SEXUAL HEALTH SOCIETY OF QUEENSLAND

POSITION STATEMENT: POINT OF CARE TESTING AND SEXUAL HEALTH MEDICINE

Point of Care Testing (PoCT) is pathology testing performed near the individual by a PoCT operator at the time of the encounter. The results can be used to make immediate informed decisions about individual care. Recent developments in the application of PoCT to sexual health medicine have brought much promise and excitement, mixed with concern and to certain degree, anxiety.

PoCT exemplifies the promise and angst afforded by other new technologies. In this way, it reflects the current milieu of "digital disruption"- new technology that dramatically alters normal social and business conventions. Yet PoCT applied to sexual health medicine represents both a promise for the future and a return to the past. Prior to the advent of urine based Nucleic Acid Amplification Tests (NAAT) for chlamydia and gonorrhoea, PoCT was an important tool for STI management with on-site laboratories a standard feature of sexual health clinics and clinicians trained in developing and reading gram stained slides. Direct Fluorescent Antibody (DFA) staining for chlamydia, gram stained smears for gonorrhoea, dark field microscopy for syphilis, and wet mount preparations for trichomonas are examples of tests that could furnish results within 30 to 60 minutes and inform management. However the complexity with developing and reading these tests necessitated their use by skilled clinicians or technicians supported by equipment and technical spaces. More recent PoCT are distinguished by their simplicity of use and interpretation allowing their use in less technical hands and surrounds. This simplicity creates greater opportunity for innovation and diversity.

Recent trials of the GeneXpert system for fast nucleic acid amplification of chlamydia and gonorrhoea samples across rural Australia have certainly demonstrated the capacity of this technology to increase testing rates and reduce time delays from testing to treatment. The benefits to improving sexual health in rural and remote Aboriginal and Torres Strait Islander communities are clear. Treatment delays due to the distance from clinic to laboratory and high client mobility can result in poor rates of follow-up for treatment and contact tracing. The simplicity with which specimens can be analysed and results interpreted allows for greater engagement of the community, use of peer workers and application in a variety of outreach settings. This flexibility and simplicity appears to come with no diminution of assay performance and certainly the current TTANGO trial has demonstrated test sensitivity and specificity equivalent to laboratory based NAAT. Improved technology will realistically bring about smaller, hand held devices generating faster turnaround times with laboratory standards of sensitivity and specificity. These assays, capable of supporting a range of STI modules, including HIV viral loads, may prove to be "game changers" in public health responses. They will also challenge the existing paradigm of pathology testing and clinical management.

The experience of rapid HIV and syphilis testing over recent years has similarly demonstrated a great potential for increasing access to testing, earlier identification of infections, reduced delays to treatment, interruption of further transmission and the capacity for innovative delivery of testing in a variety of community settings by peer workers acceptable and accessible to the target populations.

In all cases, a number of characteristics of POCT provide distinct advantages to be exploited:

- The short turnaround between application of the test and reporting of a result;
- The potential short turnaround time between diagnosis and treatment;
- The relative non invasive nature of some POCT,
- The relative ease with which tests can be administered and interpreted with minimal training and infrastructure,
- The portability and flexibility of POCT.

The identification and early treatment of persons with HIV/STI has been recognised as a critical primary prevention strategy. Persons with undiagnosed infection are considered epidemiologically significant in fuelling transmission within a population, such as undiagnosed HIV possibly responsible for 30% of infections. Consequently, increasing access to testing for persons reluctant to or lacking the opportunity to test has been prioritised, with PoCT providing a valuable tool for that strategy.

Though often not as sensitive or specific as conventional blood or nucleic acid amplification testing the availability of non-invasive and rapid alternatives to HIV/STI testing can facilitate broad community based testing of persons who are unlikely, unable or unwilling to test. International studies have demonstrated that PoCT for infections such as HIV can reduce barriers to testing, thereby potentially increasing testing access (of never tested) and frequency (of current testers) amongst target populations, particularly when complimented with specific outreach programs. The simplicity and versatility of PoCT increases opportunities for testing within a range of non-clinical settings and by allied health or peer workers comfortable and familiar to marginalised populations.

In populations with higher infection prevalence, this increase in testing will translate to greater detection of persons with undiagnosed infection and at earlier stages in that infection, both necessary for improved prevention and management. A reduction in time to treatment allows for earlier interruption of infection transmission, reduced risks of complications and earlier commencement of partner notification. These advantages are much more pronounced in rural areas given the challenge of distance.

Additional benefits to be derived from rapid testing include greater client satisfaction due to their non-invasiveness, speed and immediacy of results, reduced anxiety waiting for results, increased opportunity for clients to receive test results, potentially reduced costs for testing services and increased clinical staff satisfaction.

Experience from the TTANGO pilot identified a number of benefits for health services utilising POCT- reduced need for follow-up appointments, reduced serious morbidity resulting from delayed diagnosis, increased profile of STIs and increased STI testing in services where sexual health is less a priority.

In terms of public health benefits, reducing the time between diagnosis and treatment will reduce the duration of infection and further STI transmission, and subsequently the infectious pool and prevalence. Point-of-care testing would allow partner notification to commence more quickly- and that when coupled with more prompt management of index cases, this could reduce re-infection as well as the infectious pool. There is also the potential for PoCT to foster more targeted prescribing by reducing the need for syndromic treatment, thereby reducing unnecessary antibiotic usage.

