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1. INTRODUCTION

The development of high quality transrectal ultrasound (TRUS) in the 1980s changed the way in which prostate cancer is detected and remains the standard in clinical practice today. The development in understanding of prostate anatomy and the introduction of prostate specific antigen (PSA) into clinical practice were complimentary factors in the rapid uptake of high-frequency TRUS into standard Urological practice in the 1980s and TRUS remains the standard method of routine prostate biopsy in patients where there is a suspicion of prostate cancer to this day.

While various modifications such as micro-bubble contrast, histoscanning and modifications to produce a reliable image-guided system for prostate biopsy have been introduced, none of these technologies have yet over-taken the standard TRUS and biopsy.

MRI scanning continues to improve and more use of multi-parametric MRI images is seen in present Urological practice. At this point, MRI does not have sufficient evidence to allow its use as an image-based biopsy system. Whether this happens in the future depends on good quality studies, such as the PICTURE and PROMIS studies examining the true sensitivity and specificity of MRI compared to TRUS and biopsy on a patient by patient basis (Simmons 2014 et al). At this point in time, TRUS biopsy remains the standard as it is inexpensive, widely available and the procedure is relatively easy to learn. It is also very much an office based procedure with ease of access for patients and clinicians alike.

In the longer term, a reliable image based system is preferable to any form of systematic biopsy but modifications to TRUS will need to be compared to MRI on a cost and effectiveness basis to clarify the optimal system for diagnosis in patients with suspected prostate cancer.
2. PROSTATE ANATOMY

The development of our present understanding was complicated by many contradictory earlier studies (McNeal 1968, Lowesley 1912, LeDuc 1939, Franks 1954, Tisell 1975). The original concept of prostatic lobes was based on studies of foetal and embryonic tissue only and described five separate buds arising from the urethra (Lowesley 1912). These buds were the basis for the description of lobes in the adult prostate comprising an anterior, two lateral, a posterior and a middle lobe. As the embryonic tissue was not fully developed, there was no description of any histological difference between the lobes. This early description of prostate lobes was widely accepted although several authors disagreed with the concept of discrete histological lobes in the adult prostate (LeDuc 1939, Franks 1954, Butter 1959, Blennerhasset 1968).

The concept of an “outer” and “inner” prostate gland was developed by Franks, (Franks 1954, 1956) who could identify no histologically discrete lobes within the adult prostate. The “inner” or periurethral gland area was noted to be the area of benign nodular hyperplasia while the “outer gland” was noted as the area most usually affected by prostate cancer. The description of the peri-urethral area was vague and the studies were based on a single transverse section of the mid-prostate only. However, despite the short-comings of these early studies, the concepts of lobar anatomy and inner and outer gland persisted until more contemporary descriptions by McNeal (McNeal 1968) clarified the true histological heterogeneity of the prostate gland. This description was possible because for the first time, prostate tissue from both embryonic and adult samples was examined in a multi-section approach to allow a three-dimensional model of the prostate gland. From this model, the anatomically separate zones of the adult prostate gland were described in detail giving rise to our present day understanding of the zonal anatomy of the prostate gland.

2.1. Zonal Anatomy

The concept of zonal anatomy of the prostate gland was first propose by McNeal (McNeal 1968) and is central to our present day understanding of prostate cancer and its distribution. The original two-zone concept has now developed into four separate anatomical regions (McNeal 1978,1981)
1. The peripheral zone (PZ)
2. The central zone (CZ)
3. The transition zone (TZ)
4. The anterior fibromuscular stroma

The anatomical course of the prostatic urethra is the key to the zonal anatomy of the prostate. The ductal pattern and entry points into the prostatic urethra formed the basis for the understanding of the separate zones and their drainage into the proximal or distal urethral segment (McNeal 1981). While the central and peripheral zones are described as discrete histological areas, in trans-rectal ultrasound, they are treated as a single entity and reference to the peripheral zone is usually understood to include both zones. The description of the transition zone (McNeal 1978) was initially as part of the explanation of the development of benign prostatic hyperplasia (BPH). The TZ lies anterior to the PZ and while it only constitutes about 5-10% of the young adult male prostate, with age and the development of BPH, the TZ can occupy a large part of the glandular prostate. The histological features of the TZ and PZ are similar but there are marked differences in their stromal densities. The muscle tissue in the main portion of the prostate is normally loosely-woven and of fine texture; however the muscle fibres in the TZ are more compact and course. This difference between the PZ and TZ is accentuated by the development of BPH and is reflected in the appearance of the prostate gland on ultrasound. The final anatomic area of the prostate is the anterior fibro-muscular stroma. This area is continuous with the detrusor fibres of the bladder neck and tapers distally toward the sphincter area. The anterior fibro-muscular stroma is tightly adherent to the glandular tissue of the prostate and is not described as a separate entity in terms of trans-rectal ultrasound.

