

# An approach to implementing a workflow based clinical imaging and data management system for ophthalmology.

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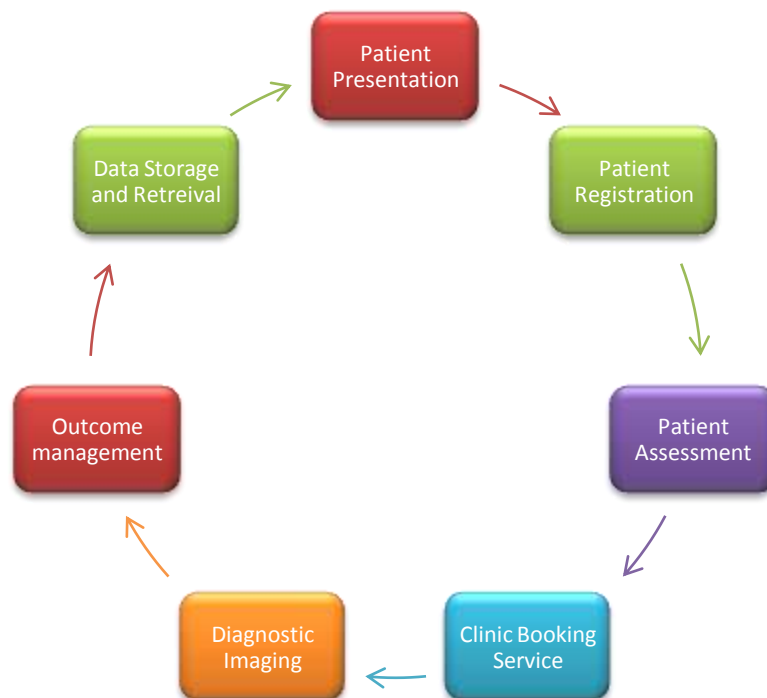
## Summary

Clinical ophthalmic services have seen a significant increase in demand over recent years, unfortunately staff numbers and budgets have not increased proportionally. Now with the introduction of systematic community based blindness prevention programs such as those for Diabetic Retinopathy, Macular Degeneration, Glaucoma and Cataracts even more patients will require assessment and specialist treatment. Add to this the introduction of new anti-VEGF compounds, the addition of new imaging technologies such as coherence tomography, and improvements in retinal surgery techniques and it is clear that demand will easily outstrip supply and patients will suffer.

It is in this context that we have developed, a digital platform that brings together information from many sources, locations and instruments to make patient management a more automated, accessible and effective method of managing patients and their clinical outcomes.

The technology solution is a modular, workflow management system designed to adapt as new modalities and locations are added to the clinical services network. It integrates to and connects with data and image storage systems to make information available on demand in the clinic and accessible across the enterprise.

## Clinical Ophthalmology - The principal workflow components



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## 1) Patient presentation and inbound referral

There are three inbound routes for clinical ophthalmology in the modern secondary healthcare environment:-

- 1) Community based Retinal Risk Assessment services
- 2) Family physician
- 3) Optometrist

The patient may therefore enter the ophthalmology service either through a systematic methodology such as a routine community screening or a risk assessment service or as a result of a direct referral from optometry or primary care.

In screening situations, the patient is often asymptomatic and the images are taken at remote locations. The images require clinical assessment and the ophthalmology department needs both the high resolution images and the primary clinical assessment in order to successfully triage the patient.

Here we describe a technology that interfaces to instruments such as slit lamps, fundus cameras and visual fields machines that are located in the community and connected to the hospital via a secure connection using messaging. Images and data from these remote devices or risk assessment programs can then be electronically referred in to the ophthalmology department using new messaging, communications and web services designed for the purpose.

## 2) Patient Registration Process

Patient data coming from accredited community programs and validated clinical partners is passed to the patient registration service to validate and authenticate demographics. A check is made to ensure that the patient is not already registered in the clinical ophthalmology system, if they are then the data is cross referenced, if the patient is not already registered then they are entered into the system for future communications. Patient authentication is based on several data points to remove the risk of duplicative entries.

## 3) Patient Assessment

Images and data inbound are made available to the ophthalmologist via a written report, secure web interface or directly in the network review software. Making this information available to the clinician on line helps decide the necessity and urgency of the inbound referral. This has a major impact on outpatient management and helps significantly reduce the over-referral issue that is commonly seen in ophthalmology. With modern high resolution imaging and data systems it is possible to triage patients well before they present to the clinic. The examining physician can then inform the clinical booking service of the priority of the patient appointment automatically.

## 4) Clinic / Surgery Booking Service

The clinic / surgery booking service is connected to both the initial patient assessment process and the diagnostic and outcome management service. This allows the clinician to prioritize workload and optimize workflow. Once the patient has been seen by the ophthalmologist follow up appointments and, if necessary, surgical intervention can be scheduled via the booking service.

