SUPPLEMENTAL REPORT OF STEPHEN TABET, M.D., MPH

<u>Leatherwood v. Campbell</u>

Case No. CV-02-BE-2812-W

IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ALABAMA

WESTERN DIVISION

DATED: MARCH 11, 2004

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QUALIFICATIONSStephen Tabet, MD, MPH

Reference Expert Report of Stephen Tabet, M.D., MPH, dated August 26, 2003.

BASIC SCIENCE OF HIV

Stephen Tabet, MD, MPH

This report uses the same basic science referenced in *Expert Report of Stephen Tabet, M.D., MPH*, dated: August 26, 2003.

STANDARDS OF CARE

This report draws upon the same standards of care referenced in *Expert Report of Stephen Tabet*, *M.D.*, *MPH*, dated: August 26, 2003.

THE LIMESTONE CORRECTIONAL FACILITY

On February 23, 2004, I toured and observed the Limestone Correctional Facility. I reviewed both living conditions and the common areas of units 6A, 6B, 7A, and 7B. I was not permitted to interview correctional or medical staff.

Presently, living conditions are such that each patient lives either one to two persons per cell. Most of the patients actually complained of the cells being cold. When I made a walk-through and reviewed the cells, I concurred with that assessment. The cells were cold with a draft. Many of the windows are broken and covered with plastic or have been covered with blankets. Also, many of the windows appear to be inoperable. (See photographs 1, 2, 3, 4 &5)

The patients are locked in their cells all night and there are no emergency call buttons.

I also noticed that none of the toilets have railings, including the room of a wheelchair bound patient. (See photograph 6)

There is a railing in one of the showers of each unit, but it is very difficult to access this shower with a wheelchair. There is no seat in the showers for a handicapped patient to sit. (*See* photograph 7)

There is also dirty water on the floors outside of the showers. (See photographs 8 & 9) But, units 7A and 7B were very clean compared to units 6A and 6B.

I observed the entire pill line for at least an hour. The pill line was a disaster. NUMEROUS patients did not have their medications on hand and were told to come back, or were told that they did not have the medications altogether. Such common medications as tenofovir and d4T were not available. This was confirmed by reviewing the Medication Administration Records (MAR) of several patients, including Patient #2, who has not had tenofovir for the last four days.

Also, as described in the previous visit to Limestone Correctional Facility, many of the medications that are FDA approved to be administered with food, were in fact not being administered with food. Such medications as Fortovase, ritonavir, and Viracept, are being administered on an empty stomach. Sometimes the separation of the medications with food is as much as 1-1/2 hours. This leads to excessive side effects, including nausea, vomiting, and diarrhea, and poor medication absorption.

I was also told that the a.m. pill line can occur at anytime between 12:30 a.m. to 3 a.m.

I observed multiple patients, including Patient #181765, who did not receive his efavirenz, but was given his other HIV medications. Patient #149422 was given his medications except for nevirapine. Patient #099831 was not given his d4T.

The patients were moved several months ago from dorm 16 to dorms 6A, 6B, 7A and 7B. This is somewhat of an improvement but there are still many problems with the current living arrangements and there are many ways in which the Department of Corrections can improve the living conditions of these inmates, especially for the handicapped or disabled.

One patient was given his insulin and was made to inject the insulin into his thigh right in front of everybody, as opposed to in a private setting. This is an infringement on the patient's privacy.

At the Limestone Correctional Facility it is important to note that one of the patients who expired from active tuberculosis was put in the HIV general population. As a result, all the patients in the dorm who are HIV positive were placed on INH therapy prophylaxis. The patient with active tuberculosis was inappropriately placed in the general population, and as a result exposed numerous patients, and perhaps all patients, with HIV to tuberculosis. As a result, all HIV patients and some correctional officers are on INH prophylaxis. The infection control procedures were not being adhered to, so the Public Health Department was called into Limestone for assistance.

The infection control procedures at Limestone Correctional Facility need to be reviewed and strictly adhered to, given the serious problem that is presently occurring.

PATIENT INTERVIEWS

PATIENT #1

Interview: 02/23/2004

I spent extensive time reviewing the patient's medical record and interviewing him. The patient is currently being housed in the inpatient unit. He is a 39-year-old male who is HIV-positive and has a history of asthma and tuberculosis exposure. His main issue is that for the last several years, he has had persistent rectal bleeding. A review of his medical record shows that the patient had been referred to surgery and had been diagnosed with anal fissures as well as anal stenosis. Apparently the surgeon did not recommend surgery. The most recent surgical consultation could not be located in the patient's medical records. The patient continues to have persistent rectal bleeding. He has not been seen by a gastroenterologist and he has not had a colonoscopy or endoscopy performed for a thorough examination despite his chronic rectal bleeding and pain.

Upon further discussion with the patient, he reports that he has large amounts of blood in his stool every single day and significant pain. The patient states that he feels the medical care at this institution has not changed since I was last at the facility approximately one year ago.

Although this is not documented in the records, it appears that the patient may have had a hepatitis A and B screening. Again, there is no documentation of this screening or any results. The patient received a hepatitis A and B vaccinations. He also received a Pneumovax vaccination in April 2003.

In September 2002, the patient informed Dr. Simon that he felt the Viracept was causing him to bleed. At the patient's request, Dr. Simon discontinued the patient's antiretroviral therapy.

IMPRESSION:

This is an HIV-infected patient whose main issue is chronic rectal bleeding. Unfortunately he has not had a thorough examination of his gastrointestinal tract and the source of the bleeding is unknown. The patient has tried different therapies and none have been successful. This patient needs to be seen again by a gastroenterologist for a thorough examination in addition to more aggressive intervention.

Additionally, the patient had been placed on nonsteroidal anti-inflammatory drugs for quite some time consisting of Motrin 800 mg t.i.d. This could be contributing to the patient's rectal bleeding. This patient also had the mistaken perception that his antiretroviral Viracept caused his rectal bleeding. As a result, he stopped his medications. There is no documentation that the patient received an explanation that the Viracept was not causing his rectal bleeding.

Interview: 02/23/2004

This patient is a 32-year-old male with a history of class C3 AIDS and chronic *Cryptococcal* meningitis which is a severe, life-threatening fungal infection. I last saw the patient at my 02/13/2003 and 02/14/2003 visit when I first visited the Limestone Correctional Facility. At that time, the patient had been unable to take all his medications because at times he was not hearing the call for the pill line. Currently the patient reports that he has been taking all his medications as directed when they are available. However, he reports that on several occasions his life-saving medication called fluconazole, which is used to treat deadly *Cryptococcal* meningitis, is unavailable. In particular, it appears as if on the dates of 12/30/2003, 12/31/2003, 01/08/2004, 01/09/2004, 01/28/2004, and 01/29/2004, the patient did not receive his medications for his *Cryptococcal* meningitis. The patient adamantly denied that he did not show up for his pill call. Instead, the medications were not available to him. In fact, he was told by the staff that they ran out of these life-saving medications. He also states that the medical staff had fluconazole available for other patients, but they did not administer him the medication.

Currently the patient is on a regimen of d4T, ddI, and Viracept. He has had an excellent response, which shows that he has been largely compliant. His CD4 count is up to 680, where before it was very, very low. His viral load is almost undetectable at about 800. The patient, like all other patients, is currently on INH for TB prophylaxis which he receives at 1:30 in the morning. The patient usually goes to sleep around 12 o'clock, but is awakened 1-1/2 hours later to take the medication, which severely disturbs his sleep. Also, the patient has received very little explanation of INH toxicity.

IMPRESSION:

This patient is a 32-year-old male with class C3 AIDS and chronic *Cryptococcal* meningitis and has had an excellent response to therapy as evidenced by his high CD4 count. Most concerning, is that the patient states, and it is documented, that he does not receive all of his medications. In fact, Limestone Correctional Facility is still running out of life-saving medications such as fluconazole. This patient needs to receive his fluconazole every single day. It is very critical. During pill call in dorm 7 on February 23, 2004, it was observed that a large number of patients missed doses of life-saving medications. These medications were not made available to the patients. It is critical that the patients receive these medications.

Also, the patient is on a regimen, which consists of d4T and ddI and Viracept. d4T and ddI are often very toxic together and largely not used unless under unusual circumstances (i.e., salvage or rescue therapy). Being that this is the patient's first regimen, it does not make sense why he would receive d4T and ddI. If taken together, these medications can cause an increase in mitochondrial toxicity and lactic acidosis. Because of the increase in toxicity and acidosis, this dual regimen has largely been abandoned in the treatment of HIV infection.

Interview: 02/23/2004

This patient's medical records were thoroughly examined. The patient was interviewed and examined.

