. Springer, 2021: 41-43. Available at: https://library.oapen.org/bitstream/handle/20.500.12657/48260/9783030567958.pdf?sequence=1#page=55.

is valid from 1 October 2021.[15] Art. 1 letter b) TLRaASL provides a definition of assisted suicide, stating that it is intentional assistance to another person in committing suicide or provision of means for the act referred to in Art. 294 par. 2, second sentence of the Dutch Penal Code (also as „DPC“)[16].

The DPC provides that if the act is committed by a doctor in accordance with the TLRaASL it is not a criminal offence. Assisted suicide must be carried out by a qualified medical professional, specifically a doctor (Art. 2, par. 1, lett. f) TLRaASL). It is not permissible for assisted suicide to be performed by a non-medical person.

This law allows for a decision to be made regarding one's death if it is the voluntary request of a patient, made after due consideration (Art. 2 par. 1 lett. a) TLRaASL). The doctor will objectively assess whether the patient is experiencing hopeless and unbearable suffering, and if they are convinced that this is the case, they may consider such a procedure (Art. 2 par. 1 lett. b) TLRaASL). In connection with this, the Supreme Court of the Netherlands addressed the case involving the criminal prosecution of a doctor who performed active euthanasia on a patient with advanced dementia.[17] Among other issues, the court examined whether it is feasible to honor a written statement, such as a previously expressed wish, requesting end-of-life measures in the event of dementia. According to legislation, it is necessary for the doctor to be convinced of the fulfillment of all legal requirements. Considering advanced dementia, it's crucial to acknowledge that the patient's condition at the time of the request may differ significantly from when the request is granted. Dementia is a progressive condition that can markedly alter the patient's state and personality over time. Generally, such cases require extreme caution and should only proceed when there is no doubt about the occurrence of the condition. These are indeed exceptional circumstances.

The Supreme Court established several principles. If adhered to, a written request for euthanasia from a patient with advanced dementia can be granted. The patient must submit a written request that meets all legal requirements, applicable only when the predicted state occurs. The doctor must proceed with extreme caution and must be convinced that the patient is indeed in a state of advanced dementia where they cannot express their will. Furthermore, euthanasia should only be granted in cases of hopeless and unbearable suffering. While such suffering typically involves physical pain, there are special instances, like advanced dementia, where the patient's condition may qualify as unbearable suffering. In this case, the court acquitted the doctor because he acted with care and caution.The doctor is required to properly inform the patient about their situation, treatment options, alternatives, and their health prognosis (Art. 2 par. 1 lett. c) TLRaASL). Assisted suicide is only permitted when there are no other solutions available in the given situation (Art. 2 par. 1, lett. d) TLRaASL).

To ensure objectivity, it is necessary to have the situation assessed by another independent doctor. This doctor thoroughly examines the patient and subsequently formulates their opinion on the aforementioned requirements in writing (Art. 2, par. 1, lett. e) TLRaASL).

The law also addresses situations in which patients under the age of 18 request assisted suicide. If a person under the age of 18 can

[15] Original: *Wet toetsing levensbeëindiging op verzoek en hulp bij zelfdoding*. Available at: https://wetten.overheid.nl/BWBR0012410/2021-10-01.
[16] Original: *Wetboek van Strafrecht*.
[17] Decision of the Supreme Court of the Netherlands, Case No. 19/04910 CW, dated April 21, 2020. Available at: https://uitspraken.rechtspraak.nl/#!/details?id=ECLI:NL:HR:2020:712.

express their will and simultaneously evaluate their condition, a doctor can grant their request to end their life. The minimum age for this is 12 years. Additionally, consent from the parents or guardian is required (Art. 3 and Art. 4 TLRaASL). From the age of 16, natural persons can make a previously expressed wish. For persons aged 16 to 18, parental consent is required (Art. 2 TLRaASL).

2. 2 Belgium

In Belgium, legal euthanasia has been possible since 2002 when the Euthanasia law (also as „EL“) came into force.[18] Prior to this, euthanasia was considered a crime and the Belgian criminal code had strict penalties for cases of euthanasia upon request, without allowing for lighter punishment.

