Strategies to improve control of sexually transmissible infections in remote Australian Aboriginal communities: a stepped-wedge, cluster-randomised trial

*James Ward, Rebecca J Guy, Alice R Rumbold, Skye McGregor, Handan Wand, Hamish McManus, Amalie Dyda, Linda Garton, Belinda Hengel, Bronwyn J Silver, Debbie Taylor-Thomson, Janet Knox, Basil Donovan, Matthew Law, Lisa Maher, Christopher K Fairley, Steven Skov, Nathan Ryder, Elizabeth Moore, Jacqueline Mein, Carole Reeve, Donna Ah Chee, John Boffa, John M Kaldor, on behalf of the STRIVE investigators**

Summary

Background Remote Australian Aboriginal communities have among the highest diagnosed rates of sexually transmissible infections (STIs) in the world. We did a trial to assess whether continuous improvement strategies related to sexual health could reduce infection rates.

Methods In this stepped-wedge, cluster-randomised trial (STIs in remote communities: improved and enhanced primary health care [STRIVE]), we recruited primary health-care centres serving Aboriginal communities in remote areas of Australia. Communities were eligible to participate if they were classified as very remote, had a population predominantly of Aboriginal people, and only had one primary health-care centre serving the population. The health-care centres were grouped into clusters on the basis of geographical proximity to each other, population size, and Aboriginal cultural ties including language connections. Clusters were randomly assigned into three blocks (year 1, year 2, and year 3 clusters) using a computer-generated randomisation algorithm, with minimisation to balance geographical region, population size, and baseline STI testing level. Each year for 3 years, one block of clusters was transitioned into the intervention phase, while those not transitioned continued usual care (control clusters). The intervention phase comprised cycles of reviewing clinical data and modifying systems to support improved STI clinical practice. All investigators and participants were unmasked to the intervention. Primary endpoints were community prevalence and testing coverage in residents aged 16–34 years for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. We used Poisson regression analyses on the final dataset and compared STI prevalences and testing coverage between control and intervention clusters. All analyses were by intention to treat and models were adjusted for time as an independent covariate in overall analyses. This study was registered with the Australia and New Zealand Clinical Trials Registry, ACTRN12610000358044.

Findings Between April, 2010, and April, 2011, we recruited 68 primary care centres and grouped them into 24 clusters, which were randomly assigned into year 1 clusters (estimated population aged 16–34 years, n=11 286), year 2 clusters (n=10 288), or year 3 clusters (n=13 304). One primary health-care centre withdrew from the study due to restricted capacity to participate. We detected no difference in the relative prevalence of STIs between intervention and control clusters (adjusted relative risk [RR] 0·97, 95% CI 0·84–1·12; p=0·66). However, testing coverage was substantially higher in intervention clusters (22%) than in control clusters (16%; RR 1·38; 95% CI 1·15–1·65; p=0·0006).

Interpretation Our intervention increased STI testing coverage but did not have an effect on prevalence. Additional interventions that will provide increased access to both testing and treatment are required to reduce persistently high prevalences of STIs in remote communities.

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South Australian Health and Medical Research Institute, Adelaide, SA, Australia (J Ward PhD, A R Rumbold PhD, J Knox MMed STI/HIV); **Flinders University, Adelaide, SA, Australia** (J Ward); **Kirby Institute, UNSW Sydney, Sydney, NSW, Australia** (Prof R J Guy PhD, S McGregor PhD, H Wand PhD, H McManus PhD, A Dyda PhD, L Garton MAP, B Hengel PhD, Prof B Donovan MD, Prof M Law PhD, Prof L Maher PhD, Prof J M Kaldor PhD); **Samson Institute, Adelaide University, Adelaide, SA, Australia** (A R Rumbold); **Menzies School of Health Research, Darwin, NT, Australia** (A R Rumbold, D Taylor-Thomson BPharm); **Macquarie University, Sydney, NSW, Australia** (A Dyda); **Northern Territory Department of Health, Darwin, NT, Australia** (L Garton, S Skov MBBS, N Ryder MPHTM); **Apunipima Cape York Health Council, Cairns, QLD, Australia** (B Hengel); **Central Australian Aboriginal Congress, Alice Springs, NT, Australia** (B J Silver PhD, D Ah Chee GCert Mgmt, J Boffa MPH); **Sydney Sexual Health Centre, Sydney, NSW, Australia** (Prof B Donovan); **Melbourne Sexual Health Centre, Melbourne, VIC, Australia** (Prof C K Fairley PhD); **Central Clinical School Monash University, Melbourne, VIC, Australia** (Prof C K Fairley); **Hunter New England Health Service, Newcastle, NSW, Australia** (N Ryder); **Aboriginal Medical Services Alliance, Darwin, NT, Australia** (E Moore MBBS); **Wuchopperen**

Introduction

The remote communities of central and northern Australia are the traditional homelands of Aboriginal people, who have lived in such environments for over 40 000 years, maintaining cultures that are among the longest surviving globally.[1] Of approximately 700 000 Aboriginal people in Australia, an estimated 20% live in remote and very remote communities. The median age of Aboriginal people is younger than the non-Indigenous population (20 years *vs* 36 years) and approximately 40% of the population is aged 16–34 years.[2]

Contact with settlers occurred as recently as the 1980s for some communities.[3] A major consequence of contact with settlers has been an expanding burden of infectious

Aboriginal Health Service, Cairns, QLD, Australia (J Mein MBBS)**; and James Cook University, Cairns, QLD, Australia** (C Reeve MBBS)

Correspondence to: Associate Prof James Ward, Aboriginal Health Equity Theme, South Australian Health and Medical Research Institute, Adelaide, 5001 SA, Australia
james.ward@sahmri.com

