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Availability of Drug Susceptibility Testing Results for *Mycobacterium tuberculosis* Culture-Positive Patients in a tertiary referral TB clinic

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Background

Tuberculosis (TB) remains a major global health challenge, with 10.6 million cases and 1.3 million deaths reported worldwide in 2023 (1). Ireland has seen a recent uptick in TB incidence in 2024 (289 cases), and in the proportion of drug-resistant TB (2).

Dedicated TB services with multidisciplinary expertise are an important step towards retaining patients in care, utilising video observed therapy, accessing newer medicines, liaising with public health, monitoring for adverse events and advising on transmission-based precautions in the community. Our TB team cared for ~40% of patients with TB notified in HSE Dublin North East region in 2024. Patients are referred to clinic from in-house colleagues, GPs and external hospitals if TB is clinically suspected.

Access to timely and reliable test results for *Mycobacterium tuberculosis* (MTB) is crucial to early and outpatient regimen starts, supported discharge and informed regimen change during care. **A recent change in Irish guidance recommends direct notification of all positive microbiology and histology results to TB teams** (which should comprise a public health and clinical specialist in TB) (3), mirroring standard practice in the UK since 2016 (4).

Rapid testing on direct samples for XpertTB® is done in-house, as is mycobacterial culture in liquid broth (BACTEC MGIT 960 System®). Positive cultures showing acid-fast bacilli are sent to the Irish Mycobacterial Reference Laboratory (IMRL) for identification, whole genome sequencing and phenotypic drug susceptibility testing (DST). Thus, results for each stage of testing of a single specimen becomes available at different timepoints and from different laboratories, which poses an information management and communication challenge. **Our hospital was a pilot site for a new national laboratory information system (MedLIS)** and transitioned away from a legacy electronic order communications system (PIPE) in August 2024 (5).

Aim

To assess availability of MTB DST results for an equal timeframe before and after a hospital-wide laboratory reporting system change. To evaluate adherence to national and international guidelines on result reporting and identify areas for improvement.

Methods

A retrospective audit was conducted from December 2023 to December 2024, to identify consecutive patients newly attending the TB clinic who were at least 3 months into anti-TB therapy (ATT), to account for DST reporting. Thirteen patient records were interrogated, 7 whose samples were processed using the legacy LIMS and 6 using MedLIS.

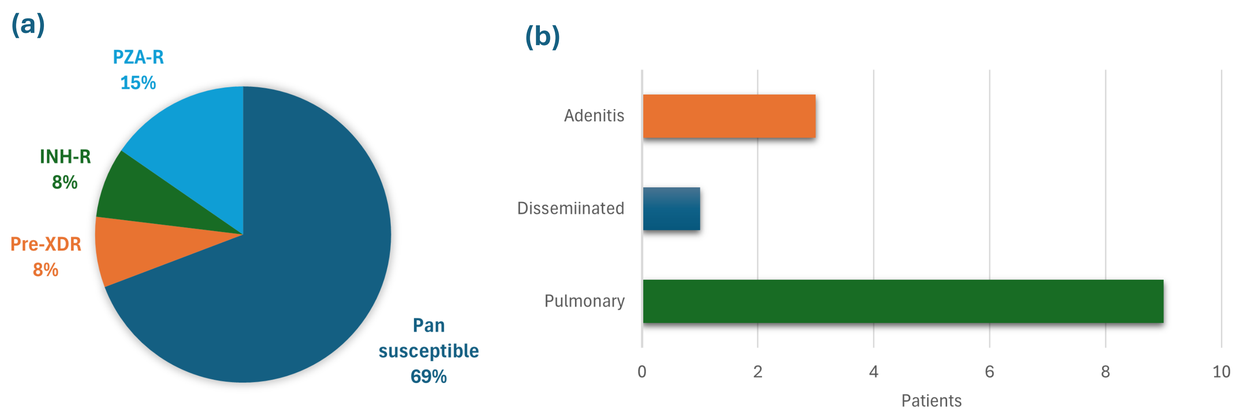
Results

Nine patients (69%) were treated for pleuropulmonary TB, and the rest for disseminated or extrapulmonary disease (Fig 1a). All patients had anti-TB therapy (ATT) commenced as outpatients. Treatment was prescribed prior to culture positivity in 11 (85%) of patients, at a median of -14 days (IQR -20 to +5 days) before positivity. Standard drug-susceptible TB regimen (rifampicin, isoniazid, ethambutol, pyrazinamide) was initiated in all but one pre-XDR patient who commenced on BPaLM and subsequently continued on BPaL. Median time to culture positivity was 27 (IQR 19-38) days. Drug susceptibility is shown in Fig. 1b.