Belgian law is more detailed than Dutch law. In principle, the legal provisions are similar. The fundamental difference is that, unlike Dutch legislation, Belgian law distinguishes between adult and minor patients, without setting a specific age limit for the latter. Belgian law also includes specific formal requirements for submitting a euthanasia request, either by the patient themselves or through their representative. Additionally, this law explicitly requires the request to be repeated after a certain period of time and provides the option to withdraw it.

For minor patients, the procedure is the same as for adults, but consultations with a doctor in the field of child psychiatry and psychology are also added. This specialist examines the patient and finds out his distinguishing abilities, then gives a written report. The patient and legal representatives are then informed of the results. The attending physician will provide the legal representatives with the same information as the patient. Legal representatives must agree to the procedure. (Art. 3 par. 2 point 7 EL)

Although the law expressly regulates active euthanasia, practice and research show that assisted suicides are also being carried out.[19]

In connection with the legal regulation of dignified death in Belgium, the European Court of Human Rights dealt with the case of Mortier v. Belgium concerning a Belgian citizen seeking euthanasia for incurable depression.[20] The request, initially rejected, was later approved after the patient donated to an organization linked to the attending physician. The patient's son raised concerns about a conflict of interest. The court ruled Belgium violated the right to life by failing to adequately investigate the circumstances. Criticism highlighted insufficient oversight and independence in Belgium's euthanasia legislation. The ruling emphasized the need for robust regulations and independent scrutiny to address ethical dilemmas, prevent conflicts of interest, and ensure effective oversight of euthanasia cases.

[18] Original: *Loi relative à l'euthanasie*. Available at: https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2002052837&table_name=loi.

[19] Parlament of Victoria. Voluntary Assisted Dying Bill 2017, Research Papers. Available at: https://www.parliament.vic.gov.au/publications/research-papers/download/36-research-papers/13834-voluntaryassisted-dying-bill-2017.

[20] Judgment of the European Court of Human Rights in the case of Mortier v. Belgium, No. 78017/17. Available at: https://hudoc.echr.coe.int/fre#{%22itemid%22:[%22002-13802%22]}.

2. 3 Luxembourg

In 2009, Luxembourg enacted the Euthanasia and Assisted Suicide Law, which allows patients to request active euthanasia and assisted suicide.[21] The legislation is similar to Belgian law regarding the formal requirements for such requests and the related procedures. However, unlike Belgian law, Luxembourg law explicitly regulates the possibility of both active euthanasia and assisted suicide. The key distinction is that Luxembourg law does not permit minors to submit such requests.

2. 4 Spain

The case of Manuela Sanlés Sanlés v. Spain sheds light on Spain's legal stance regarding assisted suicide and the right to die with dignity.[22] Ramón Sampedro, quadriplegic since a 1968 accident, sought medical assistance to end his life, but Spanish courts rejected his plea under Article 143 of the Penal Code, which criminalizes assisted suicide. His constitutional complaint was denied, and he died by assisted suicide in 1998. His sister-in-law, Sanlés, attempted to continue the case but was deemed ineligible as a non-affected party. The European Court of Human Rights also dismissed her claim as inadmissible.[23] Sampedro's story sparked public debate on euthanasia in Spain, highlighting societal divisions and inspiring literary and cinematic works. His case played a pivotal role in Spain's 2021 euthanasia legislation, with Sanlés later admitting her involvement, emphasizing its lasting impact on attitudes toward death and autonomy.[24]

Current Spanish law allows for euthanasia. With the adoption of Law No. 3/2021 on March 24, 2021, regarding the regulation of euthanasia (also as „RoE“),[25] Spain became the fourth country in the European Union to permit active euthanasia. The law explicitly states that its aim is to protect individuals who find themselves in a serious condition due to a chronic, severe, incurable disease, enduring intolerable suffering that cannot be relieved under appropriate conditions (preamble RoE).

Spanish legislation is similar to Luxembourg law. Overall, the laws are very similar and explicitly include the possibility of both active euthanasia and assisted suicide. However, Spanish law imposes concreater requirements on the formal procedure, particularly regarding the obligation to submit repeated requests for euthanasia within a specified time interval.

