



May 23, 2022

TO:

US Department of Health and Human Services
Health Resources and Services Administration
Office of Acquisition Management & Policy
5600 Fishers Lane, Rockville, MD 20857
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
Incumbent: United Network for Organ Sharing
Point of Contact: NInazawa@hrsa.gov

FROM:

The American Society of Nephrology
1401 H Street, NW, Suite 900
Washington, DC 20005
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
Point of Contact: David White, ASN Regulatory and Quality Officer, (202) 640-4635,
dwhite@asn-online.org

The Honorable Carole Johnson
Administrator, Health Resources and Health Administration (HRSA)

Dear Administrator Johnson:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to respond to the Request for Information (RFI) issued by the Health Resources and Services Administration (HRSA) related to the coordination and improvement of “the effectiveness of the nation’s organ procurement, distribution and transplantation systems and to increase the availability of, and access to, donor organs for patients with end-stage organ failure.”¹

ASN wholeheartedly supports the primary objectives HRSA identifies in its RFI:

1. Increase accountability in Organ Procurement and Transplantation Network (OPTN) operations, including board governance, financial structures, data quality transparency, and policy development;
2. Enhance the usability and performance of the OPTN IT system and related tools; and
3. Strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process.

To address these primary objectives, ASN specifically recommends three key steps:

1. Separating the technology portion of the OPTN contract as a stand-alone contract as recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) in its report *Realizing the Promise of Equity in the Organ Transplantation System*ⁱⁱ and ensuring technology systems developed for federally funded contracts belong to the Agency.
2. Requiring OPTN contractors make every effort to have complete and accurate data readily available so that all stakeholders can have timely evidence of equitable and effective treatment of donors and patients.
3. Enforcing OPTN and contractor(s) have separate governance boards as called for by HRSA in 2018 and reaffirmed by the U.S. Government Accountability Office (GAO).ⁱⁱⁱ

Addressing A. OPTN Technology questions 1-5 and E. Increasing Organ Donation and Improving Procurement.

ASN strongly advocates for HRSA to implement transparent guidelines, including clear presentation of eligibility criteria for transplant candidate listing and transplantation, to ensure clear, useful, and easily accessible data so the patient, their nephrologist, their dialysis facility, and transplant center can coordinate the care and communications necessary to identify the right transplant center fit for a patient, inform sharing decision making in organ acceptance, and to keep the patient on the path to transplantation. For example, patients need data and transparency when deciding on accepting higher risk organs such as ones with a KDPI of 85+ or from Hepatitis C+ donors.

Regulations mandate that patients receive information on the transplant center's 1-year graft and patient survival based on Scientific Registry of Transplant Recipients (SRTR) data updated every 6-months and notify patients of significant changes. However, current requirements focus on too much information of limited differentiation provided by these outcomes as most centers have similar one-year graft and patient survival outcomes and not enough information on elements that patients highly value. Not only is it burdensome for centers to maintain current written disclosure of data that are of limited value to patients, but there are also several other challenges to these communications:

- The communication is not standardized. ASN recommends standardizing how information is shared with the patient, similar to how financial information sharing has been standardized by the Consumer Financial Protection Bureau (CFPB). Standardized communication is a key step in assuring clarity, objectivity of data and providing patients the ability to compare centers based on their results. Instead, the current system which allows centers to use different formats makes it difficult for patients to understand the information they are seeking. Even information shared by transplant centers on their websites is not standardized and can be difficult for patients to follow in order to make informed choices^{iv}.
- The information shared by transplant centers is driven by data produced by SRTR that do not correspond to the information that patients want while they are on the waitlist. This was described by Husain SA et al.^v, in a survey study of patients demonstrating clear preference for process measures such as time to transplant, ease of waitlisting, and

whether a center will accept patients like them on the transplant waitlist. Critically, emphasis on less important or insufficiently adjusted measures without full context also incentivizes transplant centers to only list and subsequently transplant patients with the fewest barriers to transplant, thus exacerbating disparities in access to transplant.

