MOPOC Ltd.

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Leading modernisation

Patient consent & data protection

MOPOC-1-P Protocol

Introduction

It is essential that information about patients is shared between the clinicians who care for them. Not only is it necessary for immediate treatment, but for quality assurance and strategic management of primary ocular care.

However despite what is clearly set out in the Data Protection act, and despite the obvious necessity, hospitals are refusing to provide optometrists with information required for clinical audit. The major prompt for this scheme was to force the unblocking of the return path of audit data from hospitals to optometrists. Shared care cannot be properly managed without it.

MOPOC-1 obtains the patient's informed written consent for certain processing of their clinical data. (Business information is not covered.) The protocol explains how data should be stored, passed-on and obtained from elsewhere. There are many issues of security and confidentiality that we deal with by simple, practical measures. If as we hope MOPOC-1 becomes a de-facto standard then optometrists will have a single, routine "sign here please" procedure.

Information is a vital resource required to improve the quality of patient care. The protocol explains these quality issues in order that everyone understands the justification for yet another set of regulations.

We are surrounded by bureaucracy and nit-pickers who want us to spend all our time on paperwork at the expense of patient care. This is bad news. MOPOC-1 is aimed at dealing with the majority of the nit-picks by bluntly referring to the wider picture, and making it clear what is appropriate. *Riding on the back of MOPOC-1 will be the idea that 'Of course every optometrist doesn't need to be signed up as a Caldicott guardian in the same way as a hospital has to. Patient protection and appropriate access can be achieved by simple professional standards.'*

From time to time we may modify the protocol in the light of experience. Whoever is managing primary ocular care in your area will be responsible for bringing changes to your attention. On the other hand, if practitioners have difficulties and questions then MOPOC Ltd. wants to know so we can address the issue.

Outline

Our aim is to have a one-shot, no-nonsense, all-in-one patient consent for data processing which allows the optometrist to send and receive patient sensitive data, subject to an easily understandable and implemented protocol.[1]

In a nutshell, the MOPOC-1 form explains how data will be passed between practitioners. The patient signs the MOPOC-1 form once. They keep the description for reference, the optometrist keeps the signature. *There is no need to keep signing the form at future consultations.*

The optometrist will then use this protocol to moderate how they pass on information.

The optometrist will also use this when demanding audit data is returned from other professionals.

Notice this is *not* a consent for *treatment* form.

Protocol

1 Rubric

1.1 This protocol is issued under a licence from MOPOC Ltd., Each SHA or PCT area will have its local methods of implementing it.
Licenced areas and how to obtain a licence are listed at www.mopoc.co.uk

1.2 It may be cited in full as "MOPOC-1-P".
"1" Is the scheme. "P" stands for protocol.
Later versions will be suffixed with small letters eg MOPOC-1a-P

1.3 The version found at www.mopoc.co.uk will be the latest.
If changes are made or proposed they will be referred to the body that licences it in your area for them to pass the information on.

1.4 Optometrists are recommended to check with their Local Optical Committee to see if there are particular issues relating to them that have not been set out here.

1.5 The issues of patient consent and confidentiality are complex. Even though prescribed by civil and common law, NHS guidance and policy, contractual and ethical obligations there are many vague areas. This protocol is a practical, working guide not the final word on confidentiality or consent.

[1] Or you *could* try following the twists and turns of the legislation or applying the tracts produced by NHS task forces. - Good luck!

- *The Department of Health's web site has a number of publications including Protecting and Using Confidential Patient Information - A Strategy for the NHS*

- *The College @@@*

- *The AOP @@@*

2 Purpose

2.1 The object is to obtain informed consent for the exchange of personal medical data between Partners-In-Care (PIC).

2.2 This protocol sets out the do's and don'ts of keeping and passing on patient information. It is not a legal treatise but a practical guide which is intended to give a fairly clear working definition of professional obligations.

2.3 MOPOC-1-P is an enabling protocol. Typically it will be used to clear away other red-tape which can hamper the proper operation of quality systems.

2.4 The protocol supports both patient privacy and patient access.

3 Consent form

See the specimen appended.