The patient is a 58-year-old male with HIV infection, hepatitis C, coronary artery disease, and a history of a myocardial infarction. The patient is being housed in the inpatient unit after a recent visit to Huntsville Hospital for pneumonia. He is currently on antibiotics to treat the pneumonia. The patient also carries the diagnosis of severe wasting.

The patient reports that while being in the inpatient unit, his medications are often missing. In fact, he reports that up to three to four times a week his medications are not available. He is told that the medications have been discontinued, only to be informed the next day that they have not been discontinued or have been restarted. The patient states that he wants to take all of his medications as directed. However, they are not administered to him on a regular basis.

He also stated that he had approximately a 40-pound weight loss in the last year. This is substantiated by his medical records. The patient has rather severe facial wasting and appears very emaciated and fatigued. (*See* photograph 10) Until recently, the patient's HIV medications were d4T, ddI, and efavirenz. Today, the patient was seen by Dr. Simon who changed the d4T to tenofovir.

A thorough review of the patient's chart reveals that he has not had any fasting lipids and had not had any cholesterol obtained.

IMPRESSION:

This patient is a 58-year-old male whose major issue right now is that he is emaciated and has lost what appears to be over 20% of his total body weight in the past year. He also has very severe facial wasting. As with other patients, a thorough review of the medical records shows that he has not had a thorough evaluation of his wasting. This may include such simple laboratory draws as a testosterone level. Yet, the patient is receiving Resource protein supplement three times a day. However, this does not appear to be enough to keep up his needs because he continues to lose weight.

Until today, the patient was also on a regimen consisting of d4T, ddI and efavirenz. He responded well to this regimen. As previously noted, the combination of d4T and ddI has largely been abandoned because of their increased toxicity. The d4T has been switched to tenofovir. Also, the patient's facial wasting is likely the result of the d4T.

In addition, this patient has a history of a myocardial infarction as well as coronary artery disease. He is on multiple medications for coronary artery disease and hypertension. A thorough review of his chart reveals that the patient has never had a cholesterol or lipid panel drawn. This is a

problem. The patient needs to have this obtained, especially given his medical history and that he is on HIV medications which can increase the cholesterol level.

The patient is an elderly patient with hepatitis C who is on INH and who does not appear to be receiving regular liver enzyme monitoring. Given the patient's high risk of hepatoxicity, this decision should be thoroughly discussed again with this patient.

Interview: 02/23/2004

I have interviewed, examined, and reviewed the patient's medical records on 02/23/2004.

The patient is a 36-year-old male with HIV, chronic hepatitis B, hepatitis C, as well as chronic gastroesophageal reflux disease. The patient is currently on a regimen consisting of Kaletra, Fortovase, and Sustiva. He is being administered these medications in a "keep-on person" manner.

The patient is also on INH prophylaxis given that he may have had exposure to another patient with active tuberculosis. The patient reports, however, that the INH is being administered to him sometimes as early as 1 AM by the nursing staff. The patients often do not go to bed until just a couple of hours before this time. There is a pill call that occurs sometime between 1 a.m. and 3:30 a.m.

I reviewed the patient's chart regarding his chronic abdominal pain and reflux type symptoms. There is no appointment in the patient's chart with a gastroenterologist, despite the fact that the patient appears to have failed H2 blockers as well as treatment for *Helicobacter pylori*.

IMPRESSION:

This patient is a 36-year-old male with HIV who has had a good response to his antiretroviral therapy. His CD4 count is 697. The viral load is less than 75. However he reports, that some of his medications ran out in January 2004, before he was able to keep them on his person.

He also carries the diagnosis of chronic hepatitis B and chronic hepatitis C and is currently on INH prophylaxis, which places him at a fairly high risk for INH hepatotoxicity. It is not clear from the medical records, but this patient needs to have his liver enzymes monitored closely for the duration of his INH therapy.

This patient also needs a thorough evaluation, including a consultation with a gastroenterologist, to ascertain the etiology for his chronic abdominal pain, nausea, and reflux symptoms.

As with the other patients, the timing of the medication administration (between 1 AM and 3 AM) then breakfast at 3:30 AM is completely counterproductive to sick patients' receiving much-needed sleep and rest.

Interview: 02/23/2004

The patient is a 51-year-old male who is HIV positive. He also carries the diagnosis of hypertension. As with all of these patients, he has been exposed to tuberculosis and is on INH prophylaxis. The patient is also on d4T, ddI, and Viracept. He has been on this regimen since 2001 and has had an excellent response with a CD4 count above 1000, and a viral load of less than 50. This was his first regimen. Prior to this regimen, he had been antiretroviral naïve.

During discussion with the patient, he states that he has not had his blood pressure medications since 01/29/2004. This is confirmed by review of the Medication Administration Records (MAR). Procardia is currently not available at this institution. As a result, they will be starting him on a new medication which is called Sular. However, this medication is also not available at Limestone. Therefore, the patient is not receiving any medications for his high blood pressure. Blood pressure check at his last visit on 01/29/2004 was a systolic blood pressure of 158, a diastolic blood pressure of 99 which are too high and need treatment. The patient reports being dizzy and has headaches since he was taken off his medications.

Review of the patient's laboratory records shows that on 05/21/2003, he had lipids drawn, but they were not drawn fasting. His triglycerides are 277 which is two times normal. They have not been rechecked since then.

IMPRESSION:

This patient is a 51-year-old male with HIV infection who has had an excellent response to therapy. Unfortunately, as with many other patients, he is on a regimen which has a high toxicity profile consisting of d4T, ddI, and Viracept. d4T and ddI should be reserved only for patients who have no other therapy options given that the increased propensity for mitochondrial toxicity and lactic acidosis are potentially deadly side effects of these drugs.

Also the patient had lipid panels drawn less than a year ago with triglycerides that were elevated. Since then, this has not been rechecked.

Very concerning for this patient is that he has a history of hypertension and has had at least one visit in which he had high blood pressure. He is experiencing symptoms consistent with high blood pressure. Yet he continues to go without his blood pressure medications because of a breakdown in the medical delivery system. His blood pressure medication was discontinued, and another medication was supposed to be started, but it has not been available. His blood pressure medications need to be started immediately.

This is yet another patient who is on INH for tuberculosis exposure. He receives the INH between 1:30 to 2 in the morning, which interferes with the patient's ability to get sustained sleep.

Interview: 02/23/2004

This patient is a 31-year-old male who has AIDS and had a recent episode of very severe anemia. The anemia was likely secondary to AZT toxicity of the bone marrow.

A review of the patient's records show that he has been on a triple drug regimen consisting of Combivir (which is AZT and 3TC) and nevirapine since his initial admission to Limestone Correctional Facility. The patient reports that he has been on this regimen since approximately one year before his admission to Limestone. The patient reports that he has been taking all his medications as directed.

A review of his records show that there are multiple sick call request forms which appear to start some time around 12/03/2003 when the patient started reporting severe headache. On 12/14/2003 he reported another headache. It was documented that the patient was a "no show" but he reported that he was never called about his appointment. He was very upset about this; it was distressing to him.

On 12/23/2003 there is another sick call request form reporting headache, dizziness and suffocation. He stated that he was unable to walk because he was so short of breath. On 01/02/2004, the patient further reported more dizziness and headache, which he said he had had for the past three to four months. The patient informed me that he had been discussing these symptoms with the nurses verbally for at least several months before his sick call request forms, but he was not being seen.

The last time the patient was seen by Dr. Simon was in mid August 2003. At that time, his hematocrit was in fact 39.6. A normal hematocrit level should be in the range of 40. His CD4 count was 193 and viral load was less than 75. The patient was not seen again until 01/15/2004, which is a full five months later. During that interim time, he did not have any monitoring for toxicity that is documented. When the patient was finally seen after having requested multiple times to be seen, and having complained of very severe symptoms, he is seen and a hematocrit was finally obtained which shows a near-death hematocrit of 12. This is dangerously low.

He was emergently sent to the Huntsville Hospital where he received an incredible amount, six units of packed red blood cells, which brought his hematocrit to an acceptable level. Since he was initially seen, the patient has only had one repeat blood draw which shows some stabilization of his hematocrit. However, he has not had any further blood draws.

He had been receiving Combivir (which is AZT and 3TC), which was discontinued, and he is currently on a regimen which consists of tenofovir, 3TC, and nevirapine and he is tolerating this quite well.

