

MONITORING CATARACT SURGICAL OUTCOME (MCSO) for Windows

(version 2.4 – November 2009)

A data entry and analysis package for monitoring and evaluation of
visual outcome of cataract surgery
for IBM compatible microcomputers

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THE NEED FOR MONITORING CATARACT OUTCOME

Cataract is the most frequent cause of blindness worldwide. Most common forms of cataract are still not prone to effective prevention and great efforts are therefore being made to provide sight-restoring surgery.

With increasing longevity worldwide, cataract blindness is likely to increase further. A growth from 25 million cataract blind in the year 2000 to 50 million by 2020 is expected. On top of this the demand for cataract surgery among people with low vision is also increasing rapidly. To address this problem, cataract surgical services have to be expanded considerably above the current level. But increasing the number of cataract operations alone is not enough.

There are disturbing reports of poor visual outcomes after cataract surgery from Asia, Africa and South America. In some countries 30-50% of the operated patients cannot see 6/60 (=20/200; 0.1) with the correction available to them. This again may explain why "fear for losing sight" is one of the major reasons why patients, blind due to cataract, do not come forward for cataract surgery.

Causes of poor visual outcome can be classified in four groups:

1. Selection: due to pre-existing concurrent eye disease
2. Surgery: due to surgery or immediate pre-or post-operative complications
3. Spectacles: due to inadequate optical correction
4. Sequels: due to late post-operative complications (posterior capsule opacification, retinal detachment, etc.)

Visual outcomes can be improved by any measures that will:

1. Improve case selection and avoid surgery in patients who will not benefit
2. Improve the quality of surgery and avoid surgical complications
3. Improve the operative (IOL) and/or post-operative correction of refractive error
4. reduce late post-operative complications

Routine measuring of visual outcome after cataract surgery is likely to make eye surgeons more quality conscious. It will help the surgeons to identify the main causes of poor outcome in their hospital. When the main causes are known, corrective action can be taken to improve the outcome. This is likely to improve future results. Better results are expected to strengthen the confidence and trust of cataract patients and more will come forward for surgery.

Over the past 10 years, new surgical procedures and technology, including implantation of intra-ocular lenses, small incision cataract surgery (SICS) and phaco-emulsification, have become widely available, even in developing countries. These have improved the outcome of cataract surgery considerable. If performed by a well-trained eye surgeon with adequate surgical facilities, success rates of over 90% should well be achievable.

Instruments to measure outcome of cataract surgery were not available to most eye centres so far. In March 2000 The International Centre for Eye Health, Sight Savers International and Christoffel Blind Mission launched an operational research in eight eye centres in Africa and Asia to develop simple and practical systems for routine monitoring and evaluation of cataract outcome. The selected eye units represent a range of service providers, i.e. outreach surgical services in rural Africa; district level eye units and well-equipped tertiary level training institution in Africa and Asia. The annual output of these units varied from 300 to 10,000 cataract operations.

Monitoring systems

The ultimate objective of cataract surgery is to remove visual disability by restoring visual function. We can measure the functioning of the eye as an organ by visual acuity, contrast sensitivity, and other parameters. At the individual level, visual function can be measured with the help of questionnaires to assess activities of daily living, or quality of life.

Visual function would be the most appropriate indicator, but because it requires questionnaires, adapted to the local situation, well-trained interviewers, and relatively much time, it is less suited for routine application. It is better applied in special studies.

Visual acuity is the indicator that is easiest to perform and universally applied as a routine by ophthalmologists and paramedical staff.

Two systems are developed: a manual tally sheet system and a computerised system. The computer system is programmed in Visual FoxPro 8.0[®] and runs under Windows 2000, NT, XP and Vista. The software requires a processor of at least 200 MHz and at least 70 MB free disk space.

The information collected from each patient is purposely limited to minimise the extra work required by any cataract monitoring system. However, optional fields are provided on pre-operative and target post-operative refraction, biometry readings, type of incision and capsulotomy, IOL type and power, suturing and post-operative refraction.

Visual outcome is categorised as good (can see 6/18), borderline (cannot see 6/18 but can see 6/60) or poor outcome (cannot see 6/60).

Both the manual and the computer system provide the following main indicators:

- proportion of good, borderline and poor outcome at discharge and at follow-up
- causes of poor outcome at discharge and at follow-up
- proportion of complications and type of complications
- proportion of operations with IOL
- optional: Differential Spherical Equivalent, complications by section, capsulotomy, IOL type and suturing

Agreed definitions

Presenting vision: Visual acuity in examined eye with the available correction, if any

'Best' vision: Visual acuity in examined eye with best possible correction or pinhole

Categories of visual acuity:

- Good outcome:
Can see 6/18 (or $VA \geq 20/60$; $VA \geq 0.33$ (Decimal); $VA \leq 0.5$ (LogMar))
- Borderline outcome:
Cannot see 6/18, but can see 6/60 (or $VA < 20/60 - 20/200$; $VA < 0.33 - 0.10$ (Decimal); $VA > 0.5 - 1.0$ (LogMar))
- Poor outcome:
Cannot see 6/60 (or $VA < 20/200$; $VA < 0.1$ (Decimal); $VA > 1.0$ (LogMar))

Types of cataract surgery:

- ICCE
- Standard ECCE with sutured section
- Small Incision Cataract Surgery (SICS) - small, sutureless section with fragmentation of the lens, also called "manual phaco" or "Min-nuc" ECCE
- Phacoemulsification

All procedures can be with or without IOL (ICCE needs AC-IOL, all others mostly with PC-IOL).

Causes of poor outcome:

Causes of poor visual outcome are classified in four main groups:

1. Selection: due to pre-existing concurrent eye disease
2. Surgery: due to surgery or immediate pre-or post-operative complications
3. Spectacles: due to inadequate optical correction
4. Sequelae: due to late post-operative complications (posterior capsule opacification, retinal detachment, etc.)

Time of post-operative follow-up examinations:

- at discharge
- at 1-3 weeks post-operatively
- at 4-11 weeks post-operatively
- at 12 or more weeks post-operatively

Type of complications:

- no complication
- capsule rupture without vitreous loss
ruptured lens capsule without any loss of vitreous
- vitreous loss
any vitreous loss, whether due to zonular dehiscence or capsule rupture
- zonular dehiscence
partial or total rupture of the zonulae
- retained lens matter
any clearly visible remains of the lens, apart from the outer capsule, present in the eye at the conclusion of cataract surgery. This also includes a partial or total 'dropped nucleus'
- wound leak
any prolapse of aqueous, vitreous or iris tissue through the cataract wound
- striate keratopathy
corneal oedema due to endothelial damage
- endophthalmitis
intra-ocular infection, proven or suspected, following intraocular surgery
- other complication
any other operative or non-operative complication

Evaluation of results**WHO Guidelines**

In an Informal Consultation on Analysis of Blindness Prevention Outcome (Geneva, February 1998), the WHO proposed the following guidelines to monitor the outcome of cataract surgery:

“The visual acuity must be measured in each eye of all patients undergoing cataract surgery for age-related cataract, pre-operatively and any time between discharge and 12 weeks post-operatively, using available correction and best correction (or pinhole correction). The following levels of visual outcome should be aimed for:”

Table 1. Guidelines on outcome of cataract surgery

POST-OPERATIVE ACUITY		WITH AVAILABLE CORRECTION	WITH BEST CORRECTION
GOOD	6/6 - 6/18	>80%	> 90%
BORDERLINE	<6/18 - 6/60	<15%	<5%
POOR	<6/60	<5%	<5%

However, not all patients return for follow-up. Follow-up rates of less than 20% are not uncommon. In such situations, results of those who did come for review may not be representative for all operated patients in that clinic. The trends in results are important, because the profile of patients (e.g. distance to clinic, socio-economic background, pre-operative VA, criteria for surgery, etc.) is not likely to change much.

What if follow-up is poor?

Although VA at discharge was not predictive for VA later post-operatively, the pilot study showed that 55-75% of the operated eyes with poor outcome at discharge improved to good outcome at 6 months or more post-operatively. When follow-up is low, say, 30%, the following guidelines could be used:

VA at discharge: >50% can see 6/18 (20/60; 0.33; 0.5)

<10% cannot see 6/60 (20/200; <0.1; >1.0)

% complications: <10% (capsule rupture without vitreous loss <5%, vitreous loss <5%)

Besides visual outcome, the percentage of complications, proportion of capsule rupture, proportion of vitreous loss and the proportion of operations with IOL, as well as their trends over time, are important indicators of quality of cataract surgical services.

The proportion of IOL's is dependent upon local facilities and training of the eye surgeon. Individual centres and surgeons may set their own guideline for percentage of IOL's.

What if results are below the guidelines?

Visual outcome

- More than 10% of the operated eyes have a presenting visual acuity less than 6/60 (poor outcome) at discharge.
- More than 5% of the operated eyes have a presenting visual acuity less than 6/60 (poor outcome) at 4 weeks or more post-op.
- Less than 80% of the operated eyes have a presenting visual acuity of 6/18 or better (good outcome) at 4 weeks or more post-op.