2.2. Sonographic Appearance of the Prostate

While early studies of transrectal ultrasound (TRUS) proposed a hyperechoic appearance for prostate cancer (Resnick 1978, Peeling 1979), improvement in probe technology and an increase in ultrasound frequency utilized in transrectal imaging indicated that prostate cancer was hypoechoic (Frentzel-Beyne 1983). Important correlation studies between step-sectioned radical prostatectomy specimens and pre-operative transrectal ultrasound images allowed accurate examination of the
sonographic appearance of prostate cancer (Shinohara and Scardino 1986) and confirmed that the majority of ultrasonographically visualized cancers were hypoechoic.

The PZ/CZ area has a fine stippled appearance on TRUS, which is based on the reflection of propagated ultrasound waves by the interfaces between stroma and fluid-filled acinar lumina. The homogenous pattern in the normal PZ is different from the TZ, which is more heterogeneous with variable sized glandular areas and is accentuated by BPH. Muscular, stromal and fibrous tissue free of normal glands have few interfaces and appear hypoechoic. Hollow structures such as cysts have no interfaces and appear anechoic. Familiarity with normal structures in the prostate gland with a hypoechoic appearance improves diagnostic accuracy. These include the urethra and periurethral tissues, the ejaculatory duct complex, the seminal vesicles and the ampulla of the vasa at the base of the prostate and the entry point of the neuro-vascular bundles at the base and apex on each side of the prostate gland. Other benign entities that appear hypoechoic on TRUS are BPH nodules, cysts and areas of prostatitis. The structure of the capsule of the prostate is indicated by the interface between the prostate gland and the surrounding fat. The TZ area may be further accentuated by the presence of corpora amylacea and extensive cancers in the PZ may distort the interface between the PZ and TZ. The hypoechoic appearance of cancer in the prostate gland is due to the destruction of normal glandular tissue by the cancer cells. This produces less acoustic interfaces to reflect the ultrasound waves and a hypoechoic appearance. The widespread introduction of PSA to detect prostate cancer and the detection of smaller and earlier cancers in the prostate gland has created many more cancers that are not visible on TRUS and this has resulted in an evolution in the development of biopsy strategies in men with suspected prostate cancer.

3. BIOPSY STRATEGY

3.1. Sextant Biopsy

While early TRUS was focused on the detection and biopsy of hypoechoic lesions in the PZ, the widespread introduction of PSA as a screening tool increased the number of isoechoic cancers and a new strategy was needed to deal with men with an elevated PSA
but no visible cancer on TRUS. The development of the sextant biopsy strategy (Hodge et al 1989) was an attempt to maximize the detection of cancer in patients with no lesion visible on TRUS but with an elevated PSA. The biopsies were taken between the midpoint and lateral border of the prostate at the base, middle and apex of the gland. While the sextant biopsy protocol led to higher cancer detection than targeting hypoechoic areas alone and became the gold standard method for performing TRUS biopsy, concern developed that subsequent re-biopsy of the same patients led to a significant positive biopsy rate (Eskew et al 1997). The usual cause for the repeat biopsy was suspicious but not diagnostic histology in the original specimen or a rising PSA despite an initial negative biopsy.

3.2. Extended Core Biopsy

Taken in lateral view, sextant cores sampled a portion of the PZ but also tended to include a significant portion of TZ tissue. Subsequent studies of pathology specimens from radical prostatectomy revealed that the vast majority of adenocarcinomas arose in the posterolateral PZ (McNeal et al 1988) and helped explain some of the false negative results of standard sextant biopsy.