IMPRESSION:

The biggest problem with this patient's care is that he was on a drug called AZT. A well know side effect of AZT is serious anemia. His verbal pleas with the nurses, as well as his sick call request forms, clearly show that he was suffering from anemia which was causing him to be short of breath, as well as being tired and having a headache. He was not seen in an appropriate time period. When the patient finally was seen, his hematocrit was critically low. Fortunately, the patient did not suffer any myocardial infarction or a severe fall, and was appropriately cared for at the Huntsville Hospital.

This is yet another patient who is not being followed regularly, given the vast number of patients that need to be followed by Dr. Simon.

Interview: 02/23/2004

The patient is a 41-year-old male with AIDS who reports a history of multiple episodes of *Pneumocystis carinii* pneumonia (PCP). The patient also has a significant history of psychiatric disorder and has been diagnosed with bipolar affective disorder as well as schizophrenia and is on psychiatric medications at this time. He also has a history of anemia and oral candidiasis.

In discussion with the patient, he reports that he has had multiple episodes of PCP, his last episode being in November. On review of the patient's medical records, there is no documentation of multiple episodes of PCP. There is also no documentation of his hospital visit to the Caraway Hospital where the patient reports that he was there for almost a month recovering from his pneumonia.

The patient also states that he has been hearing voices and seeing things that other people do not see

On exam, the patient appears to be a thin male with some wasting. He has tangential speech and is a poor historian.

IMPRESSION:

This patient is a 41-year-old male with AIDS who, by history, reports having PCP multiple times, the last time being November 2003. It is unclear why his medical records do not document this, or why the records from the Caraway Hospital are not part of his current medical records. The records from the hospital should be in the chart if indeed he was at the hospital. Because of the lack of documentation of his illness, not much insight into the patient's care can be provided.

Interview: 02/23/2004

The patient is a 31-year-old male who I previously saw during my February 13/14, 2003 visit. Since October, he has been off antiretroviral therapy when he signed a refusal form. The patient has a history of non-adherence and has a large amount of frustration with the medical system. He has experienced multiple side effects and toxicities from the medications and states that he gets the same medications restarted, even though he has had toxicity in the past while on the same medications.

The patient reports that he supports the "keep-on person" or KOP medication distribution system that is in place. However, it is not working. Patients are not able to refill any of their medications until they run out of their medications and then often there are no medications available. This means that they sometimes run out of medications for two to three days. This has been consistently reported by all the patients at the Limestone Correctional Facility -- that medications are still not being supplied in a regular manner.

The patient is also on INH for tuberculosis prophylaxis. He states that he has been getting his breakfast at the usual time of 3 a.m. in the morning. This does not permit him a regular night's sleep.

IMPRESSION:

This patient is frustrated with the Limestone Correctional Facility medical system, or lack thereof medical system. He is currently not on antiretroviral therapy. He had been on HIV medications and due to multiple toxicities and side effects was taken off. However, he states that when he had these medications restarted, he was put on the same medications.

He reports that the KOP or "keep-on person" is a positive step, but that it is not working correctly and that they are running out of medications. This has been supported by many other patients.

Interview: 02/23/2004

This patient is a 49-year-old male who has a history of AIDS and non-insulin dependent diabetes mellitus. The patient also has been diagnosed with bilateral avascular necrosis, the first occurrence in his left hip in 2001, the second occurrence being in the right hip in October 2003. Of note, the patient has had radiographic examinations, which demonstrate that the patient in fact has avascular necrosis with collapse. This has led to his not being able to walk any longer. He currently gets around by using a wheelchair. He has very severe, persistent pain in both of his hips. Again, he is unable to walk or stand.

The patient has been seen by an outside surgeon, Dr. Dueland, several times, the last visit in October 2003. A referral for to be seen by Dr. Dueland is in the chart, but Dr. Dueland's consultation report can not be found. According to the patient, he was told by Dr. Dueland (and Dr. Simon was told by Dr. Dueland) that Dr. Dueland would in fact do the surgery for this patient. However, it has been several months now and the patient has been told that because of the switching of the medical system, they are not going to do the surgery at this time, and that it needs to be reevaluated.

Also, the patient states that he is currently on a regimen of efavirenz, abacavir, saquinavir, and ritonavir. He is on a mixed regimen and is able to keep two medications, efavirenz and abacavir, on him. Unfortunately he still has to go to the pill line for the ritonavir and saquinavir. The patient reports that they run out of his medications. The last time that they ran out of his medications was on 02/20/2004 and 02/21/2004.

IMPRESSION:

This patient has a very severe problem in his hips, which has led to his being severely disabled and dependent upon a wheelchair for mobility. Although he had an evaluation several months ago, he has not had much-needed surgery. Apparently the surgeon felt that the patient was eligible for surgical treatment, especially given his excellent response to therapy. His CD4 count went from 138 recently to 309. Of great concern is that medical records appear to be missing.

In addition, the patient is receiving a mixed regimen of both "keep-on person" as well as directly observed therapy, which is very confusing and leads to the patient not being given his medications correctly. In addition, the patient is receiving INH at 1 a.m.. This is completely unacceptable.

Interview: 02/23/2004

The patient is a 53-year-old male with AIDS as well as brittle insulin-dependent diabetes who has been very difficult to manage regarding his diabetes.

The patient is compliant with all his medications as well as his appointments. He tries to stabilize his blood sugar, but is unable to do so. The patient states that while he was at the Mobile County Metropolitan Jail, his blood sugars were stabilized. Yet, at that time he needed five meals a day and was receiving an insulin regimen that helped control his diabetes. Currently, the patient has multiple episodes of hypoglycemia and hyperglycemia. At one point, the patient had such a low blood sugar that he actually fell down. This was likely due to his hypoglycemia.

The patient also reports some pus filled bumps on his head. On examination, he does in fact have these bumps on his head. This is consistent with impetigo (staph infection).

On further questioning, the patient reports that he does not receive a diabetic diet. He receives the regular diet that everyone else receives. He receives a "diabetic snack", which consists of half a cup of applesauce or two slices of pineapple or half a pear.

His current HIV medications are tenofovir, 3TC, nevirapine, and nelfinavir. He is also receiving INH for his potential tuberculosis exposure, although he has not had any liver enzyme monitoring. The patient's CD4 count on 08/13/2003 was 397 with a viral load of less than 75.

IMPRESSION:

This is a patient with very brittle diabetes mellitus. Given that he is not receiving an adequate diabetic diet or small meals, as he had been before, it is going to be impossible to control his diabetes. As a result, the patient has suffered because of his uncontrolled diabetes as evidenced by the recent fall. The patient stated that he has requested diabetic diets, but they are not available at Limestone Correctional Facility. Thus, he is given a regular diet.

Also concerning is that the patient is on INH. In view of his antiretroviral therapy and AIDS, he should have his liver enzymes monitored. This is not being done.

Also, upon reviewing the chart, the patient had a lipid panel drawn. According to the patient, as corroborated by other patients, this was not obtained while the patient was fasting, even though he had an elevated triglyceride level of 349. This makes it very difficult to actually assess the level's importance.

The patient's last CD4 count and viral load were 08/13/2003. These were not repeated until 02/21/2004, which is a six-month lag. This is much too long between test results.

Interview: 02/23/2004

This patient is a 37-year-old HIV positive male with a CD4 count of 448 and a viral load of 1200 on 09/17/2003. He is currently not on any antiretroviral medications or any HIV medications. He is taking INH prophylaxis for a possible tuberculosis exposure. The patient also has hepatitis C. The patient received hepatitis A and hepatitis B vaccinations on 10/04/2003.

After much discussion with the patient, the patient does not have a good knowledge of hepatitis C and has not been counseled at Limestone. He also is not aware that there is treatment for hepatitis C, much less the mechanisms of transmission. Yet, the patient is interested in treatment. However, treatment is apparently unavailable at the Limestone Correctional Facility.

On examination the patient looks rather healthy. He is not wasted and he does not show any evidence of chronic liver disease.

IMPRESSION:

This patient is a 37-year-old male who has stable HIV and chronic hepatitis C. While he has been appropriately vaccinated, which is something that is new to the Limestone Correctional Facility, he has not had any reasonable counseling on hepatitis C has had no discussion regarding therapy. More and more, treatment for hepatitis C-infected patients in the presence of HIV is becoming the standard of care.

Interview: 02/23/2004

The patient is a 33-year-old male who is HIV positive and has hepatitis C. He also has a history of multiple skin Staph infections.

The patient reports that he is currently on medication for his HIV, which includes tenofovir, ddI, and efavirenz. Until recently, the patient was on too high a dose of ddI, which was recently decreased to an appropriate dose. The patient states that the medications are not delivered to him on a regular basis. In fact, they often miss doses. They are often out of his medications. Currently he has not had his tenofovir for the past four days. In addition, several weeks ago they ran out of his ddI for several days. He is currently receiving only one medication as "keep-on person" which is the ddI. The rest of his medications he receives as directly observed therapy, which is fairly complicated.

