



Gestion de la chimiorésistance

dans le cadre de la lutte intégrée contre la Trypanosomose

dans la zone cotonnière de l'Afrique de l'Ouest



ITC



ILRI
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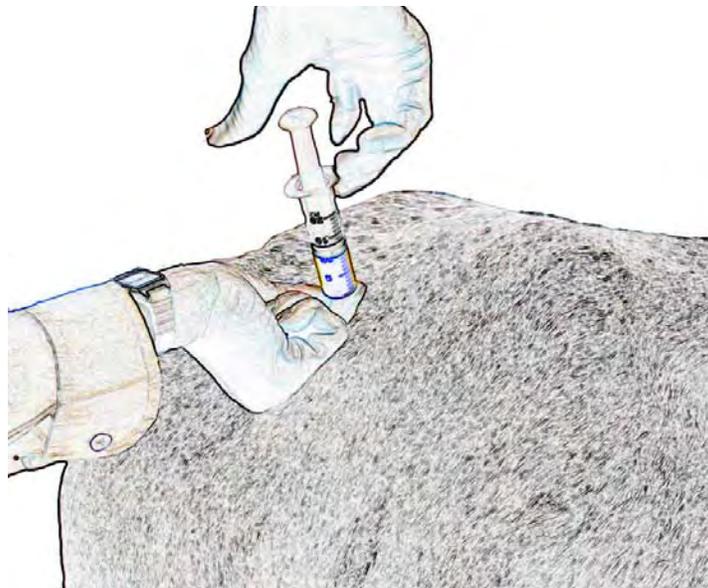


LIBERT

Projet financé par la Coopération Allemande

RESISTANCE TO TRYPANOCIDES:

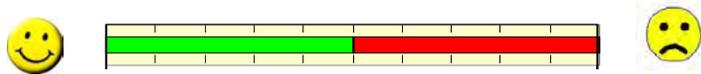
And what drug makers and sellers can do about it



This booklet explains how lack of animal health information contributes to trypanocide resistance and what makers and sellers can do to help the situation.

Examples are drawn from information provided with the 20 trypanocides widely available in Mali, and other sources. Packages are used rather than inserts because our studies showed that, in most cases, drug buyers get sachets or tablets but not pack inserts.

A 'good practice, bad practice' barometer is used to show what proportion of trypanocides conforms to good practice (green) and what proportion does not (red).



The problem: Lack of information on the safe and correct use of trypanocides

We found the main information gaps leading to treatment failure, side-effects and resistance were:

- Problem 1: Difficult and dirty dilutions
- Problem 2: Lack of guidance on 'double dose' and 'normal dose'
- Problem 3: Differing definitions of the standard cow
- Problem 4: Confusing drug names
- Problem 5: Packs that don't show what drugs are for
- Problem 6: Packs that don't show how much medicine to give
- Problem 7: Packs that don't tell or show how to give medicines
- Problem 8: Packs with difficult to read expiry dates
- Problem 9: Little information on drug storage conditions
- Problem 10: Important information missing from packs
- Problem 11: Multiple dose packs that encourage misuse
- Problem 12: Human health at risk from lack of health information

The context: Drugs and developing countries

Inadequate drug information is not just a veterinary problem. Studies on human drugs sold in developing countries show that:

- One third of drugs lack product information¹.
- Two thirds of drugs fail to provide information needed to use them safely and effectively²
- Many inserts are not in a language the literate population of the country of sale can read³.
- Indications for drug use are wider, and warnings fewer. than for the same drugs sold in Europe⁴.

The Solution

Of course, the problem of drug resistance and misuse is not just one of information lack. Quality and quantity of animal health service providers, (both formal and informal); government regulation of veterinary drugs and services; import, export and customs legislation and its application; quality of drugs (in particular amount of active ingredient); availability of alternatives to trypanocides (vector control and trypanotolerant cattle); research into new drugs/vaccines and control methods are other crucial factors to be considered in the fight against resistance. Some of these are also being addressed by the project.

However, our research suggests that drug misuse due to lack of information is a major and fixable problem in the study zone. This booklet, based on these findings, focuses constructively on what drug makers and sellers can do to ensure their products are used safely and effectively. Examples of good practice certainly exist and many are showcased here. But more needs to be done. We hope the findings and suggestions presented here will help start a constructive debate, with the ultimate objective of improving drug use and minimising the risk of resistance.

