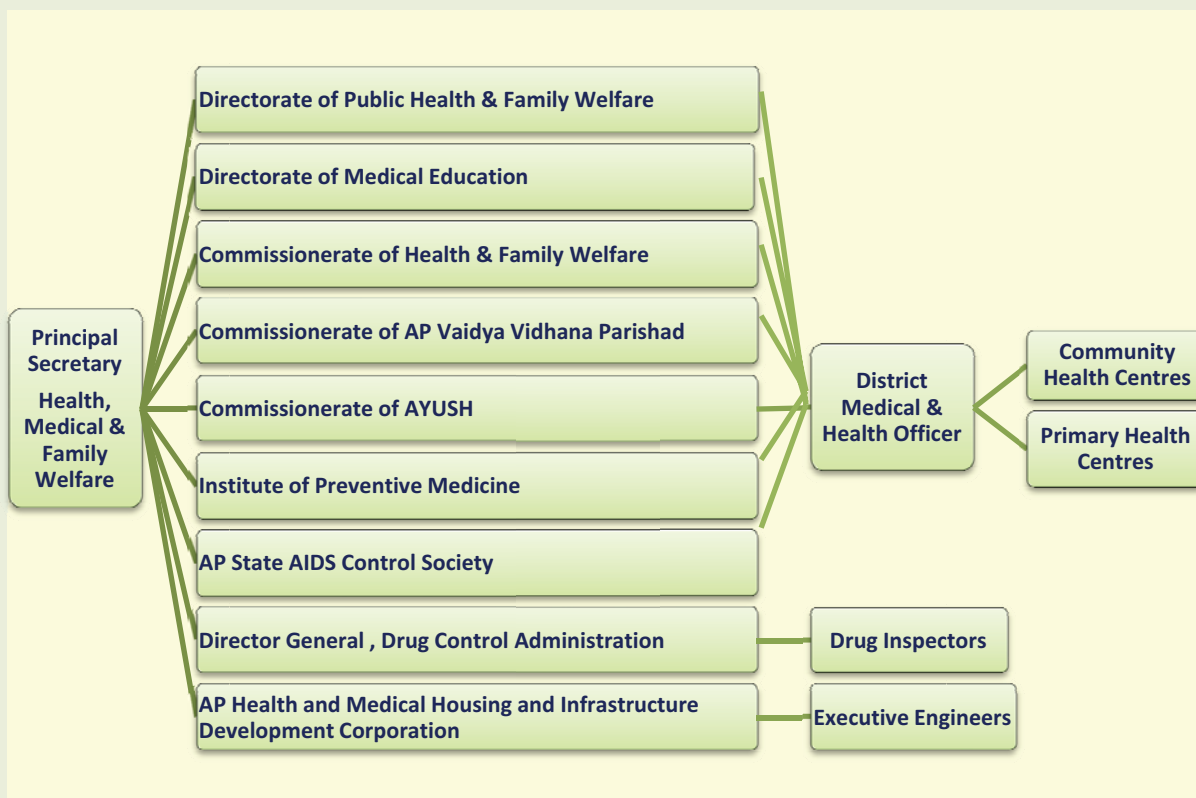


## Chapter 5 - Health, Medical and Family Welfare Department

### 5.1 Department profile

The Department of Health, Medical and Family Welfare is responsible for providing preventive and curative healthcare services to the people of the State. Its main functions include formulation and execution of health related schemes, construction of healthcare centres at various levels/locations, procurement and supply of essential medicines to Government medical institutions, monitoring the functioning of Government run hospitals, medical colleges, etc.

The Department discharges its functions through several agencies/directorates/commissionerates. The organogram of the Department is given below.



As part of our audit, during the year 2010-11, we have reviewed the functioning of *(i) Blood banks and (ii) Trauma Care Centres*. We have also brought out cases of *(iii) Fraudulent drawal of pay and allowances and advances* in a few Primary Health Centres and *(iv) Utilisation of equipment in two Government Medical colleges*. Our findings are discussed below.

