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# Living Kidney Donor Advocacy Program

## A Quality Improvement Project

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## ABSTRACT

Objective: *In 2007, the Centers for Medicare & Medicaid Services mandated that kidney transplant programs establish a living donor advocate program to ensure safe care and support for living organ donors. This quality improvement project assessed the impact of establishing a living donor advocate program and identified the ethical commitments and threats living kidney donors perceive throughout the donation process.* Method: *This quality improvement project reflects a mixed-methods methodology. Qualitative as well as quantitative data were generated through the donor-advocate consultation sessions and the written Living Donor Satisfaction Survey. Thirteen living donors participated.* Results: *No threats to donor rights were identified by either the donor or the advocate. Nonrelated donors were motivated by altruism, whereas related donors were motivated by a sense of family. A majority of donors reported being changed emotionally and spiritually by the act of serving as a living donor. The living kidney donors were overwhelmingly extremely satisfied with their decision to donate and perceived the living donor advocacy program as being very good.* Discussion: *Questions have been raised about what role the donor's spouse should have during the informed consent process. Further research is needed to better understand the role and power of an advocate when threats to the donor's rights are noted.*

Becoming an organ donor upon one's death (deceased donor donation) is a concept that was promoted through the 1968 Uniform Anatomical Gift Act; however, living donor kidney transplantations have occurred between identical twins since 1954.[1] The frequency of kidney transplantations (both deceased and living donor) increased in 1983 with the creation of the antirejection drug, cyclosporine. In 1984, The United Network for Organ Sharing (UNOS), a nonprofit organization, began to oversee the procurement and distribution of all organs for transplantation through the use of a computerized organ-matching system.[2]

Despite the oversight of UNOS, a variety of ethical concerns related to the practice of living donor kidney transplantation are possible. In response to the various ethical concerns being raised regarding the practice of living kidney donation, a new federal requirement was published on March 30, 2007, that ''the transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.''[3]

The transplantation service at a northern New England academic medical center chose to create an independent living donor advocate program. When considering who should serve as a living donor advocate (advocate), a variety of healthcare professionals were considered. Initially, the hospital's clinical ethics consultants seemed ideal for protecting the living donor's ethical rights; however, this option was not viable because of a variety of real or potential conflict of roles. Because the ethic consultants participated in the transplant service meetings and might be needed for ethics consultations, the ethics consultants did not meet the independent criterion. The hospital's interfaith chaplains were also ruled out based on concerns that some potential living donors might not be receptive.[4] Finally, a group of advocates were self-selected from the Office of Patient and Family Advocacy (registered nurses) as well as the Department of Social Work.

## Background

In the 1960s, technology improved to allow persons with renal failure to be treated with hemodialysis; however, access to the procedure in the 1960s was limited because of the small number of machines. Concerns on how to allocate these scarce resources were a major impetus for the creation of Hospital Ethics Committees. Although UNOS has been successful in matching and distributing organs to recipients, there are more than 96,000 Americans awaiting kidney transplantation. During 2010, a total of 6559 living kidney donor transplantations were performed as compared with 22,104 deceased donor transplants.[5] For purposes of this project, a living donor is a person who agrees to have a voluntary nephrectomy of a healthy kidney, which will subsequently be transplanted into another person who is experiencing renal failure. [Note: liver transplants, including living donation of liver segments, are not performed at this transplant center.] The recipient may or may not be known by the living donor, and the option exists for the identities of the donor/recipient to remain anonymous to each other.

## Ethical Concerns Regarding Living Kidney Donation

The potential exists for the living donor (donor) to experience a variety of ethical issues throughout the diagnostic workup, actual donation, and subsequent recovery period.

### Nonmaleficence

The ethical principle of nonmaleficence requires that individuals refrain from doing harm and also to act to remove the potential for harm. A harm may be physical, psychological, social, and/or spiritual in nature. The act of a living donation of a kidney is a blatant act of maleficence because the donor would experience physical harms associated with an unnecessary surgery and potential physical harm if the remaining kidney were to be injured in the future.[6] Thus, the principle of nonmaleficence would suggest that living kidney donation is not an ethically desirable act. However, the potential for beneficence (doing good) toward the recipient is generally viewed as an acceptable justification for living kidney donation despite the potential and/or actual harm(s) the living donor would experience.