Modifications to the standard sextant biopsy were therefore developed with a focus on the importance of laterally directed cores (Terris et al 1992). Presti et al (2000) showed in a study of 483 patients that by adding laterally direct cores from the base and midgland cancer detection was improved from 80% in the standard sextant scheme to 96% with a 10-core scheme. Several other studies have also shown improved cancer detection rates with the addition of laterally directed cores, (Eskew et al 1997; Chang et al, 1998; Babaian et al 2000; Brossner et al 2000; Durkan et al 2002). The extended core scheme should now be seen as the standard of care for routine prostate biopsy for cancer detection.

TZ and SVs are not routinely sampled, because these regions have been shown to have consistently low yields for cancer detection at initial biopsy (Epstein et al 1997; Terris et al 1997b). Such biopsies may however have a role in patients with persistently elevated PSA levels and prior negative biopsies (Mazal et al 2001, Gohji et al 1995).
4. PERFORMANCE OF TRUS BIOPSY

4.1. Indication

Before performing a biopsy, it is imperative that the indication for performing the procedure is confirmed as appropriate. Typically, the need for prostate biopsies is determined on the basis of the serum PSA levels and/or a suspicious digital rectal examination. This information needs to be interpreted in the context of the patient’s wider clinical history and condition. In particular a biopsy should only be performed where it is likely to influence management of the patient’s prostate related condition. The main indications for prostate biopsy are:

- Detection of prostate cancer in patients with:
  - A raised PSA level (in the absence of urinary tract infection, acute urinary retention or acute prostatitis)
  - Abnormal digital rectal examination of the prostate
- Restaging and reassessment in patients for:
  - Rising PSA following non-surgical treatment such as radiotherapy, brachytherapy, cryotherapy or HIFU
  - Active surveillance protocols in patients with known low grade cancer
  - Histology suspicious but not diagnostic for carcinoma
- As part of a protocol in an approved clinical trial

4.2. Consent

Before the TRUS and biopsy is performed, informed consent should be sought from the patient. It is good clinical practice to provide clear written information explaining the procedure, which the patient can read before attending for the procedure. When the purpose and nature of the examination has been explained to the patient, a clear outline of expected complications should be made. The patient should be aware of the risk of:

- Haematuria – up to 60% and is usually self limiting
- Haematospermia - up to 40% and is usually self limiting
- Blood per rectum - common, but severe bleeding only occurs < 1% patients
• Serious infection that could require hospital admission for intravenous antibiotic therapy - approx 3%
• UTI with dysuria - approx 5%
• Lower urinary tract symptoms – up to 50% and is usually self limiting

It is important to identify patients who have significant co-morbidities or are at increased risk of infection (see section 4.4). More recently, the concern of increasing antibiotic resistance has led to the use of rectal swabbing prior to TRUS and biopsy to prevent post-biopsy infection.

4.3. Room Preparation

The procedure should be performed in a suitable clinical room, which should be spacious enough for at least 3-people to be accommodated. Furnishings and floorings should be easily decontaminated in the event of spillage of body fluids.

In addition to a suitable ultrasound unit with transrectal probe, the room should also contain:

• A biopsy gun (disposable)
• Suitable disposable needle-guides
• A 22 gauge spinal needle and 10 cc syringe
• Suitable disposable sheaths to cover the TRUS probes
• Ultrasound-specific lubricating gel
• Suitable local anaesthetic (e.g. Chirocaine 10%)
• A suitable specimen collection system to prevent fragmentation and damage to the biopsy cores
• Specimen pots
• Lubricating jelly
• Disposable gloves
• Wipes / gauze
• Clinical waste bin

As with any invasive medical procedure, the following emergency equipment should also be readily available in the rare event of a major complication:
• Anaphylaxis kit
• Oxygen
• Intravenous fluids and cannula
• Suction
• Cardiac arrest / ‘crash’ trolley

4.4. Patient Preparation

All patients should have their clinical history reviewed prior to the procedure. This review should include the indication for the procedure (as discussed in section 4.1), any comorbidities and a list of current medication.