3.1 This consists of a single Z-folded leaflet with one of the three panels being detachable. The patient keeps the two panels with description and practice stamp on, the optometrist keeps the third with signature on it.

3.2 The information provided to the patient is intended to give them a picture in a nutshell of why we exchange data and that there are limits to what we do with it.

There is a bit of a vagueness about "NHS central registers". In practical terms this refers to the Diabetic register.

Note "Better care from better information" paragraph. This tells the patient that there is the possibility that we may want to come back to them (almost always via their optometrist) to get feedback.

3.3 **Every** shaded box on both sides **must** be completed.

- Name, address and signature - The consent
- Practice stamp and date - Assists verifying 3rd party access requests

3.4 Nobody can give consent on behalf of an adult who is incapable of making an informed decision. *However the simple absence of a signed consent form should never prevent actions deemed by professionals to be in the patient's interest.*

3.5 Parents can give consent for their children. It should be obvious from the context of other records that this is what has happened. When children become adults they ought to sign again for themselves.
Child or adult? 16 year-olds are assumed to be capable of understanding the consent for themselves. Younger children may, if assessed as competent at the time, give consent. An adult cannot override a child's informed consent.

3.6 The reverse of the part the optometrist retains has plenty of white space on it. We recommend you use this for any particular notes or hints that may be appropriate.
- Person who obtained the signature
- Objections or concerns about anything eg "Don't want to be followed-up"
- Adult signed for child

3.7 File. How you file these chits is up to individual optometrists. We recommend that you clearly mark your patient records with "M1" for example or physically attach the paper.

One possible system is to file all chits together in strict date order. You'll be able to retrieve them if required by obtaining the date from the main patient record.

Consent refused

3.8 A patient is perfectly entitled to refuse to sign.

3.9 In this case you MUST mark all the patient's notes to that effect.

3.10 Their objection might be to specific local issues or for no stated reason at all, in whole or in part. Use common sense and written notes protecting the records to decide what is a practical approach to dealing with this. Possibilities include:
- Limit access within your practice
- Give all information (eg. referral form) to the patient instead of passing it to other PIC and tell them where to go.
- Refuse to deal with the patient.

In an extreme case a patient might insist that you destroyed all their existing clinical records in your practice. Why argue? (a) Because they do not have the general right to insist on it. (b) The notes may be necessary to protect the interests of the optometrist. Possibly, if you're technically acting as an agent for the patient's GP you should refer the matter to them.

4 Record keeping

Keep data private

4.1 The Data Protection act applies to all data held about living identifiable people. In brief: Personal data has to be • obtained fairly • kept safe and up to date • used responsibly for definite purposes.[2] Optometrists should bear this in mind when using non-clinical data for business purposes.

[2] The Data Protection Act 1998 is the base legislation.

4.2 The situation with clinical records is that the interpretation of 'confidential' is much more strictly defined. Information can be passed between qualified clinicians. Optometrists come under this definition.

4.3 A bit of a fudge is applied to administrative staff, without whom of course nothing would work. Non-clinical staff should have a strongly worded confidentiality clause in their contracts. *See section 9.*

4.4 There are risks associated with keeping data on computer systems. In brief you should ensure all data is encrypted internally and can only be accessed by using a password.[3]

Keep data safe

4.5 Where there are perfectly feasible methods to take safety backups, as for example with every computerised system, suitable copies must be made to protect against loss of data.

While computer systems are generally reliable they all have a limited life and will naturally expire or be the subject of malicious attack. Backups are not optional! Please verify that your backups are readable.[4] [5]

4.6 Keep all data about a patient in a single place. If this is not possible then there must be a reliable cross reference system.

4.7 It is one of the basic principles of the Data Protection Act that data is deleted when it is no longer any use. Because we can't truthfully say when the data is no longer useful the best approach is probably to archive old records that are not wanted for commercial reasons.
As time goes by and we get better at collecting and statistically analysing health records we will use all such records as a valuable resource for epidemiology and resource planning.

5 Record access - 1 - Your records

Patient access

5.1 Patients have the right to see any records relating to their ocular care[6].

- A spouse doesn't have right of access
- A parent does not always have right of access to a child's records while they are a child.

