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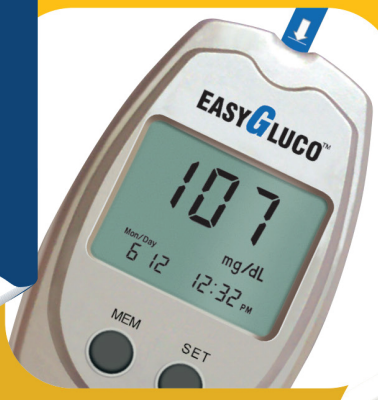

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Journal of the Malta College of Family Doctors

The mission of the Journal of the Malta College of Family Doctors (JMCFD) is to deliver accurate, relevant and inspiring research, continued medical education and debate in family medicine with the aim of encouraging improved patient care through academic development of the discipline. As the main official publication of the Malta College of Family Doctors, the JMCFD strives to achieve its role to disseminate information on the objectives and activities of the College.

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Mental Health

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CONTENTS

Guidelines for authors: mcfd.org.mt/resources/documents?did=8

FPs and the Mental Health Act

Prof Pierre MALLIA

First of all may I thank those of you who have been sending messages or speaking to me in person, commending the new format of the journal, JMCFD, and that it is being issued regularly. The idea behind this is that members deserve to have a place where to publish both scholarly articles and updates and it also serves as a good communication means. The journal would not be possible without the help of the editorial team who not only review the articles but continue till the last minute to point out typos and errors and into keeping with the format. With my responsibilities as President, handling the journal alone would have been impossible. But it is something which we all take pride in.

Our thanks goes out to our sponsors, who even in these difficult times continue to give us the support we need to go to press and send each journal free to all. We only seek enough sponsors to meet the costs of layout, printing and postage. The editorial board is all voluntary work. One hopes that members appreciate this as much as those who have been congratulating us. Our success depends, at the end of the day, also on submissions.

However being a small island, submissions cannot be that frequent, which is why we had decided to commission some articles and have themes for each issue. This time round we have decided to discuss the important Mental Health Act. There are other articles in the pipeline in this regard which did not meet the deadline. But this issue is full of practical information for GPs and how to handle those difficult situations in which we all find ourselves sometimes, namely sending someone to a mental hospital for treatment against their voluntary will.

For this issue I would especially thank Mrs. Gertude Buttigieg who had approached me to organise a CME event for college members. This was not possible immediately since the College plans CME much ahead and it involves a considerable amount of work and chasing of sponsors - much more than people think. Therefore organising a CME on mental health without the necessary funding coming from somewhere was difficult. But I offered the journal, which of course is a means which will reach everyone and indeed remains there. I thank Dr John Cachia, the Commissioner for Mental Health for his support and contribution.

In this issue Ms Buttigieg writes about the new mental health Act of 2012 and its implications for doctors. In support of this article is another article by Dr Miriam Camilleri on the new mental health act and the family doctor. An article which I thought worth reproducing was one which had appeared in The Synapse by Drs Anthony Zahra and Nigel Camilleri, 'A commentary on the new mental health act for the Maltese Islands'. I thank the authors and Dr Wilfred Galea for their kind permission to reprint. Finally an article on Good Parenting, which affects mental well being of children and their future supplements well the chosen theme. In this way I hope that this issue of JMCFD will serve as a compendium on mental issues.

From this time we will be send the journal to an updated list of college members as we felt that a number was being sent to people who never really were college members. This of course is unfair on those who pay membership dues and only in this way will the journal properly be indeed the journal of the MCFD.

Better mental health and well-being

Dr John M CACHIA

Mental ill-health imposes a huge burden on individuals, their families, society, health systems and the economy. Mental health care remains a neglected area of health policy in too many countries.

This statement by the Organisation for Economic Co-operation and Development (OECD 2014) confirms the overall bleak assessment of the reaction to mental ill-health that prevails worldwide even in well-developed economies. Mental ill-health has accompanying costs in terms of reduced quality of life, loss of productivity, and premature mortality. Data from the European Union shows that stigma and the fear of its possible effects on personal, family and employment prospects prevents around half of those who need mental health care to come forward and request such care.