In addition to physical harm, the possibility exists that psychological and/or spiritual harm may occur. For example, the living donor might grieve for the loss of his/her kidney and/or experience regrets if the donated kidney were to fail to work after transplantation. The possibility also exists for the living donor to fail to emotionally separate from the donated kidney and continue to perceive the kidney as ''being mine'' even though the kidney was given to another. Thus, the living donor may experience anger or regret if the recipient does not act to optimize the effectiveness and longevity of the donated kidney. The kidney may fail to work in the recipient, leaving the donor with a sense of failure.

Finally, social harms to familial or social relationships may occur if a potential donor feels coerced by a family member/significant other to be a donor.[7] The donor may also need to alter his/her lifestyle as a result of donation, for example, avoiding contact sports or high-risk behaviors. Finally, a potential donor must be aware that donation might impact life and/or health insurance applications.[7,8]

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The authors have disclosed that they have no significant relationship with, or financial interest in, any commercial companies pertaining to this article.

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DOI: 10.1097/NHL.0b013e318247689b

## Autonomy

A person is considered to be autonomous if he/she is 18 years of age and has never been declared legally incompetent. To make an autonomous decision, one must be free of coercion. A person could feel coerced to donate by direct comments, such as ''A good father would lay down his life for a child, all **you** need to do is donate a kidney,'' or an indirect comment such as ''the best option for finding a perfect match is from a sibling.''

Autonomy is a prerequisite for making an informed decision. Informed decision making (either consent or refusal) is a process that includes 4 steps. First, the individual must understand the problem at hand, such as ''Joe has renal failure and is being treated by hemodialysis. He finds this process time consuming and uncomfortable and would like to have a kidney transplant.'' Second, the potential donor must recognize the options available to him/her: living kidney donation (known or anonymous) or no donation. Third, the potential donor must be cognizant of the potential positive and negative consequences associated with each available option. Finally, the person must provide a clear rationale for the option selected. Signing the consent form is merely the legal record that the informed consent process has occurred.

## Altruism

Altruism is a beneficent act and is ''defined as an unselfish concern for the welfare of others.''[9(p21)] Altruistic acts go above and beyond normal societal expectations. When attempting to justify an altruistic action, an individual might say, ''This was something I had to do. If I hadn't donated, I wouldn't have been able to live with myself.'' Dutiful altruistic acts generally occur between persons with a preexisting relationship; however, the possibility exists for a person to make a supererogatory anonymous altruistic donation to the UNOS pool or to a specific person with renal failure.[10] Although the majority of altruistic donation offers are altruistically motivated, healthcare providers must be vigilant to identify persons who may in fact not be altruistic, but rather have emotional issues or other secondary motivations for donating.[11]

## Respect for Persons

Respect for persons requires that people are treated in a manner that recognizes their human status and recognizes their individual values. The deontology ethical theory would require that a person must be treated as an end and never as a means to an end. Thus, respect for persons would require that the potential donor's rights and values be honored and never placed secondary to those of the potential recipient.

Threats toward the donor's confidentiality may occur and need to be controlled. During the workup, information about the potential donor's health or lifestyle may be revealed. The transplant team has an ethical obligation to not share confidential information with others, including the potential recipient. For example, a donor might discover that he is HIV-positive and thus does not qualify to donate. Healthcare professionals often develop standardized language for conveying the fact that a potential donor will be unable to donate, for example, ''During the workup, some information was learned that precludes James from being a donor at this time.'' This standardized language is also helpful when a potential donor does not desire to donate but does not feel comfortable voicing this position to his/her family and/or the recipient.

# Importance of Having an Advocate

The potential exists for the living donor (donor) to experience a variety of ethical issues throughout the diagnostic workup, actual donation, and subsequent recovery period. An advocate is a person who puts a voice to another's concerns, which assumes that the person is unable to act/speak on his/her own behalf. An advocate may be needed when the donor is physically unable to speak for himself/herself, such as when under anesthesia or during an acute medical event. An advocate is often needed when the person is unable or unwilling to speak out/act because of fears of retaliation or coercion. For example, a potential living donor may experience coercion to donate because of psychological pressure: ''If you don't donate, Johnny will die,'' or power inequities: ''How can I say no to my wife or a doctor?'' Finally, an advocate may be necessary when a conflict of interest may be present, such as when a mother has to represent the interests of identical twins when one twin has renal failure and the other is a perfect genetic match.

