Meeting report

Has differentiated service delivery delivered? A think tank discussion

4 March 2019

Seattle, USA

DIFFERENTIATED
SERVICE DELIVERY

EXECUTIVE SUMMARY

In 2016, the World Health Organization (WHO) released revised HIV treatment and prevention guidelines recommending "treat all" and introducing the concept of differentiated service delivery (DSD). In Chapter 6, read with the subsequent 2017 *Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy*, WHO recognized differentiated service delivery for four distinct groups of clients accessing ART: two categories for those currently not on treatment (people presenting or returning when well or with advanced disease); and two categories for those currently accessing treatment (people stable or on a failing ART regimen).

The International AIDS Society (IAS) convened a one-day think tank meeting in Seattle, USA, on 4 March 2019. The think tank meeting brought together 30 global thought leaders from normative agencies, donors, academic institutions, ministries of health and implementing partners to consider and determine the critical unanswered questions around HIV DSD for the four WHO-identified groups of clients. The meeting considered the extent of scale up of differentiated ART delivery for clinically stable clients and outlined research on DSD for all four groups that is currently underway. Four plenary discussions were facilitated to highlight key research topics aligned with each of the four groups. Smaller groups were then tasked to adapt and add to the research questions generated from the morning plenary, ranking the questions in terms of priority, discussing the data necessary to answer to the question, and commenting on who could answer the question and whether or not it was currently being researched. The outcomes of the group work were fed back to the main plenary.

The agenda from the consultation can be found in Annex 1 and a summary of the research questions identified in Annex 3, where a matrix for each of the four groups is presented.

KEY TAKEAWAYS

- **Improved collaboration and sharing of the differentiated service delivery research agenda and projects that are underway has benefits**
    - First, improved collaboration can support a prioritized research agenda. Second, improved collaboration allows for a coherent research agenda where future projects can build upon work that is underway and be synergistic, not duplicative. Third, by having a strong technical group of researchers, the diverse expertise can be leveraged in the design of new projects. Finally, by working with WHO, the research agenda can align with unanswered questions that can inform future guidelines.
    - At present, a mapping of ongoing research is challenging as some stakeholders may be disincentivized to share. However, even a partial mapping is indicative and can be coherent in outlining what a priority is.
    - Strong and active engagement of the think tank participants highlights the interest in developing a coherent research agenda.
    - There is an opportunity to foster improved collaboration and sharing of research on differentiated service delivery.
    - There may be value in widening the network beyond the think tank delegates to include partners in low-prevalence settings and West and Central Africa.

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- **Many of the outstanding research questions could be answered from routine datasets**
  - These questions include: the scale up of antiretroviral therapy (ART) delivery implementation for clinically stable clients; the proportions of unstable clients at any given time; clients re-engaging in care or presenting with advanced HIV disease (AHD) in hospital versus clinic settings; retention and viral load (VL) suppression with rapid initiation; and outcomes from 12-month clinical assessments for stable ART clients. In addition, the incidence of "disengagement by year" and "re-engagement by year", as well as factors influencing the time to re-engagement, are important.
  - It is essential to identify well-placed organizations, such as the International epidemiological Databases to Evaluate AIDS (IeDEA) and the US President's Emergency Plan for AIDS Relief (PEPFAR), that can complete these evaluations.
  - Data from these routine data sources are critical for providing target benchmarks so that facility performance indicators can be identified and quality improvement (QI) processes can be implemented by ministries of health (MoHs) and implementing partners to improve quality of care.

- **What service delivery models are used to provide ART to unstable, returning to care and AHD client categories? While the package to provide to AHD clients, the "what," is defined by WHO, the "how" is largely unknown**
  - Each of these client populations are made up of key subgroups that may benefit from different service delivery models. To support scale up, the most common characteristics of these groups should be better defined. For example, unstable clients may be struggling with adherence to clinic appointments or their treatment due to challenges that are psychosocial, clinical or convenience related.

- **While there are unanswered research questions related to DSD, there are also opportunities for improved advocacy and demand creation based on existing available research**
  - Making changes to national guidelines and ensuring implementation at a subnational level is not only dependent on additional evidence. In many settings, there are gaps between existing evidence and scaled-up implementation based on that evidence. More advocacy work at global, regional and national levels could improve this.

