

## Short Report

# Measuring system safety for laboratory test ordering and results management in primary care: international pilot study

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## ABSTRACT

The systems-based management of laboratory test ordering and results handling is a significant patient safety concern in primary care internationally. In this pilot study, we describe the testing of a method to systematically measure and monitor compliance with basic safe performance in this area in different European primary care settings. The findings show high overall compliance with the safe system measures developed although

the data indicates performance variation within and between the different systems audited, which suggests that aspects of the reliability (and safety) of these systems could be improved by care teams. However, the overall utility of the method is still to be determined and this will require testing on a greater scale in more diverse practices with larger samples of patients and blood tests, and using different technology support systems.

## Introduction

The design quality of systems for managing laboratory test ordering and results handling in international general practice settings varies widely and can have multiple impacts on the safety of patient care<sup>1-2</sup>. For patients this can lead to preventable harms or poor care experiences, while for general practitioners (GPs) this can delay clinical decision-making and have potential medico-legal implications<sup>3-4</sup>. Organisationally, poor or inadequate system design, can lead to increased allocation of resources to problem-solve when things go wrong and also to deal with avoidable complaints from patients and relatives<sup>5</sup>. However, safety may be created and practice risks minimized by introducing and standardizing processes to improve the overall reliability of results handling systems<sup>6</sup>.

As part of the LINNEAUS EURO-PC programme, preliminary guidance on the safe management of laboratory tests

ordering and results management systems was developed based on the limited research available and more recent programme-related studies, including review of medical indemnity database information<sup>1-9</sup>. In this short report, we describe a collaborative programme output which aimed to develop and test a method to systematically measure and monitor compliance with basic safe performance and, where necessary, direct subsequent practice team improvement efforts.

## Method

### Intervention

We developed a 'care bundle' measurement approach which if implemented routinely would normally involve undertaking small audits on a frequent basis to determine the reliability (a safety indicator) of the results handling system using a composite "all or nothing" measure (Box 1)<sup>10-11</sup>. For the purposes of this

| <b>Pilot Study Bundle Measures</b><br><i>Evidence of:</i>                           | <b>Post-Pilot 'Refined' Bundle Measures</b><br><i>Evidence of:</i>   |
|---|--|
| 1. The test(s) was sent to the Laboratory for processing?                           | 1. Each Test requested was recorded clearly in the patient's notes?  |
| 2. The test(s) result was received back into the practice?                          | 2. The Test(s) taken were recorded as sent to the Laboratory?  |
| 3. The test(s) result was forwarded to a practice clinician for review?             | 3. All Test results were received back into the practice?  |
| 4. The test(s) result was 'actioned' by a practice clinician or appropriately filed | 4. All Test results were passed to a clinician for action within 2 working days of receipt in the practice?  |
| 5. The test(s) result was communicated to the patient, where instructed?            | 5. A definitive decision was made on ALL Test results by a practice clinician?   |
|   | 6. A practice clinician has 'actioned' all test result(s), including the patient being informed where necessary (record 'no further action' as a Yes)? |

Pilot a 'one-off' audit of 25 patients who had blood tests taken in each participant general practice was undertaken as a 'proof-of-principle' that this approach was potentially feasible and provided useful information.

The developed 'care bundle' is a small group of pre-determined questions (n=5) that auditors ask of EVERY laboratory blood test ordered for EVERY patient in the sample of patients being evaluated. The questions are answered on a Yes or No basis. However the bundle compliance approach also works as a composite measurement tool i.e. whether ALL ordered tests for EVERY patient match across to a positive (Yes) answer for ALL five questions. Based on previous research and guidance development experiences, we agreed by consensus that the bundle questions asked are of high importance in determining the safety and reliability (at a fundamental level) at different critical stages of a results handling system (Box 1). It is worth noting that, as an alternative measurement approach, the bundle method could be easily adapted as a safety checklist<sup>6</sup>.

### Setting and sample

General medical practices/primary care clinics in five participating European countries (Scotland, England, Ireland, Spain and Poland) were asked to choose a single day (4<sup>th</sup> week in September 2013) to conduct the 'one-off' audit, and

randomly sample 25 patients who had one or more specific blood tests undertaken at least three weeks previously (to allow time for tests/results to be processed, returned, actioned and communicated to patients). Random sampling advice was provided such as collating a full list of relevant patients and choosing, for example, every 3<sup>rd</sup> name until the desired number was reached, or alternatively using a free online random number generator to achieve this.

### Patient population

Participating practices were instructed to only include patients who had the following common, high volume blood tests ordered to ensure sufficient study data (although the principle will apply to any blood test ordered): Full Blood Count (FBC), Urea and Electrolytes (U&E), Liver Function Tests (LFT), Thyroid Function Test (TFT), Glucose.

### Data collection

Care bundle compliance data were recorded (on a Yes or No basis) for each ordered blood test and result returned, for every patient, by a nominated practice manager or nurse using a pre-designed data collection form.

### Data analysis

Data were input into a Microsoft Excel spreadsheet by JF and simple descriptive statistical analysis was performed, including calculating 'all-or-nothing' compliance.

### Results

18 general practices/clinics collected data on ordered blood tests for 446 patients. Mean 'all-or-nothing' bundle compliance for all participants was 90.4% (range: 44% to 100%). Details of the numbers of practices and patients per participating country, mean blood tests ordered, individual practice performance in each of the bundle measures as well as the overall composite compliance measure are outlined in Table 1.

### Discussion

This small pilot study is the first known attempt to apply the 'care bundle' principle to measure compliance with expected safe system practices in the ordering of laboratory tests and management of results in primary care settings. The findings indicate high overall compliance with the safe system measures developed, although the numbers of patients and blood tests involved are small, even for a 'one-off' study. However, there is enough available information to demonstrate performance variation within and between the different results handling systems used in the participating countries, which suggests that aspects of the reliability (and safety) of these systems could be improved.