Trypanocide Use in West Africa

The project carried out studies on trypanosomosis, trypanocide resistance and trypanocide use in South–West Burkina Faso, South Mali and North–East Guinea. Some key findings were:

Trypanosomosis is an important disease

- In South Kenedougou, Burkina Faso, 92% of farmers report trypanosomosis is the most important disease and the most important cause of mortality with one in ten sick animals dying. The prevalence on epidemiological surveys is 10% which means 46, 000 of a population of 70,000 cattle need treatment each year. Farm households spend \$46 USD a year on trypanocides, the single biggest veterinary expense (65% of the total veterinary expense).
- In Mandiana, Guinea 99% of the cattle are of the trypanotolerant N'Dama breed. Despite this, 77% of farmers in Guinea report that trypanosomosis is the most important disease and 86% of farmers experienced at least one case in the last 12 months. 88% of animals sick with trypanosomosis are treated.
- In the Sikasso area of Mali trypanosomosis prevalences of up to 30% are found in some villages.

Many trypanocides are available

- The most widely used trypanocides are those containing diminazene aceturate (DIM). More than 20 brands are available, from companies based in Europe, Canada, South America and India.
- Products containing isometamidium chloride (ISMM) are also used as preventatives and less commonly as treatments. Three brands are widely used.
- One product containing homidium is used, to a lesser extent than DIM or ISMM, mainly in South–west Mali and North–East Guinea.

The informal sector is an important source of drugs;

- In Burkina Faso 55% of trypanocides are bought in the informal sector. The informal sector offers more brands at cheaper prices than the formal sector and is more accessible to farmers.

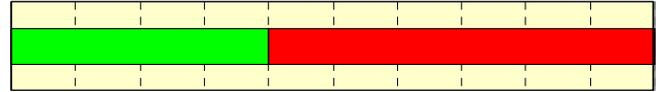
	DIM brands	Average price DIM CFA	Price Range	Average distance from farmers
Vet Pharmacy	3	675	550-800	90 km
Wholesaler	4	533	500-550	90 km
Informal Sector Seller	8	425	350-500	8 km

- In Mandiana Province in Guinea, there are 130, 000 cattle, 10, 000 farmers and one veterinary pharmacy. The shortfall is met by around 120 informal or quasi–formal sector drug providers.

The great majority of treatments are given by farmers.

- In Burkina Faso 84% of trypanocides are given in the community. Around half are given by the farmer, the rest by pastoralists (22%), vaccinators (18%) other farmers (9%) or the herder (3%).
- In Guinea 54% of farmers treat their own cattle and 21% get treatments from herdsmen, other farmers or relatives.

Problem 1: Difficult and dirty dilutions



All ISMM products have the same dilution protocol. BUT some DIM products are diluted with 12.5 ml water (Berenil®, Nozomil®, Survidium®, Diminazen®, Diminasan®, Diminaphen®) others with 15 ml water (Veriben®, Diminaveto®, Diminavet®, Trycip®, Diminazene®, Profort Diminazene®, Lobazen®, Trypadim®, Diminasan®, Pharzen®, Sangavet®).

The result is different doses for similar products, confusing for users and predisposing to wrong dilutions and under-dosage. In one study site, the project found that only 35% of sellers in pharmacies were able to correctly estimate the weight and give the correct dose of DIM for cattle⁵.

Bodyweight (kg)	Berenil®		Veriben®	
	Dose double	Dose simple	Dose double	Dose simple
50	5	2.5	5.8	2.9
100	10	5	11.6	5.8
250*	25	12.5	29	14.5
300	30	15	34.8	17.4



Action 1: Harmonize dilution protocols. That of Berenil® is preferable as it lends itself to the simple rule 'Estimate the weight, and divide by ten for the dose'.

Dilution is not only a source of error, but also of contamination. The distilled water recommended for reconstituting trypanocides is never available in villages. Often un-boiled, dirty water is used. This results in abscesses and inflammation, making the animal ill, the product less effective and fostering resistance.



Selling trypanocides as ready-to-use injections in bottles would overcome both problems of dilution and contamination, but would add to the cost. This strategy will only work if governments give incentives (such as tariff reductions) to make improved formulations cost-competitive.

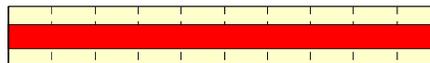


Selling in plastic sachets, as is done for other drugs would cost less, but some drugs would require reformulation to ensure a solution that remains stable.



Drug sellers could also sell or give away sachets of distilled or even clean, boiled water.