Research in context

Evidence before this study

Before commencing the STRIVE trial, we published a review of available literature that had investigated the effect of sexually transmissible infection (STI) programmes based on increased testing and treatment through primary health-care services in remote Aboriginal communities in Australia. We searched PubMed, Google Scholar, Infonet, Cochrane Central Register of Controlled Trials, and the Australian and New Zealand Clinical Trials Registry from database inception until April 30, 2011, for publications in English, using variations of the terms "Aboriginal", "programs", and "STI". We also searched conference proceedings and bulletins during this period. We found four STI programmes in remote communities. The programmes that consistently achieved high levels of testing coverage, generally through strong and ongoing community engagement processes and standardised clinical protocols, were able to reduce prevalence of STIs. These findings led us to develop a quality improvement intervention that might be capable of large-scale sustainable implementation. We also did an international review of STI quality improvement interventions, and found that two previous trials had been done, one in Tanzania and one in Peru, that had investigated STI quality improvement strategies on a large scale. These trials found an improvement in STI prevalence, but were in settings very different to remote Australian communities. Additionally, we reviewed the international literature to identify methodological strategies for programmes that would be a good fit for the remote Australian setting. The stepped-wedge design seemed to be the most practical and ethical approach for investigating the implementation of a large-scale quality improvement strategy for STI control because it allowed all participating sites to receive the intervention.

Added value of this study

The STRIVE trial was the first large-scale investigation of clinical quality improvement strategies for the control of STIs in remote Aboriginal community settings. Our quality improvement strategies improved testing coverage by 38%, across a large number of communities in diverse settings. However, this improvement in coverage was not sufficient to reduce the community prevalence of infection over the timeframe of the study.

Implications of all the available evidence

Because quality improvement strategies are insufficient to address the unacceptably high prevalence of STIs in remote communities in Australia, the task remains to identify additional mechanisms of effective control for these infections. New strategies being trialled include the use of point-of-care testing and financial incentives for young people to seek testing. One jurisdiction in Australia that participated in the STRIVE trial has adopted quality improvement as a core strategy of its STI control programme in all of its government-run clinics that are servicing remote communities. Whether longer term or wider use of these strategies than discussed here will increase the uptake of testing and treatment, and ultimately reduce prevalence of STIs, remains to be seen.

and non-communicable diseases, which has had a profound effect on Aboriginal peoples' wellbeing and livelihoods.[4] Sexually transmissible infections (STIs) are a particular area of health disadvantage for these communities, with the prevalence and incidence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in young people among the highest in the world.[5,6] Furthermore, *Trichomonas vaginalis* is endemic among women[7] and *Treponema pallidum* (syphilis) has resurged after almost being eliminated in remote Aboriginal communities and has now been declared as a major outbreak spanning several Australian jurisdictions.[8] These STIs are easily detected by accurate diagnostic tests and curable after treatments, both of which are routinely available and funded under Australia's health system. Control strategies have therefore been based on the principle of test and treat, following local guidelines.[9]

Primary health-care centres that serve populations in remote communities are typically staffed by nurses or Aboriginal health practitioners, or both.[10] Larger communities might have on-site doctors, but for most communities doctors visit periodically. STI control in remote communities is a key responsibility of primary health care. Clinical guidelines relating to STIs and clinicians specially trained in sexual health are available to support remote primary health-care clinicians.[9] Despite this support, STI control outcomes such as testing rates, follow-up, and management in primary health care are far from optimal in these remote areas.[11,12]

One way to enhance and embed STI control efforts in primary health care could be via implementation of continuous quality improvement strategies. These strategies aim to identify and minimise barriers to achieving clinical best practice and involve repeated cycles of audits and self-assessment, followed by implementation and evaluation of system change.[13,14] Supported by mathematical modelling,[15] we hypothesised that a sexual health continuous quality improvement programme could substantially reduce community prevalence of STIs if coverage of testing and treatment attained sufficiently high levels. The STRIVE trial (STIs in remote communities: improved and enhanced primary health care) was a stepped-wedge, cluster-randomised trial to assess the effect of a continuous quality improvement programme in remote communities of Australia. We have previously reported the protocol[16] and baseline findings[6,17] and now present the main trial outcomes.

Methods

Study design and clusters

In this stepped-wedge, cluster-randomised trial, we assessed an externally supported, sexual health continuous quality improvement programme.[16] The programme was based on components deemed necessary to control STIs in the primary health-care setting and the trial aimed to increase testing coverage and timely treatment for *C trachomatis*, *N gonorrhoeae*, and *T vaginalis*, consistent with clinical guidelines,[9] particularly among people aged 16–24 years who are at the highest risk of STIs. The continuous quality improvement programme introduced by the trial was supported by four regional trial coordinators, who worked in partnership with regional sexual health coordinators already in place. The stepped-wedge, cluster-randomisation design ensured that all participating health centres would participate in the continuous quality improvement programme during the trial.

We recruited primary health-care centres across Australia, and communities were eligible to participate if they were classified as very remote according to Australian Bureau of Statistics criteria,[2] had a population of predominantly Aboriginal people, and only had one primary health-care centre serving the population. We approached the management of health-care centres in communities that met eligibility criteria.

STRIVE was approved by the Central Australian Human Research Ethics Committee (HREC), the Cairns and Hinterland HREC, the HREC of the Northern Territory Department of Health and Menzies School of Health Research, the University of New South Wales HREC, the Western Australian Aboriginal Health Information Ethics Committee, and the Western Australian Country Health Service Board Research Ethics Committee. Participation agreements were signed by all primary health-care centres before trial commencement, authorising use of routine clinical and laboratory data, under strict conditions of confidentiality and de-identification of individuals and communities.

Randomisation and masking

After enrolment, the primary-health care centres were grouped into 24 clusters on the basis of geographical proximity to each other, population size, and Aboriginal cultural ties including language connections. Eight of 24 clusters were randomly assigned to the intervention phase by a study statistician (HW) each year during the trial (ie, year 1 clusters, year 2 clusters, and year 3 clusters). Randomisation was done independently by the trial statistician (HW) using a minimisation scheme to balance the allocation of the 24 clusters as much as possible with respect to geographical region, population size (below and above the median), and baseline level of STI testing (below and above the median).[18,19] The allocation of clusters to commence the intervention in year 1, 2, or 3 was done using a computer-generated randomisation algorithm. Primary health-care centres and patients in each cluster were not masked to intervention allocation due to the nature of the intervention.

