Adolescent Preexposure Prophylaxis Administration: An Education Curriculum for Health Care Providers

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ABSTRACT

On May 15, 2018, the Federal Drug Administration amended the approval of preexposure prophylaxis (PrEP) to include minors (> 35 kgs). Adolescent providers are now in need of access to a comprehensive education curriculum on the administration of PrEP to adolescents. This paper outlines such a curriculum with the goal of reaching adolescent providers unfamiliar with PrEP assessment, administration, and monitoring. A comprehensive adolescent PrEP curriculum was designed using a literature review. An expert panel of seven reviewed the curriculum for content validity. A pilot implementation of the curriculum was conducted with staff from eight school-based health clinics located in Upper Manhattan and the Bronx. A formal content-validated curriculum was established providing adolescent health care providers with the tools needed to administer PrEP in their clinical setting. Clinical providers can access our curriculum to aid in their administration of PrEP to an adolescent population. J Pediatr Health Care. (2019) *33*, 288–295

KEY WORDS

Adolescent, HIV, pre-exposure prophylaxis (PrEP), curriculum, provider

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INTRODUCTION

On May 15, 2018, the U.S. Food and Drug Administration (FDA) approved once-daily tenofovir/emtricitabine (TDF/FTC) for use as preexposure prophylaxis (PrEP) for adolescents (weighing > 35 kg) engaging in high-risk sexual behavior (Gilead Science, 2018). This decision was largely based on the Adolescent Medicine Trials Network for HIV/AIDS Interventions 113, which showed that PrEP was well tolerated among the adolescents ages 15 to 17 years enrolled in the study (Hosek et al., 2017). The use of TDF/FTC for PrEP in adults (18 years and older) was approved by the FDA in 2012 after its safety and efficacy had been shown in multiple international clinical trials (FDA, 2012). Iniciativa Profilaxis Pre-Exposición (iPrEx), Partners PrEP, and Preexposure Option for Reducing HIV in the UK: Immediate or Deferred (PROUD) showed that if taken daily, PrEP is at least 92% effective in preventing HIV transmission among men and transgender women who have sex with men and sero-discordant couples (Baeten et al., 2012; Grant et al., 2010; McCormack et al., 2016).

Since 2012, there has been mounting pressure from the adolescent health community to make PrEP accessible to individuals younger than 18 years (Burda, 2015). The Centers for Disease Control and Prevention (CDC) reported that in 2016, youth ages 13 to 24 years accounted for 21% of all new HIV diagnoses in the United States (Hess et al., 2017). In New York City in 2016, there were 882 new HIV diagnoses among individuals 13 to 29 years of age, out of a total of 2,279 new infections (39%). Seventy-nine of those new diagnoses were among individuals aged 13 to 19 years. Because the majority of HIV infections occur among individuals between the ages of 20 and 29 years, health care providers need to consider educating patients about HIV prevention and provide biomedical interventions before a patient's 20th birthday (The New York City Department of Health and Mental Hygiene, HIV Epidemiology and Field Services Program, 2017; Ocfemia, Dunville, Zhang, Barrios, & Oster, 2018). Additionally, adolescents, especially minors, take many sexual risks in pursuit of autonomy and self-exploration with concurrent poorly developed impulse control (Steinberg, 2009). It is clear that adolescents are, at least, as much in need of PrEP as individuals of other age groups.

Adolescent Provider PrEP Knowledge and Attitudes

In a recent sample of 162 surveyed adolescent providers, 93.2% of the providers had heard of PrEP; however, only 35.2% of these providers indicated that they had previously ever prescribed PrEP. Sixty-five percent of providers surveyed stated that they were "willing to prescribe PrEP to adolescents ages 13–17," and this indicator was associated with the provider having enough knowledge to safely provide PrEP to adolescents (Hart-Cooper, Allen, Irwin, & Scott, 2018, p. 243). Mullins et al. (2017) conducted a mixed-methods study that included 56 clinicians within the Adolescent Medicine Trials Network who provided care to HIV-positive adolescents and investigated their attitudes toward providing PrEP to at-risk, HIV-uninfected adolescents. The primary outcomes of the study included (a) intention to provide PrEP to at-risk adults older than 18 years of age and at-risk adolescents younger than 18 years of age and (b) actual prescriptions to adults and adolescents in at-risk groups. Significantly more clinicians had prescribed PrEP to adult men who have sex with men (MSM) than to adolescent MSM. The authors found that clinicians identified two significant barriers to prescribing PrEP to adolescents: the perceived need for a multidisciplinary team and inclusion of behavioral interventions in the visit. These results suggested that even providers who were knowledgeable about PrEP needed a "brief, streamlined and effective behavioral intervention that can be delivered with PrEP" (Mullins et al., 2017, p. 514).