The patient has absolutely no knowledge of hepatitis C, including its mechanism of transmission or its pathophysiology. In addition, he does not understand that there is treatment for hepatitis C, although I discussed with him that there is available treatment. He informed me that Dr. Simon told him "I am here to treat your HIV only; not to treat your hepatitis C. This is none of my concern."

The patient states that he has had multiple abscesses of his buttock area as well as other parts of his skin, including his face. He states that he was seen by Dr. Simon about this issue. However, Dr. Simon did not address this issue. As a result, he had to have another inmate help him drain these lesions. He reports draining a large amount of pus.

Currently, the patient is on INH therapy and has one scheduled followup liver enzyme test, although there is no regular followup testing for liver enzymes, even though he has chronic hepatitis C.

IMPRESSION:

This is a patient who fits the pattern of not receiving his medications on a regular basis. This is a huge problem given that this will set him up for resistance and these medications will ultimately fail. Also, it is unclear why the system currently exists where some patients get part of their medications as "keep-on person" and the other part of their medications as directly observed therapy. This is counter productive to the patient's care and creates a lot of confusion.

Also, the patient has absolutely no knowledge of hepatitis C and is unaware that there is available treatment. Apparently, Limestone Correctional Facility does not treat hepatitis C infected inmates.

Also, on examination the patient is edentulous. (See photograph 11) Review of his medical

records show that he has lost about 10% of his body weight or more. This needs to be addressed. All patients need to have some sort of mechanism for eating and he does need to have dentures.

Interview: 02/23/2004

The patient is a 56-year-old male with HIV infection who was examined on 02/23/2004. This was in followup of an examination on 02/14/2003. The patient was initially seen on 02/14/2003 and at that time he had a non-healing irregular ulcer on his right forearm. Since that time, after several months, on October 2003 the patient finally had the lesion removed. On pathology it showed a basal cell carcinoma. Before the lesion was removed, he had multiple visits and was told that the lesion was not carcinoma. He has had the lesion removed and it appears to be healing quite well.

The patient is currently on d4T, ddI, and nevirapine and is doing quite well. His CD4 count is 519 with a viral load of 527.

IMPRESSION:

This is a patient who had a lesion, which was very consistent with cancer (basal cell carcinoma). It took the Limestone Correctional Facility an inordinately long period of time to finally have this lesion removed. Luckily, the patient has had it removed and it appears, at least at this point in time, to be under control.

HIV infection: The patient is currently on a regimen of d4T, ddI and nevirapine. Again, as with previous patients, this patient is on d4T and ddI. Given the excessive mitochondrial toxicity and potential for lactic acidosis, this therapy needs to be reassessed. d4T and ddI are only used in combination in very unusual cases where patients have no other therapy options.

Interview: 02/23/2004

The patient is a 29-year-old male who was initially incarcerated at the Limestone Correctional Facility in January 2003. Soon after the patient's admission, he was found to have a BUN of 14 and a creatinine of 1.6. These are both abnormal. The creatinine of 1.6 signifies that he has lost close to half of his renal function.

According to the patient's incomplete medical records, it looks like his kidney function tests were not obtained until 06/16/2003. At that time, his kidney function was severely compromised; his BUN was 46, creatinine 4.6. One week later the patient's renal function continued to decline; his BUN was 57 and creatinine was 7.1.

By this time, the patient was in renal failure. He was then referred to a kidney specialist. He was seen on 08/15/2003, which was eight months after his initial renal insufficiency. He was then diagnosed with AIDS nephropathy. It was believed that he should be observed. The patient had recently received an AV shunt placement.

Soon thereafter, the patient was placed on renal dialysis and has been on dialysis for approximately two months. Since then, he has not been feeling well. Currently, the patient reports that he does not feel well overall, has low energy and generalized malaise.

On 12/19/2003 the patient was seen by Dr. Simon complaining of body aches, fever and headache. He was diagnosed with a viral syndrome. He was seen 10 days later on 12/29/2003 by Dr. Hamer who is a new part time physician here at Limestone Correctional Facility. The patient was diagnosed with severe pneumonia and admitted to the inpatient unit where he was treated with broad-spectrum antibiotics. His condition has improved.

IMPRESSION:

This patient is a 29-year-old male who, upon entering the Limestone Correctional Facility, clearly had some kidney dysfunction as represented by a creatinine of 1.6. A vast majority of the medical records have been pulled from his chart prior to July. A referral slip outlining the patient's follow-up could not be found in his medical chart. Most disturbing is that it did not appear that the patient's creatinine or renal function was checked until several months later. By that time, he was in full renal failure and progressed rapidly to end-stage renal disease. Several months later he had to be put on dialysis.

This represents yet another patient at the Limestone Correctional Facility who was not followed closely enough, given the large number of patients and the small number of providers. However, it is encouraging to see that the patient is on a triple drug regimen of AZT, 3TC, and nevirapine. This may assist his HIV status given that his CD4 count is quite low at less than 20. However, it will not at all help out his renal failure. His renal failure at this point is irreversible.

Chart Review: 02/23/2004

The patient is a 34-year-old gentleman who has a history of AIDS as well as multiple documentations by Dr. Simon in the chart that he is not compliant.

The patient reported to clinic on 01/23/2004 complaining of general body aches and weight loss. Per her examination, he looked chronically ill. Dr. Simon diagnosed the patient with bronchitis versus pneumonia. He was housed in a single room and given Levaquin as an antibiotic for bacterial pneumonia. Just two days later the patient was continued on this antibiotic and sputum was obtained for AFB.

Dr. Simon also documented that the patient had a history of noncompliance. However, Dr. Scheibel actually saw the patient at that time and initially the patient was very interested in starting a regimen. He started him on a once-a-day regimen of Emtriva, Viread, Reyataz and Norvir. This was surprising given that the patient had been reported to be noncompliant. This was an excellent starting regimen for the patient.

On 02/04/2004, the patient continued to have a productive cough. He was continued on his current medications with a serum cryptococcal antigen that was obtained. On 02/06/2004, the patient was continued on his current medications. On 02/09/2004, he was on the same medications despite having increasing respiratory demands and a fever. On 02/11/2004 the patient was on four liters of oxygen which is a lot. The patient signed a DNR for Dr. Simon. The patient was given the diagnosis of rule out PCP and started on atovaquone. Interestingly, the patient did not receive a chest x-ray, an induced sputum, or a bronchoscopy. None of these tests are indicated in the chart.

The patient continued to deteriorate until 02/17/2004 when the patient was on six liters of oxygen with a fever of 104. This is very high amounts of oxygen. There are no oxygen saturations recorded in Dr. Simon's note. The patient was in severe respiratory distress and was transferred from Limestone by ambulance to Huntsville Hospital.

The current status of the patient is unclear. Most likely, he is still at Huntsville Hospital and is critically ill. Hopefully, he has not died.

IMPRESSION:

Mr. Watkins is a young, 35-year-old patient with AIDS who was listed as noncompliant. Yet he was seen by Dr. Scheibel and started on a once a day regimen. Dr. Scheibel is a Prison Health Service medical director of the western region and apparently consulted with Dr. Simon at the facility.

The patient had a pulmonary process in his lungs, which was treated without ever getting a diagnosis. Unfortunately the patient deteriorated at the Limestone Correctional Facility, had

increasing respiratory requirements despite not having a diagnosis and was transferred to the Huntsville Hospital.

Early on, this patient should have received induced sputum or bronchoscopy to try to get a diagnosis because he probably has *Pneumocystis carinii* pneumonia. Also, there are no arterial blood gases, which would have determined whether the patient needs steroids. It is unfortunate. This patient is very critically ill and may not survive.

SUMMARIES OF HIV INFECTED PATIENTS' DEATHS AT LIMESTONE CORRECTIONAL FACILITY OCTOBER 2003 TO FEBRUARY 2004

TAB NO.	NAME	AGE AT DEATH	DATE OF DEATH	PAGES
A.	GERALD LEWIS	35	2-26-2004	
B.	ROBERT STRICKLA	ND 37	1-2-2004	
C.	NATHAN SULLIVA	N 40	10-13-2003	
D.	ALFRED THOMAS	42	10-26-2003	
E.	ROBERT WALKER	48	11-6-2003	

DEATH SUMMARY GERALD LEWIS

Gerald Lewis was a 35-year-old male with AIDS and wasting who died on 02/06/2004 at 12:40 PM at the Limestone Correctional Facility.