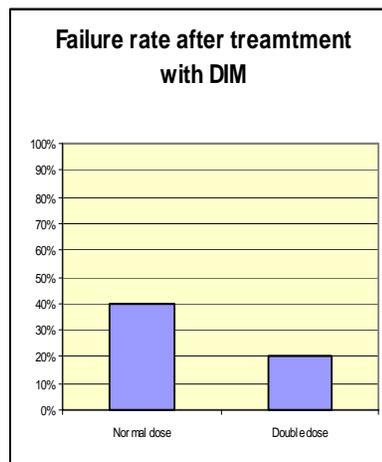
Problem 2: When 'double dose' is 'normal dose'



In areas of high resistance, it is more effective and economic to give DIM at double dose. It is also better to use ISMM as a preventative at the higher dose of 1 mg / kg rather than 0.5 mg/kg. Again there is no information on which areas should follow these regimes.

A random double-blind study on 1,570 cattle in Burkina Faso and Mali carried out by the project showed failure rate to DIM at double dose was half that of failure to normal dose.

Economic models suggested that if resistance to DIM exists at any level it is better to use the double dose⁶.



DIM and homidium should be used at double dose against *T. brucei*. But no information is given on the areas where *T. brucei* may be common.

Parasitological studies on 1,800 cows in Mandiana Guinea, showed that *T. brucei* is the most common trypanosome infection, being detected in 60% of cases⁷.

ISMM drugs give details for 6 different ways of using the drug in cattle. The dose given to one animal can vary from 2.5 ml to 20 ml depending on the method.

50 kg poids vif	1,25 ml	1,25 ml	2,5 ml	1,25 ml	5,0 ml	2,5 ml
100 kg poids vif	2,5 ml	1,25 ml	5,0 ml	2,5 ml	10,0 ml	5,0 ml
150 kg poids vif	3,75 ml	1,25 ml	7,5 ml	3,25 ml	15,0 ml	7,5 ml
200 kg poids vif	5 ml	2,5 ml	10 ml	5,0 ml	20,0 ml	10 ml

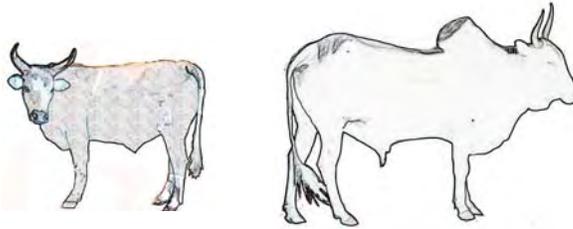


The project found evidence of failure to ISMM used preventively at 1 mg/kg was widespread in Burkina and Mali. In these circumstances using ISMM at lower dose is not recommended.

Action 2: DIM should be given as a standard dose of 7.5 mg/ kg 'double dose'.

ISMM should be used as a standard 1 mg/kg, 1% volume for prevention and 0.5 mg /kg 1% volume for cure. Pack size should be changed to reflect this.

Problem 3: Differing definitions of the 'standard cow'



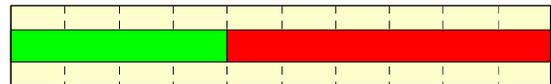
In Kenedougou, Burkina Faso the average weight of a zebu is 256 kg, that of cross-bred 240 kg and a baoule 220 kg⁸.

One standard cattle dose, but how much does a standard cow weigh?

1 small sachet of DIM product treats 300 kg of animal at ordinary dose and 150 kg at double dose, a small sachet of ISMM treats 250 kg of animal, a tablet of ethidium treats 250 kg of animal at ordinary dose and 125kg at double dose.

Action 3: Given that under-dosage is more of a problem than over-dosage all standard packs should treat an animal of 300kg.

Problem 4: Confusing drug names

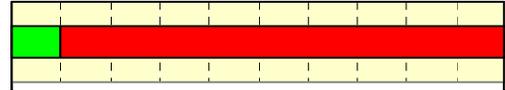


⇒ Is TRYPADIM® a diminazene containing product (like Berenil®), or an isometamidium containing product (like Trypamidium®)?
 ⇒ Is DIMINAVET® the same as DIMINAVET®?
 ⇒ Are DIMINAZENE®, pirofort DIMINAZENE®, DIMINAZEN®, DIMINASAN® different brands or the same?



Action 4: When giving the license to import, officials should take into account the name of the drug. Names likely to cause confusion with a different category of medicines or existing products should be changed.

Problem 5: Packs that don't show what drugs are for



I use Trypamidium® to give my bull force and make him gain weight.
Farmer in Mandiana, Guinea

Many farmers use trypanocides for reasons other than treating or preventing trypanosomosis.