Action to be taken:

- Check the analysis reports to find out whether the major cause of poor vision is selection, surgical problems or correction of refractive errors.

If due to selection:

- Improve pre-operative examination to reduce the number of patients with other causes of blindness who are not likely to benefit from cataract extraction.

If due to surgery:

- Improve surgery procedures.

If due to spectacles:

- Provide best spherical correction spectacles at an affordable price, ensure accurate calculation of power of IOL.

Surgical complications

- The posterior capsule rupture rate without vitreous loss is more than 5%.
- The vitreous loss rate is more than 5%.
- The total complication rate is more than 10%.

Action to be taken:

- Improve the surgical technique by asking advice from a good and experienced cataract surgeon.
- Ensure that all surgeons are adequately trained in IOL surgery and have the necessary equipment.
- Ensure that skills and facilities are available to deal adequate with complications

Proportion of operations with IOL

- The percentage of cases receiving an IOL is less than 90%.

Action to be taken:

- Improve the availability and affordability of IOL's.
- Ensure that all surgeons are adequately trained in IOL surgery and have the necessary equipment.

Trends over time

- The trend over time is static outside the recommended limits.
- The trend over time is worsening.

Action to be taken:

- Carefully analyse the reasons for lack of improvement and take action to deal with the identified problems as outlined above.

How monitoring cataract surgical outcome should be used

It is expected that routine monitoring of outcome of cataract operations will improve visual outcome, increase credibility of cataract surgical services and thereby lead to more people coming for cataract operations. It is essential to create a culture of audit and support, resulting in overall improvement and to avoid confrontation and criticism. The outcome monitoring system is intended to facilitate individual eye surgeons or centres to monitor their own results over time and to achieve the proportions of good, borderline and poor outcome as proposed in Table 1. They have their own intake criteria, surgical procedures, skills and facilities, which are not likely to change much. The monitoring system will indicate the cause of poor outcome: selection, surgery, spectacles or sequels. When causes of poor outcome are known, these can then be addressed in order to improve the results of cataract surgery. Refraction and surgical procedures can usually be modified to improve outcome, but with selection and sequels this may be difficult. When "selection" is a major cause of poor outcome, diagnostic facilities should be improved to avoid surgery on patients without reasonable prospects of improvement. This does not mean that all patients at risk should be refused surgery: they should be given appropriate counselling and be informed about the risk of incomplete sight restoration. Please realise that even a partial improvement in visual acuity may help many of these patients.

When less than 100 operations are analysed the results should be interpreted with caution.

How monitoring cataract surgical outcome should NOT be used

Outcome data should not be used to compare individual surgeons or centres, unless perhaps for residents training. Some surgeons may feel being "controlled" and be reluctant to cooperate. In other cases, donors offered "bonuses" to surgeons achieving certain levels of good outcome. Such pressure may cause eye surgeons to refuse surgery to at risk cases or show favourable data only. The net result will be a lot of extra work, but opportunities to improve outcome will not be recognised and corrective measures will not be taken.

Between cataract operations there are differences in intake criteria, skills of the surgeons, surgical procedures and facilities, all affecting outcome. The classical example is that of the least experienced surgeon who will only operate upon simple uncomplicated cases under supervision, while the most complicated cases, often with limited chances of visual recovery, will be operated upon by the most senior eye surgeon. In such a situation it could well be that the junior surgeon has a better outcome percentage than the senior surgeon.

THE COMPUTERISED SYSTEM

The cataract outcome monitoring package for Windows is programmed in Visual FoxPro® version 8.0. It is provided as a runtime version, which means that the user does not require VFP on his computer. The programme can run on all Pentium computers under Windows 2000, NT, XP and Vista with a PCU of at least 90 MHz and 32 MB RAM. To retain the original layout and to avoid compatibility problems with Microsoft Office Word 2007 it is advised to save all reports in the Rich Text Format (.RTF). This format will be read by all versions of the Ms Word software. There is no MCSO package for Apple computers.

The Windows package uses the standard Cataract Surgery Record (CSR) which can be added to the routine case notes used in your clinic, or replace the case notes. For each cataract operation, one form has to be completed. When the patient comes for operation of the second eye, a new form has to be used.

Data from each form has to be entered into a computer. The data entry facility of the package has a number of in-build checks to avoid data entry errors. At any point in time data entered into the computer can be analysed. The MCSO software produces various standard reports, graphs and lists of patients due for follow-up. The reports are selected through a menu system and can be viewed on screen, saved as file, or printed on an attached printer. Records for analysis can be selected by year, by surgical centre and/or by surgeon.

The Cataract Surgery Record

Data on cataract operations are collected using a standardised Cataract Surgery Record (CSR). Do not change any fields, options or keys for VA on this form, or sequence of the fields, as this will make all calculations in the analysis reports invalid. It is possible to translate the labels of the various fields into the local language while retaining its original meaning.

It is important to realise that the CSR is not completed at one time. Patient particulars, pre-operative examination, surgery and post-operative visual acuity at discharge may all be completed while the patient is admitted, but first, second and third follow-up visits can only be completed after several weeks or months. This means that the form has to be stored in a place where it can be retrieved whenever the patient returns for a follow-up visit.

Data entry will be done after discharge and after each follow-up visit, as it is not known if and when the patient will return for follow-up. That implies that the form has to move repeatedly from one place to the other.

Each hospital may have its own procedures for patient's records and it may not be possible to standardise such procedures. The following option should therefore be regarded as an example only.

During admission, pre-operative examination, surgery and discharge the CSR stays with the patient. After discharge, the CSR has to go to a designated data entry clerk. These CSR forms need not be collected every day, but once or twice a week. The data entry clerk enters the data into the computer and returns the forms to the outpatient department where they are put in a separate folder under section "To be seen". Divide this folder into two sections: "Seen" and "To be seen". In each section the CSR's are sorted on name, on serial number or on Hospital Registration Number, whatever is common practice. Whenever the patient returns for follow-up, trace the corresponding CSR, complete your findings for that visit and put the form back in the folder in section "Seen". Once a week the data entry clerk collects all CSR forms from section "Seen", enters the data in the computer and returns the forms to the same folder in section "To be seen" (for the next visit). To avoid double entry of the same patient, the data entry clerk should place a signature or initial behind each follow-up visit that was entered into the computer. Divide the workload in such a way that the CSR forms remain as short as possible at the data entry section.

The amount of work and the accuracy required for correct entry of all records should not be under-estimated. If designated and experienced data entry staff is not available, it may be better to use the manual tallying system to monitor cataract outcome.

The Cataract Surgery Record is shown in Annex 1. On the CD-ROM, modified versions can be found for Snellen 20 feet, decimal and LogMar visual acuity systems. All forms are in MsWord to facilitate translation of the English text into other languages. Care should be taken only to translate the text as accurately as possible and not to change any fields, options, sequence of options, or keys for VA, as this will make the analysis reports invalid.

Annex 2 contains detailed instructions how to complete the various fields of the Cataract Surgery Record.

Installation of MCSO v2.4 for Windows

The Windows version of the Monitoring Cataract Surgical Outcome (MCSO) package is programmed in Visual FoxPro 8.0®. MCSO version 2.4 for Windows is a run-time application and does not require Visual FoxPro to be installed on your hard disk.

- Insert the installation CD for MCSO v2.4.
- Wait until the opening screen appears.
- Click on 'Monitoring cataract surgical outcomes' to read the introduction and instructions for installation.
- From the screen called 'Software to monitor cataract surgical outcome' select 'Install MCSO v2.4 for Windows' and double click.
- Follow the instructions on the dialog screens.
- By default, the programme will install itself in folder 'C:\Program files\MCSO_2.4'. It is recommended to use this default location, but any other directory can also be used.
- The programme will install a shortcut button on your desktop.
- Go to the next screen and select 'MCSO v2.4 instruction manual' and double click. This will open the English manual. You can print this manual or save it on the hard disk.
- Select the Cataract Surgical Record for the VA measurement system of your choice and double click to open this file.
- If you want to train other staff members in the use of the cataract outcome monitoring package, you can find training materials and further reading on the screen 'Why monitor cataract surgical outcome?'

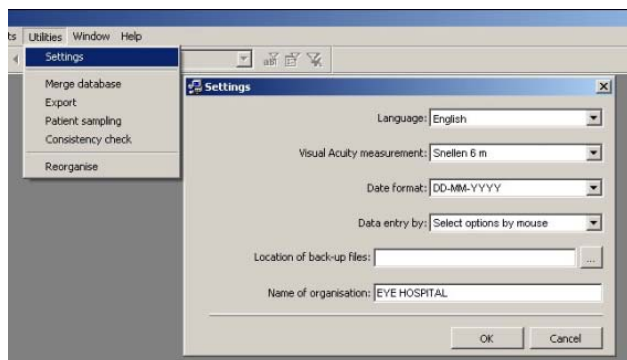
USE OF MCSO VERSION 2.4 SOFTWARE

The Monitoring Cataract Surgical Outcome (MCSO) software is started by double clicking its icon on the desktop. After the introduction screen the main menu appears.

