Supplementary File

Additional file 1.

"A continuous quality improvement intervention to improve antenatal HIV care testing in rural South Africa: evaluation of implementation in a real-world setting"

This file includes:

- Additional methods
- Semi-structured interview topic guide
- Tables S1-S4

Data sources for CQI intervention at clinics

To estimate clinic-level performance on our primary endpoints in real-time, clinic registers containing routine Department of Health (DoH) monitoring and evaluation (M&E) indicators were sourced. Antenatal registers containing information on HIV testing, HIV results and treatment were accessed by the CRH team (CQI mentors) working with health workers at each clinic during improvement activities. Average monthly estimates of women eligible for each endpoint were made and set as targets for achievement. Monthly trends in actual testing were then plotted on run charts against the desired target for each endpoint. Additional data documents were created to implement patient follow-up and document results — these included an informal logbook (exercise book) per clinic with one staff member allocated as the main custodian. Data quality was poor with incompleteness and discrepancies between source registers and monthly summaries (summary statistics submitted to the district Facility Information Officer for collation at district, provincial and national level M&E). Poor clinical documentation in patient medical records was also noted.

Improvement activities were conducted to resolve routine data quality issues in M&E documents residing at clinics. However, as patient antenatal medical records (MCRs) were not available at clinics until after delivery, real-time improvement activities targeting clinical documentation were difficult to implement. Constraints of the stepped-wedge study design precluded comprehensive efforts at improving data quality as repeated training and supervision were needed.

Routine clinic registers and clinic-based CQI data sources were not accessed for the process evaluation or impact evaluation.

Topic Guide: Semi-structured interviews with staff

General questions	Can you tell me, overall, what has your experience been, working with the Quality Improvement team? How did you find the education and training for QI? How did you find getting feedback during PDSA cycles and Learning Sessions? How did you find getting feedback from colleagues at other facilities during Learning Sessions? (NB: not applicable to clinic 1 until month 6 of study)
NPT construct	Questions about the MONARCH QI intervention
Coherence: Work to make	How different is QI from 'old' ways of working?
sense of the system	Does everyone in the team share an understanding of its aims and what it is expected to deliver?
	Does everyone in the team know what they are expected to do to deliver the system and how that differs from what they did before?
	Do people really think the new system will work for them and will work to improve quality of care?
Cognitive Participation: Work to maintain their own engagement	How easy was it to get all concerned involved in implementing the new systems, including setting up systems and procedures (e.g. entering data in all DoH registers; creating run charts)?
with and delivery of the new	Were people willing to invest time and effort in setting up the systems?
system and to involve others	Do people see the new activities they need to do as their responsibility?
	Do they know what they need to do to continue to make the system work?
Collective Action: The work	How easy is it to complete routine tasks in this system?
that has to be carried out in practice in order to implement	Do people involved have the time (or flexibility in their schedule) to complete the tasks in this system?
the system	Do people involved have the skills and training to undertake the required tasks?
	Do they have confidence that they can do this and trust that it will work?
Reflexive Monitoring: The work that has to be done to	How do those involved judge the effectiveness and/or success of the system?
monitor the system and to	What impact has the new system had on them and their roles?
assess its effectiveness	Do they feel able to adapt how the system operates in the light of their experience of how it is working?

Table S1a. Summary of barriers to HIV VL monitoring at clinics* identified prior to receiving CQI intervention.

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	Gaps in 2015 eMTCT guidelines knowledge	Poor recording in MCR of VL performed	No lay counsellor – increased workload for ANC nurse	Other staffing challenges despite lay counsellor present	VL sampled in ART department (rather than ANC)	VL results filing delays	No system for tracking eligible patients for testing, or follow-up of results
Clinic 1	V	$\sqrt{}$	-	$\sqrt{}$	-	V	V
Clinic 2		\checkmark	$\sqrt{}$	-	-	\checkmark	\checkmark
Clinic 3a	$\sqrt{}$	\checkmark	-	$\sqrt{}$	-	\checkmark	\checkmark
Clinic 3b		\checkmark	-	-	-	\checkmark	\checkmark
Clinic 4	$\sqrt{}$	\checkmark	-	$\sqrt{}$	-	\checkmark	\checkmark
Clinic 5	$\sqrt{}$	\checkmark	-	$\sqrt{}$	-	\checkmark	\checkmark
Clinic 6	$\sqrt{}$	-	-	-	\checkmark	-	-

	VL indicator no longer required in DHIS register (March 2016)	Patients leave clinic before VL test can be performed due to queues	Small clinic building	No printer cartridge or toner [#]	No eMTCT monitoring forms	Computer not working
Clinic 1	-	$\sqrt{}$	V	$\sqrt{}$	-	-
Clinic 2	-	N/A^{\S}	-	\checkmark	$\sqrt{}$	-
Clinic 3a	-	N/A§	$\sqrt{}$	$\sqrt{}$	\checkmark	$\sqrt{}$
Clinic 3b	-	N/A§	$\sqrt{}$	$\sqrt{}$	\checkmark	$\sqrt{}$
Clinic 4	$\sqrt{}$	\checkmark	$\sqrt{}$	$\sqrt{}$	-	$\sqrt{}$
Clinic 5	√	N/A^{\S}	-	-	N/A§	-
Clinic 6	$\sqrt{}$	-	-	-	N/A^{\S}	$\sqrt{}$

^{*} Clinics are listed in order of randomisation

^{*}Lack of printer cartridge or toner at clinics resulted in shortage of monthly tally sheets (for DoH monitoring and evaluation) – tally sheets were therefore supplied by Hlabisa Hospital

[§] Information not available

"√": identified as a barrier at that clinic; "-": not a barrier as clinic already had appropriate procedures or staff in place.