However, with this great promise, comes concern. Some PoCT tests may be unable to distinguish previous treated, inactive infection from current active infection (such as syphilis), contributing to increased anxiety as individuals await confirmation. While rapid testing methods does allow for more rapid identification and notification for public health responses, the absence of pathogen isolation through culture, such as for *N gonorrhoea*, may affect surveillance systems for antibiotic resistance and type patterns. However recent developments in molecular biology techniques for identifying antibiotic susceptibility does raise the prospect for rapid NAAT assays to provide quick turnaround times for both identification and susceptibility testing, thereby ensure prompt, correct treatment. The use of POCT in community settings, and particularly as self-administered tests may impact on the reliability of current notification and surveillance systems to accurately reflect infection rates. There is a potential for significant underreporting of notifiable infections unless systems are put in place for the reporting of infections diagnosed through PoCT. The use of laboratory based confirmatory testing in support of PoCT for HIV and syphilis does address this concern, and future software capacity for GeneXpert and related rapid NAAT assays to electronically communicate directly with state and commonwealth based notification systems will similarly circumvent such concerns.

Point of care tests may be limited in their detection of infection during the early or acute stage of infection. It is therefore feasible that persons who have recently acquired infections such as HIV will test “nonreactive” by the PoCT. Such recently infected persons are considered epidemiologically

significant in the transmission of infection and therefore false negative results may result in a small proportion of infected persons remaining undetected. It is important that in all cases of testing, a risk assessment is made to identify and anticipate potential situations for false reactive or non reactive results. Knowledge of the limitations of a particular PoCT within a particular context is essential for minimising the potential harm to individuals and the wider community, in the form of stress engendered from conflicting test results, and long term harm resulting from undiagnosed infection, onward transmission, and pathological sequelae. This also requires that those administering any such tests are well trained in understanding these potential concerns and can explain these clearly to clients.

Though a small proportion of infections may remain undiagnosed through the use of some lower performing POCT, an understanding of the risk context for the particular target population including prevalence, likelihood to access testing, return for results, opportunities for transmission during potential treatment delays; and the performance of the assay itself with respect to it positive and negative predictive values, will assist in form a rational judgement as to the public and individual health benefit of a particular test.

Another concern for the use of PoCT outside of a clinical setting has been the narrowing of sexual health services. The use of HIV PoCT within a community context has separated HIV from other STI testing, given that other STI tests currently require laboratory processing. The addition of syphilis PoCT has broadened the range of community testing in a limited way, given the need for further serological testing not current available as a PoCT. No doubt, technical developments will see the advent of a suite of PoCT for an ever widening range of STI pathogens.

Therefore the implementation of PoCT within a community setting, delivered by trained community workers will necessitate consultation with and technical support from clinical services. Rather than view community delivered PoCT as a challenge to the integrity of sexual health medicine, clinicians should view it as an important outreach adjunct to mainstream clinical services and work in partnership with such initiatives to ensure that referral pathways are in place and that a quality service is provided, regardless of the setting. Community based PoCT should be recognised as an important option responding to a target population that remains inaccessible to conventional clinical testing.

The versatility and simplicity of POCT and the potential it offers to the community and individual carries with it significant responsibilities to ensure these assays are used appropriately and with maximum benefit to the individual and the community.

Consequently organisations providing PoCT are accountable for the quality of their service and maintaining a high standard of care. This requires a governance framework that actively manages safety and quality risks in the delivery of PoCT including a person designated as responsible for maintaining quality control of equipment, procedures and staff competency. There should be a documented policy/protocol for the selection, use and application of PoCT tests and for the interpretation of the test results. All staff using PoCT must be trained and competent. Testing must be verified by the use of internal quality control material.

The purpose of PoCT is to provide accurate and timely test results that effectively contribute to immediate management decisions. This means that in circumstances where the POCT is delivered independent of treatment services, referral systems need to be in place to ensure the well being of the individual is assured and that their long term psychosocial and physical needs are met. The delivery of the test should always be in a manner that preserves the autonomy, privacy and confidentiality of individuals. Particular attention should be given to the provision of pre and post test counselling and the recording of informed consent.

A safe, secure working environment that addresses the storage of consumables, maintenance of equipment, storage of records and data, pre and post test counselling, infection control, specimen handling, waste disposal and result reporting must be provided to ensure PoCT testing is safely and effectively performed. Policies or protocols should be in place regarding all these aspects.

The Society welcomes the ongoing development of new, flexible PoCT as opportunities for enhancing individual and public health. The potential they represent for increasing diversity, accessibility and acceptability of testing far outweigh the disruption they may create within conventional clinical and pathology services

The Society believes that the potential for POCT to improve service flexibility and consumer choice should be supported with opportunities to develop more innovative forms of service delivery that address the needs of affected communities.

The Society believes that the experience and needs of the affected communities should be prioritised in any consideration of new testing technologies and that meaningful consultation with and participation of the community be engaged. The values of autonomy, informed consent and choice must be respected.

The Society believes that the psychosocial and structural barriers to HIV and other STI testing must be carefully assessed and considered when planning and delivering sexual health services, with a view to supporting increased options for testing within a broad framework that embraces both clinical and community based strategies.

The Society supports the work of academic, clinical and community based researchers seeking to develop testing strategies and technologies that meet the needs of the affected community, increase testing options and contribute to a broader service delivery framework.

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