5.2 If you get a request then how should you verify the identity of the requester if

[3] Most practices have terrible password security. Please be more professional. Check with your software supplier about how easy it would be for a thief to break into your data.

[4] Obviously the main imperative for most optometrists is commercial, but particularly as information technology progresses, the value of well structured clinical data is being recognised more and more.

[5] A simple scheme is to check the readability of backups when the clocks go forward and back.

[6] Except in very extreme cases where it could be detrimental to the patient's well-being, but it is difficult to imagine this in the context o optometry.

you don't recognise them? Obviously it doesn't do to pass medical records to an imposter.

- Check the signature on your MOPOC-1

or

- Ask for the date that the MOPOC-1 was signed.

The patient is the only person outside your practice who is likely to have this information. That is why it is carefully written into the patient's copy. NB For this reason do not reveal this date outside your practice.

If in doubt there are other options open such as getting more identification, passing the records to their GP or checking up on the address on the MOPOC-1.

Legally,you can charge up to £10.00 for a 'subject data access request'. *We expect most optometrists will do this as a matter of goodwill and high standard of professional medical care. Your LOC may have a policy on this matter.*

5.3 If practical, obtain a signed receipt detailing the number of pages of information supplied. This protects you against later claims of 'you never told me'. You may also want to number the pages. The lengths you go to will depend on the nature of the enquiry.

Professional access

5.4 If an 'unknown' optometrist telephones and asks for a copy of the patient records because the patient has moved away or chosen to change optometrists then suitable checks have to be made.

- Obtain a written or faxed signature and/or MOPOC-1 date on practice headed paper.

5.5 The majority of ad-hoc requests are going to come from a very few professionals. They will all have addresses, fax numbers or e-mail addresses which are known to you. Always use the established contact method to protect against impersonation. *Make it a rule never to send confidential information to an unknown fax number etc.*

Access mandated by protocols

5.6 Newer scheme protocols (such as JELOC's First Step series) demand a copy of examinations to be filed with the LOC so that it can be fed into a quality system. *There are clinical and commercial safeguards incorporated into this 'big brother'.*[7] *When we use electronic systems we will strip-out patient-identification as records pass out of the practice. (Unfortunately it is impractical for paper based systems.)*

5.7 Quality systems can't work by statistics alone. The idea is to use anonymous statistics to analyse results, then look at anomalies back at the practice where the context is known. *For example we may centrally discover that a particular child was treated at age five but not seen since when a follow-up of some sort would seem to be indicated. This is an example of how collated data can be used to trap some of the all too frequent drop-outs. Nothing to do with*

[7] JELOCS's security policy is available from their web site.

questioning professional competence here.

5.8 Where access is mandated by protocol this will be implicit in all forms (or other communications) sent between PIC. **There will be no need for additional consent sections on any other form used by optometrists.**

5.9 There is a general principle that you should only pass on the minimum necessary information to others.

5.10 The police and other bodies might ask to see your records. Seek professional advice.

6 Record access - 2 - Other people's records

6.1 As per 5.9, you should only be asking for data that is directly relevant to your role.
Optometrists who have a good working relationship with PIC are in a much better position to share information. This can be of considerable benefit to patients.

6.2 Optometrists need feedback from hospitals, in particular about their referrals. MOPOC-1 specifically refers to this situation. The patient has signed a piece of paper which states:

> Your optometrist will pass *necessary* information to your GP and hospital consultants or other medical professional and will receive *necessary* information in return.

Please inform your LOC if you have any difficulty with obtaining audit data.

6.3 If a person wishes to move to another optometrist then MOPOC-1 makes it easy to authorise the transfer of records.
• Telephoning with the date on the patients part could be acceptable if records are to be posted to a practice address.
• A written (faxed) signature on practice headed paper is a more respectable procedure.
As IT develops the actual transfer of data will become easier and more worthwhile.

7 Business matters

It is a business that has the corporate responsibility for ensuring compliance with data protection legislation. That is: A business could be taken to court and fined or face a civil suit. Businesses own the data they collect.

