Global adolescent HIV clinical trials: co-produced adolescent-friendly research information to support real informed assent/consent in the Long-acting treatment in Adolescents (LATA) trial.

#72

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Background

LATA (NCT05154747) is the largest randomised trial of long-acting injectable antiretroviral therapy (ART) in virologically suppressed adolescents aged 12-19 years living with HIV-1. It has a dedicated work package on patient engagement and works with groups of adolescents living with HIV through 'Youth Trials Boards (YTB)' in South Africa, Uganda and Zimbabwe (and soon in Kenya).

Image: LATA logo designed by young people

Clinical trials and research must provide clear and understandable patient information when recruiting for studies. Where study participants are children or young people, there can be a discrepancies between what the Independent Review Boards (IRBs) legally require, what pharmaceutical companies legally require and what the patients need to be able to properly understand and make an informed decision about being part of a study.

Traditional Patient Information Sheets (PIS) can be long and detailed, a format young people across the YTB project have said they cannot understand or engage with.

In LATA, a new direction was followed. The traditional PIS was produced, but with accompanying support documents co-created by young people.

Image: Still from video

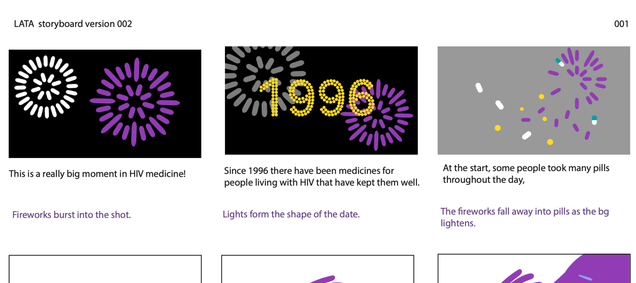
Materials & Methods

Youth Trials Board members in LATA attended a global digital meeting with representatives from South Africa, Uganda and Zimbabwe. They immersed themselves in the trial and explored what information they felt young people needed and how this should be presented.

The group were unanimous that young people prefer to get their information through videos. They also felt that, to make an informed decision about LATA, young people needed to know:

- Education on how long-acting medication has been developed and works.
- The efficacy of 2-monthly injection compared to daily pills in suppressing HIV.
- Information about possible additional side-effects.
- A clear explanation to understand where and how the injection would be administered.
- A short summary about the trial, as this is covered in detail in the PIS.

Image: Example of a story board and draft script sent to YTB groups and Trial Management Team.



Due to the content that would be included, they felt that the best way to explain this would be through animation.

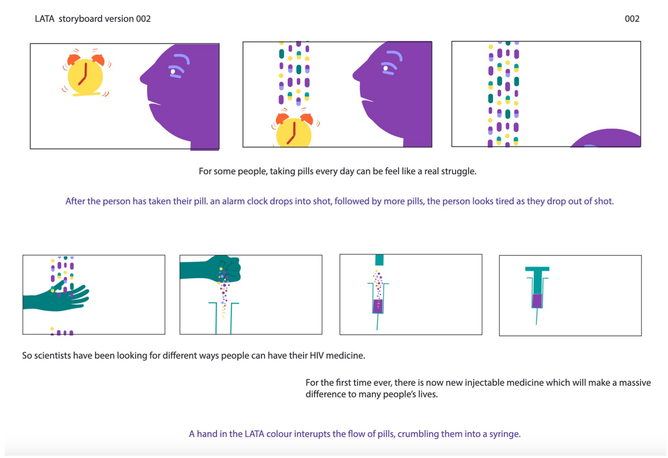
The methodology used was co-creation, with experts through experience (the young people) and experts through training (scientists and film-makers). This combination ensured the film was both scientifically and medically correct, but also clear and youth-friendly.

A community film making company – Bigger House – was commissioned due to their experience of co-created community-led film making.

The script was developed through the young people establishing the content areas, then the trial management team providing the medical and scientific information needed. Through a process of alternating script drafting, science-checks and youth-checks, over three months the final script was agreed.

The animation was also youth and science checked, to ensure it was both correct and clear and engaging. This was done initially through the use of story boards, aligning script with images.

Image: Example of a story board and draft script sent to YTB groups and Trial Management Team.

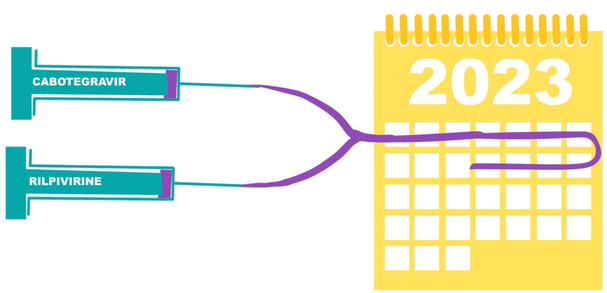


Once finalised, the scripted was translated into English, Shona, Isizulu, Swahili and Luganda.

Each trial site then sent the story board with final script to their IRB for an initial ethics check. This was to mitigate any possible ethics issues prior to building the final video.

