

Realization of the program
Diagnostics and
Treatment of MDR TB in Orel Oblast
Russian Federation
November 2002-October 2006

Date of the initiation of the program: November 2002

Participants:

- **Ministry of health of RF**
- **Health Care department of the Administration of Orel Oblast**
- **UIN Ministry of Justice of RF**
- **Orel Oblast TB Dispensary**
- **Central SRI of TB RAMS**
- **SRI of phtisiopulmonology MMA n.a. IM Sechenov**
- **World Health Organization**
- **Centers for Disease Control and Prevention (USA)**
- **US Agency for International Development**

Goal of the Study

To evaluate the preliminary results of the program of diagnostics and treatment of MDR TB in Orel Oblast.

Materials of the Study:

**200 MDR TB patients,
registered for treatment within the period
of November 2002 till December 2005.**

**56 – newly detected
144– previously treated**

Methods:

- **Sputum smear microscopy with Ziehl-Neelsen staining.**
- **Cultures were done on two nutrient medias : L-J and FINN II.**
- **Drug Resistance was detected with the absolute concentrations indirect method on solid L-J media to H, R, E, S, K, Cap, OfI, Cic, Pro, PASK.**

Chemotherapy regimen

**Intensive phase of
treatment – not less than 6
months**

Capreomycin / Kanamycin

Ofloxacin

Protionamide

Pyrazinamide

Cycloserine

[Ethambutol]

[PASK]

**Continuation phase
from 12 to 18 months**

Ofloxacin

Protionamide

Cycloserine

[Ethambutol]

[PASK]

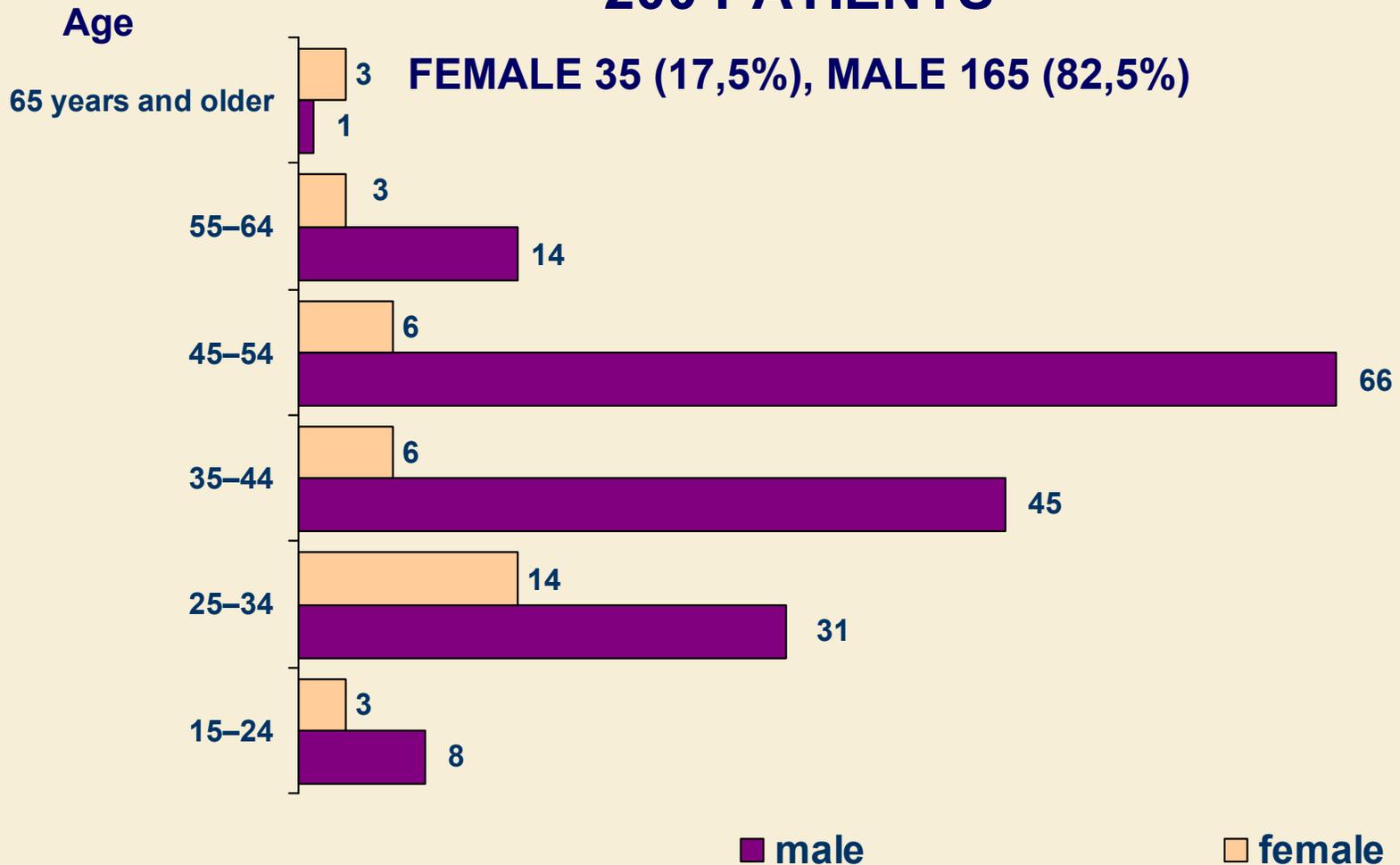
Monitoring of Side Effects of the Chemotherapy

