

GUARANI

VIDEO TITLE: Pohãnohára Katherine O'Brien ndi ñomongeta WHO | Pehẽngue 1

[00:00:10](00:00:31) Maryn McKenna - Maitei. Tapeãguahẽ porã pehẽ ñepyrũ oguerekóva ko MOOC “Momaranduháruera oikuaava'erã COVID-19 Vakúna rehegua”. Che Maryn McKenna, amo'akã ko tembiapo. Ape aime Dra. Katherine O'Brien ndive, ha'é pohãnohára, epidemióloga, omotenondéva Departamento de Inmunización, Vacunas ha Productos Biológicos, orekova Organización Mundial de la Salud.

[00:00:38](00:00:36) Maryn McKenna - Dra. O'Brien, aguyje reimére ko mbo'esyrýpe.

[00:00:40] (00:00:38) Dra. O'Brien - Avy'a aimére penéndive.

[00:00:43](00:00:48) Maryn McKenna-. Aporandútamavoi. Ikatúpa emombe'u mba'épa ojapo OMS Vakúna COVID rehegua ojejapohápe.

[00:00:53](00:01:42) Dra. O'Brien – Katuete. Heta mba'é ojapo OMS. Ñepyrũguive oñeporandu mba'épa oñeikotevẽ vakúna ojechapyty haguã. Mba'éicha oñemombarete. Mba'épa ojeipota ohupyty pe vakúna. Mba'éichava'erã. Ñ porandu hypy'ũ ha oñeikotevẽ hesakã haguã vakúna jejapo, oĩ rupi hetaiterei ohekáva vakúna apo. Upévale jaikuaava'erã mba'é jaheka, mba'é ary peguarã, mba'é perfil oñeikotevẽ ome'ẽ haguã teko añete, mba'éicha oguahẽta tapichakuérape, mbo'y dósis ojeheka oñeikotevẽ ojejapo haguã vakúna.

[00:01:43](00:02:26) Dra. O'Brien – Hapykueri ojeheka tapicha opa yvy ape ári. Oñeikotevẽ heta mba'ere, heta tapicha ojapóva ipehẽ oñemoíva'erã peteĩ ñe'ẽme, techapyrã mba'éicha oñetante'ata vakúna, mba'é mymbápa ojeiporúta, ojehechava'erã, oñembojovakeva'erã peteĩ vakúna ambu'e vakúnare, osẽva Empresa ambu'egui. Upévale ãichagua ñehenói oiko ojejuereko haguã peteĩ tenda oñeñemongeta ha oñembohasa haguã kuaapy ojejuerekóva.

[00:02:26](00:03:11) Dra. O'Brien – Avei oñemoĩ peteĩ ñe'ẽme pe protocolo orekova'erã. Rohecha umi káso oíva, mba'e ojejapóva'erã umi ensayo klínikogui osẽva. Rohecha mba'é ñe'ẽ roiporuta rojapo jave ensayo klíniko, mba'é ro'ese upe ñe'ẽme, taha'é mba'asy vai, mba'asy'i ýrõ ndaivai guasúiva. Roimeva'erã, peteĩ ñe'ẽme. Vakúnakuera iñambue ojehegui, pe rendimiento iñambue haicha a según mba'éicha ojeporu upe'ape ro'e punto de valoración de la enfermedad.

[00:03:06][00:03:33] Dra. O'Brien – Opa ã mba'e ha'e tape roguatáva ha rojapova'erã. Roguereko peteĩ tenda roñomongetaha, roiporuhápe kuaapy roguerekóva peicha avei rojeporeka kuaaha'ãhára oĩva arapyre, roguahẽhaguã peteĩ ñe'ẽme ã mba'ere.

[00:03:20] [00:04:48] Dra. O'Brien - Upéi oiko jave vakúna ñeha'ã, roikuaava'erã mba'éicha oiko. Pe tenda ojejapohápe vakúna, pe tetã ojejapohápe ojeiporuhaguã ojejapova'erã mbo'epy. Hepy ha ipohyita umi vakúna apohárape, ohohaguã opárupi oñemonéiva'erã chupekuera. Upévare oĩ peteĩ aporeko OMS rupive, oñembyaty hápe umi ñeha'ã ojavova'ekue. Ojehecha ã mba'e, ojetypeka jahecha mba'éicha ojejapo, marandu orekóva ponotei ojekyhyje vakúnagui, mba'éichaitépa oporoipytyvõta. Ko aporeko ojeikuaa proceso de precalificación térã aporeko ñembohysíi ojeporu haguã oñeikotevẽterei rupi.OMS ohecha rirẽ ã mba'e ombohysíi ojeporu haguã oñeikotevẽterei ramo, upéicha tapichakuéra arapyre ojerovia, ikatu oiporu umi kuatia osẽ pya'e haguã kuatiakuéra hetãme.

