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(The UK Focal Therapy User Group)
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12th November 2024

RE: Letter to new and potential focal therapy clinicians

Dear Colleague,

I trust you are well.

It is great to see your interest in starting a focal therapy programme in your hospital and region. In my capacity as Chair of Focal Therapy UK, representing focal therapy users in the UK, I thought it would be good to write to you with an outline of how to get started and a number of important factors to take into consideration. All the existing users and myself are keen to support you in delivering a high quality focal therapy programme that meets all the clinical governance requirements set out in the UK. This in turn will ensure that a high quality of care and clinical safety in this area of practice is available for all patients entrusted to our care.

A. NICE Interventional Procedure Guidelines

The following modalities have UK NICE Interventional Procedures Guidelines 'special arrangements' approval in the treatment of prostate cancer in a focal manner. The NICE Prostate Cancer Clinical Guidance (NG131) section on HIFU and cryotherapy has not been updated since 2008 and whilst it continues to stipulate that HIFU and cryotherapy should not be done outside of clinical trials or research, the guidance cross-references the NICE IPG documents as below for HIFU and cryotherapy. The EAU guidelines currently recommend that HIFU and cryotherapy only can be offered within the context of a research or a prospective registry. The details of the registries will be dealt with below.

Cryotherapy (IPG423) (April 2012)

<https://www.nice.org.uk/guidance/IPG423>

-HIFU (IPG756) (April 2023)

<https://www.nice.org.uk/guidance/ipg756>

Irreversible electroporation (IPG768) (July 2023)

<https://www.nice.org.uk/guidance/ipg768>

The NICE IPG guidelines stipulate for HIFU, cryotherapy and irreversible electroporation the following under 'special arrangements,

a) Inform the clinical governance leads in their Trusts.

b) Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and the risks (specifically the risk of sexual dysfunction) and provide them with clear written information.

c) Clinicians should collect data on all patients undergoing focal cryoablation (including details of case selection, methods of follow-up and outcomes) for local audit. Clinicians should enter details about all patients undergoing focal therapy onto a registry.

d) Patient selection and treatment should be carried out by a multidisciplinary urological cancer team.

It is vital that all clinicians are fully compliant with the NICE IPG guidance. Other modalities that purport to be able to treat focally should be used ONLY in the context of a clinical trial or research until that particular modality is able to get NICE IPG 'special or normal arrangements' for a cancer focal therapy indication.

B. NICE compliant registries

The following registries have been set up for the collection of all focal therapy cases. Clinicians must place all their cases onto the respective registries (whether the cases are in trials or not) and continue to update follow-up data. Follow-up data must continue until the patient no longer engages with the physician or NICE changes its guidelines to 'normal arrangements'. Even at this stage, we would encourage continued collection of long-term data.

Primary surgeons for cases will be co-authors on outputs from registry papers provided they have inputted cases and data and follow-up information robustly. Industry is not involved in data analysis or drafted or editing of any abstracts or papers.

Please contact the relevant person for onboarding with the registries. We have plans to make public clinicians use of the registry for clinical governance compliance.

HIFU

HEAT Registry

Contact Emma Cullen, Imperial Prostate

e.cullen@imperial.ac.uk

Cryotherapy

ICE Registry

Contact Emma Cullen, Imperial Prostate

e.cullen@imperial.ac.uk

Login for ICE and HEAT:

<https://redcap.imperial.ac.uk/>

Irreversible Electroporation (Nanoknife)

ARC Registry

Please contact Mr Alistair Grey, Consultant Urological Surgeon, UCLH NHS Foundation Trust

C. Primary clinician should be a urologist

The user group position is that the primary clinician for cases of focal therapy should be a urologist. Whilst joint cases with radiology colleagues is not discouraged, the primary delivery and responsibility

for the case must be under the physical presence of a urologist. Not only are there very sensitive collateral tissues that require awareness of, but there are also often situations within the operating theatre where the urethra can cause problems and require cystoscopic interventions. This can also happen post-operatively. For patient safety therefore, the focal therapy programme must be urologically led and delivered.

D. Type of devices, training and ongoing caseload

All clinicians should abide by the UK training requirements which are unique to the UK and set out by the group over the last almost two decades. This is,

- Online training pack to be completed for modality in question.
- Observation on at least two occasions, with at least 2 cases on each occasion at a reference centre where the clinician has no prior experience of the modality or focal therapy
- First cases should be booked within 3 months of the last visit to a reference centre
- Proctoring of cases for at least 2 visits with at least 2 cases per visit with most new users requiring 3-4 visits.
- Ongoing non-clinical technician support with experience of guidance of clinician not just of device set up
- **EACH CLINICIAN MUST CONDUCT AT LEAST 20 CASES PER YEAR OF EACH MODALITY (e.g., 20 HIFU or 20 cryotherapy). Where clinicians fall below this number they must be in-person or remotely proctored again. Cases cannot be counted for two urologists who may be present for the same cases.**
- Clinicians should not treat salvage cases in their first year due to high complexity and potential for morbidity of these cases.
- Eligibility criteria are outlined in the diagram below

