

The Synapse

The Medical Professionals' Network

M E D I C A L I M A G I N G

Ultrasound Evaluation of the Shoulder

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High-resolution real-time ultrasound US has been shown to be a successful imaging modality for both rotator cuff and non-rotator cuff disorders. Advances in technology have substantially improved US image quality, producing spatial resolution the may exceed that obtained with magnetic resonance imaging. Also, US is inexpensive, fast, and offers dynamic capabilities for examining the patient in multiple scanning planes and specific arm positions or during movements. Ultrasound also allows one to focus the examination on the precise region of maximum discomfort as indicated by the patient.

The rotator cuff consists of four muscles and their tendons: subscapularis, supraspinatus, infraspinatus, and teres minor. Non-rotator cuff structures include the long head of biceps tendon, the subdeltoid bursa and the acromio-clavicular joint.

All rotator cuff tendons are readily visualised with ultrasound (Figures 1-3). The tendon of



Figure 1. The subscapularis tendon (arrows) demonstrates an internal fibrillar pattern and lies below the deltoid muscle anterior to the shoulder joint.



Figure 2. Supraspinatus tendon is seen as an echogenic band superior to the humeral head, with a convex upper surface; it tapers toward the greater tuberosity. The arrow indicates a hypoechoic area due to tendon anisotropy.

the long head of the biceps is also well visualized within the bicipital groove (Figures 4 & 5).

Rotator cuff abnormalities represent a spectrum ranging from tendinosis to massive tear. Tendinosis is tendon degeneration without clinical or histologic signs of inflammatory response, and on ultrasound the tendon shows a diffuse heterogeneous hypoechoogenicity (Figure 6).



Figure 3. The infraspinatus tendon (arrows) lies posterior and inferior to the supraspinatus tendon on the posterior aspect of the humeral head. Double arrows outline the glenoid labrum.



Figure 4. Biceps tendon, longitudinal view (arrows) is seen as an echogenic structure with an internal fibrillar pattern.

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Editor's Word

Welcome to another interesting issue of The Synapse Magazine, which actually marks its sixth anniversary. Apart from the regular contributions on radiology and avian influenza, you will find articles on **The Pharmacy of Your Choice** scheme by Mary Ann Sant Fournier, Part I of **Unravelling the Tangle of Genetic Testing** by Dr Chris Scerri and the second and last part of the article discussing the controversial topic – **Data Protection Act**, presented by Professor Pierre Mallia. You will also find articles by Dr Edgar Pullicino on **Treating Gastro-oesophageal reflux disease with sense** and by Dr Charmaine Gauci discussing the **450 daily cases of Infectious Intestinal Disease in Malta**. Furthermore, as part of the series of contributions on stress management, we proudly present the first **Letter from Your clinical psychologist**.

In this issue we get to meet Dr Victor Calvagna, who is often seen on our local media representing the Puttinu Cares Support Group.

Wilfred Galea

The Synapse Magazine is published by Medical Portals Ltd. The Professional Services Centre, Guzi Cutajar Street, Dingli, Malta.

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Scientific Editor: Ian. C. Ellul
Designer: Conrad Bondin

Ultrasound Evaluation of the Shoulder



Figure 5. Biceps tendon in transverse view (BT) lies below the coraco-humeral ligament (CHL, arrows) and between the supraspinatus (SS) and subscapularis (SSC) tendons.



Figure 6. Supraspinatus tendonitis appears as heterogeneous echogenicity without any focal area representative of a tear.



Figure 7. Complete tear of the supraspinatus tendon with retraction; note that there is no supraspinatus tendon between the deltoid muscle and humeral head.



Figure 8. A full-thickness tear is seen in the supraspinatus tendon involving the anterior aspect of the tendon. The defect fills with anechoic joint fluid.

With a full thickness tear of the supraspinatus tendon, the tendon is absent on longitudinal view and the deltoid muscle lies in contact with the humeral head (Figure 7). A full thickness tear may only involve part of the tendon, where the tendon defect fills with joint fluid (Figure 8).

A partial-thickness supraspinatus tendon tear may lie either on the articular or the bursal surface of the tendon. An articular-side partial-thickness tear appears as a distinct hypoechoic or mixed hyper-hypoechoic defect of the articular surface (Figure 9). A bursal-side partial-thickness tear produces flattening of the bursal surface, with loss of the superior convexity of the tendon (Figure 10).

Secondary US signs of a tendon tear are surface irregularity of the greater tuberosity (Figure 10) and the presence of fluid in the joint and the bursae (Figure 12). Essential information for the orthopaedic surgeon includes characterization of the tear, the dimensions and location of the tear, and the amount of tendon retraction on the longitudinal view.



Figure 9. Supraspinatus tendon, longitudinal view shows an articular-side partial-thickness tear as a distinct hypoechoic defect (arrow) at the tendon's articular surface.



Figure 10. Supraspinatus tendon articular side partial thickness tear may present as cortical bone irregularity (arrows) at the greater tuberosity. (S = supraspinatus, I = infraspinatus.)



Figure 11. Greater tuberosity, transverse view. A massive fluid collection (FL) is seen in the subdeltoid bursa.

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References:

1. Philipp T. et al. Clin Therapeutics 2007; 29 (4): online 1-18
2. Poldermans D. et al. Clin Therapeutics 2007; 29 (2): 279-289

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Interactions: Caution is required with concomitant use of CYP 3A4 inhibitors (eg. ketoconazole,

itraconazole, ritonavir), CYP 3A4 inducers (eg carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone, rifampicin, Hypericum perforatum). Caution is required when used together with NSAIDs, COX-2 inhibitors, acetylsalicylic acid and non-selective NSAIDs. Concomitant use is not recommended however if the combination proves necessary, caution and monitoring of serum potassium levels when used concomitantly with potassium supplements, potassium sparing diuretics, salt substitutes containing potassium, or other drugs that may increase potassium level and of serum lithium levels when used with lithium.

Adverse reactions: The most common adverse reactions are: Nasopharyngitis, influenza, headache, oedema peripheral, pitting oedema, facial oedema, fatigue, flushing, asthenia, vertigo, tachycardia, palpitations, orthostatic hypotension, cough, pharyngolaryngeal pain, diarrhoea, nausea, abdominal pain, constipation, rash, erythema, joint swelling, back pain, arthralgia, dizziness, somnolence, dizziness postural, paraesthesia. Peripheral oedema, a recognised side-effect of amlodipine, was generally observed at a lower incidence in patients who received the amlodipine/valsartan combination than in those who received amlodipine alone. Rare adverse reactions but potentially serious are: Hypersensitivity. Additional potentially serious adverse experiences reported in clinical trials with amlodipine monotherapy are: Gastritis, gingival hyperplasia, gynaecomastia, leucopenia, myalgia, pancreatitis, hepatitis, thrombocytopenia, vasculitis. Additional potentially serious adverse experiences reported in clinical trials with valsartan monotherapy are: Viral infections, upper respiratory infections, sinusitis, rhinitis, neutropenia, insomnia. Altered renal function, especially in patients treated with diuretics or in patients with renal impairment, angioedema and hypersensitivity (vasculitis, serum sickness) can occur.

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Treating Gastro-oesophageal reflux disease (GERD) with sense

by **Edgar Pullicino**

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Gastro-oesophageal reflux disease (GERD) is a common disorder that affects an estimated 5% to 7% of the global population. Management of GERD often poses a number of challenges. In this article, the author presents a number of management modalities for this condition.

Treat now, test later

A therapeutic trial of a high dose twice daily proton pump inhibitor (PPI) (taken before food to increase acid suppression, and with good compliance) will lead to partial or complete relief of suspected acid reflux-related symptoms (e.g. heartburn, cough), in the majority of unselected cases. Gastro-oesophagoscopy is mandatory in patients with alarm symptoms (e.g. dysphagia, weight loss) and is advisable in patients with chronic reflux symptoms to exclude Barrett's oesophagus (figure 1), a columnar epithelial metaplasia with an increased risk of progression to dysplasia and oesophageal carcinoma that necessitates regular endoscopic surveillance. PPIs rarely reverse this condition but may decrease its cancer potential and they allow the pathologist to assess dysplasia better by abolishing inflammatory atypia.

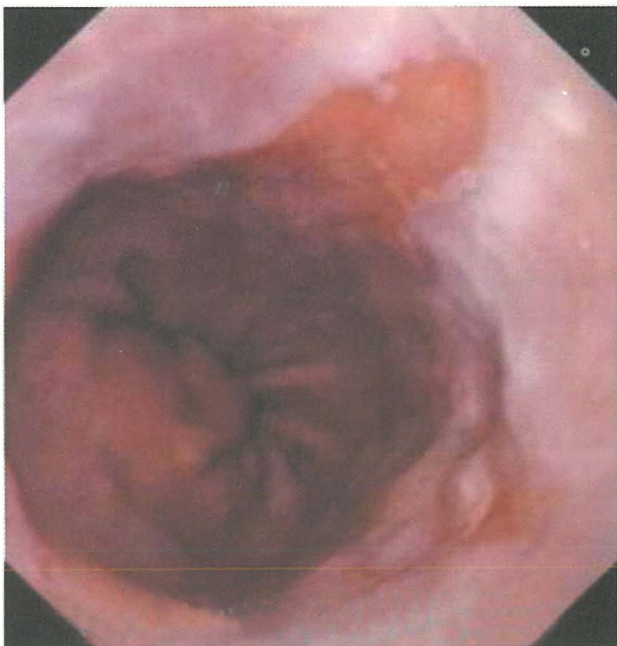


Figure 1: Barrett's oesophagus

When PPIs 'fail'

Endoscopic appearances of low-grade (figure 2) or high-grade (figure 3) oesophagitis are highly diagnostic of GERD and predict symptomatic relief by PPIs but symptoms often recur on withdrawing PPIs. Ironically, a less satisfactory group to treat are those patients with a normal endoscopy (non erosive reflux disease (NERD), figure 4). About 60% of NERD patients will obtain complete symptom relief on single dose daily PPIs. Only 5% of non-responders will