[00:04:29][00:05:59] Dra. O'Brien – Ipahápe ojehecha aja vakúna aporeko ojequereko tenda oñemo néiha, mba'éicha ojeporúta vakúna. Ojeporu ha ojehecha oikópa, ikatúpa oñemoĩ kyhyje'yre, ojejapo porãpa. He'í ikatu ojeporu ha ndeiri mba'éicha ojeporuva'erã, upe aporeko OMS gua ohenói je'y ojejapo ha oñemombe'u haãgua arapyre mba'éicha vakúna ojeporuva'erã. Omboguyguy vakúna oĩva, upépe he'í mbo'y dosi pa oñemoĩva'erã, mba'e ary peve ojeporukuaa, ha'épa opavavépe guarã térã mbovy tapicha peñarante. Upévare, oje'éva guive mba'éicha ojeiporúta ha'e hina pe aporeko politika. Av ei ojequereko aty poravopyre oĩháme tapicha kuaaha'ãhára oipytyvõva oñembyaty techaukapy ojehai haguã pe formulasiõn politika.

[00:05:32][00:06:28] Dra. O'Brien – Peicha oñepyrũ tembiapo, oje'e guive ojejapotaha vakúna, heta vore ojehasa, oguereko heta aporeko, upéi oikóma ñomongeta pe politika regula dorare. Avei oikóma ñomongeta mba'éicha oñemoõguahẽta vakúna opa hendarupi, mba'éicha oipytyvõta OMS oõguahẽ joja ha oñemoĩ haguã vakúna arapyre.

[00:05:54][00:07:18] Maryn McKenna – Aãgaitéma ñaÑe'ẽta upévare. Aguyjetaite, hesakã, mbyky ha pya'e emombe'u porãiterei oréve mba'e oikóva. Peteĩ mba'e ajaposéva, ahapykuere rekase, reikuaahaicha heta oĩva ko mbo'esyrýpe ou tetã orekóva ekonomia itekopyva. Chéve guarã OMS ojapo ã mba'e ikatuhaguã oipytyvõ organismo ha ministeriokuérape ndo rekóiva autoridad ombotekopy ha ãgua pohã ojapo haicha FDA, térã ijoguaha India yrõ China pe, upévare ã tetãnguéra ogueroviava'erã OMS ojapoha jetypeka hesekuéra.

[00:06:33] (00:08:15) Dra. O'Brien – OMS oĩ añete upépe oipytyvõ haguã opavave tetã oĩva arapyre. Katuete umi tetã imboryahúva ojepytasoveta OMS ojaopóvare. Añete ndaha'e umi tetã irekurso'iveva aňonte. Rohekombóe opavave tapicha opa tetãngua, upeicharõ ikatúta ha'ekuéraite ojapo pe tembiapo imbaretévove. Upe'a rohupytyse, opavave tetã to guereko pe kuaapy ojapo haguã tembiapo ijehegui. Pe jeguerovia ha'e peteĩ vorénte, peichahagui tetãnguera ikatupyryramojepe, ha oikuaapáro ã mba'e, oñeikotevẽ peteĩ tenda oĩ haguã ñomongeta, oñehenóijave. Oñeikotevẽ tenda oiko haũa aty, ñomongeta ñepytyvõrã.

[00:07:40] (00:08:56) Dra. O'Brien – Ñaňopytyvõtamente, ndaipori rekurso peteĩ tetã osẽhaguã ha'eño tenonde, ndaikatui. Kuaapy, marandu ha jetypeka oñeikotevẽ, péichama nte oñeġuahẽ peteĩ ñe'ẽme, mba'e ojeja'ota, mba'eicha ojehechata. Ñ mba'e ojejapo ika tuhaguã opavave ome'ẽ peteĩ ñe'ẽme, peicha avei ikatu oñembojoja, ambu'e mba'ere ojehecha haguã mba'eicha osẽ. Ndaikatumoã i ojejapo mba'eve opavave nañañe'ẽ jojáiramo pe mba'e ojejapova'ekuere.

[00:08:23] (00:09:19) Maryn McKenna – Ape ñaime arapokõindy oñepyruvo jasyapy, mbohapy vakúna oñemonéi ko Estados Unidos pe. Ambue katu ojeporúma arapyre. Aimete jehupyty pe arapokõindy OMS he'irõguare ambue arýpe ojejuerekoha Pandemia. Ajepa pya'e omỹi.

[00:08:44] (00:10:30) Dra. O'Brien – Añete upeicha ñanemondýi. Ko'a ha'e pe ñeha'ârõ jaguerekóva, arapy ojuajuvo, oiporuvo oikotevẽva, oñemoirũ, akãguapýpe ojehupyty haguã pya'e porã kotevepy. Ñ mba ojejapova'erã ha avei tohupyty opavavépe.