## 5.2 Functioning of Blood banks

Blood banks<sup>1</sup> are regulated by Drugs and Cosmetics Act, 1940 (Act) and relevant rules made thereunder. Government of India formulated the National Blood Policy (NBP) in April 2002 to bring about a “comprehensive, efficient and a total quality management approach” to functioning of blood banks throughout the country to ensure easy access to adequate and safe blood.

There were 233 blood banks<sup>2</sup> in Andhra Pradesh as of May 2010. We reviewed, during July - December 2010, the functioning of 45 (out of 126) blood banks in eight districts<sup>3</sup> over a period of three years (2007-10). Our findings in this regard are given in the succeeding paragraphs:

### 5.2.1 Absence of relevant data

The State Level Committee (SLC) constituted in May 2010 for suggesting measures for strengthening the management of blood banks, estimated the demand for blood in the State at eight lakh units per annum. As against this, the existing 233 blood banks<sup>4</sup> are able to collect only seven lakh units per annum. Considering this gap in demand and supply, there is an imperative need to utilise the available resources efficiently. However, the State does not have a centralised online database indicating the availability of various groups of blood at the blood bank level, district level and at the State level.

Blood collected is to be preserved in CPDA<sup>5</sup> solution at temperatures between 4° C and 6° C and utilised within 35 days of its collection. Audit scrutiny revealed that blood units in certain cases collected in all the 45 sampled blood banks had to be discarded due to their non-utilisation within the specified time. The concerned blood banks attributed this to low demand for blood in the neighbouring hospitals. This situation could have been averted had there been a centralised database of blood in the districts and the State as a whole, as the needy hospitals/patients in adjoining areas could have used it to the benefit of their patients.

The SLC had recommended (June 2010) setting up a well knit regionally coordinated blood banking system with structured blood transfusion services and an inbuilt mandatory quality assurance mechanism through the establishment of Mother Blood banks to ensure availability of screened safe blood, by upgrading one Government Blood bank per district to be called Mother Blood banks. However, no such blood banks had been established in the State so far (August 2011).

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<sup>1</sup> Blood bank means a place/organization/unit/institution or other arrangement made by them for carrying out all or any of the operations for collection, apheresis, storage and distribution of blood components or as whole human blood

<sup>2</sup> Adilabad: 6; Anantapur: 6; Chittoor: 10; East Godavari: 13; Guntur: 16; Hyderabad: 62; Karimnagar: 9; Khammam: 7; Krishna: 15; Kurnool: 6; Mahboobnagar: 5; Medak: 4; Nalgonda: 5; Nizamabad: 5; Prakasam: 5; Ranga Reddy: 12; SPS Nellore: 4; Srikakulam: 2; Visakhapatnam: 13; Vizianagaram: 5; Warangal: 7; West Godavari: 9 and YSR: 7. Of these, 66 blood banks are under control of Government and 167 private

<sup>3</sup> Anantapur (5), Chittoor (10), Guntur (8), Hyderabad (8), Krishna (4), Kurnool (6), Medak (1) and YSR (3); (Government: 23 and Private: 22)

<sup>4</sup> Government - 66, Red cross - 38, Voluntary/Charitable - 53 and Private hospitals - 76

<sup>5</sup> Citrate-Phosphate-Dextrose-Adenine

Blood banks are required to maintain the details of blood donors in a register, indicating vital details such as date of collection of blood, name of the donor, address, age, weight, percentage of haemoglobin (Hb), blood group, etc. Proper labelling should also be done on the blood packets to ensure that blood was collected from a physically fit and willing donor. This procedure was prescribed to ensure that blood is not collected from ineligible donors and to protect the donor. Further, this will ensure that the blood stock, that does not conform to the prescribed standard is destroyed so that infections don't get carried through blood transfusion. It was noticed that, in 24 out of 45 blood banks test checked, this vital data was not captured/recorded in the blood donors register in respect of as many as 22,995 donors<sup>6</sup>. Further, in the blood bank at Government Hospital, Anantapur, crucial information which was very essential for supply of blood, viz., **blood group**, was not recorded in the donors register in respect of blood collected (2009-10) from 240 donors.