Procedures

The continuous quality improvement programme intervention has been described in detail previously.[16] Four trial coordinators (BH, BJS, DT-T, JK) supported continuous quality improvement activities in participating primary health-care centres beginning once the centre was randomly assigned to commence the intervention, with annual visits to each health centre by the coordinator, most often accompanied by the regional sexual health coordinator. At each annual visit, all heath centre staff were invited to participate in discussions about the trial. Specifically, they were invited to review and discuss their own health centre's data for the preceding year related to the key quantitative indicators of sexual health clinical practice as detailed in the Outcomes section and to complete an assessment of health centre systems in six broad areas as shown in the panel. Through group discussion, the staff rated the performance of their centre across these six areas on a scale of 0 to 11, with 11 indicating a fully developed system. This assessment was to identify strengths and gaps for STI control at a health-centre level and address these areas as necessary so that changes at the system level could be monitored over time. The system assessment was adapted from a large-scale primary health-care

Panel: Components and ideal scenarios of the sexual health continuous quality improvement system assessment

Health centre staff rated the performance of their centre across the following key areas on a scale of 0 to 11:

- Health hardware: all necessary supplies for the diagnosis and treatment of STIs and other sexual-health-related conditions are available to clinicians
- Clinical services: the clinic is arranged in a manner that facilitates sexual health consultations, including assurance of privacy and confidentiality, and gender-specific clinicians as needed
- Electronic medical records: information is routinely and systematically entered in an accessible computerised information system
- Health promotion: mechanisms are in place to provide education to community members about STIs, their prevention and treatment, and the benefits of accessing testing
- Organisational commitment to sexual health: sexual health is a designated priority area for the health service management and clinical staff, with appropriate training, protocols, and support
- Surveillance and evaluation: the service regularly collects, reviews, and acts on quantitative and qualitative information related to its sexual health clinical activities

STIs=sexually-transmissible infections.

chronic disease continuous quality improvement project.[13] After the assessment, we invited the health centre staff to develop an action plan to improve the delivery of sexual health services in the forthcoming year on the basis of the data report and outcomes of the systems assessment. Trial coordinators also provided informal training in sexual health throughout the trial. Health centre staff were also provided with reports every 6 months on STI clinical service activity, followed by a meeting to discuss progress against the action plan. Coordinators undertook follow-up phone calls with each health centre at 3 and 9 months during the intervention phases and were also available at other times during the intervention phase for additional support. Health centres were also offered financial incentives, as previously described in our study protocol.[16] We used a formula that provided payments for achievement of specified clinical activities, and funding for small-scale health promotion activities to raise awareness of sexual health and STI testing in the target population.

Routine practice in all primary health-care centres took place according to clinical guidelines that recommend offering a test for *C trachomatis*, *N gonorrhoeae*, and *T vaginalis* at least once every 12 months for all sexually active people aged 16–34 years; testing and treating people immediately who present with one or more STI syndromes (urethral discharge, genital ulcer, or lower abdominal pain in women), or being a contact of someone with an STI, or both; offering a repeat test 2–4 months after treatment for any of these infections; and following up named recent sexual contacts to offer testing and treatment.[9,20,21] All samples collected (urine for men and urine or swabs for women depending on local guidelines) were sent to nationally accredited diagnostic laboratories for routine testing via nucleic acid technology. Although not the focus of this trial, primary health-care centres also offered syphilis and HIV testing as per clinical guidelines.

At baseline, almost all primary health-care centres used one of four patient electronic medical record (EMR)

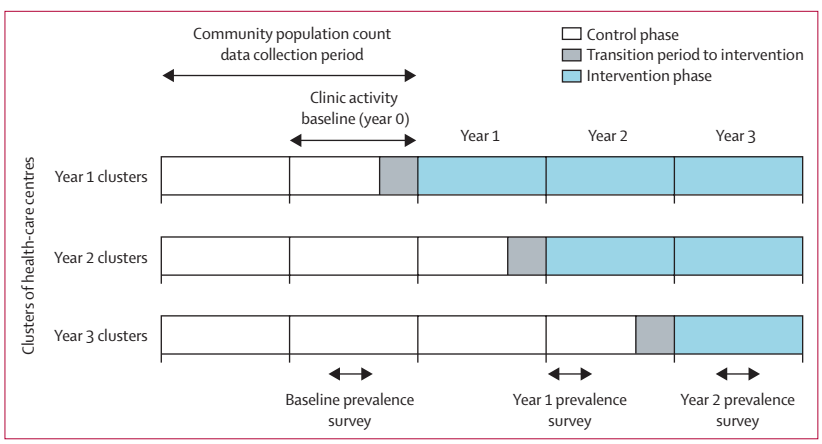

Figure: **Schematic of the STRIVE stepped-wedge, cluster-randomised trial**
STRIVE=STI in remote communities: improved and enhanced primary health care.