NEXT STEPS

Based on the think tank outcomes, a series of next steps are being defined to support further research and advocacy around DSD. These include:

1. Circulating the identified evidence gaps and priority evaluations and research questions to key stakeholders (normative agencies, donors, academic institutions and implementing partners) in the form of a two-page brief
2. Publishing a summary of the meeting outcomes as a commentary to ensure wider circulation
3. Advocating for prioritization of evaluations and research questions identified
4. Following the research identified when it is in progress and as new research arises and ensuring that interim and final outcomes are circulated to key stakeholders and are profiled on www.differentiatedservicedelivery.org.

Acronyms

AHD	Advanced HIV disease
ART	Antiretroviral therapy
CAGs	Community ART groups
CHAI	Clinton Health Access Initiative
CIDRZ	Centre for Infectious Disease Research in Zambia
CQUIN	Coverage, Quality and Impact Network (ICAP)
DSD	Differentiated service delivery
HE2RO	Health Economics and Epidemiology Research Office
IAS	International AIDS Society
IeDEA	International epidemiological Databases to Evaluate AIDS
ITPC	International Treatment Preparedness Coalition
M&E	Monitoring and evaluation
MMS	Multi-month scripting
MoH	Ministry of health
MSF	Médecins Sans Frontières
PEPFAR	US *President's Emergency Plan for AIDS Relief*
QI	Quality improvement
VL	Viral load
WHO	World Health Organization

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BACKGROUND

In 2016, the World Health Organization (WHO) released revised HIV treatment and prevention guidelines recommending "treat all" and introducing the concept of differentiated care, now referred to as differentiated service delivery (DSD). DSD serves as a way to support the growing number and increasingly diverse group of people accessing antiretroviral therapy (ART) [1]. While updating national guidelines in support of "treat all", many high HIV-prevalence countries have acknowledged the diversity of people accessing ART and defined how clinically stable clients could access less intense services.

In Chapter 6 of the WHO guidelines, recommendations for service delivery were outlined, noting four packages of care for four distinct groups of clients accessing ART: two categories for those currently not on treatment (people presenting when well and people with advanced disease); and two categories for those currently accessing treatment (stable individuals and unstable individuals). A number of recommendations were made for the stable individuals, including less frequent clinical visits, longer ART refills and care closer to home. In the subsequent 2017 *Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy* [2], these four categories were redefined (Table 1) and additional recommendations made for clients with advanced HIV disease.

Table 1: Four groups of people living with HIV

2016 consolidated guidelines Table 6.1, page 240	2017 advanced disease guidelines Page 2
People with advanced HIV disease	Individuals presenting or returning to care with advanced HIV disease
People presenting when well	Individuals presenting or returning to care when clinically well
Stable individuals	Individuals who are clinically stable on ART
Unstable individuals	Individuals receiving an ART regimen that is failing

While DSD, particularly for clinically stable adult clients, has successfully been incorporated into national guidelines, it is unclear to what extent the policies have been translated into practice. Further, there are a number of hypotheses from the genesis of DSD that have yet to be answered (see Annex 1).

[1] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed., World Health Organization, 2016.

[2] Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, World Health Organization, 2017.

OBJECTIVES

The think tank, organized by the International AIDS Society (IAS), brought together 30 global thought leaders to consider and determine the critical unanswered questions around HIV DSD for clients presenting or returning to care well or with advanced HIV, or those already in care and either stable or unstable on ART. This was a closed meeting limited to invited attendees; they came from normative agencies, donors, academic institutions and implementing partners (Annex 2).

The think tank built on discussions during the WHO Think Tank on Future Directions for HIV Service Delivery (November 2018), which considered existing evidence supporting recommendations for upcoming WHO service delivery guidance to identify gaps in DSD research needed to build the evidence base for future guidance.

The objectives of the think tank were to:

- Consider the current state of DSD scale up, particularly for clinically stable clients, and priority research questions that would be answered by research in progress
- Discuss and prioritize unanswered research questions for each of the four groups of people living with HIV (see Table 1) and outline the data required to answer these questions
- Determine a research roadmap for the way forward.