There is no general consensus on exactly which patients are at increased risk of complications. However, the following list is a guide to some of the risk factors which may require special consideration:

• Patients on anticoagulation therapy or coagulation disorders which may increase the risk of haemorrhage – these may need to be stopped or modified. Low dose aspirin is not considered a contraindication to biopsy (Giannarini et al 2007)
• Risk of endocarditis (previous rheumatic fever, heart valve replacement or endocarditis) – these patients will require prophylactic antibiotic cover. (Aron et al 2000, Gould et al 2006)
• Patients with urinary tract infection (UTI) – the risk of septicaemia may be increased and consideration should be given to deferring the procedure till after treatment of the infection.
• Patients with diabetes mellitus, on steroid medications, or immunocompromised – these patients may be at increased risk of infection and should be considered for a longer course of antibiotics.
• Patients with an allergy to latex, antibiotic prophylaxis or the local anaesthetic – this may require modification of the standard technique or purchase of alternative consumables.
4.5. The procedure

TRUS biopsy is usually performed with the patient in the left lateral position. A digital rectal examination should always be performed. This allows the examiner to assess the overall size of the prostate gland and any areas of induration that help determine areas of suspicion. A multiplaner probe is most satisfactory for TRUS and biopsy (Patel and Rickards 2002). Both longitudinal and transverse images are obtained with minimal discomfort to the patient. Probes must be adequately lubricated before introduction into the rectum. The ultrasound probe is introduced and a satisfactory image obtained.

A measurement of the dimensions of the prostate gland can be taken before commencing the biopsies. The prostate is measured in 3 planes. Typically, in the transverse view, height (H) and width (W) are measured and in the lateral view, length (L) is measured. Most ultrasound machines are capable of automatically calculating the volume, however where this is not possible then the ellipsoid formula of \( \frac{\pi}{6} \times H \times W \times L \) is the most commonly used. It is however recognised that this formula underestimates the size of the prostate (Rodriguez et al., 2008).

In the lateral view, a suitable local anaesthetic agent such as 10ml Chirocaine 10% is placed with a 22 gauge spinal needle between the prostate gland and the rectum. In the correct plane, the local anaesthetic diffuses from apex to base. Initially, a periprostatic local anaesthetic was proposed (Nash 1996, Soloway 2000) which gave satisfactory pain control but the performance of a single needle entry block is more tolerable and efficient (Taverna 2002).

Sedation and analgesia with midazolam and remifentanil used as an adjunct to the standard peri-prostatic nerve block is also safe and effective. Patients undergoing this in addition to nerve block experienced significantly less pain and higher satisfaction scores than those given nerve block alone (Doğanca T et al. 2014, Peters JL et al, 2001).

Patients should be warned before the biopsy is taken and should expect a loud click when the biopsy gun is fired. A 10 or 12 core biopsy strategy is then employed to sample tissue form the prostate gland at the base, mid-gland and apex. This is based on the original sextant biopsy protocol with added lateral cores. The initial biopsy is taken midway between the mid-point of the prostate gland and the lateral margin. The probe
is then rotated laterally and a subsequent biopsy is taken at the same level but more laterally placed to sample tissue from the anterior horn of the peripheral zone (PZ). It is important to place the biopsy needle correctly at the prostate capsule in order to sample the outer-most part of the PZ. The biopsy needle travels a few millimetres forward of its position on TRUS and a frequent error is the insertion of the biopsy needle into the PZ prostatic tissue which results in the biopsy needle passing further into the gland and not sampling the area close to the capsule which is frequently the site of the PZ cancers. It is important to ensure the biopsy sampling is spatially distributed correctly at the base, mid-gland and apex. Care must be taken not to re-biopsy the same area particularly in smaller prostates as this can give misleading information about the extent of the cancer within the gland.

Each biopsy sample should be placed in a histological preservative such as formalin (or other locally agreed alternative). There is currently no uniformly accepted method for submission of the biopsy samples. In some centres, all samples are submitted individually while in others multiple samples may be placed in one container. Such decisions will be based on local factors such as histopathologist preference, costs and availability of focal therapies. It is however, recommended that samples should at least be segregated into left- and right-sided containers.

4.6. Antibiotic prophylaxis for TRUS biopsy

Aerobic and anaerobic organisms are commonly introduced into the prostatic tissue and blood when performing transrectal biopsies. The most common organisms are the gut commensals, *Escherichia coli*, *Streptococcus faecalis* and *Bacteroides species*. While the exact and most effective antibiotic regimen for prevention of infection after prostate biopsy is not agreed, there is extensive evidence to support the use of prophylactic antibiotics at the time of TRUS biopsy (Sieber 1997, Kapoor 1998, Zani 2011). Guidelines should be made locally in consultation with microbiology advice taking into consideration regional antibiotic resistance.

