

## Survey of isoniazid preventive therapy in South Africa, 2011

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### SUMMARY

**SETTING:** Public health facilities in South Africa.

**OBJECTIVE:** To assess the implementation of isoniazid preventive treatment (IPT) in South Africa in 2011.

**DESIGN:** Cross-sectional study of 50 randomly selected facilities in South Africa. Trained interviewers administered a standardised questionnaire at each facility on aspects of IPT policy, implementation and recording and reporting. We calculated and compared descriptive statistics by province and facility type.

**RESULTS:** Of the 49 participating sites, 35 provided IPT (71%). IPT was not available in any Western Cape facility (0%), and it was available at a few Mpumalanga (40%) and Limpopo (20%) sites. In February 2011, 46% of eligible human immunodeficiency virus (HIV) infected patients at IPT-providing sites had been initiated

on IPT. Implementation by facility type was 27% among community health centres. Of all facilities with integrated tuberculosis (TB) and HIV committees (TB-HIV), 85% offered IPT compared to 59% of those without TB-HIV committees ( $P = 0.12$ ). Availability of the 2010 South African National IPT guidelines was statistically significantly associated with sites providing IPT (84% vs. 29%,  $P = 0.006$ ).

**CONCLUSION:** IPT implementation in South Africa began in February 2011. The availability of IPT guidelines was strongly associated with IPT uptake. More operational studies are needed to improve IPT implementation among HIV-infected patients in South Africa.

**KEY WORDS:** tuberculosis; HIV; co-infection; integration; prevention

GLOBALLY, the human immunodeficiency virus (HIV) and tuberculosis (TB) epidemics are profoundly intertwined: HIV is the leading risk factor for the development of active TB, and the latter is the leading cause of death and morbidity among HIV-infected individuals.<sup>1</sup> This is particularly evident in South Africa, home to the highest number of HIV-infected patients and with one of the highest TB incidences worldwide.<sup>2</sup> Co-infection rates in South Africa are high, with as many as 80% of TB patients in KwaZulu-Natal Province estimated to be HIV-positive.<sup>3</sup>

Since the 1990s, several randomised clinical trials have found isoniazid preventive treatment (IPT) to be effective in preventing active TB among HIV-infected individuals.<sup>4–7</sup> A Cochrane review of 11 randomised trials showed a 33% protective effect of IPT against active TB,<sup>8</sup> and another study showed that protection increased to 64% among individuals with a positive tuberculin skin test (TST) result.<sup>9</sup> In 1999, the World Health Organization (WHO) recommended adding IPT to existing HIV care packages, and initiating all HIV-infected individuals with confirmed latent TB infection or TB exposure on IPT.<sup>10</sup> The most recent WHO guidelines recommend that, in settings with high rates of TB transmission among HIV-infected

individuals, all HIV-infected persons in whom TB has been ruled out should be initiated on IPT.<sup>11</sup>

Accordingly, in 2010, the South African National Department of Health (NDOH) revised its guidelines on tuberculosis prevention therapy among HIV-infected individuals, recommending that all eligible HIV-infected persons be initiated on IPT, irrespective of TST results.<sup>12</sup> IPT, infection control and intensive case-finding policies together constitute the WHO ‘Three I’s’, and South Africa’s core strategy to combat the spread of TB.<sup>11–14</sup> Despite an abundance of scientific evidence and clear guidelines in place, IPT implementation has been slow worldwide, with only 30 000 persons living with HIV having started IPT in 2007.<sup>1</sup> In South Africa, no national assessment had been conducted since the publication of the revised guidelines to determine the level of implementation of IPT.

In the present study, we assessed the current implementation of IPT in South Africa.

### STUDY POPULATION AND METHODS

#### *Study population*

From 1 to 31 March 2011, we assessed 49 public medical facilities in high HIV prevalence districts in South Africa’s nine provinces.