	Year 1 clusters (n=8)		Year 2 clusters (n=8)		Year 3 clusters (n=8)		Total (n=24)	
	Population	Number tested (%)	Population	Number tested (%)	Population	Number tested (%)	Population	Number tested (%)
16–19 years								
Females	1121	280 (25%)	1176	292 (25%)	1362	359 (26%)	3659	921 (25%)
Males	1060	165 (16%)	959	130 (14%)	1278	172 (13%)	3297	467 (14%)
Both sexes	2181	445 (20%)	2135	422 (20%)	2640	531 (20%)	6956	1398 (20%)
20–24 years								
Females	1540	429 (28%)	1523	401 (26%)	1869	447 (24%)	4932	1277 (26%)
Males	1315	240 (18%)	1267	193 (15%)	1796	251 (14%)	4378	684 (16%)
Both sexes	2855	669 (23%)	2790	594 (21%)	3665	698 (19%)	9310	1961 (21%)
25–29 years								
Females	1741	400 (23%)	1572	329 (21%)	1913	433 (23%)	5226	1162 (22%)
Males	1494	234 (16%)	1309	169 (13%)	1808	195 (11%)	4611	598 (13%)
Both sexes	3235	634 (20%)	2881	498 (17%)	3721	628 (17%)	9837	1760 (18%)
30–34 years								
Females	1605	316 (20%)	1348	263 (20%)	1657	311 (19%)	4610	890 (18%)
Males	1410	181 (13%)	1133	135 (12%)	1621	184 (11%)	4164	500 (12%)
Both sexes	3015	497 (16%)	2481	398 (16%)	3278	495 (15%)	8774	1390 (16%)
Total population								
Females	6007	1425 (24%)	5619	1285 (23%)	6801	1550 (23%)	18 427	4260 (23%)
Males	5279	820 (16%)	4668	626 (13%)	6503	802 (12%)	16 450	2249 (14%)
Both sexes	11 286	2245 (20%)	10 287	1912 (19%)	13 304	2352 (18%)	34 877	6509 (19%)

Data are n or n (%). Community population were residents aged 16–34 years. Number of people tested is the number tested in the 12 months before the community health service joined the trial. STI=sexually transmissible infection. STRIVE=STI in remote communities: improved and enhanced primary health care.

Table 1: **Proportion of community population tested for STIs in baseline year in STRIVE community clusters, by age group and sex**

systems. The four EMR systems could provide counts of patients seen by time period, Aboriginal status, age, and sex, but not by STI control measures relevant to this trial. Thereafter, software providers for each EMR system were commissioned to develop standardised templates for recording test requests, results, symptoms, and treatment outcomes to encourage adherence to guidelines and for ongoing review of data. All EMR data were provided by all primary health-care centres for the period of Jan 1, 2009, to Dec 31, 2014. These templates increased completeness and consistency of data across primary health-care centres and aided in minimising any cluster-level differences in data capture, which might have introduced bias into results if correlated with study outcomes.

All laboratories serving the participating primary health-care centres also had computerised systems and provided de-identified patient-level data on testing and test results, including dates and the age and sex of those tested. These records were combined with information from EMR systems on the number of individuals and consultations to prepare reports on the proportion of community members who had an STI test (testing coverage), the proportion who had a positive result, and the proportion of those with a positive result who had a retest 2–4 months after the first test as per clinical guidelines.

Completeness of data was assessed regularly for both laboratory and clinic data, and we did audits of data coding collection procedures if we found a substantial discrepancy between laboratory and clinic data.

Outcomes

The primary outcomes, assessed at cluster level, were prevalence of *C trachomatis, N gonorrhoeae,* and *T vaginalis,* or a combination of these, in people aged 16–34 years, and performance in clinical service activity based on the best practice indicators. Prevalence of *C trachomatis, N gonorrhoeae*, and *T vaginalis* was obtained via clinic-based surveys of attendees, using urine samples for men, and urine or genital swabs for women, tested using nucleic acid technologies. We assessed prevalence in each cluster during the pre-intervention period, and twice more at 1 year and 2 years after trial commencement. We did this assessment by offering STI testing to 50 females and 50 males aged 16–34 years who attended health centres in each of the 24 clusters during the designated prevalence periods, unless they had been offered testing within the past 3 months. For clusters with multiple health centres, the target number of 100 tests were allocated proportionately to health centres by community population size.

The performance of clinical service activity was measured by the proportion of Aboriginal residents aged 16–34 years who had at least one test for *C trachomatis, N gonorrhoeae,* and *T vaginalis* during the year (ie, STI testing coverage); the proportion of health service patients presenting with STI symptoms during the year who received immediate treatment; the proportion of Aboriginal residents diagnosed by laboratory test with *C trachomatis, N gonorrhoeae,* or *T vaginalis* who were treated within 7 days of the test result being received from the laboratory; the proportion of patients found by laboratory test to have *C trachomatis, N gonorrhoeae*, or *T vaginalis* who had a test for reinfection 2–4 months after diagnosis; and the proportion of named sexual contacts of those with a positive test result who were

	Year 1 prevalence survey			Year 2 prevalence survey		
	Number of positive diagnoses	Number tested	Crude prevalence	Number of positive diagnoses	Number tested	Crude prevalence
Females						
Any STI						
Control clusters	205	876	23%	96	526	18%
Intervention clusters	82	430	19%	207	967	21%
C trachomatis						
Control clusters	73	871	8%	19	526	4%
Intervention clusters	33	428	8%	72	963	8%
N gonorrhoeae						
Control clusters	50	870	6%	27	524	5%
Intervention clusters	21	429	5%	52	963	5%
T vaginalis						
Control clusters	133	746	18%	73	433	17%
Intervention clusters	59	402	15%	138	921	15%
Males						
Any STI						
Control clusters	79	494	16%	36	291	12%
Intervention clusters	59	343	17%	98	653	15%
C trachomatis						
Control clusters	48	494	10%	17	290	6%
Intervention clusters	26	342	8%	47	653	7%
N gonorrhoeae						
Control clusters	38	492	8%	22	291	8%
Intervention clusters	24	343	7%	52	653	8%
T vaginalis						
Control clusters	10	368	3%	7	229	3%
Intervention clusters	25	316	8%	25	630	4%
Both sexes						
Any STI						
Control clusters	284	1370	21%	132	817	16%
Intervention clusters	141	773	18%	305	1620	19%
C trachomatis						
Control clusters	121	1365	9%	36	816	4%
Intervention clusters	59	770	8%	119	1616	7%
N gonorrhoeae						
Control clusters	88	1362	6%	119	1616	7%
Intervention clusters	45	772	6%	104	1616	6%
T vaginalis						
Control clusters	143	1114	13%	80	662	12%
Intervention clusters	84	718	12%	163	1551	10%

Year 1 and 2 are defined in relation to the start of the intervention. STI=sexually transmissible infection.