The clinic / surgery booking service is an administration function and does not necessarily need to be "connected" directly to the ophthalmology service, it certainly does not need access to clinical information which is successfully segmented using role authentication where only legitimate clinicians can access patient data.

## 5) Diagnostic Imaging and Measurements

Within the clinical ophthalmology context the technology needs to be highly adaptable to an ever increasing range of instruments and technologies. The technology described provides interfaces to an extremely wide range of instruments and equipment in the clinic. Typically these divide into data sources and image sources, with each presenting their own technical challenges. Each data source needs to be integrated and simultaneously presented to the clinician to help with diagnosis, treatment and outcome management.

Typical devices include:

- External photographic digital cameras
- High resolution video or Operating Microscope Cameras
- Acuity data\*
- Visual Fields Instruments
- Biomicroscopes
- Corneal / Lens Imagers
- Goniometers\*
- Tonometers\*
- Perimeters
- IOL lens meters\*
- Ultrasound devices
- Fluorescein Angiography Cameras
- ICG Cameras
- Red Free Retinal Imagers
- Wide Angle Laser Scanners
- Contact wide angle digital ophthalmoscopes
- OCT
- HRT
- HRA
- 3D OCT
- X-ray / MRI
- Electrodiagnostics

\* Data from some devices may need to be entered in via EMR in numerical form if no direct instrument interface exists

Data from the concurrent examination and historical visits are brought together in the system for clinical review and assessment. In the technology described, the workstation screen layout is programmable by the user and changeable with a single mouse click to allow the clinician to see the data relevant to the clinical investigation. Typical screen layouts could include Glaucoma, AMD, Anterior Segment, Corneal imaging & external / plastics photography, Surgery, Diabetic, or peripheral disease. In the case of glaucoma for example, historical visual fields from the left and right eye might form one view, with high resolution stereographic disk images in another window. For post pan retinal photocoagulation it might be preferable to visualize side by side fluorescein angiographic image sequences that have been aligned and encoded as a movie.

The technology solution developed allows many different data views to accommodate the widest possible range of imaging and data display and measurement functions.

An extensive array of image processing and analysis tools is included in the software. These are designed for both qualitative and quantitative assessment. Imaging tools work on individual or linked image sets depending on the context. Calibration functions in the software make it possible to make accurate standardized and normalized measurements on images to track progression and regression of disease.

The imaging platform was designed to handle multiple image types including single, stereo, stacked and movie sequences. The screen layout utility described earlier allows different types of image and data sets to be displayed on single or multiple monitors.

**6) Clinical Diagnosis and Outcome management**

This process is the heart of the clinical ophthalmology function in most departments and is carried out by the ophthalmologist and their supporting technical staff. Once the patient is seen the physician will normally review the presenting complaint, the history of the complaint itself, any ophthalmic history, general medical, family and social history as well as reviewing pharmacological and allergy information. Based on this data the clinician will order any necessary diagnostic tests as summarized in section (5) above.

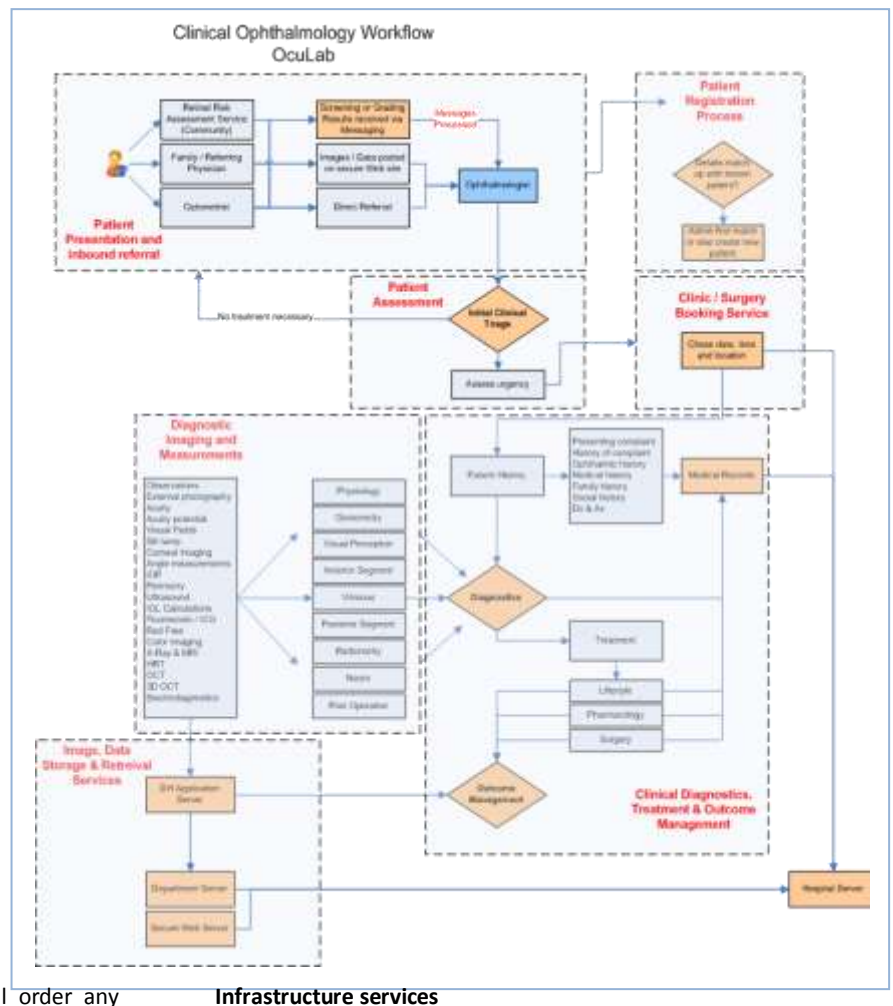
Once the patient has the diagnostic tests the resulting data is immediately available to the ophthalmologist for clinical review and assessment.