- While patients clearly prefer to receive information from their providers, there is a limited understanding of the organ allocation system or the processes of local transplant programs among dialysis staff, especially those at the patient bedside.^{vii} Websites from UNOS and SRTR are not always seen as primary sources of information by patient communities.
- Patient selectivity and transplant center thresholds are not always publicly shared with patients, dialysis providers, or referring nephrologists, making it unclear if patients are candidates for transplant at any given center. Large variations in the thresholds from center to center for accepting patients as transplant candidates make it difficult for patients and their care team to identify centers where they may have an opportunity to be listed for and to receive a transplant. As a result, regional studies in the US demonstrate significant variation in the proportion of referred patients who are subsequently waitlisted.^{viii}
- In the last two decades, there has been an increase in selectivity by transplant centers and rapid delisting of patients from the waitlist, both of which may have a direct negative impact on access to transplant but have no associated transparency.^{ix} As a result, the median survival of transplant candidates AFTER they are removed from the waitlist (for reasons other than transplant) is now approximately five years,^x while waitlist mortality has steadily dropped to approximately 5% annually compared to an overall annualized mortality rate of 20% for ESRD patients.
- Patients on the waitlist are frequently unaware of their status on the waitlist and receive little or no information from the transplant centers. This paucity of communication between patients, their dialysis facilities, and transplant centers results represents a failure of the OPTN to improve communication between various stakeholders in transplantation creating both inefficiencies of allocation and silos of care. This dysfunction is highlighted by several troubling facts:
 - a) Patients are often unaware that organ offers are being declined on their behalf without their knowledge.^{xi} These offers are often for organs that patients might have accepted had they been asked.
 - b) The waitlists are often poorly curated and maintained due to insufficient communication among transplant centers, dialysis facilities, and patients or their care partners. As a result, nearly one in five kidneys is now offered to a deceased person still on the waitlist because the transplant center is unaware that the patient is deceased.^{xii} Deceased candidates receive a median of four organ offers before they are removed from the waitlist. A recent announcement from the OPTN of the abrupt addition of 35,000 verified deaths to their standard analytical files

highlights the lack of transparency around important data concerns as well as the failure to acknowledge the nonrandom missing nature of this data suggests the failure to understand the import of the problem.

- c) Patients must be informed if their centers either pause doing transplants or inactivate patients on the waitlist. Rapid inactivation of large numbers of patients was only recently introduced and the system urgently needs to leverage any communication tools the OPTN can provide.
- d) Almost all centers use an unofficial status of “internal hold” for patients who remain active on the waitlist and continue to receive offers but are not eligible to receive transplants. This practice is detrimental to the efficiency of the allocation system, often leads to confusion on the part of the patient and may be abused by centers. Patients on internal hold can continue to attract organ offers and be used to move organs to different Donor Service Areas (DSAs) by transplant centers before they are then declined forcing a local reallocation of that organ in a different part of the country than where it ought to have been used.
- e) Patients must be informed of the criteria used by a transplant center for accepting offered organs. These criteria are not currently shared with the patients. Knowledge of these criteria would give patients the choice of which center would suit them best. Bypass filters are used by transplant centers to automatically screen out offered kidneys from donors with certain clinical characteristics. For example, donor age criteria can be set such that centers are not offered national organ offers from donors above a prespecified age. While these filters were designed initially to help accelerate allocation, their use needs to be monitored to determine the impact.^{xiii} These bypass criteria often can result in dramatic changes in the probability of transplantation because it shrinks the pool of donor organs to which patients at a given transplant center have access.
- f) Centers appear to be less willing to use organs for transplantation on the weekend, including for organs that are eventually accepted by other transplant centers. How this impacts the probability of transplantation is not currently understood nor shared with patients.^{xiv,xv}
- g) Patients, dialysis facilities and referring providers are often not informed of the status the referral and evaluation process with little information available on where patients are in the process. Perhaps more troubling, these providers are often unaware of why some of their patients are not accepted for wait listing or why they were overlooked for organs that were transplanted into patients with lower priority scores. Additionally concerning are referrals declined by transplant centers without official evaluation by transplant center providers. Often decisions about accepting or declining referrals are made by transplant coordinators who are reviewing the medical record and not directly evaluating the patient in person. Transplant coordinators may have little to no clinical experience. This practice introduces inherent biases into the transplant process.

All these processes/events occur with limited transparency and without patient-centered communications that accurately convey what is happening within the process.

