



K2 Athena™

Electronic and Personal
Maternity Health Record

Contents

Introduction	4
Integration and Interoperability	5
INFANT-Guardian® Component Integration	6
Reporting and Auditing.....	6
Compliance	6
Portal.....	7
Approvals	7
Technical Overview	8
Scope.....	8
Cloud vs On-Premises	8
Client Applications – Within the Hospital.....	9
Bedside Application	9
Central Station	9
Athena Desktop	10
Client applications – Outside the Hospital.....	11
Athena Desktop	11
Guardian Online (optional)	11
Electronic Patient Notes - MyPregnancyNotes.com & K2Hampton.com	11
Server Side Services	12
Authentication Service.....	12
Web API service	12
Real Time Ward Hub service	12
Guardian Online (optional)	12
Offline Briefcase Services.....	12
Cloud Architecture	13
Interfaces	15
HL7 v2 Inbound Interfaces	15
HL7 v2 Outbound interfaces	16
K2 HL7 Transceiver.....	16
PDS NHS Number (CIRR – Create Initial Record Request)	17
My Pregnancy Notes.....	18
Data Sharing.....	18
View Clinical Record.....	18

Neonatology.....	19
Client PC hardware technical specification.....	20
Hardware – Community Laptops	20
Hardware – Hospital Desktops and Laptops.....	21

Introduction

K2 Athena™ is an electronic and Personal Health Record system (EHR/ePHR), providing contemporaneous data capture throughout the entire pregnancy pathway. Athena supports Community Services and Remote Connectivity, Antenatal Hospital Services, Labour and Delivery Services, Postnatal Services, Support, CNST and Governance:

Community Antenatal • Booking • Antenatal Visits • GP Access • 3rd Party Clinical Access Antenatal • Scanning • Care Plans • Clinics • Admissions • Day Assessment	Labour & Delivery • Triage • <u>K2 INFANT-Guardian</u> • Anaesthetics • Baby Numbering • Enhanced Clinical Oversight	Postnatal • Postnatal Wards • Discharge Community Postnatal • Postnatal Follow Up • Postnatal Visits • GP Access • 3rd Party Clinical Access
---	---	--

Athena's modular design enables each deployment to be tailored to meet the precise requirements of the hospital or Trust, facilitating full compliance with Maternity Services Dataset (MSDS), Governance, management of care and the appropriate reimbursement for the services they provide, via Payment by Results (PbR) and Maternity Payment Tariffs. supporting a range of functions and locations

- Community Bookings, Visits and Births
- Midwifery Units, Community Hubs and Patient Homes
- Antenatal Clinics
- Antenatal In-Patient Stays and Day Assessment
- Remote Interactions, such as Telephone Helplines
- Labour and Delivery and Postnatal
- INFANT® Computer Interpretation of CTGs During Labour
- Postnatal Stays
- Postnatal Community Follow up and Discharge

K2 Athena is the first end-to-end Maternity Information System to provide a completely paperless Electronic Maternity Health Record (EHR/EMHR). Athena collects all notes from the entire pregnancy pathway electronically and provides all patient information to healthcare professionals easily, legibly and securely.

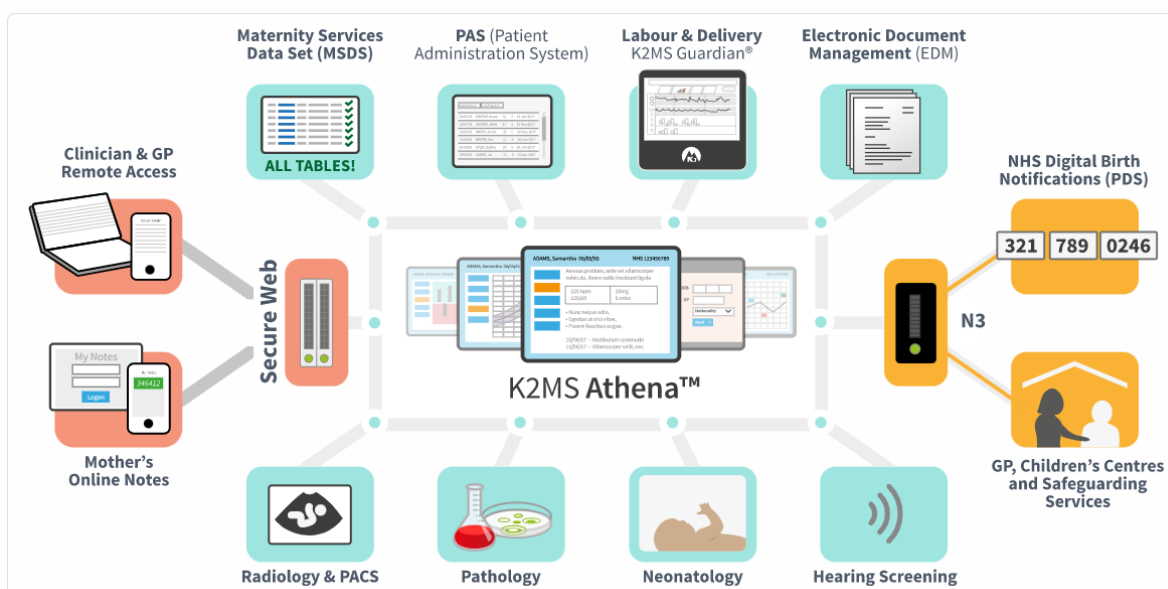
Maternity clinical data are captured once, at the point of care during the patient interaction, even in emergency situations. There is no need to rely on retrospective entry away from the