Similar findings were presented in a study of examining perceived barriers and facilitators to prescribing PrEP among Boston HIV care providers caring for adults. Although the majority of providers understood PrEP to be efficacious, they expressed desire for readily accessible, simple guidance regarding the provision of PrEP that would not require significant time and effort (Krakower, Ware, Mitty, Maloney, & Mayer, 2014).

In 2017, a web-based survey among pediatric ($n = 35$) and internal medicine providers at a large urban medical center in Upper Manhattan revealed that although pediatric providers reported taking a sexual history on majority (68.5%) of their patients above the age of 13, only 14% of these providers felt comfortable assessing these patients' eligibility for PrEP. A consistent barrier to providing PrEP across all groups of providers was lack of formal training (Zucker et al., 2018).

The FDA approval of an adolescent indication for PrEP removed an important barrier to providing PrEP to adolescents nationwide. With this development, the priority now shifts to considering implementation challenges, opportunities, and determinants of success. This calls for setting educational standards for providers, establishing PrEP guidelines specific to adolescents, offering support for providers prescribing PrEP to adolescents or information regarding referrals should adolescent providers need to outsource the provision of PrEP for their patients.

To respond to these challenges, we undertook the development of an evidence-based curriculum for the purpose of training health care practitioners in how to provide HIV prevention interventions, including PrEP, to an adolescent population.

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METHODS

A comprehensive provider curriculum was developed focused on adolescent-specific issues related to PrEP screening and monitoring. A literature review was

FIGURE 1. The institution and titles of expert panel members

(This figure appears in color online at www.jpedhc.org.)

conducted to identify the learning needs of adolescent providers, identify key domains, and design the curriculum. The articles were retrieved from medical, public health, nursing, and adolescent health journals via PubMed and SCOPUS. The search terms used were *HIV Prevention*, *Pre-Exposure Prophylaxis*, *Healthcare Provider*, *Implementation*, *Adolescent Health*, and *Primary Care*. Medical/nursing education and adult learning guides were used in the development of the curriculum (Benner, Sutphen, Leonard, & Day, 2010; Diamond, 1998; Joyce & Showers, 2002).

The Adolescent HIV Prevention Curriculum was piloted on September 21, 2017, during a 1-day training session. The purpose of this pilot was to construct the flow of the curriculum and obtain feedback about the content.

An expert panel made up of nursing and medical professionals and public health officials was contacted to review the curriculum to determine content validity (Figure 1).

The seven experts are leaders in the fields of HIV prevention, adolescent health, and medical/nursing education. They were asked to review the content of the curriculum and evaluate for importance, clarity, and relevance. To determine scale-level content validity, a three-point scale was constructed (i.e., 1 = *not relevant*, 2 = *somewhat relevant*, 3 = *very relevant*). A ratings guide was developed through Qualtrics (Provo, UT), and the experts were asked to log their responses electronically. An expert selecting *somewhat relevant* or *somewhat clear* for a reviewed section was categorized as an affirmative. All sections that received a 78% affirmative response were deemed valid (Polit, Beck, & Owen, 2007).

