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QUALITY IMPROVEMENT

Oncology Advanced Practice Provider Mentorship and Paired Clinical Research Coordinator Support to Enhance Accrual to NCI Supportive Care Trials

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Abstract

Background: Patient access to clinical trials has been identified as a key measure for delivery of quality cancer care. Effective recruitment and retention strategies remain an issue. Furthermore, clinical trial participants historically lack diversity. This project focused on advanced practice provider (APP) mentorship and paired clinical research support to enhance minority accrual to supportive care trials in Hawai'i. **Methods:** Over a 1-year period, a formal mentorship program for six participating APPs and three clinical research coordinators (CRCs) in the Hawai'i Minority/Underserved National Cancer Institute Community Oncology Research Program (HI M/U NCORP) was implemented. An introductory meeting kicked off the project. The APP and CRC teams then met weekly for targeted screening and accrual to supportive care trials. Monthly meetings between the mentor and teams were conducted to discuss barriers, best practices, and problem solve issues. **Results:** 26 unique accruals were obtained by the APP and CRC teams over the project period while increasing minority accrual. All six APPs are now actively enrolling to trials. Four of the six participating APPs are now reviewing protocols for the HI M/U NCORP for feasibility and scientific merit. Eight of the nine participating APPs and CRCs found the intervention to be acceptable and feasible. **Conclusions:** Mentorship of APP and CRC teams can be

a successful strategy in increasing accrual and participation of APPs in clinical trial activities. Measuring minority accrual based on this strategy is more complex and dependent on the APP location, clinical trial portfolio, APP patient panel and clinical interest, as well as the expertise of the APP.

Patient access to cancer clinical trials has been identified as a key measure for the delivery of high-quality cancer care (Michaels et al., 2014). However, only 2% to 8% of the adult oncology population enrolls in a clinical trial, and more than 20% of trials fail to meet accrual goals (American Cancer Society Cancer Action Network, 2019; Hallquist Viale, 2016; Rimel, 2016; Unger & Fleury, 2021). Effective recruitment and retention strategies remain an issue. Furthermore, clinical trial participants have historically lacked racial and ethnic diversity. The lack of diversity is not only true for cancer treatment trials but also for non-treatment trials, such as supportive care and prevention trials. As cancer treatments become more complex, so do aspects of symptom management, quality of life, and cancer care delivery. When trials lack diversity, it is difficult to make them generalizable to all people with cancer. Prioritizing supportive care trials and enhancing racial and ethnic diversity in clinical trials has the potential to improve patients' quality of life and cancer outcomes.

There are multiple barriers to recruitment and retention to supportive care trials, and there has been limited success with addressing them (Unger et al., 2019). Huang and colleagues (2018) reviewed the need for more inclusive and proactive approaches that extend beyond known strategies. They identified three areas essential to clinical trial recruitment, including clinical trial design and protocol development, trial feasibility and site selection, and communication to key stakeholders. Increasing communication and engagement of oncology advanced practice providers (APPs) may be one worthwhile strategic approach.

Oncology APPs, including nurse practitioners (NPs), clinical nurse specialists (CNS), and physician assistants (PAs), are clinicians who contribute significantly to quality cancer care. Oncology APPs are routinely part of cancer care teams. Over 80% of practices surveyed by the American Society of Clinical Oncology (ASCO) in 2017 and over 90% of practices participating in the National Cancer Institute Community Oncology Research Program (NCORP) in 2022 reported employing APPs (ASCO, 2017; Braun-Inglis et al., 2024). Oncology APPs enhance value across the spectrum of cancer care, with many having expertise in symptom management and care coordination (Bruinooge et al., 2018; Coombs et al., 2019).

A 2020 study by Braun-Inglis and colleagues found that APP participation in clinical research was limited. While 80% of respondents reported that they participate in the care of patients on clinical trials, only a minority of APPs surveyed reported routinely approaching potentially eligible patients (20%) or exploring potential trials for their patients (37%). Furthermore, few reported taking on leadership roles such as being enrolling or treating investigators (15%), reviewing trials for feasibility (5%), or serving as principal investigators (PIs; 5%). However, this study also found that the majority of APPs believed clinical research participation was an appropriate role for them (90%) and also reported a desire to get more involved in clinical research (73%; Braun-Inglis et al., 2022).