The Federal requirement for all kidney transplantation centers to create and implement a living kidney donor advocate program is a realistic mandate in light of the known harms associated with undergoing an unnecessary surgery as well as the potential psychological and social harms associated with decision to donate. The role of a living kidney donor advocate would be to ensure that the donor's rights and voice are heard and honored and that all possible actions are taken to minimize harms to the donor throughout the donation process.

# Previous Research Findings

Prior to the implementation of this living donor advocacy program, little research on the phenomenon of living donation existed. In 2006, donors (3 months after donation) were asked to describe what they desired from a living donor advocate. These donors described that an advocate should act to promote: (1) respect for the donor: ''Don't treat me like a cadaver''; (2) the donor's best interest: ''Give me my own healthcare team''; (3) altruism:

''Just let me do this''; (4) informed consent and emotional support: ''Educate me about the risks, carefully evaluate me, and then tell me I am going to be OK,'' while (5) concurrently minimizing harm to the donor: ''Make sure I'm healthy enough to donate.''[4(p65)]

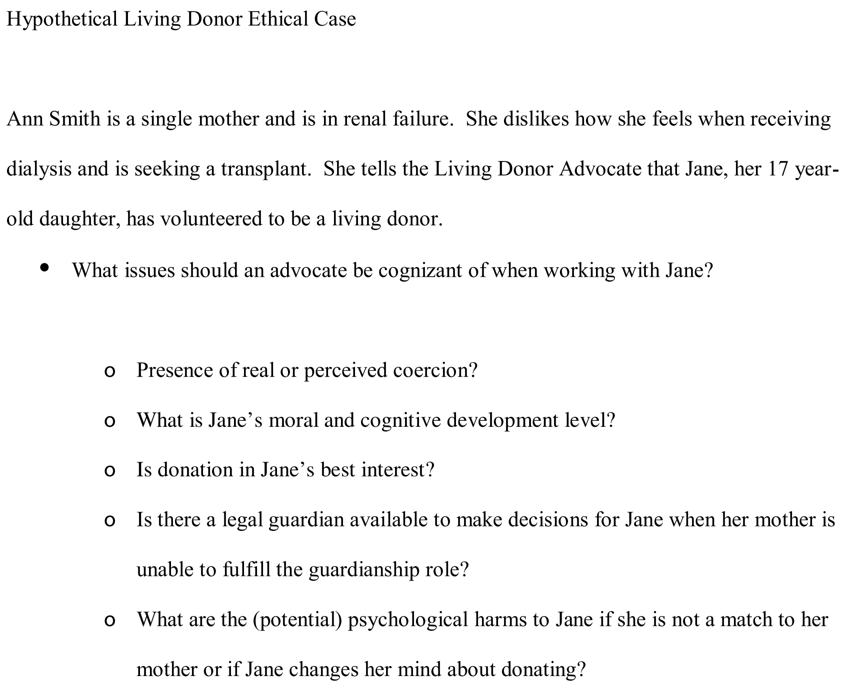
## Quality Improvement Project

This quality improvement (QI) project was designed to evaluate the effectiveness of the newly created living kidney donor advocate program and approved by the institutional review board. Quality improvement and clinical research are both conceptually and practically distinct and play different roles in healthcare. Quality improvement does yield information about what works and the way in which change can come about. When the results of QI activities in various settings are looked at together, patterns may emerge—and even a single QI endeavor may yield valuable insights for a QI practitioner in another setting. Given this, QI practitioners should be encouraged to share information about their QI activities with others in the healthcare system.[12(pS12)]

## Educating the Living Donor Advocates

An interdisciplinary team approach was used to educate the advocates about renal transplantation. A CD on living donation was used as an introduction to the process. A transplant surgeon reviewed anatomy and discussed the surgical procedures, types of incisions, and physical risks. The transplant coordinator discussed the educational process in addition to the medical workup process that all potential recipients and donors complete. The psychosocial assessments that are routinely performed with both donors and recipients were explained by the transplant social worker. In addition, financial resources (all costs for donation are covered except for postoperative pain medications) and constraints (selling organs is illegal) were reviewed.[13] The transplant nurse practitioner explained the postoperative period including common physical complaints and related follow-up care, such as physical restrictions related to lifting and returning to work.

