Exemplars/Use cases

Patients who want them should have access to their test results to help themselves better manage their care. For example, patients with Type I diabetes in particular are constantly managing their insulin and glucose levels, which are affected by many other factors, and they will be able to manage them more effectively if they can readily access their data both from their devices, and the clinical laboratory. Moreover, they should readily be able to upload their data from devices to clinical systems.

In closed loop systems, one application may drive another process, for example oxygen monitoring might tell an intravenous device to stop delivering narcotics if hypoxemia is detected. Traditionally there has been a very high regulatory bar for any closed loop approaches at the FDA, which may be preventing some beneficial closed loop approaches from being implemented.

An outpatient with asthma goes through a period in which they are having an exacerbation, and come in to be seen by a provider 4 times in three weeks. They would like to know their peak flow rate both themselves and send it to their provider so it can be seen every day. This will be tracked by a nurse through a triage dashboard, along with other information, which will also be available in the EHR.

A physician encounters a prescribing screen that results in their ordering a 10-fold overdose of a medication, and a life-threatening adverse event for a patient. When they ask, others in their group have had the issue previously. They try to share this story and report the offending screen shot which has serious human factors issues to their patient safety organization, but the vendor involved threatens to take them to court for disclosing intellectual property.

Two applications are developed which are nearly identical. However, one receives much more regulatory scrutiny than another, simply because it is in an embedded device.

A provider writes an order on the incorrect patient because they are rushing. They want to report the issue but don’t know who to send it to. Some strategies have emerged that decrease the frequency of this problem but they are not yet widely implemented.

A provider orders a large dose of intravenous potassium, which would potentially be lethal. No warning is issued by the clinical decision support system. This is reported to the hospital involved, which notifies the vendor, but no change is made in the vendor’s medication ordering application.

A diabetes management insulin dosage calculator is developed. If it is part of a prescription device, then is subject to general controls including a 510K, but if not it receives much less scrutiny.

A serious HIT issue occurs involving clinical decision support in an EHR, causing several deaths and multiple injuries. These are reported to the vendor, which does not have to report them to a specific agency. No shared learning occurs.