

COMMUNITY ARV SERVICES

THE MADWALENI HIV/ARV PROGRAMME

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Richard Cooke and Lynne Wilkinson sought out a deep rural hospital in the old Transkei area of the Eastern Cape to attempt to set up a holistic HIV programme including access to antiretrovirals (ARVs). They looked for a hospital difficult to access by road, where the majority of the people were unemployed and where HIV-positive people currently have minimal health and social support.

They identified Madwaleni hospital, a 220-bed district hospital built as a missionary hospital in the early fifties. It is approximately 30 km south-east of a small town called Elliotdale (approximately 80 km south-east of Mthatha). District statistics indicate that the hospital serves a population of approximately 256 000.

Madwaleni is approximately 110 km (including 30 km of dirt road) from its referral centre, Nelson Mandela Hospital Complex (NMH) in Mthatha. Madwaleni has a small operating theatre, an X-ray facility and a laboratory, and patients are referred to NMH for all specialist consultations, and for surgery other than minor operations and caesarean sections. By car or ambulance this route takes approximately 1½ hours, but for patients who are referred and need to use public transport, it takes closer to 2½ hours.

Madwaleni has a total of 5 doctors (including HIV/ARV programme doctors) and 117 nurses (including 46 professional nurses) at the time of writing in 2006. It has a small nursing college on site.

At the beginning of 2005 Madwaleni's HIV programme, as at many rural government hospitals, was run by a single nurse and included HIV voluntary counselling and testing (VCT) for people coming to the hospital and specifically requesting to be tested, a small HIV support group started the previous year, prophylactic treatment (when available) for those patients requesting assistance, prevention of mother-to-child transmission (PMTCT) counselling and provision of nevirapine to some of the HIV-positive women accessing the hospital's services, and provision of formula feed (when available) for mothers who chose to formula feed upon receiving PMTCT counselling.

MADWALENI'S HIV/ARV PROGRAMME

Madwaleni was accredited as an ARV site by the Eastern Cape Department of Health on 14 February 2005 on condition that a pharmacist was employed prior to rollout. Anemari Buitendach joined Madwaleni in May 2005 as both the hospital and HIV programme pharmacist. The ARV rollout began on 28 June 2005 after the first batch of ARV drugs was received on 27 June 2005.

The staff complement has increased dramatically from 3 staff members in January 2005 (site co-ordinator, doctor, nurse) to 22 staff members, including 2 doctors, 3 nurses, 1 site co-ordinator, 1 administrator, 1 data capturer, 1 hospital pharmacist, 1 hospital social worker, 5 community health workers, 6 peer educators and a driver. In addition, a community service physiotherapist has joined Madwaleni for the first time and also works with the HIV programme patients. Two more pharmacy assistants joined the programme in mid-May 2006.

Madwaleni's HIV/ARV programme centres around the support groups run by counsellors (community health workers and



Where is Madwaleni?

peer educators) and nurses at Madwaleni and 6 primary health care clinics. Based on support group attendance, patients join the HIV/ARV programme and receive regular and continuing counselling irrespective of their CD4 counts. Patients with CD4 counts lower than 200 cells/μl begin to prepare for ARV readiness and are put on ARV treatment.

A VCT outreach programme was started in which counsellors do 'door to door' HIV awareness in the communities

surrounding the hospital. Thereafter nurses do HIV testing in the communities on days arranged with the local headman/chief, often coinciding with government grant collection days.

An infant follow-up clinic (IFC) for HIV-exposed infants and a paediatric HIV wellness and ARV programme for HIV-positive children is run on a Wednesday and is closely co-ordinated with the maternity ward in the hospital and the antenatal clinics at the primary health care clinics.

The most recent initiative has been the integration of tuberculosis (TB) inpatients into the HIV programme. This aims to fast-track inpatients diagnosed with tuberculosis into the HIV programme, and where applicable put them on ARV treatment (ART).



The Madwaleni HIV/ARV team.