Hetama ro'e ha ha'e je'y, tuichaiterei mba'e vakúna ojejuereko. Ndaipori mba'eve péichagua. Heta mba'e ojehasa, heta ensayo kliniko ojejapo ojehupyty haguã ha aporeko ohogueteri hese. Tuichaiterei mba'e ha oñeikotevẽ heta gueteri. Neíra ojejuereko heta vakúna oñevakunahaguã opavave yvy pórape. Ha'evo Ko'a, neíra ojekuaa máva ra'ẽ oñevakunava 'erã, rojetypekagueteri moõ pevépa rovakunava'erã. Ndahapykuerei ningo ko mba'e, tuichaiterei, anichéne avave oimo'ã oñeġ uahẽ mombyry ha pya'ete.

[00:10:11] (00:10:47) Maryn McKenna – Oñemosarambimakatu vakúna arapyre. Anġete er ema kuri, OMS tuicha pytyvõ ojaopoha ojejueraha haũa vakúna. Mba'epa hatapyña oĩva ko'ãga vakúna oñemosarambi haũa.

[00:10:24][00:11:32] Dra. O'Brien – Hatapyña tuichavéva oïva oguhê joja vakúna opa hendárupi. Rogueroko peteĩ mekanismo arapyre, mekanismo COVAX, ojejavovakue oipytyvõ haguã opavavépe, ha'e pe mbytetépe oñemoĩ, mekanismo rupive oñembohasa dosis ojevavovakue ñembohysy'i ha upéi ojeguerahaka jojaite opa rupi, oñembohováivo epidemióloga oguerúva pandemia, kotevepy oguerékova tetãnguera oñembojovakue ko mekanismo. Ekavavéva vakúna ñemosarambi hesakã, tojegueraha jehepymevẽy're ha toguhê joja opavavépe.

[00:11:05] [00:11:57] Dra. O'Brien - Upe'ava oiko haguã opa tetã oñehavavéva'erã ijehe. Tetãnguera ipirapireveva ikatúta ojapo ñomongeta bilateral, havakue opa oipotaháicha. Ha upe'ava oikovove havakue opa orekóta vakúna oipotaháicha ha umi tetã savive ipira piréva, hasy peve ohupytyta vakúna.

[00:11:29] [00:12:29] Dra. O'Brien – Ha pe'ava naiporã, ndahavéi ñarandúva rembiapo. Ha ape ñaime mbytetépe. Ojeguereko mekanismo COVAX, upépe 190 tetã oñemoĩ oñondive, ñambue ojuehegui. Vakúna ojeguerahaka mekanismo COVAX rupive ha kovava oguhêva 92 tetã imboryahúvape, ha umi vakúna oñemoĩ ojehepymevẽy're.

[00:12:04][00:12:53] Dra. O'Brien – Avei roime heta tetã ojevavovakue heta ñevẽ bilateral mbytetépe. Upéicha rupi ikatu ro'e roimeha pavũ hibridope, rohechakuaa mba'éicha oñemosarambi va'erã vakúna arapyre avei roguereko heta ñevẽ me'ẽ, akuerdo bilateral rupi, umi tetãnguemandi.

[00:12:29][00:13:05] Maryn McKenna – Mba'épa ere, Ikatúpa ñahavavéva, umi tetãnguera ome'evavakue ñevẽ ojupe, ñambue ojuehegui ha ohasa ome'ẽ ñevẽ opa arapyre.

[00:12:38][00:13:54] Dra. O'Brien – Heta tetãme oñeme'ẽ hetave dosis oikotevẽva gui, ndoipuravã. Upe'ava oiko, ojevavovakue aja ñomongeta, ne'ra ojevavovakue mavaitépa umi ensayo kliniko oĩ potávava, oñetante'ava aja, ne'ra ojevavovakue mavaitépa oikóta. Oñepyrũ javave aporeko vakúna rekávo heta oĩ osẽ porãva, heta oĩ tetã orekovéva dosis yvy poravã. Pe'ava javave ko'ava, hetaiterei dosis ojeguereko heta sua, oñemosarambi oparupi, ha katu 10 tetã rupinte ogueroko ipovýpe aimete 80% dosis.

[00:13:34][00:14:18] Dra. O'Brien – Pea ndoikovã. Ndoikovo'ã, savã rupi tetãnguera, ipyavese rupi, ndoho mombyrivo'ã, ohevãre tapykue heta tetãme, ndaikatuiva ipyavave ohupyty haguã vakúna. Havavo ndoikovo'ã, havave opavave javavovakue opa ko mba'asy vai, opavave javave ñande rekove ymãve.

[00:14:01][00:15:09] Dra. O'Brien – Ndaikatui jajapo upé'a, upévara ñangarekova'erã ojuehe. Ndaha'ei ñane retãme añonte, avei pe mboypýre. Jahecháma ko mba'asy mba'éicha omýi Frontera háre, ha omýitagueteri. Oiméramo jepe ñavakuna peteĩ vore michíva yrõ tuicháva ñañepyrũma jahecha orekoha variante ko virus. Variante upe vakúnare oñembohorýva. Ñasẽ haguã ko mba'asy vaigui, ñamombareteva'erã pe inmunidad toñeñandu yvy ape ári, ñañeha'ã aja ñambope yvýre pe mba'asy ñembohasa ñañangareko ha jajapo pe protocolo sanitario.

