

Evidence Based Point of Care Testing for Drugs and Ethanol

- POCT for drugs and ethanol used in:
 - Drug Treatment Clinics
 - Emergency Rooms
 - Legal contexts
 - Employment
- What is the evidence of benefit/lack of benefit ?



EB POCT for Drugs and Ethanol

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EB POCT for Drugs and Ethanol

- What is the effect on outcome of rapid drug screening in:
- Emergency Room

There are studies demonstrating testing for drugs in ER patients is NOT worthwhile, we accept this extends to POCT. [Grade D I]



Bast RP, Helmer SD, Henson SR, Rogers MA, Shapiro WM, Smith RS. Limited utility of routine drug screening in trauma patients. Southern Medical Journal 2000; 93(4):397-399.

Kellermann AL, Fihn SD, Logerfo JP, Copass MK. Impact of Drug Screening in Suspected Overdose. Annals of Emergency Medicine 1987; 16(11):1206-1216.



EB POCT for Drugs and Ethanol

- Is POCT drug testing useful in: materno-fetal medicine; pain management; detoxification clinics?
- *There is little hard evidence in detoxification clinics [Grade C II-1], significantly less proof for other clinics. Sample manipulation compromises benefit [Grade I III].*



Detoxification: Expert opinion

Other clinics: no significant
evidence



EB POCT for Drugs and Ethanol

- **Are there significant differences between POCT devices?**
- *Demonstrate need for POCT, then a careful evaluation conducted by the staff in the environment in which the devices are to be used and on the relevant population [Grade A II-2].*



Buchan BJ, Walsh JM, Leaverton PE. Evaluation of the accuracy of on-site multi-analyte drug testing devices in the determination of the prevalence of illicit drugs in drivers. *Journal of Forensic Sciences* 1998; 43(2):395-399.

Eggers V, Tio J, Neumann T, Pragst F, Muller C, Schmidt LG et al. Blood alcohol concentration for monitoring ethanol treatment to prevent alcohol withdrawal in the intensive care unit. *Intensive Care Medicine* 2002; 28(10):1475-1482.

George S, Braithwaite RA. Use of on-site testing for drugs of abuse. *Clin Chem* 2002; 48(10):1639-1646.

Gronholm M, Lillsunde P. A comparison between on-site immunoassay drug-testing devices and laboratory results. *Forensic Science International* 2001; 121(1-2):37-46.



Koch TR, Raglin RL, Kirk S, Bruni JF. Improved Screening for Benzodiazepine Metabolites in Urine Using the Triage(TM) Panel for Drugs of Abuse. *Journal of Analytical Toxicology* 1994; 18(3):168-172.

Moore L, Wicks J, Spiehler V, Holgate R. Gas chromatography-mass spectrometry confirmation of Cozart RapiScan saliva methadone and opiates tests. *Journal of Analytical Toxicology* 2001; 25(7):520-524.

Poklis A, Oneal CL. Potential for false positive results by the TRIAGE(TM) panel of drugs-of-abuse immunoassay. *Journal of Analytical Toxicology* 1996; 20(3):209-210.



EB POCT for Drugs and Ethanol

- Are there significant differences between POCT and Central Laboratory Testing?
- *Laboratory confirmation of screen positives is essential if punitive action is intended [Grade A I]. POCT screening by non-laboratory staff is acceptable if they are trained [Grade A II-2]*



George S, Braithwaite RA. Use of on-site testing for drugs of abuse. Clin Chem 2002; 48(10):1639-1646.

Gronholm M, Lillsunde P. A comparison between on-site immunoassay drug-testing devices and laboratory results. Forensic Science International 2001; 121(1-2):37-46.



EB POCT for Drugs and Ethanol

- Is there an evidence base to confirm that POCT devices perform adequately at detection limits/cut-offs?
- *Our advice is: use devices from reputable suppliers and validate claims for cut-offs [Grade A III].*



Taylor EH, Oertli EH, Wolfgang JW, Mueller E. Accuracy of five on-site immunoassay drugs-of-abuse testing devices. *Journal of Analytical Toxicology* 1999; 23(2):119-124

Crouch DJ, Frank JF, Farrell LJ, Karsch HM, Klaunig JE. A multiple-site laboratory evaluation of three on-site urinalysis drug-testing devices. *Journal of Analytical Toxicology* 1998; 22(6):493-502.