Clinicians have a professional duty of confidence and are expected to comply with their governing bodies. Clinicians can be held liable for breach of confidence and are held responsible for conforming to NHS rules.

Somewhere in between we expect businesses to be run with the professional ethics of the optometrists who work there.

7.1 If a business ceases trading it should ensure that records are preserved

securely.
As IT develops this will become easier and more worthwhile.

7.2 If a business transfers patients to another business then all the obligations on the former must be accepted by the successor.

7.3 Businesses operating as optometrists need to notify the Information Commissioner, complete the forms and pay the annual £35 fee.

Additional consent is required for commercial purposes

7.4 MOPOC-1 has nothing to say about how a patient's details might be used for commercial purposes.[8] If practices are intending to use patient data, or cross-reference identifiable data for anything other than pure statistical purposes then they will definitely need additional consent.

The DoH, based on a robust interpretation of the DPA, forbids using clinical data for commercial purposes such as direct mailing. It is unlikely that anything less than an explicit 'please mail me' consent is going to be legal.

There is the potential for confusion between MOPOC-1 which says 'we'll try to leave you alone' and possible marketing pitches which say 'massive discounts each month in our newsletter' etc.

Note: The MOPOC-1 must not be modified or added to or have other consent forms attached.

Commercial confidentiality

7.5 Businesses are not too keen on having all their clinical transactions logged by an outside body. Unfortunately until we think of a better quality system we have to collect this information to be able to analyse it and give practices a feel for how they stand in relation to others. Therefore the safeguard becomes in the sensitive treatment of that data and making sure individual practices cannot be identified except for specific clinical audit and self audit. It is imperative that specific cases can be tracked back to specific business and optometrists.

Whatever body undertakes the management of primary ocular care in your area will be responsible for the appropriate commercial safeguards.

As time goes by and we gain experience with quality systems, one of the goals will be to reduce the likelihood of leaks of commercially sensitive data.

Information technology

7.6 Computer systems will be central to shared care. Appropriate interfaces and capabilities will become requirements without which participation in shared care will not be possible.

The principles of data protection are the same for manual or computerised

[8] Annual recall for eye exam doesn't count as a commercial mailing. Billing information (providing it is used for the management of that account and not say targeting all people who spent more than £750 last year) can't be classed as data use which hasn't been accepted by the customer.

systems, it is only the technology and the supporting knowledge that changes. Business will need to look out for signs of change in the world of primary care systems in order to take planned business decisions.

This is a challenge but there is no need for it to be a muddle or disaster. It all depends on savvy systems designers and good leadership answerable to the businesses that will have to implement it.[9]

8 Clinical matters

8.1 Every optometrist will find that most data requests come from a few PIC who should be fairly well known to them. Trust between PIC is a great shortcut to efficient working relationships and should be developed. This saves you time and may be very beneficial to the patient.

Be aware of the potential abuses of trust. If in doubt take a more formal approach.

A good way to destroy trust is to ask for data which is not really needed for your role. It may be that you are doing some research but there are formal ways to ask for such data. It may be you have a curious case in your consulting room but don't be tempted to take on another expert's mantle.

8.2 Protocols often require that data is required to be passed to the quality system. *One of our goals in developing better systems is to anonymise this data.*

8.3 Clinical audit using feedback from hospitals is a vital part of quality assurance. The original motivation for MOPOC-1 was to force hospitals to release this information. If optometrists have difficulty obtaining this data they should contact their LOC.

Important data can be collected as a result of non-events. For example a failed recall for diabetic retinopathy screening. These should be covered by appropriate protocols, but we remind you that sometimes you need to take action as a result of absence of information received.

8.4 Have another look at the carefully worded "Better care from better information" paragraph on the MOPOC-1 form. We are leaving the door open in case 'we' want to contact patients. The 'we' might be the optometrist themselves who would like to do a survey or another body seeking the views of patients. **The intention is that communications with patients will be via the optometrist.** Not only will this be more gentle for the patients but the 'local' approach should obtain a better response rate. *The optometrist should of course be entitled to a fee for turning a random mailing into an appropriate request to participate from a professional.*

[9] So far the plans for IT in the health service have left out primary ocular care and so we have to keep a careful watch on inappropriate systems being applied to our special circumstances.