The clinical nurse ethicist discussed the ethical considerations associated with living donation. Ethical considerations related to promoting nonmaleficence and identifying harms (physical, psychological, and social) were discussed. The federal criteria established for a living kidney donor advocate were reviewed from an ethical perspective. The informed consent process and strategies for evaluating the donor's decision-making process were discussed. Advocates were counseled about the importance of acting with moral courage because the possibility existed that an advocate may be required to exercise their advocate authority by vetoing a decision to donate against expressed opinions/decisions of other transplant team members, the recipient, and/or even the donor.[14] Last, the advocates engaged in a group discussion about a hypothetical living donation case (Figure 1).



Hypothetical Living Donor Ethical Case

Ann Smith is a single mother and is in renal failure. She dislikes how she feels when receiving dialysis and is seeking a transplant. She tells the Living Donor Advocate that Jane, her 17 year-old daughter, has volunteered to be a living donor.

- What issues should an advocate be cognizant of when working with Jane?
  - Presence of real or perceived coercion?
  - What is Jane's moral and cognitive development level?
  - Is donation in Jane's best interest?
  - Is there a legal guardian available to make decisions for Jane when her mother is unable to fulfill the guardianship role?
  - What are the (potential) psychological harms to Jane if she is not a match to her mother or if Jane changes her mind about donating?

**Figure 1** • Hypothetical living donor ethical case.

## Living Donor Advocacy Program Protocol

Individuals, who wish to be a living kidney donor (donor), are required to participate in the living donor advocate program. Refusal to work with an advocate would result in being disqualified to donate per organizational policy. After an individual has successfully completed the donation workup process and a surgical date has been set, the potential donor is assigned an advocate. Advocates are assigned by the Department of Patient Advocacy director based on availability. The standardized living donor advocate program requires that the donor meet with the assigned advocate at 3 specified intervals:

- prior to donation,
- postoperative first day, and
- 6 weeks after donation.

The first 2 encounters occur in person, whereas the 6-week contact is a telephone interview. Each donor is also provided with the opportunity to complete an anonymous written Living Donor Satisfaction Survey 7 weeks after donation. During each of these encounters, the advocate uses a standardized interview to guide the interaction and records data for QI purposes. The program is flexible and allows for the possibility that a donor could request to meet with an advocate prior to being approved or scheduled to donate; however, no special requests occurred during the January to September 2008 period.

## Methodology

This QI project reflects a mixed-methods methodology. Qualitative as well as quantitative data were generated through the donor-advocate consultation sessions as well as through the written Living Donor Satisfaction Survey. No personal identifiers for the donors were collected.

## Program Objectives

The primary purpose for this QI research project is to improve the living kidney donor experience. Two objectives were identified.

(1) Evaluate the effectiveness of the living kidney donor advocate program to protect the rights of the living kidney donor.
(2) Identify the ethical commitments and threats living kidney donors perceive throughout the donation process.

## Participants

Seventeen potential living donors were assigned advocates and participated in the preoperative meeting; however, only 13 progressed to donation during the January to September 2008 reporting period. Of these living donations, 9 were from related donors, and 4 were nonrelated donations. In total, the transplant service transplanted 35 kidneys from 22 deceased donors and 13 living donors during this period.

## Findings

### Preoperative

Potential donors (n = 17) initially learned about living donation through contact with the recipient or family member (64.7%), the media (17.6%), or other venues (17.6%), such as ''talked about it as a teenager'' or ''heard via my hairdresser.'' During the initial preoperative advocate encounter, all nonrelated potential donors (n = 6) described altruism as their motive for donating. Eleven potential donors who were biologically related to the recipient and 1 nonrelated donor (a recipient's spouse) described ''we're family'' as their motivating rationale. None of the subjects described that the recipient would die without a transplant or monetary/personal gains as motivations, which would have necessitated a referral back to the transplant coordinator for education and reassessment of the informed consent to donate.