The NCORP is a national network that brings cancer clinical trials directly to communities (NCORP, n.d.). In 2020, the NCORP developed guidelines to give APPs expanded roles in NCORP trials (Good, 2020), which included APPs serving as enrolling or treating investigators and site PIs. In 2021, these guidelines were further expanded to allow qualified APPs to order cancer treatment and investigational new drugs for NCORP, NCI National Clinical Trials Network (NCTN), and Experimental Therapeutics Clinical Trials Network (ETCTN) trials in concordance with an updated policy from the NCI Cancer Therapy Evaluation Program (CTEP; NCI, 2021). The development of the NCORP guidelines and changes to CTEP policy created new opportunities for APPs to further participate in NCI-sponsored clinical research.

The Hawai'i Minority/Underserved (HI M/U) NCORP is part of the NCORP network. The HI M/U NCORP grant is one of the major sources of funding for the Clinical Trials Office (CTO) at the University of Hawai'i Cancer Center (UHCC). This grant provides access to NCI-sponsored clinical trials to the majority of cancer patients in Hawai'i. The HI M/U NCORP is dedicated to increasing minority and underserved accruals to clinical trials, routinely enrolling participants from Hawai'i's and the Pacific's diverse ethnic communities. Seventy-five percent of HI M/U NCORP accruals are attributed to Japanese, Chinese, Filipino, or Native Hawaiian/Pacific Islanders (NHPI; University of Hawaii Cancer Center, n.d.). There is evidence suggesting that community sites with access to NCI-sponsored trials may represent a unique opportunity to expand clinical trial access to underserved and underrepresented populations (Kim et al., 2020; McCaskill-Stevens et al., 2005). In addition, it has been shown that marginalized populations participate at the same rate as White patients for both cancer treatment and supportive care trials if offered (Unger et al., 2020).

In 2021, the authors applied for and received a supplemental grant through the NCORP for a paired APP and clinical research coordinator (CRC) mentorship project with a focus on diverse accrual to supportive care trials offered through the NCORP network. The purpose of this project was to: (1) measure whether a strategy of formal mentorship for APPs and paired CRC support could increase diverse accruals to supportive care trials within the HI M/U NCORP, (2) to increase screening for supportive care trials, (3) to measure the number of APPs as enrolling or treating investigators in the HI M/U NCORP, (4) to describe the satisfaction of both participating APPs and CRCs with the intervention, and (5) to increase the number of oncology APPs participating and performing scientific and feasibility review within the HI M/U NCORP.

METHODS

Practice and Participant Characteristics

A total of six APPs and three CRCs participated in this project. There were two primary community oncology sites for this project, one being part of a larger health system and the other a private practice. All participating APPs were 100% clinical without any protected time for clinical research.

Project Design

This was a staggered 1-year program that commenced with a kick-off meeting in October 2021. This meeting reviewed the background, purpose, and plan for the program. The introductory meeting also highlighted four targeted NCORP trials for the project. The first site started the project in January 2022, while the second site started in April 2022. The duration of the project was 1 year at each site. The APP and CRC teams met weekly for approximately 15 minutes to do a quick targeted screening of trials. The mentor, an oncology nurse practitioner, and APP and CRC teams met monthly to discuss barriers, problem solve, and adjust the intervention as needed. The project initially focused on screening patients for specific targeted trials. After a few months, however, one team reported that the limited number of trials hampered their ability to enroll. In response, the project was opened up to include all available supportive care trials, leveraging the established APP and CRC team method.

Monthly protocol lists were sent to ensure mentees were aware of all available trials at their practice sites. Later in the year, the mentor assessed mentees' interest in expanding their roles, start reviewing trials for scientific merit and feasibility, and potentially serving as site PIs for appropriate protocols. Study data were collected and stored in UHCC's clinical trials management system, OnCore, developed by Advarra, Inc. This project was deemed exempt by the University of Hawai'i Institutional Review Board in October 2021.

