Inyandiko y'amakuru agenewe ubazwa – "*Trial Participation" - Isuzuma rya nyuma*

Izina ry'umushinga: Isuzuma rya Gahunda ya PDC/Baby Ubuntu

Intangiriro

Turashaka kubatumira kugira ngo mugire uruhare mu isuzuma rya nyuma ry'ubushakashatsi mwinjiyemo hagati ya Werurwe na Nyakanga 2024. Ariko wabikora ku bushake bwawe. Turagusobanurira impamvu turimo gukora ubu bushakashatsi n'ibibukubiyemo mbere y'uko ufata umwanzuro.Ndagusomera iyi nyandiko ikubiyemo amakuru. Mu gihe hari icyo udasobanukiwe cyangwa ukeneyeho amakuru y'inyongera utubaze ibibazo. Ushobora kubwira abandi iby'ubu bushakashatsi niba ubishaka. Fata umwanya utekereze ku mwanzuro wawe niba ushaka kubugiramo uruhare cyangwa utabishaka.

Ubu bushakashatsi bugamije iki?

Intego y'ubu bushakashatsi ni ukudufasha gusobanukirwa neza ingaruka za gahunda yo kumenya, kwita no gufasha abana bafite ikibazo cyo kudindira mu mikurire n'ababyeyi/abarezi babo hakiri kare. Dushaka kandi kumenya uko gahunda ifasha mu bumenyi, ubuhanga n'imibereho myiza y'abarera abana n'uko ifasha abana gukura, gutera imbere no kugira uruhare mu buzima bw'umuryango.

Iyi gahunda igizwe na porogaramu yihariye ikurikirana abana bato (bari munsi y'imyaka 5) bafite ibyago bishobora gutera idindira mu mikurire n' ubumuga yitwa "Pediatric Development Clinic" cyangwa 'PDC'. Igizwe kandi na gahunda y'amatsinda y'ababyeyi afasha abana bafite ubumuga yitwa 'Baby Ubuntu'.

Kuki nasabwe kwitabira ubushakashatsi?

Watumiwe kugira uruhare muri ububushakashatsi kubera ko winjiye mu bushakashatsi hagati ya Werurwe-Nyakanga 2024, kubera ko uri umubyeyi/umurezi w'umwana wagaragaye ufite ingorane zishobora gutera idindira mu mikurire cyangwa ubumuga, kandi ko utuye mu gace gakoreramo ikigo nderabuzima kizagira uruhare muri ubu bushakashatsi. Hari impamvu nyinshi zishobora gutuma umwana agira idindira mu mikurire cyangwa ubumuga. Zimwe muri izo mpamvu ni nk'ingorane zibaho igihe cyo kuvuka; nko kumara igihe kirekire ku nda, cyangwa abana bavuka ibiro bikeya, cyangwa bakavuka mbere cyane y'igihe. Hari abana bamwe batagira ibibazo mu ivuka ariko ntibakure mu bwenge ku rwego rumwe n'abo bari mu kigero kimwe. Turagusaba kugira uruhare mu bushakashatsi kubera ko umwana wawe yagaragayeho kuba yaragize ingorane zongera ibyago byo kuba yagira ubumuga.

Mu gutangira k'ubu bushakashatsi, wasoje isuzuma ry'ibanze hamwe n'itsinda ryacu ry'ubushakashatsi. Hakoreshejwe uburyo bwa tombola, iki kigo nderabuzima cyatoranyijwe ko cyakakire gahunda ya PDC/Baby Ubuntu guhera mu 2024 cyangwa guhera mu 2025. Vuba aha tuzatangiza gahunda ku bigo nderabuzima bitarabona iyi gahunda. Mbere yibi, turashaka kurangiza isuzuma rya nyuma hamwe n'abitabiriye ubushakashatsi, bityo dushobora kumva niba hari impinduka zabaye mumwaka ushize.