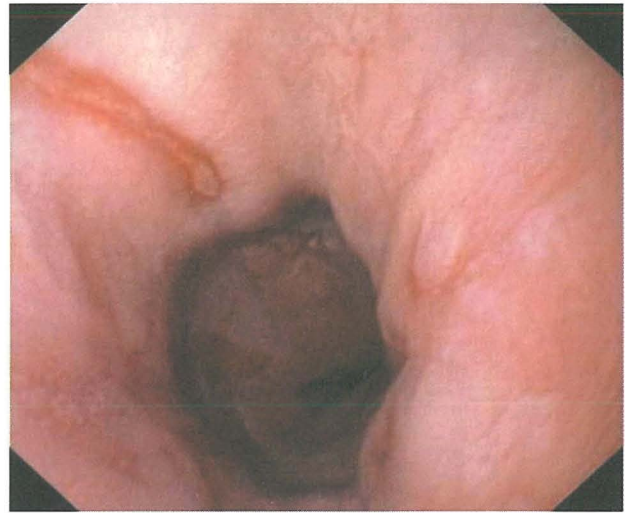


Figure 2: Mild oesophagitis

show significantly abnormal 24 hour oesophageal pH monitoring patterns during twice daily PPI treatment. Indeed, multichannel intraluminal impedance probes correlate episodes of non-acid reflux with symptoms in these patients. Biopsies from NERD patients exhibit marked widening of the spaces between the squamous epithelial cells lining the lower oesophagus that allow pepsin, refluxed duodenal bile acids and other noxious agents to sensitize

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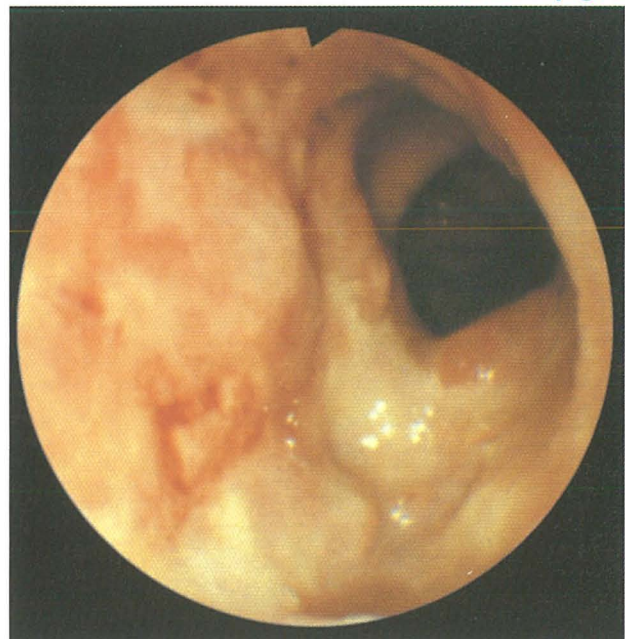


Figure 3: Severe oesophagitis



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REFERENCES: 1- Pariet[®] Summary of Product Characteristics, July 2003. 2- Review article: Relationship between the metabolism and efficacy of proton pump inhibitors - focus on rabeprazole; J. HORN, Aliment Pharmacol Ther 2004; 20 (Suppl. 6): 11-19. * TM Eisai Co., Ltd., Tokyo, Japan.

Treating Gastro-oesophageal reflux disease (GERD) with sense

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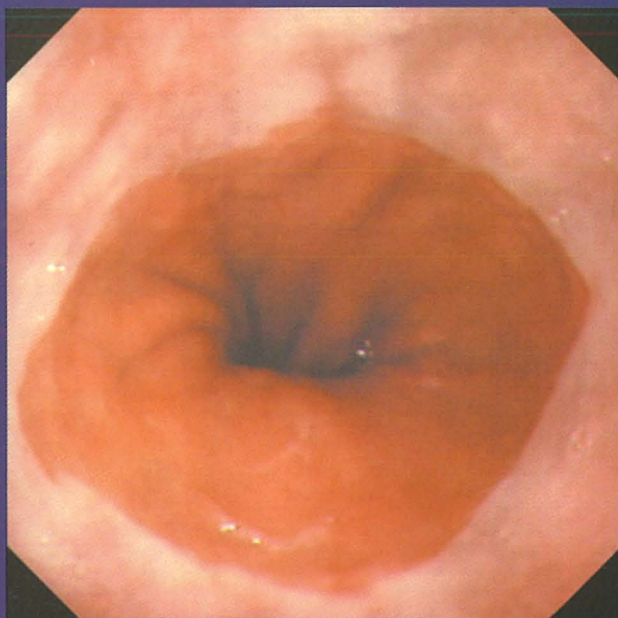


Figure 4: Normal lower oesophagus

oesophageal submucosal nerve endings. NERD patients have a higher pain sensitivity to short duration reflux episodes than those with erosive oesophagitis.

A sub-group of these NERD patients have normal pH studies off PPI and are classified as having functional heartburn. Many of these patients show pain hypersensitivity to physiologic amounts of acid exposure and to minor oesophageal distension. Not surprisingly they obtain limited relief from high dose PPIs. Another NERD subgroup do not show any correlation between acid reflux episodes during ambulatory pH monitoring and pain. They have a visceral hyperalgesia to low intensity stimuli which are totally unrelated to reflux events and will not respond to PPI. Alginates, prokinetic agents and life style changes may be tried but central pain modulators such as tricyclic antidepressants are more likely to bring relief.

PPIs on demand?

Given that endoscopically proven NERD rarely progresses to an erosive oesophagitis, it makes economic and practical sense to step down from empiric double-dose PPI therapy to single dose PPI therapy or to intermittent (doctor-driven) or on-demand (patient-driven) PPI regimens. Studies have shown that compliance to once daily PPI regimen is poor in well patients who often pursue an on-demand approach.

When necessary, long-term PPI therapy is safe. PPIs reduce the usual acid-induced inhibition of gastrin secretion by the antral 'G' cells. The resultant mild hypergastrinaemia may cause hyperplasia of the enterochromaffin-like (ECL) cells but progression from hypertrophy to dysplasia or to gastric carcinoid neoplasia, which has been observed in rats on high doses of PPIs, does not occur in humans. Acid suppression does allow mild bacterial overgrowth to occur in the upper intestine but again, no untoward effects have been observed.

Helicobacter pyloric (Hp) and GERD: strange bed fellows

Gastric Hp colonization causes focal atrophic gastritis in the body of the stomach, destroys parietal cells and reduces acid output. Eradication of this natural biologic antisecretory agent could, in theory, worsen GERD or Barrett's oesophagus and induce oesophageal adenocarcinoma. Many gastroenterologists would choose to eradicate gastric Hp in an attempt to prevent the progression of atrophic gastritis to metaplasia and carcinoma although large-scale population-controlled studies of potential cancer prevention are not available. Hp-related duodenal or gastric ulcer (past or present) or Hp-related low grade primary B-cell MALT lymphoma require Hp eradication.

Non medical treatment

Patients who persist with severe heartburn, regurgitation or aspiration despite PPIs or who refuse long term PPIs, may be considered for antireflux surgery following extensive investigation using endoscopy, oesophageal monitoring, gastric emptying studies and 24 hour pH testing. Functional heartburn, gastroparesis, achalasia and scleroderma must be excluded. The presence and size of a hiatus hernia should be assessed radiologically. The most popular operation is a laparoscopic (Nissen) fixation and wrapping of the gastric fundus around the lower oesophagus. Dysphagia and gas-bloat may result from too tight an application. The operation is not always superior to PPIs in the long term and rarely cures Barrett's oesophagus.

Endoscopic therapeutic options include endoscopic suturing, silicon injection and radiofrequency (RF) treatment. RF treatment is achieved using a cooled (Stretta®) balloon (figure 5) with retractable barbs that are deployed after endoscopy to apply current at various levels to the lower oesophageal sphincter. This treatment is reported to give

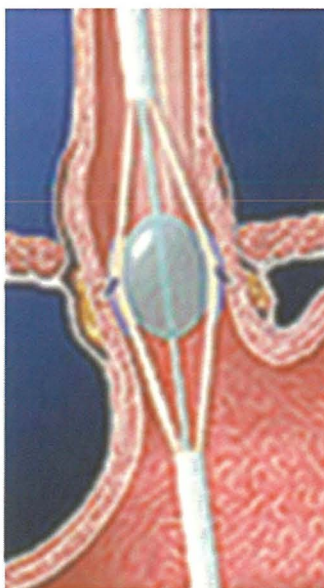


Figure 5: Stretta® device

good long-term relief but is not recommended for use in patients with a large hiatus hernia or Barrett's oesophagus.

Management of the GERD patient should be guided by an understanding of the interaction between abnormalities of anatomy or motility, patterns of acid/pepsin exposure and the corresponding responses in the oesophageal mucosa. Rational management can be planned after appropriate investigations using endoscopy, biopsies and more specialized techniques where necessary. ☐

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¹ Lam, M. *BMJ* 2000; 320: 861-864.
² Katan, MB et al. *Mayo Clin Proc* 2003; 78: 965-978.
³ Jones PJ et al. *J Lipid Res* 2000; 41: 697-705.
⁴ Poutouc, EB et al. *Eur J Nutr* 2003; 42: 154-164.