### Methods

Using a multistage sampling method, we first systematically selected the single district in each province with the highest HIV prevalence. In KwaZulu-Natal, two districts with the highest HIV prevalence were selected as the province had double the number of districts compared to other provinces.<sup>15</sup> Second, each subdistrict in each selected district was assigned a number and one subdistrict was randomly selected using the random number generator on [stattrek.com](http://stattrek.com). Third, all facilities in the selected subdistrict were assigned a number, stratified by facility type: community health centre, primary health clinic or district hospital. Using the random number generator mentioned above, a random sample of three primary health clinics, one community health centre and one hospital was chosen per subdistrict. This ratio was chosen to approximate the current distribution of public medical facilities in South Africa. The list of facilities used for this sampling was provided by the South African National Department of Health.

We then determined the availability of the latest national guidelines, as well as the presence of dedicated TB-HIV committees at each facility. These committees were defined as specific on-site bodies to enable TB and HIV integration, and included management staff from both the TB and the HIV sections in each facility. We also assessed staff training in TB and HIV, defined as any permanent facility staff trained in at least IPT and TB infection control since January 2010.

Finally, we investigated the main reasons for not initiating patients on IPT. In an effort to assess the quality of counselling offered, we asked each facility to report the four most important facts about IPT that were covered in their counselling sessions. We defined the four essential aspects of IPT as adherence, reporting of side effects, reporting of TB symptoms, and stopping or reducing alcohol intake during treatment.

### Questionnaire

A team composed of five members of the US Centers for Disease Control and Prevention (CDC) and the South African NDOH designed a standardised, anonymous survey. The questionnaire was validated in an urban district hospital and a rural community health centre in two subdistricts of Nkangala District, Mpumalanga, and appropriate changes were made. The survey contained questions on various aspects of IPT implementation, including availability of guidelines, service provision, supply, and reporting and recording of routine data.

### Data collection

The Principal Investigator conducted standardised training for 10 teams of interviewers, which included methods of conducting interviews, data collection and systematic verification of data using appropriate registers. Each data collection team was responsible

for the assessment of five sites. Questionnaires were administered to the focal person for TB and HIV in each selected facility. Information reported by interviewees was systematically verified by collecting routine data from the facility's TB and HIV registers.

### Data analysis

Questionnaire data were directly entered into an Epi Info 3.5.1 database for analysis (CDC, Atlanta, GA, USA), and descriptive statistics were calculated and compared by province and facility type using the  $\chi^2$  test.

### Ethical considerations

The collection of routine data and its analysis for this study were determined to be a non-research activity by the CDC as per United States Federal regulations. The South African NDOH waived the need for local human subjects review.

## RESULTS

### Facilities

Of the 50 facilities randomly selected, 49 (98%) participated in the survey. The missing site was a facility in Northern Cape, which had merged with another selected site situated on the same premises shortly prior to data collection.

### Service availability

Of the 49 participating facilities, 35 (71%) provided IPT. Implementation varied significantly by province: none of the sites in Western Cape offered IPT, while 20% of Mpumalanga and 40% of Limpopo sites did. Table 1 shows the distribution by province among our sample. Stratified by facility type, community health centres were the least frequent implementers of IPT, with only 56% of 10 offering IPT vs. 77% of 29 public health clinics and 80% of 10 district hospitals.

Survey participants not implementing IPT ( $n = 14$ ) reported no clear guidance or commitment from authorities (29%) and concerns about isoniazid (INH) resistance (21%). Western Cape followed national IPT guidelines, but required that patients be given a Mantoux test and be shown to be positive to be initiated on IPT. Regardless of Mantoux results, no patient had been initiated on IPT in the five facilities assessed in that province in February 2011.