RESULTS

Patient Screening, Enrollment, and Racial Breakdown

A total of 194 patients were screened during the staggered 1-year project period between the two sites. Twenty-six of the 194 patients screened were enrolled on an NCORP trial during the project period, resulting in 13% of patients screened being enrolled on to a trial (see Table 1 for the different trials that the APPs accrued to). In the year preceding the project, there were only seven total accruals to supportive care trials by APPs. Notably, there was no formal APP and CRC pairing or routine screening conducted during this period. Race and ethnicity data from both screening and

accruals were collected throughout the project period. In terms of accruals, 66% (n = 17) were Asian, 15% (n = 4) were Caucasian, 15% (n = 4) were NHPI, and 4% (n = 1) other (Figure 1A).

APPs and CRCs

Among the APPs, one was male and five were female. Racial and ethnic representation included one White, one part-Hawaiian, and four Asian participants. All CRCs were female, with two Asian and one Native American/White participant. Data were also collected for APPs as either an enrolling or treating and/or referring investigators. All APPs (100%) participating in the project either enrolled or referred a patient to an NCORP trial during the 1-year project period. Eight (89%) of the participating APPs and CRCs found the intervention to be acceptable and feasible. Four (67%) APPs reviewed an NCORP trial for scientific merit and feasibility by the end of the project (Figure 2).

DISCUSSION

This project was a success in meeting all of its aims, which included increasing minority accruals and screening, as well as expanding the pool of enrolling investigators and APPs performing scientific and feasibility review of trials. The intervention was also found to be acceptable and feasible in the HI M/U NCORP.

Prior to the project, there was some informal engagement of APPs, which resulted in a total of seven accruals in the year prior to the project. However, APP accrual increased significantly (to 26), as well as led to an increased proportion of minority races/ethnicities for the overall accrual as compared to the total adult accrual in 2021 (Figure 1B). In general, the HI M/U NCORP has diverse accrual due to Hawai'i's multiethnic population. However, this project increased both accrual and minority representation in these trials by empowering this group of health-care professionals.

Measuring accrual is important; however, the success of this project goes beyond the actual accrual metrics. The project addressed several barriers in terms of the APP's ability to accrue patients, especially when the focus was on specific trials. The targeted trial approach worked extremely well for one group of APPs who practiced in a high-risk breast clinic, as the patient population matched perfectly with the targeted trial. However, because the design of the trial only allowed for one site to participate, it limited the APPs from other sites to participate. Therefore, this limited the available trials to just three for the remaining three APPs (one of the APPs saw both high-risk breast and breast cancer patients so was able to enroll patients into all).

Unforeseen circumstances arose after the grant proposal was submitted. One of the remaining three trials closed two cohorts less than 30 days into the project, despite significant effort invested in screening for it beforehand. The remaining trials included one focused on first-line hormone receptor–positive/human epidermal growth factor receptor 2–negative metastatic breast cancer and the other on cancer survivor

Table 1. Trials That APPs Accrued to During Mentorship Project

Sponsor/Protocol	Subject	NCT#	APP accrual
Alliance A191901 (GETSET)	Optimizing breast cancer endocrine adherence	NCT04379570	1
SWOG S1703 (STM)	Serum tumor marker–directed disease monitoring in HR+/HER2- MBC	NCT03723928	2
SWOG S1904 (MiCHOICE)	Patient and provider decision support for chemoprevention for high-risk breast lesions	NCT04496739	11
Wake Forest WF1901 (IMPACTS)	Internet-based pain intervention for cancer survivors	NCT04462302	2
University of Rochester URCC-18110CD (ENABLE)	Implementing a palliative care intervention	NCT04062552	3
SWOG S2108CD (eGTB)	Electronic tumor board to increase evidence-based genome-informed therapy	NCT05455606	6
Alliance A222001	Oxybutynin for hot flashes in prostate cancer	NCT04600336	1