Another requirement compared to Luxembourg law is the applicant must be a Spanish citizen, resident, or a person with

[21] Original: *Loi sur l'euthanasie et l'assistance au suicide.* Available at: https://legilux.public.lu/eli/etat/leg/loi/2009/03/16/n2/jo.

[22] University of Minnesota, Human Rights Library. Manuela Sanlés Sanlés v. Spain, Communication No. 1024/2001. Available at: http://hrlibrary.umn.edu/undocs/html/1024-2001.html.

[23] University of Minnesota, Human Rights Library. Manuela Sanlés Sanlés v. Spain, Communication No. 1024/2001. Available at: http://hrlibrary.umn.edu/undocs/html/1024-2001.html.

[24] Esanum. The faces and laws behind the euthanasia debate in Spain. Available at: https://www.esanum.com/today/posts/the-faces-and-laws-behind-the-euthanasia-debate-in-spain.

[25] Original: *Ley Orgánica 3/2021, de 24 de marzo de regulación de la eutanasia*. Available at: https://www.boe.es/buscar/act.php?id=BOE-A-2021-4628.

permanent residence or confirmation of residence in Spain for a period longer than 12 months. An adult (i. e. aged 18) who can understand the submission of an application may apply (Art. 5, par. 1, lett. a) RoE). The patient must submit two voluntary applications, with at least 15 days between them. The procedure itself, including the deadlines associated with individual submissions, must be followed by the responsible doctor and is further specified in Art. 8 RoE.

2. 5 Canada

Current Canadian legislation allows both euthanasia and assisted suicide. Decision-making at the end of life is governed by Act No. C-14 of 2016, An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)[26] (also as „MAID“). This law was enacted following the Supreme Court of Canada's 2015 decision in Carter v. Canada. In Carter v. Canada, the court ruled that provisions in the Canadian Criminal Code that make it a crime to assist a person to commit suicide violate the Canadian Charter of Rights and Freedoms. Specifically, the court identified violations of the rights to life, freedom, and security, which prompted a legal review. As a result, in April 2016, the Canadian government introduced Bill C-14 on medical assistance in dying, which was adopted in June 2016.[27]

MAID establishes exceptions and criteria for assisted suicide, emphasizing patient autonomy and vulnerability protection. It exempts healthcare professionals from criminality but penalizes laypeople for aiding suicide. According to this law, medical assistance in dying means administering a substance that causes death at the patient's request, or prescribing it and providing it so that the patient can administer it themselves (Art. 241.1 MAID).

The law allows individuals who meet an exhaustively defined list of conditions to decide on their own death (Art. 241.2 MAID). These individuals must be eligible for government-funded public health services in Canada (Art. 241.2 par. 1 lett. a) MAID).

Regarding the formal requirements for processing the application and its form, Canadian legislation is similar to Spanish law. However, the process explicitly requires that at least 10 days must pass between the submission of the application and the actual provision of care for the dying person.

2. 6 Germany

In recent years, Germany has seen considerable development in connection with the issue of dignified death and related legislation. The crime of participation in suicide was enshrined in the Criminal Code in 2015. It follows from the facts that the act

[26] Canada, Justice Laws Website. An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying). Available at: https://laws-lois.justice.gc.ca/eng/annualstatutes/2016_3/fulltext.html.

[27] Tiedemann M. Executive Summary - Assisted Dying in Canada After Carter v. Canada. Library of Parliament, 2020. Available at: https://hillnotes.ca/2020/01/27/executive-summary-assisted-dying-in-canada-after-carter-v-canada/.

must be long-term, repeated and with the intention of killing the patient. It must be emphasized that participation in suicide continued to remain unpunished for family members and loved ones without commercial intentions.[28] The opinion that the patient should have the right to decide to end his life in extreme cases was also expressed in 2017 by the German Federal Administrative Court.[29] However, this decision did not change the position of the German Ministry of Health, which continued to refuse patients their requests for drugs that will end their lives.[30]

On February 26, 2020, the German Federal Constitutional Court in Karlsruhe[31] annulled § 217 of the Criminal Code, which criminalized professional assistance in suicide.[32] The court ruled that the right to decide on one's own death is a fundamental personal right rooted in the German Constitution[33], combining the right to free personality development with the principle of human dignity. This includes the right to self-determination over life and death, reflecting personal definitions of a meaningful existence.