It is advisable first to go to menu item Utilities \ Settings (Figure 1).

Initial Settings

Figure 1. Main menu: Utilities \ Settings



This option allows the user to select the following settings:

- preferred language: English, French, Spanish, Chinese, Arabic;
- preferred visual acuity measuring system: Snellen 6m; Snellen 20 ft; decimal; or LogMar system to be used in choice boxes on the data entry form (Table 2);
- preferred date format to be used in the choice boxes on the data entry form;
- data entry method: 'select option by mouse' or 'type code number' with the keyboard (faster);
- location where back-up data files should be saved;
- name of the organisation to appear on the opening screen and on the reports.

Table 2. Available VA measurement systems

Snellen 6m	Snellen 20ft	Decimal	LogMar
6/6	20/20	1	0
6/9	20/32	0.63	0.2
6/12	20/40	0.50	0.3
6/18	20/60	0.33	0.5
6/24	20/80	0.25	0.6
6/36	20/120	0.17	0.8
6/60	20/200	0.10	1.0
3/60	20/400	0.05	1.3
1/60	20/1200	0.02	1.8
PL+	PL+	PL+	3
NPL	NPL	NPL	4
Believed <6/60	Believed <20/200	Believed <0.1	Believed >1
Believed >6/60	Believed >20/200	Believed >0.1	Believed <1

The last two options in the measurement system are reserved for those patients who have difficulties to comply with the visual acuity assessment (mental problems, illiteracy, hearing impairment, etc.). Observation of their behaviour (do they shake your hand, can they find the door handle, etc.) may help to make a crude assessment of their visual acuity.

If records from more than one eye surgeon are entered in the data file, each eye surgeon should be listed. This will allow data analysis for operations done by each individual surgeon and for all operations together. These names have to be entered in a separate file before data entry of surgical records is started. The same also applies when operations are conducted in more than one hospital, clinic or eye camp. Each eye surgeon should know his/her individual code number, as well as the code numbers of the different hospitals, clinics and camps that fall under the same organisation.

Main Menu

File

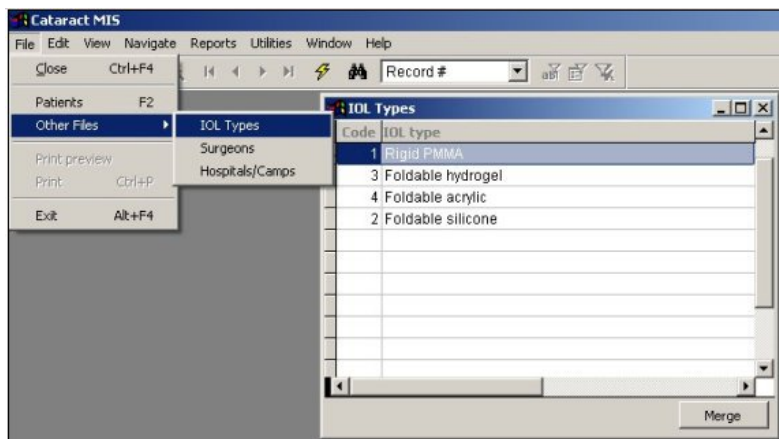
File \ Other files

This opens another sub-menu with three options: 'IOL types', 'Surgeons' and 'Hospitals/Camps'. Click on any of these options to enter the code numbers and names for all types of IOL's used, operating surgeons and hospitals or camps to be shown in choice boxes on the data entry page. To add a new name to the list, first click on the far-left button of the toolbar ("Add"), select 'Edit \ New', or press <Ctrl+Ins>. This will open a new record and you can now enter the code number and the name. Save each new row by clicking on the 'Save' button, second from left on the toolbar, by selecting 'Edit \ Save', or by pressing <Ctrl+S>. Open a new record again if more code numbers and names have to be added.

While the record is open, data entry errors can be reverted by pressing the 'Undo' button, third from left on the toolbar, or press <Ctrl+Z>. If an error is discovered after the record has already been saved then that record can be opened again, make the correction and save the record again.

Finally, records in these three tables can be deleted by pressing the 'Delete' button, fourth from left on the toolbar, by selecting 'Edit \ Delete', or by pressing <Ctrl+Del>. However, if there is any patient's records where the codes and names of a particular type of IOL, surgeon or hospital/camp are used, then that particular code cannot be deleted, as this would make the entries in those records invalid. In general, it is advisable to add new codes only and not try to delete any redundant codes. Only unused codes in the lists 'IOL types', 'Surgeons' and 'Hospitals/Camps' can be removed. Entries in these three tables can be sorted the code or alphabetically by placing the cursor on the title bar of the column to be sorted. Click when the cursor becomes a downward arrow and the entries are sorted.

Figure 2. File sub-menu to enter names or codes for IOL types, Surgeons and Hospitals/Camps



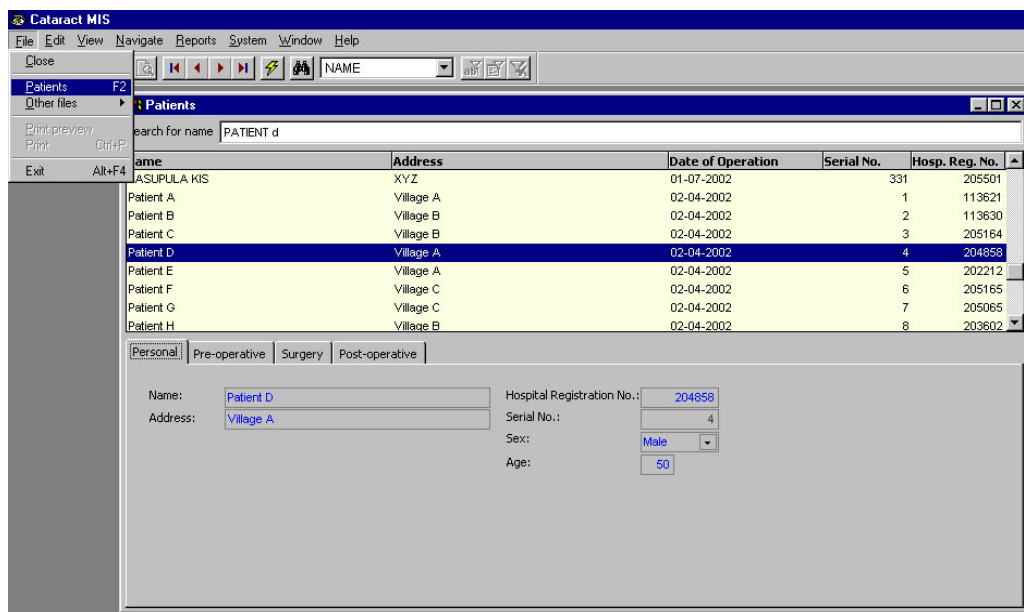
File \ Patients (or shortcut key <F2>)

This will open the data entry screen for patient details (see Fig. 3). Data is entered in boxes or choice boxes at the bottom of the screen. There are four pages, one for each section of the Cataract Surgery Record. Click on the tab of each page to make it visible. To enter a new record you first have to click on the far-left button on the toolbar ("Add"). You can also click 'Edit \ New' or use the shortcut key <Ctrl+Ins>. This will create and open a new record in the data file.

Above the data entry part is a table showing the patients already entered in the system, by name, address, date of operation, serial number and hospital registration number. This table will be very helpful to retrieve existing records in order to add post-operative visual acuity. Entries in the table can be sorted alphabetically or numerically to facilitate easy retrieval of records. Sorting can be done in two ways: first, by clicking on the arrow of the choice box in the toolbar of the main menu. All headings of the table now become visible. Make your selection and the entries in that column will be sorted. This action also changes the caption of the search box on top of the 'Patients' screen. If you want to retrieve a specific record, then type the field entry of that record in this search box and the record will automatically be retrieved.

The second way of sorting a column is by moving the cursor / pointer to the top of the column. If the pointer changes into a black arrow pointing downwards, then click and the entries in that column are sorted alphabetically or by number.

Figure 3. Data entry screen and list of entered cases



File \ Print preview

Any selected record can be printed. Highlight the record and click on the 'Print preview' button to show a form with all fields of this record. Select File \ Print, press <Ctrl + P> or click on the 'Print' button to print, or click on 'Export' to save this page.

File \ Print

This option can be used to print a report on the screen. Clicking the 'Print' button or pressing <Ctrl + p> will also print the report on the screen.

Data Entry

Most fields in the data entry screen appear as choice boxes. They seem empty, but when the pointer of the mouse is placed on the downward triangle at the right side of the box and clicked, the various options for this field will appear. Two data entry methods are available for these choice boxes. The first is the 'Select option by mouse' method, where the list of options appears and the correct option is usually selected using the mouse. The computer will store the code number belonging to this option into this field.

The second method is the 'Type code number' method, where the options are preceded by their code numbers, the same numbers that appear in brackets behind the entry on the Cataract Surgery Record Form. By typing this code number in the choice box, the option linked with the code is selected by mouse and the code number is stored into this field. The data entry screen and the options for each field are exactly the same for both methods, but the options are presented differently.