Addressing **B. Data Collection Activities** questions 1-2.

On creating public OPTN national, regional, and local performance dashboards, ASN believes patient-centered dashboards that are easy to decipher with a limited use of technical terms that provide ACTIONABLE information would help patients make informed choices is an urgent need. The information being provided should be tailored to the consumer of the data. Data reports, visualizations, summaries should be designed to different questions depending on whether these are patient facing or professional facing.

On tracking long-term patient outcomes and health and non-health-related factors that contribute to outcomes, ASN believes OPTN needs to be collecting data on social determinants of health in a responsible manner and leveraging this information to identify and mitigate disparities in access to transplantation. It is particularly important that OPTN also collect data on patients who are being denied an opportunity to be waitlisted (and the reasons for this) in order to be able to determine if there is a broader issue than the individual's medical or psychosocial suitability for transplantation. These data collection efforts can also be facilitated by the use of linkages to other datasets, both public and proprietary, for purposes of monitoring OPTN. These data linkages need to be robust, recurrent, and used to inform policies that would support equity in the allocation system and the development of interventions necessary to improve access to transplantation.

The OPTN data registry is an important asset for the transplant community, and yet the OPTN contractor has failed to ensure that there are important quality checks in place in the form of data validation, verification at the time of data entry, the elimination of biological implausible values and/or the ensuring that there is a robust, verifiable and reproducible method to confirm that all deaths and graft failures are accurately captured. Large errors for critical data suggest that the OPTN contractor does not view the maintenance of the registry as a critical function. The absence of a robust data dictionary with detailed instructions and definitions are another example of the failure to invest in the data capture system.

Transplant Patient Safety Data: Among patients selected for organ transplant, one-year post transplant graft survival is excellent, averaging ~ 97%.^{xvi} Critical issues are the organ shortage and discard rate as well as the lack of transplant access for many patients who could benefit from increased uptake of transplantation (resulting in a shrinking waitlist), a process that would require improving the discard rate and organ shortages. Expanding practices to procure and utilize all usable organs, even those that are deemed not of the highest quality, requires a system-wide perspective that is framed around a comparison of the benefits of the patient receiving that organ versus continuing on dialysis. The current regulatory penalties incite transplant centers to reject less than ideal organs even if these organs would still greatly improve the quality of life and longevity of transplant recipients when compared to dialysis. The Kidney Donor Profile Index (KDPI) is a measure of organ quality relative to other organs that does not adequately reflect the value that organ provides to a specific recipient. As such, the KDPI is a seriously

flawed guide for clinicians, and it should never replace the quality-of-life perspective of the patient. While the idea of using a composite measure of organ quality to reduce cognitive load in evaluating organ quality is a good one, alternative strategies need to be considered along with ongoing research to improve kidney allograft quality measures. ASN recommends that the KDPI be withdrawn immediately, and the Kidney Donor Risk Index (KDRI) be used to overcome the inherent cognitive biases that result from a percentile score rather than a measure of relative risk of failure.

Living Donor Safety: OPTN has several mandates directed at living donor safety. Policy 14 defines minimal criteria that must be included in the living donor evaluation and informed consent. Policy 18 defines clinical and laboratory parameters that must be collected at 6 months, 1 year, and 2 years post donation. These data are summarized in SRTR Program Specific Reports, and complications (national level) in the Annual Data Report, although these reports are directed at professionals and are unlikely to be accessed by most patients.

Under its contract with HRSA, SRTR has recently started a project to create a lifelong living donor registry, the Living Donor Collective (<https://livingdonorcollective.org/>). The first phase of data has been published^{xvii} with updated reporting appearing in a new Annual Data Report, and participating programs receive Program Specific Reports. Under this model, transplant centers register donors and SRTR conducts follow-up. At this time, participation is voluntary and transplant centers cite concerns for costs as a barrier to participation.

To ensure a meaningful commitment to living donor safety, ASN encourages OPTN, SRTR, and the Centers for Medicare & Medicaid Services (CMS) to partner to ensure access to post-donation follow-up and incentivize donor registration in the Living Donor Collective. ASN notes that there is little long-term data on the outcomes following kidney donation, particularly among racial and ethnic minorities, which has impeded the growth of living donation. More recent advances in genetics of kidney disease, including the APOL1 alleles, raises new concerns and questions for the long-term risk of potential donors with genetic markers of kidney diseases. These questions need to be answered in order to ensure optimal and equitable access to living donation and reassure potential donors and optimize their safety.