Table 2: **Crude STI prevalence of *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* detected in the year 1 and year 2 surveys, by cluster phase, STI type, and sex**

	Year 1*	Year 2†	Overall‡	p value
Females				
Any STI	0·87 (0·75–1·00)	1·13 (0·96–1·34)	0·94 (0·83–1·05)	0·26
C trachomatis	0·97 (0·62–1·54)	1·90 (1·12–3·24)	1·24 (0·89–1·73)	0·21
N gonorrhoeae	0·87 (0·35–2·13)	1·05 (0·54–2·01)	0·94 (0·51–1·74)	0·84
T vaginalis	0·86 (0·61–1·20)	0·88 (0·65–1·18)	0·83 (0·66–1·05)	0·13
Males				
Any STI	1·09 (0·68–1·73)	1·09 (0·68–1·76)	1·09 (0·77–1·54)	0·64
C trachomatis	0·89 (0·57–1·39)	1·14 (0·58–2·25)	1·03 (0·68–1·58)	0·88
N gonorrhoeae	0·91 (0·37–2·21)	1·02 (0·45–2·33)	0·96 (0·49–1·88)	0·90
T vaginalis	3·07 (1·33–7·09)	1·03 (0·64–1·66)	1·81 (0·99–3·31)	0·054
Both sexes				
Any STI	0·92 (0·75–1·12)	1·11 (0·88–1·39)	0·97 (0·84–1·12)	0·66
C trachomatis	0·97 (0·66–1·42)	1·44 (0·89–2·31)	1·15 (0·84–1·58)	0·39
N gonorrhoeae	0·92 (0·41–2·05)	1·00 (0·53–1·91)	0·94 (0·54–1·64)	0·84
T vaginalis	0·92 (0·65–1·31)	0·86 (0·63–1·18)	0·88 (0·68–1·13)	0·31

Data are relative risk, with 95% CIs in parentheses. All comparisons are adjusted for baseline (before intervention) prevalence, and a relative risk of >1 indicates a higher STI prevalence in intervention clusters than in control clusters. STI=sexually transmissible infection. *Comparing prevalence in year 1 intervention phase clusters with year 2 and year 3 control phase clusters. †Comparing prevalences in year 1 and 2 intervention phase clusters with year 3 control phase clusters. ‡Comparing prevalence in intervention phase clusters with control phase clusters.

Table 3: **Adjusted relative prevalence of *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* for the intervention clusters versus control clusters, by sex**

followed up, tested, and treated. Data for this endpoint were obtained from a combination of laboratory and health centre EMR systems.

For STI testing coverage, the community population was defined as the average annual number of regular patients who had a health-related visit in the each of the past 2 years, working back from the date the clinic was determined to have entered the trial. This is a standard approach in Aboriginal primary health care to account for a population that is mobile, with people often staying for extended periods in other remote communities.[22] Clinical reports were cross-checked with laboratory records to provide a count of the number of individuals tested in each calendar period. The other performance activity indicators were inconsistently recorded across the EMR systems, so could not be accurately analysed and are not reported here.

Statistical analysis

We did sample size calculations using the method of Hayes and Bennett.[23] With an assumed *C trachomatis* and *N gonorrhoeae* prevalence of 15% in the population aged 16–34 years, based on a previous review of STI programmes in remote communities,[24] and an average 65% uptake for the prevalence surveys in each cluster, 14 clusters were required to detect a reduction to 7·5% in the prevalence of *C trachomatis* and *N gonorrhoeae* prevalence in intervention clusters with 80% power, two-sided α=0·05, with no adjustments for multiple comparisons, and equal numbers of clusters in each group.

We hypothesised that the continuous quality improvement intervention would lead to an improvement in STI-related clinical performance and a reduction in community prevalence of the STIs under investigation. Under the published statistical plan, analyses of the primary endpoints[16] involved two separate comparisons (figure). For prevalence endpoints, the two comparisons were based on the prevalence surveys done 1 year and 2 years after the commencement of the intervention (ie, year 1 and year 2 surveys) and adjusted for prevalence in the baseline survey. Also, for communities that undertook prevalence assessments when they were in the control group (eg, year 2 and year 3 clusters), the testing count for the prevalence period was subtracted from the count for that year and replaced by an estimated count for the period based on the corresponding time period immediately before the prevalence period to avoid overcounting due to the fact the surveys were being done. For testing coverage endpoints, two comparisons were made to measure relative changes in testing: these were year 1 intervention phase clusters versus year 2 and year 3 control phase clusters combined, and year 1 and year 2 intervention phase clusters combined versus year 3 control phase clusters. Both comparisons were adjusted for time period as an independent variable, including baseline performance at the cluster level on the basis of data for the 12 months before intervention initiation in the year 1 intervention phase clusters, 12–24 months before for the year 2 intervention clusters, and 24–36 months before for the year 3 clusters. To facilitate interpretation, we undertook additional analyses that combined the outcomes from the two separate evaluation timepoints to create an overall estimate of effect. All comparisons were based on an intention-to-treat approach, so did not account for the extent to which interventions were implemented at each site. We present results as relative risks (RRs) in all analyses of STI coverage and prevalence.

We used STATA 9.4 for randomisation and the analyses, using generalised estimating equations under a Poisson assumption with clusters as panel variables to account for within-cluster and between-cluster variation. We assumed an exchangeable variance structure, but with robust variances calculated. The trial is registered with the Australian and New Zealand Clinical Trials Registry, ACTRN12610000358044.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

Results

Between April, 2010, and April, 2011, we recruited 68 primary health-care centres to 24 clusters: 57 were in the Northern Territory and were allocated to 18 clusters, eight were in Western Australia and were allocated to

three clusters, and three communities in Queensland were each classified as a cluster. The intervention period of the trial ran from September, 2011, to September, 2014. Over 70% (n=48) of participating primary health-care centres were government run and the remainder were governed by local Aboriginal people—known as Aboriginal community-controlled services.[25] The median number of staff per health centre was 5·5 full-time equivalent. 15 (22%) health centres had 50% or more of their clinical staff employed for less than 12 months before trial commencement.