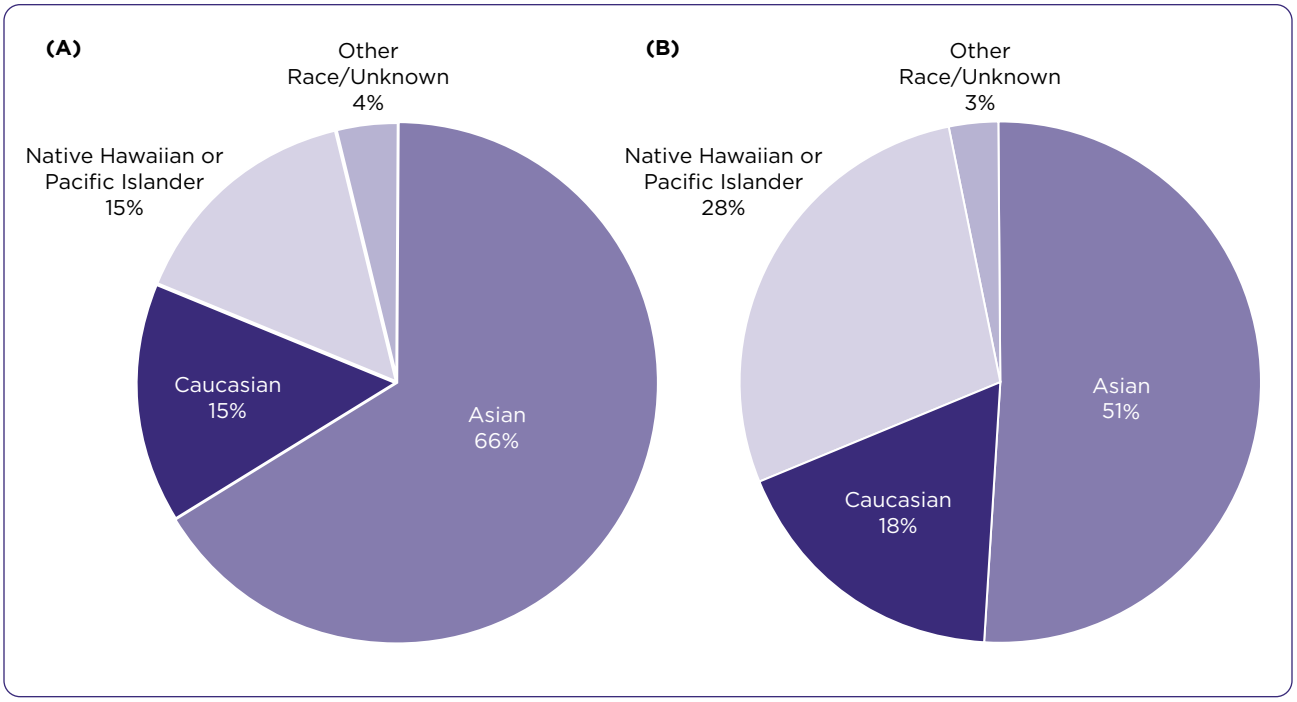

Figure 1. (A) Hawai'i Minority/Underserved NCORP APP accrual by race in 2022 (*n* = 26). (B) Hawai'i Minority/Underserved NCORP total accrual by race in 2021 (*n* = 186).

pain management. Due to concerns raised by three APPs and two CRCs that the targeted trial approach was too restrictive, the project was opened to include any available supportive care trials opened at their practice sites.

The mentor made herself available for any questions regarding the trials in between mentor/mentee meetings and continued to act as a resource for the CRCs who were involved in the project. The mentor made sure that the APPs had updated protocol lists to keep them aware of current trials. Of note, the project was open to supportive care trials where the APP had a keen interest in the subject matter even if they were not able serve as the enrolling or treating investigator for the trial. This was the case for two different cancer care delivery research (CCDR) trials: one focusing on early palliative care and the other on genomic tumor testing.

It became evident that a flexible approach to measuring accrual credit was needed, as there were nine accruals where the APPs could only get referral credit as it limited enrolling or treating investigators to physicians. Additionally, APPs who encountered more barriers with accruing participants gained a better understanding of the NCORP and became even more engaged. Everyone involved in the project recognized this as a significant success. For example, three of the four mentees who faced barriers to accrual during the project are now serving as site PIs for NCORP trials. Two of the four are active in the local disease site working groups within the NCORP, with one co-chairing the supportive care/CCDR working group. The fourth APP who encountered barriers during the project is now the Clinical Director at UHCC CTO and routinely works to address APP barriers in clinical research.