A review of the patient's medical records prior to his death, reveals that the patient had a significant weight loss. In fact, the patient's weight recorded in July 2003 was 171 pounds. Although his weight was not regularly documented, in January 2004 the patient's weight was 110 pounds which is an extreme amount of weight loss; one-third of his total body weight was lost. The patient's weight loss was fairly progressive. As far back as 10/08/2003, the patient was seen by PA Ebby because of weight loss as well as diarrhea. At that time, no workup was done and no assessment of his diarrhea was initiated. Notes from January 2004 document that the patient had significant weight loss, which was reported consistently in the notes by Dr. Simon. At one point she documented the patient's significant weight loss and wanted to rule out hyperthyroidism, a rare cause of weight loss in this setting, and heart failure. Unfortunately there was no assessment of this patient for more common diseases that might cause such severe wasting.

Also listed in the patient's chart were multiple references to noncompliance. There was no thorough counseling that the patient underwent because of his supposed noncompliance. The patient was placed on protein supplementation. At one time, however, Dr. Simon felt that the patient should have received a high protein drink, but was told "kitchen was called for high protein drink, but is not available since milk was added to the diet at Limestone." So, the patient did not get what the doctor believed he should have received.

On 01/15/2004 the patient had blood cultures for MAC and tuberculosis. Again, there was no workup of his stool for any kind for pathogens that might have caused wasting. No testosterone level, repeat blood cultures or any medications that might have increased the patient's lean body mass were performed.

IMPRESSION:

Mr. Lewis is yet another patient at the Limestone Correctional Facility who had AIDS, was labeled noncompliant, and had a progressive course. It is clear that he either had AIDS wasting, or some common HIV-associated pathogen that was causing him to have such wasting. However, there was no thorough workup of the patient's wasting syndrome. Even such a simple laboratory test as a testosterone level, which is a male hormone, which can often be low in AIDS patients, was not even assessed.

The patient was not given any common medications that would increase his lean body mass or that would have increased the patient's appetite. There is a large body of literature that currently exists that shows that there are multiple medications that can increase a patient's appetite, increase their weight and increase their decreasing body mass. A few examples can be found in Clinical Infectious Diseases, 2003, volume 36, pages 69-78, HIV Clinical Trials, May-June 2003, volume 4, pages 150-163, Journal of Parenteral Enteral Nutrition, November-December 2002, volume 26, pages 357-365, The Journal of the Acquired Immunodeficiency Syndromes and Human Retrovirology, 1999, volume 20, pages 137-146, and Annals of Internal Medicine, 1998, volume 1, pages 18-26. These are just a few examples of the large body of literature that currently exists which demonstrate that patients who have wasting from AIDS can be administered different whole modality medications. Many of these medications are not expensive, such as testosterone or androgens, appetite stimulants, or even thalidomide. These medications have all been shown to increase body mass and furthermore, increase a patient's quality of life.

It is puzzling why these medications are not being used at the Limestone Correctional Facility.

DEATH SUMMARY ROBERT STRICKLAND

Robert Strickland was a 37-year-old male with AIDS who died on 01/02/2004 at 11:35 p.m. at the Limestone Correctional Facility. The patient's medical history is significant for being HIV infected and having (1) AIDS (CD4 count less than 20) in 03/2001; (2) hepatitis C with cirrhosis; (3) presumptive metastatic cancer to the lungs of unknown primary; and (4) pancytopenia. The patient was incarcerated multiple times prior to this incarceration at the Limestone Correctional Facility. The patient's medical records date back to the mid-late 1990's.

The patient died in the inpatient facility at Limestone Correctional Facility on 01/02/2004. Dr. Hamer notes on 12/31/2003 that the patient "needs DNR" because the patient was coughing up blood. On 11/17/2003 there was a discussion regarding end-of-life care and "states that he does not wish to be on life support. He understands his condition, so we can let him go when the time comes." This was documented by Dr. Simon.

The events leading to the patient's death are that he was vomiting blood in early November 2003 when he was seen by Physician's Assistant Ebby. As a part of this workup, a chest x-ray was done which incidentally showed that the patient had lesions in the lung. The patient was then sent out to the local hospital where he was evaluated. No records can be found in the patient's chart from this hospital visit. It was decided that he would not have an invasive diagnostic workup given his advanced AIDS, and that this appeared to be metastatic cancer, likely originating from the liver.

Reviewing the patient notes, it is obvious that on many occasions he reported having uncontrolled vomiting starting as far back as November, then worsening in December. He was put on a drug called Phenergan which did not appear to control his nausea or vomiting. I am not able to find where any other drug was tried. There are multiple notes stating that the patient refused meds. On 10/02/2003 Dr. Simon writes "not on any medications. Had refused all of them." On 09/30/2003, she also writes that "still does not wish to take any meds whatsoever." On 06/05/2003, it is documented in the patient's notes that he was counseled regarding the need to take his medications. Earlier that year on 03/25/2003, the patient apparently just stopped his medications, but from August 2002, the patient had a CD4 count of 81 and a viral load of less than 50, indicating that he did have full suppression of the virus, was responsive to therapy and was able to be compliant.

On 04/09/2003, the patient's total white blood cell count was 1500 with 437 neutrophils (normal neutrophil count is 1500 to 7800). A low neutrophil count is something that we call neutropenia and places the patient at high risk of getting an infection and dying; it is concerning that the patient's neutropenia was not addressed. The patient did not receive any medications to bring up his neutrophil count. It is unclear why this was not done.

Further back in the chart, dating back to 02/02/1998, the patient was seen by Dr. Moore. At that time, the patient was on three-drug therapy with d4T, 3TC, and Indinavir. But the patient told Dr. Moore that he wants to stop his Indinavir. So Dr. Moore continued him on a two-drug regimen of d4T and 3TC for an unspecified time period. It is unclear why a third drug was not substituted for the Indinavir.

Also, during that time on 09/09/1998, the patient signed an HIV adherence agreement. I have seen these agreements before, and they have always struck me as being an impediment to a good therapeutic relationship. One of the statements in this agreement provides that "if you do not follow the treatment as prescribed, you will be taken off the medication permanently." The patient is forced to sign this agreement if he wants to go on HIV medications. Later on, the patient was put on appropriate therapy with triple drugs of Combivir (which is AZT and 3TC) and efavirenz.

IMPRESSION: Mr. Strickland was an unfortunate gentleman who had AIDS as well as hepatitis C and likely developed cancer possibly from the liver, which then spread to the patient's lungs. His end-of-life care was somewhat appropriate in that he decided not to pursue any aggressive workup or treatment, so he received hospice care. From the notes, it appears that his pain was well controlled.

What is concerning is that his vomiting was not well controlled on the medication he was prescribed. It is unclear why another medication was not tried such as ondansetron. This is a medication used for cancer patients and AIDS patients with severe nausea. Yet, the patient continued to suffer needlessly from nausea and vomiting

Also, a Do Not Resuscitate form signed by the patient can not be found in the medical records. On 12/31/2003, Dr. Hamer writes in the note that the patient "needs a DNR."

Also of concern, is that the patient was apparently forced to sign an adherence agreement on 09/09/1998. This forces the patient into either perfect adherence (something that is rarely possible when taking combination therapies) or, as a consequence, the medication(s) can be stopped. Since failure is in most cases unavoidable, this adherence agreement can be construed as a setup for failure.

The patient had a low neutrophil count which is technically diagnosed as neutropenia. This was not addressed and it was not treated. Again, the treatment for neutropenia is a drug called GCSF. It is the standard of care that when a patient is neutropenic that he be given GCSF.

The patient also had hepatitis C. The treatment for this disease was never addressed previously in the patient's visits at the Limestone Correctional Facility because they apparently do not treat hepatitis C, even though it is becoming the standard of care to treat hepatitis C, even in HIV infected patients. The National Institutes of Health do NOT exclude HIV+ patients from being treated given the secondary complications that can occur such as cirrhosis, cancer and liver failure.

DEATH SUMMARY NATHAN SULLIVAN

Nathan Sullivan was a 40-year-old male who died on 10/13/2003 at the Huntsville Hospital.

The patient's history is significant. He had AIDS with multi-drug resistance and uncontrolled high blood pressure.

The patient's medical records reveal that he had been on multiple medications in the past and in fact was noncompliant on many occasions. There are several notes where the patient was asking for his medications to be discontinued; that he was feeling the medications might be toxic to his body. Absent from the chart are any very good explanations to the patient why he should be taking the medications. The patient's medications were just stopped. Yet, the patient agreed to continue with his prophylactic type medications that would prevent PCP and MAC.