The decision also affirmed the right to seek and use assistance in ending one's life. However, the court acknowledged the conflict between this right and the state's duty to protect individual autonomy and life itself, which remains a priority. In light of the above, legislative proposals are being prepared in Germany to address assisted suicide.

2. 7 Austria

In 2021, Austria is experiencing a development similar to what occurred in Germany. In 2014 and 2015, the issue of dignified retirement and euthanasia was addressed by a parliamentary commission of inquiry.[34] Several discussions on specific issues took place, but after analyzing the situation and having discussions, the council did not reach a conclusion on the legalization of euthanasia.[35] Instead, it focused on expanding options for the terminally ill and those nearing the end of life in terms of

[28] Deutscher Bundestag. Geschäftsmäßige Hilfe zum Suizid wird bestraft. Available at: https://www.bundestag.de/webarchiv/textarchiv/2015/kw45_de_sterbebegleitung-392450.

[29] Original: *Bendesverwaltungsgericht*.

[30] Soliman T, Schiele K. Sterbehilfe: Vom Gericht erlaubt, vom Minister verhindert. Available at: https://daserste.ndr.de/panorama/archiv/2018/Sterbehilfe-Vom-Gericht-erlaubt-vom-Minister-verhindert,sterbehilfe272.html.

[31] Original: *Bundesverfassungsgericht*.

[32] Judgment of the Federal Constitutional Court dated February 26, 2020, case no. 2 BvR 2347/15. From: Bundesverfassungsgericht. Urteil vom 26. Februar 2020 - 2 BvR 2347/15. Available at: https://www.bundesverfassungsgericht.de/SharedDocs/Entscheidungen/EN/2020/02/rs20200226_2bvr234715en.html.

[33] Bundesministerium der Justiz und für Verbraucherschutz. Grundgesetz für die Bundesrepublik Deutschland. Available at: https: https://www.gesetze-im-internet.de/gg/.

[34] Original: *Die parlamentarischen Enquete-Kommission*. And also: Republik Österreich Parlament. Enquete-Kommission zum Thema "Würde am Ende des Lebens" (491 d.B.). Available at: https://www.parlament.gv.at/PAKT/VHG/XXV/I/I_00491/index.shtml.

[35] Republik Österreich Parlament. 491 der Beilagen zu den Stenographischen Protokollen des Nationalrates XXV. GP. Bericht der parlamentarischen Enquete-Kommission. Available at: https://www.parlament.gv.at/PAKT/VHG/XXV/I/I_00491/fnameorig_386917.html.

palliative care, which it recommended expanding.

On November 12, 2020, the Austrian Constitutional Court[36] issued a decision declaring the criminal act of participation in suicide unconstitutional.[37] The decision thus nullifies § 77 of the Austrian Criminal Code, which had criminalized active euthanasia (killing on request),[38] and § 78 of the Austrian Criminal Code, which had criminalized assisted suicide.[39]

The Constitutional Court asserts that no fundamental right obligates the state to prohibit euthanasia or requires individuals to endure suffering. It prioritizes an individual's right to self-determination over the state's duty to protect life, emphasizing that the right to life does not imply an obligation to live. Decisions regarding euthanasia must reflect free will and be permanent, not temporary. The Court highlights the importance of regulating euthanasia, setting requirements for expressing one's will, ensuring patient integrity, and evaluating doctors' competence. It argues that patients, as part of their autonomy, should have the freedom to end life actively, just as they can refuse or discontinue treatment.

Effective January 1, 2022, the Federal law, which introduces a death warrant provision and amends the Narcotics Drugs Act and the Criminal Code,[40] known as the Death Directive Act (also as „DDA"),[41] has come into effect in Austria.[42] This law not only alters existing regulations but also stipulates requirements that must be met for a death decision to be considered valid.