Ese ntegetswe kwitabira ubushakashatsi ?

Oya. Ni wowe ugomba guhitamo kwitabira ubushakashatsi cyangwa kutabwitabira. Niba udashaka kubwitabira nta kibazo. Umuganga wawe azakomeza aguhe serivisi z'ubuvuzi kandi icyemezo cyawe ntikizagira ingaruka ku ireme ry'ubuvuzi wahabwaga. Niba utarabona iyi gahunda, kutitabira isuzuma rya nyuma ntibizakubuza guhabwa serivisi z'iyi gahunda nimara mu kigo nderabuzima. Tuzaganira ku bushakashatsi kandi tuguhe kopi y'iyi nyandiko y'amakuru. Niwemera kwitabira, nzagusaba mbere na mbere gushyira umukono/gutera igikumwe ku nyandiko yemeza ko wasobanuriwe ubushakashatsi kandi ko wemera kubwitabira.

Ninemera kwitabira ubushakashatsi bizangendekera bite?

Nuramuka wemeye gukomeza kwitabira ubushakashatsi, uzasoma kandi ushyire umukono ku cyemezo cyo kwemera ubwitabire. Ibi bigamije kugaragaza ko wemeye ko umwana wawe yitabira ubushakashatsi ku bushake. Nutanga ubushake bwanditse, umwana wawe azasuzumwa, n'imikurire ye isuzumwe. Isuzuma ry'imikurire y'umwana wawe rikubiyemo isuzuma ry'uko agenda, uko akoresha ibiganza bye n'uko akorana n'abandi n'uko

atanga amakuru. Ibi bikorwa cyane cyane mu gukinisha umwana wawe no kukubaza ibibazo ku byo ashobora gukora cyangwa adashobora. Iri suzuma rimara hafi igice cy'isaha.

Noneho tuzakubaza ibibazo kuri wowe bwite no ku mwana wawe. Ni ibibazo ku buzima n'imibereho myiza by'umwana wawe, kugera no kubona serivisi ndetse no nuko agira uruhare mu bikorwa bya buri munsi. Tuzakubaza kandi ibibazo ku buzima bwawe bwite, imibereho myiza yawe, n'imyifatire y'abandi kuri wowe. Nanone tuzakubaza kandi ku bumenyi ufite kubijyanya n'ubumuga, uko ugenzura ukanita ku myitwarire y'umwana wawe n'uko umuhana, ndetse no k'ubufasha butandukanye ubona. Ikiganiro kizamara hafi isaha imwe. Tuzakubaza kandi aderesi yawe na nimero ya telefone, kugira ngo tujye tukuvugisha ngo duhane gahunda zo kugusura mu minsi iri imbere. Tuzafata kandi ibipimo bya GPS by'aho mutuye kugira ngo tujye tubageraho bitatugoye.

Tuzongera guhitamo kandi muri bamwe mubitabiriye iri suzuma kugira ngo basurwe nanone mu byumweru bibiri. Ibi bizaba bigamije kongera gukora isuzuma rya kabiri ry'iterambere ry'umwana wawe. Kuri iri suzuma rya kabiri, tuzakoresha uburyo bunyuranye bukoreshwa mu gusuzuma iterambere ry'umwana wawe. Ibi bizongera kubamo gusuzuma uko bakoresha ingingo z'umubiri, gukoresha amaboko yabo no gusabana. Iri suzuma rizatwara iminota 30. Turimo gukora iri suzuma rya kabiri mu bitabiriye ubushakashatsi kuko dushaka kumenya ni ubuhe buryo bukoreshwa mu gusuzuma iterambere ry'umwana bufite akamaro kanini kugirango twumve iterambere ry'abana.