**At baseline and then not less than monthly during
treatment**

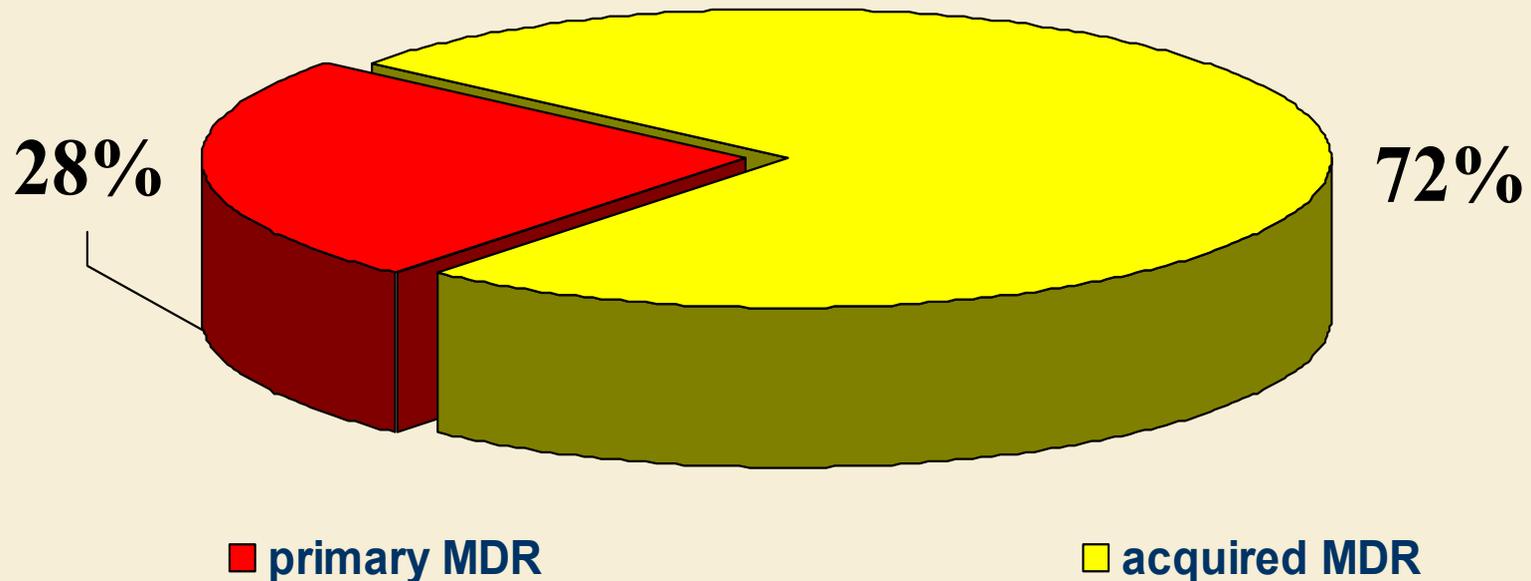
- **General blood and urine test**
- **Bilirubin, transaminase, acid urea, glucose, creatinine of blood serum, electrolytes (K^+ , Na^+ , Mg^{2+} , Ca^{2+})**
- **Thyroid gland hormones**
- **Stool test for disbacteriosis**
- **EEG, ECG, audiogram**
- **Consultations: psychiatrist , ophthalmologist and otorhinolaryngologist**