### Guidelines availability

The 2010 National IPT guidelines were available in 39 (80%) of the 49 participating facilities. Table 1 shows little variation by province, with the notable exception of Western Cape, where none of the facilities had the latest guidelines. Of the survey participants, 64% reported using the latest guidelines. Facilities that had the 2010 IPT guidelines were more

**Table 1** Distribution of TB-HIV services and policy in selected sites, South Africa, 2011 (N = 49)

Province	Selected sites n	Availability of IPT for HIV-infected individuals n (%)	Availability of May 2010 IPT guidelines n (%)	Staff trained in TB-HIV services since January 2010 n (%)	Facilities with dedicated TB-HIV committees n (%)
Eastern Cape	5	5 (100)	4 (80)	3 (60)	1 (20)
Free State	5	4 (80)	5 (100)	5 (100)	4 (80)
Gauteng	5	5 (100)	5 (100)	4 (80)	2 (40)
KwaZulu-Natal	10	9 (90)	4 (80)	7 (70)	5 (50)
Limpopo	5	1 (20)	4 (80)	4 (80)	0
Mpumalanga	5	3 (40)	4 (80)	4 (80)	3 (60)
North West	5	5 (100)	5 (100)	4 (80)	2 (40)
Northern Cape	4	3 (75)	4 (100)	4 (100)	2 (50)
Western Cape	5	0	0	3 (60)	1 (20)

TB = tuberculosis; HIV = human immunodeficiency virus; IPT = isoniazid preventive therapy.

likely to offer IPT than those who did not (84% vs. 29%,  $P = 0.006$ ).

#### *IPT initiation*

In the month prior to the survey, 46% of eligible patients had been initiated on IPT in the 35 facilities implementing IPT. The 616 patients who had been diagnosed with HIV that month and screened negative for TB were deemed eligible for initiation on IPT. Implementation by facility type was lowest among community health centres where only 27% of eligible patients were initiated on IPT.

#### *TB-HIV staff training*

Of the 49 facilities assessed, 38 (78%) had at least one staff member recently trained in TB and HIV integrated services. Of the facilities implementing IPT, 83% had at least one recently trained staff member. These figures are shown stratified by province in Table 1; of those facilities with staff trained, 75% had no physicians trained and 84% had no nurses trained in TB and HIV integrated services since January 2010.

#### *TB-HIV committees*

Of our sample of 49 facilities, 20 (41%) had TB-HIV committees. In our sample, facilities with TB-HIV committees were no more likely to offer IPT than those that did not (85% vs. 59%,  $P = 0.12$ ). There was considerable variation by province (Table 1).

**Table 2** Number of essential aspects of isoniazid preventive therapy covered in counselling (n = 35)

Number of essential topics*	n (%)
0	1 (3)
1	4 (11)
2	11 (31)
3	13 (37)
4	6 (17)
Total	35 (100)

\*Four essential topics included adherence, reporting of side effects, reporting of tuberculosis signs/symptoms, and reduction or elimination of alcohol consumption during treatment.

#### *IPT counselling*

All 35 facilities offering IPT also offered patients counselling prior to initiation on therapy. Table 2 illustrates the distribution of counselling content among facilities providing counselling. The four essential topics were covered to varying degrees by the 35 facilities. Of the 35 facilities providing counselling to IPT patients, 30 (86%) covered two or more essential topics, 19 (54%) three topics or more, and only 6 (17%) covered all four essential topics. Only 3% did not cover any of the essential topics. Table 3 illustrates the coverage of key counselling topics by the 35 facilities.

#### *IPT recording and reporting*

IPT data were recorded in 34/35 (97%) facilities—the exception being one primary health clinic in Mpumalanga. No official IPT register was available for facilities at the time of assessment; however, 20/34 facilities (59%) had made their own registers, allowing them to record patient information and IPT data throughout treatment. Of these, 33 (97%) also reported monthly IPT statistics, except for one primary health clinic in North West Province. We separately investigated recording practices for antiretroviral therapy (ART) patients, and found that among the 35 sites providing IPT, 27 (77%) initiated ART patients on IPT. Recording of IPT information for ART patients at these facilities was poorer, with only 21/27 sites (78%) doing so.