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A dosage of more than 4mg glimepiride per day gives better results only in exceptional cases. The maximum recommended dose is 6mg glimepiride per day. In patients not adequately controlled with the maximum daily dose of metformin, concomitant glimepiride therapy can be initiated. While maintaining the metformin dose, the glimepiride therapy is started with a low dose, and is then titrated up depending on the desired level of metabolic control up to the maximum daily dose. The combination therapy should be initiated under close medical supervision. In patients not adequately controlled with the maximum daily dose of Amarel, concomitant insulin therapy can be initiated if necessary. While maintaining the glimepiride dose, insulin treatment is started at low dose and titrated up depending on the desired level of metabolic control. The combination therapy should be initiated under close medical supervision. Normally a single daily dose of glimepiride is sufficient. It is recommended that this dose be taken shortly before or during a substantial breakfast or if none is taken - shortly before or during the first main meal. If a dose is forgotten, this should not be corrected by increasing the next dose. Tablets should be swallowed whole with some liquid. If a patient has a hypoglycaemic reaction on 1 mg glimepiride daily, this indicates that they can be controlled by diet alone. In the course of treatment, as an improvement in control of diabetes is associated with higher insulin sensitivity, glimepiride requirements may fall. To avoid hypoglycaemia timely dose reduction or cessation of therapy must therefore be considered. Change in dosage may also be necessary, if there are changes in weight or life style of the patient, or other factors that increase the risk of hypo- or hyperglycaemia. Switch over from other oral hypoglycaemic agents to Amarel: A switch over from other oral hypoglycaemic agents to Amarel can generally be done. For the switch over to Amarel the strength and the half-life of the previous medication has to be taken into account. In some cases, especially in antidiabetics with a long half-life (e.g. chlorpropamide), a wash out period of a few days is advisable in order to minimise the risk of hypoglycaemic reactions due to the additive effect. The recommended starting dose is 1 mg glimepiride per day. Based on the response the glimepiride dosage may be increased stepwise, as indicated earlier. Switch over from insulin to Amarel: In exceptional cases, where Type 2 diabetic patients are regulated on insulin, a changeover to Amarel may be indicated. The changeover should be undertaken under close medical supervision. **Contraindications:** Amarel should not be taken in the following cases: • under coma or ketoacidosis status, • insulin dependent diabetes, severe renal or hepatic function disorders, • hypersensitivity to glimepiride, other sulphonylureas or sulphonamides or excipients in the tablet, • pregnancy and lactation. In case of severe renal or hepatic function disorders, a change over to insulin is required. **Special precautions and warnings for use:** Amarel has to be taken shortly before or during a meal. In case of meals at irregular intervals, especially skipped meals, treatment with Amarel may lead to hypoglycaemia. The possible symptoms of hypoglycaemia include e.g. headache, ravenous hunger, nausea, vomiting, lassitude, sleepiness, disordered sleep, restlessness, aggressiveness, impaired concentration, alertness and reaction time, depression and confusion, dizziness and visual disorders, aphasia, tremor, paresthesia, sensory disturbances, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and loss of consciousness up to and including coma, shallow respiration and bradycardia. In addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac arrhythmias. The clinical picture of a severe hypoglycaemic attack may resemble that of a stroke. The symptoms nearly always subside by immediate intake of carbohydrates (sugar). Artificial sweeteners have no effect. It is known from other sulphonylureas that, despite initially successful countermeasures, hypoglycaemia may recur. In case of severe hypoglycaemia or over a protracted period, only temporarily controlled by the usual amounts of sugar, immediate medical treatment and occasionally hospitalization is required. Factors favouring hypoglycaemia include: • unwillingness or (more commonly in older patients) incapacity of the patient to cooperate, • undernutrition, irregular mealtimes or missed meals or periods of fasting, • alterations in diet, • imbalance between physical exertion and carbohydrate intake, • consumption of alcohol especially in combination with skipped meals, • impaired renal function, • serious liver dysfunction, • overdosage with Amarel, • certain uncompensated disorders of the undesired increases and decreases in the hypoglycaemic action of glimepiride can occur. For this reason, other medicines should be taken with the knowledge (or at the prescription) of the doctor. Glimepiride is metabolized by cytochrome P450 2C9 (CYP2C9). Its metabolism is known to be influenced by concomitant administration of CYP2C9 inducers (e.g. rifampicin) or inhibitors (e.g. fluconazole). Results from in vivo interaction study reported in literature show that glimepiride AUC is increased approximately 2-fold by fluconazole, one of the most potent CYP2C9 inhibitors. Based on the experience with Amarel and with other sulphonylureas, the following interactions are to be mentioned. Potentiation of the blood-glucose-lowering effect and, thus, in some instances hypoglycaemia may occur when one of the following drugs is taken: for example phenylbutazone, azapropazone and oxyfenbutazone, sulphinpyrazone, insulin and oral antidiabetic products, certain long acting sulphonamides, metformin, tetracyclines, salicylates and p- amino salicylic acid, MAO-inhibitors, anabolic steroids and male sex hormones, quinolones, antibiotics, chloramphenicol, probenecid, coumamm, anticoagulants, miconazole, fenfluramine, pentoxifylline (high dose parenteral), fibrates, triptolaine, ACE inhibitors, fluconazole, fluroxetine, allopurinol, sympatholytics, cyclo-, tri- and phosphamides. Weakening of the blood-glucose-lowering effect and, thus raised blood glucose levels may occur when one of the following drugs is taken: for example oestrogens and progestagens, salicylates, theobromine, diuretics, thyroid stimulating agents, glucocorticoids, phenothiazines, derivatives, chlorpromazine, adrenaline and sympathomimetics, nicotinic acid (high dosages) and nicotinic acid derivatives, laxatives (long-term use), phenylon, diazoxide, glucagon, barbiturates and rifampicin, acetazolamide, H2 antagonists, betablockers, clonidine and reserpine may lead to either potentiation or weakening of the blood glucose lowering effect. Under the influence of sympatholytic drugs such as betablockers, clonidine, guanethidine and reserpine, the signs of adrenergic counter-regulation may be reduced or absent. Alcohol intake may potentiate or weaken the hypoglycaemic action of glimepiride in an unpredictable fashion. Glimepiride may either potentiate or weaken the effects of coumamm derivatives. Based on the metabolic reaction the glimepiride dosage may be increased stepwise, as indicated earlier. **Overdose - Treatment:** After ingestion of an overdose hypoglycaemia may occur, that may last 12 to 72 hours and that may recur after recovery. The symptoms may not occur till 24 hours after ingestion. In general observation in a hospital is therefore recommended. Nausea, vomiting and epigastric pain may occur. The hypoglycaemia may in general be accompanied by neurological symptoms like unrest, tremor, visual disturbances, coordination problems, sleepiness, coma and convulsions. Treatment primarily consists of preventing that glimepiride is absorbed by inducing vomiting and then drinking water or lemonade with activated charcoal (adsorbent) and sodium-sulphate (laxative). In case large quantities have been ingested, gastric lavage is indicated, leaving activated charcoal to be used afterwards and sodium-sulphate. In case of (severe) overdose hospitalization in an intensive care department is indicated. Start as soon as possible with the administration of glucose, if required first 50ml of a 50% solution intravenous as bolus, followed by infusion of a 10% solution under strict control of blood glucose. Further symptomatic treatment. In particular when treating hypoglycaemia due to accidental intake of Amarel in infants and young children, the dose of glucose given must be carefully adjusted in view of the possibility of producing dangerous hypoglycaemia, and must be controlled by close monitoring of blood glucose. **Undesirable Effects:** Based on experience with Amarel and with other sulphonylureas the following side effects have to be mentioned: • **Immune system disorders:** In very rare cases mild hypersensitivity reactions may develop into serious reactions with dyspnoea, fall in blood pressure and sometimes shock. Allergic vasculitis is possible in very rare cases. Cross allergy with sulphonylureas, sulphonamides or derivatives is possible. • **Bleeding and lymphatic system disorders:** Changes in haematology are rare during Amarel treatment. Moderate to severe thrombocytopenia, leucopenia, erythrocytopenia, granulocytopenia, agranulocytosis, haemolytic anemia and pancytopenia may occur. These are in general reversible upon discontinuation of medication. • **Metabolism and nutrition disorders:** In rare cases hypoglycaemic reactions have been observed after administration of Amarel. These reactions usually occur immediately after intake and are not always easy to correct. The occurrence of such reactions depends, like for every diabetes therapy with medicines, on individual factors such as dietary habits and the dosage (see further under 'Special warnings and special precautions for use'). • **Eye disorders:** Transient visual disturbances may occur especially at the commencement of treatment, due to changes in blood glucose levels. • **Gastrointestinal disorders:** Gastrointestinal complaints like nausea, vomiting and diarrhoea, pressure or a feeling of fullness in the stomach and abdominal pain are very rare and seldom lead to discontinuation of therapy. • **Hepato-biliary disorders:** Elevation of liver enzymes may occur. In very rare cases, impairment of liver function (e.g. with cholestasis and jaundice) may develop, as well as hepatitis which may progress to liver failure. • **Skin and subcutaneous tissue disorders:** Hypersensitivity reactions of the skin may occur as itching, rash and urticaria. In very rare cases hypersensitivity to light may occur. • **Investigations:** In very rare cases, a decrease in the sodium serum concentrations may occur. **Expiry date of the product:** It should be stated on the outer and inner package. Do not use after the expiry date shown. **Special precautions for the storage of the product:** Amarel must not be stored above 25 °C. In order to be protected from moisture, it should be stored in the original package. **MODE OF SUPPLY:** This medicine is subject to a medical prescription. **Holder of Marketing Authorization:** Aventis Pharma AEBE (2, Afrocatoros Nicolau str., GR-176 71 Athens, Greece, tel.: 0030 210 90 01 600, tel. Malta: 21493022) MA No: 082/00201-4

Letter from Your clinical psychologist

As summer approaches, more and more members have some time to reflect on the stresses of life and what one can do to minimise the effects of these stresses. TheSYNAPSE has invited a highly experienced clinical psychologist to share some useful advice with members. This will be spread out over a series of articles, each in the form of a letter. The aim of these articles is to help readers improve the quality of their personal lives.

Dear colleague,

I have been invited by the editorial board to write four brief letters that will sow some seeds of personal awareness and self care in you as an esteemed reader of *The Synapse Magazine*.

I have been asked to share with you a few practical tips and ideas about how you, as a professional person and a human being working in our health sector, can achieve a healthier work-life balance. This is my first letter to you out of four, all of which will cover different but complementary areas of work-life balance.

I know that the area of self care and anything to do with psychology is often considered as 'exotic' by many in the medical and paramedical professions. So for you to read on, I really have to trigger your curiosity fast. Will certain buzz words that you might imagine as being linked to you personally, like communication, loneliness, stress, burnout, anxiety and depression do the trick? Or are you more into the scarier tactics like 'have a heart attack' or 'you need to see a psychologist' help you to read on?

I would appreciate some of your time because I am sure that like me, you too are aware that the number of colleagues finding themselves in psycho-social difficulties and seeking professional help is increasing. I also know that a contribution like this in such a publication is different to what you are normally used to. Shining a spot light on our own needs is not generally welcome but this initiative by *The Synapse* is genuine and truly deserves support and praise.

I take it for granted that you care for yourself even if you work too many hours and find it hard to relax and reflect on your own personal needs and expectations. I believe that for someone who is constantly looking after and addressing the needs of other persons, like patients and clients, so that they can be reasonably happy and healthy, you too merit the same treatment and care.