DISEASE PROFILE IN THE HIV/ARV PROGRAMME

The most common presenting signs and symptoms are productive coughing, weight loss, dermatological conditions (especially papular pruritic eruptions, ringworm, fungal lesions and herpes zoster), and peripheral neuropathies. Chronic diarrhoea is common in AIDS patients and ARVs are now an option where management by repeated rehydration and antibiotics fails. Common diagnosis on clinical grounds include oral and vaginal candidiasis, genital condylomas and herpes simplex virus (HSV) 1 and 2. Tuberculosis is by far the most common disease affecting patients at Madwaleni and remains a major problem. Common WHO stage 4 conditions seen include cryptococcal meningitis and Kaposi's sarcoma, but relatively few cases of *Pneumocystis jiroveci* pneumonia (PJP) are seen.

Conditions such as cervical dysplasia diagnosed on pap smear and extrapulmonary tuberculosis (EPTB) are under-diagnosed. It is therefore necessary that HIV/AIDS patients are actively screened for these conditions, the latter when clinically indicated.

Neurological conditions are also under-diagnosed and patients often present on anticonvulsant medication with a longstanding 'epilepsy' diagnosis written in the OPD card. Neurocysticercosis is common in this part of South Africa and is frequently treated empirically. Owing to culture/language barriers faced by English-speaking doctors, counsellors are encouraged to recognise signs of confusion and mental deterioration through repeat counselling sessions. Counsellors

can prove valuable in referring neurological cases that could be HIV encephalopathy or organic CNS pathology.

Early indications are that syphilis does not have a high prevalence in the current programme. Of 376 baseline serological tests, 28 (7.4%) tested positive for syphilis, but 24 were only weakly reactive (false positives occurring at low titres).

The first 90 patients started on ARVs at Madwaleni HIV clinic were staged according to the WHO classification as follows: stage 1 – 4%; stage 2 – 30%; stage 3 – 52%; stage 4 – 13%. A further 60 patients were staged on entry to the HIV Wellness programme: stage 1 – 43%; stage 2 – 20%; stage 3 – 30%; stage 4 – 7%.

SIDE-EFFECTS AND ADVERSE EVENTS

The majority of patients report initial dizziness on efavirenz which improves after a week. Two patients – a man and a woman – presenting with psychiatric symptoms were switched from efavirenz to nevirapine. While the man is doing well, the woman had a Stevens-Johnson drug reaction to cotrimoxazole/nevirapine progressing to toxic epidermal necrolysis (TEN), and died at the referral hospital.

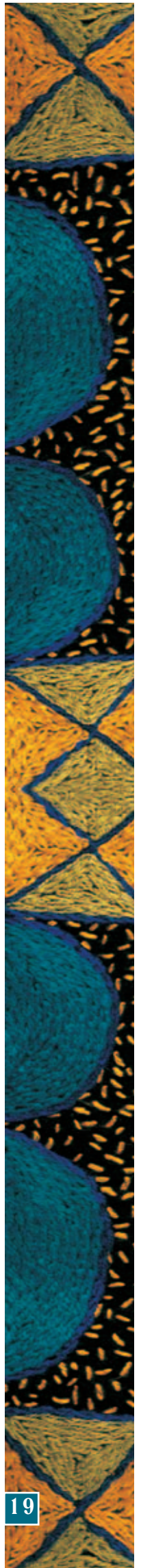
Women of child-bearing age are encouraged to take the nevirapine-containing regimen, although more blood sampling for drug safety monitoring is required. Only one woman has fallen pregnant after starting ARVs, but this will increase as general health and quality of life continue to improve. Family planning is encouraged and every woman is counselled on injectable contraceptive options.

High alanine transaminase (ALT) levels are common (see Table I), but only one patient on nevirapine discontinued medication, owing to an isolated drug hepatitis. She is soon to commence regimen 2 ARV treatment.

Two patients on regimen 1b were screened for hyperlactaemia. Both are women, obese and with high CD4 counts. Both had lost weight. A handheld lactate meter indicated a lactate level of 8.2 mmol/l in the first patient and 3 mmol/l in the second. Serial measurements were similar. The first was switched to zidovudine (AZT), and her condition appeared to settle. Unfortunately she was transferred to another site before the switch could be assessed properly, including haematological toxicity. The second settled on symptomatic treatment alone.