YTB members were invited to record the voice overs in their first language to ensure they were authentic.

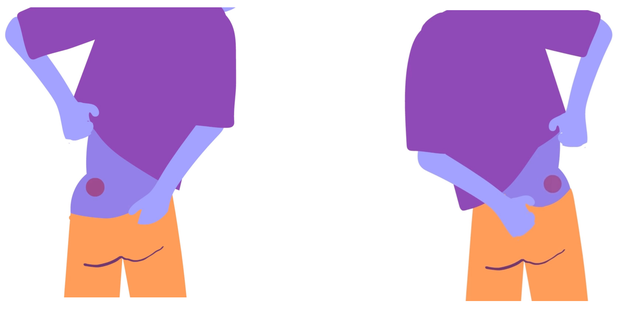
Image: Still from video



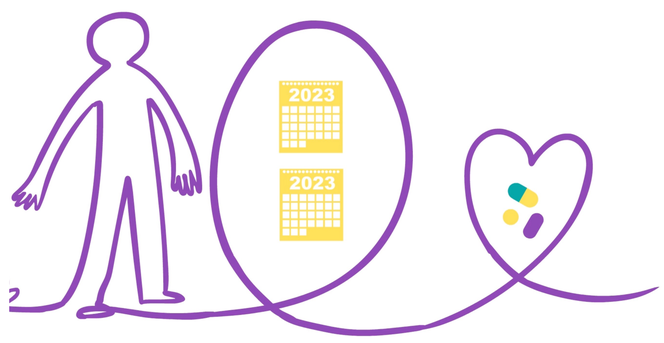
Results

A 4-5 minute video (depending on the language) was produced in five different languages. These are now part of the education and recruitment process for LATA. All sites using the videos are collating patient and study staff feedback to see how useful, helpful and impactful the video has been.

Image: Stills from video



mage: Still from video



Conclusion

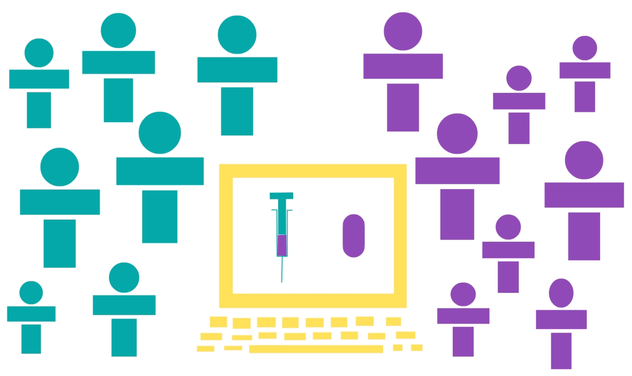
Although the process of co-production of the video is time consuming, we believe the end result is something young people can genuinely understand and engage with.

Some of the trial sites have felt that the video is such a good educational resource, that they are showing it in waiting rooms as it is an educational tool to support community understanding of this new form of medication.

Aspects of the video have been edited and will be used across Penta's youth social media platforms to educate the wider HIV community about long-acting injectable ART.

Through genuine youth engagement and co-production, LATA will be recruiting for a study in the knowledge that study participants truly understand what they are choosing to be a part of. While this video is additional to a PIS, in future, we hope by setting this standard that videos such as this could replace the lengthy complex language provided to trial participants, which we believe merits further discussion with IRBs and regulators.

Image: Still from video



References

To find out more about LATA please visit the MRC/CTU University College London website www.mrcctu.ucl.ac.uk/studies/all-studies/l/lata

To find out more about Youth Engagement and Patient Involvement at Penta

Penta has since produced Quality Standards for the ethical and meaningful participation of children and young people in clinical trials and research to support rolling-out of this practice. penta-id.org/patient-involvement-quality-standards/

THANK YOU

All the YTB members, past and present, in South Africa, Zimbabwe, Uganda and UK
Site coordinators and staff at: King Edward hospital, Durban; MUJ-HU, Baylor and JCRC in Kampala; UZCRC, Harare; CHIVA, UK; Psychologists from Republican Clinical Hospital of Infectious Diseases, St Petersburg, St. Petersburg AIDS Centre and Irkutsk AIDS Centre.
The Trial Teams for LATA, at Medical Research Council, Clinical Trials Unit at University College London.
The LATA Consortium: Penta Foundation, Italy; MRC CTU at UCL, Institute of Clinical Trials and Methodology, UCL, London, UK; Joint Clinical Research Centre, Kampala, Uganda; University of Zimbabwe Clinical Research Centre, Harare, Zimbabwe; Moi University, Eldoret, Kenya; Department of Paediatrics and Child Health, King Edward VIII Hospital, University of KwaZulu-Natal, Durban, South Africa; Baylor College of Medicine Children's Foundation-Uganda, Kampala, Uganda; Africa Health Research Institute, Durban, South Africa; Uganda Virus Research Institute, Entebbe, Uganda; London School of Hygiene and Tropical Medicine, London, UK; MU-JHU Care Ltd.
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To the film maker: Bigger House https://www.biggerhousefilm.co.uk/

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