Health policy makers and service providers must reflect on the implications of such devastating statements that affect the personal life of a sizeable proportion of the population. The Maltese Parliament has provided an initial strong and meaningful response by approving unanimously a new Mental Health Act, which was developed with the contribution of hundreds of stakeholders and professionals. This Act comes fully into force on 10th October 2014.

The new Act provides a framework within which professionals and patients can interact on the basis of a set of nineteen rights and a number of obligations with specific timeframes and checks and balances ensuring that such rights are upheld and safeguarded. The full implementation of the Act will take a number of years but it is encouraging to note that the first steps are already being taken by service providers within the public mental health services.

In the past three months, my staff and I have had the privilege of visiting 43 different wards, units and services that cater for the needs of persons with mental disorder. The level of awareness to the new law is encouraging, staff is becoming more attuned to the new methods and approaches, and one visible proof is the introduction of consent forms to treatment. Although not 100% complete, this exercise has been embraced by many professionals who realise the importance of dialogue with patients and carers and the opening up of service delivery to a multidisciplinary team of professionals each contributing to the wellbeing of the service user. There are many other changes that will occur in the coming months and the goodwill of most stakeholders is the best guarantee of success. It may seem an uphill struggle and the necessary resources may not be fully available but the evidence is now overwhelming: there is a very hefty price-tag attached to neglecting mental ill-health. These are the main challenges for the providers of specialised mental health services.

Prevention of disease has always been the main thrust of family medicine. In this regard, primary care is further empowered by the provisions of the new Mental Health Act. Beyond shared care with specialist teams, about which you can read further articles in this edition of the JMCFD, the family medicine specialist is challenged to reflect on the impact of the preventive approach to mental ill-health. This requires the ability to look for and recognise high risk situations which lead to mental disorder such as major life-events, trauma, family discord, etc.; the increased mental ill-health burden of chronic disease; and the increased severity of chronic disease in the presence of mental disorder. In all these aspects the family physician has a pivotal role in the early diagnosis and treatment or referral of those at increased risk of mental disorder. This is an integral part of the new challenge for the entire health system which is the mainstreaming of mental health in all aspects of care provision.

The deep concerns expressed by OECD regarding the impact of mental ill-health on economic growth and prosperity require a societal response. The determinants of better mental health for all in Malta and Gozo transcend the traditional health and social care boundaries and include individual behaviour and

lifestyles including ability to cope and good interpersonal relationships; better work-life balance; improved social and environmental factors like income, social status, education, employment, housing and working conditions; and finally good physical health which includes access to good quality health and social services. Tackling these determinants will alleviate the burden of mental disorders in our society. Every citizen has a personal responsibility for better mental health and well-being.

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OECD, 2014. *Making Mental Health Count – The Social and Economic Costs of Neglecting Mental Health Care.* OECD Health Policy Studies: OECD Publishing.

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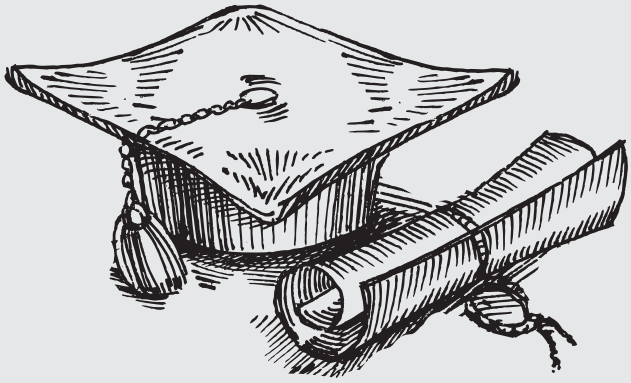
NOTICE

MSc in Clinical Ethics and Law Under the auspices of the Faculty of Medicine and Surgery



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A commentary on of the new mental health act for the Maltese Islands

Anthony ZAHRA & Nigel CAMILLERI

Legal notice 276, published in September 2013, has set out the time windows for the implementation of the Mental Health Act, which was approved by parliament in 2012. The changes are expected to be rolled out over a period of one year, with the totality of the Act being in force by 10th October 2014. The first set of changes, implemented last November, brings in effect the first half of the provisions of the Mental Health Act.