Austrian legislation is similar in basic aspects to Spanish law. However, the key difference is that patients who meet the criteria can request assisted suicide but not active euthanasia. The formal requirements for the application and process are comparable to those in Spanish law. Assisted suicide is only available to adults, and the decision must be made in person (Art. 4 DDA). Additionally, it can only be requested by Austrian nationals or

[36] Original: *Verfassungsgerichtshof Österreich.*

[37] Judgment of the Austrian Constitutional Court dated December 11, 2020, case no. G 139/2019-71. Available at: Verfassungsgerichtshof Österreich. Ausgewählte Entscheidungen 2020. VfGH 11.12.2020, G 139/2019: Tötung auf Verlangen und Mitwirkung am Suizid. Available at: https://www.vfgh.gv.at/rechtsprechung/Ausgewaehlte_Entscheidungen.de.html.

[38] *Killing on Demand: „Who kills another at his earnest and urgent wish.."* Original: Tötung auf Verlangen § 77 des Bundesgesetzes vom 23. Jänner 1974 über die mit gerichtlicher Strafe bedrohten Handlungen (Strafgesetzbuch - StGB), BGBl. 60/1974: *„Wer einen anderen auf dessen ernstliches und eindringliches Verlangen tötet, ist mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen."*

[39] *Participation in suicide: „Who induces or assists another to commit suicide..."* Original: Mitwirkung am Selbstmord § 78 des Bundesgesetzes vom 23. Jänner 1974 über die mit gerichtlicher Strafe bedrohten Handlungen (Strafgesetzbuch - StGB), BGBl. 60/1974: *„Wer einen anderen dazu verleitet, sich selbst zu töten, oder ihm dazu Hilfe leistet, ist mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen."*

[40] Parlament Österreich. Regierungsvorlage. Bundesgesetz, mit dem ein Sterbeverfügungsgesetz erlassen wird sowie das Suchtmittelgesetz und das Strafgesetzbuch geändert werden. Available at: https://www.parlament.gv.at/dokument/XXVII/I/1177/fnameorig_1012536.html.

[41] Original: *Sterbeverfügungsgesetz* .

[42] Parlament Österreich. Sterbeverfügungsgesetz; Suchtmittelgesetz, Strafgesetzbuch, Änderung (1177 d.B.). Available at: https://www.parlament.gv.at/gegenstand/XXVII/I/1177.

individuals with habitual residence in Austria (Art. 1, par. 2 DDA). The patient's decision to end their life cannot be finalized earlier than 12 weeks after the first medical opinion (Art. 8, par. 1 DDA). The Austrian cabinet introduced a 12-week waiting period for patients to maintain a consistent decision on assisted suicide, based on a study showing this duration helps patients overcome the worst phase of a crisis. If the patient remains firm after this time, it is likely a mature and considered decision. Exceptions apply for patients in severe suffering, allowing the waiting period to be shortened.[43]Among other things, the law also prohibits the commercial provision of assistance for assisted suicide.

2. 8 Italy

2. 8. 1 Eluana Englaro case

The case of Eluana Englaro was a landmark legal battle in Italy over end-of-life decisions. After a 1992 accident left Eluana in a permanent vegetative state, her father, Beppino Englaro, fought for 17 years to respect her previously expressed wish to end life-prolonging treatment. The Corte di Cassazione ruled in 2007 that life-sustaining treatment could be withdrawn if two conditions were met: the patient is in a permanent vegetative state, and clear evidence shows they would not wish to be kept alive artificially. Unlike the Sampedro case (where it was a „living" head attached to a „dead body"), this is an unresponsive being. [44] This condition is assessed according to scientific standards that are internationally recognized. Furthermore, it is necessary to provide clear and convincing evidence that the patient would not wish to be kept alive by artificial means. Information about the patient's personality, lifestyle, and beliefs can be used as evidence.[45] After appeals and constitutional challenges, the courts allowed Eluana's disconnection from artificial nutrition,[46] and she passed away on February 9, 2009. The case sparked widespread debate in Italy, highlighting ethical and legal issues around the right to a dignified death.