Both methods are also shown in Figure 4a and 4b.

In Figure 4a, the method is set to 'Select option by mouse'. In this mode, the text in the field is self-completing: when a "p" is typed, the option "Pseudophakia" is highlighted. Press <Enter> to store the selection. In practice, however, most users will only select the appropriate option by mouse click. Typing the code number will not select any option and will not store any entry.

In Figure 4b, the method is set to 'Type code number'. Typing the "p" will not select any option, but typing code number "6" will highlight the option "Pseudophakia". Pressing <Enter> will confirm the entry and move the cursor to the next field.

Typing code numbers is more suitable for experienced data entry operators and can reduce the data entry time considerably, especially when a second person reads out the code numbers from the CSR. In this way the data entry operator does not have to turn his eyes from the keyboard to the form and back.

The preferred data entry method can be selected in Utilities \ Settings \ Data Entry.

Figure 4a: 'Select option by mouse' method

Figure 4b: 'Type code number' method

To add a new patient's record, click on the 'Add new record' button, far left on the toolbar, click on Edit \ New, or press <Ctrl+Ins>. A new record is created and you can start data entry. The cursor automatically starts at the first field (Name) on the first page (**Personal**). Most fields have a pink colour. That is because these fields are empty and the system requires that data are entered in these fields. When you make a valid entry the colour changes to white. When the name is entered, press <Enter> and the cursor will move to the next field. Address is an optional field and may be left empty, if you do not intend to re-visit patients at home. Please refer to Annex 2, 'Coding Instructions for Cataract Surgery Record' to see which entries are allowed in each field.

The 'Serial No.' on the 'Personal' page is generated by the computer and cannot be changed by the user. The data entry operator should write this number on the CSR. The Serial No. links the computer record with the hospital record.

When the last field on the first page is completed, and you press <Enter>, the cursor will automatically move to the first field of page two.

On the '**Pre-operative**' page, the VA system appearing in the choice box for presenting and best corrected vision, depends upon the setting in Utilities \ Settings. In case you want to change this setting, close the 'Patients' screen first, otherwise the changes in VA measuring system cannot be implemented.

On the lower part of this page, there are optional fields on pre-operative refraction, biometry (K1, K2, axial length), and targeted post-operative refraction. These fields are used to evaluate outcome, complications and Deviation in Spherical Equivalents for various technical parameters like type and power of the implanted IOL and the type of section, capsulotomy and suturing applied.

On the '**Surgery**' page, the name or ID of the hospital or camp where the operation was conducted and the name or ID of the operating surgeon can be selected from combo boxes. New hospital/camps or surgeons have to be added to the respective lists first (see File \ Other files) before they can be selected in the three choice boxes on this page.

Also on this page there are optional fields on the type of section and capsulotomy, the type and power of the IOL implanted, and the type of suturing. Additional types of IOL's have to be added to the list first (see File \ Other files \ IOL types) before they can be selected on the 'Surgery' page.

On the '**Post-operative**' page, the date of operation appears automatically. The time of discharge, being the number of days since surgery, has to be entered. In case of day-care surgery, the date of the first review after the operation should be entered, usually the first or second post-operative day.

When the CSR comes for the first time for data entry, all fields up to the findings at discharge have to be entered, except those marked by 'optional'. While entering date, all entries are checked for completeness, validity and consistency. If an entry is made that is inconsistent or very unlikely, this field will turn pink. If the cursor is moved on the same field a message will be seen indicating the error. If the inconsistency is not corrected and the user wants to save the record, an error message will appear reporting the same error.

When data entry of a record is complete, save your entries by clicking on the 'Save' button, second from left on the toolbar, by clicking 'Edit \ Save', or by pressing <Ctrl+S>. A second consistency check for incomplete or inconsistent entries is carried out before the record is saved. When an error is suspected, a message will appear and the cursor will automatically move to the box with the entry that is questioned. Check the entry against the original CSR and make the necessary corrections. If no errors are found, the record is automatically saved when you open a new or another existing record.

Please note that when typing an entry in a field, the characters in this field are black. When moving to the next field, the same characters turn red. When the entire record is saved, all entries in that record change from red to blue. Hence, the colour of the entry shows whether the entry has just been made or is already stored in the data file.

When the data entry is completed, the data entry operator should write the date of entry and signature or initials in the left margin of the CSR, next to the row with the last data entered. This will avoid double entry of records. Remember that the same operated person may appear twice in the data file: one record for each operated eye. Each operated eye should have a separate record, even when both eyes are operated in a single session.

When a record is entered with the same name, date of operation and operated eye as another record entered earlier, a warning message will appear. Check whether this patient has been entered twice. If so, the double record can be deleted by highlighting this record and pressing the 'Delete' button, fourth from left on the toolbar, or by pressing <Ctrl+Del>. However, typing errors in one of the names will make the names different and this check will not work. It is therefore advisable to sort the names alphabetically and compare the Name, Date of Operation and Hospital Registration Number and right or left eye operated check once a month to identify any remaining double entries.

The flow of the Cataract Surgery Records is important for data entry. In most cases the CSR remains with the patient until discharge. Then data entry takes place up to the cause of poor outcome at discharge, and the CSR is signed to indicate that data entry was done. The form then goes back to the outpatient department where operated patients will be seen for follow-up. The findings at all follow-up visits will have to be added to the record created after discharge.

There are several options to retrieve existing records in order to add data on follow-up visits. The easiest option is to type the patient's name in the search box on top of the 'Patients' window. This is not case sensitive: you can type in capitals or in lower case characters. The first record with that name will appear highlighted in the table, and other data concerning the same patient is visible in the four 'tab sheets'. To add follow-up visit data, click on the tab 'Post-operative' and enter the additional data of the follow-up visit. Please be aware that whenever any changes are made in any field of a record, these changes are saved to disk as soon as you place the cursor in another record. Clicking the 'Close' or the 'Save' button on the toolbar, or pressing <Ctrl+S> will also save the record. Don't forget to sign the CSR next to the row with the last entered data.

You can change the search field to 'Hospital Registration No.', 'Address', 'Serial No.' or 'Date of Operation' in the combo-box on the toolbar just below the main menu. By default it will show the 'Name' field. Click on the down-arrow right in the combo-box to change to the other fields.

In order to protect the privacy of patients, the data file is always encrypted on the hard disk and records are unreadable. Only when the programme is running, it loads the data file into memory, decrypts the data and performs all operations.

File \ Exit

Click this option, or press <Alt+F4>, or click on the Close button in the upper right corner of the screen to close the programme. When the data in any of the data files has been modified, the programme will ask whether you want to make a back-up of the data files in the location specified under Utilities \ Settings.

Edit

Edit \ Cut, Copy, Paste

When inside a record, highlight a text and the functions 'Cut' (or shortcut key <Ctrl+X>), 'Copy' (or shortcut key <Ctrl+V>) and 'Paste' (or shortcut key <Ctrl+V>) can be used as in other Windows packages.

Edit \ New

Click on this option to create a new record. You can also use the shortcut key <Ctrl+Ins> or the 'Add' button on the toolbar.

Edit \ Delete

Click on this option to delete a record. You can also use the shortcut key <Ctrl+Del> or the 'Delete' button on the toolbar. Once deleted, a record cannot be retrieved by the 'Undo' button.

Navigate

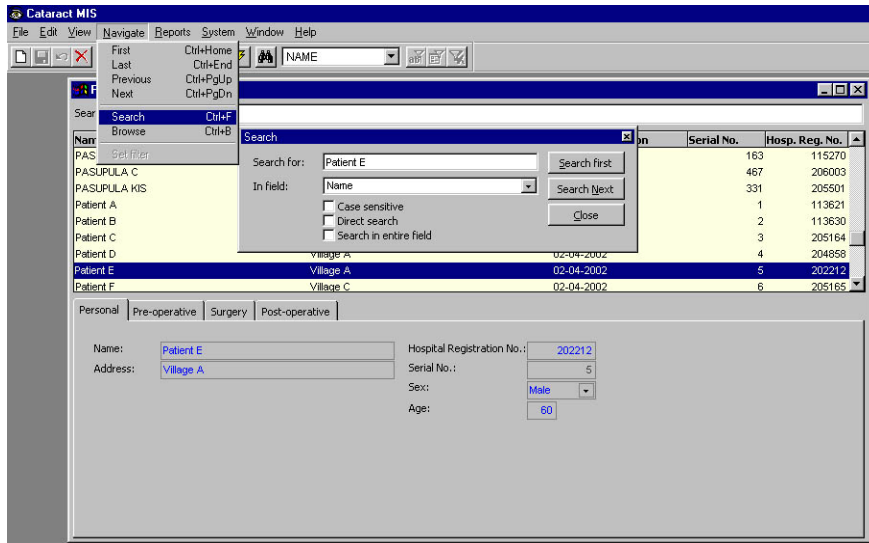
Navigate \ First, Last, Previous, Next

These menu options allow you to move between records. You can also use the shortcut keys or the red arrow buttons on the toolbar.