Cleansing rectal enemas carried out before biopsy do not reduce the risk of infection but cause greater discomfort to patients (Carey and Korman 2001). In most centres, antibiotic regimens include the use of fluoroquinolones which have been found to give
superior prophylactic cover (Aron et al 2000). Gentamicin or metronidazole may also be given in addition (Bootsma et al 2008). Fluoroquinolones are well absorbed orally and demonstrate good serum and prostate tissue levels (Webb 2002, Lange et al 2009, Hori et al 2010). However, while fluoroquinolone antibiotic use has been standard in many units for many years, recent evidence advises caution because of increased bacterial resistance to this antibiotic group (Carignan 2012) and development resistance following previous ciprofloxacin exposure. The increase in concern regarding antibiotic resistance has led to proposed use of rectal swab testing for bacterial culture before prostate biopsy (Duplessis 2012, Steensels 2012).

In patients where particular risks occur such as patients with artificial heart valves or other cardiac conditions, consideration should be given to antibiotic protocols such as intravenous Teicoplanin and Gentamycin to prevent severe complications such as endocarditis (Gould et al 2006).

4.7. Post-procedure care

After the procedure, it is important to re-iterate to the patient the potential complications of the procedure and particularly what signs to look for in terms of infection, retention or persistent bleeding. They should be advised to rest, take their prophylactic antibiotics, drink good amounts of fluid and not drive immediately after the procedure. Patients with an indwelling catheter, diabetes mellitus, immunosuppression, etc. should be particularly vigilant for the signs of infection.

For patients on anti-coagulation treatment, local advice should be sought from the haematologist as to when it is appropriate to restart treatment. The risk of aggravating bleeding needs to be weighed up against the indication for which the anticoagulation has been prescribed. Nonetheless, for most patients, in the absence of severe or persistent bleeding, anticoagulation treatment can be restarted within 24-48 hours.

5. COMPLICATIONS AND THEIR MANAGEMENT

Published evidence suggests that discomfort relating to the procedure and major complications are independent of the number and location of prostate biopsy cores
performed but younger men suffer significantly more discomfort and may benefit from additional pain relief (Rodriquez et al 1998).

5.1. Types of complication

The majority of patients tolerate the procedure with low levels of discomfort and experience minimal side-effects including haematuria, haematospermia, blood in the stools, and dysuria. Quoted rates of haematuria range from 62% to 6.5%; haematospermia from 37.4 to 9.8%; rectal bleeding 2.4% to 0.7%; dysuria infection 7.2% to 6%. (Djavan et al 2001, Ecke et al 2008, Heidenreich et al 2011). While these complications frequently resolve within a few days, they may persist for around two weeks but are mostly self-limiting.

The rate of severe complications following prostate biopsy is low. Fever episodes have been reported in up to 2.9% of cases (Djavan et al 2001). Urinary retention is rare with quoted frequencies as low as 0.2-0.3% of cases (Ecke et al 2008, Heidenreich et al 2011). Quoted figures for hospitalisation following prostate biopsy range from 0.3-0.6% (Ecke et al 2008, Heidenreich et al 2011). More recent information is available from the GPIU study (Wagelehner et al, 2013).

5.2. Management of complications

In patients with a severe infection related complication such as fever, UTI, prostatitis or epididymitis) a prolonged course of antibiotic treatment should be considered. In severe septicaemia, patients should be admitted to hospital and given intravenous antibiotics.

In cases of urinary retention or severe haematuria with potential clot retention, a catheter should be inserted. Again this may require hospitalisation depending on the cause of retention and the patient’s ability to manage a catheter.

Profuse bleeding from the rectum will often respond well to direct pressure by either a digit or the TRUS probe. For more severe haemorrhage, insertion of a Foley catheter into the rectum with the balloon filled has been shown to be effective (Kilciler et al 2008) as has endoscopic haemostasis (Brullet et al 2000).
6. Recommendations for training and accreditation.

It is recommended that training for TRUS and prostate biopsy consist of theoretical and practical components.

6.1 Theoretical

The ability to undertake prostate biopsy competently and safely is a developmental process and is a skill only expected to be undertaken by a trained specialist healthcare professional (HCP). The HCP is not simply expected to act as a technician but as a rational decision maker.