2. 8. 2 Ruling of the Constitutional Court 242/2019 on the Cappato-Antoniani case[47]

Italy recognizes the right to refuse life-prolonging treatment and informed consent withdrawal. A 2019 Constitutional Court decision affirmed that, under certain conditions, medically assisted suicide aligns with the rights to self-determination and

[43] Bundesministerium Justiz. Sterbehilfe. Available at: https://www.bmj.gv.at/themen/Fokusthemen/Dialogforum-Sterbehilfe.html.

[44] Moratti S. The Englaro Case: Withdrawal of treatment in Italy from a patient in a permanent vegetative state. European University Institute, 2012, 04. Available at: https://cadmus.eui.eu/bitstream/handle/1814/21757/MWP_2012_04_Moratti.pdf?sequence=1&isAllowed=y.

[45] Corte suprema di cassazione, Sentenza 16 ottobre 2007, n. 21748. Available at: https://www.law.nova.edu/files/CassazioneOctober2007Italian.pdf. In english available at: https://www.law.nova.edu/files/CassazioneOctober2007English.pdf.

[46] Corte Costituzionale, Ordinanza 8 ottobre 2008, n. 334. Available at: https://www.law.nova.edu/files/ConstitutionalCourtOctober2008Italian.pdf. In english available at: https://www.law.nova.edu/files/ConstitutionalCourtOctober2008English.pdf.

[47] Original: *Sentenza della Corte costituzionale 242/2019 sul caso Cappato-Antoniani.*

health. The case involved Marco Cappato, who assisted his friend Fabiano Antoniani (DJ Fabo), left paralyzed and blind after a 2014 accident, in traveling to Switzerland for assisted suicide in 2017. Cappato knowingly faced legal consequences, aiming to challenge the law and pave the way for legalizing assisted suicide in Italy.[48]

The Italian Constitutional Court ruled that assisted suicide is not a criminal offense under Article 580 of the Italian Criminal Code, provided certain conditions are met. The request must come from the person themselves, who must be kept alive by life-saving treatment, fully autonomous, and capable of understanding the consequences of their actions. They must also suffer from an incurable and serious physical or mental condition. Assisted suicide is not allowed if the individual cannot self-administer the lethal substance, such as in cases of ALS.[49]

Article 580 of the Italian Penal Code regulates complicity in suicide, which can take three forms. Article 580 of the Italian Penal Code reads: *„Whoever induces another to commit suicide, strengthens another's intention to commit suicide, or in any way facilitates its execution shall be punished. If the suicide occurs, the punishment is imprisonment for five to twelve years. If the suicide does not occur, and the suicide attempt causes serious or very serious bodily harm, the punishment is imprisonment for one to five years.“* The Constitutional Court, therefore, determined that assisting suicide is not a crime, but only under the above-mentioned conditions. In Italy, criminal acts still apply when: 1) a person incites another to commit suicide, and 2) a person strengthens another's intention to commit suicide. The same applies to the criminal act of performing active euthanasia.[50]

2. 8. 3 Informed consent and regulation

Ruling of the Constitutional Court 242/2019 effectively binds Law No. 219/2017 on informed consent and advance directive for treatment (also as „ICADT“)[51] also known as the End of Life Act.[52] Italian law allows passive euthanasia or deep and continuous sedation (note: unintended hastening of death). Similar to previous laws on dignified death, it imposes comparable requirements on the form of the request and any previously expressed wishes. Strict conditions also apply to the process related to the request. The decision is not age-restricted; however, stricter conditions apply to minors. A representative may decide on behalf of the patient, but only if the patient has previously expressed their wish. The decision is not dependent on nationality.

[48] Associazione Luca Coscioni. Il processo a Marco Cappato, punto per punto. Available at: https://www.associazionelucacoscioni.it/processo-marco-cappato-punto-punto.

[49] Corte Costituzionale. Sentenza n. 242, anno 2019. Available at: https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2019&numero=242.

[50] Quotidianosanità.it. Il suicidio assistito come diritto costituzionale. Un’analisi della sentenza della Consulta. Available at: https://www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo_id=79083.

[51] Original: *Norme in materia di consenso informato e di disposizioni anticipate di trattamento*.