Many farmers believe drugs such as worm tablets and antibiotics are effective against trypanosomosis

- ⇒ In villages in Guinea, 88% of farmers believed antibiotics were effective against trypanosomosis.
- ⇒ In villages in Burkina Faso nearly one third of farmers use worm tablets to treat trypanosomosis
- ⇒ In villages in Sikasso, 62% of farmers believe tetracycline capsules treat trypanosomosis⁹.



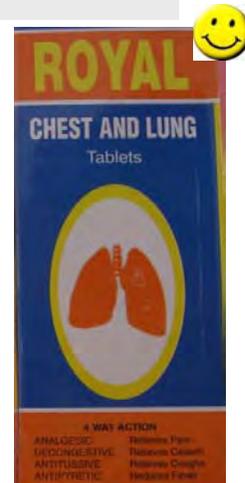
Tetracycline capsules for human use and Nescafé® mixed together and injected - a treatment for trypanosomosis in Kenedougou.



Looking at this trypanocide packet does not help the farmer know what the medicine is used for.



Human drugs often give more information.





This anti-malarial medicine has an uncluttered layout with clear large writing and a picture of a mosquito.

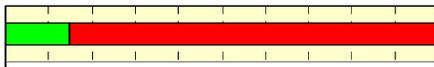
In studies in Burkina, Mali and Guinea, most farmers knew trypanosomosis is spread by tsetse flies, and could pick out tsetse when shown photos of different flies. So this example could be followed, in areas where farmers recognise tsetse.

Or a picture of an animal with signs of trypanosomosis could be used.

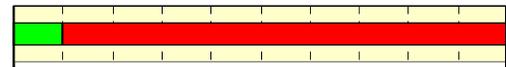
We found the combination of anaemia, weight loss, enlarged lymph nodes and hair loss was a reliable indicator of trypanosomosis in high prevalence areas and that farmers could understand simple pictures showing these signs.



Local language



Pictures



Only one pack has a West African language (sumaya fura = trypanosomosis medicine in Bambara). Two packs have instructions in Swahili.

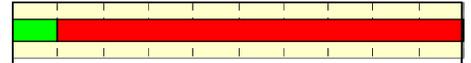
But as most farmers are illiterate, pictures may be easier to understand. This trypanocide shows a yellow medicine in a syringe which farmers can recognise as 'the yellow' that is, a DIM product



Action 5: Drug packages should have pictures and writing in local language to show-

- What type of medicine is contained
- What disease the medicine is used to treat.

Problem 6: Packs that don't show how much medicine to give

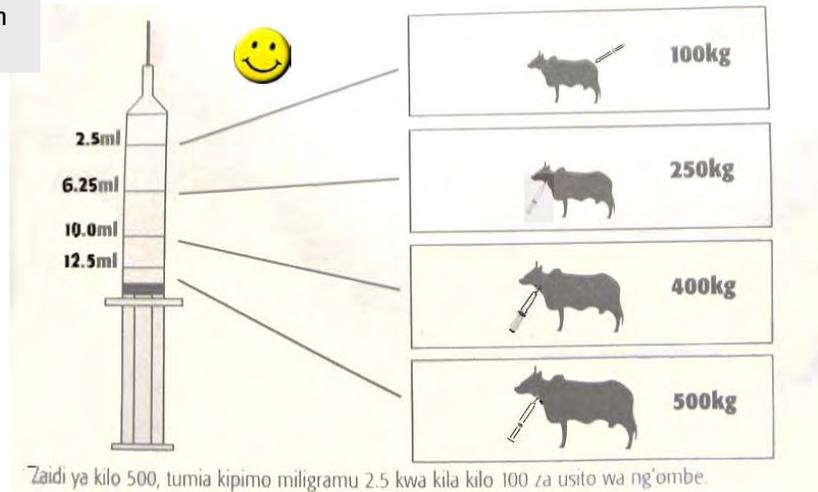
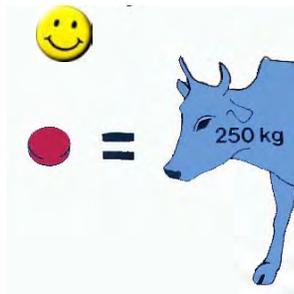


Each sachet contains 1.05 g DIMINAZENE Aceturate, sufficient for 300 kg of body weight. Dissolve in 15 ml of water to prepare an injectable solution.



These instructions do not help farmers know the right amount of drug for their animal.

Instructions with simple pictures, and written in local language are easier to understand.