Clinical

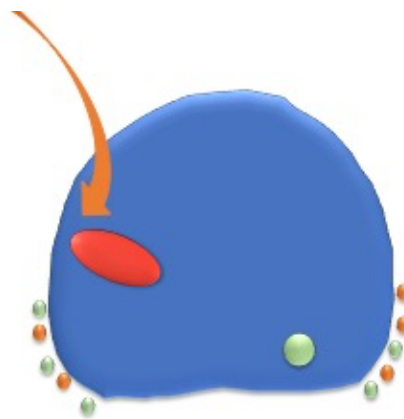
- PSA \leq 20ng/ml
- Radiological T3aN0M0
- Lesion no more than one quadrant on MRI

Histology

- Gleason 7 (4+3 or 3+4)
- Maximal Gleason 4+4 on targeted biopsies provided lesion is Gleason 7 is permitted
- No cancer length limit for Gleason 7
- Gleason 3+3=6 if \geq 6mm and MRI lesion 3, 4 or 5

Biopsy

- Template or targeted/systematic biopsies



Contralateral lobe

Up to 5mm of Gleason 3+3 permitted (will be placed on surveillance)

MRI score 1, 2, 3

For Sonablate HIFU users, dose escalation focal treatment is required for primary cases. This is the UK standard for this device.

For those users starting to use the Focal One HIFU device, there is little experience of this in the UK and you must be proctored by an expert until deemed independent. Current good international practice for Focal One HIFU points to the use of contrast enhanced ultrasound to determine whether further treatment is required and users will need to justify any deviation from this practice.

For cryotherapy, there are two devices being used (Boston and Varian).

For irreversible electroporation, there is currently one device being used (Angiodynamics).

E. Contacts for devices and charities

Please contact the following for further information about each device and how you might be able to get it into your unit. We have shared a basic business plan which all the below have available and can share with you.

In addition, there are some charitable organisations who are keen to partner up with units in order to start focal therapy through help with pump-priming programmes. The details of each charity and what they can offer will be available from them. They are keen to work with local charities and support groups to fundraise if you think appropriate.

Industry contacts:

Sonablate HIFU
Barton Shannon
bartonshannon@sonablate.com

Focal One HIFU
Hugo Embert
Hugo.Embert@FocalOne.com

Cryotherapy – Boston
Neil Turner
Neil.Turner@bsci.com

Cryotherapy – Varian
Tara Djanani
tara.djanani@varian.com

Irreversible Electroporation - Angiodynamics
Jason Ford
Jason.Ford@angiodynamics.com

Charity Contacts
Prost8
Paul Sayer
paul.sayer@prost8.org.uk

Graham Fulford Charitable Trust
Graham Fulford
grahamfulford47@gmail.com

The Focused Ultrasound Foundation
Lasie Riceborough
lriseborough@ukfusf.org

F. Trials

PART: we are keen to support PART which is an RCT between radical prostatectomy and focal HIFU or irreversible electroporation. A number of focal therapy sites such as Imperial and UCLH are sites for PART to enable delivery of focal treatment where other sites are unable to do so. It is important that sites recruiting to PART ensure their patients know that focal therapy is routinely available in the NHS outside of trials. It is important that clinicians no longer use terminology such as 'experimental' or 'unproven' as these are clearly no longer true with the data so far.

TRANSFORM: as Chief Investigator for the TRANSFORM screening trial, I would be keen to hear from any colleagues who would like to be a secondary site for TRANSFORM. Secondary sites must have focal therapy programme in order to participate, and in some circumstances, we may include sites which have close referral links to another focal therapy centre. It is our firm belief that screening harm mitigations include focal therapy as well as MRI, transperineal biopsy, targeted biopsy, and active surveillance.

G. Centres currently interested in or recently started focal therapy

Bath, Plymouth, Cornwall, Dorset, Portsmouth, Birmingham, Warwick, Coventry, Northampton, Worcester, Wolverhampton, Dudley, Colchester, Kings Lynn, Ilford, Watford, Frimley, Wexham Park, Guildford, Newcastle, Leeds, Sheffield, Airedale, Liverpool, Stockport, Lancashire, Wrexham Maelor, Fife, Glasgow, Edinburgh, Aberdeen, Canterbury, Orpington, Isle of Wight.

Please email the TRANSFORM team on transform@imperial.ac.uk for further information.

Please do reach out if you have any questions or queries or need any help.

Best wishes,

A handwritten signature in blue ink, appearing to be the name Hashim, written in a cursive style.

Hashim