Ubushakashatsi buzakorwa mu gihe cy'imyaka 3. Wasoje isuzuma ry'ibanze kandi niba wemeye iri suzuma rya nyuma, tuzongera kuvugana nawe mumezi 12 kugeza tukubaze ibibazo bisa n'ibya mbere kuri wowe bwite no ku mwana wawe. Nyuma y'igihe ariko ububushakashatsi bugikomeza dushobora kukuvugisha kugira go tugusabe kwitabira ubushakashatsi bw'inyongera buzareba ibyabaye ku muryango bitewe no kwitabira iyi gahunda n'ibintu bishobora gutuma kwitabira byoroha cyangwa bigorana.

Nk'uko ari kimwe mu bigize ubushakashatsi, Gahunda ya PDC/Baby Ubuntu izashyirwa mu bigo nderabuzima 60 mu Rwanda, ariko ntizashyirirwa muri ibyo bigo byose igihe kimwe. Ibigo nderabuzima bimwe byakiriye gahunda mu 2024. Nyuma y'iri suzuma rya nyuma, tuzatangira icyiciro cya 2, kandi tuzatangiza gahunda mubindi bigo nderabuzima BYOSE. Gahunda nitangira mu kigo nderabuzima cyawe, uzabimenyeshwa, uhabwe n'ubutumire bwo kwitabira.

Nyuma yo kurangiza ubu bushakashatsi, twifuza amahirwe yuko twazongera kuvugana nawe mugihe kizaza kugirango ugire uruhare mu bundibushakashatsi n'izindi gahunda. Ushobora guhamagarwa n'ishuri rikuru ry'ubuzima rya kaminuza ya londoni ("LSHTM") cyangwa umuryango Inshuti Mu Buzima ("Partners In Health"), nubwo aba badashobora byanze bikunze kuba aribo bantu bamwe bomeza ubu bushakashatsi. Tuzagusaba gutanga uruhushya kuri ibi. Niba udashaka gutanga uruhushya, ubwo rero ntabwo bizahindura uruhare rwawe muri iri suzuma ryanyuma, ubutumire bwawe muri gahunda ya PDC/Baby Ubuntu, cyangwa izindi gahunda z'ubuzima.

Muri porogaramu ya PDC/Baby Ubuntu haba iki?

Nk'umwe mu bagize Gahunda ya PDC/Baby Ubuntu, uzasabwa kwitabira ibikorwa ku kigo nderabuzima cyawe ku buryo buhoraho. Igihe uzaba witabiriye, abakozi bashinzwe kwita ku buzima b'ivuriro bazasuzuma ubuzima bw'umwana wawe, imikurire ye, imirire ye n'imikurire ye mu bwenge. Bazaguha inama n'ubufasha byihariye bitewe n'ibyo umwana wawe akeneye. Niba umwana wawe afite ubumuga, uzasabwa no kujya mu itsinda rya 'Baby Ubuntu'. Amatsinda ya Baby Ubuntu ahura ku buryo buhoraho mu gihe kirekire ngo yigishe ababyeyi/abarezi ubumenyi bwo kwita ku bana babo no gusangira ibitekerezo. Amahuriro y'aya matsinda ayoborwa n'umukozi ushinzwe kwita ku buzima n'umubyeyi wahuguwe nawe urera umwana ufite ubumuga. Gahunda y'amatsinda ya Baby Ubuntu igizwe n'amasomo 11, bakaba bahura buri byumweru 2 cyangwa3. Ayo masomo yigisha: gusobanukirwa ubumuga, gufata umwana no kumuterura, kurya no kunywa, kwiga kugenda, gushyikirana, gukina, ibikorwa bya buri munsi n' ibyo duhura na byo aho dutuye. Buri somo rimara hagati y'amasaha 2 na 3.

Niwitabira Gahunda ya PDC/Baby Ubuntu, tuzagusaba kutubwira agaciro k'ibyo ukoresha mu kwita ku mwana wawe no kwitabira amasomo. Ibi tubikora kugira ngo bidufashe kumenya ikiguzi imiryango isabwa mu kwitabira iyi gahunda. Mu byo tuzakubabaza hazaba harimo ibyo winjiza, ibyo utanga mu kugura ibikoresho byo gufasha umwana wawe n'igiciro cya tike ukoresha iyo witabiriye amasomo y'iyi gahunda.