Recently, the OPTN Board of Directors approved a new policy combining pretransplant (offer acceptance, waitlist mortality) and posttransplant (90-day graft survival and conditional one-year graft survival) indicators to motivate attention to all phases of care by transplant centers. ASN does not support that new policy and hopes this RFI will lead to the reversal of that approval. This opposition is in part because of the inclusion of a waitlist mortality measure that would only encourage selective and delayed waitlisting of dialysis patients who continue to accrue waitlisting time from the time that they initiate dialysis. This approach has substantial adverse consequences to potential transplant recipients.

ASN notes that OPTN has moved forward with new measures while being fully aware of the effort from SRTR to develop new metrics for transplant centers (“The Task 5 initiative”^{xviii}). This failure to coordinate is going to result in another compilation of a variety of quality measures from different agencies that will create confusion among transplant centers – much to the disadvantage of patients. The confusing array of quality measures from different agencies

also creates confusion for hospital leadership which adversely impacts their willingness to invest and support transplant programs and the much-needed quality improvement resources.

- Ensuring that centers are performing quality improvement activities on an ongoing basis requires the establishment of a robust effort in the form of a quality specialist focused on continuous improvement and monitoring of process and outcomes measures of the transplant center. This needs to be seen as a necessary investment on the part of hospitals with transplant centers and enforced by the OPTN contractor that has failed to discipline transplant centers that have not reported significant amounts of data for their patients.
- Incentivizing maximum access to waitlists, optimal organ use, and transplant rates, while maintaining post-transplant outcomes requires a harmonized, system-wide perspective. Published research shows that net survival benefit conferred by even the ‘lowest performing’ centers is far superior to dialysis.^{xix} To avoid risk aversion, recertification should focus on achievement of an absolute survival benefit over dialysis.

Finally, transplant centers are not currently equipped to handle a deluge of patient referrals should nephrologists decide to indiscriminately refer all of their dialysis patients immediately for evaluation for transplantation. Improvements are needed in pre-referral evaluation and in communication among nephrologists, dialysis facilities, and transplant centers to optimize the pre-transplant evaluation process and eliminate disparities. Currently, reimbursement policies do not incentivize the adequate staffing of pretransplant programs to appropriately expand and manage transplant center waitlisting. The current policies are exacerbated by the absence of any meaningful reimbursement from private payers for pretransplant related coordination of care and other activities to maintain patients active on the waitlist.

In order for transplant programs to function optimally and to increase access to transplant, transplant programs require robust, adequately funded pre-transplant teams that will aid patients in navigating the multistep evaluation process and will keep patients informed of changes in a timely manner; additionally, these pretransplant teams also must ensure regular communication with dialysis units and nephrologists so that changes in health status that require either temporary inactivation or delisting (when truly indicated) happen in a timely manner.

Making the patients’ experience of pretransplant evaluation easier is an important goal (that will require adequate funding) that should help to address some of the barriers to transplant that disproportionately affect patients who do not live in close proximity to a transplant center. Some transplant centers seek to perform much of the pretransplant testing locally at their center. However, in the age of electronic medical records, efforts should be made to allow much of this testing to happen in a location that is of most convenience to the patient and their families, obviating the need for travel costs, time off from work, and other challenges that may inadvertently create barriers to consideration for transplant.

Pretransplant testing is a significant source of revenue for many transplant centers. Maintaining the financial stability of transplant centers is clearly a crucial objective in order for them to remain open to provide transplants. Accordingly, if patient-centered changes are made to baseline pretransplant testing, it will be necessary to understand and mitigate any deleterious

impacts on the financial viability of transplant centers so that they can, in turn, continue to serve patients.