Ntura ba ani cikε misi



foroko dennin 2



Ntura ni ani cikε misi



foroko dennin 1,5



Misi san fila



foroko dennin 1



foroko 0,5

Across the region, drug-users follow a rule-of-thumb of *'one pack treats one animal'*.

This results in too little drug being given to large animals and where *T. brucei* or drug resistance are a problem.

Work by the project showed that even illiterate farmers can understand information on dosages if pictures are used.

But would changing the pack size be cheaper and easier than changing the behaviour of millions of drug users?

Action 6: Drug packages could have pictures and writing in local language to show the amount of drug needed.

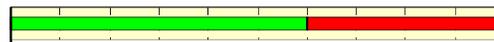
Problem 7: Packs that don't tell or show how to give injections

Injections given by the wrong route can result in inflammation, necrosis, anaphylactic shock and even death.

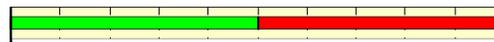
Injections given subcutaneously are poorly absorbed resulting in in-effective treatment and encouraging resistance.

Injections in the wrong sites can damage blood vessels and nerves resulting in permanent debility and damage.

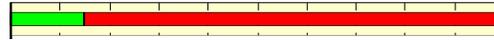
60% of packs specify the injection route



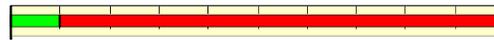
50% of packs specify 'deep' injection



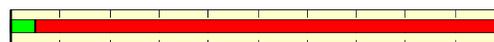
15% of packs show pictures of injections



10% of packs specify the injection site



5% of packs give instruction to massage



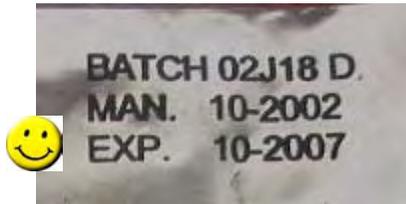
These simple pictures help show how and where to make injections.

chect contient:
rate de dimnazène: 1,05 g
ne: 1,21 g
our 300 kg de poids corporel.
e dans 12,5 ml d'eau à injecter.
ATION: conserver à l'abri de la chaleur
(au-dessous de 20°C) et de l'humidité.
ATTENTE: abattage 21 jours-livraison de
. Consultez la notice d'emballage pour
mations détaillées.
armaceutica N.V. Belgium
04 09 Fax: 03 340 04 23
A.N.V. - P.O.Box 4

Action 7: All drug packages should have full details on the route, the depth, the site and any specific recommendations related to injections (massage after, give slowly or divide doses for large quantities). Pictures and local languages will help ensure that injections are given properly.

Problem 8: Packs with unclear expiry dates

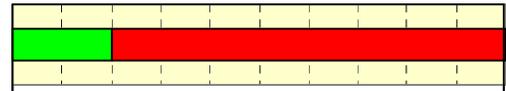
Expired medicines contain less active ingredient. They don't work well and foster resistance.



Most farmers are illiterate but they can often understand dates and numbers if clearly written. The first date can be easily read, the date on the other package is difficult to make out.

Action 8: All drug packages should have clear and easy to understand expiry dates.

Problem 9: Little information on storage conditions



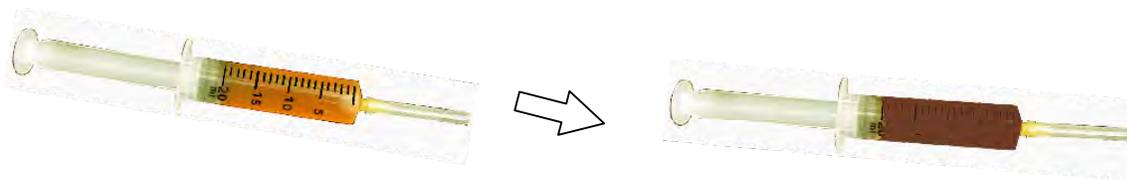
Badly stored drugs lose their active ingredients. They are less effective and using them fosters resistance.

- ⇒ Keep in dry place - 55% trypanocides
- ⇒ Keep in cool place - 60% trypanocides
- ⇒ Keep in dark place - 15% of trypanocides
- ⇒ Full information - 20% of trypanocides

Of the few packs which explain 'cool' place, the definition of cool varies from 23 to 30 degrees.



Badly stored drugs in a farmer's house in Burkina Faso.



Tetracycline drugs turn brown when exposed to heat and sunlight - a good indication that storage conditions are not ideal. If photo-sensitive strips were added to trypanocide packs, users could tell if drugs were properly stored. This would be an incentive for farmers to go to veterinary pharmacies rather than open-air sellers.