[00:14:48]

[00:15:31] Maryn McKenna – Angete ere ha aime nendive, opavave jaipota opa ko mba'as y vai. Mba'épa ereko ne akãme, pe ára jehasa, mba'éichatapa ko mba'e. Mba'éichapa oñemosarambita vakúnasíon ha, mba'e esperansapa jareko jahupytyvo Inmunidad opavave

[00:15:05][00:15:50] Dra. O'Brien- Añete che ñe'ã mbytégui che kuaaha'ãhára, upévale naiporã ha'e che hechapyrãite, ikatu ha'e opavave jaikuaava oikotava ha upéi mba'épa jakalkula oikone ára pukukue.

[00:15:21] [00:16:42] Dra. O'Brien- Opavave tetã yvy ape ári ohupytyta 25% hetãgua oñevakunáva ko 2021pe. Oíta avei sa'imi tetã ovakúnatáva hetave hetãgua ohupyty rupi hetave dosis. Jaikuaa oñekotevẽha hetave 25% sa'i. Pe 25% omeẽ'va oikóma oñevakuna haguã tapicha prioritariova, omba'apóva tasyópe, pohãnohára, oje apeligra ikatuhaguã oñangareko ha ojoko Sistema de salud ko mba'asy vai aja. Avei umi ijedadmava, téra umi orekóva mba'asy ikatúva omanõ ohupyty rupi chupekuéra COVID.

[00:16:08][00:17:07] Dra. O'Brien – Upévale ñaime peicha, mba'asy vai, omokechembaite ñande Sistema de salud heta tekovépe ojukáva, oikotevẽva opa mba'e. Upeicharõ ñañeha'ãva'erã ñambogueji pe mba'asy, ponove oñemanõ. Ñañangareko ñande Sistema de Salud re, peicha jajaporõ tuicha ñaipytyvõta.

[00:16:43][00:17:18] Dra. O'Brien – Ko'ã ha'e la prioridad. ko'ã mba'e jajapova'erã ko 2021 pe. Opavave tetã yvy ape ári oñangarekova'erã.

[00:16:55][00:17:56] Dra. O'Brien – Jaipota añete ko patógeno opa, ndaikatumoãi jajei chugui. Ikatúta ñamokangy, ova mbegueveta, sa'ivéma oikóta perupi upévarã yvate porãva'erã pe inmunidad, ndaha'ei pohã ñaname, ikatu rupi mba'asy vaive oporo aho'í. Ojehupytyva'erã pe Inmunización, jaikuaamieve jahavo mbeguekatu, jahecháta ã vakúnapa ojoko virus ñembohasa ikatútapa oñangareko ponotei oike mba'asy ñane pytühẽme.

[00:17:54][00:18:32] Dra. O'Brien - Upévare heta mba'e oĩ ha'eva virus re, ha heta mba'e ndahaikuaaiva. Virus ojeadaptá, oñemo ambue, jahasa jahavo ára ha ha'e ova ohovo. Jahechámvava'erã

oñekotevẽtapa dosis de refuerzo, omombaretéva vakúnape, Jahechava'erã pe vakúnape ojeadaptáta jahape joko haña umi variante óuvape. Oĩtapa Inmunización mitãme guarã, neĩra roguereko ensayo kliniko.

[00:18:34][00:18:42] Dra. O'Brien – Ñ porandu neĩra oñembohová, mba'e ojejapóta, ikatútapa ko vakúna ojoko ko pandemia.

[00:18:46][00:19:03] Maryn McKenna – Porandu pahã areko, ha'éma ajei, heta oĩva ko mbo'esyrýpe momaranduhára omba'apóva tetã orekova sa'ive rekurso. Ha'ekuéra oiko ohapykuerereka marandu vakuna rehegua, mba'erepa ojehesarekovéva'erã. Mba'erepa ohai va'erã

[00:19:08][00:19:22] Dra. O'Brien – Chéve guarã Momaranduhárakuéra arapýre oĩva, ojehesarekovaerã jehaire, Toiporu hekopete marandu. Hetaiterei oĩ maranduỹ oparupi. Upévare iporã ja'e marandu ha'etéva, ani ñaporombotavy. |

[00:19:28][00:19:58] Dra. O'Brien – Avei vakúna ome'ẽ esperansa, upe oñeha'ãrova, peteĩ faroicha opavave ñañeha'ãva ñañemboja hese, ajepa upéicha, vakúna ndaha'ei mba'e pajé, ndaha'ei remoĩva ha opáma mba'asy, eñangarekogueteriva'erã nde jehe, ejohéi nde po, emo'ã nde juru, eñemomombyry, ani resẽreinte pérupi, ani reho atyhápe. Emomichĩ tapichakuéra re ñe'ẽvandi.