The number of enrolling or treating investigators was increased through this project. Four of the six APPs had not served as enrolling or treating investigators prior to the project. The mentorship component proved crucial in equipping these APPs with the knowledge to enroll participants in specific protocols and navigate the distinctions between enrolling or treating investigators and sub-investigators. Two of the four new investigators focused on a particular protocol that addressed education for high-risk breast lesions, as they practice in a high-risk breast clinic. Demonstrating sustained success, these two clinicians have continued enrolling patients in trials even

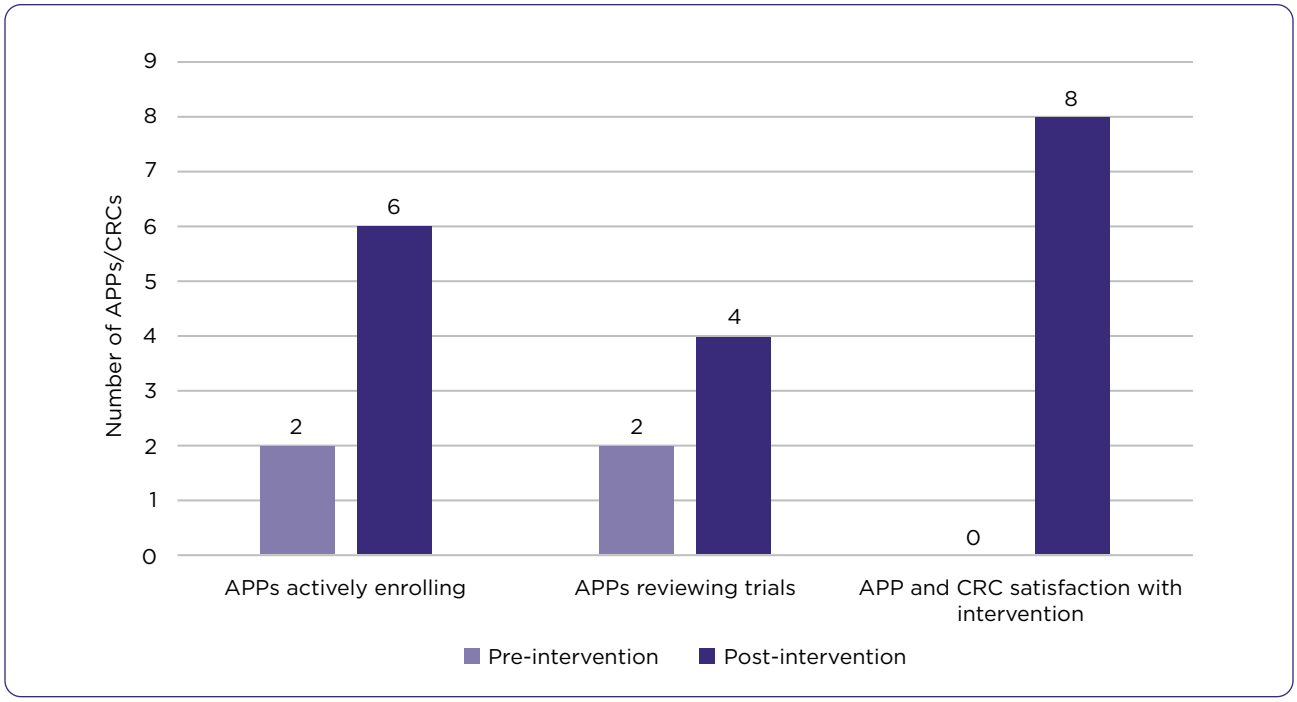

Figure 2. Project Aims 3-5. APPs = advanced practice providers; CRCs = clinical research coordinators.

after the project's conclusion. Although NCORP protocols are limited in this population, these two APPs have been engaged in another pertinent protocol focusing on *BRCA1* mutations and ovarian reserve. They have reported that the success in the project has led to increased understanding of how they can contribute to clinical research and improve overall care for their patients.

This project has increased capacity within the NCORP. Not only have the APPs from this project continued to enroll patients beyond the project period, but they have also taken the lead in supportive care and CCDR research with the HI M/U NCORP. The success of this project has also inspired other APPs within the NCORP to take on a more active role in clinical research. There is now a total of 11 APPs actively enrolling patients on trials, and APP accruals account for more than 65% of the current supportive care clinical trial portfolio.