To me, good health implies a reasonably happy balance in the following human dimensions – mental, physical, emotional, spiritual and social. If one or more dimension is not within personally acceptable limits, then the person tends to pass through a distressing or vulnerable stage whereby his/her behaviours are also influenced. The longer this stage persists, the more worrisome and difficult the situation becomes.

I believe that the first step towards a happier and healthier well-being is good **intra-personal communication**. With good intra-personal communication you enjoy a level of self awareness that in turn allows for a better appreciation of and response to core personal needs and expectations. Once your needs and expectations are being truly respected and

understood, then the first and most important step towards self care and a better work-life balance is done. With this achievement secured, intrinsic motivation for more self awareness and action increases naturally. In turn this encourages you to pursue previously considered alien behaviours that will in turn help you achieve the work-life balance and self care you deserve.

Being able to communicate with yourself in a healthy and constructive manner is both necessary and satisfying. I encourage you to take some time and space to perform a short pencil and paper exercise as my first recommendation for the day.

Take a clean sheet of paper, empty on both sides, and something to write with and follow the following 5 simple steps outlined here below. Do not skip any steps and this 'activity map' exercise will take you about 15 minutes to do.

Step 1

On one side of the paper, make a general list of where your time goes over a normal 7-day period. How do you normally spend the 168 hours in a week? What do you generally do with your time? Consider how much time you dedicate over one whole week to sleep, to work, to hygiene, to eat, to shop, to exercise, for chores, pets, television, etc. Take the most obvious chunks of time and list them down so that when you add them all up, altogether, you reach a total of 168 or thereabout. Do not worry too much about reaching an exact 168 hours!

Step 2

Once you are ready and you have a reasonable breakdown of activities, turn the piece of paper and find a creative way to map the sub totals you listed in terms of hours. You can either map the hours in a terms of a pie chart, or a histogram with activities along the x-axis and time on the y-axis. Just find a simple and visual way to represent your activities.

Step 3

Once you finish your 'activity map', look at it as objectively as possible and reflect on this question: *'When I look at this map, what does it say about the person who drew it?'*

Take a few moments to reflect and write down what comes to your mind on your piece of paper. Write down what the map says about the person who drew it. Try to be as objective as possible.

Step 4

Well, what do you think? Are you happy or dissatisfied with what you objectively see in yourself? Is there something in particular that concerns you or that you are proud of? Is there something you would like to address or do

differently? Note your answers down on your piece of paper for future reference.

Step 5

Now look at the map again and see whether there is any time dedicated to you. A slot just for you. The actual amount of time you spend with yourself is not too relevant but the important thing is that you have some time for yourself that is enough for you. This is the actual personal free time that can fluctuate somewhat depending on family obligations, but which still remains important and necessary at all times during your life. This is the personal time you need to be with yourself and communicate intra-personally. It is the time you need to perform certain activities, physical and mental, that in turn help you to remain reasonably healthy and happy over time.

Note

When persons occupying similar positions to you perform this exercise, they normally become consciously aware of how little time they actually dedicate and have for themselves personally. They realise that they have no time to reflect on their own personal needs and expectations, as well as little, if any, time to plan what they can do to address these needs and expectations. This implies that there is little intra-personal communication and that self awareness is low and potentially counterproductive to a positive self-esteem and self-confidence. In turn, this influences how we tend to deal with and view personal problems. The 'me' starts to vanish and instead one finds it easier to focus on the needs and expectations of other people rather than oneself. These include family members, patients, clients, friends and acquaintances.

If on the other hand you are pretty self disciplined and regularly take the time to respect your own needs sometime during the week or at the weekend, then you are lucky and doing the right thing. Do your utmost to protect and consolidate this enviable position and time because you are likely to be more satisfied and happy with yourself and your work.

If you lack enough time for yourself, then the question which obviously follows is, *'When are you going to start reorganising your needs and expectations so that you too can get some attention and space?'*

In the next three letters to be published over the coming issues, I will write to you about how mental programming and assertive communication skills heavily influence the way we view ourselves and the decisions we take to self care and to achieve a healthier work-life balance. Later on, I will also outline ways for you to recognise and address signs and symptoms of negative pressure, stress and burnout and will highlight ways to enhance self-esteem and personal confidence to prevent anxiety, depression and loneliness in your life. ☐

On Data Protection Act – Part II

by **Pierre Mallia** MD MPhil PhD FRCGP
Director, Centre for Bioethics, Medical School

Perhaps the greatest local myth with our own Data Protection law is its overuse into areas where it should not be used. For example, if I form part of an association, be it a band club or college, which elects its own council and to which I, say, pay a membership fee, I have a right to know the data of individual members. If I wanted to contest an election, it would be unfair that someone who handles data has an unfair advantage. Moreover all members must be kept updated on new members and their status with regard to rights should be made clear to everyone concerned. I have unfortunately witnessed this. The Registrar must make all data available to all members at any time; otherwise it would be an illegal abuse. Conversely only data that is relevant should be collected; and if data is necessary which does not pertain to others, *it is the members* of the group that should decide whether this is to be kept only by a trusted person *and not the data commission*. It is unfortunate that an act aimed at protecting the fundamental rights and freedoms can thus be used to the contrary.

You often call a government department and ask for information; they reply that because of data protection they cannot give you information, which by right is yours. In another scenario I know a family who were robbed. The robber left traces of his own blood on a broken glass. When the woman asked that the sample be taken, the inspector said that he would need the consent of the robber!!! Why not ask him for consent for taking fingerprints then?

Data protection is nothing more than what already existed within the framework of the law. Local laws protect my fundamental rights and freedoms to privacy. The EU directive extends transfer of information to within the EU. It also imposed strict protection on data which *leaves* the EU. This of course includes data concerning multi-centre trials and research. This does not of course mean that local data protection acts constrain research, for example, more than the Directive. The Directive is there to allow the EU to work as a single market; local laws follow the rights and freedoms laid down elsewhere once one joins the European Union.

We often frown at the notion that what is written in patients' files is *owned* by the patient. This is stipulated in the Recitals of the directive, which therefore imposes the constraints of obtaining consent for research each and every time. Anonymization is usually a reason for exemption for this unless stated otherwise by a Research Ethics Committee which considers the research as sensitive enough for the patients still having a right to know about the use of their files or samples. It is within the EU law that what is written down in files is in fact owned by patients. Patients have been known to challenge what is put down in their files in courts of law. It is no longer acceptable to say that files should not be handled by patients. By this we do not imply that they may have a direct right to take their files at home, and neither perhaps that they may have a right to view it on a computer (in the hopefully not too far future); but certainly they have a right for someone to explain what is in it – as this is *not* confidential information (which is an exercise between two people, usually a professional and his or her client), but *private* information – private property. No one, therefore, has a right to look into my file without my prior permission. Presumed consent is only there when people attend hospital and their files have to be looked up in order for doctors to look into the history. It is *this* context which is exempted when the act says that exemptions are given for medical reasons.

When we scribble into a file, it is perhaps important to realise that we are making notes into the private life of a person; it is a legal note, and no excuse that the patient can misunderstand or misinterpret is allowed in a court of law. One should therefore give due consideration to accurate notes and not put anything which may offend or which is not transparent. Careless notes are therefore a precedent for malpractice suits – as we have seen there is a breach in ones' duty which may cause harm. Whilst sometimes it is difficult to explain what one is going to write down, if one writes 'paranoid personality', one must be able to substantiate such a label. ☑

*Perhaps the
greatest local myth
with our own Data
Protection law is its
overuse into areas
where it should
not be used*



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JANSSEN-CILAG

Letters to the Editor

Obtaining consent in clinical practice... and other settings

From Dr Tanya Von Avendonk MD DCH

I would like to draw the attention of your readers to an ambiguous situation that exists in Malta. As practising physicians we are legally obliged to obtain consent from a parent or guardian when examining a minor (i.e. under 18 years).

However any 'body-artist' who performs body piercing can carry out any form of this practice on minors without any consent required. This is because body piercing is not considered as a potential health hazard. Many physicians have seen complications and the permanent scars that arise from body piercing. Also according to regulations for blood donations anybody who has had body piercing or tattooing is not allowed to donate blood for at least 6 months after the procedure because of the potential risk of blood transmitted infections.

I believe that as a profession we are obliged to create

an awareness campaign of the potential health risks and apply pressure on the health authorities to regulate such practices. In the tattooing act (Act 270, 1976) it is illegal for minors to request, suffer or allow a tattoo to be performed. However there are still many minors who are having tattoos because they are accompanied by an adult who consents. Apparently this adult does not have to be a parent/guardian, it could be a 'friend' who has just turned 18 years!

As you know, as parents we are now obliged to give consent for any pictures that are taken of our children at school (activities)! Isn't it ridiculous that there is the data protection law that protects the images of our children but no law that protects the very bodies of our children?

I suggest that an action group is set up to coordinate the campaign. Anybody who is willing to involve himself is invited to send an email to action@thesynapse.net and together we can get things going.

The Human Papilloma Virus

From Mr Christopher Farrugia Dip
MLS PgD Forensic Science(UK)

I refer to the article by Prof Albert Cilia-Vincenti entitled, "The Human Papilloma Virus" (May 2007 Issue 03/07). I take exception to his comments and in particular the section where he states, and I quote *ad verbatim*, "Molecular testing for viral DNA (and also molecular testing for detection of progression from HPV to CIN) is an expensive matter when carried out properly in suitable laboratories. Beware of claims that these PCR (polymerase chain reaction)

techniques can be carried out in some small corner of a local private laboratory, to offer cheap and reliable testing".

MLS BioDNA Ltd., is currently the only DNA facility in Malta carrying out DNA HPV testing using state of the art facilities and top-notch expertise in the area. May we assert that quality assurance regarding all our tests is in place. We follow standard operating procedures and regularly participate in proficiency testing programmes. Moreover, the facilities have been assessed by

quality assessors under the stewardship of the National Accreditation Board and recently have been awarded ISO 17025 Accreditation. Physicians and patients can rest assured that all results emanating from MLS BioDNA Ltd. are indeed tried and tested.

Furthermore, DNA HPV is carried out at the KBIC at Kordin, and is licensed by the Health Authorities in Malta to conduct such tests.

Mr Christopher Farrugia is director of MLSBioDNA Ltd.