Barriers listed were those identified during situational analysis of each clinic (during two-week lead-in to Intervention step)

ANC, antenatal care; CQI, Continuous Quality Improvement; DHIS, District Health Information System; eMTCT, elimination of mother-to-child transmission of HIV; MCR, maternity case record; eMTCT, elimination of mother-to-child transmission of HIV; VL, HIV viral load.

Table S1b. Summary of barriers to repeat HIV testing at clinics identified prior to receiving CQI intervention.

	Gaps in 2015 eMTCT guidelines knowledge	Poor recording in MCR of HIV tests performed	No lay counsellor – increased workload for ANC nurse	Other staffing challenges	No system for tracking eligible patients for testing	Patients attend first ANC visit in 3 rd trimester and do not return	Small clinic building	No printer cartridge or toner [#]
Clinic 1	√	-	-	√	√	N/A§	√	√
Clinic 2	\checkmark	-	\checkmark	\checkmark	\checkmark	\checkmark	-	\checkmark
Clinic 3a	\checkmark	-	-	\checkmark	\checkmark	N/A§	\checkmark	\checkmark
Clinic 3b	\checkmark	-	-	-	\checkmark	N/A§	\checkmark	\checkmark
Clinic 4	\checkmark	-	-	\checkmark	\checkmark	N/A^{\S}	\checkmark	\checkmark
Clinic 5	-	-	-	\checkmark	\checkmark	N/A§	-	-
Clinic 6	$\sqrt{}$	-	-	-	-	N/A§	-	$\sqrt{}$

^{*} Clinics are listed in order of randomisation

Barriers listed were those identified during situational analysis of each clinic (during two-week lead-in to Intervention step).

ANC, antenatal care; DHIS, District Health Information System; eMTCT, elimination of mother-to-child transmission of HIV; MCR, maternity case record.

[#]Lack of printer cartridge or toner at clinics resulted in shortage of monthly tally sheets (for DoH monitoring and evaluation) - tally sheets were therefore supplied by Hlabisa Hospital

[§] Information not available

[&]quot;\forall ": identified as a barrier at that clinic; "-": not a barrier as clinic already had appropriate procedures or staff in place.

Table S2. Summary of first ever PDSA start dates and dates of first PDSA cycle review in relation to intensive Intervention rollover date, per clinic.

Clinic number,	Intensive Intervention	First PDSA start	Review of first PDSA	A cycle	Time to PDSA start	Time to PDSA
(size, setting)	start date	date	Scheduled	Actual	_	review (from PDSA start)
Clinic 1 (medium, rural)	29 September 2015	01 October 2015	07 October 2015	21 October 2015	2 days	20 days
Clinic 2 (large, urban)	24 November 2015	25 November 2015	08 December 2015	27 January 2016	1 day	62 days
Clinic 3a* (small, rural)	26 January 2016	21 April 2016	Not documented	30 June 2016	86 days	70 days
Clinic 3b (very small, rural)	28 January 2016	04 February 2016	11 February 2016	09 February 2016	7 days	5 days
Clinic 4** (large, urban)	17 March 2016	19 May 2016*	Not documented	13 July 2016	63 days	55 days
Clinic 5 (small, rural)	18 May 2016	07 June 2016	14 June 2016	23 June 2016	20 days	16 days
Clinic 6 (medium, rural)	19 July 2016	26 July 2016	09 August 2016	22 September 2016	7 days	58 days

^{* &}quot;Gross" staffing shortages at clinic 3a; delays implementing PDSA likely due to unavailability of operational manager +/- professional nurse to kickstart activities

PDSA dates refer to activities relevant to HIV VL monitoring and/or repeat HIV testing (Figure 1, Change Ideas). General data quality improvement activities including PDSAs (e.g. checks for consistency between source documents) are not included in this table.

PDSA, Plan-Do-Study-Act cycle.

^{** &}quot;Extreme" staffing shortages were noted at this clinic which was frequently full. The operational manager was on annual leave at the start of the intervention, and the Acting operational manager was often providing clinical services and unable to attend CQI meetings.

Table S3. Summary of factors influencing delivery and 'normalisation' of the intervention as reported by the CQI mentors (CRH): Tailored Implementation of Chronic Diseases (TICD) framework.