RESULTS

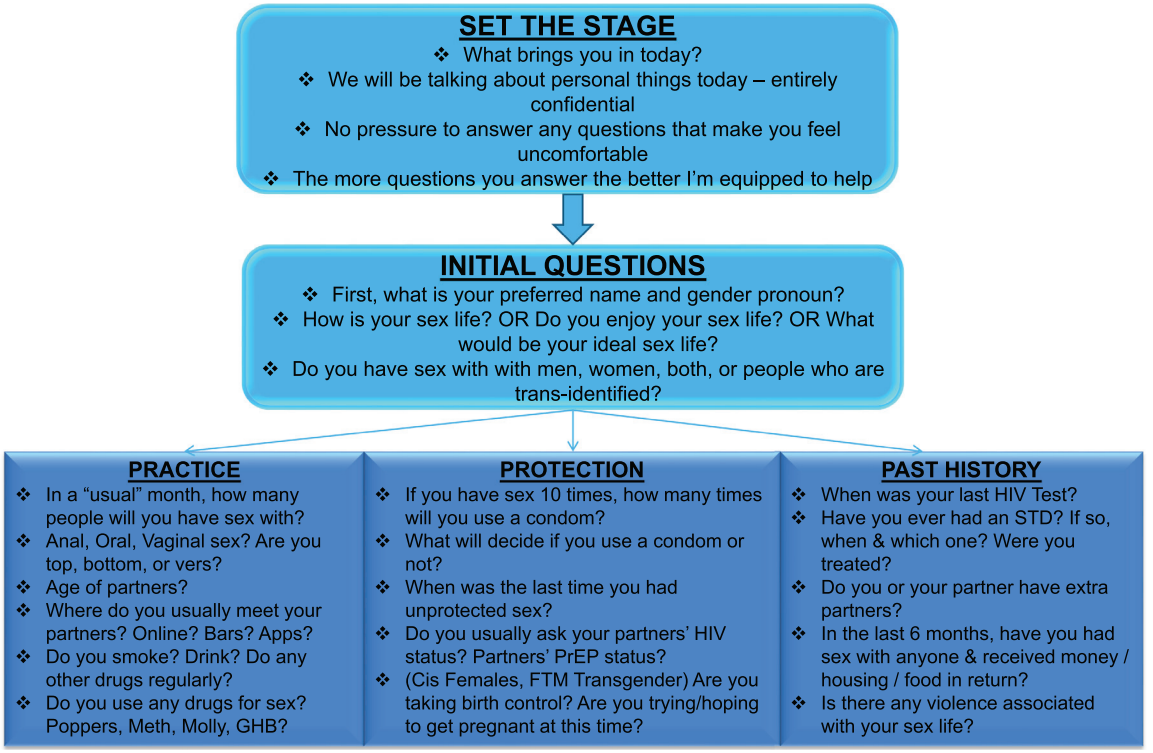
Curriculum Content

Eight domains were identified as essential for inclusion in the curriculum: What is PrEP/PEP?, Overview of PrEP Efficacy—Clinical Trials, PrEP Eligibility, PrEP Eligibility, Sexual History Taking in the PrEP Era, Can Adolescents Access PrEP?, How to conduct an Adolescent PrEP Medical Visitm and Benefits and Insurance Navigation.

The curriculum starts with a comprehensive overview of the PrEP efficacy clinical trials and reviews of some the real-world demonstration projects indicating PrEP's effectiveness. It is recommended that clinicians receive an overview of the published PrEP clinical trials and demonstration projects, which will provide the context to questions that may arise with patients or their caretakers. Having ready access to comprehensive yet concise data supporting the safety, efficacy, and tolerability of PrEP both in research and real-world settings is important for any clinician prescribing PrEP.

Additionally, this curriculum includes an in-depth look at how to assess if a patient is a candidate for HIV prevention biomedical interventions. In the United States, HIV risk varies based on location and age; the curriculum encourages providers to develop a thoughtful and individualized approach in their practice that incorporates the CDC and local department of health guidelines but, importantly, also includes careful behavioral screening of the patients they serve and examination of local HIV and sexually transmitted infection incidence rates. Instructions on how to assess for prospective risk, especially when working with adolescents, is included. The adolescent in front of a clinician may answer *no* to every question about historic risk behaviors but over the next year may begin to explore his/her sexuality through engaging in risky sex.

FIGURE 2. Sexual history algorithm. FTM, female to male; PrEP, preexposure prophylaxis; STD, sexually transmitted disease.