Ni izihe ngaruka mbi cyangwa ibihombo bishobora kubamo?
Igihe urimo gusubiza ibibazo, birashoboka ko kuvuga ibyakubayeho bishobora gutuma ugira agahinda. Icyemezo cyawe cyo kwitabira ubushakashatsi cyangwa ibyo uzatubwira nta ngaruka bizagira ku buvuzi usanzwe uhabwa. Abantu bamwe bashobora guterwa ipfunwe no kwitabira gahunda y'abana bashobora guhura n'ingorane. Gahunda ya PDC / Baby Ubuntu ikubiyemo amasomo yerekeye gupfobya, ivangura no guhezwa mu gutera inkunga abarezi n'imiryango yabo. Abakozi bacu bose biga batojwe gushyigikira imiryango ifite imyumvire mibi mubaturage kubera ubumuga bwabana. Urahawe ikaze kuvugana nabagize itsinda ryubushakashatsi niba wumva ko ukeneye izindi nkunga. Igihe icyo ari cyo cyose wakumva utagishaka kwitabira iyi gahunda cyangwa ubushakashatsi, wabihagarika kandi nta ngaruka byagira ku buvuzi uhabwa n'ikigo nderabuzima.

Ni izihe nyungu zishobora kubamo?
Ntitwakwizeza ko ubushakashatsi buzagufasha, ariko amakuru tuzabukuramo azadufasha gusobanukirwa byimbitse uko dushobora gufasha abana bafite cyangwa bashobora kugira ubumuga. Twizeye ko ibi ari inyungu kuri wowe no ku mwana wawe kubera ko buri mwana izajya akorerwa isuzuma ry'imikurire ye hanyuma ugahabwa inama n'ubufasha ku kwita ku mwana wawe.
Kugirango twishyure umwanya wawe watanze mu kwitabira ubu ubushakashatsi, tuzaguha 4000 RWF nyuma yo kwitabira buri bushakashatsi.

Ni nde nabaza amakuru y'inyongera?
Igihe ugize ikibazo gifitanye isano n'ubu bushakashatsi, wabigeza ku bashakashatsi na bo bagakora ibishoboka byose bakaguha ibisubizo "ushobora guhamagara kuri nimero ya telefone: 0788447693, cg ugakoresha imeli: ebaganizi@pih.org. igomba gushyirwaho". Igihe utanyuzwe ukaba ushaka gutanga ikirego mu nzira yemewe, wabigeza ku biro bya "The Research Governance and Integrity Office" ukoresheje imeli: rgio@lshtm.ac.uk cyangwa ugahamagara iyi nimero ya telefoni: +44 (0) 20 7927 2626 cyangwa The Rwanda National Ethics Committee (RNEC) Research Governance and Integrity ukoresheje iyi imeli: info@rnecrwanda.orgrgio@lshtm.ac.uk cyangwa ugahamagara iyi nimero: +250 788 592 004+44 (0) 20 7927 2626..

"The London School of Hygiene and Tropical Medicine" itanga ubwishingizi bukoreshwa kuri ubu bushakashatsi. Igihe waba ugize uburwayi cyangwa igikomere bitewe n'ubu bushakashatsi, ufite uburenganzira bwo gusaba indishyi.

Nshobora kwisubiraho muri ubu bushakashatsi?
Yego. Ushobora kuva mu bushakashatsi igihe icyo ari cyo cyose. Icyo usabwa ni ukutubwira ko wumva utagishaka kwitabira ubushakashatsi. Igihe uretse kwitabira ku bushake, nta ngaruka bizagira ku buvuzi no kwitabwaho umwana wawe yahabwaga. Nuhagarika kwitabira ubushakashatsi, tuzasiba amakuru yose yatuma umenyekana , ariko tuzabika amakuru twakusanyije kuri wowe kugeza igihe uhagarikiye ubwitabire, kereka udusabye kuyasiba.