Crouch DJ, Hersch RK, Cook RF, Frank JF, Walsh JM. A field evaluation of five on-site drug-testing devices. *Journal of Analytical Toxicology* 2002; 26(7):493-499.



EB POCT for Drugs and Ethanol

- Does the matrix (blood/serum/plasma, saliva, sweat, urine, meconium) affect acceptability for POCT for drugs and what is the evidence supporting this recommendation?
- *Urine cut-offs, interferences and interactions are better documented and standardized than in other matrices [Grade A I]. Saliva (oral fluid) performance requires independent confirmation [Grade B II-3], sweat testing may be effective [Grade C II-3].*



Dasgupta A, Wahed A, Wells A. Rapid spot tests for detecting the presence of adulterants in urine specimens submitted for drug testing. *American Journal of Clinical Pathology* 2002; 117(2):325-329.

Bendtsen P, Hultberg J, Carlsson M, Jones AW. Monitoring ethanol exposure in a clinical setting by analysis of blood, breath, saliva, and urine. *Alcoholism-Clinical and Experimental Research* 1999; 23(9):1446-1451.

Silvaggio T, Prezzia CP There are disadvantages, too, for oral fluid, on-site urine testing. *Occup Health Saf* 2001; 70(12):8.

Samyn N, van Haeren C. On-site testing of saliva and sweat with Drugwipe and determination of concentrations of drugs of abuse in saliva, plasma and urine of suspected users.

International Journal of Legal Medicine 2000; 113(3):150-154.



EB POCT for Ethanol and Drugs

- Are there specific recommendations regarding alcohol testing by POCT? What is the effect of breathalyzers in the ED, outpatient clinic or other healthcare settings on patient management?
- *POCT for ethanol devices are available for breath and saliva, not blood. Patient outcome unaffected, rule-out use is best [Grade I II-2]. Operator ability and result recording are issues. [Grade C II-3]*



Cherpitel CJ, Soghikian K, Hurley LB. Alcohol-related health services use and identification of patients in the emergency department. *Annals of Emergency Medicine* 1996; 28(4):418-423.

Soderstrom CA, Dailey JT, Kerns TJ. Alcohol and other drugs: an assessment of testing and clinical practices in U.S. trauma centers. *J Trauma* 1994; 36(1):68-73.



EB POCT for Drugs and Ethanol

- Are POCT panels of drugs preferred over single tests?
- *If using POCT panels, consider the prevalence of drug types used in your population with the panel. Would single POCT devices be more flexible and cost-effective? Balance this against the breadth of testing available from a central laboratory.*
[Grade C III]



Kranzler HR, Stone J, Mclaughlin L. Evaluation of A Point-Of-Care Testing Product for Drugs of Abuse - Testing Site Is A Key Variable. Drug and Alcohol Dependence 1995; 40(1):55-62.

Verstraete AG, Puddu M. Evaluation of different roadside tests. In: Verstraete AG, editor. Rosita. Roadside testing assessment. Ghent: Rosita Consortium, 2001: 167-232.



EB POCT for Drugs and Ethanol

- **Does POCT influence compliance with medication?**
- *There is no evidence base that indicates POCT for compliance affects outcome.
[Grade I III]*



There is no evidence base to
support use of POCT for
compliance



EB POCT for Drugs and Ethanol

- **What are the chief quality issues associated with POCT?**
- *Purchasers and users of POCT devices should ensure appropriate training in their use, application and interpretation. This includes quality issues and recognition of any device limitations. [Grade A I]*



EB POCT for Drugs and Ethanol

- What analytical accuracy issues could impact on the use of POCT devices?
- *Users of POCT devices must understand any limitations of the devices, including: sensitivity, specificity and nomenclature to facilitate appropriate use [Grade A I].*



Taylor EH, Oertli EH, Wolfgang JW, Mueller E. Accuracy of five on-site immunoassay drugs-of-abuse testing devices. *Journal of Analytical Toxicology* 1999; 23(2):119-124.

Buchan BJ, Walsh JM, Leaverton PE. Evaluation of the accuracy of on-site multi-analyte drug testing devices in the determination of the prevalence of illicit drugs in drivers. *Journal of Forensic Sciences* 1998; 43(2):395-399.

Knight SJ, Freedman T, Puskas A, Martel PA, Odonnell M. Industrial Employee Drug Screening - A Blind-Study of Laboratory Performance Using Commercially Prepared Controls. *Journal of Occupational and Environmental Medicine* 1990; 32(8):715-721.