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The final curriculum includes tips on how to conduct an adolescent PrEP focused sexual history by expanding on the CDC's 5Ps (CDC, 2005; Figure 2). The algorithm guides providers through questions that could be important in establishing a patient's risk profile. When initiating a PrEP-focused sexual history, we recommend starting with *What is your ideal sex life?* This helps show adolescent patients that they can feel free to discuss with the provider what they imagine their sex life to be like once they start PrEP. It not only gives the provider insight into what patients' desires are but also sets a positive and optimistic tone for the visit. Conducting the sexual history in a sex-positive manner increases patient comfort and will ultimately lead to better retention.

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We also recommend including a brief self-administered sexual history as part of the adolescent clinic visit. This is designed not to replace a comprehensive sexual history but as an opportunity for adolescents to show behaviors that they may not feel comfortable showing to a provider or coordinator.

A key component of the curriculum was a development of a detailed checklist of evaluations conducted at each visit and visit schedule (Figure 3). The aim is to provide guidance on how to conduct a PrEP visit within the time constraints of the clinic setting. Our graphic, adapted from the New York City Department of Health AIDS Institute guidelines (New York State AIDS Institute, 2017) provides a quick overview of the visit components separated by areas or tasks (laboratory tests, psychosocial evaluation, next steps) to encourage task sharing between providers and PrEP navigator/coordinator or social worker to create efficiencies and save time. Because of the increasing incidence of sexually transmitted infections (STIs), especially in New York City (CDC, 2017; The New York City Department of Health and Mental Hygiene, 2017), we recommend testing for STIs at every PrEP visit, including the 1-month follow-up. Not only does this offer an opportunity to test a cure if there is an STI diagnosis at the first visit, but it can have the beneficial effect of normalizing three-site STI testing for patients. We also recommend self-collection Gonorrhea/Chlamydia testing when possible (Taylor et al., 2013).

Curriculum Pilot

The curriculum was tested during a 2-day training of 54 staff members from eight high school–based health clinics. Staff members consisted of 14 health care providers, social workers, registered nurses, medical assistants, health educators, and the clinics' front desk staff. In a post-training

FIGURE 3. Adolescent preexposure prophylaxis visit schedule. Hep, hepatitis; Labs, laboratory tests; PrEP, preexposure prophylaxis; STD, sexually transmitted disease.