Navigate \ Search

A more detailed search facility is available under 'Navigate \ Search', by pressing the 'Search' button on the toolbar (binoculars), or by pressing <Ctrl+F>. With this option, any record(s) can be traced by the value of any of its fields. Select first the field you want to search. For fields with fixed options, these options can then be selected in the 'Search for' choice box (Figure 5).

Figure 5. Detailed search facilities



Navigate \ Browse

This option opens the entire table that is used for the active screen. You can look at the values of all fields in all records in the table, but you cannot change any of the entries. You can also use the shortcut key <Ctrl+B>.

Navigate \ Set filter

This option allows the user to select all records with a certain value in a specified field. Place the cursor in the selected field, say the field age with a value of 60. Click on Navigate \ Set filter, or press the second button from the right on the toolbar ('Field filter'), and only records of operated persons of age 60 will be shown. You can scroll through the list of cases, or view them in a table by clicking on Navigate \ Browse or by pressing <Ctrl+B>. Please note that the font of the value in the field that determines the filter, changes to *Italics*. Release the filter again by clicking on the 'Release all filters' button, far right on the toolbar.

Reports

Click on 'Reports' to open a sub-menu of ten reports that can be generated automatically. Select the report you wish to produce and the 'Make report' dialog screen will appear (see Figure 6). In this dialog screen the title of the report is shown on top. Click on the down arrow of this choice box to select any of the other reports.

Under 'Sample file' a special data set with patient records can be selected. If a special data set is selected with this option then the Hospital/Camp, the Surgeon and the Period have already been determined and these fields are therefore disabled for this option.

Select for which Hospital/Camp you wish to produce a report. If left blank, records from all hospitals and/or camps will be used for analysis. Then select for which Surgeon you wish to produce a report. If left blank, records from all surgeons will be used for analysis.

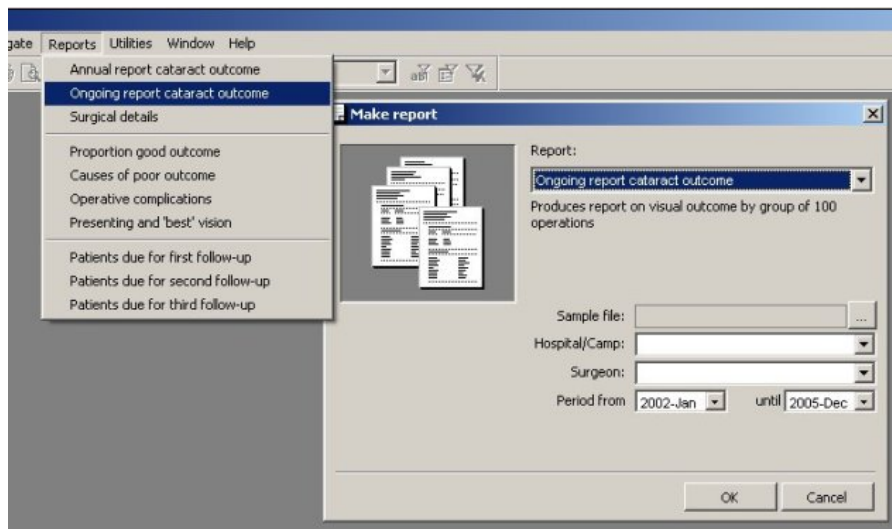
Next to 'Period from' you can indicate the year and month when the analysis should start and next to 'till', when this period should end. The software checks when the operations in the data set were done. By default, the start date is the first month of the year in which the first operation of the stored records is done and the end date is the last month of the year in which the last operation was done. This means that all records in the data set are included. The user can select to create a report for operation conducted in a defined period only by clicking on the combo boxes to select the start and end date of the

In two reports, 'Causes of Poor Outcome' and 'Presenting and Best Vision' an extra combo box appears where the duration of the post-operative period can be selected.

If all entries are completed, press <OK> and the report will appear. The first three reports contain tables only; the middle four create a graph and a data table. The last three reports do not use the 'Make report' dialog screen, but produce a list of patients due for follow-up directly. All reports can be read on screen, be printed or be saved in a file.

When a report is on screen, the toolbar expands to the right end and shows navigation buttons to move through the various pages of the report, an 'Export' button to save the report in various formats and a choice box to change the size of the report. Click on the navigation arrows to move between pages. To save the report, click on the 'Export' button on the right side of the toolbar and type a name for the document. To maintain the layout in the report, it is best saved as a Rich Text Format (.RTF) file. A second advantage is that this file format can be read by all versions of Ms Word. The report can also be saved as .HTML or as an Excel file, in case you wish to create custom graphs. To print the report click on the Printer button on the toolbar, click on File \ Print, or press <Ctrl+P>. To close a report, click on the 'Close' button in the right upper corner of the screen, or click on File \ Close.

Figure 6. Report menu and 'Make report' dialog screen



If several reports have to be produced for the same hospital/camp, surgeon and period, then keep the 'Make report' dialog screen open and select the various reports through the topmost choice box of the 'Make report' screen. This will retain the settings for hospital/camp, surgeon and period. When you close the 'Make report' screen first and then select a new report from the main menu, then all selections of hospital/camp, surgeon and period will be the defaults again.

Annual Report

The annual report contains the following tables:

1. Age and gender of operated patients
2. No. of first eyes and second eyes operated
3. Proportion known ocular pathology in operated eye
4. VA in the operated eye pre-op, at discharge and at follow-up
5. VA in the better eye pre-op, at discharge and at follow-up
6. Good / Borderline / Poor outcome at discharge by month (presenting VA)
7. Proportion Good / Borderline / Poor outcome by follow-up (presenting VA)
8. Operative complications by month
9. Operative complications by place of surgery
10. Operative complications by cadre of surgeons
11. Operative complications by additional ocular pathology
12. Operative complications by type of surgery
13. Causes of poor outcome at discharge and follow-up
14. Percentage poor visual outcome at discharge and follow-up

Ongoing Report

This report analyses results by groups of 100 operated patients.

1. Operative complications
2. Good / Borderline / Poor outcome at discharge
3. Causes of poor outcome at discharge
4. Good / Borderline / Poor outcome at follow-up (4 weeks or more)
5. Causes of poor outcome at follow-up (4 weeks or more)

Surgical Details

This report contains the following tables:

1. Deviation of Spherical Equivalents by case at 4-11 weeks post-op.
2. Deviation of Spherical Equivalents by case at 12 or more weeks post-op.
3. Average Deviation of Spherical Equivalents at 4-11 weeks post-op. by month
4. Average Deviation of Spherical Equivalents at 12 or more weeks post-op. by month
5. Complications by type of section
6. Complications by type of capsulotomy
7. Complications by type of type of IOL
8. Complications by type of suturing

Proportion GOOD Outcome

Graph and table of proportion of good outcome by month and by post-operative period.

Causes of POOR Outcome

Graph and table of proportion and causes of poor outcome by month and by post-operative period.

Operative Complications

Graph and table of surgical complications by month.

Presenting and 'Best' Vision

Graph and table of presenting and 'best' post-op. vision at various post-operative periods by month.

Patients due for first follow-up

This creates a list of the operated patients that are due for a follow-up visit 1-3 weeks after operation to record their post-operative vision. Only patients that have been operated between 1 and 3 weeks before the current date, who did not yet come for review, will be listed. This may help to trace cases due to come and thereby increase follow-up.

Patients due for second follow-up

This creates a list of the operated patients that are due for a follow-up visit 4-11 weeks after operation to record their post-operative vision. Only patients that have been operated between 4 and 11 weeks before the current date, who did not yet come for review, will be listed. This may help to trace cases due to come and thereby increase follow-up.

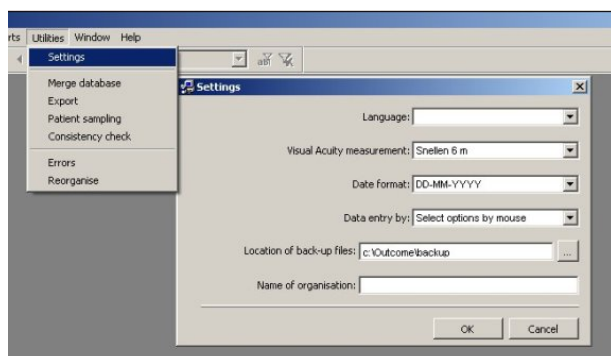
Patients due for third follow-up

This creates a list of the operated patients that are due for a follow-up visit 12 or more weeks after operation to record their post-operative vision. Only patients that have been operated 12 weeks or more before the current date, who did not yet come for review, will be listed. This may help to trace cases due to come and thereby increase follow-up.

Utilities

Utilities \ Settings

When this menu option is clicked a dialog screen will appear (Figure 7).



The 'Settings' screen contains six important settings for the Cataract Outcome programme:

Language: select the language of the software package (English, French, Spanish, Chinese or Arabic);

Visual Acuity measurement: select here the VA system that you want to appear in the choice boxes on the data entry form. Options are: Snellen 6M, Snellen 20ft, Decimal and LogMar;

Date format: select the date format used as dd-mm-yyyy or mm-dd-yyyy.