The patient's inciting event that caused his death appears to have started on 10/05/2003 when the patient presented to the clinic. There was an emergency note treatment record by RN Weaver that states "I am so sick, I can't even walk. Inmate crying, praying to God to deliver him from this illness. Achy head to toe, nausea, headache, diarrhea after taking meds." Diagnosis: Rule out PCP." Further, the nurse documents that the patient has an increased respiratory rate of 24 which is almost twice the normal rate. He also has a high fever of nearly 103.

At that time, physician's assistant Ebby is called and the patient is housed in the infirmary and given IV fluids. While the patient is in the infirmary, the RN writes that the patient's condition is "poor." The patient's skin temperature is "hot."

The next day, 10/06/2003, the respiratory rate had increased to 28, pulse 120, and the fever had increased to over 103 degrees. The patient continued to have fever. It was not until three days later that blood cultures as well as *Cryptococcal* titers and a chest x-ray were ordered. Unfortunately, the results of the chest x-ray can not be found in the chart.

During this time, when the patient was clearly in severe respiratory distress, there is no documentation of any oxygen saturations or near complete workup until 10/09/2003 when the patient was noted to be confused. Again, PA Ebby is called who requests a CT of the head as soon as possible. However, this is not done. On 10/10/2003 the patient has increased confusion. His respiratory rate had further increased. His fevers continued. This is the first and only time an oxygen saturation is documented. The oxygen saturation level was a very low 89% on two liters.

When the ambulance personnel arrived, they initially refused to transport the patient because the patient's oxygenation status was so poor. Yet, after talking with the nursing staff, they decided to transport the patient immediately to Huntsville Hospital, where the patient died only three days later.

Unfortunately, no medical records from the Huntsville Hospital can be found in this patient's chart, so it can not be determined what was done at the hospital. It is expected that a complete workup including the head CT, cultures for MAC and induced sputum from bronchoscopy were performed. However, these were not performed while the patient was declining at the Limestone Correctional Facility.

Also, on 09/25/2003, the patient's CD4 count was 1% and the viral load was 35,000.

IMPRESSION: This patient represents a patient who was critically ill. It is clear that this patient's critical illness was not appropriately evaluated and the severity of the patient's illness was not appreciated. This was evidenced by the fact that the patient felt that he was dying a full week before his actual death, given his written own statements and the statements of the nursing staff describing the patient's condition as poor, noting that the patient continued to decline and having poor respiratory status. Unfortunately no workup of his oxygenation was performed until the patient was sent out in extremis by ambulance to the local Huntsville Hospital where he died.

DEATH SUMMARY ALFRED THOMAS

Alfred Thomas was a 42-year-old male who died on 10/26/2003 at Carraway Hospital while in the custody of Limestone Correctional Facility.

The patient was received from the Kilby Correctional Facility on 09/29/2003 and carried the diagnosis of AIDS, tuberculosis, and drug-induced hepatitis. A review of his laboratory results show that the patient had very severe hepatitis (inflammation of the liver) which, according to the notes, was diagnosed at the Kilby Correctional Facility.

The patient also had a CD4 count of less than 20 which was obtained on 10/02/2003.

During a previous incarceration in the Department of Corrections during 2001, the patient received INH therapy for TB exposure. At that time, he had liver dysfunction from the INH and his treatment was discontinued.

The patient was again started on TB treatment on 03/24/2003 with four drugs which later was decreased to two drugs. Several months later, while at Kilby Correctional Facility, the patient had very high liver enzymes. In fact, laboratory tests from 09/19/2003 show an AST of 1,095 which is about 25 times above normal; an ALT of 387, which is approximately 10 times above normal; and a bilirubin of 16, which is about 15 times above normal. This indicates severe liver dysfunction.

When the patient was received at the Limestone Correctional Facility, he was not on any medications (TB treatment or otherwise) and his liver dysfunction was somewhat improved. The patient was seen on 10/02/2003 by Dr. Simon. He was then housed in the HIV dormitory.

While at the Limestone Correctional Facility, the patient deteriorated very quickly and was transferred on 10/16/2003 to Carraway Hospital. At that time, the patient was housed in a respiratory isolation room at the hospital. The patient was noted to have a fever and progressive liver failure, and was also noted to have a mediastinal mass in his chest, as well as kidney failure and severe anemia.

The patient progressively deteriorated at the Carraway Hospital and subsequently died, most likely from liver failure, renal failure, and an overwhelming infection.

A review of the patient's chart shows that at one time he was negative for hepatitis C antibodies, although no PCR was done. The patient had also stated on his intake screening form that he had hepatitis C. He had no further work-up of his hepatitis.

The patient's records from the Kilby Correctional Facility are not complete in the patient's current

medical records at the Limestone Correctional Facility. This is very concerning.

After the patient was already transferred to Carraway Hospital, Dr. Simon received results of a chest x-ray which appeared to show active tuberculosis in the patient. Sometime after the patient's death, the medical staff was notified by the Health Department that Mr. Thomas had active tuberculosis during autopsy. Because Mr. Thomas was housed in the population of the HIV dormitory, the entire HIV infected inmate population at Limestone is currently being treated with INH tuberculosis prevention medication.

IMPRESSION: Mr. Thomas was at the Limestone Correctional Facility for only a short time. He progressively deteriorated and then was admitted to an outlying hospital and died.

Of most concern about this patient's care and medical records is that there are not complete medical records from the Kilby Correctional Facility, even though the patient was transferred from that institution with severe, life-threatening conditions. It is clear that there is very little communication between the prison facilities and charts are almost never transferred with the patient. The charts should be transferred with the patient. This lack of continuity of care is dangerous for the patient.

Also, this patient clearly had INH toxicity on 09/15/2001 during a previous incarceration. INH was restarted with three other TB medications on 03/24/2003 when the patient was at the Kilby Correctional Facility. It is uncertain whether this patient had any liver enzyme monitoring during this time, which he clearly should have had before he became very symptomatic and presented with very severe liver toxicity.

Many of the patients I examined at the Facility on 02/23/2004 are co-infected with HIV and Hepatitis C and are now being given INH therapy. Most of these patients are not having their liver enzymes monitored appropriately.

In addition, HIV positive individuals with liver dysfunction and test negative for hepatitis C antibodies, should be in fact screened for hepatitis C using a PCR which is a much more sensitive test. In fact, approximately 20% of patients who have AIDS and who have hepatitis C, will screen hepatitis C antibody negative. Thus, hepatitis C PCR is the standard of care for screening for hepatitis in a patient who is hepatitis C antibody negative yet is suspected of having hepatitis C. Stated more simply, the screening test was inappropriate for this patient and he may have had hepatitis C. It was also inappropriate that the INH was restarted given that he already had INH toxicity previously. He most likely did not receive appropriate monitoring of his liver enzymes, although again the Kilby Correctional Facility records were not complete for this patient. This is a tremendous problem.

Finally but very importantly, this patient had active Tuberculosis of the lung and was placed in general population and thus all the other HIV-infected patients (and staff) were potentially exposed to TB. This case demonstrates the lack of an organized system of infection control at

Limestone Correctional Facility. As a result of not putting this patient in respiratory isolation, numerous patients (and possibly even some staff) are having to take INH for TB prevention.

DEATH SUMMARY ROBERT WALKER

Robert Walker's date of birth was 10/01/1955. Because of incomplete medical records, the exact date of his death is unclear. It appears that he died on 11/07/03.

Mr. Walker was an HIV positive patient. He also had hepatitis C and poorly controlled diabetes mellitus. His last CD4 count that was recorded in the chart was in 08/2003 which was 276 with a viral load of approximately 3000. The patient was seen by Dr. Simon on 06/19/2003 with painful swelling in his neck. It was so painful, he was unable to swallow. The patient was given Keflex for lymphadenitis. He returned approximately two weeks later on 07/03/2003, and at that time Dr. Simon documented that the patient had resolved lymphadenitis and had no more lymphadenopathy.

The patient returned on 09/04/2003 and was conspicuously found to have a large mass at the angle of the temporomandibular joint. He subsequently underwent a workup of this swelling which was found to be a lymphoma. At that time, he was also noted to have lymphadenopathy in his neck. On 10/22/03, the patient underwent lymph node dissection and chemotherapy. The procedure was performed four months after initially presenting to the physician with symptoms.

There are multiple entries stating that the patient was not on antiretroviral therapy. Any entries that discussing whether this should be initiated can not be found in the chart, even though the patient's CD4 count met the Department of Health and Human Services criteria for starting treatment.

