

ADVANCING RESTORATIVE JUSTICE THROUGH CLINICAL GENOMICS:

A MULTI-STAKEHOLDER FRAMEWORK TO ETHICALLY INTEGRATE



KEY FINDINGS

ETHICAL PRIORITIES

Safety & Efficacy

Beneficence, Nonmaleficence,

& Utilitarianism



Mentor: Hadley Smith, PhD, MPSA, Harvard Pilgrim Health Care Institute

BACKGROUND



- On December 8, 2023, the U.S. Food & Drug Administration (FDA) approved two novel gene therapies (GT), each of which aim to cure sickle cell disease (SCD), a debilitating and historically marginalized condition.
- One of these GT marks the first clinical approval of a CRISPR-based therapy

Image: Victoria Gray, the first recipient of GT for SCD, sitting in a hospital bed to receive long-term follow-up care,

OBJECTIVES

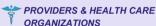
- 1. Explore and synthesize diverse stakeholders' perspectives around the clinical implementation of GT for SCD in the United States (U.S.).
- 2. Identify urgent issues complicating this pivotal milestone in SCD care & genomic medicine
- 3. Recommend interventions that address the underlying issues identified and ultimately promote restorative justice through the delivery of SCD care & GT.

METHODS

Conducted a targeted literature review organized around 8 kev stakeholder groups...



















- Consulted with thought leaders
- · Participated in relevant community meetings & listening sessions

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- Melissa Creary, PhD. MPH Assistant Professor. University of Michigan School of Public Health

UNDERLYING ISSUES

- · GT outcomes vary by person & are not always "curative"
- GT is novel & still experimental: long-term outcomes are unknown
- Severe risks & side effects are associated with GT & the chemotherapy conditioning required

Burdensome treatment process

Minority of SCD population is

and support systems

eligible for GT

requiring significant time, resources,

across SCD treatments, which risks

inequities within the SCD population

Informed consent to pursue GT is

undermined due to misinformation.

limited GT education, & disparate

Poor baseline in trust & shared

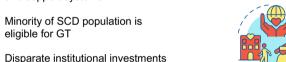
racism & medical paternalism

decision-making for SCD due to

Paucity in critical needs for delivery

investments across SCD treatments

Accessibility & **Equity**



Liberal Egalitarianism & Well-being Theory of Justice

Shared Decision-Making



Respect for Autonomy. Care Ethics, & Feminist Ethics

RECOMMENDATIONS

- · Identify key age range to consider GT Prioritize patient-reported outcomes in
- evaluating long-term safety & efficacy Compensate for longitudinal research
- Create a long-term SCD survivorship program
- · Develop SCD GT clinical guidelines
- · Continue research & development for new
- and improved SCD treatments Insure key expenses & wraparound services
- · Collaborate with community groups to promote bidirectional learning & communitybased, outpatient care support
- · Ensure social securities & safety nets
- Standardize screening process for GT & social determinants of health
- Research if current eligibility standards are appropriate or overly stringent
- Create parity in coverage across SCD
- treatments & the population Communicate about GT transparently & objectively in both the media & clinic
- · Implement a standardized, interdisciplinary practice of genetic counseling for SCD & GT that engages various learning styles
- · Create parity in access, investment, and counseling for all SCD treatments
- · Train providers in relationship-building & shared decision-making in SCD care

SUMMARY

- Complex and multi-faceted issues complicate GT's integration into the SCD clinic.
- Stakeholders must collaboratively and comprehensively address these issues to ensure the clinical integration of GT for SCD promotes restorative justice throughout the U.S. SCD population.

LIMITATIONS

- · This research was limited to the U.S., despite the majority of the global SCD population living abroad.
- · The resulting framework is conceptual and should be validated through primary data collection with stakeholders

FUTURE DIRECTIONS

- Disseminate initial framework outlining these findings & specific opportunities to take action (see "Framework" QR code below).
- Solicit feedback & advocate for action from key stakeholders.

FRAMEWORK, **CITATIONS &** CONTACT

Access the "Framework" for more detailed findings:



Citations: bit.ly/GTSCDCitations

Contact: tessayoungner@gmail.com

of any SCD treatment, such as trained health care providers. comprehensive treatment centers, & national data collection programs

High upfront costs to prepare health care systems, manufacture GT, & deliver necessary procedures

Feasibility · Promote SCD education & training in medical



Liberal Egalitarianism & Capability Theory of Justice

- schools & hospitals · Invest in the establishment of SCD
- comprehensive care centers
- Strengthen SCD data collection & sharing
- · Insure & deliver basic SCD standards of care recommended in clinical guidelines
- · Mandate anti-racism training
- · Advance other quality improvement initiatives

SCD Community