[52] Ministero della Salute. Norme in materia di consenso informato e di disposizioni anticipate di trattamento. (18G00006). Available at: https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=62663.

In situations where the patient's prognosis is poor and short-term, or the patient is in imminent danger of death, the doctor must refrain from obstinate futile treatment. At this stage, with the consent of the patient, they can resort to so-called continuous deep palliative sedation, which, in conjunction with therapy and pain relief, will lead to the patient's death (Art. 2 par. 2 ICADT).

2. 9 France

2. 9. 1 Informed consent and regulation

In 2005, the Law relating to the rights of patients and the end of life was enacted in France, also known as Leonetti Law (also as „LL“).[53] This is the first law in France that explicitly addresses the end of a patient's life and allows the patient to refuse treatment when they believe it no longer has any effect. The purpose of the law is to prevent the practice of euthanasia and hastening death, while also aiming to prevent the continuation of futile treatment for patients. A key aspect is prioritizing care over patient suffering and comfort. The law was later amended in 2016. The amendment expanded and improved the law, strengthening patients' rights and dedicating efforts to improving the availability of palliative care. Together, these two laws form the framework for medical care at the end of life in France. There is an increasing emphasis on respecting the autonomy of patients' will, dignity, treatment of suffering, and patient information, with decision-making maximally transferred to the patient.[54]

The Leonetti Law in 2005 introduced a ban on what is known as unreasonable obstinacy. In cases where the doctor concludes that the actions they are performing appear to be useless, unreasonable, and have no other effect than the artificial maintenance of life, such actions can be suspended or not performed. In such situations, the doctor focuses on preserving the dignity of the dying patient and ensuring a quality of life that aligns with the care provided (Art. 1 LL).

The Leonetti Law (2005) prohibits unreasonable obstinacy in treatment, allowing doctors to suspend futile actions that merely artificially sustain life (Art. 1 LL). Doctors must inform patients if the side effects of treatment during the terminal phase of an incurable illness might hasten death (Art. 2 LL). Patients have the right to limit or stop treatment, with doctors obliged to explain the consequences and respect their decision (Art. 6 LL).

Patients can record advance wishes for situations where they cannot decide for themselves, retaining the right to revoke these wishes at any time. Advance wishes are binding if made within three years before the patient becomes unconscious (Art. 7 LL). Patients may also designate a trusted person to

[53] Original: *Loi relative aux droits des malades et à la fin de vie*. Available at: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000000446240/.

[54] Ministère du Travail de la Santé et des Solidarités. Comprendre la loi Claeys-Léonetti de 2016: De nouveaux droits en faveur des personnes malades et des personnes en fin de vie. Available at: https://sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/les-soins-palliatifs-et-la-fin-de-vie/la-prise-en-charge-palliative-et-les-droits-des-personnes-malades-et-ou-en-fin/article/comprendre-la-loi-claeys-leonetti-de-2016.

make decisions on their behalf (Art. 8 LL). If no wishes are recorded, doctors may stop futile treatments while ensuring the patient's dignity and quality of life are preserved (Art. 9 LL).

Leonetti Law was amended in 2016 by Law no. 2016-87 creating new rights for the sick and people at the end of life, also as *Claeys-Leonetti Law* (also as „CLL").[55] This law ensures patients the right to a dignified end of life in cases of persistent suffering, emphasizing respect for their wishes (Art. 1 CLL). It abolishes the time limit for previously expressed wishes (Art. 8 CLL) and strengthens the role of a trusted person chosen by the patient to make decisions on their behalf if they become incapacitated (Art. 9 CLL).

In addition, the law now allows patients to request deep and continuous sedation, causing an alteration of consciousness maintained until death, along with analgesia. In essence, deep continuous sedation can be understood as inducing a state of unconsciousness with the aim of relieving pain, and death typically occurs within hours to days.[56] Deep continuous sedation can have several variants, such as light (superficial) or deep (the patient is truly asleep and not restless). It can also be administered continuously or temporarily and intermittently until death.[57] The medical board must approve deep and continuous sedation for patients with serious, incurable conditions, short-term prognoses, and visible suffering, upon the patient's request. This sedation can be administered at home (Art. 3 CLL). Doctors are required to inform patients about the process and its consequences (Art. 4 CLL).

