



14th
**International Donor Registry Conference
& WMDA Meetings**

25 – 29 June, 2024 – Cape Town, South Africa

All Patients and Donors Matter

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Development of an Operational Process for Managing Post-transplant Genetic Findings of Potential Donor Origin: NMDP's Experience



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Case Study

Case Details

- Donor: 27 yo F donated PBSC in JAN 2019
- Recipient: 60 yo F with MDS received PBSC transplant in JAN 2019
- Recipient D+37 NGS test results identified the following variants *not present in recipient prior to transplant*:
 - **ATM** (tier 2, potential clinical significance)
 - **MYD88** (tier 3, VUS)
- Chimerism testing at same time is 99% donor

Considerations

- Who did this information come from and where was it reported?
- What is the timeframe between transplant date and report of information?
- Is donor related? Has TC contacted donor?
- Have donor and recipient been in contact?
- Is donor domestic (NMDP DC001/contract) or international?
- Did donor report any known mutations or potentially relevant personal or family history at workup?
- What is the potential impact of this information for donor? For recipient?
- **Should we notify the donor???**

WHY?

**Increased frequency
of genetic testing**

**Donor registries are
tasked with what to
do with these
findings**

**Donor safety,
wellbeing, health
autonomy**

Methods



December 2021

Donor Genetic Mutation Reporting Task Force established, discussed current state/increasing concerns, proposed project to the executive team



January-December 2022

Task Force meetings to review existing procedures, consult with genetics and ethics experts, design new processes, update consent and forms, create trainings