AGE AND GENDER DISTRIBUTION OF THE ENROLLED PATIENTS,

200 PATIENTS



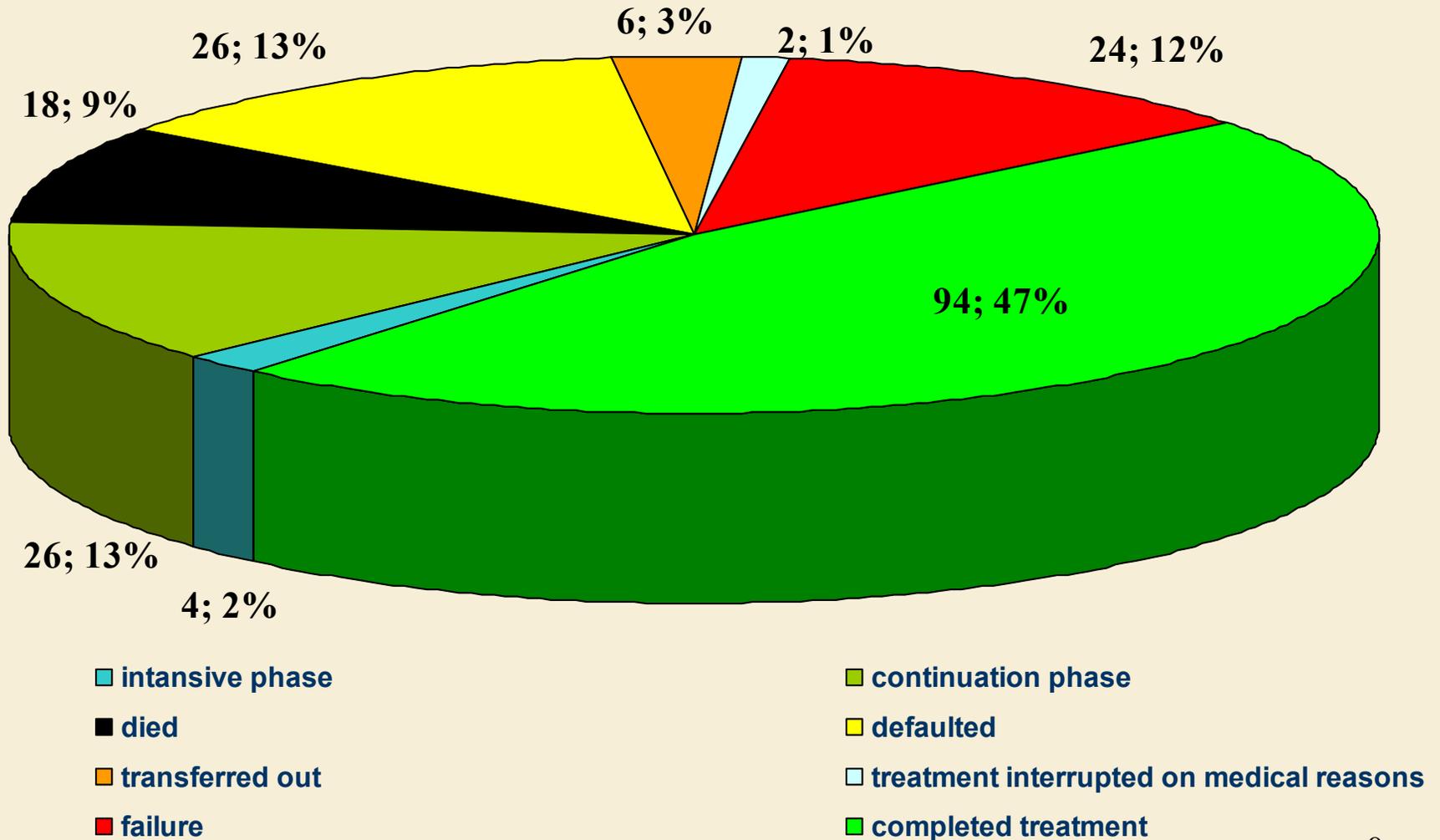
DRUG RESISTANCE OF MBT IN THE ENROLLED PATIENTS (%)



In combination with DR to all the 1st line drugs– in **29** out of **56** patients

In combination with all the 1st line drugs – in **95** out of **144** patients

STATUS OF THE ENROLLED PATIENTS BY 01.10.2006 (abs number, 200 patients)



