# *IDENTIFY: The Investigation and Detection of Urological Neoplasia in Patients Referred with Suspected Urinary Tract Cancer: A Multicentre analysis*

**BURST collaborative group**

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**Small Research Project – Final report – 8 January 2020**

**Project start and completion date**
Data collection: December 2017 – 2018
Analysis and dissemination: Jan 2019 – Dec 2019

**Background and the rationale for the project**
A common sign of bladder cancer is blood in the urine (haematuria). GPs will refer to a Urologist for further investigation of haematuria if they suspect cancer. Shared-decision making is extremely important in patients presenting with haematuria and the outcomes of IDENTIFY will allow a more personalized approach to the diagnosis of urinary tract cancer. Rather than a blanket approach in which all patients undergo flexible cystoscopy and one or more imaging tests, we will generate data that could offer patients information on the likelihood of a flexible cystoscopy or other test finding cancer for them, given their personal characteristics, thus creating a personalised diagnostic approach for each patient and reducing unnecessary and potentially harmful tests.
Despite patient and public involvement being critical in the development of novel bladder cancer diagnosis pathways, their involvement is often not made integral to key consultations in pathway development. Patient focus groups throughout the study process will be paramount, as we will require patient support in implementing a practical way to change diagnostic practice and patient-informed decision making.
A key aspect of the data generated from the study is to be able to use it to influence patient pathways and approaches to diagnostic tests in bladder cancer. IDENTIFY results are also hoped to help inform national and international guidelines on referral for haematuria.

**The objectives**
1. Establish what current practices are for urinary tract cancer diagnosis in patients presenting with haematuria in the UK and internationally
2. Give the diagnostic performance of key diagnostic tests (cytology, US, CT, flexible cystoscopy) used in practice
3. Assess the cost-effectiveness of different diagnostic strategies for patients presenting with haematuria
4. Identify key patient predictors for diagnosing men with high risk bladder and upper urinary tract cancer
5. Recommend changes in the diagnostic pathway that will reliably diagnose cancer but cause the least harm to patients, whilst remaining cost-effective

**Your study criteria/design for delivering the project**
- This is a prospective multi-centre cohort study

- It will be carried out in 100 sites, each collecting data for 50 to100 patients depending on centre size

**Problems encountered (if any)**
Engaging centres in different countries due to different local and national approvals required. However this was overcome and we produced the largest study ever performed in this area (11,000 patients).

**Key Findings**

Over 11,000 patient records were collected from 110 hospitals in 26 countries (Dec 2017 - Dec 2018). 65.5% had visible haematuria [VH], 28.9% non-visible haematuria [NVH] and 5.6% no haematuria [NH].

The prevalence of bladder cancer [BC] overall was 17.9%; (VH: 22.4%, NVH: 5.2%, NH: 30.6%. The prevalence of Upper tract urothelial cancer [UTUC] was 1.17% (VH: 1.60% NVH: 0.28%), renal cell carcinoma [RCC] 0.98% (VH:1.26% NVH:0.41%) and prostate cancer 1.14% (VH:1.37% NVH:0.54%).
The vast majority of cancers were found in patients referred with VH.

Prevalence varied vastly between hospitals and countries. Prevalence increased with age. No one under the age of 60 with non-visible haematuria had UTUC.

**Significance of Findings**
Clinicians can counsel patients with these figures as to their personalised risk of having cancer which can influence the diagnostic approach that a particular patient may face. This can aid a shared decision-making approach between patients and clinicians so that appropriate diagnostic tests are chosen leading to optimal cancer detection with minimum patient harm. These figures can influence national and international guideline makers (e.g. NICE, European Association of Urology Guidelines, American Urology Association Guidelines) and clinicians into adopting particular pathways for patients with suspected cancer presenting with different risk factors.

**Overview of the project progress**
We are very pleased with the outcome of this study. The approach to research and execution of this study is unique. We have received a lot of attention and credit for the work achieved. Through collaboration we have achieved a phenomenal number of patient records and exceeded our expected outcomes well within the timeframe. This is now an exciting time as we begin to influence a safer and more efficient way in utlitsing resources to diagnose bladder cancer and other urinary tract cancers.

**Detailed breakdown**

1st May 2018 – A breakdown of sites registered and their locations
December 2017 – March 2018: Registration of hospital sites
We managed to advertise and receive interest from 175 hospitals in 33 countries around the world. This was an incredible achievement through the network of registrars, residents and trainees around the world. By the end of the study we had 110 hospitals in 26 countries around the world. A full breakdown of those can be seen in Appendix A.