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
Clinic 1 (29 Sep 2	2015)	1		
	Capacity for organisational change: mandate; leadership; regulations	Operational manager frequently absent from CQI meetings	• Sickness	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Individual health professional factors: cognitions (self-efficacy) Professional interactions: communication and influence		Competing priorities: district DoH meetings, clinical duties	
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			One professional nurse resigned months after study start	Difficult for staff on duty to find time to implement improvement activities
			Two professional nurses died in April/ May 2016	Staff turnover slowed uptake of CQI skills and consistency of implementation
			Pay day each month – many staff not on duty	
		DoH eMTCT monitoring forms not available	Delay in arrival of stock from district hospital by >6 months	Missed opportunities for testing patients eligible for VL monitoring

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
		No printer cartridge available	Delays in procurement of replacement cartridge	Difficult to implement data quality improvement activities
		Unable to telephone patients identified for tracing	Landline out of order	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes	Limited sharing of CQI skills between clinic CQI team members and other clinic staff	Only some clinic staff could attend CQI meetings given need to continue routine clinical activities in parallel	Delayed implementation of improvement activities throughout clinic
			Clinic CQI team selected by operational manager at start of intervention step	
			Lack of time to formally share CQI tools and disseminate improvement activities	
	Professional interactions: team processes	Staff turnover within clinic CQI team	Staffing shortages	Delayed implementation of improvement activities due to need for repeated training and progress updates
	Guidelines factors*: recommended behaviour (trialability)		Non- clinic CQI team staff keen to participate in CQI by direct interaction with CRH team	Better awareness of CQI tools throughout clinic at end of project
	Individual health professional factors: knowledge and skills	Staff not familiar with changes in guidelines for HIV VL monitoring and repeat HIV testing	Insufficient training on 2015 eMTCT guidelines	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for VL monitoring and repeat HIV testing
	Incentives and resources: information system		Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc)	Unreliable estimates of progress towards monthly targets
			Paper-based systems with multiple sources of information	
	Patient factors: needs; knowledge; motivation; behaviours.	Patients leave clinic before HIV VL test or repeat HIV test	Long queues	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
		Patients not attending scheduled follow-up visit for HIV VL monitoring or repeat HIV testing	Not answering phone	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
			Incorrect phone number provided	
			Contacted but do not attend scheduled appointment	

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
,		• Patient with elevated HIV VL ~3500 copies/mL	Not taking ART regularly as no regular food	Risk of MTCT of HIV and compromised maternal health
			Vomits if takes ART without food	Risk of ART drug resistance given viral replication in presence of drug selection pressure
			No income	
Clinic 2 (24 Nov	2015)	1	1	1
	Capacity for organisational change: mandate; leadership; regulations Individual health professional factors: cognitions (self-efficacy) Professional interactions: communication and influence	Operational manager frequently absent from CQI meetings	Competing priorities: district DoH meetings, clinical duties	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Individual health professional factors: cognitions (attitudes)	Staff would love to be involved in CQI	Prospect of improving service areas	Improved motivation to participate in CQI
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			Several staff on annual leave December 2015-January 2016	Difficult for staff on duty to find time to implement improvement activities

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
			 2 professional nurses retired 2 professional nurses resigned	
		Delay identifying eligible patients for HIV VL monitoring and repeat HIV testing (from clinic registers, monthly summaries, during capturing of VL results)	DC very busy due to competing clinical priorities	 Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing Difficulty finding time to implement improvement activities
		DoH eMTCT monitoring forms not available	No printer cartridge available for photocopying	Missed opportunities for testing patients eligible for VL monitoring
		 VL results not filed on time VL tracking notebook not completed 	ANC clinic rooms flooded due to heavy rains and inaccessible for VL results follow-up and filing	 Risk of MTCT if elevated HIV VL Missed opportunities for testing patients eligible for VL monitoring
		HIV test kits out of stock	Delays in procurement	 Missed opportunities for testing patients eligible for repeat HIV testing Delays in maternal HIV
	Professional interactions: team processes	Limited sharing of CQI skills between clinic CQI team members and other clinic staff	Only some clinic staff could attend CQI meetings given need to continue routine clinical activities in parallel	diagnosis and treatment Delay in implementation of improvement activities throughout clinic

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
			Clinic CQI team selected by operational manager at start of intervention step	
			Two professional nurses participating in clinic CQI team very motivated, but when absent CQI implementation varied	
			Lack of time to formally share CQI tools and disseminate improvement activities	
	Professional interactions: team processes	Staff turnover within clinic CQI team	Staffing shortages	Delayed implementation of improvement activities due to need for repeated training and progress updates
		Duplicate documentation of testing rates among eligible women (August 2016)	NGOs supporting VL monitoring and repeat HIV testing had separate logbooks	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
				Unreliable estimates of progress towards monthly targets
	Professional interactions: team processes	Lack of ownership of improvement activities	Staff turnover within clinic CQI team	Delayed implementation of improvement activities
	Individual health professional factors: cognitions		Operational manager unavailable to lead decisions and improvement activities	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing

Clinic number (intervention	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
start date)				nave been influenced
	Individual health professional factors: knowledge and skills; cognitions	Gaps in knowledge of guidelines criteria for HIV VL monitoring	Insufficient training on 2015 eMTCT guidelines	Missed opportunities for testing patients eligible for VL monitoring
				Inappropriately timed HIV VL monitoring
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc) Paper-based systems with	Unreliable estimates of progress towards monthly targets
			multiple sources of information	
	Patient factors: knowledge; motivation; behaviour	Improved patient awareness of VL —some patients return to follow-up results	Improved patient education by healthcare providers	Improved follow-up of results and timely management of virologic failure