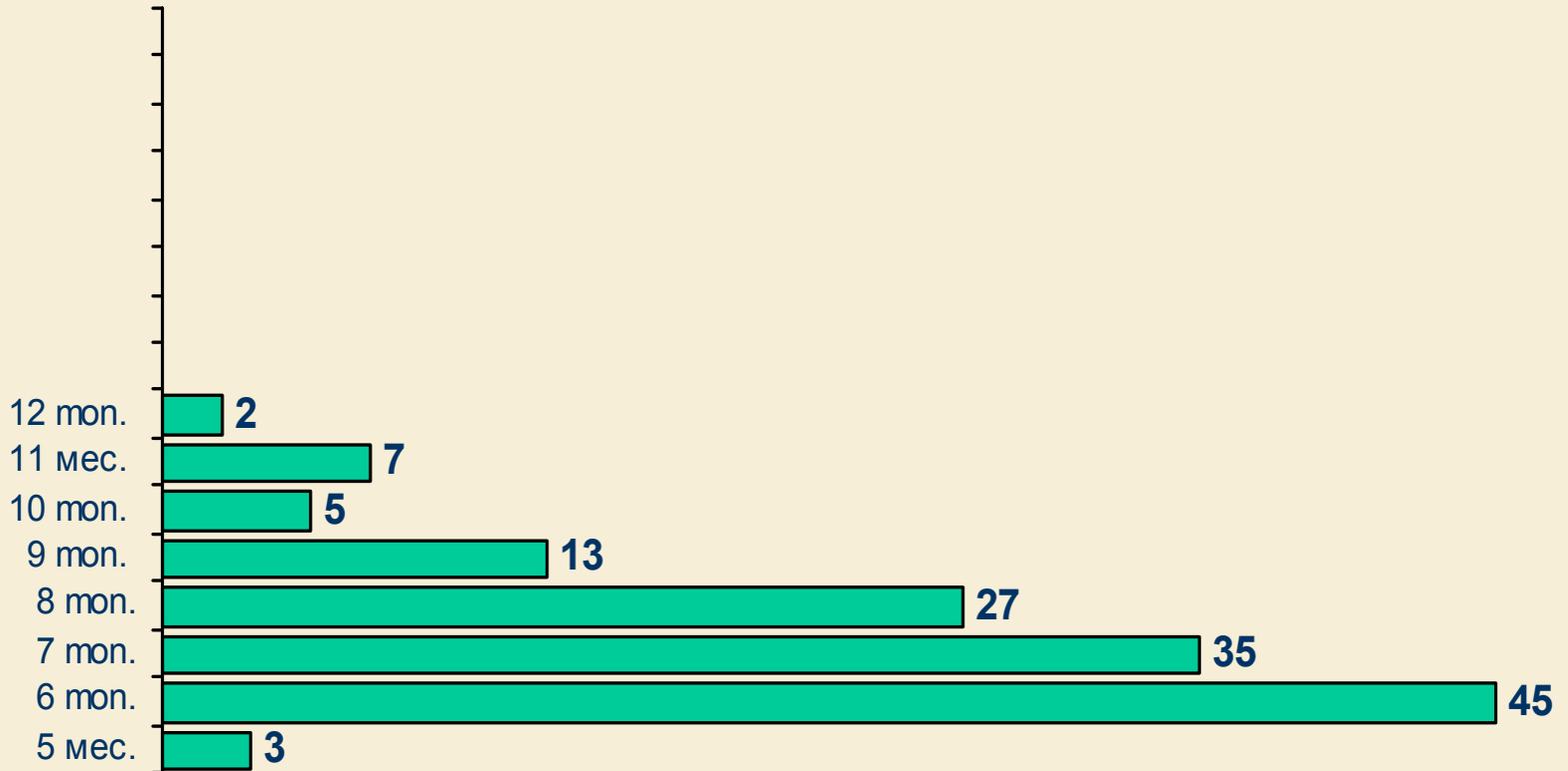
Location of Treatment

**30 patients, registered within the period of 11.02-12.05 (by
01.10.2006)**

- **Orel Oblast TB Dispensary**
 - In-patient facility – 4 patients**
 - Day-patient facility – 4 patients**
 - Home treatment – 3 patients**
- **TB Hospital at SIZO # 1 Orel – 2 patients**
- **Orel Oblast Psychiatric hospital – 1**
- **TB cabinets at Central rayon hospitals– 8**
- **FOP – 8**