Schwartz JG, Zollars PR, Okorodudu AO, Carnahan JJ, Wallace JE, Briggs JE. Accuracy of Common-Drug Screen Tests. *American Journal of Emergency Medicine* 1991; 9(2):166-170.

Jehanli A, Brannan S, Moore L, Spiehler VR. Blind trials of an onsite saliva drug test for marijuana and opiates. *Journal of Forensic Sciences* 2001; 46(5):1214-1220.



EB POCT for Drugs and Ethanol

- **What knowledge of cross-reactivity of POCT devices is required for their use?**
- *Users of POCT devices need to be aware of any known interferences from drugs or metabolites that could impact on results interpretation [Grade A I]*



Colbert DL. Drug-Abuse Screening with Immunoassays -
Unexpected Cross-Reactivities and Other Pitfalls.
British Journal of Biomedical Science 1994; 51(2):136-146.

Baden LR, Horowitz G, Jacoby H, Eliopoulos GM.
Quinolones and false-positive urine screening for opiates by
immunoassay technology. JAMA 2001; 286(24):3115-3119.



EB POCT for Drugs and Ethanol

- What knowledge of adulteration is required for the use of POCT devices?
- *Users need to know of interpretative problems of interferences from chemicals or adulterants. Protocols ensuring specimens are tamper-free advised. In critical situations the type of POCT chosen should enable the tester to detect manipulation by the donor [Grade A II-1].*



Cody JT, Valtier S. Effects of Stealth (TM) adulterant on immunoassay testing for drugs of abuse. *Journal of Analytical Toxicology* 2001; 25(6):466-470.

Wu AHB, Bristol B, Sexton K, Cassella-McLane G, Holtman V, Hill DW. Adulteration of urine by "Urine Luck". *Clinical Chemistry* 1999; 45(7):1051-1057.

Caldwell JP, Kim ND. The response of the Intoxilyzer 5000 to five potential interfering substances. *J Forensic Sci* 1997; 42(6):1080-1087.



EB POCT for Drugs and Ethanol

- What is the impact of quality assurance and quality control on POCT screening
- *All users of POCT devices must use QC material and participate in EQA schemes [Grade A I].*



Wilson JF, Smith BL. Evaluation of detection techniques and laboratory proficiency in testing for drugs of abuse in urine: an external quality assessment scheme using clinically realistic urine samples. *Annals of Clinical Biochemistry* 1999; 36:592-600.

Lafolie P, Beck O. Deficient performance of drugs of abuse testing in Sweden: an external control study. *Scand J Clin Lab Invest* 1994; 54(3):251-256.

Dubowski KM. Quality assurance in breath-alcohol analysis. *J Anal Toxicol* 1994; 18(6):306-311.

Badia R, Segura J, Artola A, de la Torre R. Survey on drugs-of-abuse testing in the European Union. *Journal of Analytical Toxicology* 1998; 22(2):117-126.



Burnett D, Lader S, Richens A, Smith BL, Toseland PA, Walker G et al. A Survey of Drugs of Abuse Testing by Clinical Laboratories in the United-Kingdom. *Annals of Clinical Biochemistry* 1990; 27:213-222.

Cassani M, Giuliani L, Amigoni M, Buratta A, Marocchi A. Experience with External Quality Assessment of drugs of abuse testing in the Lombardy region in Italy. *Clinical Chemistry and Laboratory Medicine* 2002; 40(2):156-164.



EB POCT for Drugs and Ethanol

- **Are there corporate and liability issues with using POCT for drugs or ethanol?**
- *The decision to use POCT should be a formal Corporate decision following a formal evaluation process of the options to ensure fitness-for purpose. Only authorised, competency assessed staff, should be allowed to perform POCT within agreed governance arrangements [Grade A III].*



EB POCT for Drugs and Ethanol

- Are there specific quality issues around interpretation of results obtained from POCT devices?
- *Procedures must be agreed and in place to ensure only those recognised by the organization as being competent to interpret POCT results do so. The consequences to the patient/client, analyst and Corporately must be recognised [Grade A III].*



EB POCT for Drugs and Ethanol

- Are there specific quality issues for POCT v central laboratory testing (CLT)?
- *All analyses, whether POCT or CLT must be subject to quality control and quality assurance. This should encompass a quality system that includes effective training, record keeping and review [Grade A II-2].*



Crouch DJ, Hersch RK, Cook RF, Frank JF, Walsh JM. A field evaluation of five on-site drug-testing devices. *Journal of Analytical Toxicology* 2002; 26(7):493-499.