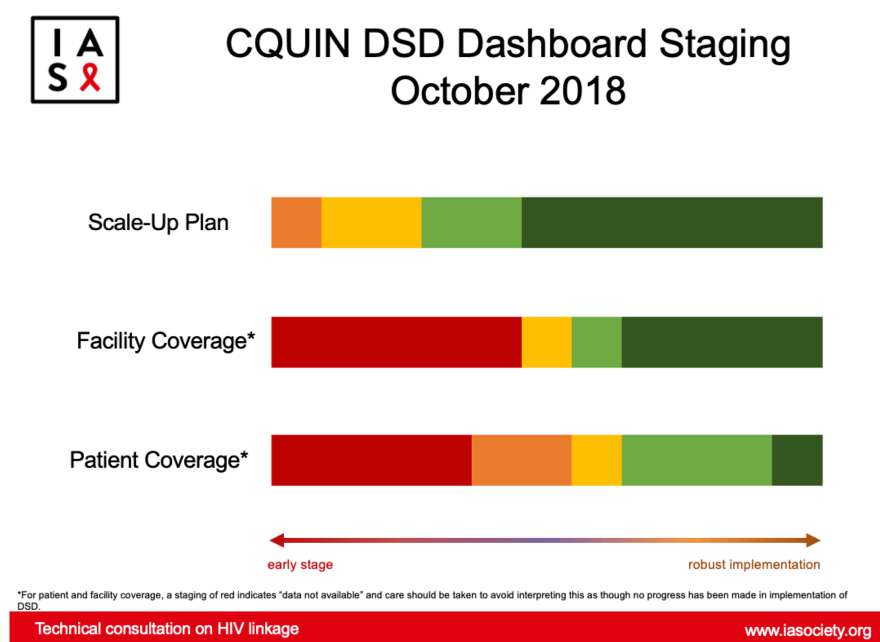
MEETING OUTCOMES

The presentations, discussions and group work are summarized below.

SESSION 1 – Introductions and framing

Introductions and framing – Anna Grimsrud (IAS, South Africa)
Anna provided an overview of the day, starting with all participants introducing themselves. She outlined the four groups of people living with HIV as defined by WHO. To give an idea of the extent of scale up of differentiated service delivery, data from the November 2018 annual meeting of ICAP's Coverage, Quality and Impact Network (CQUIN) was shared. The CQUIN DSD Dashboard is a self-assessment tool used by countries to monitor 13 different areas of DSD programme development. The scale ranges from dark red to dark green, with red reflecting insufficient data and dark green reflecting robust implementation. Data on the three domains – national DSD scale up, facility coverage and patient coverage (Figure 1) – highlight scale up in the 11 CQUIN countries.

Figure 1: CQUIN DSD dashboard staging



Anna then outlined research on differentiated service delivery that is currently underway, including:

- AMBIT – A systems-wide look for differentiated models of service delivery for HIV treatment in Africa, https://sites.bu.edu/ambit/, Boston University and HE2RO
- CommunityART – The CommunityART programme implemented by Centre for Infectious Disease Research in Zambia (CIDRZ), http://www.cidrz.org/wp-content/toolkits/commart/
- The HIV Coverage, Quality and Impact Network (CQUIN) Monitoring and Evaluation Community of Practice, https://cquin.icap.columbia.edu/projects/differentiated-me/
- A study on multi-month dispensing in Zimbabwe by EQUIP, http://www.equiphealth.org/
- A study on multi-month scripting and dispensing (MMSD) in Lesotho by EQUIP, http://www.equiphealth.org/
- Assessing the impact of the National Department of Health's National Adherence Guidelines for Chronic Diseases in South Africa

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- The INTERVAL study, UCLA, Partners in Hope-EQUIP in Malawi, EQUIP Zambia, and the Malawi and Zambia Ministries of Health, https://www.ncbi.nlm.nih.gov/pubmed/29029644
- Cluster randomized trial comparing extending adherence club ART refill dispensing intervals from two to six monthly, Médecins Sans Frontières (MSF) Khayelitsha, South Africa
- Village-based refills of ART (VIBRA), Swiss Tropical and Public Health Institute, University of Basel, SolidarMed, Lesotho, https://clinicaltrials.gov/ct2/show/NCT03630549.

Think tank participants also flagged the DO-ART study in South Africa, additional work from the World Bank, some work in Malawi on a wellness model, and various projects on identifying those at risk of treatment failure, including those by Ingrid Katz, Kate Dovel and Margaret McNairy.

SESSION 2 – Setting the research agenda

In session 2, four discussions were facilitated to highlight key research topics aligned with each of the four WHO categories of people living with HIV. Before the first discussion, participants discussed the scale up of DSD to date, whether the scale up was fast or slow, how quickly countries in sub-Saharan Africa had adopted WHO service delivery policies, the potential need for context-specific DSD evidence from outside sub-Saharan Africa, and the strength of the evidence base. Thereafter, Lynne Wilkinson, Charles Holmes, Kate Dovel and Izukanji Sikazwe facilitated discussions aligned with the four WHO categories. Key themes from the plenary discussions were then used to populate draft matrixes for the post-lunch group work.