[00:20:04][00:20:37] Dra. O'Brien – Mba'erépa ha'e ñ mba'e, ojequerahaka vakúna opa hendarupi katu ndahetái. Hetave neĩra oñevakuna, ha ndoroikuaai umi oñevakunamáva orekópa protección ponotei oñepama, ikatu oipe'a mba'asy vaigui, ha katu ndoroikuaai jahecha oñembyaínepa, mba'eichaitépeve oĩmeta protegido, pono ombohasa mba'asy vai ambue tapichápe. Ikatu gueteri oiméramo jepe oñevakuna ha'e amensasa ambue tapicha peguarã

[00:20:44][00:21:10] Dra. O'Brien – Jaikuaa porãva'erã, ndaikatuigueteri jaipe'a ñande py aseleradorgui, ndaikatui ñamboyke umi mba'e jajapóva ha oikóva. Ñañeha'ã ñaime py'aguapýpe. Jaheja vakúna tojapo hembiapo ñane pytyvõ haguã. Ha ojeipotarõ upe'a oiko oñemboguejyva'erã pe mba'asy ñembohasa, pe transmision. Peicha añoite pe virus ikangýta ha vakúna oipytyvõta.

[00:21:23]

[00:21:20] Dra. O'Brien- Ñ ha'eva tuichaiterei mba'e, iporã hesakã ñepyrũme, ojejapo porã haña ha avei oñeñuahẽ haguã opavavépe.

[00:21:30][00:21:55] Dra. O'Brien – Avei tuicha py'apy ojeguereko vakúnare, ndojekuaa porãï jahecha oikópa, orekópa mba'asy ikatúva osẽ hapykueri, hetaiterei mba'e oje'e hese. Upévare oĩ nomoĩkáiva, ndoikuaaporãï oĩ porãpa vakuna ñemoĩ, pe'a tuicha mba'e, vakúna opytáva sobradope avave ndo aprovechái. Añete vakúna oñemoĩva'erã tapicha oikotevẽvape ra'ẽ.

[00:21:59][00:22:25] Dra. O'Brien – Upévare ojeguerekova'erã marandu hekopete, ome'ẽ haguã py'a guapy. Vakúna ikatu ome'ẽ akãnundu, jyva rasy, ikatu iruru ýrõ pytã, oĩ vakúna ikatúva ne mbo hasy peteĩ ýrõ mokõi ára, oiko jepi, peicha oñeha'ãro oiko. He'ise upe'a nde rete ombohováï ohovo pe vakuna. Upéicha reñandurõ ã mba'e oĩ porã.

[00:22:46][00:22:59] Dra. O'Brien – Heta ára pe reacción oguerekóva nde rete ha'e avei pe nde apytu'ũme reguerekóva, oĩ oguerekóva mba'asynte iñakãme. Ña producto iseguro, ojevichea, ogehapykuere reka jahecha mba'épa oiko, ojeguereko Sistema de Seguridad mbarete, omañava ára ha ára umi marandu oguhẽvo, mba'e oiko. Ko'agaite vakúna kuéra ojeguerahakama heta henda rupi isarambima.

[00:23:28][00:23:28] Maryn McKenna – Aguyjetaite ko ñe'ẽ eme'ẽva tapichakuéra oĩva ko mbo'esyrýpe. Ha'e ñomongeta mbarete, heta marandu roguenohẽ. Rome'ẽ aguyje Dra. Kate O'Brien OMS guápe.

Aguyje opavavépe peimére. Che Maryn McKenna, omotenondéva ko mbo'esyrý, hetave mba'e oĩ pe'ẽme guarã. Jajohechata mbo'esyrý rendape.

Aguyje peimére.

Interview with Dr. Katherine O'Brien | Module 1

[00:00:10] Hello and welcome to the first video segment in our unfolding MOOC "Covering the COVID-19 vaccine: What journalists need to know."

[00:00:20] I'm Maryn McKenna, your chief instructor. And I'm here today with Dr. Katherine O'Brien, who's a physician and epidemiologist and director of the Department of Immunization Vaccines and Biologicals at the World Health Organization.

[00:00:38] Dr. O'Brien, thank you for joining this course.

[00:00:40] I am so pleased to be with you.

[00:00:43] So, let me get right to my questions. Could you please explain the role that the WHO has played in vaccine development for COVID?

[00:00:53] Sure. There are quite a number of roles that WHO is responsible for. Beginning first from defining what the target product profile is for vaccines. What are we aiming to develop? What were the characteristics that we wanted a vaccine to meet? What were those minimum characteristics and what would be the ideal characteristics?

[00:01:13] And this is a really important part of vaccine development. Because, with so many developers out there, we need to be clear what we're aiming for in terms of what we want a vaccine to actually do; what age group we wanted in; what kind of safety profile is needed; what sort of delivery characteristics; how many doses we're aiming for. All of the elements of describing what we want designed as a vaccine.

[00:01:43] So, the second thing is really convening people around the world. Because so many of the parts of vaccine development require agreements among different people in different constituencies, to all agree, for instance, on how we will test the vaccines; what kind of animal models will be used. Because we need to compare between one vaccine and another vaccine, or one part of a vaccine made by one company and another part of a vaccine made by another company.