Data entry by: select data entry by 'Select options by mouse' method, using the mouse or by 'Type code number' method, typing code numbers by keyboard. The second method is faster, especially when a second person can read out the code numbers to the data operator.

Location of backup data files: select the path where backup data files should be stored. Whenever any changes are made to the database the user will be asked to make a backup of the latest changes. The best option is to use a memory stick for the backup.

Name of organisation: type here the name and address of your organisation. This will then appear in the opening screen and on top of all reports.

Utilities \ Merge database

Be very careful using this option! Always make backups of your data files before you try to merge data files. Codes and records may be changed and if anything goes wrong this can not be undone.

This option can be used to import data from an earlier version into the current – empty – data file or to merge different databases with MCSO data. It is important to realise that each file with patient data uses codes from three other files specifying the hospital, the eye surgeon and the type of IOL used. From these three files only the code number is stored in the patient file, not the name. When patient data from different files are merged, the corresponding codes for IOL type, Surgeons and Hospital/Camp are also added. That means that in these three 'other files' certain options may appear twice, each with a different code number. For the patient file it means that for example the same IOL type 'Rigid PMMA' may have code 1 in the some records and code 5 in others. To create one code for the same IOL type, open File | Other files | IOL types. Place the cursor on the title 'IOL type' and click. The IOL types will now be sorted alphabetically. If an IOL type appears twice, then highlight the one that has to be modified and click on the Merge button. A small dialog screen appears, with a combo box. Click on the down arrow and select the corresponding code with which you want to merge it and which should be the final code. Click on the Merge button in this screen and all original codes will be updated. Repeat this procedure until all double codes have been removed. Then follow the same procedure also for the Surgeons and the Hospitals/Camps files.

Utilities \ Export

This option will convert the entire patients file into an Excel 2000 © spreadsheet for custom analysis outside the MCSO software. In the exported file the names and addresses of patients have been removed to protect the privacy of the patients.

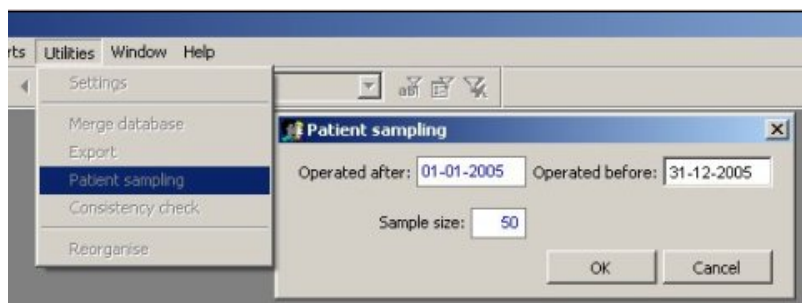
Utilities \ Patient sampling

When less than 80% of the operated cases return for follow up, as is the case in many developing countries, the results of the analysis become less reliable because it is not known what the finding are in those patients that did not return for follow up. Are people with good outcome not coming for follow-up because they are satisfied, or dare those with poor outcome not coming for follow-up because they prefer to go to another doctor?

A possibility is then to take a random sample of at least 50 patients, operated during a particular period, and actively visit and examine the VA in those patients of the selected 50 who did not complete their follow up visits.

If this menu is selected a Patient sampling dialog screen will open where the user can indicate the start and the end of the period when the patients were operated and the sample size. (Figure 8) The software will then randomly select the indicated number of patients from all patients operated during the marked period.

Figure 8. Dialog screen to select sample of patients for active follow up.



When OK is clicked a name should be given to the sample of the original patient records just created. It may be advisable to use the year selected, say 'Sample_2005'. The file will be saved under this name. This file can be opened exclusively in the patients screen by clicking on the Table filter button on the toolbar (second from right) and selecting the name of the sample file in the Open File screen. Print-outs of the individual forms can now be by clicking on File | Print preview. In this way it becomes much easier to complete the missing data for the patients in this sample.

The records of this sample can also be analysed as a separate group. Use the Reports menu, select the required report and click. When the Make report screen appears, click on the search button right from the Sample file box and select the sample file created earlier. When this file is selected the possibility to select the hospital, surgeon or time period is disabled, since that was done already when the sample was created. Click OK and the selected report will be created. When other reports for the same sample file have to be created, then don't close the Make report screen, but select another report in the topmost combo box of this screen.

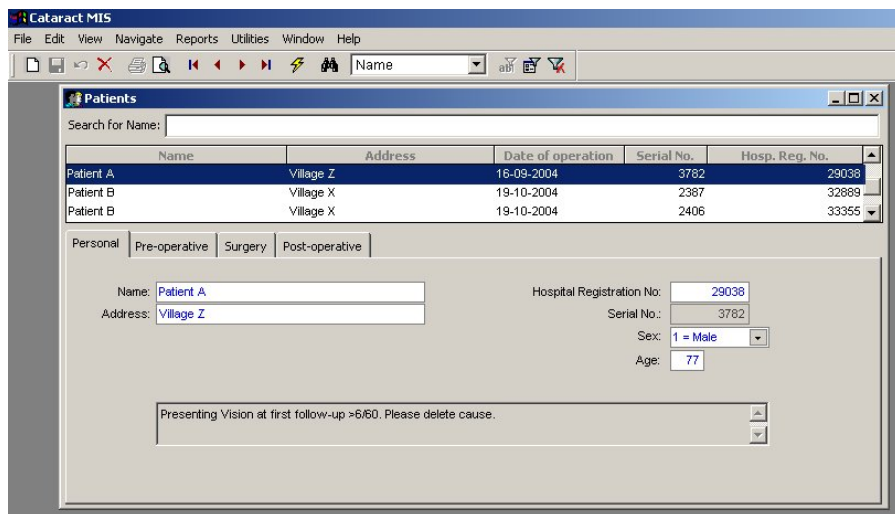
Utilities \ Consistency Check

Despite many in-built checks to avoid data entry errors, experience shows that such errors still occur. By pressing this option, the programme will check all entries for empty fields, invalid codes, inconsistencies and double entries, and a list of records with such errors will be produced. Records with the same name, same date of operation and same operated eye are listed as possible double entries. Print this report and use it to correct the errors in the data file by comparing them with the original Cataract Surgery Record forms. After corrections are completed, run the consistency check again and again until no record is listed anymore with inconsistencies.

Not all errors can be detected. If a male has been operated and this patient is recorded as a female, this will not be detected. If an incorrect post-operative vision is entered this may not be noticed as an error. Therefore it is very important that all data are carefully checked during data entry. Supervisors are advised to check the quality of data entry regularly by randomly selecting about 20 CSR forms and comparing the forms with the entries in the database.

The table filter function can also be very handy for making corrections in those records with errors. Open the patients screen if not yet open by pressing <F2>. Now click on the Table filter button and select the file called PatFalse.dbf. This table, which contains only those records with a an error, will now open in the patients screen with an extra box on the Personal tabular page, showing the error(s) in this record. (Figure 9)

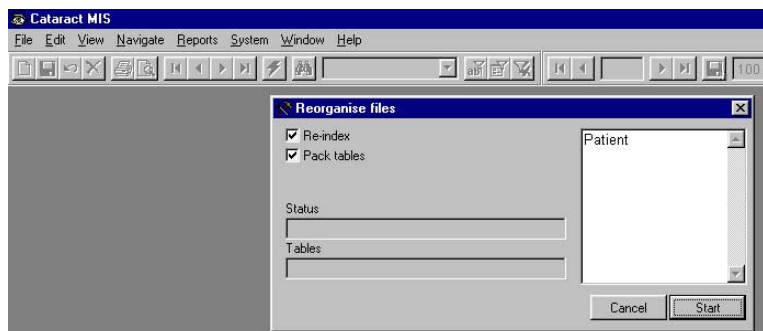
Figure 9. Correction of errors in Patients screen



Utilities \ Reorganise

Whenever new records have been added and old records have been deleted, the indexes that are attached to records and fields and facilitate searches, have to be updated and deleted records have to be removed. Close all data entry windows before you use this option. Click on 'Utilities \ Reorganise', place tick marks before 'Re-index' (to make new indexes) and 'Pack table' (to permanently remove deleted records) and click on 'Start'. Progress of the reorganisation can be monitored on the status bar. (Figure 10)

Figure 10. Reorganise data files



Window

Window \ Arrange all

Click this option and all open screens will be arranged on the desktop.

Window \ Hide

Click this option and the active screen will be hidden.

Window \ Cycle

Click this option, or press <Ctrl+F6>, and all open screens will one by one be activated and placed on top. A list at the bottom of this sub-menu shows all open screens. Place a tick mark before one of the listed screens to activate it and place it on top.

Help

Help \ Manual

Click this option or press <F1> to open the Manual for MCSO version 2.4. The text of this Help file is exactly the same as this manual. Hyperlinks are placed on the 'List of contents' to facilitate browsing and quick searching of topics.