patient. Athena facilitates patient consultation, captures interactions and enhances clinical oversight and communication.

Developed entirely by K2 Medical Systems, Athena uses a single database and, by linking seamlessly with medical device equipment and interfacing with other hospital systems, provides accessible data and facilitates contemporaneous workflow. There are no gaps in the data and no internal interfacing is required. Athena manages obstetric risk and offers a complete solution to patient data capture, Governance and learning.

Integration and Interoperability

Athena's back-end services can be hosted in the cloud, with monitoring and display elements necessarily deployed on-premises. Powerful interfaces allow interoperability with critical dependent hospital systems, including PAS, Radiology, Pathology, Neonatology. Athena integrates with NHS Digital services, including Birth Notifications, Maternity Services Data Set (MSDS) and Safeguarding Services



Athena is remotely accessible to clinicians from any location, and to patients through the provision of online handheld maternity notes.

All clinical records can be exported and synchronised upon re-entry into the hospital network, or offline records created and merged seamlessly with the master record, facilitating efficient community working. Athena provides enhanced oversight by allowing clinicians to view all notes and foetal monitoring data remotely, via a secure internet connection, from anywhere in the world.

Women may view their handheld maternity notes online (see image below). Athena's ePHR ensures that data can be accessed instantly, or granted to other healthcare professionals.

INFANT-Guardian® Component Integration

K2 Guardian for Labour and Delivery integrates seamlessly with Athena providing full electronic capture of patient information during childbirth. With the optional K2 INFANT software to interpret antenatal CTG, K2 offers a complete risk management solution to support clinicians, increase communication and reduce poor birth outcomes.

Reporting and Auditing

Athena's capture of the electronic medical record is a fundamental requirement but equally important is the ability to audit and report on the information collected. Any report can be constructed for:

- Audit
- Governance
- Process Improvements
- Clinical Research
- Management Control

Compliance

Athena offers full compliance against national guidelines and schemes. These include:

- **Management Plans and Business Intelligence Options** – Providing comprehensive solutions for reporting and auditing, ensuring all governance and requirements are met.
- **Care Bundles** – Addresses recommendations for local and national guidance, including NHS England's Saving Babies' Lives Care Bundle and Clinical Negligence Scheme for Trusts (CNST) guidance. Continually supporting the improvement in quality and consistent management of care.
- **Maternity Services Data Set (MSDS)** – Fully compliant with ISB 1513, the national standard for data management within the NHS. Ensuring the capture of key information at each stage of the Maternity Care Pathway and brings maternity healthcare in line with core structures, managed by NHS Digital.
- **PDS Birth Notifications (formerly NN4B)** – Athena allows users to instantly register and obtain NHS numbers for babies and is fully compliant with ISB 1555, the operational information standard for Birth Notifications.

Portal

Bedside interactions are supported through integration with K2 Portal™, a medical-grade panel touchscreen PC designed and manufactured by K2 Medical Systems for use within the most demanding clinical bedside environment. It is a certified medical device that combines with Microsoft Windows® embedded operating system for reliable and stable hosting of the K2 Guardian™, K2 INFANT™, and K2 Athena™ software products.