Yang JM, Lewandrowski KB. Urine drugs of abuse testing at the point-of-care: clinical interpretation and programmatic considerations with specific reference to the Syva Rapid Test (SRT). *Clinica Chimica Acta* 2001; 307(1-2):27-32.

Kranzler HR, Stone J, McLaughlin L. Evaluation of A Point-Of-Care Testing Product for Drugs of Abuse - Testing Site Is A Key Variable. *Drug and Alcohol Dependence* 1995; 40(1):55-62.



EB POCT for Drugs and Ethanol

- How well do non-laboratory personnel use POCT devices for drugs of abuse in urine for definitive actions?
- *Non-laboratory staff perform worse than laboratory staff. Policy makers need to decide the acceptable benefit/risk ratio they seek in taking definitive actions; advice from laboratorians should be sought [Grade C II-1].*



Crouch DJ, Hersch RK, Cook RF, Frank JF, Walsh JM. A field evaluation of five on-site drug-testing devices. *Journal of Analytical Toxicology* 2002; 26(7):493-499.

Kranzler HR, Stone J, Mclaughlin L. Evaluation of A Point-Of-Care Testing Product for Drugs of Abuse - Testing Site Is A Key Variable. *Drug and Alcohol Dependence* 1995; 40(1):55-62.

Brookoff D, Cook CS, Williams C, Mann CS. Testing reckless drivers for cocaine and marijuana. *N Engl J Med* 1994; 331(8):518-522.



EB POCT for Drugs and Ethanol

- **Is there evidence for an economic impact of POCT for drugs of abuse and ethanol in any context?**
- *Independent studies to assess the economic value of POCT for drug testing are urgently needed, particularly given the multi-million dollar nature of the market [Grade I III].*



French MT, Martin RF. The costs of drug abuse consequences:
A summary of research findings. *Journal of Substance Abuse
Treatment* 1996; 13(6):453-466.



EB POCT for Drugs and Ethanol

- What is the effect of POCT devices on the outcome of drug testing in non-clinical settings?
- *There is no evidence that point of care drug testing offers any incremental benefit over laboratory testing. There may be non-generalizable logistical, and perhaps economic, advantages [Grade I II-3].*



EB POCT for Drugs and Ethanol

- Are POCT devices reliable for non-clinical applications relating to drug abuse?
- *Point of care devices lack sufficient specificity for non-clinical applications. Results may be subject to legal challenge unless positive results are confirmed by a definitive method [Grade I I].*



Crouch DJ, Hersch RK, Cook RF, Frank JF, Walsh JM. A field evaluation of five on-site drug-testing devices. *Journal of Analytical Toxicology* 2002; 26(7):493-499.

Gronholm M, Lillsunde P. A comparison between on-site immunoassay drug-testing devices and laboratory results. *Forensic Science International* 2001; 121(1-2):37-46.

Steinmeyer S, Ohr H, Maurer HJ, Moeller MR. Practical aspects of roadside tests for administrative traffic offences in Germany. *Forensic Science International* 2001; 121(1-2):33-36.

Fraser AD, Zamecnik J. Substance abuse monitoring by the Correctional Service of Canada. *Ther Drug Monit* 2002; 24(1):187-



EB POCT for Drugs and Ethanol

Overall Recommendations

- *Introduction and use of POCT for drugs is a policy issue for an organization.*
- *Use should be within a clearly defined framework.*
- *The objective of testing should be clear; the benefits and risks recognised.*



EB POCT for Drugs and Ethanol

- *Development of interfaceable devices with unequivocal recording of patient/client identification are needed and are still largely lacking.*
- *Collaboration between manufacturers, laboratory personnel, end-users and managers requires a more informed and balanced approach.*



EB POCT for Drugs and Ethanol

- *Involving laboratory professionals in the decision making process is necessary and essential where definitive punitive action may result.*
- *Quality issues, maintenance, record-keeping and cost/benefit all require consideration.*



EB POCT for Drugs and Ethanol

- *Evidence-based studies are lacking to inform stakeholders of the health outcomes and economic impact of POCT for Drugs and Ethanol*
- *Without such studies is the current multi-million dollar spend value for money? Fit for purpose?*