Help \ QuickGuide

This is a condensed version of the manual listing brief commands how to operate the software.

Help \ Info

This will open an information screen indicating the version and year of the package and contact addresses.

Annex 1. Cataract Surgery Record

CATARACT SURGERY RECORD																																																																												
A. PATIENT Name: _____ Address (optional): _____ Sex: Male: <input type="radio"/> (1) Female: <input type="radio"/> (2)					Hosp. Reg. No.: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> Serial No.: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> Age (years): <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>																																																																							
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Lens Examination: <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Clear lens:</td><td style="width: 25%; text-align: center;"><input type="radio"/> (1)</td><td style="width: 25%; text-align: center;"><input type="radio"/> (1)</td></tr> <tr><td>Opacity, not ready for operation:</td><td style="text-align: center;"><input type="radio"/> (2)</td><td style="text-align: center;"><input type="radio"/> (2)</td></tr> <tr><td>Operable cataract:</td><td style="text-align: center;"><input type="radio"/> (3)</td><td style="text-align: center;"><input type="radio"/> (3)</td></tr> <tr><td>Inoperable cataract:</td><td style="text-align: center;"><input type="radio"/> (4)</td><td style="text-align: center;"><input type="radio"/> (4)</td></tr> <tr><td>Aphakia:</td><td style="text-align: center;"><input type="radio"/> (5)</td><td style="text-align: center;"><input type="radio"/> (5)</td></tr> <tr><td>Pseudophakia:</td><td style="text-align: center;"><input type="radio"/> (6)</td><td style="text-align: center;"><input type="radio"/> (6)</td></tr> <tr><td>Cannot examine:</td><td style="text-align: center;"><input type="radio"/> (7)</td><td style="text-align: center;"><input type="radio"/> (7)</td></tr> </table>					Clear lens:	<input type="radio"/> (1)	<input type="radio"/> (1)	Opacity, not ready for operation:	<input type="radio"/> (2)	<input type="radio"/> (2)	Operable cataract:	<input type="radio"/> (3)	<input type="radio"/> (3)	Inoperable cataract:	<input type="radio"/> (4)	<input type="radio"/> (4)	Aphakia:	<input type="radio"/> (5)	<input type="radio"/> (5)	Pseudophakia:	<input type="radio"/> (6)	<input type="radio"/> (6)	Cannot examine:	<input type="radio"/> (7)	<input type="radio"/> (7)	<p style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">CLINICAL DATA</p>																																																		
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C: SURGERY <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%; vertical-align: top;"> Date of operation: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> Place of operation: <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">Base hospital</td><td style="width: 70%; text-align: center;"><input type="radio"/> (1)</td></tr> <tr><td>Other hospital</td><td style="text-align: center;"><input type="radio"/> (2)</td></tr> <tr><td>Out of hospital</td><td style="text-align: center;"><input type="radio"/> (3)</td></tr> </table> </td> <td style="width: 60%; vertical-align: top;"> Hospital / camp ID: _____ Surgeon ID: _____ Training <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">Ophthalmologist</td><td style="width: 70%; text-align: center;"><input type="radio"/> (1)</td></tr> <tr><td>Resident / trainee</td><td style="text-align: center;"><input type="radio"/> (2)</td></tr> <tr><td>Cataract surgeon</td><td style="text-align: center;"><input type="radio"/> (3)</td></tr> </table> </td> </tr> </table>					Date of operation: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> Place of operation: <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">Base hospital</td><td style="width: 70%; text-align: center;"><input type="radio"/> (1)</td></tr> <tr><td>Other hospital</td><td style="text-align: center;"><input type="radio"/> (2)</td></tr> <tr><td>Out of hospital</td><td style="text-align: center;"><input type="radio"/> (3)</td></tr> </table>				Base hospital	<input type="radio"/> (1)	Other hospital	<input type="radio"/> (2)	Out of hospital	<input type="radio"/> (3)	Hospital / camp ID: _____ Surgeon ID: _____ Training <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">Ophthalmologist</td><td style="width: 70%; text-align: center;"><input type="radio"/> (1)</td></tr> <tr><td>Resident / trainee</td><td style="text-align: center;"><input type="radio"/> (2)</td></tr> <tr><td>Cataract surgeon</td><td style="text-align: center;"><input type="radio"/> (3)</td></tr> </table>	Ophthalmologist	<input type="radio"/> (1)	Resident / trainee	<input type="radio"/> (2)	Cataract surgeon	<input type="radio"/> (3)	Operative complications in operated eye: <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">None</td><td style="width: 40%; text-align: center;"><input type="radio"/> (1)</td><td style="width: 30%;"></td></tr> <tr><td>Capsule rupture without vitreous loss</td><td style="text-align: center;"><input type="radio"/> (2)</td><td>Wound leak</td><td style="text-align: center;"><input type="radio"/> (6)</td></tr> <tr><td>Vitreous loss</td><td style="text-align: center;"><input type="radio"/> (3)</td><td>Striate keratopathy</td><td style="text-align: center;"><input type="radio"/> (7)</td></tr> <tr><td>Zonular dehiscence</td><td style="text-align: center;"><input type="radio"/> (4)</td><td>Endophthalmitis</td><td style="text-align: center;"><input type="radio"/> (8)</td></tr> <tr><td>Retained lens matter</td><td style="text-align: center;"><input type="radio"/> (5)</td><td>Others</td><td style="text-align: center;"><input type="radio"/> (9)</td></tr> </table>					None	<input type="radio"/> (1)		Capsule rupture without vitreous loss	<input type="radio"/> (2)	Wound leak	<input type="radio"/> (6)	Vitreous loss	<input type="radio"/> (3)	Striate keratopathy	<input type="radio"/> (7)	Zonular dehiscence	<input type="radio"/> (4)	Endophthalmitis	<input type="radio"/> (8)	Retained lens matter	<input type="radio"/> (5)	Others	<input type="radio"/> (9)																															
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D. VISUAL ACUITY OF OPERATED EYE POST-OP. Cause of presenting vision <6/60 (Key 8, 9, 10, 11, 12)																																																																												
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Annex 2: Coding instructions for Cataract Surgery Records

The Cataract Surgery Record (CSR) has to be completed for each eye operated for cataract (if all patients are included in the monitoring of visual outcome) or for patients randomly selected for follow-up. If the same patient is operated at a later date for cataract in the second eye, a new form should be completed for the second operation. Each operated eye should be treated as a separate event.

On lines, text (name of patient, address, etc) should be written. In the square boxes, a number has to be entered. Circles can be made black or tick marked. For each parameter, only one circle can be marked. All fields need an entry, except those marked 'optional'. Write clearly and make it a habit to check all data you have written on the form before you send it for data entry. Be aware that the data entry operator, who has not seen the patient and in most cases is not an eye surgeon, should not make any errors in transferring your findings into the computer. When an entry on the CSR cannot be entered into the database because of an error message, the data operator should return the form to the eye surgeon and request the CSR to be reviewed.

Annex 1 shows a CSR with VA in decimal measurement system. Similar CSR forms are provided with VA measured in Snellen 6 metres, Snellen 20 feet, the decimal and the LogMar system.

Please note that the following patients might be excluded from monitoring because the expected visual outcome after cataract surgery could be less than optimal:

- persons, operated for cataract and younger than 20 years
- persons with traumatic cataract
- persons having combined procedures (e.g. cataract surgery with corneal graft, or cataract surgery with trabeculectomy, etc.)

A. Patient

Name

Write the surname first, followed by the first name and other name(s). The name can have a maximum of 23 characters. Names will not appear in analysis but are used to identify records to enter follow up data.

Address

Write the address to identify and locate the patient. The address can have a maximum of 40 characters. This field is not used for analysis. If you do not intend to follow-up patients, you may skip this field.

Registration No.

Enter the hospital registration number of the patient here. This may help to retrieve medical records of patients.

Serial No.

This number will be generated by the computer and is used to select a random sample for follow-up studies. The data entry operator has to write the number that appears on the computer screen on the corresponding CSR. This Serial number is unique and cannot appear twice.

Sex

Mark 'Male' or 'Female'.

Age (in years)

For age 20 to 98, write the age in years. For age of 99 years and over, write "99". Do not make a record when the operated patient is younger than 20 years. The computer only allows entry of ages of 20 to 99 years.

B. Pre-operative examination

Presenting VA (right and left eye)

Measure the visual acuity of each eye separately, with the available correction, if any (=presenting vision). Use the categories listed in the box on the right (category of visual acuity) and write the acuity next to VA on the appropriate line. You can use the Snellen 6/60, Snellen 20/200, the decimal or the LogMar system. If you want to change the visual acuity measurement system for data entry, close the 'Patients' screen first, then click Utilities | Settings and select the VA system of your choice.

Best corrected VA (right and left eye)

Measure the visual acuity with the best possible correction. If refraction cannot be done, vision with pinhole can substitute for best correction. Use the categories listed in the box on the right (category of visual acuity) and write the acuity next to VA on the appropriate line. You can use the Snellen 6/60, Snellen 20/200, the decimal or the LogMar system. The 'best' VA cannot be worse than the presenting vision. If this is the case you cannot continue until the correct entries are made.