9 Quality issues

9.1 Compliance with legal requirements

The primary legislation covering this is the Data Protection Act(1998). There is some secondary legislation of which The Data Protection (Processing of Sensitive Personal Data) Order 2000 is probably the most relevant. Guidance on confidentiality is also available from HSG(96)18.

The important aspects in a nutshell are:

a Data collected and processed as part of NHS duties (or any professional activities) (if properly looked after according to protocols) does **not** need explicit patient consent to be processed. Schedules 2(6) and 3(8).

b Reasonable steps must be taken to prevent the mis-use of all information (not only sensitive clinical data). The common law duty of confidentiality remains. The security measures should be proportionate to the risk and consequences.

c A 'data controller' has responsibility for overall management and access to data, but that person does not have to be a health professional. Health professionals are responsible for individual acts of processing in their day-to-day work but not necessarily overall control of information. *A data controller is responsible for ensuring that the people processing data do so with the appropriate level of diligence.*

d A receptionist is not a 'health professional' but it is accepted that so long as their duties and responsibilities are clear i.e. a written contract of employment with confidentiality and obligation to process patient data with extreme care, they are working on behalf of and under the control of the Health Professional. *So for example extra care is required to see the right patient notes go in the right envelope when compared with routine clerical duties.*

e A business is not a 'health professional' although it will probably be the data controller. It's ability to process medical records derives from the professional standing of the optometrists who work for it.

f Consequentially (from d and e) the professional optometrist should assure themselves that data is being processed on their behalf for only legitimate clinical purposes, fairly, privately, securely and with proper care and attention.

g Technically, there is no general right of a patient to prevent data being lawfully processed, which in the NHS context means the optometrist carrying out their NHS duties. So for example a patient cannot insist on the destruction of a completed but unsent GOS1. However processing can be prevented on the grounds of 'substantial harm or distress'. There is an exception if this would not be in the patient's 'vital interest'.

h A patient has the right of access to their records and the right to add a correction. In theory a fee of up to £10 could be charged.

i In the NHS context it is deemed that a patient would have to give explicit permission to have their details used for direct marketing. In short, clinical and commercial records should not be mixed since different rules apply.

j Where consent is obtained it must be informed. A reasonable picture of what data will be used for must be given.

k Using data for research is not a problem provided it is for statistical, general purposes (ie not identifying individuals) and the nature of the

research is not likely to cause distress.

l Clinical data should not be passed to non-clinicians without informed consent.

m **Any data** should **not** be passed to **anyone** unless the patient has agreed or it is obvious to the patient that this sort of thing will happen.

n Consequently (from l and m) for example if a LV patient should be referred to a rehab worker then:
1. Passing-on clinical data is not appropriate(l) and
2. the patient needs to be asked if they want the social services to be contacted(m).

o The prevention and detection of illegal acts or dishonesty are grounds that may be cited to demand access and processing of sensitive records by an appropriate authority.

p Optometry businesses need to inform the Information Commissioner that they process personal data of a sensitive nature and show that they have basic security procedures.

9.2 Patient confidence

Patients have the expectation that their data will be well looked after and not misused and can easily become frightened by a scare story in the papers into refusing to cooperate. But good care is not possible without the exchange of clinical information. By setting out why we need data and the protections and limitations we hope to eliminate big-brother fears. *Optometrists are reminded that it only takes a very few bad cases to taint the whole profession.*

9.3 Patient access

The MOPOC-1 form (which the patient keeps for reference) explains clearly the patient's right of access.

9.4 Efficient service - good access to data wherever the patient is

Nobody stands to gain by taking a curmudgeonly attitude to letting authorised people have access to clinical records. The only hoop that should need to be jumped through is that 'authorised' bit. A signature should suffice and should be checked. MOPOC-1 offers another possibility which can be used where a signature is difficult, for example on the phone. The date the MOPOC-1 was signed is unlikely to be known outside the patient's family and providing the destination for the records is verified there should be no reason to withhold them. This is a balance between sensible customer service and caution when passing on data. *Even if an impersonator phoned and asked for a prescription the damage done by giving that information is going to be trivial when compared to the danger of say somebody having lost their glasses on holiday trying to drive without replacements.*

9.5 Access to data required for quality assurance

Optometrists should be receiving Clinical audit data back regrading their referrals as a matter of course. It is probably a good idea to keep a log of referrals and replies. *See appendix A.*

The assured availability of this data should enable schemes for self-audit, peer-review and statistical analysis to be implemented.