Overall the proposed Mental Health Act is much improved on the previous Act; it reads well and brings the law up to date with modern psychiatry practice. At first glance the Maltese Mental Health Act seems to stem from the basis of the UK 1983 Mental Health Act as amended in 2007, although the authors are not familiar with other EU Mental Health Acts, therefore they could not comment on whether there are resemblances to other Acts.

In the section below, the authors will discuss and make comments on some of the seminal parts of the new Mental Health Act.

Article 2 defines the many terms used in the Act. Of particular note is the term *mental disorder,* which has been pegged to disturbances of thought, mood, volition, perception, cognition, orientation or memory, to a degree that would be considered as pathological in international classifications. This is particularly useful in that it sets widely recognisable evidence-based standards, which are in turn supported by extensive field trials. However the authors point out in the definition of mental disorder, "*... considered pathological in accordance with internationally accepted medical and diagnostic standards….*" We believe that this leaves a definition which may be too broad in the determination of classificatory systems to be used. This may result in the possible idiosyncratic use of different diagnostic systems which have varying input of field tests and evidence-base. A specific reference to the International Classification of Diseases (WHO) or the Diagnostic and Statistical Manual of mental disorders (APA) may provide more definite guidance to the users of the Act as to which classificatory systems to refer to.

Part IV 7(2)(e): 'shall have a multidisciplinary care plan formulated in consultation with the patient and, or the responsible carer and finalised within 168 hours of admission.' One of the authors questioned what will the patient do and receive in the terms of care package in those seven days during admission to hospital? The authors are aware that the formulation of a care plan takes time to process, however a best practice suggestion could be that an initial care plan should be written up in the first 48 hours of the patients' admission into hospital, after which such care plan would be elaborated in more depth to meet all the needs of the in-patient over the following 5 days. As a result, the patient's management would commence as soon as possible, thus potentially reducing the acute impact of the condition and enabling his/her stay to be a short as possible. The outcome would be of benefit to both the in-patient and the service, as this will result in higher turnover rates of patients and lower mean number of days in hospital stays.

It is best clinical practice that a care plan and a discharge plan are formally drawn up in the immediate early phases of admission, whilst the law prescribes the maximum amount of time allowed for the formulation of such a plan. It should not be taken to mean that the law is prescribing the minimum number of days stipulated to write up a care plan, but the maximum. Further to this, the clinical focus of the clinicians remains upon devising a care plan formulation at the earliest, in the best interest of the in-patient, whilst being mindful of the legal parameters.

Part IV 7(3): This is a proviso which allows "in cases of voluntary admissions the nurse in charge of the patient may prevent self discharge for up to four hours to allow review by a medical practitioner if it is perceived that there are grounds for involuntary admission." This seems to be based on section 5.4 of the UK Mental Health Act. The Act specifies "*the nurse in charge of patient*"; does that mean there will be a named key worker/care coordinator

who will be responsible for the care of each patient (based on the Choice and Partnership Approach (CAPA)) model in the UK? If this is the case, if the appointed nurse is not on duty, then who becomes the nurse in charge? And what does 'nurse in charge' actually mean? In the UK, this falls within the remit of responsibilities of a registered mental health nurse. Shifted to the local context, would this be a nurse specifically trained in mental health or any nurse working on the ward who happens to be duty on the day? The authors feel that an action to detain a voluntary patient is a serious decision requiring formal mental health training, so limiting this responsibility to nurses who are specifically trained in the field would improve the standard of care.

Part IV 9(1). "Prior to an involuntary admission for observation, an initial medical assessment shall be made by two medical practitioners, one of whom shall be a specialist" Within the framework of the new Act, two doctors, one of whom being a specialist in mental health, need to provide a recommendation within 72 hours of each other. The application has to be signed by a responsible carer who is appointed by the patient, and in the absence of such, an approved mental welfare officer may apply for admission. In the case of disagreement between the two doctors responsible for the recommendation process, a third independent person, being also a specialist in psychiatry, will carry out an assessment, with the majority recommendation prevailing. This process promotes greater autonomy, in that the responsible carer nominated by the patient will be ultimately responsible for the application process. It is worth noting that provisions exist within the law for the substitution of carers through the Commissioner of Mental Health if there is reasonable doubt that the carer may not be acting in the patient's best interests.