Amakuru nzatanga azakoreshwa ate?
Amakuru yawe azagirwa ibanga. Ni ukuvuga ko tuzakuramo umwirondoro wawe: amazina yawe, nimero ya telefoni na aderesi kugira ngo hatazagira ukumenya barimo kureba amakuru watanze. Abari mu gikorwa cy'ubushakashatsi n'abayobozi bagenzura ko ubushakashatsi burimo gukorwa neza ni bo bonyine bashobora kureba umwirondoro wawe ; nk'amazina na nimero ya telefone. Umwirondoro wawe uzashyirwa ahantu hizewe nko mu kabati gafunze n'urufunguzo cyangwa mudasobwa ifunguzwa umubare w'ibanga, hatandukanye n'aho andi makuru yakusanyijwe mu bushakashatsi (urugero : Amajwi, inyandiko) azashyirwa. Umwirondoro wawe uzasibwa nyumay'imyaka ibiri

(2) ubushakashatsi burangiye. Kopi y'amakuru yawe atariho umwirondoro izoherererezwa ikipe ishinzwe ubushakashatsi kuri LSHTM mu Bwongereza.

Umushinga nurangira, amakuru yakusanyijwe mu bushakashatsi azashyirwa ahantu hizewe hanyuma dushyire amakuru atagaragaza umwirondoro ku rubuga rushobora kugerwaho na buri wese. Amakuru atagaragaza umwirondoro bivuga ko amakuru yose ashobora kugaragaza uwo uri we azaba yakuwemo. Ububiko bw'amakuru ni urubuga nkoranyambaga abandi bashakashatsi batari mu ikipe ikora ubu bushakashatsi bashobora kureberamo amakuru yavuye mu bushakashatsi bunyuranye kugira ngo babe bakwemeza ibyo twagezeho. Bashobora kandi gukoresha amakuru yacu mu gukora ubundi bushakashatsi. Dushobora kandi guha amakuru abandi bashakashatsi cyangwa abafatanyabikorwa bacu bakora kuri iyi nsanganyamatsiko hashingiwe ku 'masezeano yo guhana amakuru'. Ariko twongere tubisubiremo, ntidushobora gutanga amakuru yatuma umenyekana. Amakuru azakurwamo umwirondoro wawe.

Ni he handi warebera uko amakuru yawe akoreshwa?

Ushobora kureba uko dukoresha amakuru yawe:

- *Ku rubuga https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf*
- *Kubaza umwe mubagize ikipe y'ubushakashatsi*
- *Kohereza ubutumwa kuri DPO@lshtm.ac.uk*

Ibizava mu bushakashatsi bizakoreshwa iki?

Ibizava mu bushakashatsi bizatangazwa mu kanyamakuru no muri raporo kugira ngo abashyiraho ingamba n'abazishyira mu bikorwa babyigireho. Tuzasangiza kandi ku buryo butaziguye ubumenyi twakuyemo n'abashyiraho ingamba n'abazishyira mu bikorwa. Umwirondoro wawe ntuzashyirwa mu bikoreshwa mu bushakashatsi kugira ngo utazamenyekana.

Ni nde wasuzumye ubu bushakashatsi?

Ubushakashatsi bwose burimo ikiremwa muntu busuzumwa n'itsinda ry'abantu ryigenga ryitwa Research Ethics Committee (Komite Ngenzuramyitwarire mu Bushakashatsi), ngo irengere inyungu zawe. Ubu bushakashatsi bwasuzumwe maze buhabwa uburenganzira bwo gukomeza na The London School of Hygiene and Tropical Medicine Research Ethics Committee (28527) na *The Rwanda National Ethics Committee (RNEC213/2023).*

Andi makuru na aderesi wadushakiraho

Turagushimira kwigomwa igihe cyawe no gusoma aya makuru. Niba wumva ushobora kwitabira ubu bushakashatsi, turagusaba gusoma icyemezo cy'ubushake no kugishyiraho umukono. Igihe waba ukeneye andi makuru, wamenyesha Erick Baganizi cyangwa Francois Uwinkindi akaguha ibisubizo by'ibibazo byose waba ufite kuri ubu bushakashatsi.