SESSION 3 – Working lunch (outside the box or blue-sky thinking)

Participants had completed two pre-readings and were placed in one of four discussion groups over lunch. The pre-readings were:

- The Ghost Statistic That Haunts Women's Empowerment, The New Yorker
- Generous Giving Or Phony Philanthropy? A Critique Of Well-Meaning 'Winners', National Public Radio

Reflecting on these readings, facilitated discussions were convened and participants were asked to reflect on the following six questions:

1. Are we, the policy makers/civil society/donors/implementers/academics who are trying to be at the leading edge of promoting person-centred care for people living with HIV, doing enough to support women and girls?
2. Is the attention that we are giving to DSD distracting us from advocating for/addressing the underlying social/policy issues that are responsible for the conditions that produce poverty, make it more likely for HIV to be transmitted, and make it more difficult for people to access and remain in care?
3. Are there social or policy issues that we should be working on instead? How could we use the energy around our DSD agenda more effectively to address these greater issues?
4. What are the unintended consequences of pushing the DSD agenda? Are we taking a vertical HIV programme and further fractionating it so that we are providing higher quality, more person-centred care to certain groups, but weakening the rest of the health system?
5. Is our focus on one piece of the problem (initiation and retention of people living with HIV in care in the context of person-centred care) making the rest of the health system (and general ecosystem) better or worse?
6. What is the role of the private sector versus government in helping us solve the micro and macro issues of HIV care and health systems improvement more broadly? Are each being leveraged sufficiently? What are the best examples of private-public partnership that you know of?

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SESSION 4: Group work

In group work, participants were assigned to one of six groups and asked to focus on completing a research question matrix for one of the four WHO categories of people living with HIV. Two groups were assigned to Category 1 (individuals who are clinically stable on ART) and Category 2 (individuals receiving an ART regimen that is failing), and one group was assigned to both Category 3 (individuals presenting or returning to care when clinically well) and Category 4 (individuals presenting or returning to care with advanced HIV disease).

Each group was tasked to complete a matrix for a specific population group by adapting and adding to the research questions generated from the morning plenary, ranking the questions in terms of priority, discussing the data necessary to answer to the question, and commenting on who could answer the question and whether or not it was currently being researched.

A summary of the research questions identified in the plenary session 2 and adapted and prioritized through the group work can be found in Annex 3, where a matrix for each of the four groups is presented.

SESSION 5: Report back and closing remarks

A rapporteur from each of the six small groups reported back on the prioritized research questions. These report backs are summarized below around the four client groups.

For individuals who are clinically stable on ART

1. Evaluation of country scale up of differentiated ART delivery models is required to understand whether the majority of eligible clients have access. Such evaluations should identify barriers and enablers to scale up, including impact of multi-month scripting and client and healthcare worker satisfaction with such models in their facilities.
2. Health system research is key to determine and support health system reorientation to facilitate implementation and embed service delivery as routine, including resource allocation, drug supply chain and monitoring and evaluation (M&E) indicators.
3. Research studies should be undertaken to determine how simple we can get to enable self-care by stable clients. Further optimization opportunities were identified. This would be supported by evidence on how frequently clients in these models self-report to facilities when unwell.
4. Implementation science studies and quality improvement projects should be undertaken to determine the role, capacity and impact of differentiated ART delivery models integrating other healthcare provision, specifically chronic disease management, tuberculosis preventative and active disease treatment and family planning services for women. For low HIV-prevalence settings, the opposite should be considered – integration of differentiated ART delivery into existing integrated healthcare provision. Some best practices exist and should be identified and profiled.

Individuals receiving an ART regimen that is failing

1. Evaluation of existing evidence and datasets is required to estimate the proportion of clients who are on a failing ART regimen or at risk of failure at any given time.
2. Research should focus on determining the key defining reasons for or pathways to failure to enable the refining of tools to identify them (viral load, pharmacy refill data, a clinical prediction rule), frequency of their use, and development of appropriate DSD models geared toward the needs of broad subgroups identified.