If we take the view that each of the five bundle elements being measured is judged to be 'safety-critical' from the patient and practice perspective then, arguably, anything less than 100% compliance is creating unnecessary clinical risk and should, therefore, be a 'red flag' prompt for the care team to reflect on and improve the design of the system.<sup>6</sup> In this respect, there is additional potential for this method to facilitate important patient-safety related opportunities for collective learning and improvement in the practice. However for this to be achieved

**Table 1:** Evidence of compliance with bundle measures (individual and composite) by country and practice.

| Country and No. of Practices | Mean Blood Tests Per Patient (n, range) | 1. The test(s) was sent to the Laboratory for processing? | 2. The test(s) result was received back into the practice? | 3. The test(s) result was forwarded to a practice clinician for review? | 4. The test(s) result was 'actioned' by a practice clinician or appropriately filed | 5. The test(s) result was communicated to the patient, where instructed? | Composite Measure – % Bundle Compliance ('all or nothing') |
|------------------------------|---|---|--|---|---|--|--|
| <b>Scotland (n=11)</b>       | 3.16 (1-5)                              | 25  | 25   | 25  | 22  | 25   | <b>88%</b>   |
|                              | 2.36 (1-5)                              | 25  | 25   | 25  | 25  | 25   | <b>100%</b>  |
|                              | 3 (1-5)                                 | 25  | 25   | 25  | 24  | 25   | <b>96%</b>   |
|                              | 2.8 (1-5)                               | 25  | 25   | 25  | 25  | 24   | <b>96%</b>   |
|                              | 2.56 (1-4)                              | 25  | 25   | 25  | 24  | 24   | <b>96%</b>   |
|                              | 3.52 (1-5)                              | 25  | 25   | 25  | 25  | 25   | <b>100%</b>  |
|                              | 2.76 (1-5)                              | 25  | 25   | 25  | 25  | 25   | <b>100%</b>  |
|                              | 2.52 (1-5)                              | 25  | 25   | 25  | 25  | 23   | <b>92%</b>   |
|                              | 2.6 (1-5)                               | 25  | 25   | 25  | 25  | 25   | <b>100%</b>  |
|                              | 2.44 (1-5)                              | 25  | 25   | 20  | 20  | 20   | <b>80%</b>   |
| 2.8 (1-5)                    | 25                                      | 25  | 25   | 25  | 25  | <b>100%</b>  |  |
| <b>Ireland (n=2)</b>         | 2.16 (1-4)                              | 25  | 25   | 25  | 25  | 25   | <b>100%</b>  |
|                              | 3.36 (1-5)                              | 25  | 25   | 25  | 25  | 23   | <b>92%</b>   |
| <b>England (n=1)</b>         | 4.16 (3-5)                              | 25  | 25   | 25  | 25  | 23   | <b>92%</b>   |
| <b>Poland (n=3)</b>          | 3.08 (1-5)                              | 21*   | 19   | 19  | 11  | 11   | <b>44%</b>   |
|                              | 2.04 (1-4)                              | 25  | 19   | 19  | 19  | 19   | <b>76%</b>   |
|                              | 2.64 (1-5)                              | 25  | 25   | 24  | 20  | 20   | <b>80%</b>   |
| <b>Spain (n=1)</b>           | 1 (1)                                   | 25  | 25   | 25  | 24  | 25   | <b>96%</b>   |
|                              |   |   |  |   |   | Mean   | <b>90.4%</b>   |

\*Details of 4 tests were not returned

effectively will involve care teams implementing the bundle (or alternatively a safety checklist based on the bundle components) on a routine basis and also getting to grips with learning more about 'measurement', including understanding basic statistical variation in systems and the use of visual Run Charts to drive improvement (see Siriwardena & Gillam<sup>12-13</sup>). Evidence for the feasibility of this type of measurement and improvement approach in general practice is steadily accumulating<sup>11, 14-15</sup>.

However, even with this technical understanding there are still many socio-cultural, psychosocial and educational barriers to contend with when improving laboratory test ordering and results handling processes in complex primary care systems<sup>16</sup>. For example, the practice leadership firstly needs to recognise and prioritise the problem and then create the right environment for improvement<sup>17</sup>. Other staff groups, particularly able and experienced frontline administrators, need to be engaged and 'permitted' to contribute their ideas, lead quality improvement projects, or point out system deficiencies, without fear or ridicule<sup>6,8</sup>. Additionally, all staff should have

a basic understanding of how human-system interactions in the workplace can contribute to error and inefficiency, while practice managers should be familiar with systems-centred design thinking and related techniques such as process mapping, care bundles and task analysis. There is now growing interest in formally educating healthcare professionals in human factors and quality improvement sciences<sup>18-19</sup>. Arguably, however, there is an abundance of online resources freely available to general practices to begin targeted training at a basic level for all staff groups as part of continuing professional development arrangements, including GP administrators who often feel neglected in this respect<sup>8,20-21</sup>.

## Conclusion

The early testing of this 'care bundle' approach to measuring and monitoring safe systems for laboratory test ordering and results management shows some promise as a potential method of audit for improvement. Post-pilot feedback and discussions have now led to further refinement of the care bundle measures (Box 1), a similar version of which is currently being tested in a

small number of Scottish general practices. However, evaluation of the overall utility of the method is still necessary, particularly in terms of its routine feasibility in everyday practice and safety improvement impact, which will require development and testing on a greater scale in more diverse practices with larger samples of patients and blood tests, and using different technology support systems.

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