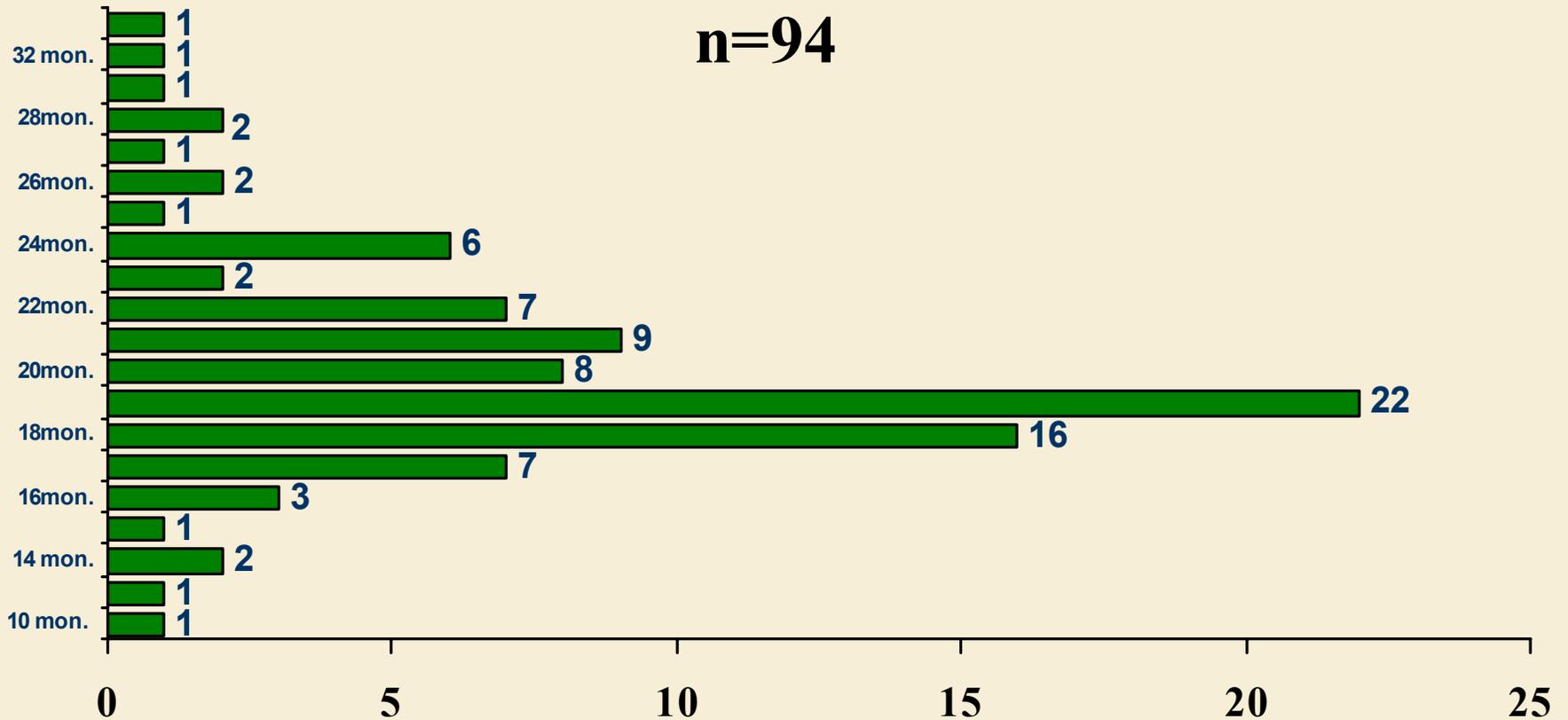
DURATION OF THE INTENSIVE PHASE

137 patients who have completed it



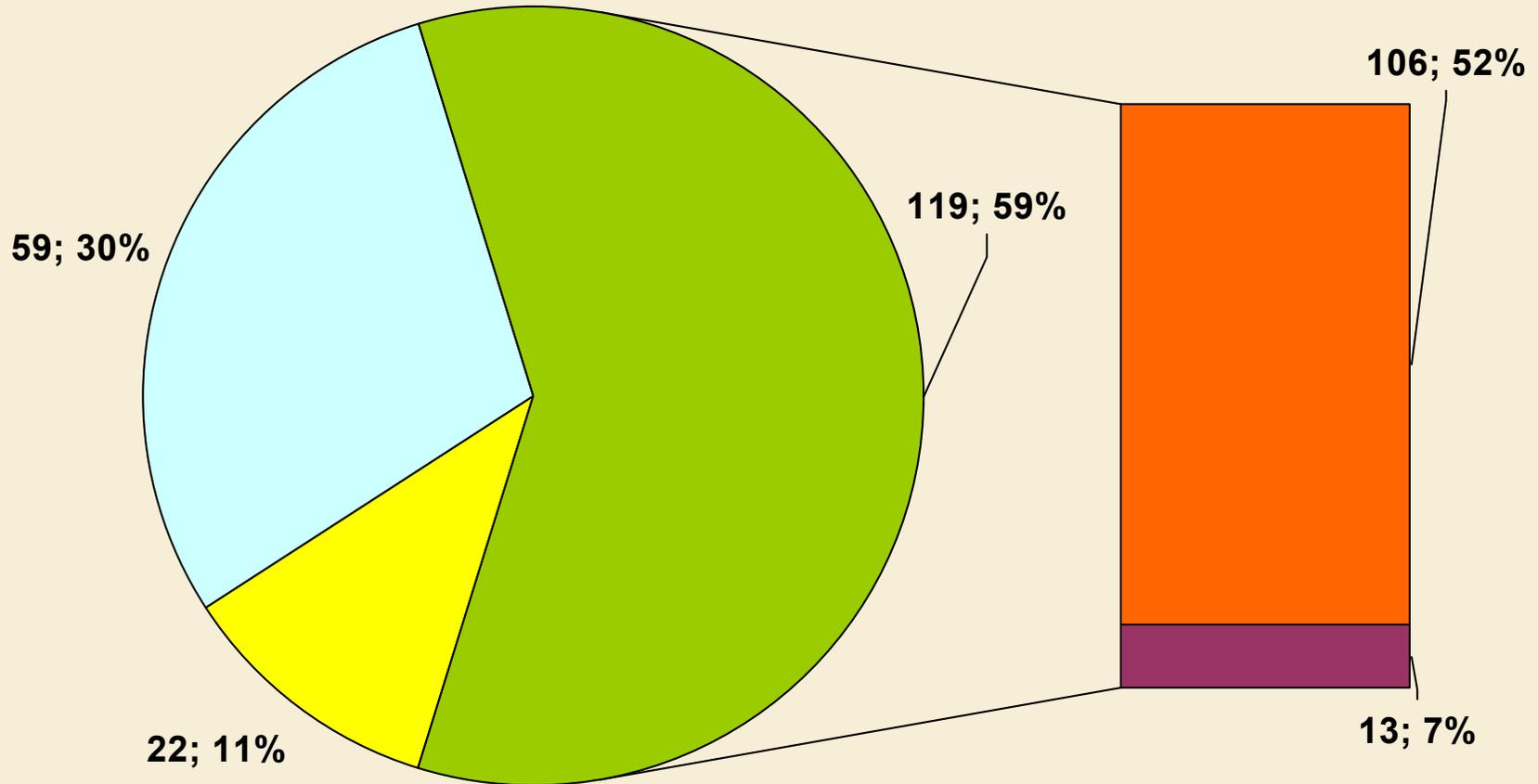
Duration of treatment in patients with completed treatment (by 01.10.06)

n=94



SIDE EFFECTS

(in 200 patients, who were on treatment for more than 1 month.)



- no side effects
- correction of side effects without any changes in the regimen
- dose decrease, temporal discontinuation of the drug
- discontinuation of the drug

The accompany diseases in all 200 patients (75%)

- Alcoholism – 68%
- Diabetes – 10%
- Cardiovascular diseases – 11%
- Drug addiction – 5%
- Diseases of urinary system – 7,5%
- Disturbance of nervous system – 9%
- Gastrointestinal disturbances – 17%

Rate of side effects in all the 200 patients (1)