In the UK it is the approved mental welfare officer (AMPH) who is responsible for organising the admission process. The AMPH is one of the three people needed to be present to organise and carry out the assessment to decide on whether or not the patient should be detained involuntarily. It is considered good practice for the three professionals to carry out the assessment together; this will result in asking a similar set of questions once and providing room for discussion following the same patient review. That way you get a medical perspective but also a social care perspective, which is also useful as there is a multidisciplinary approach adopted from the start. This system also helps to solve any problem which arise when you have two people who don't agree on an outcome; in this case, with three persons, there will always be a majority agreement. The two doctors have a responsibility to make a recommendation after which the AMPH takes a final decision.

Part IV 9(2): The presence of the emergency order has its advantages, especially when there is a lack of specialists who can assess potential admissions in the community prior to admission. In Malta, the emergency order is made use of frequently when it comes to admit a patient into a mental health hospital. This has been a loophole which has been used by many doctors, who refer patients for involuntary admission to a psychiatric hospital; however, as a result, this leaves the psychiatrists at the acute inpatient admission phase without any power to take an expert decision on whether or not the person needs to be admitted or not. The authors believe that basing the admission decision solely on one medical recommendation leaves room for potential misuse. As a matter of practice, there should be a best practice clinical direction making an emphasis that the observation order is to be used as first priority. That is the reason why an observation order gives both parties 72 hours to fill in both forms; from a practical side, two doctors, one of whom being a specialist in mental health, should be possible to find.

Part IV 10(2): The current role of responsible relative has been expanded to that of a responsible carer, and extends beyond marital and familial relationships to include persons of trust that are nominated by the patient. This allows a greater degree of autonomy. Whilst at prima facie it would appear that the trusted person will act in the patient's best interest, this clause leaves a lot of power in the hands of the trusted person which may not reflect the patient's intentions. After all, this is a decision about mental health, which is a medical disorder based on international diagnostic criteria, making it an objective decision. There is a complex issue of competence for a person with an acute mental disorder with lack of insight to choose a person of trust at that moment in time. Would this person of 'trust' be chosen beforehand using an advance directive? The authors agree that the nearest relative should be consulted for a collateral history and involved fully in the decision making process and care planning; however the application process may be safer if an approved mental welfare officer is involved.

Part IV 11(1): Whilst the observation order is valid for 10 days, there seems to be no clause on whether or not medication could be given during this time, unless in urgent situations and to prevent further deterioration. This period may not be sufficient to ensure the treatment of a mental disorder. It will be useful to audit the number of patients who will be converted to a treatment order and

determine any correlation with the newly implemented decreased length of time of the observation order.

Part IV 16: The community treatment order seems to be based on the UK Mental Health Act; it reads well and is practical.

Part V 24(2): The Act states: "Only a specialist may certify a person suffering from a mental disorder as having mental capacity or lack thereof.".

The law determines that the specialist needs to be a mental health specialist. All doctors should be trained in assessing capacity since a patient's health is the responsibility of any doctor; the doctor should be empowered to carry out an assessment of capacity in the first instance. However, if a second opinion is needed, then a psychiatrist is involved on a case by case basis. It is however noteworthy that within this Mental Health Act, capacity of understanding is mostly restricted for the management of civil matters, and issues of capacity falling within the remit of the mental health act need to be assessed by a specialist in mental health. It is necessary that further legislation is developed to fully regulate all aspects of the capacity and competence, including medical decision making.

The many other changes to be introduced in 2014, including the definition of the role of Commissioner for Mental Health, clear informed consent, services and treatment for underage persons, prescription of restrictive care, prisoners with mental health problems, the licensing of facilities for the provision of mental health care and commitment towards social inclusion will be addressed in later articles. Our impression is that the underlying drive and values in the 2012 Mental Health Act is to make the law more consonant with changes that have permeated the practice of mental health care, respecting autonomy, providing humane and expert care, whilst providing further checks and balances to ensure transparency and professional accountability.

WHAT ARE THE PRACTICAL IMPLICATIONS OF THIS MENTAL HEALTH ACT FOR PROFESSIONALS?