Vacancy



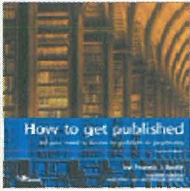
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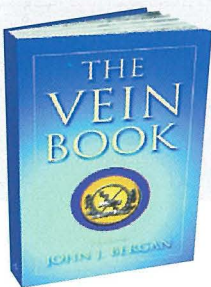
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Winning with TheSynapse

Last June 2007, through TheSynapse, invited Medical Doctors, members of TheSynapse, to participate in two online questionnaires, one relating to Daflon and another linked to Stablon. Quite an interest was shown in both questionnaires and, as advised, winners from those who completed these questionnaires were randomly selected.



Drs Julian Mamo, Michael Refalo, Alex Magri and Jason Attard, who took part in the STABLON survey won a CD ROM 'How to get published – All you need to know to publish in Psychiatry' by Frank J Bayle.



Dr Yves Muscat Baron and Dr Patrick Mahoney, who completed the DAFLON survey, won a fully illustrated hard back book entitled 'The Vein Book' published earlier on this year and which has been edited by John J Bergan.

STABLON and DAFLON are products of Les Laboratoires Servier.



Call for interest – Environment and Health

Environmental health comprises those aspects of human health including quality of life that are determined by the physical, biological, social and psychosocial factors in the environment. It also refers to the theory and practice of assessing, correcting, controlling and preventing those factors in the environment that can potentially affect adversely the health of present and future generations. (Helsinki Declaration, 2nd European Conference on Environment and Health, 1994)

Professionals in the medical field (doctors, pharmacists, scientists, nurses, other health professionals, as well as students in these areas) interested to focus on the linkages between human health and environmental factors, and to take action locally, nationally and internationally are encouraged to contact family doctor Jason J. Bonnici MD, MMCFD, on jasonjbonnici@hotmail.com. Actions include building local capacity through education and training, raising awareness, research and publication, advocacy and being a good role model.

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For more details, send an email to ukjobs@thesynapse.net or visit TheSynapse Portal: within the "Opportunities" area at TheSynapse Main Page.

450 daily cases of Infectious

by **Charmaine Gauci** MD PhD MSc Dip(Fit & Nut) FRSH
 Head – Disease Surveillance Unit
 Department of Public Health

Infectious intestinal disease refers to gastrointestinal symptoms due to micro-organisms or their toxins. The main symptoms include diarrhoea, vomiting, fever, abdominal pain and nausea. Many persons refer to this illness as food poisoning or gastric flu, however infectious intestinal disease is a term which encompasses a variety of illnesses. These illnesses are caused by the transmission of micro-organisms through food, water, environment or from an infected person to another. These micro-organisms include viruses, bacteria and parasites.

An improvement of hygiene methods and sanitation as well as early management, have greatly reduced the deaths caused by this illness in developed countries like Malta, however not the same can be said for developing countries. In these countries we are still seeing a number of deaths especially in children. Furthermore although the number of deaths have been radically reduced in developed countries, the burden of illness from sickness remains high.

Most of the information on the number of cases of infectious diseases in many countries comes from notifications from doctors and laboratories. However this does not include those persons who develop the illness and do not go to a doctor, and cases where the doctor does not suspect that food is implicated. Hence information on the number of cases occurring in many countries is not known. An estimate of the frequency of this illness is important to be able to control this illness.

This promoted the author, who is the head of the Disease Surveillance Unit within the Ministry of Health, to initiate a series of research studies to identify the gaps in the epidemiology of this disease. This doctoral study estimated the frequency and defined the distribution of infectious intestinal disease in Malta. 3,504 randomly selected persons participated in this study which was carried out over a period of 16 months. From this study it was estimated that 3.18% of the population experienced an episode of infectious intestinal illness at any point in time in a year. This can be extrapolated to the general population giving an average rate of 0.421 episodes per person per year which is equivalent to 450 episodes of illness occurring in the Maltese Islands per day. This was the first estimate of the frequency of this condition to be



estimated in Malta. Knowing that there may be about 450 persons suffering from gastrointestinal illness due to microbiological agents puts everyone on their toes to see what we can do to minimize this burden. Usually some have the impression that this illness is of short duration however this study revealed that the duration of illness can vary from 4 to 9 days with an average of 3 days. The study also dwelled on what infectious intestinal illness at community level is costing us from a societal aspect. The largest proportion of cost is due to provision of health-care services costing Lm 4,558,970 per year; followed by Lm 2,209,393 in lost productivity; Lm 561,078 in medicines; Lm 66,452 in stool culture testing and Lm 31,183 in personal costs, giving a total cost of illness of over 7 million Maltese liri per year. The burden and cost of infectious intestinal disease are high enough to justify efforts to control the illness since most cases of this illness can be prevented.

The results of this study have been published in local and international scientific peer-reviewed journals by the author, who obtained a doctorate

in epidemiology in 2006.

What is the health division doing in terms of minimizing the risk of illness? The Disease Surveillance Unit investigates all notified cases and undertakes action where food operations are implicated, advises the persons involved on safe food handling practices and advises on measures to prevent transmission from one person to another. The Public Health Department ensures that all food operations are registered with the Food Safety Commission in terms of Legal Notice 180/2001, which guarantees that regular inspections are performed to ensure compliance with all food safety regulations in terms of the Food Safety Act (2002). It is the responsibility of the food operators to ensure compatibility – they should not allow food handlers who are suffering from gastroenteritis to work during the period of time in which they are symptomatic.

In addition, food handlers need to follow a course in food hygiene in order to be registered. The course includes measures to be taken to prevent food-borne illness and lectures

s Intestinal Disease in Malta

1. Cook raw foods thoroughly. Under normal circumstances raw foodstuffs and water may become contaminated with pathogens. Thorough cooking will kill the pathogens, which means the temperature of all parts of the food must reach at least 70 °C.

2. Eat cooked food immediately. When cooked foods cool to room temperature, bacteria begin to grow. The longer the wait, the greater the risk. To be on the safe side, eat cooked foods as soon as they come off the heat.

3. Prepare food for only one meal. Foods should be prepared freshly and for one meal only, as far as possible.

4. Store cooked food properly. If foods have to be prepared in advance, or if there are leftovers, they should be stored cold, i.e. below 5 °C (in a refrigerator), or hot, i.e. above 60 °C. This rule is vitally important when it is planned to store food for more than 4–5 hours.

5. Reheat stored food thoroughly. Cooked foods that have been stored must be thoroughly reheated before eating, i.e. all parts reheated to at least 70 °C.

6. Avoid contact between raw foods and cooked foods. Safely cooked food can become contaminated through even the slightest contact with raw food. This cross-contamination can be direct, e.g. when raw fish comes into contact with cooked foods. It can also be indirect. For example, preparing raw fish and then using

the same unwashed cutting surface and knife to slice cooked food should be avoided, or all the potential risks of illness that were present before cooking may be reintroduced. Cross-contamination may also occur in a freezer when the power has been off for some time and this should be checked for. The juice of raw meat and poultry may drip onto other foods.

7. Choose foods processed for safety. Many foods, such as fruits and vegetables, are best in their natural state.

8. Wash hands repeatedly. Hands should be washed thoroughly before preparing, serving or eating food and after every interruption, especially after use of the toilet or latrine, changing a baby or touching animals. After preparing raw foods, especially those of animal origin, hands should be washed again before handling cooked or ready-to-eat foods.

9. Keep all food preparation premises meticulously clean. Since foods are so easily contaminated, any surface used for food preparation must be kept absolutely clean. Scraps of food and crumbs are potential reservoirs of germs and can attract insects and animals. Food should be stored in closed containers to protect it from insects, rodents and other animals.

10. Use safe water. Safe water is just as important for food preparation as for drinking.

Figure 1: Golden rules for safe food preparation (Source WHO – http://www.paho.org/english/ped/te_gold.htm)

on the nature of symptoms which may indicate gastroenteritis and hence their obligation to refrain from work whilst symptomatic. In instances where there is a serious violation in breach of the Food Safety Act various legal actions are contemplated including the possibility of closure of premises.

What can the general public do to minimize the risk that he/she or the family can fall ill? Taking up safe food handling practices in their home is the best measures to avoid infectious intestinal disease that is transmitted through food. By following the ten World Health Organization golden rules (Figure 1), the risk can be greatly reduced. Another important measure is to avoid transmission of infection from one person to another by proper cleaning of areas where persons who are sick are staying with proper disinfectant agents, and personal protection during cleaning of material from infected persons e.g. vomitus.

The role of hand washing cannot be over-emphasized.

Health care professionals including doctors and pharmacists who have the first encounter with the patient, are in a position to offer advice on preventive measures to reduce the burden of this illness.

More information can be obtained from the Disease Surveillance Unit website at <http://www.health.gov.mt/dsu> and by contacting the Unit on 21332235 /21324086 or email Dr Gauci on charmaine.gauci@gov.mt. ☐

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Unravelling the Tangle of Genetic Testing

by **Christian A. Scerri MD PhD (Molecular Genetics)**
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In the past 60 years the identification of the genetic basis of various diseases has steadily increased. Whilst great strides have been made in sequencing the whole human genome project, the identification of disease causing mutations especially for multifactorial conditions is still in its infancy. On the other hand, in the majority of genetic disorders where the causative gene is known, molecular genetics tests are available with which to identify the causative mutations.

'Do you know of anyone else in your family that has a similar condition?' This question has become almost a routine one in clinical practice. It reflects the growing awareness that practically all pathological conditions have some genetic background. Though most probably the inheritance of physical characteristics must have been known since time immemorial, the major breakthrough in the identification of the units of inheritance (genes) came about in the mid 19th century, when the Augustinian monk Gregor Mendel carried out his noted pea-breeding experiments. Through his observational and experimentation work, Mendel set the basic principle of one gene one trait.