Known causes of death on ARVs include 1 case of TEN (see above), 1 case of proven multidrug-resistant (MDR) TB, 1 patient in whom a computed tomography (CT) scan of the brain revealed a pontine lesion (tuberculoma/lymphoma), 1 pulmonary tuberculosis (PTB) retreatment failure (sputum positive at 5 months), and 1 case of tuberculous meningitis (immune reconstitution). Four died of unknown causes – in each case the baseline CD4 count was below 50 cells/ μ l, including a 5-year-old child with a CD4% of 0.24%.

The first two patients with virological failure are soon to start on regimen 2.



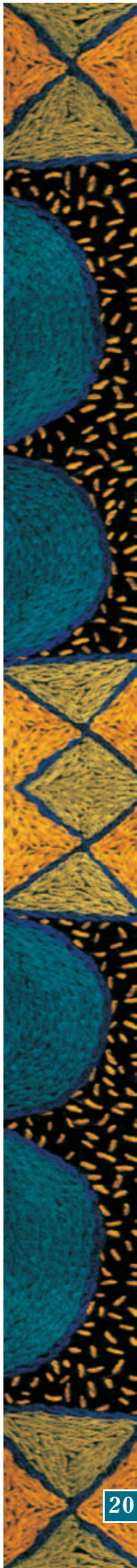


TABLE I

At end March 06		Notes
Total people tested for HIV at Madwaleni (since Jan 05) and 6 clinics (since Oct 05)	4 119	The monthly average for the last 6 months is 445 (Madwaleni and clinics)
HIV prevalence rate	23.7%	Jan 05 - Mar 06
June 05 - April 06		
Total No. of adults on HIV/ARV programme	513	
% of adults with CD4 < 200 cells/ μ l	57.1%	
Total No. of children on HIV/ARV programme	42	
% of children with CD4% < 15%	51.7%	
Adults initiated on ARV treatment		
Male	63 (33%)	
Female	128 (67%)	
Total	191	
Children initiated on ARV treatment		
Male	6 (55%)	
Female	5 (45%)	
Total	11	
Average No. of patients initiated on ARV treatment per month		
% adults on regimen 1a	64.9%	
% adults on regimen 1b	28.2%	
Mean absolute CD4 in 'decision to treat' (DTT) group (cells/ μ l)	105.03	<i>N</i> = 178 (excludes children on ARV treatment and patients transferred in from other sites)
Mean CD4% in DDT group	8.9%	<i>N</i> = 178 (excludes children on ARV treatment and patients transferred in from other sites)
Adults on ARV treatment for 6 months that have not achieved undetectable viral loads (< 400/ml)	7 patients, of whom 3 patients have < 1 log decrease	<i>N</i> = 62 (excluding deaths before 6 months, transfers out before 6 months, patient stopped on ARV treatment, missed or still outstanding viral loads)
Adults on ARV treatment for 6 months - mean increase in absolute CD4 count (cells/ μ l)		
Baseline	118.52	
6 months	250.41	
Increase	131.89	<i>N</i> = 61 (excludes deaths before 6 months, transfers out before 6 months, patient stopped on ARV treatment, missed or still outstanding CD4 counts)
Adults on ARV treatment for 6 months - mean increase in absolute CD4%		
Baseline	8.89%	
6 months	16.51%	
Increase	7.62%	<i>N</i> = 61 (excludes deaths before 6 months, transfers out before 6 months, patient stopped on ARV treatment, missed or still outstanding CD4 counts)
Patients died on ARV treatment	9	Includes 1 child See notes
ARV patients lost to follow-up	1	
Patients in whom ARVs discontinued	2	
Hepatotoxicity related to nevirapine (<i>N</i> = 56)		
Any > ULN	44.6%	
ALT > 3 X ULN	10.7%	
ALT > 5 X ULN	3.6%	
ULN = upper limits of normal; ALT = alanine transaminase.		

SUCCESSSES

COMMUNITY INVOLVEMENT

Intensive community involvement has led to specific successes for the Madwaleni HIV/ARV programme. As stated above, there are 5 community health workers and 6 peer educators (HIV-positive members of the programme) who work permanently on the programme with the further assistance of certain community health workers at the clinics. This has allowed intimate access to patient attitudes, feelings and expectations. In addition, their contribution has been invaluable in lightening the workload of the remaining staff (especially nurses) without compromising patient relationships and care. The counsellors are involved at all levels of the programme,

which also ensures their full participation, including running support groups (group counselling), individual ongoing counselling of HIV wellness programme patients, preparing patients for ARVs from an individual commitment perspective,



Certification of adherence counsellors.