9.6 Long term preservation and development of medical history

There are obvious benefits in long-term knowledge of patients and their

general health and their family backgrounds. However these matters remain in the optometrist's head.

Here we are concerned that if a patient moves that their formal records can move with them so that important medical history isn't lost.

9.7 Collecting data for strategic planning
Statistical analysis of clinical audit data could be a very powerful tool. For example it would allow us to correlate the experience of optometrists with their referral competencies and develop training strategies based on actual experience.

9.8 Preserving business confidence
Almost uniquely in the NHS optometrists are in business competition. Whilst on the one hand there is no escaping that quality assurance will affect individual businesses and specific cases must be related to individual businesses, on the other hand there are commercial confidences that should not be breached. Simple statistics can give a lot away.

There is no doubt that quality of patient care must come before commercial privacy and that there is bound to be some disquiet about the activities of auditors and analysts. We recommend that all data collection and analysis is justified against a set of quality goals so that the value is clear.

10 Administration

10.1 MOPOC-1-P is licenced on a PCT or SHA area basis for use by all optometrists in their areas. They will coordinate the implementation with appropriate instructions to hospitals and optometrists.

10.2 There are two possible approaches to integrating MOPOC-1 with referral protocols:

a As a blanket procedure that covers all referrals as a matter of course: The logic of this is that if a referral arrives at a hospital then, because **all** optometrists are using MOPOC-1 the consent may be taken for granted.

b Every referral contains a passing reference to MOPOC-1 along the lines of "The patient's consent for the exchange of information has been obtained".

Method a is preferable because it is one less bit of bureaucracy but it is dependent on **all** optometrists in the area using the scheme. This should be a simple matter of primary care management, although of course LOC backing should be unequivocal.

Quality issue: Primary Ocular Care management will need to check that all optometrists are actually using the system. Such an audit would presumably be part of a general check-up of clinical audit activities.

10.3 Whoever is managing POC will have a strategy for taking advantage of the supply of CA data. This will cover such things as what data should be returned, how optometrists should record the results and how self-audit and peer review should work.

A handy record sheet is given in appendix A.

10.4 MOPOC Ltd. and whoever is managing POC partners want to hear about could-do-betters, concerns, complaints

Note: This protocol or the form must not be modified without the express approval of MOPOC Ltd. There is no future in a hotch-potch of well-meaning or convenient variants. MOPOC Ltd. is committed to maintaining protocol and form so that useful adaptations can be implemented globally with the benefits of universality and careful analysis of the implications.

10.5 Whoever is managing POC in the area will determine if there are particular accreditation requirements. MOPOC Ltd. suggest a simple blanket introduction backed by a formal requirement notice from the PCT.

Appendix A

Referrals record sheet

This is not part of the MOPOC-1-P protocol. It is given here as an aid to making use of clinical audit data being returned from hospitals.

Whoever is managing POC in the area should have some procedure for ensuring basic self-auditing is taking place. The most likely scenario is that optometrists will be asked to report basic statistics from time to time and write a short appreciation of their own results as reported back from the hospitals as a contribution to peer review.

Notes

- The left part of the form is filled in when the referral is made
- The right hand part is for recording returned information
- These records are never going to have to stand on their own so abbreviated entries and short-hand is perfectly acceptable. For example, if always referring to the same hospital just put an abbreviation at the top of the column. Initials or short-hand for consultants are likewise acceptable.
- Large numbers of blanks on the RH side should be reported to whoever is managing POC in the area so the procedures in the hospital can be improved.
- All direct referrals should be recorded.
- These records will form the basis for self-audit and peer review.

Referral record

Optometrist : .....

Date	Patient	Hospital	Reason	Form	Date	Consultant	Accurate	Appropriate	Comment