Approvals

CE Marked	Medical Device Directive 93/42/EEC EMC Directive 2004/108/EC RoHS Directive 2002/95/EC WEEE Directive 2002/66/EC
BS EN 60601-1:2006 +A12:2014	Medical electrical equipment. Part 1. General requirements for safety.
BS EN 60601-1-2:2007	Medical electrical equipment. Part 1-2. Electromagnetic compatibility – Requirements and tests.
BS EN 62366-1:2015	Medical Devices Part 1: Application of Usability Engineering to Medical Devices.

Technical Overview

This overview is intended for an IT audience and not a clinical one. Rather than provide a clinical rationale for the system, this section describes core applications and services and how they might be deployed within a hospital.

The system comprises client applications used inside and outside the hospital and back-end services that support those client applications. Athena also supports various interfaces, described towards the end of this document.

Scope

Athena an electronic and Personal Health Record system that collects all maternity related information both within the hospital and in the community. Athena shares technology and the database with K2's Guardian electronic patient data capture system. The two are effectively seamless, creating an end-to-end maternity solution. Athena relies upon Guardian for real time data collection on maternity wards, whereas Guardian may be deployed on its own. For more information on these products, please visit www.k2ms.com.

Cloud vs On-Premises

Athena's back-end services can be hosted in the cloud, with monitoring and display elements necessarily deployed on-premises. K2's back-end services are predominantly built using Microsoft .NET core technology, which makes its deployment flexible. Containerised versions of all back-end services are provided by K2 and can be deployed in a Kubernetes cluster, creating a highly robust solution with extensive monitoring capabilities.

Client Applications – Within the Hospital

Each of the client applications that can run within the hospital require access to K2's back-end services, which are all supplied over https (for API and HTML data) and secure WebSocket where there is a requirement to stream data.

Each of the applications below are designed to run on a Windows OS using .NET framework, please see the latest technical specifications for each application.

Bedside Application

The Bedside application is typically deployed on K2 Portal hardware and is used at the point of care, collecting contemporaneous data and facilitating the physical connection to a foetal monitor for extracting CTG. The Portal hardware runs a restricted version of Windows 10 and a custom shell, permitting only use of the Bedside application.

Considerations: The Portal can be connected to the network using an ethernet cable or wirelessly. It can also optionally be connected to a foetal monitor (K2 can supply the necessary serial connection cables). The Portal can be wall mounted using a suitable mounting arm, or it can be mounted on a suitable trolley with the fetal monitor.

Central Station

The Central Station application provides an overview of the activity on a ward and has been designed to be displayed on large screens, often at a midwives' station, or the ward reception. It consists of an electronic chalkboard (SaFERR board) and a multi-view of all active CTGs. The application supports multiple displays; each display can be configured to display multiple rooms of chalkboard data, or 9 rooms of CTG traces.

Although the Central Station application can be interacted with, it has been designed to be predominantly noninteractive, as a passive display. If considering the passive display option, then hardware with a sufficient number of screens to allow all rooms on the ward to be monitored simultaneously should be acquired.

Please note: The software has been designed to run on hospital supplied hardware (PC, GPU and screens). There can be multiple central stations per ward.

Athena Desktop

The Athena desktop client is used within the hospital as a point of care application for clinics, consultations and also on maternity wards. It is the main application used for data collection and review, outside of the Bedside application. The software also provides access to a reporting module to further analyse the data from both applications.

The client PC will require sufficient specification (see minimum requirements) and is deployed on trust-supplied hardware (PCs/laptops/tablets) running the Windows OS. The application is primarily designed for use with a keyboard/mouse/trackpad. It may be used on tablet, but is not specifically designed for this environment.

Client applications – Outside the Hospital

Athena Desktop

The same Athena desktop application used within the hospital has also been designed to work in the community to help facilitate bookings, clinics and home births. To utilise Athena “online” within the community, access must be provided to K2’s back-end services; this can be through the provision of services over the internet, or by using a VPN connection. If a cloud solution is utilised, then it’s likely that the back-end services will already be made available over the internet.

Athena desktop also facilitates review of patient notes and data collection without a network connection, using the “Offline Briefcase”. This supports data collection and review of patient notes in the absence of a network connection, taking a patient record offline, then later merging it when back within the appropriate network.

Guardian Online (optional)

This browser-based application allows the remote viewing of real time data from the bedside. In essence, it provides access to the same feature set as Central Station (the ability to view the SaFERR Display and real time CTG). The intent of this application is to provide access to mission-critical data for clinicians that are off site and need to make an assessment of a case.