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Ufite kandi ibibazo ku bijyanye n'uburenganzira bwawe nk'umuntu wakoreweho ubushakashatsi, wahamagara Umuyobozi mukuru w'ikigo gishinzwe kurengera abakorerwaho ubushakashatsi mu Rwanda (Rwanda National Ethical Committee), Dr. Vedaste Ndahindwa kuri telefone 0788454613 cyangwa Umunyamabanga w'icyo kigo witwa Dr. Marie Francoise Mukanyangezi kuri telefone 0788672656.

ICYEMEZO KO UMUNTU YEMEYE KWITABIRA KU BUSHAKE

Ubuhamya	**Andika inyuguti za mbere z'amazina yawe cg utere igikumwe* muri buri kazu**
Ndemeza ko nasomye, cyangwa nasomewe, ko nsobanukiwe Inyandiko y'amakuru aganewe Ubazwa mu mushinga: **Isuzuma rya Gahunda ya PDC/Baby Ubuntu**. Nabonye amahirwe yo kuzirikana ku makuru yose nahawe, kubaza ibibazo ku bushakashatsi no guhabwa ibisubizo biboneye.	
Nsobanukiwe ko ubwitabire bwanjye buturutse ku bushake kandi ko mfite uburenganzira bwo kwikura mu bushakashatsi igihe icyo ari cyo cyose ntagombye gutanga impamvu ntibigire ingaruka kuri serivisi z'ubuvuzi mpabwa cyagwa uburenganzira mpabwa n'amategeko.	
Nemeye ko amakuru nzatanga muri ubu bushakashatsi azifashishwa, kandi nsobanukiwe neza ko azafatwa nk'ibanga.	
Nasobanukiwe ko amakuru kuri njye/natanze/ku wagize uruhare cyangwa yatanzwe n'uwagize uruhare mu bushakashatsi ashobora gusangirwa binyuze mu bubiko bw'amakuru bugerwaho na buri wese cyangwa agahabwa abandi bashakashatsi ariko ko ntazamenyekana bivuye muri ayo makuru.	
Nemeye ko umwana wanjye akorerwa isuzuma ry'iterambere kandi ko ibi byabikwa mu gihe bikenewe.	
Nemeye ko mu gihe kizaza ishuri ry'ubuzima rya Londoni (LSHTM) na / cyangwa umuryango Inshuti Mu Buzima ("Partners In Health) bazamvugisha kubijyanye n'ubu bushakashatsi n'ubundi bushakashatsi cyangwa izindi gahunda.	
Nemeye kugira uruhare muri ubu bushakashatsi bwavuzwe hejuru.	

Amazina y'ubazwa — Umukono w'ubazwa — Itariki

Amazina y'umutangabuhamya udafite aho abogamiye* — Umukono w'umutangabuhamya udafite aho abogamiye — Itariki

Nemeye ko nasobanuriye ubazwa amakuru ku bushakashatsi ku buryo bwumvikana kandi ko yayasobanukiwe kandi ko yemeye ku bushake bwe, imbere y'umutangabuhamya udafite aho abogamiye wavuzwe hejuru (aho bishoboka), kugira uruhare* mu bushakashatsi.

Amazina y'uwakiriye icyemezo cy'ubushake — Umukono y'uwakirinye icyemezo cy'ubushake — Itariki

[*Bisabwa gusa iyo ubazwa adashobora gusoma no kwandika.]