3. DSD models should be trialled for these clients. Such models should clearly define the method of identification of eligible clients and differentiate service delivery for broad subgroups with differing needs (psychosocial support, clinical support, simplified and easier access to ongoing care, or a combination of these), understanding that one size does not fit all and that increasing visit frequency for many of these clients may not support sustained retention and viral suppression.

Individuals presenting or returning to care when clinically well

1. Research studies should focus on determining what sets a client up to do well in the first year on ART. Can communicating the roadmap for ongoing care to the client, including eligibility for stable client models, support early retention? Can earlier eligibility for stable client models be considered?
2. With same-day and rapid ART initiation routinely implemented in many non-research settings, evaluations of retention and viral suppression outcomes in public sector cohorts are needed to understand impact.
3. With increasing numbers of clients presenting to care no longer ART naïve but returning to care after a treatment interruption, models should be piloted and trialled that differentiate service delivery according to the differing needs of broad subgroups of returning clients.

Individuals presenting or returning to care with advanced HIV disease

1. Evaluation of existing evidence and datasets are needed to estimate the proportion of clients who are presenting with advanced HIV disease (AHD) disaggregated by those presenting to hospital and to clinics (well or sick) to enable the development of appropriate DSD models geared toward the needs of these subgroups.
2. Research should focus on determining the key defining reasons for, or pathways to, late presentation or returning to care with AHD to develop appropriate interventions that enable or support earlier presentation.
3. If semi-quantitative rapid CD4 assay can feasibly be conducted as simply as an HIV rapid test, we need piloting and trialling of models that establish effective utilization thereof for identification of AHD clients to ensure triggering of appropriate service delivery approaches. If not, alternative approaches to establish CD4 would need to be undertaken with the same purpose.

For all four WHO-defined groups, routine assessment of public sector facilities with above-average proportions of clients on an ART regimen that is failing or presenting or returning with AHD should be undertaken to red flag for quality improvement interventions.

Meg Doherty of WHO made the closing remarks in the meeting. She supported the need for a prioritized collaborative DSD research agenda aligned with the unanswered questions that are required to inform future WHO guidance and outlined the time frames for the WHO guideline process. WHO held a technical consultation on HIV service delivery in November 2018. This consultation included discussions on future service delivery guidelines from WHO and areas to review for the next guideline process. She stressed that WHO intended to bring out new consolidated testing, treatment and prevention guidelines in 2020 and, importantly, that this updated guidance should provide recommendations for re-engagement and package of services for all four WHO-identified groups of clients.

Annex 1: Agenda

AGENDA

Time	Description	Facilitator
09h30-10h00	Arrival and registration	
10h00-10h30	SESSION 1: Introductions and framing	Anna Grimsrud (IAS, South Africa)
10h30-12h15	SESSION 2: Setting the research agenda	
10h30-11h15	Discussion 1 – Individuals who are clinically stable on ART	Lynne Wilkinson (IAS, South Africa)
11h15-12h00	Discussion 2 – Individuals receiving an ART regimen that is failing	Charles Holmes (Georgetown, USA)
12h00-12h15	Discussion 3 – Individuals presenting or returning to care when clinically well	Kate Dovel (Partners in Hope, Malawi)
12h15-12h30	Discussion 4 – Individuals presenting or returning to care with advanced HIV disease	Izukanji Sikazwe (CIDRZ, Zambia)
12h30-13h30	SESSION 3: Working lunch *Rapporteurs: Jessica Haberer (Mass Gen, USA), Sydney Rosen (BU, USA) and Ade Fakoya (GF, UK)*	Peter Ehrenkranz (BMGF, USA)
13h30-14h30	SESSION 4: Group work *Finalize research questions, prioritize, discuss data required*	
14h30-15h00	SESSION 5: Report back & closing remarks	*Meg Doherty (WHO, Switzerland)*
15h00-16h00	Reception	