Electronic Patient Notes - MyPregnancyNotes.com & K2Hampton.com

This national browser-based application has been developed so that patients are able to create a record of their pregnancy. When interfaced with Athena (and after the user has given explicit permission), information can be shared bidirectionally. This allows patients to view information such as appointments and observations that have been retrieved from the Athena database. My Pregnancy Notes also facilitates access to the full clinical record, essentially replacing the requirement to carry paper notes.

Server Side Services

Athena comprises five core services, listed below.

Authentication Service

As the name suggests, this authenticates devices, services and users against information stored in the database. It then supplies the client with a JavaScript Web Token (JWT) that can be used to access the other services.

Web API service

This service primarily provides access to the database resource and is used as the means to read and write data from the database.

Real Time Ward Hub service

This provides the backbone of the contemporaneous and real time data sharing of information collected at the bedside.

It consists of CTG, INFANT and SAFERR functionality, as well as user entered data, collected at the bedside. The Real Time Ward Hub service is essentially a multiple sender/multiple receiver protocol, which is underpinned by Microsoft's SignalR technology. This technology can adapt to the services available on the client, but will typically connect as a WebSocket. Essentially, each bedside will send its information to the Real Time Ward Hub service, allowing Central Stations and remote viewers visibility of the information (including CTG) in real time.

Guardian Online (optional)

Guardian online is an optional service that allows the presentation of the real time data (as collected by the Real Time Ward Hub service) in the browser. This allows clinicians to remotely view the activity of the various wards within the trust from any browser. This is implemented as HTML5/CSS/JavaScript application and has been designed to be responsive, so that it works as well on a mobile device as it does in a desktop browser. This browser-based application is available via https on port 443.

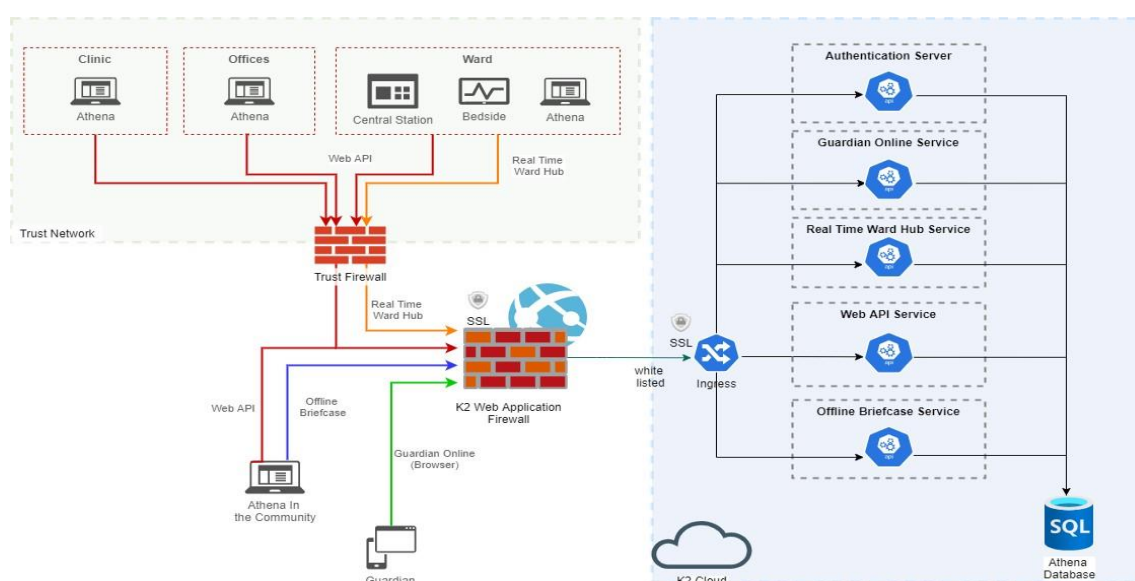
Offline Briefcase Services

The offline briefcase functionality within Athena allows off-site and community-based clinicians to export a snapshot of a patient record, allowing them to continue working within it in areas where they expect to have difficulty accessing the internet. This is a specialist service

which utilises Signal-R to stream data between the client and server in the most efficient manner.

Cloud Architecture

These five services can be installed locally on hospital infrastructure or as a managed service in the cloud. These services are all developed as ASP.NET Core applications and can be deployed as applications in IIS, or any web server that supports ASP.NET Core applications (including on Linux). K2 can also provide containerised versions of these applications for running in a suitable environment. If opting for a cloud solution, this would be running the containerised versions of the services in Kubernetes. The diagram below shows how core services are configured in the cloud environment.