[00:02:14] So, those kind of leadership convenings to have a place where those conversations can happen and agreements can take place. Including sharing of reagents and sharing of knowledge.

[00:02:26] And then, the third thing that does in vaccine development is set the standards for what the protocols need to look like.

[00:02:37] What we've seen is that we need to know what the case definitions are for outcomes and clinical trials. When we're using clinical trials to test for either severe disease, mild disease, moderate disease. What do we mean by those words? And can we agree what those definitions are?

[00:02:56] Because vaccines do change. The performance of vaccines, varies according to the definition that we use of what is considered a disease endpoint.

[00:03:06] So, those are all sort of what we refer to as norms and guidance. Having a place where those conversations to take place, using our expertise and convening expertise from around the world to come to agreements on those things.

[00:03:20] And then when vaccines are tested, we also need to have regulatory processes. And the manufacturing site of a vaccine, the country in which it's manufactured, is the primary country where a vaccine is registered for its use and an assessment is done by regulators.

[00:03:38] But it's really very burdensome for manufacturers to then have to go to every country in the world to get authorization for a vaccine.

[00:03:47] And so, there is a process through WHO, that brings together the evidence from a manufacturer, looks at that evidence, looks at the quality of the manufacturing, the safety information of the vaccine, the efficacy of the vaccine. And can go through, what's referred to as, a pre qualification process or an emergency use listing process.

[00:04:09] When WHO has looked at the evidence and gives either emergency use listing or pre-qualification, any other regulator in the world can rely on that, can use that authorization as a means for them to go very quickly for their own national authorization.

[00:04:29] And then finally, in the vaccine development and authorization sort of space, is developing policies for how you use a vaccine. So, the regulatory step tells you whether a vaccine is efficacious, safe and manufactured with quality. It says it can be used, but it doesn't say how to use it.

[00:04:51] And so, the policy process, WHO convenes again to provide a global recommendation on vaccines, is convened and looks at each of the vaccines to provide a recommendation on the number of doses; the age groups that a product should be used in; should it be a universally used vaccine or their subpopulations in whom it should or should not be used.

[00:05:15] So, all of the decisions about how to use a vaccine is what the policy process does. And we have a strategic advisory group of experts on immunizations that provides advice to an expert review of the kind of evidence that's needed for a policy formulation.

[00:05:32] So, that really takes us from the early stages of the idea of a vaccine all the way through to that regulatory part and the policy part. And then, of course, we can talk also about actually delivering vaccines in countries and the work that WHO does to support and assure that vaccines can roll out in every country around the world.

[00:05:53] So, we'll talk about that in just a minute. Thank you for that incredibly cogent explanation. So quick and just so, so precise.

[00:06:01] One thing that I wanted to follow up with, because as you probably know, many of the members of this course are coming from developing economies. Am I right to think that WHO does all this work in part to take the burden off whatever national agencies or ministries they have? That they may not have a drug development authority with the muscle of the FDA or the equivalents in India or in China. And so, those countries can trust that the WHO has done the vetting for them?

[00:06:33] So, WHO is really there to support all countries around the world. And clearly countries that have fewer resources at the national level, would lean more on the work that WHO does. But it's not really only about countries that have fewer resources.

[00:06:52] We do training per country staff, so that at any point in time, the ability and the capacity of countries to actually take on this work themselves in the future is ever more strength. And I mean, that's really the goal, is that countries have this capacity in their own national programs.

[00:07:14] So, it is both a reliance part, it's a training component. But even if we didn't need either of those things, there is still a need. If every country was of high capacity, we would still need WHO to do some of these things. Because there does need to be a place.

[00:07:31] There does need to be a convening. There does need to be a gathering place for people to have conversations that have to do with collaboration.

[00:07:40] And unless we are collaborating around the world, there simply aren't enough resources for any one country to do it alone.

[00:07:48] The knowledge, the information, the research. We do need to have ways of collaborating together, coming to agreements about what it is we're going to do, how we're going to measure things. So that we have standardization. And therefore, as a result of standardization we can make comparisons between a range of different products and the ways that they're being measured.

[00:08:11] If we're all off doing our own thing, deciding on how we're going to do a study, we just can't make any comparisons or come to adequate conclusions about what products actually do.

[00:08:23] So, at the point at which we're speaking, which is the first week of March, three vaccines have been authorized here in the United States, where I'm sitting. Others are in use already around the world. We are just about in the week when a global pandemic was declared by WHO a year ago.

[00:08:42] Are you surprised that things moved this fast?

[00:08:44] Oh, I think everybody is surprised. I think this was the hope that we had that the world would come together, would use every lever it has, would put all of the resources out there publicly in a collaborative fashion, in a coordinated way. So that we could get speed, quality and success, really.

[00:09:06] Those are three of the things that were essential. And then added to that, the fourth dimension is scale and access.