Advanced practice provider participation in scientific and feasibility review was also increased, with APPs now being the primary clinicians responsible for reviewing supportive care trials within the NCORP. Prior to the project, only two of the APPs had participated in the formal review of trials. After the project, four of the six routinely participate in scientific and feasibility reviews of potential protocols. This has also been expanded out to other APPs who did not participate in the project. This expansion acknowledges the effectiveness of utilizing APPs in protocol review and aims to further leverage their expertise.

This mentorship and paired APP and CRC team intervention was found to be acceptable and feasible by all participants who completed the post project survey. One CRC was lost to follow-up as they left UHCC prior to project completion. Coordinating monthly 1-hour meetings presented scheduling challenges due to the APPs' busy clinic schedules. The mentor ensured flexibility to accommodate these constraints, recognizing the importance of respecting the APPs' time. All APPs and CRCs who participated in the project continue to work together, except for one CRC who retired. Clinical research coordinators involved in the project have observed a significant increase in APP engagement and participation across all aspects of clinical research. This includes not only a focus on supportive care trials but also routine patient identification for treatment trials, greater involvement in the overall clinical trials process, and participation in research base meetings.

This project undoubtedly highlighted the need for more basic education in terms of clinical trials and the NCORP network, its role for providing access to clinical trials in Hawai'i, as well as the interpretation and implementation of the NCORP APP guidelines. Many of the mentoring meetings conducted during the project required dedicated time for review of the NCORP guidelines for APP enrollment and addressing institutional barriers precluding APP enrollments despite the trials being sponsored by the NCORP.

This project understandably had its limitations. First, measuring an increase in minority accrual is complex in an NCORP that predominately serves minorities. Overall, both the total accruals and minority accruals increased, but it is unclear whether this could be replicated in a less diverse setting. While the project incorporated introductory information on diversity, equity, and inclusion during the kick-off meeting through dedicated slides, the inclusion of a focused cultural sensitivity training program or a health equity initiative like "Just ASK" (a minority participation in research program that helps not only to ensure patients are aware and knowledgeable about clinical trial participation but also that researchers are well equipped with the necessary skills to communicate with diverse populations) might have further enhanced the diversity of patients enrolled (Oyer et al., 2022). Second, measuring accruals in general as the primary outcome is multifaceted due to multiple barriers faced. These barriers included continued prioritization of treatment trials over supportive care trials at some practices, restrictive protocol language that limits the APPs' ability to serve as enrolling or treating investigators, trials meeting national accrual goals, and sites deciding not to open certain trials due to workforce limitations. One site had to drop out completely as they were not able to open trials pertinent to the project. Despite this project's limitations, the participants felt it was worthwhile, with several of the mentees now interested in serving as mentors for other APPs in the NCORP network.

CONCLUSION

In conclusion, the project was successful in achieving 1) more minority accrual, 2) increased screening for supportive care trials, 3) an increased pool of APP investigators in the NCORP, 4) a satisfactory intervention among participants, and 5) more APP involvement in scientific and feasibility review of protocols.

This project has the potential to be replicated at other sites if there is an APP mentor available and a supportive infrastructure in place. Increasing the role APPs play in clinical research provides opportunities to expand clinical activities at rural and underserved sites where the APP may be the primary oncology provider. While it is unknown whether a project such as this could be replicated with the same impact on minority accrual, it can certainly be utilized as an approach to build capacity at practice sites and potential to further reduce health disparities. Despite advances in NCI policy, educational opportunities, and APP participation over the past 3 years (Braun-Inglis et al., 2024), significant potential remains for APPs to make even greater contributions in this space.

FUTURE DIRECTIONS

The pilot data from this project were used to develop a national study (Wake Forest 2403-Building Capacity) within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP) that recently opened throughout the NCORP (NCT06904391). The study opened on April 21, 2025.

Three APPs who participated as mentees in this pilot project are now serving as mentors for the NCORP study, which is measuring APP research self-efficacy, team effectiveness, overall practice accruals, and capacity. As treatments continue to improve and diversify, with patients living longer, supportive care and CCDR research is becoming more important. Advanced practice providers are uniquely positioned to make a significant impact in this type of cancer research, as much of their clinical focus is on supportive care (Hylton & Smith, 2017; Bruinooge et al., 2018; Coombs et al., 2020). Oncology is a team science (Pickard et al., 2023). Empowering APPs to excel in certain aspects of cancer research elevates the whole team and improves care for our patients.

Disclosure

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