K2 Cloud Option

K2's services use a mixture of web API calls, web browser traffic and web sockets. The web socket calls are underpinned by Microsoft's Signal-R technology, which negotiates connection using a https call. A table of the services and their associated protocols and ports is given below.

Service	Protocol	Port	Notes
Authentication Service	https	443	https API calls
Guardian Online Service	https	443	Browser application
Real Time Ward Hub	https/WebSocket	443	Signal R connection
Web API Service	https	443	https API calls
Offline Briefcase Service	https/WebSocket	443	Signal R connection

Interfaces

Athena and Guardian support many interfaces that can be tailored to work with existing services, both inside and outside of the hospital infrastructure. K2 can also build completely bespoke interfaces across several different technologies. Many of the systems for which interfaces are requested are legacy systems that still communicate using plain text HL7. Most organisations have an integration engine which can be used to 'wrap' these interfaces in more secure protocols. In the absence of this facility, K2 can supply adapters that will wrap these insecure connections into secured protocols for transmission to their back-end services.

HL7 v2 Inbound Interfaces

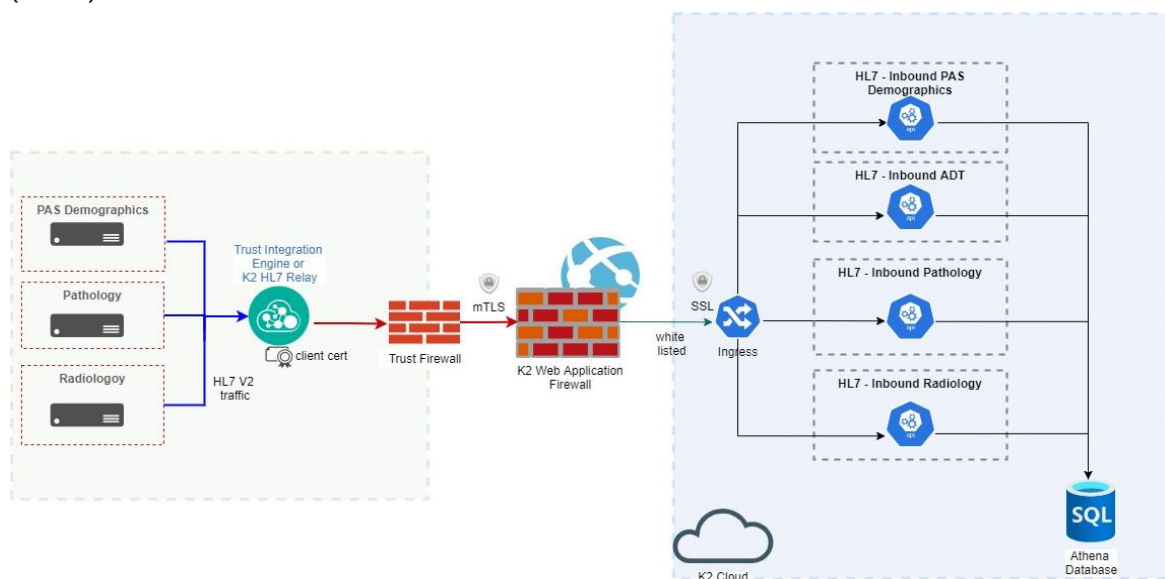
K2 supports inbound HL7 v2 interfaces which are typically used for (but not limited to) K2 to receive the following types of information from various providers, either directly, or preferably from the Trust Integration Engine (TIE).

- PAS demographics and ADT
- Pathology
- Radiology
- Antenatal MIS

K2's interface can support ADT, ORU & MDM message types as standard and can be customised to suit any requirements to support clinical workflow and information exchange.

The interface also accepts the HL7 message payload over a secure https connection, using mTLS and whitelisted endpoints.

The diagram below depicts a typical HL7 bound interface configuration, which shows how the client services communicate securely with K2's services, using Mutual Transport Layer Security (mTLS).