In practice, there may be cases where the patient believes that the treatment is not providing a positive result and chooses to discontinue it. Patients have the right to refuse or discontinue treatment if they believe it is not beneficial, even if the doctor disagrees. Informed consent is essential for medical care, and a doctor may only act without it in life-threatening emergencies. Patients can withdraw consent at any time, and doctors must inform them of the consequences, but ultimately, the doctor must respect the patient's decision.[58]

Summary

The legalization of a dignified end-of-life remains a debated topic, with euthanasia and assisted suicide gaining attention in the past two decades. Legal frameworks from nine states were analyzed and divided into three groups based on their approach. The first group included countries allowing active euthanasia and assisted suicide: the Netherlands, Belgium, Luxembourg, Spain, and Canada.

[55] Original: *Loi n. 2016-87 du 2 février 2016 créant de nouveaux droits en faveur des malades et des personnes en fin de vie*. Available at: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000031970253.

[56] Fin de vie Soins Palliatifs. Exprimer ma volonté. Available at: https://www.parlons-fin-de-vie.fr/mes-droits/.

[57] Vitale C, Nonneville A, Fichaux M, Salas S. Medical staff opposition to a deep and continuous palliative sedation request under Claeys-Leonetti law. BMC, 2019, 18. Available at: https://bmcpalliatcare.biomedcentral.com/articles/10.1186/s12904-018-0384-3.

[58] République française. Code de la santé publique. Available at: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041721056.

The basic requirements for requesting euthanasia are similar across states. All require a written application, except the Netherlands, which does not specify the form. Voluntariness and the patient's true will, assessed without external interference, are emphasized, along with clear and proper instruction. Multiple doctors from different specialties must review the case.

To ensure the decision is firm, repeated expressions of will are required, verified by doctors. Spain and Canada mandate minimum intervals of 15 and 10 days, respectively, between consultations, while Belgium requires at least one month between the request and execution.

States differ in their requirements for patients. The Netherlands and Belgium allow requests from minors under 18, with age-specific conditions and the consent of legal representatives. Spain restricts euthanasia to nationals, residents, or those registered in Spain for over 12 months. Canada limits eligibility to patients covered by government-funded health services.

Patients must be in a hopeless health situation, enduring constant, unbearable suffering from a serious and incurable condition. Applications can be revoked at any time. Most states allow medical staff to refuse to perform euthanasia, provided they notify the patient promptly and face no discrimination for their decision.

In Germany (2020) and Austria (2022), assisted suicide was legalized following Constitutional Court rulings. Both states require requests to be made voluntarily, in writing, by an adult, and include patient education about their condition, treatment, and alternatives. The decision must reflect a permanent intention, not a temporary crisis.

Austria mandates a 12-week waiting period for the patient to confirm their decision and restricts eligibility to Austrian nationals or residents. Applications must be filed before a notary or specialized hospital staff. Both states require the patient to suffer from an incurable or severe, permanent illness causing unrelievable suffering and impose similar requirements as the states in the first group. Healthcare worker participation remains voluntary, and patients can withdraw their request at any time.

In the third group of countries, France and Italy focus on improving end-of-life care and palliative medicine. In these states, patients capable of expressing their will can refuse or discontinue treatment. Minor patients also have this right, but final decisions require parental (or legal guardian) consent or court approval.

Only adults can create a previously expressed wish for situations where they cannot articulate their will, such as life-sustaining treatment scenarios. This requires understanding the consequences of their actions. Italian law demands that such documents be notarized or certified to ensure authenticity. Patients may also designate someone to participate in decisions about their care. These wishes must confirm that patients received clear instructions about their diagnosis, prognosis, treatment options, risks, and potential outcomes of refusal or withdrawal of care.

In cases where patients are in a very serious medical condition, with a poor prognosis and imminent death, they may request so-called continuous deep palliative sedation. It must be mentioned here that this is not active euthanasia, as the intended effect is to alleviate pain, not hasten death. Italy's legislation is very similar to France; however, under strict conditions, assisted suicide has been allowed since 2019.

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