Though the concept of the gene was established at around this time, it took almost 100 years before the first experimental evidence that DNA transmits genetic information was published by Avery et al¹ of the New York's Rockefeller Institute followed by Franklin and Gosling² and Wilkins et al³, of King's College in London, who through x-ray diffraction patterns of DNA showed that it had a regular and helical structure. In 1953, armed with this information and knowledge of the chemistry of DNA, James Watson and Francis Crick⁴, then at the Medical Research Council laboratories in Cambridge, England, proposed a model composed of two helically twisted strands connected to each other by a number of molecular rungs. These rungs were made up of either an adenine (A)-thymine (T) or guanine (G)-cytosine (C) base pair. Thus the theory that it is the order of these G, A, T and C bases on the DNA strand that determined the genetic make up of every living organism was born. This arrangement could also account for the way DNA strands and thus the genes, were copied and transmitted to the offspring. The next piece of the jigsaw puzzle was put in place in 1966 with the identification of the triplet of bases (e.g. CTG) that code for particular amino acids (in this case

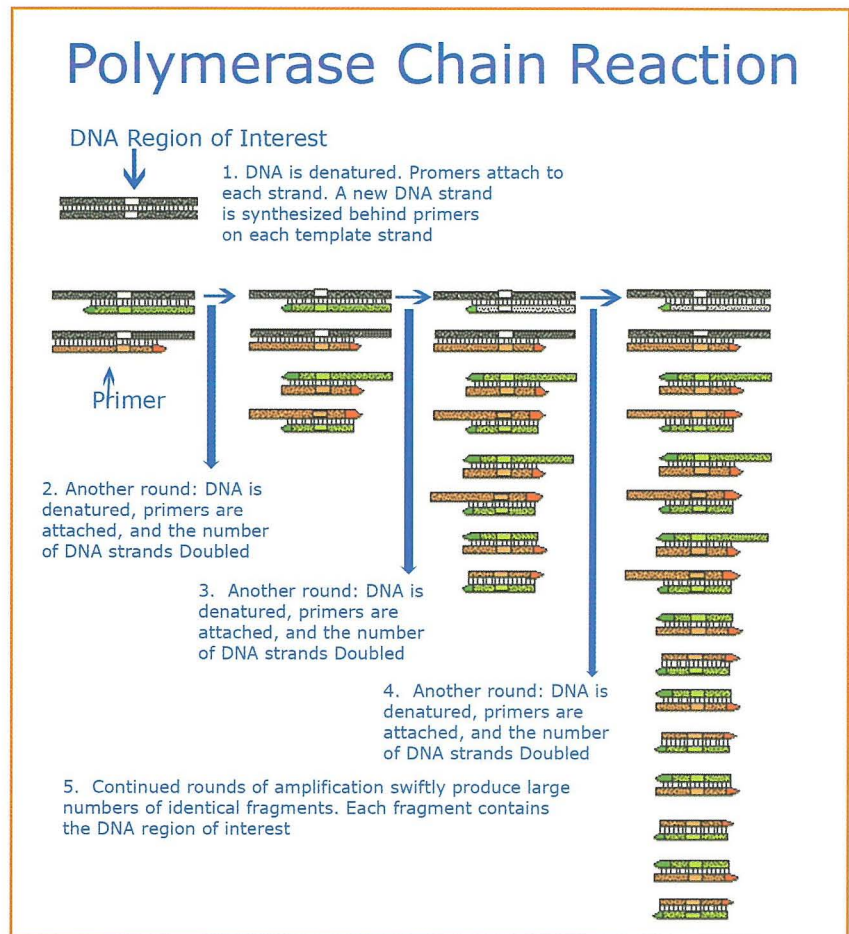


Figure 1. The steps and reactions in the Polymerase Chain Reaction (adapted

leucine) or else for the start (usually ATG) or stop (TGA, TAG, TAA) of protein coding regions.⁵

The scene was thus set for the hunt for disease-causing genes. Initially the tools that the molecular geneticist could use consisted of enzymes called restriction enzymes (RE), ligase and heat labile DNA polymerase. RE are enzymes present in eukaryotic cells that protect them against invading phages (bacterial viruses). These enzymes recognise specific sequences and cut the DNA strand. The ligase could then ligate the fragment with

other fragments and the polymerase could replicate the fragments. These tools enabled researchers to digest genomic DNA and then separate the fragments by size through gel electrophoresis as well as introduce DNA fragments into bacteria for amplification followed by sequencing. With these primitive tools, researchers started to recognise background patterns of RE sites (haplotypes) that were linked to certain genetic disorders. In the late 1970's and early 1980's these techniques enabled researchers to identify the first molecular causes of genetic disease.

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(1) Corsini A, et al. The Use of Statins in Optimising Reduction of Cardiovascular Risk : Focus on Fluvastatin. Int J Clin Pract 2004; 58(5) : 494-503
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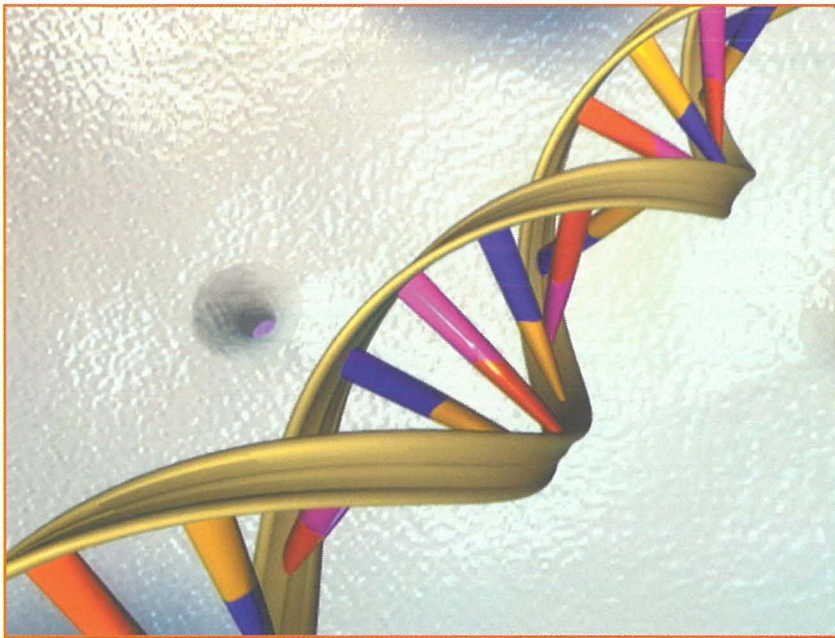
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Unravelling the Tangle of Genetic Testing

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Since then, it was a rapid progression both in techniques and identification of possible mutations that could cause genetic disorders. The pivotal discovery was the principle of the Polymerase Chain Reaction (PCR) in 1986 by Mullis et al.⁶ This technique utilises four components - the template DNA (usually full genomic DNA), two short DNA fragments (primers) that are synthesised in the lab, a buffer solution containing the nucleotides, and heat stable DNA polymerase. The genomic DNA can be

obtained from any cell (apart red blood cells – they contain no nucleus) of the body and even from one single cell. The primers are two short (15 to 30 nucleotide-long) fragments of DNA that are artificially synthesised. The sequences of these fragments are chosen so as to be complimentary to the 3' region upstream of the gene of interest in both strands.

The sequence of events in PCR (figure 1) involves a cycle (25 to 30) of heating and cooling steps. The initial step is that of heating the mixture of genomic DNA, primers, nucleotides and polymerase enzyme to a temperature, high enough to obtain complete separating of the two complimentary strands of DNA (this step is called denaturing and usually takes place between 95°C and 99°C). The mixture is then cooled to a temperature that is optimal for the two primers to anneal to their respective complimentary sequence (usually between 63°C and 68°C). The last step brings the mixture to the ideal temperature for the polymerase to build a new complimentary strand starting from the annealed primers (depends of the enzyme which is used but the ideal temperature of the most commonly used enzyme – *Thermus aquaticus* (TAQ) polymerase – is 72°C). With every cycle, the number of fragments of interest doubles up and thus after 25 cycles and starting from the genomic DNA from one single cell, one would, theoretically, end up with 2^{25} (33,554,432) copies of the fragment of interest within 3 to 4 hours. This technique opened the doors for various important research and

diagnostic techniques, including large scale, rapid sequencing as well as rapid methods to identify mutations. ☐

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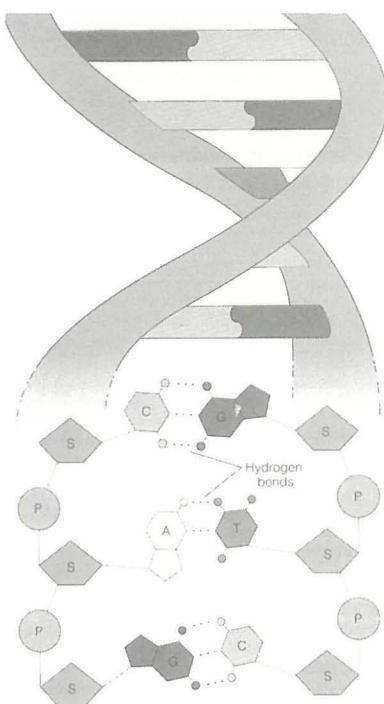
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For the sake of children

by **Marika Azzopardi**

Most people have heard of 'Puttinu'. The Puttinu Cares Support Group was set up with the establishment of the Wonderland paediatric oncology ward at St Luke's Hospital. This coincided with the appointment of Dr Victor Calvagna as paediatric oncology consultant in September 2000. The Synapse gets up close to this paediatric oncologist whose work brings him exclusively in contact with children and teenagers afflicted by cancer.

"It was the nurses working on the ward who came up with the idea of setting up this foundation. At the time, we were joined by a number of volunteers like Claudia Taylor East and Toots Birch and through the latter two contacts, we obtained a sponsorship from HSBC and the right to use 'Puttinu' as part of our logo. The main aim of the group was to improve the quality of life of children with cancer by supporting them and their families socially, financially and emotionally, as well as making sure that they receive the best evidence-based treatment which was available to all children in the developed countries."

The support group keeps Dr Calvagna particularly busy with tasks such as chairing the monthly committee meeting, as well as representing the group at most of the fund-raising activities. "Nowadays, these activities take place on a regular basis. I attend most of the interviews, being regularly invited to make appearances and interventions on TV and radio programmes. I liaise with the committee officials to make sure that the strategies decided by the committee are on the right track. Most of the trouble shooting is also done by myself. I also represent the group in any discussions with health officials or other important functionaries. Initially these activities were not very time-consuming but as the popularity of the support group increased, these activities have become part of my weekly schedule!"

'Puttinu Cares' raises funds through varied methods. Monies come in the form of donations received from private individuals or organizations who take up calls for support and offer financial assistance. Next in line come the fund-raising activities which are organized on the own initiatives of some organizations who pass on their proceeds to the support group.



Incidentally, the 'Puttinu Cares' support group recently made the headlines through a very well-attended fund-raising activity. This was a football marathon that raised almost Lm 50,000, an event which called for massive organization.