Many family doctors encounter the use of the Mental Health Act when faced with a situation where a person presents with an acute mental disorder which poses a threat to either the person or other parties. In circumstances where a period of containment and observation is warranted, even if such a measure is not acknowledged by the patient involved, the Mental Health Act specifies that an involuntary admission to a mental health setting may be invoked. Up to October 2014, there will be no changes in the period of time for which an emergency order will remain valid. The emergency order will remain for a period of 72 hours up to October 2014, with the new timeframes projected to be introduced at that point.

In conclusion, furthermore to the above, the authors suggest that the best practice for professionals would be to utilise the *admission for observation* in all circumstance unless there is truly an emergency; by this we mean a physical lack of doctors present to assess and make a recommendation for involuntary admission over a 72 hour period. We believe it would be useful for the Commissioner of Mental Health and/or the Malta Association of Psychiatrists to set up educational lectures or issue best practice guidelines, to be used by all professionals, furthering one's understanding of which section of the Mental Health Act should be used in specific clinical scenarios. In cases of encountered difficulties, it would be a safe and feasible option to approach the office of the Commissioner for Mental Health to seek clarification.

WHAT HAS CHANGED IN OCTOBER 2013?

- Within mental health services, informed consent for any form of therapy shall be formalised through the use of a standardised form
- The use of restraint, including the use of single rooms, shall be limited solely to periods of acute behavioural dyscontrol
- The use of electro convulsive therapy shall need the approval of two specialists, even when the patients are able to provide informed conset
- Introduction of terms and statutory offices aimed at introducing more checks and balances at a clinical and administrative level

Urinary tract infections in the community

Jason J BONNICI, Francesca LENTINI

ABSTRACT

Urinary tract infections (UTIs) are defined as significant bacteriuria in the setting of symptoms of cystitis/pyelonephritis. Urine dipstick is diagnostic in most cases. Urinalysis and Microscopy (U&M) and Culture and Sensitivity (C&S) prior to starting antibiotic therapy is indicated for the diagnosis and as an aid to the correct management of UTIs in certain settings. Antibiotics to treat UTIs must be carefully chosen and their prescribed duration depends on the type of UTI. Over-the-counter products for the treatment and prevention of UTIs are available: these include cranberry products and potassium citrate. Recurrent UTIs in females, UTIs in catheterized men, pyelonephritis and UTIs with unusual organisms require further investigation.

Keywords/ phrases: urinary tract infections; cystitis; bacteriuria; pyelonephritis

INTRODUCTION

Urinary tract infections (UTIs) are defined as significant bacteriuria in the setting of symptoms of cystitis or pyelonephritis (Health Protection Agency, 2006).

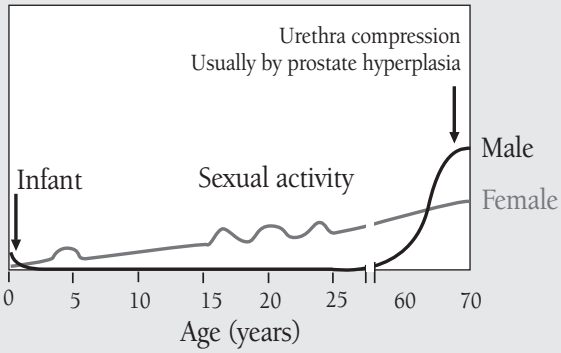
Asymptomatic bacteriuria is a laboratory diagnosis. In women it is present when there are two consecutive specimens with an isolation of 100,000 cfu/mL of single bacterial species (cfu is colony forming units; mL is millilitre) (Health Protection Agency, 2006). In men it is diagnosed when there is one specimen with an isolation of 100,000 cfu/mL of single bacterial species is present (Health Protection Agency, 2006). The diagnosis in catheterized patients is done when a specimen with an isolation of 100cfu/mL of single bacterial species is present (Health Protection Agency, 2006).

The epidemiology is shown in Figure 1. It is relatively common in infancy. With the advent of sexual activity, it is commoner in females than in males. However with the advent of benign prostate hypertrophy it becomes more common in males.

PREDISPOSING FACTORS

A number of predisposing factors make the occurrence of a urinary tract infection more possible. Being female makes a UTI more likely. Urinary stasis is a major determinant. This can be due to obstruction to flow of urine e.g. a person might be too busy to empty the bladder, the presence of urinary stones or bladder tumours, enlargement of the prostate, the effect of pregnancy, after anaesthesia and after major surgery.