Action 9: Better information on drug storage conditions.

Problem 10: Missing information

- ⇒ No packs give information on resistance
- ⇒ Only one pack gives information on toxicity or contraindications
- ⇒ One pack had no expiry date
- ⇒ One pack had no information on the country of origin of the drug
- ⇒ Some packs combine trypanocides with vitamins but without giving the evidence-base for this
- ⇒ Only one pack gave a contact address in west Africa for clients to report problems or get information

The country of the drug maker can be a useful indicator to customers. Only one trypanocide gave information in a way illiterate farmers could understand.



Action 10: Information on the above points should be provided at least in the language used in veterinary / pharmacy training and if possible with pictures and local languages.

Problem 11: Multiple dose packs encourage misuse

Large pack sizes give rise to 3 problems;

- ⇒ Users are more likely to make errors in dosage, and be tempted to treat more animals;
- ⇒ There is risk of contamination of the solution and of mechanical transmission of infections *via* the needle, between cattle injected;
- ⇒ If some made-up drug is left over it is likely to be kept to treat other animals and will often become ineffective due to long storage or poor storage conditions.



Ethidium® is only packaged in tins of 100 tablets. It is usually sold as single tablets in unlabelled plastic sachets. Given its potential toxicity this is a dangerous practice.

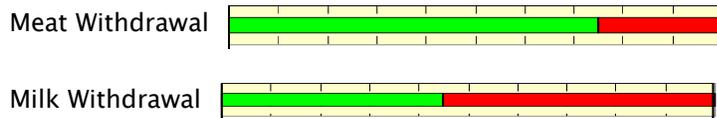
The advantage of large packs is that they are slightly cheaper. However this difference is small suggesting that there are little savings on packages and production for large size packets. Large packs are also more convenient for service providers who treat many animals.

Action 11: Tariff reductions or other financial instruments should be used to ensure there is no price incentive to use large packs. Farmers should be encouraged to buy and use individual packs. Ethidium ® could be packed in single dose labelled blisters as is done for other drugs.

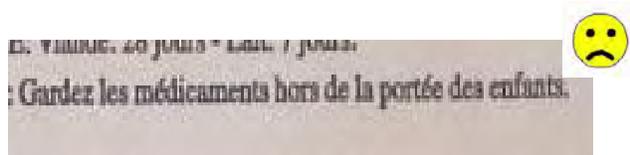


Problem 12: Human health at risk from drug misuse

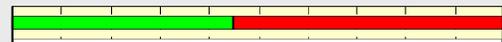
Information on withdrawal periods is often missing or incomplete.



For DIM products meat withdrawal periods vary from 21 to 28 days and milk from 3 to 5 days. Different drug persistence or different interpretation?

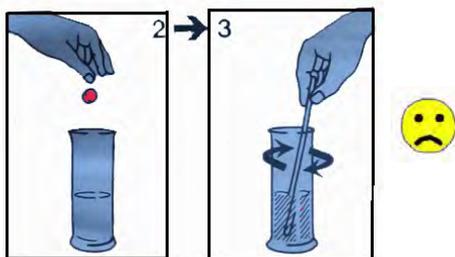


Medicines can be dangerous to people. Most trypanocides contain warnings about keeping medicine away from children.



Warnings written in French are not understood by farmers. In tests in Burkina Faso only a minority of farmers understood the Poison symbol but the 'Mr Yuk' symbol, developed by the Pittsburgh National Poison Center was understood by more farmers.

Pack information for Ethidium® does not contain advice to wear gloves. ISMM products contain some homidium and the same precautions may apply.



'..molecular biologists use Ethidium bromide in their colorations with great care because it is highly mutagenic, and therefore potentially carcinogenic; this fact appears to be as yet little known in the veterinary world. It is not uncommon to see the hands of inoculators, unprotected by gloves, deeply stained with the drug.' (FAO Manual)



Used drugs and their packages should be properly and safely disposed of but no information is given on this.

Action 12: All packs should have full and comprehensible information on aspects of drug use which could provide a risk to human health.