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Capacity for organisational change: mandate; leadership; regulations	Operational manager did not join clinic CQI team	Competing priorities: district DoH meetings, clinical duties	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Individual health professional factors: cognitions (self-efficacy)			
	Professional interactions: communication and influence			
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			ART professional nurse resigned	Difficult for staff on duty to find time to implement improvement activities
		Computer not working March- November 2016	Delayed repairs	Backlog in capturing routine data including VL results on TIER.Net
				Missed opportunities for testing patients eligible for VL monitoring
		DoH eMTCT monitoring forms not available	Delay in arrival of stock from district hospital	Missed opportunities for testing patients eligible for VL monitoring
		HIV VL results not available in a timely manner	Delays in HIV VL results dispatch from district hospital	Missed opportunities for managing virologic failure in a timely manner

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
				Missed opportunities for testing patients eligible for VL monitoring
	Individual health professional factors: cognitions (self-efficacy)	HIV VL and repeat HIV testing tracking notebook not used for 3 months	HIV VL and repeat HIV testing tracking notebook ceased by district staff June-August 2016	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
			Clinic staff not empowered to justify its ongoing use to district-level staff	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
				Unreliable estimates of progress towards monthly targets
	Individual health professional factors: knowledge and skills	Staff not familiar with changes in guidelines for HIV VL monitoring and repeat HIV testing	Insufficient training on 2015 eMTCT guidelines	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		Poor documentation of tests performed and test results in source documents (patient)	Unreliable estimates of progress towards monthly targets

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
,			medical records, clinic registers etc) • Paper-based systems with multiple sources of information	
		HIV counselling and testing (general clinic) register not updated with patient's pregnancy status	NGO assisting clinic with HIV testing (September 2016) was not documenting pregnancy status in HIV counselling and testing register	Missed opportunities for testing patients eligible for repeat HIV testing
				Unreliable estimates of monthly testing targets for repeat HIV testing
				Unreliable estimates of progress towards monthly targets
	Patient factors: needs; knowledge; motivation; behaviours.	Rearrangement of antenatal patient clinic times to early morning (PDSA cycle to streamline workflow) unsuccessful	General clinic patients unwilling to attend clinic later in the morning – complaint lodged to Health Committee	Difficult for staff on duty to find time to implement improvement activities
		Patients not traceable	Incorrect phone number provided	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
Clinic 3b (28 Jan	2016)	1	1	<u>'</u>
	Capacity for organisational change: mandate; leadership; regulations	Operational manager frequently absent from CQI meetings	Competing priorities: district DoH meetings, clinical duties	Operational manager (leadership) presence required for decision making and

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Individual health professional factors: cognitions (self-efficacy) Professional interactions: communication and influence			ownership of improvement activities
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
		Improvement activities completed quickly	Lower clinical workload compared with other clinics	Easier to complete improvement activities
		DoH eMTCT monitoring forms not available	Delay in arrival of stock from district hospital	Missed opportunities for testing patients eligible for VL monitoring
		No printer cartridge available to print tally sheets or data charts	Delays in procurement of replacement cartridge	Difficult to implement data quality improvement activities
		Overcrowding during doctor's day at clinic	Small clinic	Possible missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
			Extra patient turnout for Old Age Pension authorisation	Difficult for staff on duty to find time to implement improvement activities
		Busy clinic during Ideal Clinic assessment preparation	Nationwide DoH project to improve quality of primary care entitled "Ideal Clinic"	Difficult for staff on duty to find time to attend CQI meetings
				Difficult for staff on duty to find time to implement improvement activities

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Professional interactions: team processes	Good team work and team spirit	Small clinic	Easier to complete improvement activities
	Professional interactions: team processes; communication and influence	Ill feelings when lower cadre staff (e.g. data capturer, lay counsellor) feedback new information to more senior staff in clinic	More senior staff (professional nurses, operational manager) unable to attend CQI meeting, therefore lower cadre staff provide updates	Difficult to disseminate new information
			Strong hierarchy in clinic	Delayed implementation of improvement activities
				May impact on sustainability
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		 Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc) Paper-based systems with multiple sources of information 	Unreliable estimates of progress towards monthly targets

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Individual health professional factors: knowledge and skills; cognitions	Gaps in knowledge of guidelines criteria for HIV VL monitoring at first ANC visit (for pregnant women who are HIV-positive)	Insufficient training on 2015 eMTCT guidelines	 Missed opportunities for testing patients eligible for VL monitoring Inappropriately timed VL monitoring
	Patient factors: needs; behaviours.	Clinic healthcare providers know community members very well	Deep rural clinic, many healthcare providers live in the same community as clients	Improved patient tracking and tracing
Clinic 4 (17 Mar	2016)			
	Capacity for organisational change: mandate; leadership; regulations Individual health professional factors: cognitions (self-efficacy) Professional interactions: communication and influence	Operational manager frequently absent from CQI meetings	Competing priorities: district DoH meetings, clinical duties	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			Antenatal professional nurse on maternity leave	Difficult for staff on duty to find time to implement improvement activities
			Increased demand on clinical services with nationwide rollout of Universal Test and Treat (UTT) September 2016	Staff turnover slowed uptake of CQI skills and consistency of implementation