Figure 1: Epidemiology (University of South Carolina, 2011)



Other predisposing factors are sexual intercourse, menopause, instrumentation of the urinary tract, anomalies of the urinary tract, constipation in both children and the elderly and poor perineal hygiene in the elderly. Patients with diabetes are more prone to UTIs.

PATHOGENS INVOLVED

In cystitis or in pyelonephritis a number of pathogens can be involved. Some are more common than others. The commonest cause is *Escherichia coli* (Mifsud, 2013). *Proteus* species are associated with renal stones. *Staphylococcus saprophyticus* is associated with UTIs in young women. Other common pathogens are *Klebsiella pneumonia, Pseudomonas aeruginosa*, *Enterobacter* species and *Enterococcus fecalis.* Other pathogens are uncommonly encountered: Adenovirus types 1-47, *Mycobacterium tuberculosis, Leptospira interrogans, Schistosoma* species and *Candida albicans. Candida albicans* is associated with UTIs in people with diabetes and in people who are immunocompromised. Cystitis originates primarily from pathogens in the bowel flora. The infection then ascends to the urinary tract: this mechanism is the most common, especially in females.

At times General Practitioners/Family Doctors need to distinguish the presence of urethritis. This is characterized by dysuria without suprapubic discomfort. Urethritis makes a General Practitioner/Family Doctor think of a Sexually Transmitted Infection. Here the common organisms are *Chlamydia trachomatis* (which gives sterile pyuria in the sexually active), *Ureaplasma urealyticum*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis*.

At times a UTI is the result of a blood-borne infection. In this case the culprit organisms are *Mycobacterium tuberculosis*, *Leptospira interrogans* and *Salmonella*.

CLINICAL FEATURES

The clinical features help to distinguish between an acute cystitis and a pyelonephritis. This in turn impacts on the management options.

The clinical features of an acute cystitis are dysuria, urinary frequency, urgency, suprapubic pain and tenderness and haematuria. In the elderly confusion and/or incontinence can be the presenting clinical features of acute cystitis. In children acute cystitis can present with fever, anorexia, lethargy, irritability, failure to thrive, abdominal pain and vomiting. Haemorrhagic cystitis is additionally characterised by macroscopic haematuria. However, apart from bacterial infection and adenovirus type 1-47 infection there are other causes of haemorrhagic cystitis. The latter include bladder stones, schistosomiasis, after radiation therapy, cancer chemotherapy and immunosuppressive medication.

The clinical features of pyelonephritis include flank pain/back pain and fever (these features are indicative of both bacteraemia and of kidney involvement), nausea, vomiting and chills.

Owing to the many natural defences to infection of the urinary tract in males, UTIs in males are considered to be complicated. This is because they are more likely to be associated with anatomical abnormalities, requiring surgical intervention to prevent sequelae. Imaging studies in males are to be considered in patients with diabetes, in patients with polycystic kidneys, in patients with tuberculosis and in patients with a history of kidney stones.

COMPLICATIONS OF UTIs

Patients with UTIs at times present to the consulting room afraid of some of the possible complications. These include bacteraemia, chronic pyelonephritis, kidney abscess, septicaemia and eventually death. UTIs are particularly important in infants and children < 4 years due to the association with vesico-ureteric reflux; and renal scarring (National Institute for Health and Care Excellence (NICE) Guidelines, 2007). Renal scarring leads to reflux nephropathy with associated eventual hypertension and renal failure.