All 24 clusters were included in all assessments with only one health-care centre withdrawing before starting the intervention because of restricted capacity to participate; no data from this centre were used. The conservative sample size estimation was robust to this withdrawal and the study was powered to estimate the outcomes despite this event.

The baseline population of individuals aged 16–34 years were similar in size across all clusters, comprising 11 286 people in the year 1 clusters, 10 288 people in the year 2 clusters, and 13 304 in the year 3 clusters. The mean ages were similar, at 25·2 years (SD 5·4) for the year 1 clusters, 24·9 years (SD 5·4) for the year 2 clusters, and 25·0 years (SD 5·4) for the year 3 clusters. Women comprised over half of regular patients in all three cluster groups, at 53% (n=6007) in the year 1 clusters, 55% (n=5619) in the year 2 clusters, and 51% (n=6801) in the year 3 clusters.

Community testing coverage for STIs (each of *C trachomatis*, *N gonorrhoeae*, and *T vaginalis*) in the baseline year was slightly higher at 20% in the year 1 intervention phase clusters, than the 19% coverage in the year 2 and the 18% coverage in year 3 control phase clusters. Among males, baseline testing coverage was much lower across all age groups and all clusters than among females, with an overall 14% of males tested compared with 23% of females (table 1).

Three rounds of prevalence assessments (baseline, year 1, and year 2 surveys) were completed at all sites, as were 270 systems assessment visits by trial coordinators, and a further 340 contacts for 6-month follow-ups. During the three prevalence assessments, 2292 patients were tested for STIs at baseline, 2143 in the year 1 survey, and 2437 in the year 2 survey. More than half of all patients tested were women: 56% at baseline, 61% in year 1, and 61% in year 2 (table 2). Crude prevalences of STIs at year 1 and year 2 differed little between intervention and control clusters (table 3). *N gonorrhoeae* and *C trachomatis* were detected at similar prevalences between control and intervention clusters and differed little by sex. For example, in the year 1 prevalence survey, the proportion of females with *C trachomatis* was 8% in both the control and intervention clusters, and in males it was 10% in the intervention clusters and 8% in the control clusters. In females the crude prevalence of *T vaginalis* was approximately twice the prevalence of *N gonorrhoeae* and *C trachomatis*, and in males it was approximately half the prevalence of *N gonorrhoeae* and *C trachomatis*, apart from among males in the intervention clusters at the year 1 prevalence survey, for whom the prevalence of *T vaginalis* was similar to the prevalence of *N gonorrhoeae* and *C trachomatis*.

	Year 1			Year 2		
	Number tested	Estimated resident population	Coverage	Number tested	Estimated resident population	Coverage
Females						
Any STI						
Control clusters	2684	12 420	22%	1332	6801	20%
Intervention clusters	1628	6007	27%	2999	11 626	26%
C trachomatis						
Control clusters	3042	12 420	25%	1701	6801	25%
Intervention clusters	1782	6007	30%	3182	11 626	27%
N gonorrhoeae						
Control clusters	3037	12 420	25%	1697	6801	25%
Intervention clusters	1781	6007	30%	3181	11 626	27%
T vaginalis						
Control clusters	2691	12 420	22%	1332	6801	20%
Intervention clusters	1632	6007	27%	3000	11 626	26%
Males						
Any STI						
Control clusters	1339	11 171	12%	530	6503	8%
Intervention clusters	1109	5279	21%	1551	9947	16%
C trachomatis						
Control clusters	1555	11 171	14%	737	6503	11%
Intervention clusters	1214	5279	23%	1671	9947	17%
N gonorrhoeae						
Control clusters	1553	11 171	14%	736	6503	11%
Intervention clusters	1209	5279	23%	1668	9947	17%
T vaginalis						
Control clusters	1344	11 171	12%	531	6503	8%
Intervention clusters	1112	5279	21%	1554	9947	16%
Both sexes						
Any STI						
Control clusters	4023	23 591	17%	1862	13 304	14%
Intervention clusters	2737	11 286	24%	4550	21 573	21%
C trachomatis						
Control clusters	4597	23 591	19%	2438	13 304	18%
Intervention clusters	2996	11 286	26%	4853	21 573	22%
N gonorrhoeae						
Control clusters	4590	23 591	19%	2433	13 304	18%
Intervention clusters	2990	11 286	26%	4849	21 573	22%
T vaginalis						
Control clusters	4035	23 591	17%	1863	13 304	14%
Intervention clusters	2744	11 286	24%	4554	21 573	21%

Year 1 and 2 are defined for each cluster in relation to the time when it commenced involvement in the trial. Coverage is calculated as the crude ratio of number of individuals tested in the period divided by the estimated resident population at baseline. STI=sexually transmissible infection.

Table 4: **Crude STI testing coverage for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in intervention years 1 and 2, by cluster phase, STI type, and sex**

	Year 1*	Year 2†	Overall‡	p value
Females				
Any STI	1·23 (1·06–1·43)	1·35 (1·05–1·75)	1·26 (1·08–1·48)	0·0035
C trachomatis	1·18 (1·07–1·29)	1·07 (0·90–1·26)	1·12 (1·02–1·24)	0·023
N gonorrhoeae	1·18 (1·07–1·30)	1·07 (0·91–1·26)	1·12 (1·02–1·24)	0·019
T vaginalis	1·23 (1·06–1·43)	1·35 (1·05–1·75)	1·26 (1·08–1·47)	0·0036
Males				
Any STI	1·61 (1·12–2·32)	1·83 (1·23–2·71)	1·62 (1·23–2·14)	0·0006
C trachomatis	1·50 (1·11–2·01)	1·36 (1·07–1·73)	1·41 (1·17–1·71)	0·0003
N gonorrhoeae	1·49 (1·11–2·01)	1·36 (1·07–1·73)	1·41 (1·17–1·70)	0·0004
T vaginalis	1·61 (1·12–2·31)	1·83 (1·23–2·71)	1·62 (1·23–2·14)	0·0006
Both sexes				
Any STI	1·35 (1·11–1·64)	1·50 (1·12–2·01)	1·38 (1·15–1·65)	0·0006
C trachomatis	1·27 (1·11–1·46)	1·16 (0·97–1·38)	1·22 (1·09–1·36)	0·0004
N gonorrhoeae	1·27 (1·11–1·46)	1·16 (0·98–1·38)	1·22 (1·09–1·36)	0·0004
T vaginalis	1·35 (1·11–1·64)	1·50 (1·12–2·01)	1·38 (1·15–1·65)	0·0006