*Failure to record such vital details is not only fraught with the risk of transfusion of wrong blood to the patients, but may finally leave the blood unutilised and discarded and would result in wastage of a scarce resource defeating the very objective of the donors to save another precious life.*

### 5.2.2 Donor safety

As per the eligibility criteria fixed for blood donation under the Drugs and Cosmetics Rules, 1945 (Rules), the donor of blood should be in good health, mentally alert and physically fit. We observed the following violations of these standards in the test checked blood banks.

| Conditions stipulated for drawal of blood                                                                                                                                                                                                                                                                              | Audit findings                                                                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Age: Donor should be within the age group of 18 to 60 years.                                                                                                                                                                                                                                                           | In 23 out of 45 blood banks verified, blood was collected from 291 donors who are below the age of 18 years.                                                                                                               |
| Weight: Weight of donor should not be less than 45 Kg                                                                                                                                                                                                                                                                  | In 10 out of 45 blood banks verified, blood was collected from 71 donors whose weight was less than that specified.                                                                                                        |
| Haemoglobin content: Haemoglobin content of donor's blood should not be less than 12.5 gm/dl. Persons with haemoglobin less than this prescribed quantity cannot be treated as healthy person for blood donation. Further, blood weak in haemoglobin content does not help in carrying oxygen to cells of the patient. | In 41 out of 45 blood banks checked, blood was collected from 3,617 donors (details given in <i>Appendix-5.1</i> ) whose haemoglobin content was less than the prescribed rate i.e.12.5 gm/dl, the lowest being 8.5 gm/dl. |

As can be seen from the details tabulated above, donor safety was compromised by violating the eligibility criteria for blood donors.

<sup>6</sup> HB percentage not recorded: 22,114; Age, Weight, etc. not recorded: 881

### 5.2.3 Extract of blood components

World Health Organisation (WHO) had emphasised the need for optimal utilisation of donated blood by use of specifically required components instead of whole blood. In view of the gap between demand and actual collection of blood units, conversion of blood into various components was an inherently effective way of overcoming the shortage of blood. In none of the 45 test checked blood banks, there was any evidence to prove that the blood banks had made any effort to extract blood components from the units collected. Thus, optimal utilisation of the scarce resource was not ensured.

### 5.2.4 Calibration of Equipment

Rules stipulate that the equipment used in collection, processing, testing, storage and sale/distribution of blood and its components should be observed, standardised and calibrated at regular intervals as described in the Standard Operating Procedures Manual wherein details of frequency of calibration of various equipments are also prescribed. Though the prescribed equipment was available in adequate number in all the test checked blood banks, calibration of 102 equipments in 11 (out of 45) blood banks reviewed in audit had not been done.

*In the absence of equipment calibration at regular intervals the risk of the results/readings (obtained by using these equipments) not being accurate and reliable was ever present. Therefore, there was no assurance about the quality of the blood supplied by these blood banks.*

### 5.2.5 Ineffective monitoring by Drug Inspectors

The Drugs Controller (India), Directorate General of Health Services, New Delhi issues licences to blood banks only after verifying it and carrying out a joint inspection along with the Director General, Drug Control Administration (DG, DCA).

Prior to issue of licence/renewal of licence to any blood bank for carrying out its operations, Drug Inspectors (Inspectors) working under the control of DG, DCA, are required to examine the premises and appliances/equipments, inspect the process of manufacture along with the means for operation of blood bank, processing of whole human blood for components, manufacture of blood products together with their testing facilities and also enquire into the professional qualification of the expert staff and other technical staff employed.

If the licensee fails to comply with any of the conditions of the licence or with any provisions of the Act or Rules thereunder, the licence may be cancelled or suspended. Licence to blood banks is valid for five years from the date of its issue and it has to be renewed thereafter from time to time. Rejected licensee can re-apply within six months after complying with.

We observed that:

- A majority of the Inspectors in the sampled districts have not complied with the above procedures. Monitoring of the blood bank operations/activities by the Inspectors was

also found to be ineffective. Out of 45 blood banks verified, 22 had not been inspected by the licensing authority during 2008 and 2009.

