

01/10/2021

TO: AHCCCS Pharmacy and Therapeutics Committee
RE: In Support of an Open Access Formulary for HIV Therapy

My name is Janice Piatt MD. I am a pediatrician/HIV specialist and medical director of the Bill Holt Pediatric Infectious Disease Clinic at Phoenix Children's Hospital. I have been caring for infants, children and adolescents exposed to or infected with HIV for over 25 years. Over those years I have been able to observe the incredible advances in therapy which have led to improved virologic control, longer lifespan and diminished side effects. Recent advances in HIV medication management have led to significant reduction in resistance to antiviral therapy and rapid virologic control can generally be achieved in compliant patients. This not only improves the health of individuals, but also leads to decreased viral spread into the community. We are now working to reduce the impact and even potentially eradicate the HIV epidemic with the use of these newer and more potent medications for Rapid Start treatment in conjunction with PrEP and more widespread routine screening. This can be achieved most successfully with increased availability of medicines that are most effective and well tolerated. Patients naturally find it less frightening and daunting when presented with a more simplified medication regimen such as single tablet regimen (STR). Such regimens result in higher confidence in the treatment offered, thereby improving adherence and reducing rejection of such treatments. Adherence is key to this success as in the treatment of any other chronic illness, with the caveat that this disease can also be transmitted to others when not adequately controlled. The costs of poor adherence are high, with poor virologic control leading to sicker patients, increased potential for spread into the community and the risk of developing medication resistance requiring expensive specialized testing, the use of more complicated medication regimens, increased hospitalizations, and potentially new diagnoses; all with potentially higher costs.

The benefit of STRs is significant in promoting adherence, as has been documented in the medical literature. The use of these medications has been recommended as the standard in clinical guidelines for these reasons. Adherence can be particularly challenging for adolescents and young adults who have been shown to have lower rates of virologic control and also may have increased viral transmission into the community. I have personally seen improved adherence rates in adolescents able to switch to a single tablet regimen even when this only involves decreasing from two tablets once daily to a single tablet once daily.

Limiting options also means that patients who may react to one medication will not have the option to switch to a medication that may be more tolerable. For example, there are significant rates of insomnia and other neuropsychiatric effects with Dolutegravir and some patients may have GI side effects with

one integrase inhibitor, but not with another. It is important to ensure that options are available to find the best fit for patients who face chronic lifelong adherence to these regimens. Continuing on a regimen that is causing side effects is challenging and may lead to patients giving up and falling out of care altogether. I have even seen improved adherence in patients able to switch from a larger single tablet once daily to a smaller tablet once daily. The easier and less confusing therapies lead to better compliance, improved health and lower costs in the long run with decreased infections and lower potential for developing cancers or other complications. Additionally with U=U, improved compliance leads to decreased spread of the virus and fewer new patients.

The challenge of adherence affects individuals of all ages but as mentioned, it is most significant for adolescents and adults. There are different challenges for parents of younger infants and toddlers due to the need for liquid medications which are less available and have significant taste challenges. They also require more than once daily dosing due to their unique pharmacokinetics. The possibility of future STR options for younger children would be a wonderful advance for them. Currently children weighing less than 25 kg must take an average of 5-7 pills twice daily.

As each new drug option becomes available, it has opened possibilities for successful treatment for those who have exhausted all available options as well as offering improved outcomes for others. As HIV requires successful control for lifetime, it remains essential to minimize side effects over the long term.

Finally, many of our patients do not speak English as their primary language or at all. Some are illiterate. This often leads to confusion when different medication bottles arrive and as doses change. Decreasing the complexity of the regimen absolutely assists them in being more successful.

The successes that have been achieved in the treatment of HIV have minimized hospitalizations, closed hospices and saved lives, resulting in more productive lives and decreased community spread. Taking a backward step by removing STR's towards MTR's will ultimately result in decreased adherence, more expensive testing, increasing numbers of infections ultimately reduce the quality of life for those infected while increasing costs for patients and the medical system. Certainly these adverse outcomes are not worth the decision to change or restrict medication treatment regimens given the vast improvements that recent HIV therapeutics have achieved.

Thank you very much for your attention.

Sincerely,

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