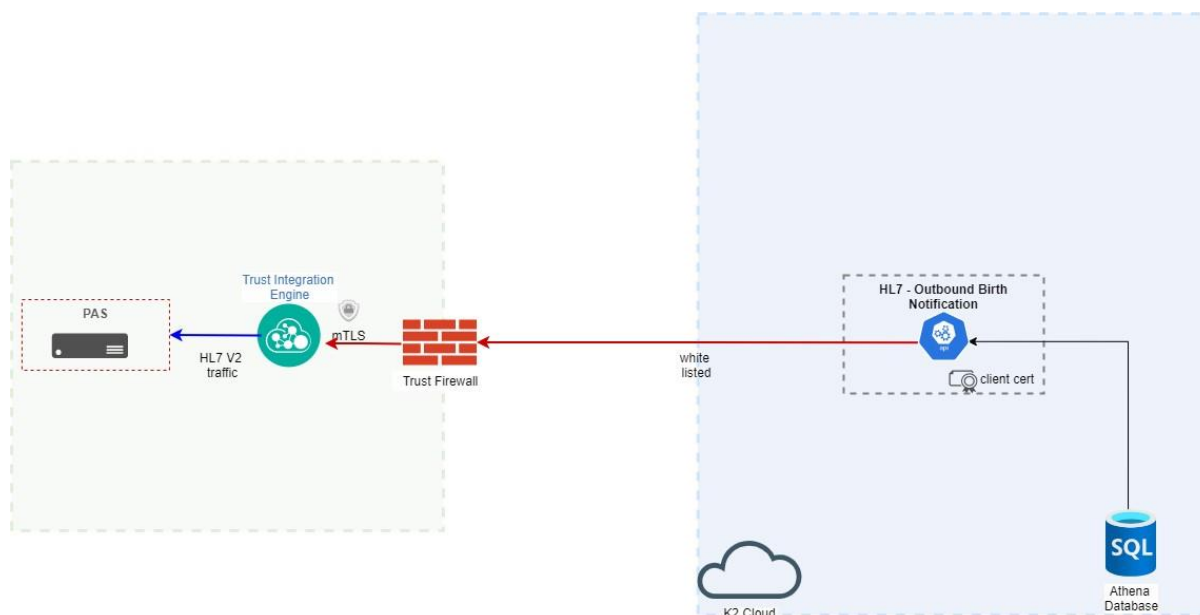


HL7 Inbound interfaces

HL7 v2 Outbound interfaces

K2 can provide almost any information it collects over a HL7 v2 outbound interface. This can connect directly to the TIE or service using suitable authentication over a secure channel. K2 can be flexible in how that is solved, depending on the functions supported by the TIE.

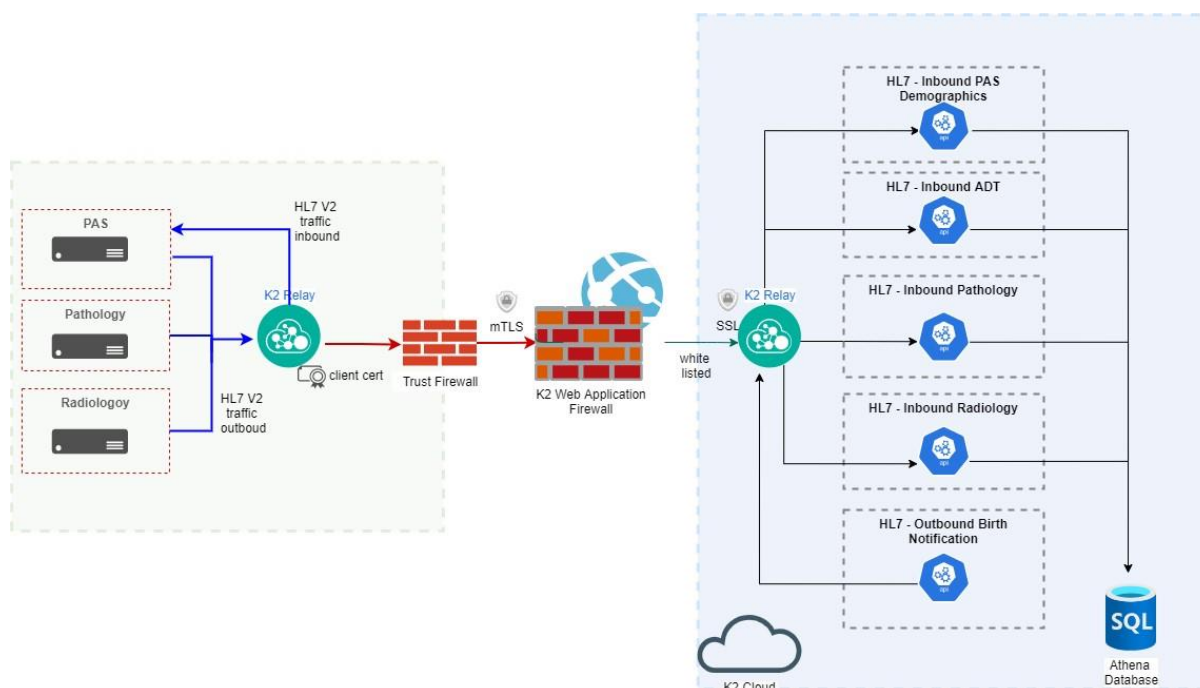
One interface that is typically requested is the Birth Notification, which is used to register new born babies to the local PAS system. K2 will send a registered patient message when birth information has been entered into Athena and subsequently update when/if the NHS number is obtained.