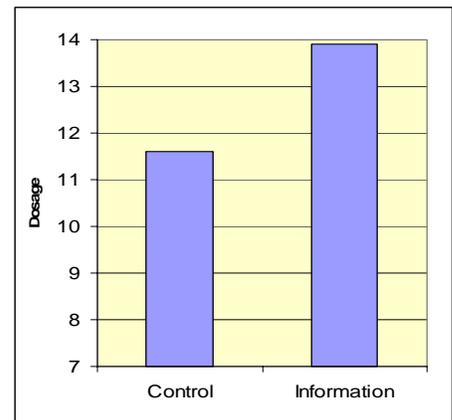
The package is an important source of information as it is available to the person giving the treatment at the time they need it. Other possible sources of information are:

- Leaflets and brochures given with drugs (pack inserts)
- Messages given by the person selling the drugs
- Posters at the drug shop or public venues
- Radio programs
- Information incorporated into rural literacy training or education on livestock
- Training for animal health service providers
- Training for farmers (Farmer Field Schools) or Community Animal Health Workers.

The project carried out an evaluation of the effects of giving information to farmers. A picture brochure with simple words in Bambara was designed. This was iteratively tested with farmers and modified to produce a final version which could be understood by 80% of farmers (even illiterate).

A randomised, blind trial was carried out in which the booklet was given to 230 farmers, owning 460 sick animals in 23 villages in Mali. A control group did not receive the booklet.

Knowledge of dosage (ml) of DIM in farmers receiving information and control group

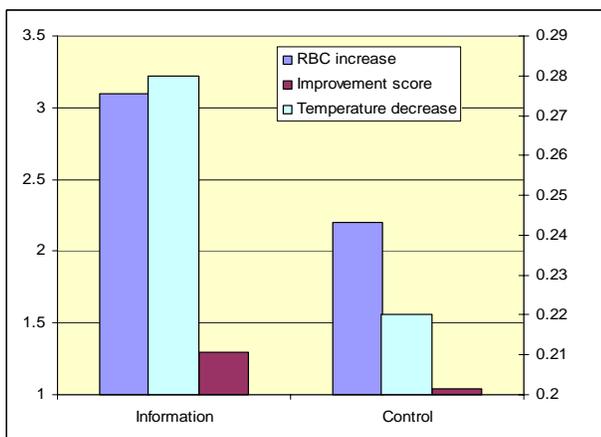


Follow-up at 14 days and 4 months showed that farmers getting the booklet were more likely to know the correct dose than those who did not receive information. Farmers who did not have information tended to under-estimate dosages; a major cause of resistance.

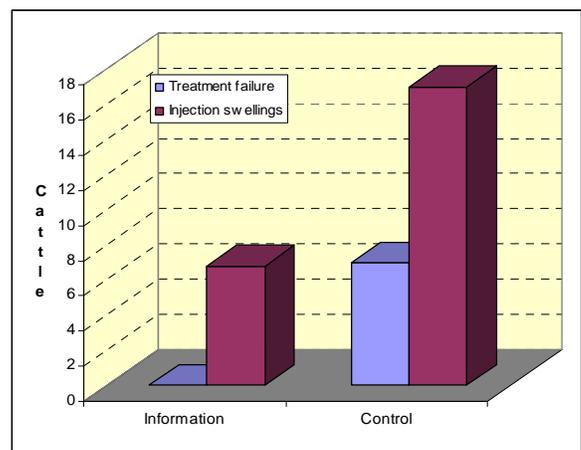
There was a greater increase in the red blood cell count (RBC) and a greater decrease in the temperature of the animals treated, suggesting treatments were more effective.

There were fewer treatment failures and fewer reactions at the site of the injection in cows belonging to farmers who got information.

Clinical outcomes in cattle treated by farmers receiving information compared to control group (no information)



Side-effects and treatment failures in cattle treated by farmers receiving information and control group



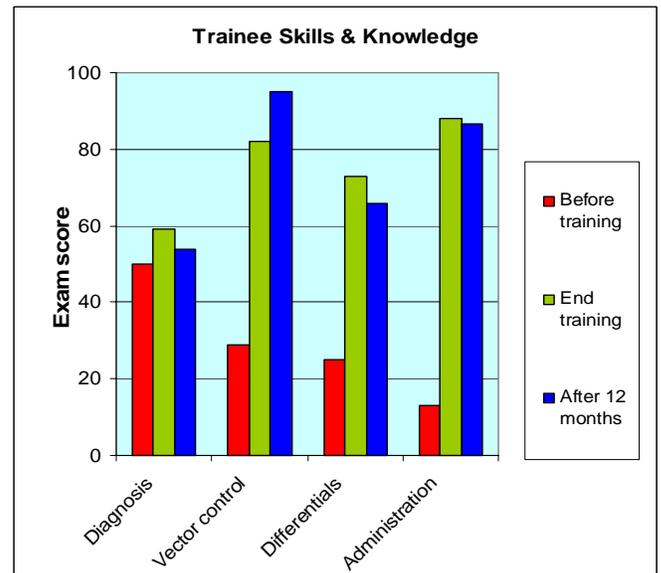
Action 13: Messages on the proper and safe use of drugs can also be given by pamphlets and posters.