Annex 2: List of participants

	First name	Last name	Organization	Country	Email
1	Tsitsi	Apollo	Ministry of Health and Child Care	Zimbabwe	tsitsiapollo2@gmail.com
2	Solange	Baptiste	International Treatment Preparedness Coalition (ITPC)	South Africa	SBaptiste@itpcglobal.org
3	Ruanne	Barnabas	University of Washington	USA	rbarnaba@uw.edu
4	Aleny	Couto	Ministry of Health	Mozambique	aleny78@hotmail.com
5	Meg	Doherty	World Health Organization (WHO)	Switzerland	dohertym@who.int
6	Kate	Dovel	UCLA/Partners in Hope	Malawi	kdovel@mednet.ucla.edu
7	Peter	Ehrenkranz	Bill & Melinda Gates Foundation (BMGF)	USA	peter.ehrenkranz@gatesfoundation.org
8	Elvin	Geng	University of California, San Francisco (UCSF)	USA	elvin.geng@ucsf.edu
9	Katy	Godfrey	The Office of the U.S. Global AIDS Coordinator and Health Diplomacy (OGAC)	USA	cgodfrey@niaid.nih.gov
10	Anna	Grimsrud	International AIDS Society (IAS)	South Africa	anna.grimsrud@iasociety.org
11	Ade	Fakoya	The Global Fund to Fight HIV, TB and Malaria (GF)	UK	Ade.Fakoya@theglobalfund.org
12	Risa	Hoffman	UCLA/Partners in Hope	USA	RHoffman@mednet.ucla.edu
13	Charles	Holmes	Georgetown University Medical Centre	USA	Charles.Holmes@georgetown.edu
14	Jessica	Haberer	Massachusetts General Hospital Global Health	USA	JHABERER@PARTNERS.ORG
15	Vivek	Jain	University of California, San Francisco (UCSF)	USA	Vivek.Jain@ucsf.edu
16	Ingrid	Katz	Harvard Global Health Institute	USA	ikatz2@bwh.harvard.edu
17	Niklaus	Labhardt	Swiss Tropical and Public Health Medicine	Switzerland	n.labhardt@unibas.ch
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19	Catherine	Orrell	Desmond Tutu HIV Centre	South Africa	Catherine.Orrell@hiv-research.org.za
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28	Francois	Venter	Wits Reproductive Health and HIV Institute (Wits RHI)	South Africa	FVenter@wrhi.ac.za
29	Lynne	Wilkinson	International AIDS Society (IAS)	South Africa	lynne.susan.wilkinson@gmail.com

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Annex 3.1: Matrix 1 – Individuals who are clinically stable on ART

All DSD research on clinically stable individuals should consider the following:

i) **Effects of DSD intervention/model should be evaluated at facility level (that is, entire facility cohort, possibly even sub-district cohort) and across all groups of patients (stable, unstable etc.). We need to move away from comparing the DSD model patients (stable) with other patients (mixed bag).**

ii) **Stability is not very stable – today's stable patient is tomorrow's unstable.**

Priority/ranking	**Research question**	**Data required**	**In progress/ ongoing**	**By whom**
		Scale up of DSD models for stable clients		
HIGH	Extent of country-level DSD implementation, including - % of patients being assessed for stability	- Sentinel site data (IeDEA) - Survey sampling approaches	AMBIT	BU/HE2RO IeDEA needs to be utilized better
HIGH	How to utilize existing and emerging data to determine whether DSD ART delivery is working/doing no harm? - Examples: Assess: i) same-day/rapid ART initiation retention outcomes; and ii) 12-month clinical consultations for stable patients.	- Health outcomes - Longitudinal data (*requires dedicated M&E approach and needs to be funded in the long term*) - Cost data	AMBIT	BU/HE2RO IeDEA has potential

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Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
	- Impact on family planning (FP) /other healthcare (especially community-based DSD)			
HIGH	Barriers to adoption: - Are there barriers to scale up? For example, access to VL - Where does the data that shows that MMS isn't being scaled up? - What is the value proposition of community-based DSD in context of MMS?	- VL access versus DSD scale outcomes - Country-level data on MMS - Key informant for barriers to implementation (MoH)		CHAI/IeDea?
MEDIUM – HIGH	Changes in health system orientation are required to manage chronic care/DSD, including drug supply chain/logistics/M&E/resource allocation - Need to regularize and standardize supply chain?	- Health system research - Build business case (including marketing and human resources) to implement for large-scale models		CHAI (Elizabeth McCarthy?) Management consultant approach – broaden
MEDIUM	DSD model's relative "implementability" versus comparative effectiveness	- What outcomes for comparative effectiveness? Viral load suppression (problem) versus retention (based on visit) - Implementable – look at uptake		