30th June 2018 – Presentation of project and preliminary site and patient demographics at BAUS Annual conference
IDENTIFY was presented at BAUS 2018 and was very well received. There was a lot of excitement about what a study of this calibre can deliver in terms of changing guidelines and

improving healthcare. ABC UK was acknowledged and thanked. The full presentation can be seen at https://www.youtube.com/watch?v=YhsdGrmHbV8 from 15:13 min onwards.

31st December 2018 – Data collection complete: aim to collect 5000 patient records
We finished data collection for 11,130 patients in 28 countries around the world. Following data cleaning we had just over 11,000 records in 26 countries. The data was then being sent to our statisticians for the primary analysis. We had also submitted to all major international urological conferences and were accepted to BAUS, EAU, AUA and SIU, as well as many other smaller conferences. A list of conferences and prizes won by the study can be found in Appendix B.

1st April 2019 – quality control and data cleaning complete
We sent the data to the Test Evaluation Research Group in Birmingham with whom we are working closely. They prepared our primary analysis by March in time for the EAU conference. The primary analysis looked at prevalence of cancer in the data set and how it differed in each site and country. We started to explore patterns and look at the reason behind this and learnt how varied the diagnostic practice of haematuria is around the world, and the effect this has on the efficiency of diagnosing cancer.

30th August 2019 – submit work for scientific conferences and prepare paper for publication
As per Appendix B, IDENTIFY has been submitted and presented at many major conferences internationally so that clinicians and patients around the world can benefit from our work. We have written the first paper for publication which is due for submission. In the meantime, further analysis has been performed on risk factors associated with urological cancers and diagnostic test evaluation to make the implications of our work go even futher. The results from these have been submitted to all major international conferences for 2020 (EAU, AUA and BAUS).

**Was the project a success? Did you prove what you set out to prove? If not, what do you think the reasons were?**
Yes, it was a huge success and we over recruited more than twice what we expected to. It has received much recognition and won awards and prizes.

**Potential Clinical Impact - what changes, if any, will you make to patient care or service delivery?**
We hope to standardise the type of investigations for patients referred to secondary care with haematuria. This will be done according to the patient's risks, which will be determined from the study. In doing this we hope to use resources more effectively, reduce unnecessary tests, and reduce costs of haematuria investigation, whilst improving the efficiency of cancer detection.

**How will you be disseminating the information gained from your project so that practise can be updated and improved?**
See appendix B for list of conferences where results have been disseminated. Furthermore, we will be submitting for publication the main study in a high impact journal.

**Appendix A**

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| Canada | Vancouver General Hospital |
| Italy | Cattinara |
| Italy | SanGiovanni Battista Hospital |
| Canada | University of Alberta |
| UK | Royal Derby Hospital |

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| UK | Western General Hospital |
| UK | Queen Alexandra Hospital |
| UK | Salford Royal NHS Foundation Trust |
| UK | Doncaster Royal Infirmary |
| USA | University of North Carolina Hospitals |
| Spain | Cruces University Hospital |
| UK | Bradford Teaching Hospitals NHS Foundation Trust |
| UK | Aberdeen Royal Infirmary |
| UK | Royal Devon and Exeter Hospital |
| UK | Southmead Hospital |
| Italy | Careggi |
| UK | Royal Alexandria Hospital |
| UK | Whipps Cross Hospital |
| UK | Cambridge University Hospitals NHS Trust |
| USA | Northwestern Memorial Hospital |
| UK | New Cross Hospital |
| UK | Hereford County Hospital |
| UK | St James University Hospital |
| Spain | HOSPITAL UNIVERSITARIO DE FUENLABRADA |
| UK | Morriston Hospital (ABMU Health Board) |
| Portugal | Hospital Professor Doutor Fernando Fonseca |
| UK | Guy's and St Thomas' |
| Spain | La Paz University Hospital |
| Italy | Policlinico San Martino |
| UK | Southend University Hospital |
| UK | Freeman Hospital |
| UK | James Cook University Hospital |
| UK | St George's Hospital |
| Hong Kong | Queen Mary Hospital |
| UK | West Hertfordshire NHS Trust |
| UK | University Hospital of Wales |
| Denmark | Copenhagen Unirvesity Hospital Herlev Gentofte |
| Slovenia | University Clinical Centre Ljubljana |
| UK | Royal Glamorgan Hospital |
| UK | Sandwell and West Birmingham Hospitals NHS Trust |
| UK | Ninewells Hospital |
| Ireland | St James's Hospital |
| Turkey | Medeniyet University |
| USA | Penn State Milton S. Hershey Medical Center |
| China | Peking University Third Hospital |
| France | CHU Dijon |
| France | CHU Kremlin Bicetre |