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
,		DoH eMTCT monitoring forms not available	Delay in arrival of stock from district hospital	Missed opportunities for testing patients eligible for VL monitoring
		HIV test kits out of stock	Delays in procurement	Missed opportunities for testing patients eligible for repeat HIV testing
				Delays in maternal HIV diagnosis and treatment
		Limited space for sorting laboratory results	Small clinic building	Missed opportunities for testing patients eligible for HIV VL
				Difficult for staff on duty to find time to implement improvement activities
	Professional interactions: team processes	Staff turnover within clinic CQI team	Staffing shortages	Delayed implementation of improvement activities due to need for repeated training and progress updates
	Professional interactions: team processes	Good teamwork identifying eligible patients for VL monitoring and repeat HIV testing; bringing ART files to antenatal clinic	Good staff motivation to improve quality of patient care	Easier to complete improvement activities
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing

Clinic number	TICD framework category	Observation	Reason(s)	How intervention delivery may
(intervention start date)				have been influenced
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc)	Unreliable estimates of progress towards monthly targets
			Paper-based systems with multiple sources of information	
		HIV counselling and testing (general clinic) register not updated with patient's	NGO assisting clinic with HIV testing (September 2016) was not documenting pregnancy	Missed opportunities for testing patients eligible for repeat HIV testing
		pregnancy status	status in HIV counselling and testing register	Unreliable estimates of monthly testing targets for repeat HIV testing
				Unreliable estimates of progress towards monthly targets
	Individual health professional factors: knowledge and skills; cognitions	Decrease in repeat HIV testing after main professional nurse went on maternity leave	Other professional nurse was including HIV tests performed in a previous pregnancy	Missed opportunities for testing patients eligible for repeat HIV testing
			Insufficient training on 2015 eMTCT guidelines	

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Capacity for organisational change: mandate; leadership; regulations Individual health professional factors: cognitions (self-efficacy) Professional interactions: communication and influence	Operational manager frequently absent from CQI meetings	Competing priorities: district DoH meetings, clinical duties	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Incentives and resources: availability of necessary resources	Staffing shortages	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			Increased demand on clinical services with nationwide rollout of Universal Test and Treat (UTT) September 2016	Difficult for staff on duty to find time to implement improvement activities
			Several staff on annual leave December 2016 -January 2017	Staff turnover slowed uptake of CQI skills and consistency of implementation
		HIV test kits out of stock	Delays in procurement	Missed opportunities for testing patients eligible for repeat HIV testing
				Delays in maternal HIV diagnosis and treatment
		ART out of stock	Delays in procurement	Delays in initiating maternal ART
				Risk of MTCT of HIV and compromised maternal health

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
				Risk of ART drug resistance if break in already initiated treatment
		MCRs out of stock	Not recorded	Missed opportunities for clinical communication between ANC facility and delivery site including HIV status and treatment history
	Professional interactions: team processes; communication	Period of missed documentation (in HIV VL and repeat HIV testing notebook) of HIV VL performed and results, prior to results filing	Staff member in charge of this task went on annual leave without handover to colleagues	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes	Limited sharing of CQI skills between clinic CQI team members and other clinic staff	Only some clinic staff could attend CQI meetings given need to continue routine clinical activities in parallel	Delay in implementation of improvement activities throughout clinic
			Clinic CQI team selected by operational manager at start of intervention step	
			Lack of time to formally share CQI tools and disseminate improvement activities	
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		 Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc) Paper-based systems with multiple sources of information 	Unreliable estimates of progress towards monthly targets
	Patient factors: needs; behaviours.	Patients (including general clinic patients) demanding and attend overnight even for non- emergencies	Community aware of nurse on duty overnight, although same nurse continues working throughout the following day	Difficult for staff on duty to find time to attend CQI meetings
			Reluctance to stay in queues during the day	Difficult for staff on duty to find time to implement improvement activities
Clinic 6 (19 July	2016)	,	1	
	Capacity for organisational change: mandate; leadership; regulations Individual health professional factors: cognitions (self-efficacy)	Operational manager frequently absent from CQI meetings	 Competing priorities: district DoH meetings, clinical duties Retirement 	Operational manager (leadership) presence required for decision making and ownership of improvement activities

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
	Professional interactions: communication and influence			
	Incentives and resources: availability of necessary resources	Staffing shortages: gross	Pre-existing shortages	Difficult for staff on duty to find time to attend CQI meetings
			Several staff on annual leave December 2016 -January 2017	Difficult for staff on duty to find time to implement improvement activities
			Lay counsellor retraining as pharmacy assistant	Staff turnover slowed uptake of CQI skills and consistency of implementation
			Two professional nurses resigned	
			Increased demand on clinical services with nationwide rollout of Universal Test and Treat (UTT) September 2016	
		HIV test kits out of stock	Delays in procurement	Missed opportunities for testing patients eligible for repeat HIV testing
				Delays in maternal HIV diagnosis and treatment
	Professional interactions: team processes; communication	120 eligible patients for HIV testing missed during 3-month period	Lay counsellor sole custodian of HIV VL and HIV testing notebook	Missed opportunities for testing patients eligible for repeat HIV testing
			Lay counsellor in charge of repeat HIV testing	Delays in maternal HIV diagnosis and treatment