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Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
MEDIUM	Scaled up for specific populations; DSD – children/adolescents/pregnant and breastfeeding women/key populations to support inclusion in policy & implementation – including MMS	- Model building blocks - Scale of implementation - Retention and VL outcomes		MMS – IeDEA/Research cohorts?
	Effectiveness of community monitoring of scaled-up implementation		?	ITPC?
How simple can we get? Further reductions in frequency of ART refill and clinical visits/optimization of stable-client DSD models				
MEDIUM-HIGH	6-monthly versus 3-monthly ART refills	- Retention and VL outcomes - Buffer stock/expiry/capacity of system	6-monthly versus 2-monthly adherence club refills (Khayelitsha, South Africa) 6-monthly versus 3-monthly clinical ART refills INTERVAL trial (Malawi)	MSF Partners in Hope/UCLA CHAI? Others supporting supply side?
MEDIUM-HIGH	6-monthly versus 12-monthly clinical consultations	- Observational from routine data		CIDER – Boulle/Matthew Fox from South African data where 12-

Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
				monthly clinical consultations implemented for number of years already
MEDIUM	How simple can we go? 6-12-month refills/annual clinical consultations - What is the package to enable self-care? - Can we only recall clients with high VL and not see those that continue to suppress? - What is the impact on clubs, community ART groups (CAGs), fast track, etc.? - Can CAGS/clubs be used for other patient groups needing more support – unstable?		SMART study? (need more detail)	Geng et al.
MEDIUM	Client preferences: ART refill as long as client wants	- Patient outcomes	Some work being done (not detailed by whom?)	
MEDIUM	VL results sent directly to client – empower to act		Ongoing	MSF Khayelitsha, South Africa
	Client satisfaction in DSD models. How can we improve on individual-level patient experience?	Qualitative	Some work being done: Qualitative adherence clubs	MSF Khayelitsha (in press) Risa Hoffman

Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
			6-monthly ART refills	
Integrated care DSD models				
HIGH	DSD for wellness health – pilot in low-prevalence settings - Pay attention to the systems: institutionalize role of managers (human-centred design)	- Health outcomes - Cost outcomes - Implementation models - Causes of mortality among people living with HIV	Malawi piloting wellness model Clubs in Western Cape? PrEP models? HIV-positive hypertension: Monika Roy	Risa Hoffman CIDER Bring in people with other system expertise (interdisciplinary work), e.g., Project Last Mile (USAID) Routine data collection on causes of death by HIV status
HIGH	Mixed care – FP/chronic care (basic) – pilot in high-prevalence settings			
Decongestion/resource utilization evaluation and impact				
	Impact of stable ART delivery models on resource utilization – if any - QI models to harness	- QI research		MSF?

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Annex 3.2: Matrix 2 – Individuals receiving an ART regimen that is failing

Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
HIGH	Define magnitude of the problem? - How will this change in era of transition to dolutegravir?	- Longitudinal routine data		IeDEA? Other researched cohorts? PEPFAR possibly working on problem within era of DTG
HIGH	Key is defining reasons for/pathways to failure: - Adherence - Tolerability - Clinical status – OIs/co-morbidity, etc - Convenience	- Resistance testing if failing 2nd-line regimen - Targeted pharmacokinetics data (for tolerability) - Socio-economic behavioural research		Biological – National Institutes of Health (NHI) RfA drug research Behavioural - National Institute of Mental Health (NIMH)
HIGH	What is the best way to identify those at risk of failing? (VL? Pharmacy refill? TDF urine assay? A profile? How do we balance specificity and sensitivity of this?) How often do we need to do this assessment? Passive/active? - Validating algorithms along the elevated VL cascade	- Quantitative research	In progress (study concept/link?)	Ingrid, Kate, Molly McNairy working on screening assessment: Ingrid (point of testing) and Kate (point of initiation)

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Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
HIGH	How do you encourage use of the result of this assessment/high VL? - Research on actions taken when red flag assessment/high VL result - How to develop action plan and look at outcomes measures of plan	- QI research		
HIGH	THE HOW: Effective patient-centred DSD model/s for patients identified at risk of failing that offer choice of tailored services for differing needs: - Psychosocial (need more education/adherence counselling support) - Clinical (need clinical support, not necessarily more counselling) - Need easier-to-access care/simplified care (not more frequent visits – access to DSD model)	- Building blocks of model - Retention and VL outcomes for model as a whole - Implementation feasibility		
MEDIUM	Understanding the limitations of DSD models for patients at risk of failing and evaluating less punitive models of care - When should patients be up-referred out of a DSD model?	- Evaluate DSD ART delivery research data already collected – outcomes of patients who accessed DSD ART delivery models when not eligible or who stayed in models after high VL/missed visits		CHAI (Prust) – Malawi? MSF/CIDER – clubs in the Western Cape? CDC (Auld) Mozambique – CAGs?