The patient can then be treated according to the care pathway defined by their physician, this may include laser or invasive surgery, pharmacological intervention or lifestyle advice or whatever combination is deemed appropriate.

**7) Data Storage and Retrieval services**

It was necessary to include a comprehensive inbuilt PACS technology based on a MS SQL database providing near or distant image storage and retrieval services. DICOM variants were also designed in.

The image storage service was designed to work either as a local storage system for images and data or as a gateway to hospital or clinic systems using standard interfaces and protocols



The system was built using industry standard technology from Microsoft, including SQL Server (with full support for clustering and failover on 2000, 2005 and 2008 [beta]), Windows Server (2000,2003). It integrates with typical SAN and NAS technology

from major vendors, and has integrated supported for EMC's "Centera" Content Addressable Storage system.

In the enterprise, the Smart Client can be deployed on Windows XP or Windows Vista using Microsoft Systems Management Server for manageability, and our Web Clients support Windows, Linux and MacOS through Internet Explorer [6.0/7.0] and/or Firefox [2.0 and above].

### **Messaging**

The technology supports a range of standard HL7V2 and HL7V3 messages for inter-application communication, including support for patient registrations, merges, demographic updates, appointments and walk-ins, and semantic requests such as encounter review and referrals.

The messaging infrastructure uses a plug-in architecture, allowing developers to add new transports, protocols and message types. The workflow engine makes it possible to customize the messages sent in response to events and activities, using an XML-based clinical workflow definition language. Out-of-the-box, the system supports a number of transports and protocols such as HTTP[S], TCP/IP, file-based, and WS-\*

A sophisticated message broker helps manage identity, keeping the Patient Master Index clean, and an easy-to-use interface lets administrators resolve conflicts and failed-to-match conditions.

The internal messaging infrastructure in the application fully enables occasionally connected and remote-working scenarios, allowing information exchange as and when network connectivity is available, without requiring user intervention.

### **Security & privacy**

The sensitivity of patient information requires a rigorous security policy, coupled with a regime of audit and review.

The system described here enables this policy by supporting role-based access to information, full audit of information

updates and patient information access, consent and confirmation processes. It can also integrate with Active Directory, and enterprise single-sign-on system (such as CA SiteMinder), to centralize administration and access controls.

Inactivity timeouts on logins mitigate against the risk of users walking away from a workstation and leaving it accessible to the public.

In addition, all messages are encrypted using public/private key encryption, to prevent snooping, and signed to prevent tampering. Application communications with the database can be performed using SSL encryption, and (using SQL Server 2005), critical database information can be encrypted to prevent access by database administrators who should not have access to clinical information.

### **Conclusions**

Clinical ophthalmology has been chronically underserved for many years; it has been the "poor relation" in terms of technology usage and uptake. In part this has been because healthcare technology has been focused on data repositories and network infrastructure. Now we are seeing an emergence of workflow based solutions that integrate and share information across the enterprise and manage its flow through the discrete services that are performed in the clinic.

While there are still issues where some instruments do not share or publish data efficiently, there have been massive strides in software architecture design that make it possible to implement a technology platform that can integrate, share and distribute clinical information. More importantly, automated workflow technologies such as the system described here make it possible to manage more patients more efficiently by managing their entire care journey from disease detection to outcome.

Further information is available from Ythos Ltd.

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