IMPRESSION: Mr. Walker is an unfortunate AIDS patient who appears to have died of lymphoma at the Limestone Correctional Facility. This is yet another patient with incomplete medical records that appear to have been thinned. It is unclear why there are no records prior to his death. The biggest problem with this patient's care is that he was diagnosed with lymphoma and then not treated with antiretroviral therapy. The standard of care for an HIV positive individual with lymphoma should include HAART. Multiple studies have shown that patient's who have lymphoma and are treated with HAART therapy, and chemotherapy, will do much better than patients who are only treated with chemotherapy, as this patient was treated.

Also concerning is the lack of full medical records, especially at the time prior to his death. These records should be reviewed to further evaluate the care of this patient which is clearly suboptimal.

SUMMARY OF THE MEDICAL CARE AT THE LIMESTONE CORRECTIONAL FACILITY

Stephen Tabet, MD, MPH

ASSESSMENT

The medical care at Limestone Correctional Facility has improved in a few areas, has declined in other areas, but has generally remained the same since my last visit on February 13 and 14, 2003 (as detailed in my initial report of August, 2003). In this section of the report, I will review my last report's summary, paragraph by paragraph, and discuss the specific issues supporting the overall assessment of the Limestone Correctional Facility's medical care. More strongly than ever, I feel that the Limestone Correctional Facility is in dire need of outside intervention and oversight.

DEATHS

One of the most egregious medical failures at Limestone is the number of preventable deaths. In the initial report, I reviewed 38 deaths since 1999. Since that time, I have reviewed five additional HIV patient deaths at the Limestone Correctional Facility. Patients continue to die because of the failure of the medical system. One of the most disturbing problems described in the prior report addressed a patient who literally suffocated in front of the medical staff. Sadly, another patient has recently declined right in front of the medical staff and suffered the same fate at the Limestone Correctional Facility.

Cardiopulmonary resuscitation (CPR) continues to rarely, if ever, be attempted in any deceased patient that was reviewed. This is a very concerning trend that continues at Limestone Correctional Facility. It is still relevant to question whether the nursing staff at Limestone Correctional Facility is adequately trained in CPR.

The deaths of HIV-infected inmates at Limestone continue without any appropriate thorough internal review. A cursory review is conducted by Dr. Simon. However, Dr. Simon's cursory reviews contain no substantive content and are of no real value. It is extremely disturbing that officials at Limestone, and particularly the Medical Director, would not want to review the deaths at this institution in detail, if only to identify and attempt to resolve the problems that so obviously exist within the current medical system. This is unacceptable.

PREVENTATIVE CARE

The medical system at Limestone continues to undervalue the cost-effectiveness of insuring that patients receive preventative care. A positive step is that hepatitis A and B vaccinations are now being provided. However, there continue to be a large number of patients who are not receiving their prophylactic or maintenance medications. These medications are life-saving medications used to treat or prevent such common and preventable illnesses such as *Pneumocystis carinii* pneumonia. Despite being addressed in the previous report, this pattern continues unabated.

It is also clear that patients continue to not fully understand the consequences of failing to take these life-saving antibiotics. From limited documentation, there appears to be some attempt by the medical staff to try to explain to a few patients why they must take their medications. However, the documentation for addressing this issue is wholly inadequate. There are many more patients who receive no counseling at all regarding the importance of medication compliance. And there are no attempts to solve the problems that cause noncompliance in the first instance.

Currently, one of the positive new measures at Limestone Correctional Facility is the "keep-on person" system. The biggest problem, however, with the "keep-on person" system is that it is not being effectively managed. As a result, patients often do not receive enough supply of their medications and run out. This may eventually lead to individual resistance to the medication(s). It is also accepted among infectious disease specialists that the effectiveness of the medications is largely dependent upon consistent dosing, which cannot exist in this kind of situation.

PILL LINE

During the first visit to Limestone, one of the concerning issues was that patients were treated like nuisances. This attitude continues to occur. Previously much-needed sleep was terminated for medication dosing at 3 a.m. or earlier. This was further compounded by breakfast at 3:30 in the morning. Currently, however, sleep is further interrupted so that patients can be distributed their much-needed medication dosing at 1 a.m. in the morning. This seems to be an arbitrarily imposed dosing time. This dosing time makes no practical sense and clearly is not healthy, mentally or physically, for an HIV- infected patient. However, this practice continues to occur, largely for the convenience of the staff and because of staffing needs. It is an unacceptable practice to have a patient go to bed at 10 or 11 p.m., or even midnight, and then to wake him up at 1 o'clock or 3 o'clock a.m. for medication distribution. Clearly, this will cause serious sleep deficits for the patients who are ill and have depressed immune systems.

During this visit, a considerable amount of time was spent observing the pill line at the Limestone Correctional Facility. There were numerous problems with the pill line during the previous visit. It is distressing to report that the pill line, which is the patient's life- line to receive his life-saving medications, continues to pose a significant problem. Multiple medications were not available for the patients. Patients were told either to return at a later time, or at a later date,

thereby missing their dosing. For patients on HIV medications, this can lead to drug resistance, rendering the drugs ineffective and useless in the battle against HIV. Ultimately, this can lead to death. It is absolutely unacceptable that the facility continues to run out of much-needed HIV and other medications as frequently as it is occurring at Limestone.

ACCESS TO PROGRAMS AND ACTIVITIES

Previously HIV- infected patients at Limestone Correctional Facility were completely segregated from other inmates. This segregation is ongoing. Although it now appears that some of the HIV-infected inmates will be allowed to participate in limited activities with HIV- negative inmates.

RESPONSE TO MEDICAL EMERGENCIES

At this time, an accurate assessment of what occurs during a medical emergency at the facility could not be ascertained. Previously, the slow response time to medical emergencies was concerning. However, the response time to medical emergencies could not be reassessed during this visit.

DIET

Medically necessary dietary requirements for HIV patients, such as diabetics or under-nourished patients, are still virtually nonexistent at Limestone Correctional Facility. The medical staff continues to write orders for special diets for patients, and the Alabama Department of Corrections consistently ignores and refuses to honor these medical orders. This is a problem, especially for patients who are under-nourished or malnourished, because it can result in death. Documentation exists of patients dying of malnourishment at Limestone Correctional Facility. Medications which can increase a patient's lean body mass are still not being used at Limestone Correctional Facility.

ACCESSIBILITY

Previously, the physically handicapped and the disabled suffered disproportionately at Limestone Correctional Facility. This remains true. While the Alabama Department of Corrections has made a half- hearted attempt to install some railings for the disabled to shower, there were no shower chairs. Shower chairs are needed for patients who are wheelchair-bound who need to shower in a sitting position.

HOUSING

The HIV-positive patients at Limestone were previously housed in an open bay warehouse where over 250 inmates lived in over-crowded conditions. Currently, the inmates have been moved into other housing units with one or two-person cells. These housing units are slightly better. However, there are still drafts and broken windows in these housing units, making living conditions unbearable for these immune-compromised patients. Also, the presence of standing water in the housing units is concerning, and there is a lack of cleanliness in some of the areas of the housing units.

INFECTION CONTROL POLICY

Unfortunately, infection control policy and practices are virtually nonexistent at Limestone Correctional Facility. Although some infection control policies exist on paper, it seems these practices are not in place at Limestone. In the prior report's summary, a concern about the possibility of an outbreak of tuberculosis was raised. True to the warnings and concerns, because there is no infectious disease prevention protocol in practice, a patient with active tuberculosis was housed with the HIV population. The result is that virtually all of the HIV- infected inmates, and possibly some of the staff, were directly exposed to tuberculosis. Infectious disease prevention protocols are incredibly important in correctional institutions. They need to be strictly adhered. Few of these infection control policies are being followed at the Limestone Correctional Facility.

MEDICAL RECORD TRACKING SYSTEM

Although patients continue to be followed on a somewhat regular basis, the medical system at Limestone Correctional Facility continues to be highly stressed. Such basic services as the dictation and transcription of medical records, simply do not exist at Limestone. In fact, the medical providers hand write their notes into the chart. This method of medical record keeping has largely been abandoned in the medical profession.

In addition, the Limestone Correctional Facility has an extremely poor to non-existent medical record tracking system. This is caused by not having a computerized system of medical care. This poses a problem in a large institution, such as Limestone, that has a large population of HIV-infected inmates and other medically ill inmates.

STAFFING

One of the recent positive changes at Limestone is the presence of another part-time physician. While this is a positive step, Limestone Correctional Facility continues to be understaffed. Because of understaffing, patients will continue to suffer and die from a lack of reasonable medical care and adequate nursing personnel.

There is still a sense of hopelessness and helplessness among the patients at Limestone. This was also observed during the last visit. While some of the changes that have been described are somewhat positive, the improvements have been far outweighed by the problems that continue to plague Limestone Correctional Facility. Additionally, new problems have arisen at Limestone.