Clinic number (intervention start date)	TICD framework category	Observation	Reason(s)	How intervention delivery may have been influenced
			Lay counsellor on study leave during same 3-month period for retraining as pharmacy assistant	
	Individual health professional factors: knowledge and skills; cognitions; professional behaviour	Routine data quality challenges	Inconsistent application of data quality improvement activities – repeated training and supervision needed	Missed opportunities for testing patients eligible for VL monitoring and repeat HIV testing
	Professional interactions: team processes		Communication between different cadres of staff (each responsible for completing different source documents) needed	Unreliable estimates of monthly testing targets for HIV VL or repeat HIV testing
	Incentives and resources: information system		Poor documentation of tests performed and test results in source documents (patient medical records, clinic registers etc)	Unreliable estimates of progress towards monthly targets
			Paper-based systems with multiple sources of information	
		HIV counselling and testing (general clinic) register not updated with patient's	NGO assisting clinic with HIV testing (September 2016) was not documenting pregnancy	Missed opportunities for testing patients eligible for repeat HIV testing
		pregnancy status	status in HIV counselling and testing register	• Unreliable estimates of monthly testing targets for repeat HIV testing
				• Unreliable estimates of progress towards monthly targets

*"Guidelines" referred to here are CQI tools and activities

CRH CQI team could only identify eligible patients for both VL and HIV re-testing based on clinic-based documentation (clinic registers) of HIV testing and positive diagnoses, ART initiation and VL monitoring as MCRs are retained by patients until delivery. Discrepancies between data sources were noted in all clinics at the start of CQI: registers vs tally sheets vs monthly summaries. This may have influenced targeted testing rates per month as well as interpretation of progress over time.

Observations described here were documented after the Intensive intervention phase had commenced (after the situational analysis) – some factors persisted after the situational analysis (eg, knowledge gaps in guidelines).

ANC, antenatal care; ART, antiretroviral therapy; CQI, Continuous Quality Improvement; CRH, Centre for Rural Health, University of KwaZulu-Natal (CQI mentors); eMTCT, elimination of mother-to-child transmission of HIV; MCR, maternity case record (antenatal medical record); MTCT, mother-to-child transmission of HIV; NGO, non-governmental organisation; PDSA, Plan-Do-Study-Act cycle.

Table S4. Summary of factors influencing delivery and 'normalisation' of the intervention reported by clinic healthcare providers (interview quotes): Tailored Implementation of Chronic Diseases (TICD) framework.

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
Guidelines factors (CQI as a 'guideline'): feasibility of the recommended intervention; compatibility of the recommended behaviour with previous practice; effort; trialability; observability	Lay counsellor (LC3)	"It's different right now, especially I will speak about the viral load for the pregnant female. It's different right now 'cause before we were not sure if we're missing some people we were not taking bloods from them but now since we are recording, we can see the difference of how many people we were missing before since we were not recording."	Improved evidence of better practice may have motivated staff to continue clinical documentation or comple registers More time spent documenting may have been perceived as extra work
	Lay counsellor (LC1)	"It was not easy. Because I'm working in counselling, I'm the only one counsellor on weekend I have to come and complete the tasks that I have to do."	Difficult for staff on duty to find time to implement improvement activities
	Data capturer (DC3)	"Yeah, but it's (CQI data variables in MONARCH) different from the government books. So, it's difficult to there's some elements that MONARCH did wants us to work with. We don't have in the source documents, in the government source documents. So sometimes it's difficult to work ifwe don't have information."	More time spent documenting perceived as extra work Challenges maintaining extra source documents for patient tracking and tracing may threaten sustainability as not part of routine DoH monitoring & evaluation
	Data capturer (DC1)	"There is a problem in that because when MONARCH team came, they want each team [member] per category [to be at meetings] Yes, others that are left, they want to know that what is happening."	Non-clinic-CQI team unable to participate in CQI due to need to maintain clinical activities in parallel, were interested in CQI

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
	Enrolled nurse (EN1)	"Even yesterday they (CRH) came here and I wasn't there in that meeting because I was very busy helping on the ARTs, the sister on the ART side was not there so I have to go there."	Difficult for staff on duty to find time to attend CQI meetings Difficult for staff on duty to find time to implement improvement activities Staff turnover likely to have slowed uptake of CQI skills and consistency of implementation
	Professional nurse (PN1)	"It is effectiveI know it is effective. I know because I see"	Improved motivation to continue implementing CQI due to visible improvements in patient care
Individual health professional factors: knowledge of own practice; skills needed to adhere; cognitions (including motivation, self-efficacy);	Data capturer (DC3)	"It's (CQI) very interesting and it's very helpful, especially, it's like, it's an eye opening program. Like it helped us to understand also the guidelines."	Improved motivation to take up and continue CQI due to novelty of intervention, supportive approach, relevance to current practice (guidelines implementation)
	Data capturer (DC1)	"In our facility we have no operational managerThe one is acting and is busy like any other Sister. So we need someone who will told us what to do."	Operational manager (leadership) presence required for decision making and ownership of improvement activities
	Professional nurse (PN2)	"It was umm, it was interesting. We were able to see our shortfalls. We were able to, to see where we were doing wrong then, it helped us a lot."	Improved motivation to take up and continue CQI due to novelty of intervention, supportive approach, relevance to current practice (guidelines implementation)
			Non-judgmental approach to identifying gaps in clinical practice would have improved motivation
	Professional nurse (PN3)	"and they (CRH team) are so nice yes because they are trying to help us to improve our quality care to our patients, not that they are doing it for themselves they are doing it for us and for our patients. We appreciate although we are not doing well you see and we know."	Improved motivation to take up and continue CQI due to novelty of intervention, supportive approach, relevance to current practice (guidelines implementation) Non-judgmental approach to identifying gaps in clinical practice would have improved motivation