390 side effects

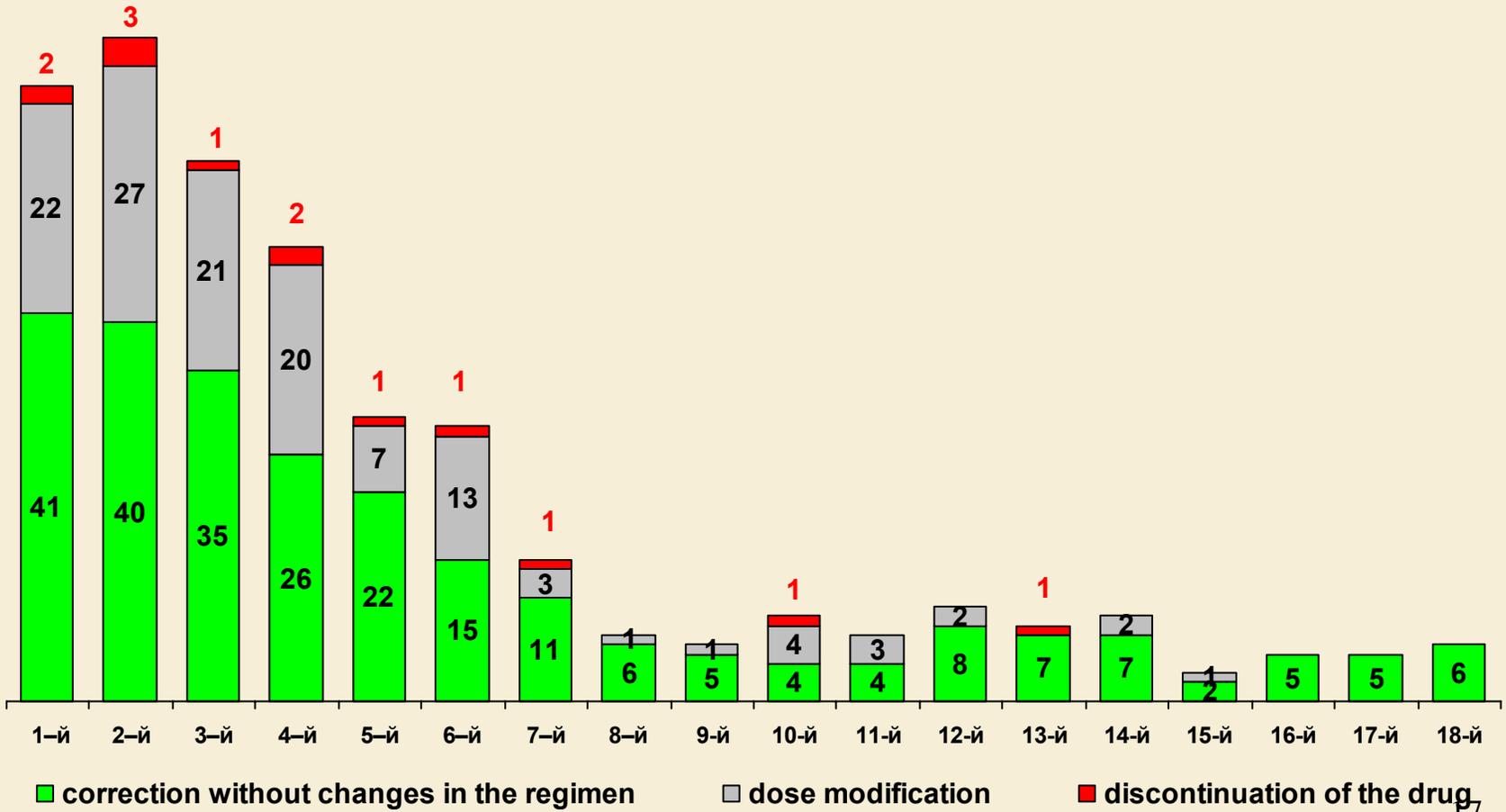
SIDE EFFECTS	Abs. number	%	DRUG
Hearing deterioration	63	31,5	K; Cap
Vestibular disturbances	3	1,5	K; Cap
Nephrotoxicity	15	7,5	K; Cap; OfI
Laboratory hepatotoxicity	15	7,5	OfI; Prot
Toxic hepatitis	3	1,5	OfI
Dyspeptic disorders, diarrhea	50	25,0	Prot; OfI
Sic reactions	11	5,5	K; Cap
Stomach bleeding	1	0,5	OfI
EEG changes	29	14,5	Cs
EEG changes and clinical symptoms	55	27,5	Cs, OfI

Rate of side effects in all the 200 patients (2)