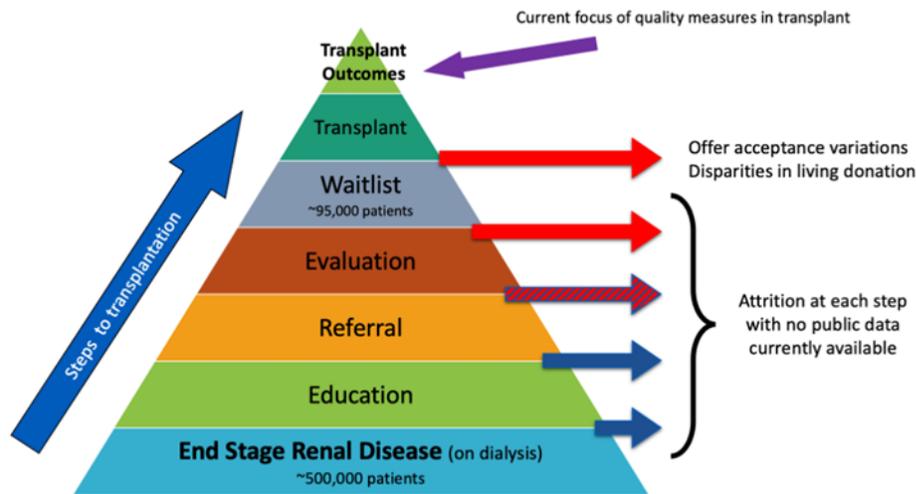
At present, interest in taking care of transplant recipients (and living donors) in the long-term plummets on the part of transplant programs after one-year post-transplant and there is no clearly established pathway to community care, to the detriment of patients. It would be beneficial to establish—as well as provide reimbursement to support—a pathway for these individuals to receive skilled care from professionals. A variety of approaches could be undertaken to achieve this goal, and the care would not necessarily have to be provided at the transplant center itself.

Telemedicine may be an ideal venue to provide these patients access to long-term, post-transplant or post-donation care. It may also be possible for transplant centers and transplant nephrologists to forge connections with internists with knowledge about transplant or general nephrologists to provide this care at the community level. HRSA should consider these approaches in its contracting efforts.

Similarly, referring nephrologists and transplant centers need to increase coordination when providing a continuum of care for patients post transplantation. Most patients are clinically stable after transplantation and could be managed by referring nephrologists in partnership with transplant centers, particularly as transplant recipients move beyond the early post-transplant period. Improved partnerships require the creation of systems that allow for easy referral back to centers in the event of complications, with a significant resource investment into coordination of care activities.

There is a need for physician practices, transplant centers, dialysis units, and independent laboratories to share patient results in a seamless manner, particularly if the care of these patients will be co-managed by two or more sets of clinicians in partnerships or transform patient care silos to integrated care along a continuum.

Currently the quality measures are focused almost exclusively on post-transplant outcomes. This singular focus has created several negative unintended consequences and encouraged increasing selectivity. Overcoming this situation will require recognition that we should be assessing care along the continuum of patient experience in the steps to transplantation. This approach would mean creating quality measures (process or outcomes measures) for each step in the process.



One method to potentially avoid unintended consequences is to calculate quality measures in such a way that considers the spectrum of the process from dialysis to transplant at any given time, to leverage the multistep nature of the process of education, referral, evaluation, waitlisting, transplantation, and post-transplant outcomes. Specifically, measures of quality should use the numerator from the prior step as the denominator for the next step along this continuum to discourage gaming of metrics or a singular focus on just one step of the process.

For example, the proportion of patients referred should be based on the number of patients who completed the education step, while the proportion of patients evaluated should be reported as a fraction of those patients who were referred for transplantation. This multistep process, however, spans different stakeholders – and would require that Conditions of Participation (CoPs) for transplant centers are aligned with Conditions for Coverage for dialysis facilities and with value care programs in which nephrologists are currently participating.

Post-transplant outcome measures currently focus on very short-term outcomes of graft survival and patient death but fail to account for the impact on quality of life. For example, patients who receive a transplant that is complicated by a prolonged hospital course, multiple readmissions, multiple complications with poor allograft function but is dialysis independent at the end of a year would be considered a success by the current CoPs but has potentially resulted in a significantly worse quality of life for the patient. Similarly, from an access and health equity perspective, focusing on short-term, time-limited outcomes post-transplant limit the opportunity to spur growth in transplantation.