Prior to donating, the subjects noted considering various harms before deciding to donate. These harms included pain, potential for infection and/or surgical complications, effect on routine activities, need to protect remaining kidney, and nonreimbursed expenses. Subjects also discussed impact on significant other, for example, how to tell a subject's 6-year-old daughter about donation decision. One potential donor considered the possibility that her sister (the recipient) might feel indebted and thus could make the donor feel uncomfortable. Finally, a potential donor from out of state had to consider the logistics of where to stay before and after donation.

### First Day After Donation

The day after providing a living kidney donation, 11 donors participated in the first-day postoperative advocate session. Ten donors reported knowing that the recipient was doing ''good,'' whereas 1 donor noted ''being optimistic'' about the recipient's status. The majority of donors (82%) had not yet seen the recipient postoperatively because the recipient was still in the intensive care unit as is routine for the first postoperative day.

Each of the 11 donors reported his/her postoperative pain as ranging between 2 to 6 on a 0- to 10-point Likert pain scale. These surgeries are done laparoscopically, and the pain was generally associated with the carbon dioxide gas instilled to improve the viewing field. Thus, this group of donors appeared to be receiving adequate postoperative pain management.

## Six Weeks After Donation

Ten donors completed the 6-week postdonation telephone interview; 90% of the donors (n = 9) did not identify any new benefits related to donating that were not recognized prior to donating; thus, donors perceived being quite informed prior to donating. However, 1 donor identified seeing the recipient feel better so quickly as a newly noted and desirable benefit related to serving as a living kidney donor. Similarly, 80% of the donors (n = 8) reported no new risks related to donating that were not recognized prior to surgery. However, 2 donors described discomfort with gas pains as an unanticipated risk associated with donation. In addition, 1 donor expressed a desire for parking vouchers when at the hospital, whereas another had expected to be given names of other donors, which did not happen.

When questioned about whether they believed they had been changed physically by the experience of donating, 80% stated no they had not been changed beyond feeling a little tired. In fact, 1 donor described feeling healthy and having gone kayaking 3 days after donating. One donor noted being changed physically related to the length of time to recovery, which the donor had assumed would be faster and uncomplicated. A final donor was undecided explaining that he was still feeling the effect of surgery.

When asked if the donor believed he/she had been changed emotionally by the experience of donating, 60% replied yes, noting having ''family support and interest high'' and a ''great outlook on life enhanced,'' feeling ''emotionally healthier—feels good to have done it,'' and concluding that donating had been a ''rewarding experience.'' The remaining 4 donors (40%) noted not being changed emotionally, but describe being ''just tired.''

In contrast, 60% of donors (n = 6) perceived that they had been changed spiritually by the experience of donating. These donors described:

> Going into it (donation), your life is in their hands. Don't have fear of dying because of my trust in God. Reinforced my belief.
>
> Meant to happen.
>
> I joke with my sister (the recipient) when I answer the phone: ''(my name), giver of life!''

## Satisfaction With Decision to Donate

During the preoperative interview (n = 17), 88.8% of the potential donors noted being extremely satisfied with their decision to donate, with 11.2% feeling satisfied. One day after donation (n = 11), 90.1% reported being extremely satisfied, with 9.9% of the donors feeling satisfied with their decision to donate. By 6 weeks after donation (n = 10), 100% of the donors reported being extremely satisfied with their donation decision. In fact, each of the donors (100%) would recommend the experience of being a living kidney donor to others if the person was ''truly committed. It's not to be taken lightly.'' One donor reported telling everyone about the experience. Another donor explained being ''pleasantly surprised how quickly I was able to get up and back to my life.''

## Living Donor Advocate Concerns

During the preoperative interview, the advocates identified concerns related to specific potential donors. One potential donor wanted to know more about available options and was referred back to the transplant coordinator. A second advocate concern was voiced to the transplant team regarding a potential donor's mental health history. A third advocate concern arose when the advocate learned that a spouse (jokingly?) threatened not to donate during an argument.

During the initial postoperative period, a donor's spouse requested that no visits were to occur between the recipient and donor. This request raised concerns regarding the donor's motives and questions regarding whether assent to donation should be obtained from the donor's spouse before donation occurs. No advocate concerns were identified during the 6-week follow-up session.