January 2023

New reporting/management process implemented

Results

Updated consent form with donor opt in/out of notification

Dedicated post-transplant findings reporting form and SOPs

Medical Services nurse review with escalation to provider as needed

Donor notification decision pathway

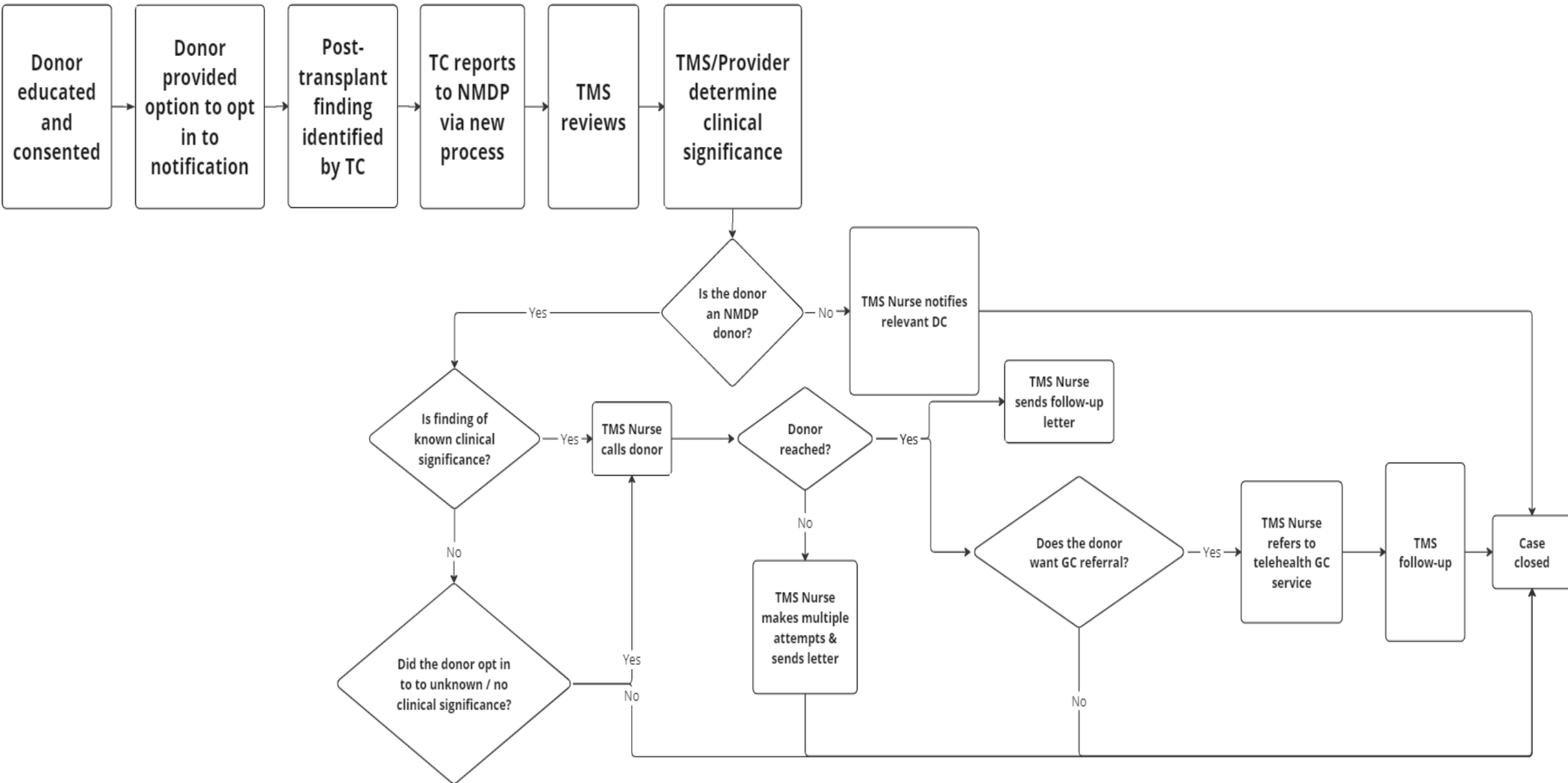
Donor notification script/video

Partnership with genetic counseling group to offer services

Internal/external education and training

Post-implementation data tracking

Operational Process Map



Process Highlights

- **Donor educated upfront** about possibility of post-transplant genetic finding
- Consent with **option of opt-in to notification** of findings *of no/unknown significance*
- **TCs report findings** via FormsNet3 (preferred), email, phone call and **TMS nurses review**
- Use American College of Medical Genetics (ACMG) or ClinVar* and NMDP-created tool to **determine if variant finding is “actionable”** – i.e. mandatory or optional notification
- **Donor contacted** by medical team if appropriate **or** info passed to appropriate DC
- Contacted donors referred to partner or local **genetic counseling service**

*<https://www.ncbi.nlm.nih.gov/clinvar/docs/acmg/>

New Consent Language

Can I learn about my health by being in this study?

After the transplant, your PBSCs will make all the cells in the recipient's blood stream. This means when doctors do tests on the recipient, they may look at your cells and DNA. The tests could show new information about you and your health. If we learn new information that could be an immediate or serious impact on your health (for example, if the recipient's blood shows signs of cancer cells), we will reach out to you and let you know.

We may also learn information about you that's unusual, but is not considered serious according to current research (for example, the recipient's cells show a mutation but we don't know if or how the mutation will affect you). You can choose if you'd like us to reach out to you and let you know about this information.

- YES, I want to be contacted with non-serious information or if it isn't currently known how it'll impact my health.
- NO, I do not want to be contacted with non-serious information or if it isn't currently known how it'll impact my health.

If we contact you with information about your health, we can help explain the results to you and provide resources.

Since process implementation...

- **91% of donors have opted in** to notification of findings at consent
- **30 transplant centers** have reported **54 cases** of post-transplant findings
- Attempts were made to **contact 13 donors**
 - Accepted counseling: N=8
 - Declined counseling: N=4
 - Outreach unsuccessful: N=1
- Ongoing tracking of reports, referrals to genetic counselor, donor testing, and mutations identified in either recipient and/or donor

Lessons Learned



MULTIDISCIPLINARY
EFFORT AND INPUT



THOROUGH STAFF
TRAINING



PSYCHOLOGICAL
EFFECT ON DONOR



UNDERSTANDING OF
FINDINGS IN FLUX



NEED A
FRAMEWORK



HARMONIZATION OF
REGISTRY APPROACH



CENTRAL LOCATION
FOR REPORTING



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QUESTIONS?

**Thank you to the NMDP GMR Task Force
and Medical Services team!**



See [Poster #27](#) for more about this topic
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