Addressing **C. OPTN Finances** questions 1-2.

Regarding charging for functions that are OPTN contract-supported functions, currently the OPTN contractor charges a fee for certain data reports and visualizations that are needed by transplant centers and Organ Procurement Organizations (OPOs) in order to understand how the allocation system is working with respect to organ offers, organ acceptance, and bypass filters. Given that the current OPTN contractor is already being funded to do this, ASN believes that this practice should not be allowed to continue moving forward.

In addition, given that there are now quality measures that encourage transplant referral and waitlisting at the dialysis facility level, there is likely to be a substantial increase in the number of patients being referred to transplant centers that may overwhelm those centers. As a result, this is likely to change listing behavior on the part of the transplant centers by rapidly increasing the number of individuals who are listed as inactive with thousands of patients thus being waitlisted without any real hope of being evaluated in a timely manner yet incurring fees for waitlisting. ASN believe that HRSA should carefully monitor this situation and move quickly to address it if, and when, it sees this activity occurring.

Addressing **D. OPTN Governance** question 1.

The current governance of the OPTN contractor is perceived as opaque to the community with no clear process for how individuals who volunteer for participation are selected to serve on committees. The agenda setting for the committees is done by the contractor staff even though there is considerable staff turnover, limited institutional memory, or desire to change the status quo sometimes resulting in situations where the necessary expertise to make important decisions is lacking. ASN believes separate governance boards is an important first step in addressing this and other issues. In addition, there needs to be the ability to invite external experts or even require that committees identify experts who would be able to inform committee discussions.

Addressing **F. Organ Usage**

While organ utilization rates are plummeting, the OPTN contractor continues to plow ahead with the effort of continuous distribution without a meaningful effort to improve processes or communication that arise from the logistical challenge in the KAS250 form. With increasing focus on the ESRD Treatment Choices Learning Collaborative (ETCLC) and the need to improve organ utilization, the oversight of this challenge by the OPTN contractor is disappointing. The contractor failed to have a contingency plan that would be capable of identifying early process challenges and mitigating these problems before the rapid increase in discard rates took a hold further reinforces the general perception that the contractor is not actively engaged in the process.

The protracted process by which the current OPTN contractor commits resources to introduce changes in the information technology (IT) systems is problematic. For example, the long-drawn-out process of implementation of new organ decline codes took nearly five years, and the extensive delays as a result of inadequate IT resources committed highlight a problem that stems from inadequate resources to invest in infrastructure and the apparent absence of a desire to invest proactively in the system. Similarly, the lengthy delays in implementation of the data lock and protracted processes used for implementation of even the smallest of changes suggest a contractor invested in avoiding meaningful changes necessary to optimize an efficient organ allocation system.

ASN is committed to working with HRSA, HHS, OPOs, and transplant centers to ensure that every individual facing kidney failure has equal access to life-saving kidney transplantation should they so desire and are medically able. Currently, Black Americans, Latinx Americans,

Native Americans, and Native Hawaiian/Pacific Islanders as well as individuals with lower educational and socioeconomic status face disparities in nearly every step of the process for kidney transplantation. For example, Black Americans are less likely than White Americans to be identified as transplant candidates, referred for evaluation, placed on the kidney transplant waitlist or receive kidney transplants, especially living donor kidney transplants, while also being more likely to receive lower quality kidneys, have organ offers declined for them and have poorer transplant graft survival. These trends must be reversed – anything less is neither equitable nor acceptable.

Again, thank you for the opportunity to provide comments on HRSA's request for information. ASN stands ready to provide assistance in achieving the goals HRSA has identified in any way possible. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,



Susan E. Quaggin, MD, FASN
President

ⁱ [file:///C:/Users/David/Downloads/OPTN+RFI+\(4.8.22\)-2.pdf](file:///C:/Users/David/Downloads/OPTN+RFI+(4.8.22)-2.pdf)

ⁱⁱ <https://nap.nationalacademies.org/download/26364#>

ⁱⁱⁱ <https://www.gao.gov/assets/b-416248.pdf>

^{iv} <https://pubmed.ncbi.nlm.nih.gov/33353493/>

^v <https://pubmed.ncbi.nlm.nih.gov/29945305/>

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