RECOMMENDATIONS

Limestone Correctional Facility continues to have a vast array of significant medical problems. The medical care provided at Limestone Correctional Facility falls well below the standard of medical care for patients in the community or those standards established by organized bodies described in the beginning of this report. For this report, I will continue to only make follow-up recommendations of issues that need to be addressed urgently. The following recommendations must be addressed, or patients will continue to needlessly suffer and die at the Limestone Correctional Facility.

dying continues to be a problem and is potentially a serious medical liability.

Unfortunately, despite describing this issue in the previous report, there remains no thorough, organized system of reviewing patient deaths. The Department of Forensic Sciences provides cursory external autopsies which are not routinely reviewed by the Warden, Dr. Simon, the Medical Advisory Committee or any other reviewing body. In addition, there is no attempt to try and decrease the number of deaths. This is evidenced by Dr. Simon's own statement that she was not concerned about the number of HIV patient deaths at Limestone Correctional Facility. This is a very disturbing problem that needs to be urgently addressed. All patient deaths need to undergo a full internal and external autopsy, and all deaths need to be reviewed in detail by an outside physician/monitor.

In addition, the staff needs to provide more compassionate education to patients before signing "do not resuscitate" orders.

2. **MEDICAL DIRECTOR:** Currently, there does not exist a Medical Director at the Limestone Correctional Facility. The Medical Director's role is defined by understanding the system of care and working administratively in the system of care. Although Dr. Simon is designated as the Medical Director in the policies and procedures for PHS, she does not perform the administrative or leadership duties required by this position. In fact, Warden Mitchem was not even sure who the Medical Director is at Limestone, and has absolutely no contact with Dr. Simon. This is almost impossible to believe. This confusion explains why so many medical system problems are occurring at Limestone Correctional Facility. The Alabama Department of Corrections leadership has no understanding about what the medical staff is doing and the medical staff does not communicate with the Alabama Department of Corrections. The analogy I would use that exists at Limestone is that the head of the institution (the Warden) has been severed from the body (the Medical Director). Initially, the Medical Director should write detailed monthly reports describing the components of the medical system and ongoing medical activities. This report should be reviewed by an outside, independent monitor. An outside independent monitor should review Dr. Simon's clinical decisions.

3. PHYSICIAN AND MID-LEVEL STAFFING: While Limestone added one part-time physician to their staff, it remains obvious that the Limestone Correctional Facility continues to be dangerously understaffed with medical personnel. According to the National Commission on Correctional Health Care Guidelines, a facility with 2,200 inmates is expected to have a minimum of 110 physician hours per week. With the current number of patients, including approximately 250 HIV-positive patients, Limestone should have at least two full- time physicians, and two additional mid-level practitioners, in addition to the current physician's assistant. This staffing number was recommended in the previous report. It has not been followed.

Patients need to be followed more closely. Patients need to have their T-cells and viral load checked regularly. Also, liver enzymes of patients with any liver disease on INH need to be monitored on a regular basis. When patients have irregular lab values that need medical intervention, patients should receive automatic follow-up visits.

Hepatitis C testing and treatment is becoming the standard of care. Therefore, patients should receive hepatitis C testing and treatment. In addition, patients presenting with signs of liver dysfunction should receive a HCV PCR test (when the HCV antibody test is negative).

Patient care is compromised because Limestone medical records contain little or no medical records from Kilby C.F. or other outside facilities. A patient's medical records from Kilby need to be transferred with the patient to Limestone. In addition, the staff needs to retrieve all records of off-site medical care that was provided while the patient was housed at Limestone.

- 4. <u>INMATES PROVIDING CARE</u>: It was noted in the last visit that inmates were providing health care to other inmates. This practice continues. Inmates can assist other inmates with certain needs, but should not provide health care. Limestone needs a written policy detailing the services that inmates can provide to sick inmates. In addition, those inmates providing services need to have ongoing training.
- 5. NURSING: Nursing continues to be severely understaffed and many of the nurses are poorly trained at Limestone. The nurses at Limestone continue to make serious errors, especially at the pill line. As stated in the prior report, the nurses at Limestone are poorly trained and need better training, training in cardiopulmonary resuscitation, and ongoing medical education. The Limestone Correctional Facility needs to mandate that nurses receive certified nursing education as part of their continuous training and education. In addition, the current lack of nurses at the Limestone Correctional Facility is a problem and the National Commission on Correctional Health Care Guidelines need to be followed in terms of adequate nursing levels and training.

- 6. INFECTIOUS DISEASE CONTROL: Infection control practices and guidelines either do not exist or are not followed at the Limestone Correctional Facility. As detailed in this report, an inmate with active tuberculosis was placed in the general population and, unfortunately, likely exposed all HIV- infected patients as well as staff members to tuberculosis. Tuberculosis can be a deadly disease. The concern that this event might occur was raised in the prior report's recommendations. Unfortunately, this has occurred. The Limestone Correctional Facility needs an active infection control department and a well-trained, full time infection control nurse. They also need to have a high suspicion for patients with tuberculosis in order to avoid another potential disaster, like the one that has already occurred when a patient with active tuberculosis was housed in the HIV inmate population.
- 7. PHARMACY MEDICATION SUPPLY: During this visit, a large amount of time was spent observing the pill line and watching the patients receiving, or in many cases, not receive their medications. Unfortunately the patients continue to be told that their medications are not available. This is a significant problem for HIV- infected patients and can lead to deadly drug-resistant HIV where the patient will fail therapy and die. The Limestone Correctional Facility needs a more organized pill line distribution system. The current system is antiquated and largely nonfunctional. As a result, patients are not receiving their medications appropriately.
- 8. PATIENTS NOT TAKING THEIR ESSENTIAL MEDICATIONS: This problem continues to occur. Patients continue to be administered medications that should be taken with food on an empty stomach. This is a significant problem which causes poor medication absorption and side effects. When necessary, the Limestone Correctional Facility needs to coordinate the dosing of their medications with food. Many patients also take themselves off of medications after getting medications inconsistently at pill line because they fear becoming resistant to the medications. Often these patients are blamed for this failure in the medical system and are labeled noncompliant.
- PILL LINE: As stated above, the pill line is a disaster at the Limestone Correctional Facility. The Limestone Correctional Facility has instituted a "keep-on person" program, in which the patient is allowed to keep the medications on his person to be taken later. However, this program has not worked properly because patients run out of medications. Also, certain HIV medications are "keep on person", while other medications still require the patient to stand in line. This system needs to be coordinated better. One problem that continues is that medications are administered not only at 3 or 3:30 in the morning, but now at 1 in the morning. As described in the previous report, this needs to stop. Patients need to be administered medications at normal hours and not during hours that are convenient only to the medical and correctional staff.

- 10. <u>DIETARY REQUIREMENTS</u>: Nutritional supplements and diets continue to not satisfy minimal medical requirements of patients. Patients are given only one meal twice a day on weekends and on holidays. This is not adequate. The special needs of malnourished AIDS patients need to be met and adequate supplementation and medications to increase lean body mass need to be used. This continues to be a significant problem at the Limestone Correctional Facility.
- 11. <u>MEDICAL EMERGENCIES</u>: This report does not reassess whether medical emergencies continue to be a problem at Limestone Correctional Facility. However, the medical emergency system at Limestone needs to be reviewed and emergency care of HIV- infected patients needs to timely and adequate.
- **AMERICANS WITH DISABILITIES ACT:** The Limestone Correctional Facility has made a half- hearted attempt to try to comply with some of the Americans with Disabilities Act regulations. They fall far short of the minimal requirements. Wheelchair-bound inmates continue to struggle with mobility in the housing units with access to toilets and beds and moving between buildings that are not wheelchair accessible. The Limestone Correctional Facility should hire an expert to help them in this area to make sure that they are compliant with the Americans with Disabilities Act.
- 13. CROWDED CONDITIONS IN THE HOUSING UNITS: This is less of a problem. However, the patients continue to live in cold, drafty housing units. The housing units need to be renovated so that patients can have their basic housing needs met.
- 14. MONITORING: The Limestone Correctional Facility has made a very minor attempt to try to correct their current failed system. While the current contractor for medical services with the Department of Corrections in Alabama, Prison Health Services, has policies and procedures for providing medical care, and a system of medical care that is provided at other facilities throughout the U.S., it is clear that they will be unable to implement such policies and procedures and to provide medical care unless there is oversight and monitoring to assure that such medical care is going to be provided to the patients. Therefore, the Limestone Correctional Facility needs to be monitored closely by an outside HIV specialist, as well as experts in the field of health care management, until they provide medical care that complies with acceptable standards.