Data are relative risk, with 95% CIs in parentheses. All comparisons are adjusted for baseline (ie, before intervention) testing rate, and a relative risk of >1 indicates higher testing coverage in intervention clusters than control clusters. STI=sexually transmissible infection. *Comparing testing coverage in year 1 intervention phase clusters with year 2 and year 3 control phase clusters. †Comparing testing in year 1 and 2 intervention phase clusters with year 3 control phase clusters. ‡Comparing coverage in intervention phase with control phase clusters.

Table 5: **Adjusted relative testing coverage for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in the intervention phase versus control phase clusters, by sex**

See Online for appendix

In the corresponding adjusted analyses (table 3), taking into account baseline prevalence, the overall relative risk comparing intervention clusters and control clusters was 0·97 (95% CI 0·84–1·12). The prevalence did not significantly differ between intervention and control clusters for males or females overall, or for any of the individual STIs.

Testing coverage varied substantially by sex, STI, and intervention phase. Crude coverage (table 4) of testing for all of three STIs in year 1 was 24% in intervention clusters compared with 17% in control clusters, and 21% for the intervention and 14% for the control clusters in year 2, giving an overall crude coverage of 22% in intervention clusters compared with 16% in control clusters. The difference in crude coverage between intervention and control clusters was more pronounced for males than for females—eg, in year 1, male testing coverage was 21% in intervention clusters compared with 12% in control clusters, whereas for females testing coverage was 27% in intervention clusters and 22% in control clusters. The differences between intervention and control clusters in crude coverage were generally also greater for *T vaginalis* testing, particularly for males, than for *N gonorrhoeae* and *C trachomatis*.

In the adjusted STI coverage analyses (table 5), accounting for baseline testing and time periods, the overall coverage of testing was 38% (RR 1·38, 95% CI 1·15–1·65; p=0·0006) higher in intervention clusters, with relative increases of 26% (1·26, 1·08–1·48; p=0·0035) in females and 62% (1·62; 1·23–2·14; p=0·0006) in males. The biggest relative increases were for *T vaginalis* testing, in both males and females. The absolute difference of STI testing coverage was 6% in the proportion comprehensively tested (95% CI 2–9; p=0·001), and among males it was 7% (3–12; p<0·001) compared with 5% among females (1–8; p=0·006; appendix p 1).

Discussion

After implementation of a continuous quality improvement programme for STIs, we did not detect any reduction in STI prevalence despite significant increases in testing among both females and males. The increase in STI testing coverage was substantial, overall (38%) and among males (61% at year 1, 83% at year 2, and 62% overall) across all three infections. In females the difference in testing coverage was substantially smaller (23% at year 1, 35% at year 2, and 26% overall) and driven largely by the increase in testing coverage for *T vaginalis*.

The premise of the continuous quality improvement intervention was that health centres in remote communities had qualified clinical staff, diagnostic services, and curative drugs for the three STIs of interest, and most people at risk attended a centre at least once a year.[26] Therefore, if an intervention could reduce barriers to STI testing and management it should lead to an increase in the performance of these activities. The continuous quality improvement strategies investigated by STRIVE achieved this goal as shown here by the increase in STI testing coverage, but not to a great enough extent to reduce STI prevalence.

The absence of effect of the continuous quality improvement intervention on the prevalence of infection could be due to several reasons. One major issue is that, at baseline, the proportion of the target population who had at least one STI test in a year was low (23% in females, 14% in males), so although an increase of 38% overall (26% in females and 62% in males), adjusted for baseline coverage, in the study population is impressive in relative terms, it only translates to absolute increases of 6–9 percentage points. Previous modelling suggests that a relative increase of 200% in testing to attain an 80% testing coverage would be needed to achieve a sustainable decrease in prevalence.[17] The discrepancy in testing between males and females requires further study to identify strategies to improve access to primary healthcare centres and STI testing among males.

Our findings are not dissimilar to those from other cluster-randomised controlled trials that aimed to improve STI testing in high prevalence settings and that have also not shown a reduction in the prevalence of infection despite substantial increases in testing.[27,28]

Although screening might be an important part of STI control, particularly for STIs with a long duration of untreated infection due to little recognition of symptoms—eg, *T vaginalis* in women—the early presentation of symptomatic individuals might also be critical, particularly for gonorrhoea, which is symptomatic in up to 90% of male urethral infections and generally

uncommon in populations with high levels of access to health care. In remote communities of Australia, presentation with symptoms might be delayed due to barriers in accessing health services or stigma about STIs. Future efforts in STI control might require interventions to increase both screening and attendance of symptomatic individuals.

An additional issue is that our choice of population age group of 16–34 years might have been too broad and that an increased shift in community prevalence might have been achieved if efforts had been concentrated in those aged 16–24 years, for whom prevalences of *N gonorrhoeae* and *C trachomatis* are particularly high in this setting.[6,17,29]

The barriers to STI testing in remote communities are enduring and well documented and include prioritisation by clinicians of other urgent health concerns,[30] very high levels of turnover of all clinical staff,[31] a lack of familiarity with STI protocols, clinical settings that do not feel welcoming for Aboriginal people to engage on a topic that is highly personal and sensitive, and a cross-cultural environment in which clinician gender is particularly relevant to health-centre patients.[30] Furthermore, health literacy of remote community residents in relation to STIs is lower than for other Australians.[32] Ongoing advocacy is required to address these issues, because comprehensive solutions are unlikely to be achieved at the individual health centre level.