Our pharmacist and nurse explain the complexities of ARV treatment to a patient.

assisting in the selection of patients ready for ARV treatment and doing ongoing adherence counselling. They also conduct home visits to prepare the patient's family for his/her ARV treatment, to report any socio-economic problems to the social worker. The counsellors are involved with the adult, child and pregnant women components of the programme.

In addition to the counsellors, the programme is supported by many 'HIV programme activist' support group members who assiduously attend the support group, get involved in every initiative that the programme presents, counsel people in their homes and villages and introduce new members to their support groups on a weekly basis. These people are key to spreading the programme's 'follow-up' net widely.

As a result, of over 200 patients on ARV treatment in the programme, only 1 has been lost to follow-up.

RURAL HOSPITAL STAFF MOTIVATION

Much criticism is levelled at public sector nurses in South Africa with regard to lack of motivation and work ethic. This is often unfair, as it is rarely the nurses themselves who are the root cause of the problem. Nurses are frustrated by years of isolation in rural district hospitals, unsupported by management and administrative functions, with few career development paths or remuneration incentives. Consequently they adopt attitudes of resignation and defeat. At Madwaleni patient and counsellor enthusiasm and participation in the programme have served as catalysts for renewed involvement of the nurses and improved performance.

CO-ORDINATION FUNCTION

Lynne Wilkinson (an attorney by profession) has taken on the role of project manager for the programme. Many rural programmes are left either to doctors or to nurses to set up and manage in addition to their many clinical duties. The programme has greatly benefited from having a dedicated person to set up administrative and data systems, staff management, funder reporting, government liaison and co-ordination of tasks within the programme. This system has allowed Dr Richard Cooke to head the clinical programme and cover general hospital responsibilities.

PRIVATE-PUBLIC PARTNERSHIPS

In the Eastern Cape, government budgets support employment, ARV drugs and laboratory costs. Operating



The Madwaleni HIV support group in full swing.

budgets are small, however, and in many instances extremely difficult to utilise through general hospital procurement and payment systems. It was intended that the Madwaleni HIV/ARV programme would be set up as a government accredited and funded site for purposes of long-term sustainability and that private funding would be brought in only to facilitate and accelerate the building up of the programme. In addition to government funding, the Madwaleni HIV/ARV programme has been funded by the Rural Health Initiative (RHI), Difaem, a few private individuals, and since October 2005, the Aurum Institute for Health Research (PEPFAR funding). This has allowed us to accelerate the implementation of the programme.

CHALLENGES

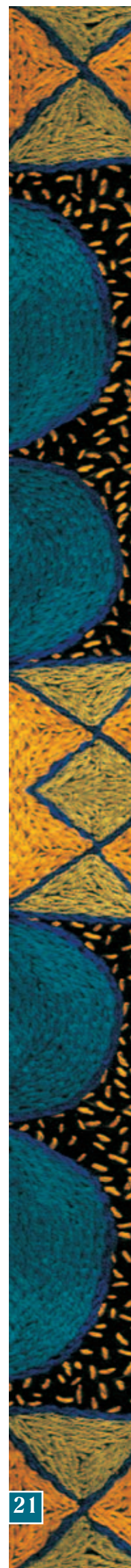
HIV AND TB CO-INFECTION

While many opportunistic infections can be managed routinely, the TB epidemic is a challenge of huge proportions. Madwaleni's TB beds (80 of 220) are normally full to capacity. The DOTS system is ineffectively implemented and large numbers of patients needing retreatment are admitted to hospital for daily streptomycin injections. During 2005, 75 inpatients died. Multidrug-resistant (MDR) TB is an increasing problem: in 2005, 16 of 500 inpatients were identified as having MDR TB. Adult TB prophylaxis regimens are not provided by the central pharmacy depots.

Of the patients on ARVs, 103 (54%) have a history of TB (29% of these 103 are retreatment cases). Of the patients on ARVs 57 (30%) were on TB treatment at the time they started on ARVs (39% of these 57 were retreatment cases); 10 patients (9.7%) were started on TB treatment while on ARVs.