DIFFERENTIATED SERVICE DELIVERY

Priority/ranking	Research question	Data required	In progress/ ongoing	By whom
	- To what extent do patients at risk of failing or failing ART or considered unstable for another reason benefit from staying in a group DSD model (with or without extra support?)			
MEDIUM	Site-level assessment of patients failing (proportion of patients with high VL)? To what extent is quality of care offered by specific facility impacting proportion of patients with a high VL? - How to red flag these facilities - Effective QI facility processes once red flagged	- Routine data		PEPFAR?
MEDIUM	How can we implement QI processes that encourage and support use of "additional" resources available when stable patients are decanted?	- QI research		

DIFFERENTIATED SERVICE DELIVERY

Annex 3.3: Matrix 3 – Individuals presenting or returning to care when clinically well

Priority/ranking	Research question	Data required	By whom
HIGH	Determine what sets clients up to do well. Treatment literacy/communicating roadmap for early months (first 12 months)/client-friendly services?	- Possibly routine data + qualitative research	
HIGH	Loss to follow up and suppression after rapid and same-day initiation (3, 6, 9 and 12 months)	- Routine data as both rapid and same day are already being implemented in many contexts to some degree	- IeDEA? - Matthew Fox in SA? - PEPFAR data?
HIGH	THE HOW: Effective patient-centred DSD model/s for patients returning to care that offer choice of tailored services for differing needs: - Psychosocial (need more adherence counselling support) - Clinical (need clinical support, not necessarily more counselling) - Need easier-to-access care/simplified care going forward (not more frequent visits) – access to DSD model	- Building blocks of model - Retention and VL outcomes for model as a whole - Implementation feasibility	
MEDIUM	What is the earliest that clients should be able to access DSD models? Can we accelerate access?	- Routine data + quantitative research	
MEDIUM	Determining warning indicators – trajectory to not safely continue?	- Routine data (where electronic sources integrated (laboratory, pharmacy and health system encounter information)	- CIDER SA?

DIFFERENTIATED SERVICE DELIVERY

Priority/ranking	Research question	Data required	By whom
			- Matthew Fox group?
	Does a primary healthcare approach improve outcomes in the longer term for these clients? (Not only about HIV, but also other health needs)		
	What works for those who are well on presentation but have co-morbidities? THE HOW: Effective patient-centred DSD model/s for patients presenting well to care with co-morbidities.		
	How do we encourage people to become those who present early? What can we learn from pregnant women who are clinically well?		

DIFFERENTIATED SERVICE DELIVERY

Annex 3.4: Matrix 4 – Individuals presenting or returning to care with advanced HIV disease

Priority/ranking	Research question	Data required	By whom
HIGH	Define magnitude of the problem? Proportion presenting with AHD. - Of those presenting with AHD, what % are new versus previously on ART? - % low CD4 versus % sick or hospitalized on presentation	- Retrospective routine data analysis - Should M&E be set up to routinely monitor % AHD at presentation? How best to do this?	Possibly PEPFAR-supported sites – testing sites and TB clinics
HIGH	Understanding who these patients are: key defining reasons for presenting or re-engaging late to enable service delivery planning. - Psychosocial, including stigma/social constructs/personal health management - Structural issues, including lack of service convenience/flexibility - Clinical status – presence of opportunistic infections/mental ill-health	- Qualitative research at testing sites yielding higher proportions of AHD – TB clinics/STI clinics/inpatients	
HIGH	Geographical and site-level assessment of % patients presenting with AHD? To what extent is quality of care offered by region/specific facility impacting proportion? - How to red flag these regions/facilities - Effective QI regional/facility processes once red flagged	- Routine data - QI studies	CHAI? PEPFAR? NHLS? ICAP?
HIGH	What is the impact of semi-quantitative rapid CD4 on identification for linkage and clinical management of patients with AHD? How can it best be utilized within testing and ART initiation models (service delivery approaches)?	- Quantitative research: impact morbidity and mortality	

Priority/ranking	Research question	Data required	By whom
		- Disaggregate hospitalized and outpatient AHD	
MEDIUM	How do we improve understanding/messaging and therefore uptake of CD4 at baseline utilization among key stakeholders (including clinicians)?	- Qualitative research: both in hospital and outpatient/clinic settings	