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
	Professional nurse (PN1)	"I don't want this MONARCH to leave usMONARCH opens our eyes."	Improved motivation to continue CQI due to supportive approach and relevance to current practice (guidelines implementation)
			Need for ongoing support (unable to continue without external support or motivation: limited self-efficacy)
	Professional nurse (PN3)	"In terms of recording you see yeah our recording is very poor, I cannot write that	Poor documentation would have resulted in inaccurate measures of target testing rates at clinics
		because now you will see our antenatal book that oh but we are trying maybe because there	Measurement bias for primary endpoints in impact evaluation
		are many things we are doing as I am allocated here I am looking after the first ANC, the second ANC and you see so it become very difficult."	Missed opportunities for testing, including risk of virologic failure or undiagnosed HIV
	Lay counsellor (LC2)	"to follow or to trace and track that woman I was do as I'm doing my job. She's coming or not	Understanding rationale of guidelines is key to rigorous implementation
		coming I was not give a damn but now I see the importance of why. I must make sure to get them and know where is she now"	Different staff cadres working in silos, limited team work in general – lay counsellor not responsible for clinical decision making
	Lay counsellor (LC1)	"It was not easy. Because I'm working in counselling, I'm the only one counsellor on weekend I have to come and complete the tasks that I have to do."	Difficult for staff on duty to find time to implement improvement activities
	Lay counsellor (LC3)	"It is good because we have learnt something that we were not doing here at the clinic, like the recording. Now we know that we have to record everything that we are doing. Yes."	Poor documentation would have resulted in inaccurate measures of target testing rates at clinics Measurement bias for primary endpoints in impact
		21.21 y ming man we are noting. 100.	evaluation Missed opportunities for testing, including risk of virologic failure or undiagnosed HIV

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
	Enrolled nurse (EN2)	"I can say they do have skills. I can give them 60% on thatMaybe it's they don't deal with those patients on daily basis as nurses. Honestly, the people who should be engaging themselves on this are the nurses, but then it's the people who are just doing minor, you see."	Limited implementation of CQI due to limited participation in CQI by professional nurses Lower cadre staff not empowered to transfer information up the hierarchy Lower cadre staff not involved in clinical decision making
	Enrolled nurse (EN2)	"You did a pledge; you can't say 'I solemnly pledge myself to the service of humanity' if you can't listen to other people when they say, 'ok, let's do this.'"	Intrinsic motivation (medical ethics) to provide good quality care
	Enrolled nurse (EN2)	"because they were giving a chance to talk about what we have just understood and they gave us a chance to do the tasks that they were laid on the table. They were able to explain what QI is about. It was not like they had to explain everything and no exercises."	Adult learning style – more interactive and interesting allows better engagement
	Operational manager (OM1)	"it is different because, I think we will have more healthy babies who are not infected with HIV because as I have said it was not easy for us to see those mothers, we would see them after their children became sick"	Intrinsic motivation (medical ethics) to provide good quality care Understanding rationale of eMTCT guidelines
	Nutritional advisor (NA2)	"it was the way they introduced themselves, so it's fine. They didn't came here to change things, but they told us that they are here to help."	Improved motivation to improve quality of care by feeling supported Non-judgmental approach by external CQI providers
	Nutritional advisor (NA1)	(needing more training) "Yes and viral load Others are taken viral load but not written down, yes."	Persistent gaps in documentation may have resulted in measurement bias
Patient factors	Enrolled nurse (EN2)	"if there is a patient that is for, that is due for re-testing, you find that if you do a follow-up on	Reduced successful tracking of patients for repeat HIV testing or VL monitoring