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| Hong Kong | Prince of Wales Hospital |
| Ireland | Tallaght hospital |
| Italy | University Hospital 'Ospedali Riuniti' |
| Portugal | Coimbra Hospital and University Centre |
| UK | Forth Valley Royal Hospital |
| UK | Gloucestershire Hospitals NHS Foundation Trust |
| UK | Great Western Hospital |
| UK | University College London Hospital |
| UK | Wexham Park Hospital |
| Ireland | Galway University Hospital |
| UK | Bedford Hospital |
| UK | Royal United Hospital Bath NHS Foundation Trust |
| UK | Northwick Park Hospital |
| Portugal | Beatriz Ângelo |
| USA | Tampa General Hospital & USF Health Morsani Center for Advanced Healthcare |
| Argentina | HOSPITAL ITALIANO DE BUENOS AIRES |
| Hungary | Hungarian Defense Forces Medical Center |
| Argentina | Hospital Aleman de Buenos Aires |
| France | CHRU LILLE |
| Spain | Hospital Clínico Universitario Lozano Blesa |
| Spain | HOSPITAL UNIVERSITARIO SEVERO OCHOA |
| UK | Barts Health NHS Trust |
| UK | Wrightington Wigan and Leigh |
| USA | Charleston Area Medical Center |
| USA | University of Alabama at Birmingham Hospital |
| Australia | Royal Brisbane & Women's Hospital |
| Spain | Hospital Universitario Virgen de las Nieves |
| Australia | Eastern Health |
| Netherlands | UMCG |
| Netherlands | Universitair Medisch Centrum Utrecht |
| Slovenia | University medical centre Maribor |
| Spain | Hospital Universitario Miguel Servet |
| Turkey | Marmara University School of Medicine |
| France | Bichat |
| Ireland | Mercy University Hospital |
| Malaysia | UNIVERSITI KEBANGSAAN MALAYSIA MEDICAL CENTER |
| Poland | Department of Urology and Urological Oncology |
| Poland | University Hospital Jagiellonian University |
| UK | Churchill Hospital |
| UK | Nottingham City Hospital |
| UK | Russells Hall Hospital |
| UK | Wycombe General Hospital |

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| Uruguay | Hospital de Clinicas Manuel Quíntela |
| Belgium | University Hospitals Leuven |
| Croatia | Sestre milosrdnice University Hospital Center |
| Czech Republic | General University Hospital |
| Greece | Evangelismos General Hospital |
| Iraq | Rizgary Teaching Hospital, Hawler Medical University |
| Japan | Juntendo University Graduate School of Medicine |
| Singapore | NG TENG FONG GENERAL HOSPITAL |
| Spain | HOSPITAL PARC TAULI |
| Spain | Hospital Universitario Puerto Real |
| Turkey | University of Health Sciences Bagcilar Hospital |
| UK | Charing Cross Hospital |
| UK | Kent and Canterbury Hospital |
| UK | King's College Hospital |
| UK | North Middlesex University Hospital |
| UK | Raigmore Hospital |
| UK | Royal Preston Hospital |
| UK | St Peter's Hospital |
| UK | Whittington Hospital |
| USA | Geisinger Health System |
| USA | University of Connecticut Health Center |

**Appendix B**

| Conference | City | Date | Presentation type | Presenter | Prizes |
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| | | | | | |
| EAU 19 | Barcelona | March 19 | Oral Poster presentation | Sinan Khadhouri | Best poster |
| | | | | | 1st Prize best abstract |
| ASiT 19 | Belfast | March 19 | Oral presentation SARS/ASiT prize | Tara Sibartie | SARS/ASiT |
| RSM Urology | London | March 19 | Oral presentation BAUS academic research prize | Luke Chan | - |
| ISU 19 | Dublin | Sept 19 | Oral presentation | Shakeel Mohammud Inder | |
| AUA 19 | Chicago | May 19 | Oral presentation | Sinan Khadhouri | - |
| ASC 2019 | Bangkok | May 19 | Oral presentation | Sheliyan Raveenthiran | Best Research paper prize |
| Annual research day | Vancouver | June 19 | Oral presentation | Miles Mannas | - |
| BAUS 19 | Glasgow | June 19 | Oral presentation | Sinan Khadhouri | Best poster prize |
| CUA 19 | Quebec | June 19 | Oral presentation | Mark Assmus | - |
| SIU 19 | Athens | October 19 | Oral presentation | Sinan Khadhouri | |
| Spanish national meeting | Bilbao | June 19 | Poster presentation | Diego M. Carrión Monsalve | Best poster in conference |
| UAA 19 | Malaysia | August 19 | Oral presentation | Shomik Sengupta | - |
| ANZUP | Brisbane | July 19 | Poster presentation | Mo Li | |
| EAU Urol Research (ESUR) | Porto | October 19 | | Tom Austin | |