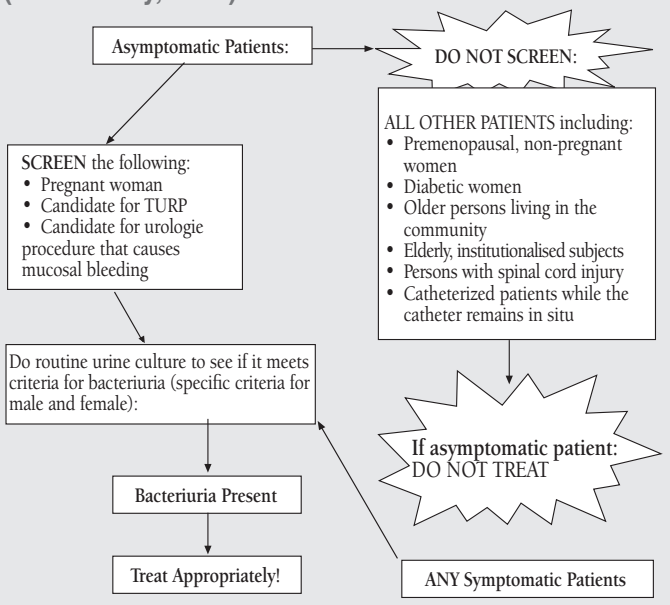
INVESTIGATIONS

The investigations start at the clinic. The physical appearance of the urine sample gives an indication of what may be going on. A urine sample that looks cloudy is strongly suggestive of a bacterial UTI. A red sample points to the presence of haematuria and the cause of this is to be defined.

The investigation of a urine sample demands a 'clean-catch' urine specimen. This would need careful cleansing of the perineal area, removal of skin that is in the way, and the collection of a mid-stream specimen.

The next step is the dipstick analysis. A combination of classical clinical features and the result of dipstick analysis are enough for a diagnosis of UTI in healthy adult women. The nitrite test points towards enterobactericeae if positive. The leucocyte-esterase test detects intact and lysed leucocytes; this needs contact time with bacteria (hence ideally the first morning

Figure 2: Asymptomatic Bacteriuria (Chowdhury, 2012)



specimen should be used). The pH is important as it may assist in choice of antibiotic: a high urinary pH may be indicative of a pathogen that produces urease enzymes, e.g. *Proteus* or *Serratia*, which are intrinsically resistant to nitrofurantoin. Nitrofurantion should not be prescribed for infections characterised with a urine pH >7. Other tests in the dipstick analysis are for protein and blood.

The subsequent tool in the investigation portfolio is many a time a urine culture. Once again a 'clean-catch' specimen is warranted. The indications for a urine culture are: a man with symptoms of UTI, a child with possible UTI, a suspected UTI in pregnancy, a suspected UTI in a patient with abnormal urinary tract, a suspected UTI in a patient with renal impairment, in cases of suspected pyelonephritis, in cases of unresolved, relapse or recurrent infection, in patients who are immunosuppressed and when instrumentation of the urinary tract was recently performed.

DIAGNOSIS

Dipstick analysis results provide General Practitioners/ Family Doctors with a diagnosis in a number of occasions (Table 2).

Together with a urine culture a sample is usually sent for urine microscopy. A 'clean-catch' specimen is warranted. The sample is examined as a wet preparation to detect the presence of significant pyuria (white blood cells $\geq 10^7$ cells/ml of urine), red blood cells, epithelial cells (an indication of perineal contamination), yeast cells, *Trichomonas vaginalis* trophozoites, *Schistosoma haematobium* eggs, crystals and casts.

For the diagnosis of a UTI, a urine mid-stream specimen of urine (MSU) for culture and sensitivity (C&S) has to be taken prior to starting the patient on any antibiotic treatment. A UTI is diagnosed when a symptomatic patient has a urine MSU C&S of $\geq 10^5$ CFU bacteria/ml of urine (Simon, Everitt and Kendrick, 2006). This amount i.e. $\geq 10^5$ CFU bacteria/ml of urine denotes a significant bacteriuria. If the bacteria specimen grown is *Escherichia coli* or *Staphylococcus saprophyticus* at $\geq 10^3$ CFU bacterial/ml of urine, this is enough for diagnosis of significant bacteriuria (Health Protection Agency, 2006). If the amount is $< 10^4$ CFU bacteria/ml of urine or there are more than one bacterial type, this is indicative of bacterial contamination (Health Protection Agency, 2006).

In a UTI an MSU C&S will show pyuria, bacteriuria and nitrates. If in an MSU C&S shows pyuria without bacteriuria this signifies inflammation whereas bacteriuria without pyuria signifies colonization. Causes of the above are tabulated in Table 3.

A UTI is defined as a significant bacteriuria in a symptomatic patient. There will be instances where a significant bacteriuria will be found in an asymptomatic patient when screening with MSU C&S in done. Asymptomatic screening is only warranted in the categories of patients listed in Figure 2. If significant bacteriuria is found in one of these patients, they should be treated appropriately as is shown in Figure 2. All other asymptomatic patients should not be routinely screened.