Lens examination (right and left eye)

The lens of both eyes should be examined. For each eye, only one option may be marked. At least one eye should have operable cataract; otherwise, there is no indication for cataract surgery. 'Cannot examine' should only be marked in those cases where the lens cannot be seen, as in phthisis bulbi, dense corneal scarring, etc.

Type of other eye disease in operated eye?

Mark one of the other concurrent eye diseases in the operated eye, likely to affect the outcome. Mark 'corneal scar', 'old iritis', 'retinal disease', 'glaucoma' or 'other' and specify the condition. If there are no concurrent eye diseases, mark 'None'.

Optional:

The fields under this heading are optional and can be left empty. Entries should only be made for the eye to be operated.

Eye to be operated

Mark the eye that is to be operated upon.

Pre-op refraction

Sp (spherical): allowed: -15 to +15

Cyl (cylindrical): allowed: 0 to -10

Axis: allowed: 0 to 180

Biometry

K1 (highest curvature) allowed: 35 to 50

K2 (lowest curvature) allowed: 35 to 50

Axial length allowed: 20 to 27

Targeted post-op spherical equivalent

Formula: Spherical equivalent = spherical correction + cylindrical correction/2

Allowed values are: -10 to +5

Enter the target post-operative refraction in spherical equivalents (SE) for this operation. For example, if you aim at -1, enter "-1". If emmetropia is your goal, enter "0". Should you aim at, for instance, S= -3 and Cyl= -1, enter "-3.5" (SE= -3+(-1 / 2)). The programme will calculate the difference in spherical equivalents between the estimated and actual refraction obtained after the operation.

C. Surgery

Date of operation

Write the date of cataract surgery in the format you as dd-mm-yyyy (default). If you want the mm-dd-yyyy format, select this option at Utilities | Settings. You can enter "02" for the year 2002.

Place

Mark the place where the surgery was performed.

Eye operated

Mark which eye was operated upon.

Type of surgery

Mark the surgical technique used. "SICS" stands for Small Incision Cataract Surgery (SICS) or Blumenthal method.

IOL

Mark which type of IOL was used. ICCE cannot be combined with PC-IOL.

Hospital/camp ID

If you intend to analyse outcome by hospital(s) or camp(s), you should create a code for each hospital, clinic or camp in File | Other files | Hospitals/Camps. Make sure all participating staff knows these codes and uses them correctly. This will make it possible to analyse visual outcome of cataract operations for each of the coded centres or for all centres together. Even if all records are from one centre only, a number and a name have to be entered in the Hospitals/Camps file.

Surgeon ID

If you wish to analyse outcome by surgeon, you should create a list of codes for each surgeon in File | Other files | Surgeons. Make sure all eye surgeons know these codes and use them correctly. It is possible to analyse visual outcome of cataract operations for each coded surgeon or for all surgeons together. Even if all records are by one eye surgeon only, a number and a name have to be entered in the Surgeons file.

Training

Mark the level of training of the surgeon. The term 'Cataract surgeon' is reserved for non-doctors, specially trained and qualified to perform cataract surgery.

Peri-Operative complications in operated eye

Mark if there were any operative complications in the operated eye. Only one complication may be marked. In case of more than one complication, the principal complication most (likely) responsible for the reduction in post-op vision, should be marked. In case the complication is not listed, mark "Other" and specify the condition.

Optional:

The fields under this heading are optional and can be left empty. Entries should only be made for the eye that was operated upon.

Section

Mark the place and type of the section.

Capsulotomy

Mark the type of capsulotomy.

Type IOL

Create a list of the most commonly used IOL's and enter the codes and names of these IOL's in File | Other files | IOL Types. Make sure all eye surgeons know these codes and use them correctly.

IOL power

Enter the power of the IOL implanted. Allowed values are between +8 and +30 Dioptres.

Suturing

Mark the type of suturing used.

No. of sutures

Only when interrupted suturing is the number of sutures (1-9) can be entered. When "No suture" is entered under Suturing, you should enter "0" here. In case of "Continuous", "1" should be entered here.

D. Visual acuity of operated eye post-operatively

The visual acuity of the operated eye only can be assessed at several periods after the operation. First assessment should be done at discharge. If the patients was operated and discharged the same day, and will be seen again after one or two days, then record the discharge findings can be taken on the first or second post-operative day.

No days between operation and discharge

Write the number of days after the actual operation when the discharge assessment is made. You can enter 1 to 7 days. If the patient is discharged more than 7 days after the operation, then enter the findings on the 7th day and enter these in this row. When patients are operated and return home the same day, to be reviewed on the first or second day post-operatively, enter "1" or "2" respectively and measure the VA on this day. This field cannot be left empty.

Discharge - presenting VA

Write the visual acuity of the operated eye with available correction, if any, on the line next to VA. Use the categories listed in the box on the right (category of visual acuity) and write the code that goes with the acuity next to VA on the appropriate line. You can use the 6/60, 20/200, the decimal system or the LogMar system. This field cannot be left empty.

Discharge – Best corrected VA

Write the visual acuity of the operated eye only with best correction. If refraction cannot be done, pinhole vision can be used. Use the VA categories as given. This field cannot be left empty and 'Best corrected VA' cannot be worse than presenting vision.

Discharge - cause of presenting VA <6/60

If presenting VA at discharge is less than 6/60, mark one of the three causes of poor outcome. If the presenting VA at discharge is 6/60 or better, this field should not be marked.

1-3 weeks postop. (first follow-up visit) - date

The first follow-up visit should take place 1-3 weeks post-operatively. Write the date in dd/mm/yyyy or mm-dd-yyyy format. Only entries between 1-3 weeks after the date of operation are allowed in this field.

1-3 weeks post-op - Presenting VA

Enter the visual acuity of the operated eye only, with available glasses, if any, at this first follow-up visit, 1-3 weeks post-op. Use the VA categories as given.

1-3 weeks post-op – Best corrected VA

Enter the visual acuity of the operated eye only, with best correction or with pinhole. Use the VA categories as given. Best corrected VA cannot be worse than presenting VA.

1-3 weeks post-op - cause of presenting VA <6/60

If presenting VA at first follow-up visit is worse than 6/60, one of the four causes of poor outcome must be marked. Post-operative sequelae, like retinal detachment, PCO, etc. can be marked here. Only one cause can be marked. If there is more than one cause for poor outcome select the cause that contributes most to the poor outcome. If the presenting VA at discharge is 6/60 or better, do not mark any of the boxes under 'cause'.

4-11 weeks post-op (second follow-up visit) - date

The second follow-up visit should take place 4-11 weeks post-operatively. Write the date in dd/mm/yyyy or mm-dd-yyyy format. Only entries between 4-11 weeks after the date of operation are allowed in this field.

4-11 weeks post-op - presenting VA

Enter the visual acuity of the operated eye only, with available glasses, if any, at second follow-up visit, 4-11 weeks post-op. Use the VA categories as given.

4-11 weeks post-op - Best corrected VA

Enter the visual acuity of the operated eye only, with best correction or with pinhole. Use the VA categories as given. Best corrected VA cannot be worse than presenting VA.

4-11 weeks post-op - cause of presenting VA <6/60

If presenting VA at second follow-up visit is <6/60, one of the four causes of poor outcome must be marked. If there is more than one cause for poor outcome select the cause that contributes most to the poor outcome. If the presenting VA at discharge is 6/60 or better, do not mark any of the boxes under 'cause'.

12+ weeks postop. (third follow-up visit) - date

The third follow-up visit should take place 12 weeks or more post-operatively. Write the date in dd/mm/yyyy or mm-dd-yyyy format. Only entries of 12 weeks or more after the date of operation are allowed in this field.

12+ weeks postop. - presenting VA

Enter the visual acuity of the operated eye only, with available glasses, if any, at third follow-up visit, 12 or more weeks post-op. Use the VA categories as given.

12+ weeks postop. - Best corrected VA

Write the visual acuity of the operated eye only with best correction or with pinhole. Use the VA categories as given. Best corrected VA cannot be worse than the presenting VA.

12+ weeks postop. - cause of presenting VA <6/60

If presenting VA at third follow-up visit is <6/60, one of the four causes of poor outcome must be marked. If there is more than one cause for poor outcome select the cause that contributes most to the poor outcome. If the presenting VA at discharge is 6/60 or better, do not mark any of the boxes under 'cause'.

Optional:

The fields under this heading are optional and can be left empty. Entries should only be made for the eye that was operated upon.

4-11 weeks post-op. refraction

Sp (spherical): allowed: -15 to +15

Cyl (cylindrical): allowed: 0 to -10

Axis: allowed: 0 to 180

DSE: calculated value: Difference in Spherical Equivalent between targeted SE and actual SE

12+ weeks post-op. refraction

Sp (spherical): allowed: -15 to +15

Cyl (cylindrical): allowed: 0 to -10

Axis: allowed: 0 to 180

DSE: calculated value: Difference in Spherical Equivalent between targeted SE and actual SE