**Table 3** Coverage of key elements of IPT counselling (n = 35)

Elements of IPT counselling	n (%)
Importance of adhering to entire 6-month course of treatment	34 (97)
Importance of immediately reporting side effects	23 (66)
Importance of immediately reporting signs/symptoms of tuberculosis	10 (29)
Importance of reducing or stopping alcohol during IPT	9 (26)

IPT = isoniazid preventive therapy.

## DISCUSSION

Our study assessed IPT implementation in South Africa in early 2011. Our data show that IPT is being partly implemented. We found that 71% of randomly selected medical facilities had begun to implement IPT and that, in February 2011, 46% of eligible newly diagnosed HIV-infected patients in the IPT-providing facilities were initiated on IPT. In this survey, many of the sites that were not implementing IPT did so due to a lack of province-level policy, a lack of guidance from authorities or fear of INH resistance. This lends support to current literature indicating that staff concerns about INH resistance due to a failure to rule out active TB are a major barrier to IPT implementation.<sup>14–19</sup> Some of these concerns might be due to inexperienced staff or other organisational barriers, and some studies have suggested that clinical opinion leaders could be instrumental in allaying fears about INH resistance.<sup>20–22</sup>

We found that facilities where the 2010 national IPT guidelines were available were almost three times as likely to offer IPT, confirming findings that development of operational guidelines and strong policy presence are essential for effective IPT implementation.<sup>23–26</sup>

The lack of association between recent staff training in TB and HIV integration and IPT implementation was not expected. Overall, recent training in TB and HIV among core staff in our sample sites was poor; although most surveyed sites had at least one recently trained staff member, only some facilities had at least one trained doctor or nurse. This is of particular concern, as the latter are key in initiating patients on ART and TB and IPT treatment.<sup>9,27</sup> Further training of public clinical facility staff is needed in TB and HIV integration.

Furthermore, while effective communication and joint decision-making between managers of TB and HIV services on site seem paramount to the efficient integration of these services, only a minority of sampled sites had TB-HIV coordination bodies. We did not find an association between having TB-HIV committees and increased IPT uptake, but believe that such an association would have been likely with a larger sample size.

### Limitations

The survey was a rapid assessment, and thus included few facilities in each province, limiting generalisability. The small sample size further limited the power of the survey, and may have prevented us from finding statistical significance in differences that truly did exist. A greater sample size might have shown an association between factors such as staff training in TB-HIV and on-site TB-HIV committees and increased IPT uptake. In addition, facilities were selected in those districts with the highest antenatal HIV prevalence,

which might not be representative of areas with lower HIV prevalence. We sought to maximise external validity through random sampling and selecting a range of facility types in each province, which approximated national distribution. Furthermore, twice the number of study sites were selected from KwaZulu-Natal compared to other provinces; it had double the number of districts compared to most other provinces and the highest overall HIV prevalence in 2008.<sup>15</sup> Northern Cape only had four study sites, as two of the facilities initially selected merged into a single entity shortly before data collection. No data on adherence and side effects in patients initiating IPT, or further data on barriers to implementation, were collected. Finally, while having numerous data collection teams might have introduced interviewer bias, all teams underwent standardised training conducted by the Principal Investigator prior to data collection.

## CONCLUSION

Our study demonstrates that some progress is being made towards IPT implementation in South Africa, where almost half of eligible patients among IPT-providing sites were initiated in February 2011. The presence of the latest guidelines, with simplified algorithms for the identification and initiation of eligible patients on IPT, was associated with better IPT uptake. Barriers to IPT implementation included fear of INH resistance and lack of clear guidance from health care authorities. Few of the surveyed facilities had on-site TB-HIV committees and recent TB-HIV training remained low, particularly among nurses and physicians. One of the key measures for efficient integration of TB and HIV services might be effective communication between facility TB and HIV coordinators, and updated staff knowledge in TB and HIV integrated services. Further studies are needed to investigate the effects of on-site TB-HIV coordination bodies and staff training on IPT implementation.