Learners should attend a BAUS/BAUN recognised course on TRUS and biopsy to ensure they have adequate knowledge of the anatomy of the prostate and the mechanism of prostate biopsy.

The performance of the technical procedure of TRUS and biopsy should not be seen as independent of the clinical management of prostate cancer. With particular reference to patient consent, the clinician performing such a procedure must possess adequate theoretical knowledge to assess the indication and be satisfied it is appropriate. The guidance for training of all health care professionals is based on the presumption that individuals will gain considerable experience in the clinical diagnosis and management of prostate cancer.

To ensure standards and evidence based practice in prostate cancer diagnostics is maintained it is important that clinicians / trainees / specialist nurses remain up to date with the developments in this field both in relation to technology and scientific advances and maintain ongoing competence in this field.

6.2 Skills acquisition and development

The HCP is required to have an intimate understanding of the anatomy and physiology of the male urinary system, factors which affect PSA measurement and other conditions of the urinary system and their management. An understanding of the role of transrectal ultrasound and possible ultrasound findings are important. The HCP must also be familiar with the possible complications of TRUS and their management and
must always ensure that the senior staff are available should an emergency situation arise.

It is important that the health care professional is able to demonstrate knowledge and understanding in several areas: legislation, clinical expertise, technical knowledge and the ability to communicate effectively with the patient. In addition it is paramount that the HCP is aware of any limitations in knowledge or ability to manage a situation and that the health care professional knows how and when help from a senior colleague is required.

The HCP should be trained by a competent HCP but ultimately competence should be assessed by an experienced urologist or radiologist, in the case of urological trainees using either DOPS (direct observation of procedural skill) form or PBA (procedure based assessment) form, available at www.iscp.org.uk. The individual HCP is responsible for their continuing professional development in relation to prostate cancer and prostate biopsy and should work within their own professional code of conduct.

6.3 Skills Acquisition and Record Keeping

Training should take place in an appropriate Urology or Radiology department under the supervision of a trainer who is experienced in the performance of TRUS and biopsy. A variety of healthcare professionals may be involved in the training of an individual.

During specialised training in Urology in the UK, it is recommended by the Specialist Advisory Committee that all trainees should perform at least 50 TRUS (both supervised and latterly unsupervised) and record their outcomes in the ISCP logbook, attaining a competency level of 4 for the procedure. The trainee should continue to have direct supervision by the trainer until such time as the trainer is satisfied that the trainee is competent to perform the procedure. Competency assessment should be recorded as:

D = Development required
S = Satisfactory standard for CCT (no prompting or intervention required)
For nurse specialists a minimum of 20 cases should be performed under supervision (EAUN Guidelines; Turner et al. 2011).

TRUS and biopsy data should be audited to ensure adequacy of biopsy specimens, complication rate of patients undergoing TRUS and biopsy and a comparison of positive biopsy rates against the standard should also be recorded. The cases may be recorded in the same manner as the standard logbook record for other clinicians / specialist nurses.

Each practitioner should have a named consultant directly responsible for the regular audit of outcome and management of complications. Examples and guidance for how this can be achieved exist within the published literature (Turner and Pati 2010).

In the case of trainee urologists the trainer should sign off the trainee once 50 cases have been performed (the JCST indicative number) and this evidence may be submitted to JCST on completion of training. This information can then be recorded as part of the trainee’s application for CCT and can be used as evidence of competency in TRUS and biopsy.
## Guidelines and Best Practice for Clinicians Undertaking Trans-rectal Ultrasound and Biopsy

In-depth understanding of:

- National guidelines and local policies and guidelines for undertaking trans-rectal ultrasound guided biopsy of the prostate.
- National and local infection control and policies and guidelines and their application to transrectal biopsy of the prostate.
- The national and local policies and guidelines for risk management and adverse incidents.

### Clinical and technical

- Describes indications, anatomy, physiology, procedure and complications
- Obtains consent, after explaining procedure & possible complications
- Prepares patient and equipment for procedure
- Administers effective local anaesthesia
- Performs the technical aspects of the procedure
- Deals with any unexpected event or seeks help when appropriate
- Completes required documentation
- Communicates clearly with patient & staff throughout the procedure
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