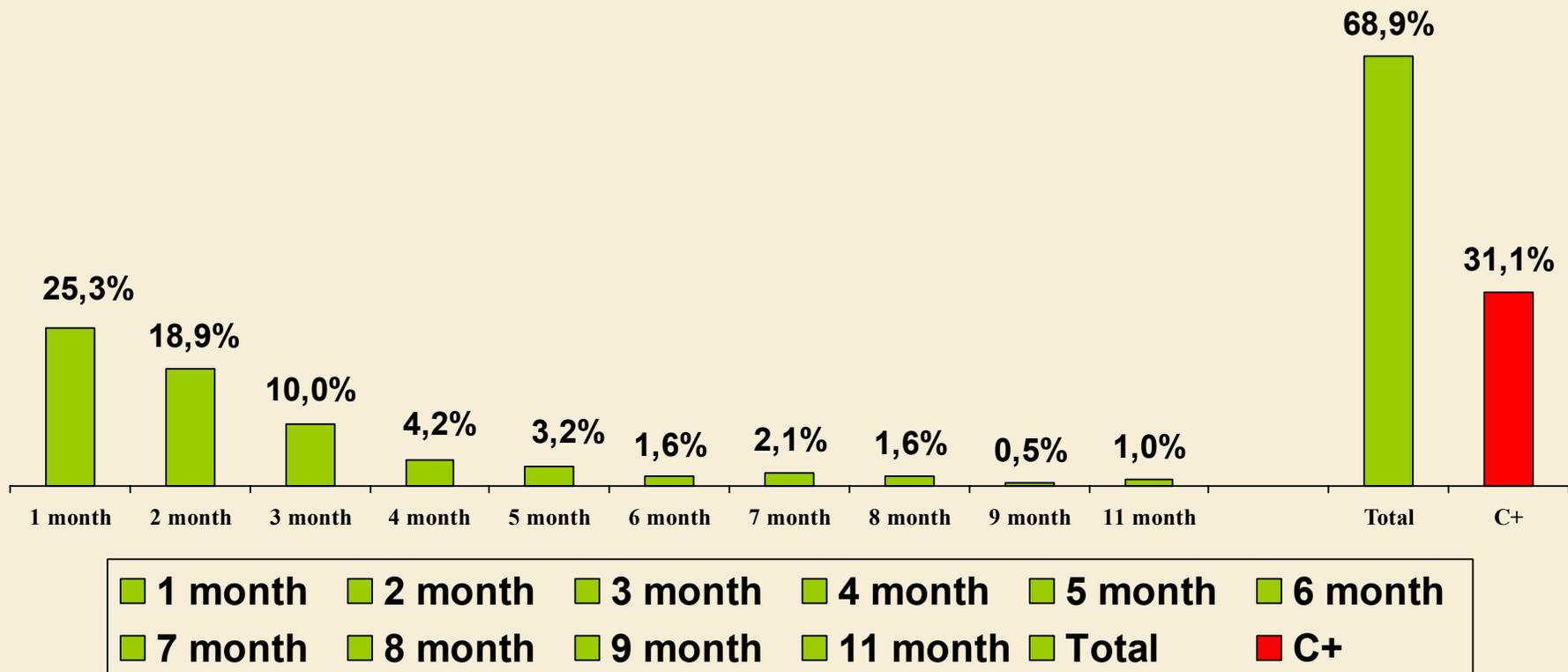
390 side effects

SIDE EFFECTS	Abs. number	%	DRUG
Arthralgia	42	21,0	Z; Prot; OfI
Anemia	10	5,0	OfI; Cap; Cs
Leucopenia	1	0,5	Prot
Laboratory hypothyroidism	29	14,5	Prot
Eosinophilia	11	5,5	Cap;K; OfI
Hypomagnesemia	14	7,0	Cap;OfI
Hyperleucocytosis	2	1,0	OfI
Exacerbation of the chronic gastritis	3	1,5	OfI
Cardiovascular disturbances	14	7,0	OfI
Disbacteriosis	17	8,5	OfI
Hypokalemia	1	0,5	OfI
Candidosis	1	0,5	OfI

TIME SPAN OF THE DEVELOPMENT OF SIDE EFFECTS OF CHEMOTHERAPY



Culture conversion in MDR TB patients under the DOTS+ program



Results:

- **Culture conversion in MDR TB Patients was achieved in 68,9% of patients, enrolled into the program.**
- **Side effects of the treatment with second line drugs are not the serious obstacle for the adequate TB treatment.**
- **Experience of the DOTS + project in Orel Oblast proves possibility of the effective treatment of MDR TB in oblast level TB service facilities.**