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## R É S U M É

**CONTEXTE :** Services de santé publique en Afrique du Sud.

**OBJECTIF :** Evaluer la mise en œuvre actuelle du traitement préventif à l'isoniazide (IPT) en Afrique du Sud, 2011.

**SCHEMA :** Etude transversale de 50 services sélectionnés au hasard en Afrique du Sud. Des interviewers entraînés ont administré un questionnaire standardisé dans chaque service sur les aspects de la politique IPT, sa mise en œuvre, son enregistrement et sa déclaration. Nous avons calculé et comparé les statistiques descriptives par province et par type de service.

**RÉSULTATS :** Sur les 49 sites participants, 35 (71%) assurent l'IPT. L'étude par province révèle l'absence (0%) dans tous les services du Western Cape, et la disponibilité dans quelques sites de Mpumalanga (40%) et Limpopo (20%), ce qui a comme conséquence qu'en février

2011, 46% seulement des patients infectés par le virus de l'immunodéficience humaine (VIH) et éligibles pour l'IPT l'ont reçu. La mise en œuvre de l'IPT a été de 27% dans les centres de santé de la collectivité. Parmi les services ayant des comités de tuberculose (TB) et VIH (TB-HIV), 85% ont fourni l'IPT par comparaison avec 59% des services sans comité TB-VIH ( $P = 0,12$ ). La possession des directives nationales d'Afrique du Sud 2010 sur l'IPT est en association significative avec les sites fournissant l'IPT (84% vs. 29% ;  $P = 0,006$ ).

**CONCLUSION :** En Afrique du Sud, la mise en œuvre de l'IPT a commencé en février 2011. La présence d'une disponibilité des directives est en association étroite avec l'adoption de l'IPT. Un plus grand nombre d'études opérationnelles s'impose pour améliorer la mise en œuvre de l'IPT chez les patients infectés par le VIH en Afrique du Sud.

## R E S U M E N

**MARCO DE REFERENCIA:** Los establecimientos de atención de salud en Suráfrica.

**OBJETIVO:** Examinar la ejecución actual del tratamiento preventivo con isoniazida (IPT) en Suráfrica, en el 2011.

**MÉTODOS:** Fue este un estudio transversal de 50 establecimientos sanitarios escogidos en forma aleatoria en Suráfrica. Entrevistadores capacitados administraron un cuestionario normalizado en cada establecimiento sobre aspectos de las directrices, la ejecución, el registro y la notificación del IPT. Se establecieron las estadísticas descriptivas y se compararon en función de las provincias y del tipo de establecimientos.

**RESULTADOS:** De los 49 centros que participaron, 35 suministraban el IPT (71%). En el análisis por provincias, ningún centro aplicaba el tratamiento en el Cabo Occidental (0%) y unos pocos centros en Mpumalanga (40%) y Limpopo (20%); con ello, 46% de los pacientes con infección por el virus de la inmunodeficiencia humana (VIH) y aptos para el IPT iniciaron el tratamiento

en febrero del 2011. La ejecución del tratamiento en función del tipo de establecimiento fue de 27% en los centros de salud comunitarios. El 85% de los establecimientos que contaban con comités de atención de la TB y el VIH (TB-HIV) suministraban el tratamiento, en comparación con 59% de los centros sin este tipo de comités ( $P = 0,12$ ). El hecho de poseer en el centro de atención las normas nacionales surafricanas del 2010 sobre la aplicación del IPT se asoció de manera estadísticamente significativa con el suministro del tratamiento (84% contra 29%;  $P = 0,006$ ).

**CONCLUSIÓN:** Según se observó en febrero del 2011, la ejecución del IPT ya ha comenzado en Suráfrica. La existencia de las normas nacionales al alcance en los centros se asoció con la aplicación del IPT. Se precisan nuevos estudios operativos a fin de mejorar la administración de este tratamiento a los pacientes con infección por el VIH en Suráfrica.