These figures support channelling of resources to diagnose TB as early as possible. If extending national guidelines on HIV/TB co-infection is not the answer, then district hospital staff must be in regular consultation with expert clinicians with respect to management of HIV/TB co-infections.

Strict monitoring of patient symptoms by counsellors, regular weight monitoring, regular sputum collection and a screening chest X-ray are helpful for diagnosing pulmonary/pleural TB. More TB cultures are now done routinely in smear-negative pulmonary tuberculosis diagnosed clinically and radio-



graphically, but the required 4 - 6-week waiting period is unhelpful. Extrapulmonary TB is under-diagnosed in this resource-limited setting. With the recent arrival of an ultrasound machine (supplied by government), doctors must now acquire skills to aid ultrasound diagnosis of abdominal TB in addition to the regular obstetric and gynaecological investigations. Unfortunately the high turnover of short-term community service doctors means that the benefit of this training is short lived.

To address the high HIV prevalence among TB inpatients, the HIV/ARV programme has been extended to the TB ward by fast-tracking patients assessed clinically and identified by the ward doctor. Counsellors then provide HIV education, assess individual commitment and provide adherence counselling so that patients can be started on ARV treatment while in the ward. Further emphasis is placed on education of all TB/HIV patients before discharge to ensure continued participation in the ARV programme on an outpatient basis.

Owing to the high prevalence of TB among the ARV programme members, adherence to TB medicine needs to be included in ARV adherence counselling, especially in view of the high pill burden for TB/ARV patients. However, this does not solve the problem of TB patients who do not form part of the programme, which needs to be addressed with TB ward staff and clinic staff. No ARV programme can be successful without an effective TB programme.



HIV education in our communities.

MEDICINE INTERACTIONS AND TOXICITY

Patients often present with multiple pathologies, but in resource-constrained hospitals too many conditions are treated empirically. Madwaleni is no exception. Faulty diagnostic tools (e.g. unavailability of X-rays or laboratory reagents out of stock), lost/delayed results, and lack of specialist guidance all contribute to this practice, which has the negative consequences of medication interactions, toxicities and high financial costs. Madwaleni is attempting to address this in part by outsourcing a specialist one day a month to guide junior doctors. Doctors are also increasingly trying to stop prophylactic co-trimoxazole as early as possible. While useful for 'adherence practice', co-trimoxazole is religiously swallowed (960 mg daily) to the extent that doctors struggle to convince patients to stop when their immune systems improve. The introduction of single-drug TB medicine formulations at district hospital level will go some way towards improving our management of TB drug toxicities.

INCREASED DIAGNOSIS DOES NOT ALWAYS INCREASE MANAGEMENT CAPABILITY

As a service is built up and more clinical diagnoses are made, it is frustrating when treatment/management capabilities do not increase in tandem. For example, the women's health clinic is identifying more genital condylomas and abnormal pap smears, but unreliable equipment and an imperfect referral system result in too few cauterisations and colposcopies. Similarly, our laboratory offers the full range of basic tests, as well as investigations such as liver function tests and cryptococcal/bacterial antigen tests. CD4 cell counts, polymerase chain reaction assays, viral loads, biochemistry and many others are done in Mthatha. Others including cytology investigations have to be done in East London (4 hours' drive away). Blood cultures are not routinely available at Madwaleni.



Mothers in the support group bring their children for testing.

ARV DRUG FORMULATIONS

While ARV drug supply has been good, it is maintained by programme staff fetching the orders. In addition, in the months of December and January limited numbers of new patients could be started on ARV treatment because the Mthatha depot had no electrical power and placement of new orders was therefore difficult.

Changes in dosage formulations causes frustration. Intensive adherence counselling is hampered by an abrupt change in pill colour. Lamivudine, for example, changed from white to red and stavudine from orange/brown to red/yellow. Similarly, unavailability of certain dosage formulations such as efavirenz 600 mg meant that Madwaleni was supplied with 200 mg tablets. A number of the ARV patients on the programme are illiterate, and changing colours and number of pills raises concerns about adherence and increased pill burdens. This problem was solved by selecting 10 highly adherent and focused patients to receive the 3 x 200 mg dosage of efavirenz until the stocks ran out, while other patients were kept on the simpler single-pill regimen. Similarly, 20 mg stavudine tablets have repeatedly been unavailable, resulting in paediatric patients having to take ridiculously large quantities of the liquid formulation.