- In case of two blood banks<sup>7</sup>, we noticed that their licences had expired in 1999 and 2007. However, joint inspection was conducted belatedly only in January 2010. Thus, the blood banks functioned unauthorisedly during the intervening years. There were no recorded reasons for the inordinate delay in the conduct of joint inspection.

### 5.2.6 Huge shortages of Drug Inspectors

The jurisdictional area of a Drug Inspector depends on the number of pharmaceutical units in the area and more than one Inspector may be required in a district.

We observed (August 2010) that there was acute shortage of 'Drug Inspectors' in the Department. There were only 24 Drug Inspectors against 558 posts required as per norms. Although, Government had sanctioned 75 additional posts during 2007-09, even these were not deployed as of August 2011. The Department stated (August 2010) that there were no eligible persons in the Department in respect of vacancies to be filled in through promotions and action was underway for direct recruitment.

### 5.2.7 Conclusion

*As brought out in the foregoing paragraphs, the functioning of blood banks in the State is far from satisfactory. Although specific rules were framed for ensuring the safety of blood donors, a majority of the blood banks verified in audit flouted the rules. Non-compliance with the Rules and ineffective monitoring by the Drug Inspectors had resulted in several deficiencies, endangering the safety of both the donor and the needy patients.*

### 5.2.8 Recommendations

- Government should initiate immediate steps for creating a centralised online database indicating the availability of various blood groups to facilitate efficient use of this scarce resource.
- Government should ensure that vital details like name, blood group, age, weight, address, etc. of the donors are captured scrupulously by all the blood banks to eliminate the risk of transfusion of wrong blood to the patients and avoid wastage.
- Measures should be initiated to ensure that equipment used in collection, processing, testing, storage and sale/distribution of blood is calibrated at regular intervals to ensure that the readings are accurate and reliable.
- Government needs to address the problem of huge shortage of Drug Inspectors to ensure effective monitoring of blood banks.

The matter was reported to the Government in June 2011; reply had not been received (December 2011).

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<sup>7</sup> District Hospital, Machilipatnam and Area Hospital, Gudiwada

Appendix-5.1  
(Reference to paragraph 5.2.2 page 51)

**Blood banks in which blood was extracted from ineligible donors**

| Sl. No. | Name of the district | Area of Drug control Inspector | Name of the blood bank                                           | Government/ Private | Under aged | Under weight | HB < 12.5% |
|---------|----------------------|--------------------------------|------------------------------------------------------------------|---------------------|------------|--------------|------------|
| 1       | Anantapur            | DI, DCA, Hindupur              | IRCS, RCH-II , Kadiri, ATP district                              | Private             | 13         |              | 0          |
| 2       |                      |                                | Sri Satya Sai Institute of Medical Sciences, Puttaparthi         | Private             |            |              | 18         |
| 3       |                      | AD, DCA, Anantapur             | Government General Hospital, Anantapur                           | Government          | 6          | 1            | 0          |
| 4       |                      |                                | Rural Development Trust Blood bank , Batthalapalli, ATP district | Private             |            |              | 4          |
| 5       |                      |                                | IRCS , Anantapur                                                 | Private             |            |              | 58         |
| 6       | Chittoor             | AD, DCA, Tirupati              | TTD Central Hospital , Tirupati                                  | Private             | 2          |              | 22         |
| 7       |                      |                                | Ashwini Hospital , Tirumala                                      | Private             | 1          |              | 37         |
| 8       |                      |                                | Sri SVS Charitable Trust                                         | Private             | 1          | 10           | 7          |
| 9       |                      |                                | SVIMS, Tirupati                                                  | Government          | 2          |              | 8          |
| 10      |                      |                                | Government Maternity Hosp , Tirupati                             | Government          | 23         | 6            | 49         |
| 11      |                      |                                | SVRRG, Tirupati                                                  | Private             | 11         | 8            | 44         |
| 12      |                      | AD, CA, Chittoor               | IRCS, Chittoor                                                   | Private             | 10         |              | 46         |
| 13      |                      |                                | IRCS Area Hospital, Madanapalle                                  | Private             |            |              | 25         |
| 14      |                      |                                | District Hq Hospital , Chittoor                                  | Government          | 83         | 4            | 25         |
| 15      |                      |                                | PES Institute of Medical Sciences & Research , Kuppam            | Private             | 2          |              | 43         |
| 16      | Guntur               | DI, DCA, Narsaraopet           | IRCS, Narsaraopet                                                | Private             | 10         |              | 8          |
| 17      |                      |                                | Blesed Blood bank, Narsaraopet                                   | Private             |            |              | 25         |
| 18      |                      | AD,DCA, Guntur                 | IRCS, Guntur                                                     | Private             |            |              | 69         |
| 19      |                      |                                | Government General Hospital Guntur                               | Government          | 4          |              | 1891       |
| 20      |                      |                                | Municipal Hospital , Guntur                                      | Government          |            |              | 15         |
| 21      |                      |                                | NRI Academy of sciences , Medical college , Hospital , Guntur    | Private             |            |              | 0          |
| 22      |                      | DI, DCA, Tenali                | District HQ Hospital , Tenali                                    | Government          | 9          |              | 115        |
| 23      |                      |                                | IRCS ,Repalle                                                    | Private             |            |              | 74         |