"The marathon was held on the 20, 21, and 22 April of this year and involved 60 hours' worth of football-playing which saw the participation of some 400 football teams at the Marsa grounds. The event involved collaboration with the Kunsill Malti għall-Isports and TV coverage by Channel 22. The Maltese people were encouraged to send their financial support through mobile phone text messages, or by depositing money directly into our account. Some TV programmes like Tista Tkun Int and Replay were of great help, as was the visit by the Italian goalkeeper Gianluca Buffon who took part in a charity football match on our behalf."

On the flip side of the fund-raising coin, Dr Calvagna has also very recently been fundamental in work linked to another just cause – the Jose Carreras Leukaemia Foundation

which was in the limelight following Mr Carreras' memorable concert held in June. Thanks to the hard work shouldered by all those involved, a cheque of Lm 2,200 was presented to Jose Carreras himself on June 9, during a friendly football match. This was held between an Austrian team led by former Austrian Chancellor Wolfgang Schussel and a Maltese contingent of parliamentarians and other personalities. Although the Maltese team was beaten 3-2 by a visibly older team of Austrians, the Maltese were winners through and through. Dr Calvagna explains what eventually happened ...

"The Carrera event was organized through the initiative of Bawag Malta Bank and various other local and foreign commercial institutions. They planned the fund-raising football match between Maltese MPs and a selection of Austrian Parliamentarians. I participated in the game and played for the Malta side. The proceeds of this match were passed to Mr Carrera's Leukaemia Foundation and the latter very generously passed on these funds to our support group."

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For the sake of children

It is thought-provoking how things and coincidental events may bring surprises. The initial contact between Bawag Malta Bank and the Maltese support group came through a friend of one of the Wonderland patients. Mr Jose Carreras himself had developed leukaemia during the eighties and survived following treatment and a successful bone marrow transplant and as Mr Calvagna rightly points out, "...is still with us performing with his exquisite baritone voice."

Meanwhile, 'Puttinu Cares' has other plans for the future. "Presently our main aim is to buy property close to the Royal Marsden Hospital in Sutton, London. This will ensure that when our patients go to the Royal Marsden Hospital for treatment that can't be carried out in Malta, as in the case of a stem cell transplant, they will have all the accommodation that they require without any hassle. This venture will cost around 200 to 300 thousand Maltese Liri and we are still a long way away from that target. However through the generosity of the Maltese and that of others we will eventually get there."

Dealing with very sick children is what Dr Calvagna's work is all about. He describes life in the Wonderland ward. "On average, we see one new case a month. However during 2006 we saw an average of two cases per month. There is no one age when children are more prone to being admitted to this ward. It depends on the type of tumour, as for example, acute leukaemia is more common in children aged two to four."



Quizzed on the emotional difficulty of working on a daily basis with very sick children, Dr Calvagna remarks, "It is hard to work with sick children. However I believe that working with chronically sick patients of any age is difficult for every person involved. In the case of children's cancer it is even more difficult because we have to deal with the emotional, psychological and sometimes social problems of the family as well. On the positive side, I can confirm that we still manage to cure about 70% of cases and this gives us enough courage to be optimistic. There come times when the ward is full of very sick children who are going through hard times. However, it is not always like that and as these patients' conditions improve, their smile will return, as will their quality of life, their growth and development. In most cases once children manage to beat their cancer they grow into normal healthy adults." □

A V I A N I N F L U E N Z A

Update on Avian Influenza

by **Tanya Melillo Fenech MD MSc(HSM) Dip(HSM)**
Public Health Physician, Disease Surveillance Unit,
Department of Public Health

Avian Flu virus change lowers vaccine effectiveness

A change in the avian flu virus strain H5N1 has diminished the effectiveness of the vaccine against the disease. Avian flu vaccines are produced according to the gene type Z found in the avian flu virus strain H5N1 in 2003 but another gene type G was detected in 2005 and these two genes are not similar. So vaccines are more effective against type Z and less effective against type G.

New antiviral drug – Peramivir

A new antiviral drug to treat both avian and human flu, developed by United States-based BioCryst Pharmaceuticals, will be tested across Asia this summer.

In animal trials, the drug boosted the survival rates of mice and ferrets infected with the H5N1 avian flu virus.

The development of peramivir may be an answer to experts who want to have several antivirals to choose from when fighting the different types of flu, especially since the viruses mutate quickly.

Mild avian flu in Britain this May has pandemic potential

Four human cases tested positive for H7N2, a mild strain of avian flu, in Wales this May from a small farm which reported the death of several chickens. This is a reminder that the next flu pandemic can be sparked by a virus other than the feared H5N1 strain.

Health officials are currently investigating 142 people who

may also be infected, of whom 12 have symptoms of flu or conjunctivitis. Health officials are treating hospital staff and patients after a health care worker caught the virus and also a primary school where one of the pupils developed symptoms.

Low pathogenic viruses can quickly morph into highly pathogenic ones, sometimes within weeks. Too little is known about flu viruses to predict with any certainty which ones are most lethal for humans.

Unlike many other avian flu subtypes, which disappear off the radar after a short period, H5N1 has remained entrenched in the environment, and continues to spread to new areas.

Still, while no avian flu virus can be ruled out when it comes to igniting the next pandemic, some clues may exist. Though H5N1 has several worrying characteristics, other flu subtypes are also in the running for the pandemic title. The last two flu pandemics were the result of a human flu virus recombining with low pathogenic avian viruses.

Antibodies from survivors may hold clue to bird flu remedy

An article published in May in The Public Library of Science Journal PLoS Medicine describes how antibodies from survivors of the Vietnamese H5N1 strain were used to prevent mice from developing the infection by neutralizing the virus. Human monoclonal antibodies were created and trained to recognize the H5N1 virus. The role of antibodies in the body is to recognize and initiate an attack against the offending antigen – in this case the avian virus – and destroy it. The study showed that this treatment could be administered up to 72 hours from the onset of symptoms for it to be effective. □

Pharmacy Of Your Choice – Patient-Centred Service By Community Pharmacists

by **Mary Ann Sant Fournier** BPharm MPhil
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In historical and cultural contexts, the community pharmacist, like the family doctor has always been a central figure in our towns and villages. Throughout the past decades and especially in the last few years, the role of the community pharmacist is being given more importance.

Ciappara¹ opined that “an evaluation of patients’ expectations is important as this enables the profession to meet today’s challenges to set practice standards and develop pharmacists’ services to meet patients’ needs.” The majority of patients interviewed in the Ciappara study (92%, n=80) had a positive view of pharmacists as health care professionals. This was found to influence their perception of their relationship with their pharmacist. Moreover, patients identified interpersonal qualities, professional approach and knowledge as the most significant characteristics of a good pharmacist. Promoting the good of patients (48.8%), communication (38%), and a friendly approach (30%) were the interpersonal qualities considered to be of greater importance. Furthermore, over 96% (n=80) of the patients said that they trusted pharmacists, 39% expected to be given more information about their medicines, 15% expressed desire to actively participate in decisions about their health and 61% recognized the pharmacist’s efficacy in giving information on medicines.

Pharmacists’ private practice in the community has always focused on the establishment of good patient-pharmacist relationship which is fundamental to the provision of patient-focused pharmaceutical services. On the other hand, those patients who receive their medicines through the government primary health care system are being deprived of such a service because the system is a barrier to the development of personalised services in an area where direct pharmacist-patient contact is essential to attain positive outcomes of medicines usage and a better quality of life.

In the coming days a Memorandum Of Understanding (MOU) shall be signed by the Malta Chamber of Pharmacists and the GRTU pharmacy section, representing pharmacists and pharmacy owners, respectively and the

Government. After about 20 years of negotiations (the first document on the ‘Pharmacy of Your Choice’ (POYC) was submitted by the Chamber to the Government in 1987), this will bring about a turning point in the delivery of a fundamental service by community pharmacists to patients who are beneficiaries under the Social Security Act for free medicines. Significantly, the MOU highlights the special nature of the community pharmaceutical sector wherein pharmacies are places where essential public health services are delivered by community pharmacists and that community pharmacies are an *integral part* of the primary health care sector.



Malta Chamber of Pharmacists Founded 1900 To Serve, To Protect To Educate

Indeed, the main objective to implement the POYC is that patients choose their private community pharmacy, not only on the basis of convenience in the location *but significantly on the basis of the nature and quality of professional services that are delivered by the pharmacist.*

At present, patients entitled to receive national health service medicines may collect them only through the government primary health care (PHC) system from dispensaries that service different regions of the island and through a ‘postal system’ (*bereg*). This

‘postal system’ is available through small government clinics located in nearly every town and village. There is no contact whatsoever with a pharmacist in the latter system. The government primary health care system is thus mainly one of supply and distribution where contact between pharmacists and patients is limited.

In the **first** phase of the POYC project, which will be co-managed by a standing advisory committee consisting of representatives of the partners signatory to the MOU and other resource persons, the ‘postal system’ (*bereg*) will be phased out. Patients shall be invited to register with the pharmacy /pharmacist of their choice. They shall leave their prescriptions with their pharmacist at their chosen pharmacy. The PHC will collect these and they shall be filled by the PHC pharmacists and pharmacy technicians. These patient-specific pre-packed medicines packages will be distributed to the participating pharmacies for dispensing, which shall be organized at the discretion of the managing pharmacists with guidelines from the standing advisory committee. Protocols shall be established to provide necessary quality assurance to ensure professional responsibility for the accuracy and safety of dispensed medication and avoidance of errors. Appropriate channels of communication between all professionals involved shall be established. The project will be piloted in two selected areas i.e. Gzira and Mosta, for a period of 4 months after which it shall be rolled out nationally.

It is envisaged that in the **second** phase of the project the participating pharmacies will be responsible for the preparation and dispensing of patient-specific drug entitlement. Discussions are underway to set up the organized dispensing of those items that are supplied in hospital packs at a dedicated premise governed by good pharmacy practice protocols. This is envisaged to facilitate the work of community pharmacists.

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Ultrasound Evaluation of the Shoulder



Figure 12. Subscapularis tendonitis with calcification (arrows).

continued from page 2

Calcific tendinitis is a common disorder caused by deposition of calcium hydroxyapatite crystals in various shoulder tendons. The cause is considered to be dystrophic, and all tendons can be affected, although the most common site is within the supraspinatus tendon near its insertion (Figure 12).