The project carried out a workshop for animal health service providers in Guinea. Information was given on diagnosis of trypanosomosis, correct use of trypanocides and trypanocide resistance. Tools such as thermometers, weigh bands, needles and anaemia charts were given to help improve the diagnosis and treatment of trypanosomosis. Evaluation is ongoing but initial results show this training had positive impact on service provider knowledge and skill.

Action 14: Training of service providers can improve their knowledge and competence

The project, in collaboration with government veterinary services, trained 42 Community Animal Health Workers from 8 villages in Burkina Faso. This consisted of 2 weeks residential course followed by practical ‘Farmer Field School’ type training in the villages.

Testing trainees’ knowledge and skill before training, at the end of training and 12 months after training showed a significant and worthwhile improvement as the result of training.



Action 15: Training farmers and Community Animal Health Workers in the correct use of drugs is an effective way of improving drug use.

The project carried out a study on the information given to clients buying drugs in veterinary pharmacies in one of the study sites. Researchers directly observed the transactions taking place in the pharmacies. This showed that:

- In 35% of cases no information was provided on dosage
- In 91% of cases no information was given on withdrawal periods
- In 91% of cases no information was given on disease prevention or ancillary care
- In 100% of cases no information was given on what to do in the event of treatment failure

ACTION 16: Messages on drug use should be given when clients are buying drugs.

Most drugs are made outside Africa and problems could be addressed by the exporting country. For example under the German Drug Law (1989) some federal states have banned drug exports or required a translation of the German package insert to a language understood in the importing country. Unfortunately OECD country legislation on drug exportation is confusing; non-OECD countries often have less capacity to assure the quality and safety of exported drugs.

Nearly all importing countries require that imported drugs should be licensed. It would be possible to make information provision a requirement of this license. However many developing countries lack resources to effectively implement or monitor this.

Action 17: Exporting and importing countries should ensure drugs have the information needed for their safe and proper use.

**SUMMARY OF ACTIONS FOR IMPROVING DRUG INFORMATION TO CLIENTS IN ORDER TO
IMPROVE DRUG MISUSE AND MINIMISE DEVELOPMENT OF RESISTANCE**

1: Harmonize dilution protocols, at least within DIM products and if possible between DIM, ISMM and homidium. The protocol for Berenil® is preferable as it lends itself to the simple rule '*Estimate the weight, and divide by ten for the dose*'.

2: DIM should be given as a standard dose of 7.5 mg/ kg 'double dose'. ISMM should be used as a standard 1 mg/kg, 1% volume for prevention and 0.5 mg /kg 1% volume for cure. Pack size should be changed to reflect this.

3: Given that under-dosage is more of a problem than over-dosage all standard packs should treat an animal of 300kg.

4: When giving the license to import, officials should take into account the name of the drug. Names likely to cause confusion with a different category of medicines or existing products should be changed.

5: Drug packages should have pictures and writing in local language to show what type of medicine is contained and what disease the medicine is used to treat.

6: Drug packages could have pictures and writing in local language to show the correct amount of drug the animal should receive.

7: All drug packages should have full details on the route, the depth, the site and any specific recommendations related to injections (massage after, give slowly or divide doses for large quantities). Pictures and local languages will help ensure injections are given properly.

8: All drug packages should have clear and easy to understand expiry dates.

9: Better information on drug storage conditions should be given.

10: Information on toxicity, contra-indications, resistance and country of origin should be provided at least in the language used in veterinary / pharmacy training and if possible with pictures and local languages.

11: Tariff reductions or other financial instruments should be used to ensure there is no price incentive to use large packs. Farmers should be encouraged to buy and use individual packs. Ethidium could be packed in single dose labelled blisters.

12: All packs should have full and comprehensible information on aspects of drug use which could provide a risk to human health.

13: Messages on the proper and safe use of drugs can also be given by pamphlets and posters.

14: Training of service providers can improve their knowledge and competence

15: Training farmers and Community Animal Health Workers in the correct use of drugs is an effective way of improving drug use.

16: Messages on drug use should be given when clients are buying drugs.

17: Exporting and importing countries should ensure drugs have the information needed for their safe and proper use.

End notes

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