Conversely, the fact that the intervention led to increases in testing, albeit to less of an extent than was required for a reduction in STI prevalence, could also be viewed as an indication of the potential for improvement in testing coverage and other indicators of clinical practice. In-depth interviews with clinicians from participating sites have shown that aspects of the continuous quality improvement programme were highly valued and integrated and normalised into routine clinical care.[33] These aspects included the regular clinical data reports, sexual health action plans, and systems assessment discussions with clinical staff. Other aspects associated with the continuous quality improvement programme, such as financial incentives, almost certainly added little value to the programme, because they represented a negligible proportion of clinic operating budgets and the health promotion grants were not viewed as influential by clinicians and centre staff in driving the increase in testing.[33]

Although the continuous quality improvement intervention did not influence one of the primary outcomes of the trial, it has led to other favourable outcomes. First, the trial was deliberately set up in a manner intended to be as pragmatic as possible, regarding both the nature of the intervention and the extent to which its processes were based on the existing clinical structures and context of remote primary health care. Specifically, the trial has resulted in the adoption of more standardised approaches to testing and treatment protocols and templates for recording clinical encounters within EMR systems, which were not available to clinicians at the beginning of the trial. Data were collected in the trial from both routine clinical and laboratory records with no additional workload for health centre staff.

This study has also generated evidence about the importance of tracking the numbers of people tested as a programmatic indicator, for both community coverage and as a denominator against which information on the number of infections can be interpreted. This study has also provided information on the prevalence of STIs across remote communities, including estimates of the incidence of STIs,[6] and co-infections,[17] which before the trial were not available

Another benefit of this study is that continuous quality improvement methods developed for STRIVE have been embedded as a central element of the STI control programme within the Northern Territory Government clinics across 70 remote communities.[34] The goal remains to maximise access to testing and treatment for individuals, and ultimately to decrease prevalence.

This study had several limitations. First, our data collection systems, which were custom built across multiple EMRs, meant we did not have independent verification of the completeness or accuracy of data on clinic attendance and STI testing and treatment. Hence, data quality might have differed between control and intervention periods, thereby introducing bias, but we have no way to determine the extent or direction of any bias. The quality of information about treatment and partner notification was too low to report here due to inconsistent recording of this information or not being able to capture the data because it was recorded as text in the EMR systems. Better information on treatment, its timeliness, and partner testing and treatment will complement the comprehensive data that we have compiled on testing. Ongoing work is underway to improve methods to capture such data across multiple EMR systems. Another methodological weakness was the way that the prevalence surveys were run. One problem was that we were not able to fund extra staff at the participating clinics or put other measures in place to ensure that a high level of participation could be achieved during the prevalence survey period. Additionally, the extra testing that took place during the prevalence survey might have reduced the difference in testing created by the intervention. For instance, over 50% of the testing in control cluster populations took place because of the prevalence surveys (data not shown), so we adjusted these counts using testing rates from adjacent time periods to estimate the number of tests that would have taken place had no prevalence assessment occurred. Despite the limitations of our data collection system, an alternative means of collecting truly representative data on prevalence in studies of this kind was not apparent. Household-type surveys in this setting would not have been feasible both logistically and financially and testing without returning results would have been ethically unacceptable. Another methodological weakness might

have been the definition we used for a regular patient, which could have resulted in an undercount of community members, particularly among males because they are infrequent clinic attendees.[35]

A few other limitations include that testing coverage estimates might be underestimated because we have taken all people in the age group as the denominator, whereas the small minority (up to 15%) who are not sexually active would not require testing. Furthermore, we were unable to distinguish what proportion of undertesting was because of patient refusal, but we believe on the basis of qualitative data that the gap is primarily related to the lack of offer by the clinicians because of competing priorities, inexperience, or other factors.

In conclusion, STRIVE has shown that a continuous quality improvement programme for STIs can lead to improved STI testing, but the challenge of reducing unacceptably high prevalences of STIs in remote communities remains. Our study has shown that continuous quality improvement strategies will need to be intensified and sustained over time if they are to affect STI community prevalence and ideally be implemented alongside other STI control strategies.

Contributors

JMK, JW, RJG, and ARR conceived the idea for the study and developed the initial study proposal. Statisticians ML, HW, and HM contributed to study design, randomisation procedures, sample size calculation, and analyses. SM and AD contributed to development of the study (particularly through protocol development and ethics applications), data analysis, and study procedures. BH, BJS, LG, JK, and DT-T were regional study coordinators for the trial and advised on procedures via regular meetings throughout the trial. BD, CKF, and SS were content experts involved in an advisory capacity in all aspects of the trial. LM was responsible for qualitative research undertaken in parallel with the primary data collection for the trial. JB and DAC were study investigators who contributed to site specific assessments and procedures. JW wrote the first draft of the manuscript and all authors contributed to subsequent drafts. NR, JM, and CR provided public health expertise in the design and conduct of the study.

STRIVE investigators

John M Kaldor, James Ward, Alice R Rumbold, Rebecca J Guy, Robyn McDermott, Lisa Maher, Steven Skov, John Boffa, Donna Ah Chee, Skye McGregor, Bronwyn J Silver, Debbie Taylor-Thomson, Linda Garton, Belinda Hengel, Janet Knox, Amalie Dyda, Matthew Law, Christopher K Fairley, Basil Donovan, David Glance.

Declaration of interests

We declare no competing interests.

Data sharing

Data were collected for the study under strict agreement with participating health services and will be not be made available to others. Our study protocol, a data dictionary defining each field in the statistical analysis plan, and participation agreements with health services are available upon request via the corresponding author or Prof John M Kaldor (jkaldor@kirby.unsw.edu.au; Kirby Institute, UNSW, Sydney, NSW, Australia).

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