[00:09:15] And so, I think that the actual success of the development of the vaccines, is really just, we've said it so many times, but it just it bears repeating - it's extraordinary. It is unprecedented.

[00:09:30] The number of products that have come through clinical trials, the number of successful products and the pipeline continues. And the reason that's important is that, we need as much product as we can get our hands on. The world doesn't have enough vaccine to vaccinate everybody in the world who needs this vaccine.

[00:09:48] That being said, we don't actually know exactly what fraction of the population should be vaccinated. We're still learning just how far and wide we should be vaccinating. But this has been absolutely unprecedented, extraordinary. And I think there's nobody who expected that we would be going this fast, this far, this wide and at this scale.

[00:10:11] So, we're already into distribution of vaccines around the world. What are the you mentioned distribution and WHO playing a moment ago. What are the challenges at this point for getting vaccine distributed?

[00:10:24] The biggest challenge we have right now is the equitable access to vaccines. We have a global facility, the COVAX facility, that was designed to be the clearinghouse for doses that are manufactured to be aggregated together and then to distribute them in a fair and equitable way to respond to the epidemiology of this pandemic, the needs of every country around the world who wanted to join the facility. So that, we would be able to distribute those vaccines with transparency at the least expense possible, in a fair and equitable way.

[00:11:05] The alternative to that, is that every country had to do it alone. Countries that had resources would be able to do bilateral deals, in size and scope of their liking. And with limited supply, when we're in a situation where there's constrained supply, that would mean that countries that were less able to pay would have less vaccine or less speed in accessing vaccine.

[00:11:29] And that's not a neither wise nor really morally justifiable way of distributing vaccines. And we're somewhere in the middle of those two sort of ends of the spectrum.

[00:11:43] We do have a global facility, the COVAX facility, that one hundred and ninety countries have become a part, countries or economies. And vaccines are rolling out through the COVAX facility now, and they do serve the ninety two countries with the least ability to pay. And those vaccines are being provided to countries without cost to the country.

[00:12:04] But we're also in a place where there are dozens and dozens of countries that have done one or more bilateral deals. And so we're in sort of a hybrid space right now, where we have both the global vision of how vaccines should be distributed. And we're on the other extreme, we also have a large number of bilateral deals with countries.

[00:12:29] Do you think there's a hope for encouraging the countries that have done their private deals to share what they've committed to with the rest of the world?

[00:12:37] So, a substantial number of countries have actually got more doses than they can really use. And the reason that that happened is that at the time when the deals were being done, nobody knew which of the clinical trials, that were testing products, which of them would actually reach success.

[00:12:55] With the large number of products that have reached the minimum measures of success, for a vaccine, there are a substantial number of countries that that have more doses than they do have people. That along with the idea that, it's not just the the total number of doses that a country has access to, it's also the timing of those doses.

[00:13:18] And what we're seeing right now is with the tens and now hundreds of millions of doses that are being distributed worldwide, there are a very limited number of countries, about 10 countries, that have administered about 80% of the doses that are being distributed right now.

[00:13:34] That's not going to work. It's not going to work for a small number of countries to go very far and very fast, while leaving behind, both in pace and scale, a large number of countries that don't have access to be going as fast or with as high coverage.

[00:13:52] And when I say it's not going to work, what I mean is: what we all want is we want the pandemic to end. We want our lives to get back to some kind of new normal.

[00:14:01] We can't do that until there's widespread protection, not just within a country, but across borders. We've seen this pathogen move across borders and it will continue to do that.

[00:14:14] Even if we immunize some parts of some countries or immunize large parts of some countries, we're starting to see variants of the virus. They may become variants that now are not protected by the vaccines. And the smart way to actually get out of this

pandemic is to assure that the benefit of immunity is felt around the world, while we're crushing transmission with our non-vaccine interventions.

[00:14:48] You just said, and I completely agree, we all want the pandemic to end. What in your head is your timeline, for what this is going to look like? How do you think vaccination is going to roll out? And what's our hope for reaching population immunity?

[00:15:05] So, I'm really a scientist at heart. And so, I don't like to speculate, but I'll tell you what I think we know is going to happen. And then, what can we envision will happen out in that distance.

[00:15:21] Every country in the world is going to be able to achieve somewhere around 25% coverage of their population in 2021. There are a smaller number of countries that will reach higher population coverage of vaccine, because they have access to doses.

[00:15:39] We know that it is very likely that countries do need to go beyond 25%. Now, that number is enough to cover the highest priority individuals in countries: health workers who are the ones who have been putting their lives on the line and sustaining our health systems through this pandemic; those who are in older age groups or who have underlying conditions that put them at risk of having severe disease or death from COVID.

[00:16:08] And that's the reason why we're in this situation in the first place, is the severity of the disease. That's the thing that has put our health systems at risk and it has caused so much loss of life, severe disease, and required that all of the other interventions that we've put in place.

[00:16:27] So, if we can really turn down the volume on that severe disease spectrum, the risk of death and the protection of our health system, that's going to take a lot of air out of the balloon in terms of why we're having to do what we're doing in the first place.