While debriefing at the end of the QI project, the advocates pondered the significance of having identified only a small number of concerns regarding the donors' rights and/or decision to donate. Does this mean that the workup process is effective, or is there a need for advocates to be involved earlier during the donation workup period? In addition, the advocates questioned whether the advocate program was merely serving as a rubber stamp, or would an advocate in fact have sufficient skills to identify an as yet unrecognized ethical concern and subsequently the professional power necessary to stop a scheduled transplantation despite the donor's, recipient's, and/or transplantation team's continued desire/decision to complete the donation?

## Impact of the Living Kidney Donor Advocate Program on Workload

Each of the living kidney donor advocates self-selected to participate in this program, thus adding a new role/responsibility to his/her existing job descriptions. Each advocate recorded the amount of time spent during each donor contact. During this project, the advocate role required on average

- 23.2 minutes (range, 10–47 minutes) for the preoperative visit (n = 16)
- 13.6 minutes (range, 5–20 minutes) for the postoperative visit (n = 11)
- 10.8 minutes (range, 4–20 minutes) to complete the 6-week visit (n = 10)

Thus, on average, a living kidney donor advocate spent 47.6 minutes supporting each living kidney donor's rights.

## Future Considerations

Bramstedt[7] claimed that potential donors should always be evaluated privately without significant others being present in order to maximize the potential donor's ability to verbalize concerns about and/or actual incidents of coercion. However, during a postoperative visit, 1 advocate recognized a concern related to the donor spouse's disagreement with the donation and concerns related to the motivations of donating to a ''friend'' of the opposite sex. Thus, further research is needed to better understand how potential donors communicate to significant others their decisions to become altruistic, nonrelated donors. Should the potential donor's family/significant others sit in on the meetings (especially preoperative) between the donor and the advocate if he/she is not the intended recipient? The living kidney donor advocate program is designed to protect the potential donor's rights; however, little is known about what ethical and legal obligations are due the spouse of a potential donor, such as the need to obtain the spouse's assent prior to donation.

Second, when ethical concerns are identified during the initial workup process, what is the best way for handling these? Should the advocate be involved earlier in the process, or should an ethics consult be requested or be standard practice?

Third, what is the scope of the advocate's role? Should the advocate have access to the potential donor's comprehensive medical record beyond the records generated during the transplant workup? Finally, living kidney donor advocate programs will need to evaluate their procedures to ensure that the rights of a donor will be adequately protected as paired allocation patterns become more common.

## Implications for Managers

Advocacy is an ethical obligation for all healthcare professionals including nurses. In addition to advocating for patients, managers have an ethical obligation to advocate for their staff and unit/organization. Thus, a manager may experience a conflict of roles if supporting a living donor advocate's decision to prohibit a donation is in opposition of the organization's goals. For example, transplant services are required to meet annual transplantation quotas, which could be threatened if an anticipated transplantation is blocked by an advocate near the end of the year. When faced with this type of business ethics dilemma, the manager's primary ethical obligation should be to protect the rights of the potential donor over the organization.

Managers responsible for the living donor advocates must create a culture of empowerment where everyone (healthcare professionals as well as potential donors and recipients) recognizes and supports the advocate's role. Within a culture of empowerment, incidents of advocacy should be expected and welcomed as an opportunity to reevaluate and/or refine the predonation process. In addition, managers should ensure that the organization's ''no retaliation'' policy specifically addresses persons serving in official advocacy roles.

## Summary

Awareness of the recipient's need for a transplant as well as the possibility of using a living donor is a prerequisite to establishing the motivation to serve as a living donor. Nonrelated living kidney donors are motivated by altruism, whereas related living kidney donors are motivated by a sense of family. A majority of donors reported being changed emotionally and spiritually by the act of serving as a living donor. The living kidney donors were overwhelmingly extremely satisfied with their decision to donate and perceived the living donor advocacy program as being very good. However, the advocates have raised questions related to whether the advocates are being involved early enough in the process and have the ability to effect change in the event that an ethical concern is identified. Thus, this QI project was effective in identifying ways to improve the current living donor process. The potential to benefit future donors and advocates as well as other members of the renal transplantation service exists as advocacy skills are honed.

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