INCREASING OUR KNOWLEDGE OF TRADITIONAL XHOSA MEDICINE

Counsellors encourage support group members not to use traditional Xhosa medicine without first consulting our clinical

staff rather than forbidding them to do so. The support group members themselves have adopted a negative attitude towards traditional medicine, often as a result of their own personal experiences, and convey these stories and attitudes to new support group members. As a result, clinicians are not currently experiencing problems on the HIV programme with Xhosa medicine interaction with ARV drugs. Staff, however, do not have a full understanding of the patients' opinions relating to Xhosa medicine and their interaction with their ARV drugs, and this needs to be studied further.

POOR ACCESS TO HEALTH CARE

Access to both the hospital and the primary health care clinics is hindered by many factors including impassable dirt roads, few ambulances and limited taxi routes. The direct impact on the programme is manifested by a low conversion rate of VCT-positive individuals onto the HIV/ARV programme through the support group 'gateway', as well as precious resources spent on ensuring patient follow-up: clinic visits by doctors, database monitoring of follow-up visits, a driver transporting counsellors on home visits and patient searches.

BUILDING A ONE-STOP SHOP

The intention is to provide a comprehensive primary ARV service. The programme will need to be adapted in the future when the breadth of service itself becomes a barrier to increasing the numbers on the programme. Currently new adult patients are initiated onto ARVs on only one day per week as a result of stretched resources. Other HIV/AIDS services provided by the hospital include a VCT service, an infant follow-up clinic, a paediatric ARV treatment clinic, peripheral clinic HIV wellness and ARV readiness programmes, (during which the doctor rotates through three clinics per day), a prenatal clinic, and a women's health clinic. Doctors are also involved in all areas of rural medicine, including ward rounds, OPD work and theatre time.

While this system is not currently limiting access to ARV treatment, in that the programme is coping with the demand for ARV treatment (no waiting list), this is likely to change in the future and a further day would then need to be considered. Increased nurse participation in clinical monitoring of ARV patients would also be of assistance.

A further difficulty to overcome is that a patient who falls into a number of categories (e.g. she is on ARV treatment, her child is part of the infant follow-up (IFC) and she requires a pap smear) cannot be expected to attend a number of different days in a week.

DECENTRALISING THE PROGRAMME

Decentralising the programme to the clinics, including the wellness and ARV programmes, improves health care access but more resources are needed to implement, monitor and maintain the programme at this level. At present patients join the HIV wellness programme and are prepared for ARVs at the clinics. They are, however, required to go to Madwaleni for their ARVs. The ARV patient follow-up and monitoring is only done by the largest of the clinics or at Madwaleni. The

programme's aim is to ensure that this takes place at all clinics, and newly appointed pharmacy assistants are in the process of being trained to assist the nurses with dispensing repeat medication. When resources allow, it is envisaged that the initial ARV take up will also be done at the clinics with the assistance of the clinic doctor.



Egg-catching on Teambuilding Day.

PALLIATIVE AND HOME-BASED CARE: UNDER- PREPARED

The increasing numbers of patients accessing hospital treatment and the Madwaleni ARV programme may have two negative consequences in the long term: the hospital will not have the resources to cope, and the number of treatment failures will grow. Facilities to improve the palliative care of these chronically ill patients are urgently needed. Such a facility could provide intensive short-term step-up treatment and care. It could also serve as a training venue for relatives and counsellors, enabling early discharge into home care. The programme has motivated the Eastern Cape Health Department to include such a facility as part of the planned hospital revitalisation.

SUSTAINING HIV-POSITIVE SUPPORT GROUPS

Currently the main motivation for attendance at an HIV support group is gaining an understanding of HIV, living with HIV, and ARV treatment. This is crucial but will not provide experienced members with an incentive to continue attending on a weekly basis. Resources need to be found to support income generation and education or training opportunities to sustain the support groups.

CONCLUSION

The HIV/ARV team realises that success is ultimately dependant on sustaining the programme. With continued district, provincial, hospital and, most importantly, community support, this is an achievable goal.



The local countryside.