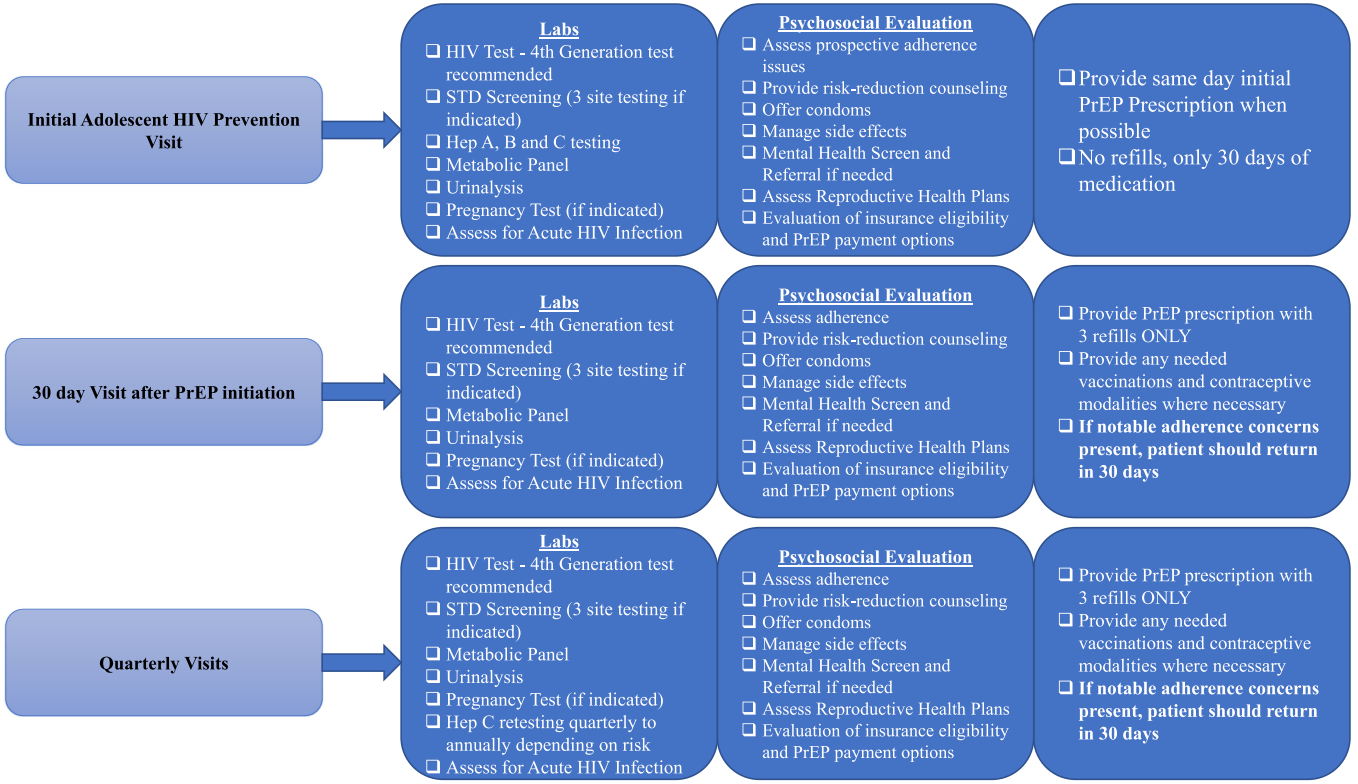

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TABLE. Adolescent PrEP curriculum expert panel evaluation with item-level content validity

Curriculum sections	Inclusion, %	Clarity				Relevance			
		Not clear at all, %	Somewhat clear, %	Very clear, %	Item CVI	Not relevant at all, %	Somewhat relevant, %	Very relevant, %	Item CVI
What is PrEP/PEP?	100	—	16.67	83.33	1.00	—	—	100.00	1.00
Overview of PrEP Efficacy—Clinical Trials	100	16.67	50.00	33.33	0.86	—	—	100.00	1.00
Who should be on PrEP?	100	—	—	100.00	1.00	—	—	100.00	1.00
Who should take PEP?	100	—	—	100.00	1.00	—	16.67	83.33	1.00
Sexual history and PrEP	100	—	16.67	83.33	1.00	—	—	100.00	1.00
Can adolescents access PrEP?	100	—	33.33	66.67	1.00	—	—	100.00	1.00
How to conduct an adolescent PrEP medical visit	100	—	33.33	66.67	1.00	—	—	100.00	1.00
Benefits/insurance navigation	100	—	33.33	66.67	1.00	—	—	100.00	1.00
Mean (item-level) content validity index	1.000			0.983				1.000	

Note. CVI, content validity index; PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis.

assessment, the majority of providers found the content helpful but wished the curriculum included more training on how to conduct a PrEP-focused sexual history. The providers stated that, although they had been working in the field of adolescent health for some time, their sexual histories typically focused more on family planning concerns, and they stated that very rarely did they have young MSM seeking services in their school-based clinics. Based on this feedback, a PrEP-focused sexual history was added to the final curriculum before expert panel review.

Expert Panel Review

There was 100% agreement among all seven experts in the relevance and importance of each of these sections of the curriculum. One expert indicated that the section entitled "Overview of PrEP Efficacy" was unclear, but the overall affirmative response rate for this section was greater than 78%, indicating its validity (see Table).

The experts unanimously agreed that the content was appropriate for a professionally diverse audience.

DISCUSSION

A comprehensive curriculum on the provision of HIV prevention modalities to adolescents has been successfully developed, piloted, and validated by a panel of experts. Although the provision of PrEP can be as simple as writing a prescription, more is needed to engage and assess an adolescent and administer a multicomponent HIV prevention intervention. This curriculum contains content-validated components that should be included when training clinicians in how to administer PrEP to adolescents. It has been shown that certain misconceptions regarding PrEP efficacy, for example, have led providers away from prescribing PrEP to their patients (Silapaswan, Krakower, & Mayer, 2017). While recognizing this, our curriculum seeks to shape providers' attitudes regarding integrating PrEP into their adolescent health practices by initially describing the efficacy trials. We then give providers the concrete skills needed to implement a PrEP assessment, PrEP initiation, and the PrEP follow-up.