| Sl. No. | Name of the district | Area of Drug control Inspector | Name of the blood bank                                        | Government/ Private | Under aged | Under weight | HB < 12.5% |
|---------|----------------------|--------------------------------|---------------------------------------------------------------|---------------------|------------|--------------|------------|
| 24      | Krishna              | AD,DCA, Vijayawada             | Government Blood bank, Vijayawada                             | Government          |            |              | 8          |
| 25      |                      | DI, Machilipatnam              | Area Hospital , Gudivada                                      | Government          | 2          |              | 70         |
| 26      |                      |                                | District Hospital , Machilipatnam                             | Government          | 7          |              | 51         |
| 27      |                      |                                | Dr. Patabhi Red cross, Machilipatnam                          | Private             | 53         |              | 37         |
| 28      | Kurnool              | DI, DCA, Nandyal               | Santhiram Medical College & Hospital , Nandyal                | Private             |            |              | 40         |
| 29      |                      |                                | Government District Hospital , Nandyal                        | Government          |            |              | 78         |
| 30      |                      | AD, DCA , Kurnool              | IRCS, Kurnool                                                 | Private             | 2          |              | 55         |
| 31      |                      |                                | Government General Hospital Kurnool                           | Government          |            | 1            | 27         |
| 32      |                      |                                | Viswa Bharathi Super specialty Hospital , Kurnool             | Private             |            |              | 27         |
| 33      |                      |                                | RR Hospital , Kurnool                                         | Private             |            |              | 6          |
| 34      | Medak                | DG , DCA, Hyderabad            | Government District (Hq) Hospital , Sangareddy                | Government          | 1          |              | 0          |
| 35      | Hyderabad            |                                | Gandhi Hospital, Secunderabad                                 | Government          |            |              | 37         |
| 36      |                      |                                | NIMS, Hyderabad                                               | Government          |            |              | 265        |
| 37      |                      |                                | IPM , Hyderabad                                               | Government          | 22         | 1            | 46         |
| 38      |                      |                                | MNJ Institute of Oncology & Regional cancer Centre, Hyderabad | Government          |            |              | 3          |
| 39      |                      |                                | ESI Hospital , Hyderabad                                      | Government          |            |              | 6          |
| 40      |                      |                                | Government Maternity Hosp , Koti, Hyderabad                   | Government          |            |              | 11         |
| 41      |                      |                                | Modern Government Maternity Hospital , Hyderabad              | Government          | 14         | 1            | 81         |
| 42      |                      |                                | Nilofer Hospital , Hyderabad                                  | Government          |            | 5            | 57         |
| 43      | YSR                  | AD, DCA, YSR                   | RIMS , Kadapa                                                 | Government          |            |              | 57         |
| 44      |                      |                                | IRCS, Kadapa                                                  | Private             | 9          |              | 17         |
| 45      |                      |                                | Government Area Hospital , Proddutur                          | Government          | 4          | 34           | 55         |
| Total   |                      |                                |                                                               |                     | 291        | 71           | 3617       |

Source: Information obtained and consolidated during the test-check of Blood banks