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
		that patient, the cell phone isn't working. The cell phone that the patient left isn't working or is always off, and when you find if you find the patient, the number that she gave wasn't hers. So you just have to leave a message; a message that you don't even know if it will be passed on."	Reduced motivation of staff to pursue the exercise of tracking patients if this is a frequent problem Risk of undiagnosed HIV or VL failure
	Data capturer (DC1)	"They (patients) are contactable although maybe for example; you give her return date of August then she decide to came in September."	Reduced motivation of staff to pursue the exercise of tracking patients if this is a frequent problem Risk of undiagnosed HIV or VL failure Measurement bias of targets
	Lay counsellor (LC1)	"The rate for viral load now I think it's because most of them they were starting clinic late, so now we have a understanding for early booking how to talk to them, yeah. And then how to manage those who's having a viral load, how to doing testing, it's easy for us now."	Late ANC booking as a barrier to timely HIV testing and VL monitoring Better understanding of how to manage patients (understanding of guidelines) facilitates better care
	Professional nurse (PN4)	"They (patients) don't (forget)when it's your day to come for results they come. If there is a problem they phone me all of them, they have my phone number."	Motivated patients facilitate results follow-up and timely management
Professional interactions: communication and influence; team processes	Enrolled nurse (EN2)	"I can say QI gave us team spirit. It made us be able to work together because the only thing that brings people together is the group workIf you are an individual, you do not benefit, you just do what you are supposed to do but if you are working in groups you benefit a lot."	Improved motivation to continue implementing CQI due to feelings of collegiality through group work
	Professional nurse (PN2)	"Like MONARCH, MONARCH register, it ends up being used by a professional nurse and a data	Improved motivation to continue implementing CQI due to feelings of collegiality through group work

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
		capturer. Others are continuing with the other stuff andwe're yes, we're quite a team."	
	Data capturer (DC1)	"In our facility we have no operational managerThe one is acting and is busy like any other Sister. So we need someone who will told us what to do."	Operational manager (leadership) presence required for decision making and ownership of improvement activities
Incentives and resources: availability of necessary resources; non-financial incentives and disincentives; continuing education system; assistance	Enrolled nurse (EN1)	"Yeah is become difficult to get the QIT all of them at the same time when you have to have a meeting because the lay counsellor its only one, no there are two but the other one is doing a training for pharmacy assistantthe lay counsellor is the one who have to do ongoing counselling, adherence, counselling, testing and everything so you only find that "ooohh today is a QIT meeting" but we try to attend the meeting."	Difficult for staff on duty to find time to attend meetings or implement improvement activities
	Enrolled nurse (EN1)	"they must appoint new counsellors because people are there outsideif there is no counsellors in the clinic it won't work, it won't because as a nurse I have a job to do, vital signs, injections, what what"	Reluctance by other staff to take on additional duty of HIV counselling and testing due to increased workload Absent lay counsellors during study leave or annual leave resulted in fewer repeat HIV tests being performed (noted by CRH in reports)
	Enrolled nurse (EN2)	"The in-service training that we do as the clinic is far more different of the QIbecause we just do it for the sake of doing it. Not that maybe it is important or we will benefit from itWhile you on the other hand as MONARCH, you come up with something new. So something new is interesting."	Improved motivation to learn and participate in the CQI intervention due to novelty

TICD framework category	Interview respondent*	Quote	How intervention delivery may have been influenced
	Operational manager (OM1)	"I can say they (CRH team) are nice people, they are able to talk and you understand clearly what they are saying. But it did work but I was not always with them, to be clear."	Improved motivation to continue implementing CQI due to feeling supported by the external CQI providers
	Lay counsellor (LC1)	"just to say thank you for giving us the support to our team. It helped us a lot."	Improved motivation to continue implementing CQI due to feeling supported by the external CQI providers
	Lay counsellor (LC1)	"I think now I can because on that time we're having a huge number of patient for testing that we are doing result testing. So it was hard for us, from now it's easy cause we having the an NGO that's helping us with testingIt's Humana."	Improved motivation to continue implementing CQI due to feeling supported by NGO for HIV testing Reduced motivation to participate in CQIdue to heavy workload
Capacity for organisational change: priority of necessary change	Operational manager (OM1)	"You know people have a resistance to change but if you keep on emphasizing the importance of why are we doing this, they end up doing it."	Emphasizing rationale for behavioural change may be a motivator
	Lay counsellor (LC3)	"Before, it wasn't easy because they were we were seeing like you are adding more job on top of what we were doingBut right now since we are getting used, it's getting easy."	Perceived extra workload would have resulted in resistance to engaging with CQI
	Professional nurse (PN1)	"People will continue, except when because there is a change over. You change to other clinics maybe, some people go to training, the new one comes I don't know what will happen there but at the moment I think they will."	Staff turnover will reduce available expertise and may demotivate ongoing implementation of CQI activities
	Enrolled nurse (EN2)	"First few months will be good, we will do it. Maybe after three months, I don't think we will be doing it, not unless you will come and check We need a push. "	Need for external motivation to continue with CQI

TICD framework category	Interview	Quote	How intervention delivery may have been
	respondent*		influenced
	Data capturer (DC1)	"In our facility we have no operational managerThe one is acting and is busy like any other Sister. So we need someone who will told us what to do."	Operational manager (leadership) presence required for decision making and ownership of improvement activities

^{*}Clinic details are not provided in order to maintain anonymity of respondents, given the small number of facilities and small number representing each staff cadre. Staff numbers are not in order of clinic randomisation

ANC, antenatal care; CQI, Continuous Quality Improvement; CRH, Centre for Rural Health, University of KwaZulu-Natal (CQI mentors); DC, data capturer; eMTCT, elimination of mother-to-child transmission of HIV; NGO, non-governmental organisation.