HL7 Outbound interface

K2 HL7 Transceiver

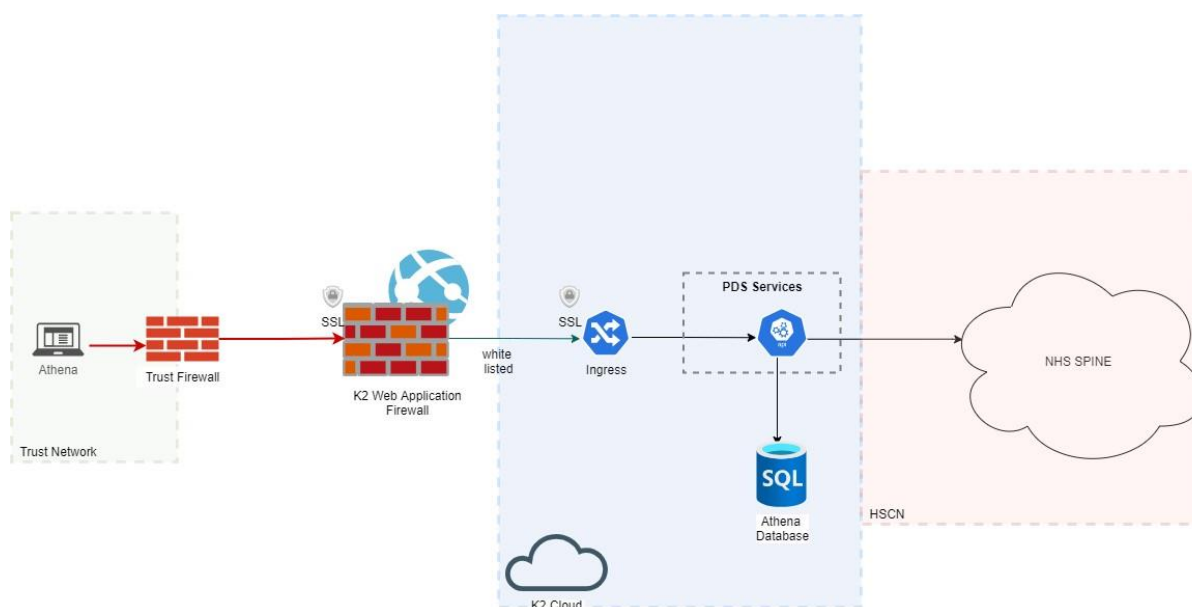
K2 can optionally supply a HL7 Transceiver service, running on trust infrastructure, which is able to secure the connection between on-premises HL7 services and K2 infrastructure in the cloud. The advantage of this solution is that the trust only needs to provide a standard HL7 stream to the transceiver and it will secure the connection. The additional advantage of this bi-directional service is that the connection will be established from the transceiver to the cloud, meaning there is no additional configuration of the trust firewall for any incoming interfaces.



K2 HL7 Relay

PDS NHS Number (CIRR – Create Initial Record Request)

K2 supports the automatic allocation of an NHS number from the PDS service. The K2 system guides the clinician through a set of data entry screens to collect and validate the mandatory information surrounding the baby and the birth. Once the dataset is validated and complete the NHS number can be requested. Communication between K2 and the SPINE PDS is direct and is not required to be routed through the TIE.



PDS NHS Number interface

My Pregnancy Notes

The My Pregnancy Notes product allows patients to contribute to their own personal pregnancy record. This is a national solution that has its own separate database. When integrated with Athena (and if the user has given explicit permission), there are two distinct interfaces supported.