XpertTB results done in-house were visible in all 11 patients who had the test requested, with a 91% positivity rate (Table 1). Whole genome sequencing with predicted resistance was only visible in a single patient (pre-XDR TB), as this is not an INAB-accredited test in Ireland, despite its widespread use globally.

Phenotypic DST results were reported for all patients. Median time from culture positive isolate to DST visibility on PIPE or MedLIS was **48 days** (IQR 37-64 days), with no significant difference between PIPE and MedLIS (*p=0.67*) [vs target ≤30 days (6)]. However, this likely overestimated the time to DST result, as the delay between IMRL authorisation date and local upload to MedLIS is 18 (IQR 10-27) days.

Figure 1. TB Drug Susceptibility Distribution and Sites of TB disease



INH-R = Isoniazid-resistant; PZA-R = pyrazinamide resistant; Pre-XDR = pre-extensively drug resistant.

Uploading of IMRL reports decreases the risk of error and omissions, and can include results that do not have specific MedLIS test repertoire fields. IMRL reports were not uploaded to PIPE.

Typically, ATT is switched from intensive to consolidation phase at 8 weeks. IMRL final phenotypic **DST results were authorised at this decision point (ATT+8 weeks) for 12 (92%) of patients, although only visible on PIPE or MedLIS for 6 (46%)** of patients (Table 1). Delays in availability of DST results to clinicians posed a risk for **adverse clinical impacts in 39% of cases**, including delayed regimen refinement, additional patient visits, potential inappropriate treatment selection, and increased transcription errors.

Table 1. TB Result Availability by Electronic Patient Record

TB Result Availability	PIPE	MedLIS
XpertTB (n=11)	5/5 (100%)	6/6 (100%)
XpertXDR (n=1)	N/A	0/1 (0%)
DST @ATT + 8 wks (n=13)		
IMRL Authorised	6/7 (86%)	6/6 (100%)
Visible on LIMS	4/7 (57%)	2/6 (33%)
IMRL WGS Report	0/7 (0%)	1/6 (17%)
IMRL DST Report	0/7 (0%)	4/6 (67%)
Transcribed DST results only	7/7 (100%)	3/6 (50%)

DST = drug susceptibility testing; ATT = anti-TB therapy; IMRL = Irish Mycobacterial Reference Laboratory; LIMS = laboratory information system; WGS = whole genome sequencing

Discussion

Delay and variability in MTB susceptibility reporting represents a patient safety issue, and a significant barrier to efficient TB management. **MTB DST results are not visible in the electronic patient record at the time of planned switch from intensive to consolidation phase for most patients,** despite authorised results, and IMRL is currently unable to facilitate posting or emailing of requested authorised results to the TB team. Significant clinic time is consumed in calling for results - while the patient waits - which may be prone to reading and transcription errors. Given that verbal results are then handwritten in the patient chart, and do not form part of the electronic record, they are unavailable to other healthcare providers in the multidisciplinary team.

Availability of results remained a challenge regardless of electronic system. The new national laboratory information system has significant advantages. It timestamps multistep resulting to allow audit, and can upload scans of reference laboratory reports (after hard copy received to source laboratory by post), although some of this information remains incomplete. The onboarding of national reference laboratories to MedLIS should allow direct interfacing such that authorised results are immediately visible to clinicians, eliminating extra steps and delays and clinical risk. It is essential to ensure that MedLIS can handle complex stepwise resulting and visibility of complete external reports.

Communication of new molecular, culture, identification and DST results to dedicated TB teams is currently piecemeal and unreliable, and should be adopted as in the national guidance. Prompt access to authorised molecular MDR-TB results are also necessary to apply for funding for first-line drugs such as bedaquiline and pretomanid. Results should be communicated by non-verbal methods (e.g., email or uploading) to ensure timely availability of information, allow appending to electronic patient record and enhance patient care and workflow efficiency.

References

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