Adherence to PrEP is critical to its efficacy, and it undoubtedly will be what adolescents struggle with the most (Grant et al., 2014; Hosek et al., 2016). Health care providers planning to provide PrEP to adolescents must incorporate adherence assessments into their routine care. These assessments do not necessarily have to be completed by a health care provider but must be included in routine visits

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to ensure quality care. We recommend that if adherence concerns arise, the adolescent patient should return to the clinic monthly for evaluation and receive only 30 days of medication at a time to ensure there has been no HIV seroconversion. The development and implementation of methods to track and support adherence using technology-based tools that appeal to adolescents are under way in a variety of settings (Fuchs et al., 2018; Hightow-Weidman, Muessig, Bauermeister, LeGrand, & Fiellin, 2017; Koss et al., 2017).

Toxicities related to PrEP such as renal function decline and bone mineral density (BMD) loss are rare although particularly worrisome in an adolescent population. Providers need to understand the nature of these toxicities when prescribing PrEP; therefore, inclusion of these topics in the training is crucial (Hosek et al., 2017). In our curriculum, we educate providers on the clinical trials examining bone mineral density loss and renal function decline with the understanding that more research is needed in a younger population.

Finally, as previously mentioned, one of the clinicians' concerns with providing PrEP to adolescents is navigating how the adolescent can ultimately receive the medication (Mullins et al., 2017). Insurance coverage and the concern of parental involvement is a prohibitory barrier for adolescents receiving PrEP. It becomes very important for clinicians to understand how their adolescent patients can receive PrEP beyond simply writing the prescription. Education and training about the resources available to cover provision of PrEP to adolescents is critically important to retention. Our curriculum provides health care providers with strategies in navigating payment for PrEP in an adolescent community, although this may vary at the state and local levels.

Consensus from the expert panel supports the dissemination of this adolescent PrEP curriculum. It is recommended that when training clinicians on the provision of PrEP to adolescents, all eight domains presented in this curriculum be included.

A limitation of this study is a smaller-sized expert panel of seven experts. Further quantitative evaluation of the curriculum's effectiveness is needed through implementation and pre- and posttesting. These efforts are underway. Additionally, content needs to be developed on how best to engage the parents of adolescents in the administration of PrEP. Another limitation of our curriculum is the lack of supporting data associated with same-day PrEP starts, which we recommend in the visit schedule. New York City Department of Health and other health departments have recommended starting PrEP at the initial visit as a way of avoiding potential barriers that may arise in the follow-up to a prescription (Kamis et al., 2018; New York State Department of Health AIDS Institute, 2014). There have been arguments that starting PrEP on the same day as the first visit without having access to an HIV-negative confirmatory test result can overlook a potential acute HIV infection and therefore lead to the chance of a resistant HIV virus. Experts have estimated that resistance to TDF/FTC while receiving PrEP can develop within 15 to 540 days and, in the presence of an acute HIV infection, would occur in only approximately 25% of the infections (Dimitrov et al., 2016; Lehman et al., 2015). We contend that same-day PrEP starts are effective in ensuring that patients initiate PrEP, and we also conduct a repeat HIV test at the 1-month visit as a fail-safe to catch any possible acute HIV infections. More research regarding retention outcomes is necessary on this topic.

CONCLUSION

We have learned a great deal in the first 6 years of PrEP implementation in the United States, and this can be applied to the roll-out of PrEP for adolescents. However, adolescents have a unique set of needs when it comes to a biomedical intervention for HIV prevention. The health care community, for the first time, has an intervention that can prevent the transmission of HIV among at-risk individuals if taken correctly. Given the high rates of HIV in the younger age groups, we have a considerable responsibility to determine how to efficiently and safely provide this intervention to youth. PrEP implementation in a younger population requires a new set of youth-focused guidelines, teaching points, and educational methodologies. The validated curriculum developed through the stakeholder-driven process may be an important contribution. Preventing HIV transmission in adolescents is a national and international priority and is undoubtedly an essential step necessary to end the HIV epidemic.

To access our validated curriculum, please use the following link: prevention.nyc/learn/adolescent-prep/.

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