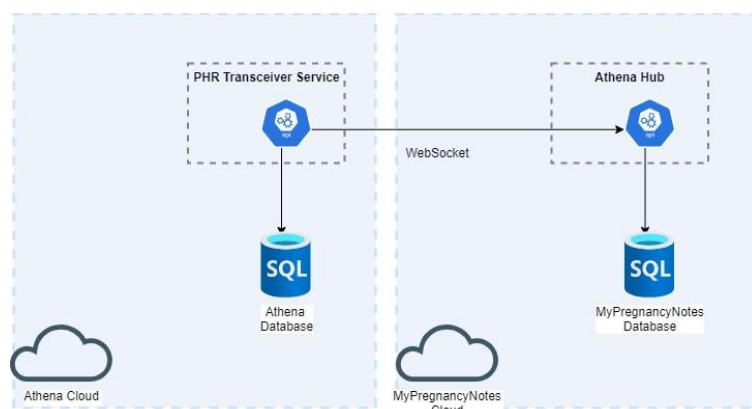
Data Sharing

Information the patient has entered into My Pregnancy Notes can be shared directly into the Athena pregnancy record. Similarly, any responses to data, entered via Athena, can be transferred back to My Pregnancy Notes. There are various data items that can be transferred back and forth but a simple example is 'Questions for My Midwife'. Users can enter questions into their My Pregnancy Notes record, which will be immediately transferred to the care provider's Athena system (providing sufficient authorisation has been granted). Any response entered by the clinical team is then transferred back to My Pregnancy Notes to be viewed by the patient.

Please note: These options can be enabled/disabled by an administrator within the hospital organisation.

View Clinical Record

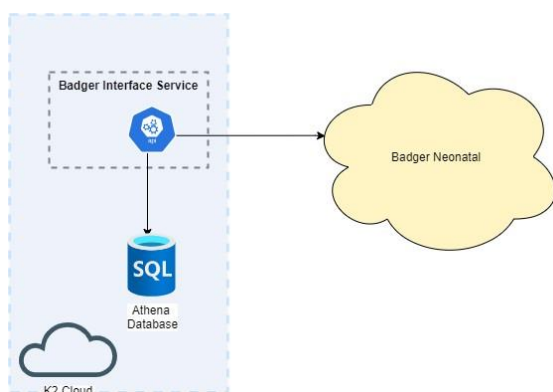
Prior to electronic solutions, patients would be expected to carry around a large set of paper notes relating to their pregnancy. This would ensure that wherever they have a clinical encounter, the notes would always be available. With Athena this is no longer the case as the notes are now provided electronically. Whilst the clinical record is not transmitted to My Pregnancy Notes, it does facilitate patient access, or the ability for the patient to grant third party access to those who need it.



My Pregnancy Notes Interface

Neonatology

K2 can supply an interface to neonatal systems, enabling quick transfer of care between the two systems. This Maternity Details Import interface provides all the information required to populate the neonatal system with baby and maternal outcome information for continuity of care. This significantly reduces the duplication of effort required on the neonatal system. The interface is provisioned directly between K2 and the neonatal provider and is not required to be routed through the trust TIE.



Neonatology Interface

Client PC hardware technical specification

Hardware – Community Laptops

The minimum and recommended system requirements for community equipment is as follows:

Component	Minimum Requirement	Recommended Specification
CPU	Minimum specification of latest Windows version	Hospital current standard specification
Memory	4gb	≥6gb
Storage	2gb Free Disk Space	2gb Free Disk Space
Display	1280 x 1024 Effective resolution (accounting for Windows display scaling)	1920 x 1080 Effective resolution (accounting for Windows display scaling)
GPU	Minimum specification of latest Windows version	Minimum specification of latest Windows version
OS	Windows version still under Microsoft support	Windows – Latest Version
Software	.NET Framework 4.8.2	.NET Framework - Latest version
Network	Network connection to live database. Where records are taken offline, a connection is required to first obtain data and then later synchronise it.	Network connection to live database. Where records are taken offline, a connection is required to first obtain data and then later synchronise it.
Deployment	Software installation via MSI deployment	Software installation via MSI deployment

Hardware – Hospital Desktops and Laptops

The minimum and recommended system requirements for hospital equipment is as follows:

Component	Minimum Requirement	Recommended Specification
CPU	Minimum specification of latest Windows version	Hospital current standard specification
Memory	4gb	≥6gb
Storage	2gb Free Disk Space	2gb Free Disk Space
Display	1280 x 1024 Effective resolution (accounting for Windows display scaling)	1920 x 1080 Effective resolution (accounting for Windows display scaling)
GPU	Minimum specification of latest Windows version	Minimum specification of latest Windows version
OS	Windows version still under Microsoft support	Windows – Latest Version
Software	.NET Framework 4.8.2	.NET Framework - Latest version
Network	Network connection to live database	Network connection to live database
Deployment	Software installation via MSI deployment	Software installation via MSI deployment