Long head of biceps tendonosis is seen as thickening of the tendon within the bicipital groove (Figure 13). A long head of biceps tear results in an empty bicipital groove due to tendon retraction (Figure 14).

High-resolution US has been shown to be an efficient imaging modality for the assessment of a wide spectrum of rotator cuff and non-rotator cuff disorders. It is fast and



Figure 13. LHBT, transverse view. The biceps tendon is enlarged with an inhomogeneous echotexture in keeping with tendinosis.



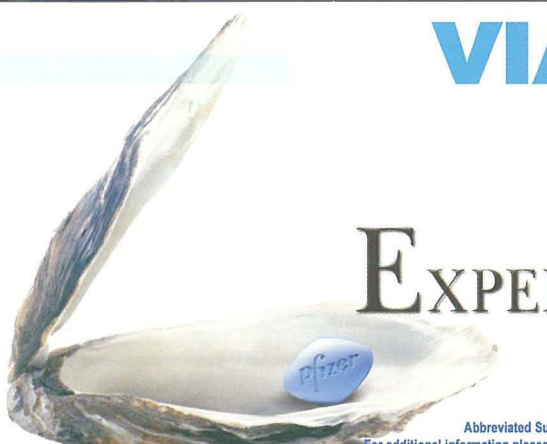
Figure 14. LHBT, transverse view. Chronic rupture results in absence of the tendon from the bicipital groove.

inexpensive and allows dynamic assessment of the joint. It may also be used to guide interventional procedures.

The above short review serves as a pictorial demonstration of the most common disorders in the rotator cuff and surrounding tendons as shown on ultrasound. Ultrasound has become a very valuable tool in the assessment of musculo-skeletal disorders. Further musculo-skeletal applications of ultrasound will be discussed in coming articles.

Acknowledgement: The author would like to thank Dr Martin Borg suggesting the theme of the above article. Further suggestions for future articles from other colleagues would be greatly appreciated. ☐

Dr Pierre Vassallo can be reached at the DaVinci Hospital on 21 491 200 or by email on pvassallo@davincihospital.com.mt



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Based on efficacy and toleration, the dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended dose is 100 mg. The maximum recommended dosing frequency is once per day. If VIAGRA is taken with food, the onset of activity may be delayed compared to the fasted state. Use in the elderly: Dosage adjustments are not required in elderly patients. Use in patients with impaired renal function: The dosing recommendations described in 'Use in adults' apply to patients with mild to moderate renal impairment (creatinine clearance = 30 - 50 ml/min). Since sildenafil clearance is reduced in patients with severe renal impairment (creatinine clearance < 30 ml/min) a 25 mg dose should be considered. Based on efficacy and toleration, the dose may be increased to 50 mg and 100 mg. Use in patients with impaired hepatic function: Since sildenafil clearance is reduced in patients with hepatic impairment (e.g. cirrhosis) a 25 mg dose should be considered. Use in children: VIAGRA is not indicated for individuals below 18 years of age. There is no relevant indication for use in children. Use in patients using other medicines: With the exception of nitrate for which co-administration with sildenafil is not advised a starting dose of 25 mg should be considered in patients receiving concomitant treatment with CYP3A4 inhibitors. In order to minimise the potential for developing postural hypotension, patients should be stable on alpha-blocker therapy prior to initiating sildenafil treatment. In addition, initiation of sildenafil at a dose of 25 mg should be considered. CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients. Consistent with its known effects on the nitric oxide/cyclic guanosine monophosphate (cGMP) pathway, sildenafil was shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form is therefore contraindicated. Agents for the treatment of erectile dysfunction, including sildenafil, should not be used in men for whom sexual activity is inadvisable (e.g. patients with severe cardiovascular disorders such as unstable angina or severe cardiac failure). VIAGRA is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. The safety of sildenafil has not been studied in the following sub-groups of patients and its use is therefore contraindicated: severe hepatic impairment, hypotension (blood pressure < 90/50 mmHg), recent history of stroke or myocardial infarction and known hereditary degenerative retinal disorders such as retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases). WARNINGS AND PRECAUTIONS A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes, before pharmacological treatment is considered. Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure. Prior to prescribing sildenafil, physicians should carefully consider whether their patients with certain underlying conditions could be adversely affected by such vasodilatory effects, especially in combination with sexual activity. Patients with increased susceptibility to vasodilators include those with left ventricular outflow obstruction (e.g. aortic stenosis, hypertrophic obstructive cardiomyopathy), or those with the rare syndrome of multiple system atrophy manifesting as severely impaired autonomic control of blood pressure. VIAGRA potentiates the hypotensive effect of nitrates. Serious cardiovascular events, including myocardial infarction, unstable angina, sudden cardiac death, ventricular arrhythmia, cerebrovascular haemorrhage, transient ischaemic attack, hypertension and hypotension have been reported post-marketing in temporal association with the use of VIAGRA. Most, but not all, of these patients had pre-existing cardiovascular risk factors. Many events were reported to occur during or shortly after sexual intercourse and a few were reported to occur shortly after the use of VIAGRA without sexual activity. It is not possible to determine whether these events are related directly to these factors or to other factors. Agents for the treatment of erectile dysfunction, including sildenafil, should be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease), or in patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia). The safety and efficacy of combinations of sildenafil with other treatments for erectile dysfunction have not been studied. Therefore the use of such combinations is not recommended. Visual defects and cases of non-arteritic anterior ischaemic optic neuropathy have been reported in connection with the intake of sildenafil and other PDE5 inhibitors. The patient should be advised that in case of sudden visual defect, he should stop taking VIAGRA and consult a physician immediately. Co-administration of sildenafil with nitroglycerin is not advised. Caution is advised when sildenafil is administered to patients taking an alpha-blocker, as the combination may lead to symptomatic hypotension in a few susceptible individuals. This is most likely to occur within 4 hours post sildenafil dosing. In order to minimise the potential for developing postural hypotension, patients should be haemodynamically stable on alpha-blocker therapy prior to initiating sildenafil treatment. Initiation of sildenafil at a dose of 25 mg should be considered. In addition, physicians should advise patients what to do in the event of postural hypotensive symptoms. Studies with human platelets indicate that sildenafil potentiates the antiaggregatory effect of sodium nitroprusside in vitro. There is no safety information on the administration of sildenafil to patients with bleeding disorders or active peptic ulceration. Therefore sildenafil should be administered to these patients only after careful benefit-risk assessment. The film coating of the VIAGRA tablet contains lactose. VIAGRA should not be administered to men with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. VIAGRA is not indicated for use by women. UNDESIRABLE EFFECTS Very common (≥ 1/10): Headache, flushing, Common (≥ 1/100 and < 1/10): Dizziness, altered vision (increased perception of light, blurred vision), Chromatopsia (mild and transient, predominantly colour fringe to vision), Palpitation, Nasal congestion, Dyspepsia. There were reports of muscle aches when sildenafil was administered more frequently than the recommended dosing regimen. In postmarketing surveillance the following adverse events have been uncommonly (≥ 1/1000 and < 1/100) or rarely (≥ 1/10,000 and < 1/1000) reported: Hypersensitivity reactions, eye pain, red eyes, bloodshot eyes, tachycardia, ventricular arrhythmia, myocardial infarction, unstable angina, sudden cardiac death, hypertension, epistaxis, syncope, cerebrovascular haemorrhage, transient ischaemic attack, vomiting, skin rash, prolonged erection, priapism. In postmarketing surveillance, adverse events that have been reported with an unknown frequency in patients taking VIAGRA include: Eye disorders: Non-arteritic anterior ischaemic optic neuropathy (NAION), retinal vascular occlusion, visual field defect. SUPPLY CLASSIFICATION POM

MARKETING AUTHORISATION HOLDER: Pfizer Limited, Sandwich, Kent CT13 9NJ, United Kingdom
MARKETING AUTHORISATION NUMBER(S): EU/1/96/07/001-012
DATE OF REVISION OF THE TEXT 21 December 2007

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Pharmacy Of Your Choice

Patient-Centred Service By Community Pharmacists

continued from page 21

Pharmacies will also be encouraged to implement an Information and Communication Technology (ICT) system. It is envisaged that this will lead to the introduction of patient medication record keeping, facilitating better medicine management and reducing drug misadventures. This is also expected to facilitate better communication with family doctors in the best interest of our patients. Important tools such as data collection and data mining could be used for pharmacoeconomic reasons and for research on medicines usage. The opportunities for innovative pharmacy practice developments and rewarding job opportunities for pharmacists and others are unlimited.

The principle of a fee for such a service in the community pharmacy shall also be introduced. Such a fee shall be borne by the government.

The **third** phase will entail the taking over of the responsibility for the procurement, distribution, packaging and dispensing of free medicines to beneficiaries directly and fully by the pharmacies and the introduction of a Government reimbursement model on the lines of European and international practices, with mechanisms in place to ensure acceptable price levels of medicines.

Studies have consistently shown that there is strong support by the public for the decentralization of these services to the private community pharmacies in the towns and villages in Malta. Significantly, a body of knowledge has also been building up, nationally and internationally, whereby research has revealed evidence that pharmaceutical services in community settings make a positive impact on patient outcomes, eg. clinical, humanistic and economic.^{2,3}

A Foresight study⁴ explored possibly successful scenarios for the POYC project implementation. The objectives of the study were to encourage wider participation in policymaking in pharmacy services; to use scenario methods to explore possible futures for pharmacy in Malta and address alternative



pathways for pharmacy and its impact on and contribution to the health of the Maltese society; and provide guidelines to an action-oriented vision and develop recommendations to be incorporated into possible policies.

Top-down scenarios were considered such as looking to the future and asking 'how' questions, eg. how could a future scenario be attained, where pharmacist expertise in the public and private service is fully utilised with a positive impact on the health of the community and on the sustainability of the national health budget? The resultant top priorities to include immediately in a national health policy with the long term objective of attaining equity, sustainability, and economic viability in the pharmaceutical sector were:

- Convergence on the implementation of a POYC system;
- Full implementation of ICT;
- Standing advisory committee of stakeholders to implement and monitor the project;
- Better patient management;
- Necessity to take a Policy Decision.

It appears that the future of Community Pharmacy for the benefit of pharmacists and the society they serve is finally here. ☐

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