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Development of whole blood and serum microsampling LC/MS/MS methods for clinical analysis with a goal towards point-of-care therapeutic drug monitoring

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Whole blood microsampling is emerging as an attractive, alternate approach to the invasive vena-puncture, large volume blood conventional method for clinical diagnostics testing. One explanation for this paradigm shift is the vast improvement in sensitivity and ease of use of high performance triple quadrupole and QTOF mass spectrometers introduced recently. In this poster, we present two methods – micro-serum processing and a new whole blood microsampler method, Mitra. These methods are evaluated for their potential to aid in personalized medicine and individual therapeutic drug monitoring. For personalized medicine, we show the power of the technology and its application to vitamin D testing. For therapeutic drug monitoring, opiates are chosen for this evaluation as the model analyte class. In the arena of illicit drug use, therapeutic drug monitoring can provide a mechanism for improved compliance or more appropriate titrating of dose to achieve the pharmacological effect. Late phase development of centrally acting analgesics is complicated by the risk of opioid diversion or abuse and therefore requires monitoring of opioid study drugs and any concomitant opioids. Traditional compliance monitoring is performed using urine samples; however, there is a high risk of urine sample adulteration and urine drug levels are difficult to interpret pharmacologically. In this poster, we present preliminary data using a whole blood microsampling device that has the potential for therapeutic drug monitoring.

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Personalized medicine: Complications in implementation of precision medicine into medical practice

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Personalized medicine attempts to identify tailored treatment based on the susceptibility profile of each individual. Although this approach has generated much excitement, few personalized-medicine therapies have achieved high levels of clinical adoption. To personalized medicine, one needs robust diagnostics and a clear understanding of disease pathomechanism. We have observed four main obstacles to the advancement of personalized medicine: Scientific challenges (a poor understanding of molecular mechanisms or a lack of molecular markers associated with some diseases, for instance), economic challenges (poorly aligned incentives and high cost of new medications), lack of outcome based data (a comprehensive study of cost effectiveness/health benefit of personalized medicine) and operational issues. Although economic challenges remain, the scientific shortcomings and operational issues now seem to be the biggest hurdle. Diagnostics/companion diagnostics is the key to personalized medicine, yet it is hard to identify which tests truly save costs and select effective responders. On the other hand experimental testing leads to fears that although individual tests may not be very expensive, the overall eventual costs could be unjustifiably high. A third concern is the difficulty of enforcing standard protocols to ensure that physicians follow through with appropriate patient care based on test results. Fourth, test information could be misused—particularly in the early stages of investigation and development—which could harm patients and payers. Finally, there is no longitudinal accounting, which would enable payers to capture long-term cost savings from near-term testing. Even if operational issues get resolved within a particular stakeholder group, overcoming the scientific burden and correcting the incentive structure and modifying the relationships between stakeholders could be more complex.

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