[00:16:43] So, that is the first priority and the critical priority for 2021, is that every country everywhere is able to protect against that most urgent need.

[00:16:55] Now beyond that, what we really want is this pathogen to go away. We're not we're not going to get rid of this pathogen. I don't think anybody thinks that anymore.

[00:17:04] But will it become something that is much less severe? Is it something that would circulate in a much slower pace, because there is such high immunity in the population as a result of either vaccination or natural immunity?

[00:17:21] And we are not advocating that we get to immunity through natural means, because of the risk of severe disease and death. So, we need to get to that place and the size of that immunity. How many people need to have immunity in order to, as I sort of call it, take the air out of the balloon on this, is not really a known value.

[00:17:40] We are learning as we go. We're learning about whether these vaccines interrupt transmission of the virus, whether they can protect against infection of our upper respiratory tract.

[00:17:54] So, there are components of this whole response and components of the virus itself, that remain unknown for us. And the virus is adapting and it is changing as time goes on and as more transmission takes place.

[00:18:13] So, we are going to have to learn about whether booster doses are needed. About whether or not we need an adaptation of the vaccines to get out in front of the virus, in terms of the variants of the virus. Whether or not there will be a role for immunization of children, for which we don't have clinical trial data, yet.

[00:18:34] So these are some of the questions that are yet to be answered and will influence what the strategy is for using these vaccines and ending the pandemic.

[00:18:46] So, as a final question, let me just ask you. I told you earlier, many of the participants in this course are journalists who are working in lower resourced countries, developing economies. As they cover their vaccination campaigns, what would you want them to be most alert to? What's your counsel for what they should be writing about?

[00:19:08] I think the most important thing is that journalists around the world are very scrupulous about writing, using credible information.

[00:19:20] There is so much misinformation out there. It's extremely important that accurate information is used.

[00:19:28] The second thing is that vaccines are really this beacon. It is this hope that we all have. It's the lighthouse we're all trying to row towards, right?

[00:19:38] But vaccines are not a "magic bullet". And, just because you get vaccinated does not mean that you can stop using the other interventions that we have: handwashing; masking; physical distancing; protecting yourself by not going out with large numbers of people; really constraining the people that you're interacting with.

[00:20:04] And the reason I say that is that, first of all, vaccines are rolling out for most countries in a very constrained supply.

[00:20:13] The majority of people are not vaccinated. And, we don't have the information about the degree to which if you're vaccinated, you are protected either from getting infected. You may be protected against getting disease. But, we don't know the degree to which you're protected against getting infected.

[00:20:31] And if you are infected, your ability to go on and transmit to somebody else. So, you may still be a threat to somebody else, even if you aren't a threat to yourself, because of your vaccination status.

[00:20:44] So that's a really important thing. It is not the time, even if you're vaccinated, to take our foot off the pedal for all of the other interventions that are working, and do work when they're actually implemented. We need to be patient to let the vaccines roll out, to give them the best chance to provide protection.

[00:21:06] And the best way that they can provide protection is when transmission is really low in the community. Because then the virus is not being put under pressure through its own circulation to actually try to evade the immunity that vaccines are giving.

[00:21:23] So, those would be a couple of the points that, I think in this early rollout phase, are really important points to get across to people.

[00:21:30] And then the final one is there has been concern, of course, about the safety of the vaccines, the potential side effects of vaccines. And we hear a lot of rumors about the vaccines. And as a result of some of those people are hesitant.

[00:21:45] They're not sure whether or not they feel safe getting the vaccines. This is really important.

[00:21:51] A vaccine that sits on the shelf is of no value to anybody. It actually needs to be administered to people who most need the vaccines.

[00:21:59] So, really getting the information across about the very strong information we have about the safety of these products. They do cause local reactions. They do cause soreness of the arm, some swelling, some redness. For some of the vaccines, they also don't make you feel very well for about a day or two.

[00:22:19] And that is expected. It's a normal part of the reaction to the vaccine. It is, in fact, some indication that your body is responding to the vaccine.

[00:22:30] So in a way, if you have some of those reactions, in some almost paradoxical way, an individual might feel like something is happening. This is a good thing.

[00:22:46] So, I think also people's preparedness and readiness, their expectations that there will be some time limited, reversible, modest or mild side effects from the vaccine.

[00:23:03] But these are very safe products. They're being monitored for anything that might happen, that is rare, rare events.

[00:23:12] We have a very strong safety system that is monitoring on a daily basis all of the safety information that is coming through, as these vaccines are being deployed now in hundreds of millions of doses.

[00:23:28] Thank you so much for that advice for our participants. This was a wonderful conversation.

[00:23:34] It was incredibly informative. We thank you so much, Dr. Kate O'Brien of the WHO. Thank all of you for watching again. I'm Maryn McKenna. You were chief instructor and we have more segments coming for you. We'll see you in the course site.

[00:23:48] Thanks for watching.