FURTHER INVESTIGATIONS

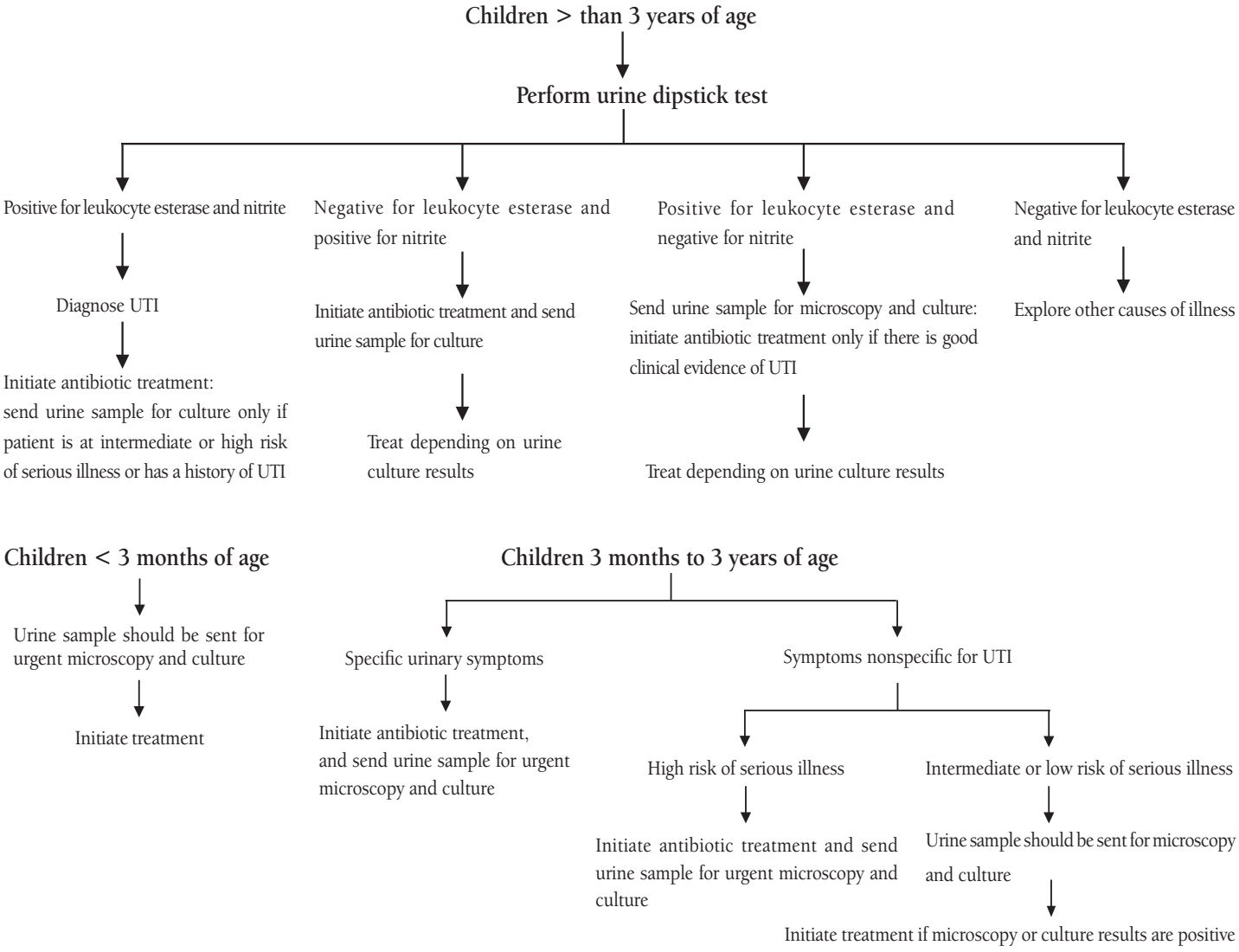
UTIs in uncatheterised males, recurrent UTIs in women, pyelonephritis, where the diagnosis is unclear and in cases where unusual pathogens are grown, require further investigations. These include blood tests for renal profile and possibly a Prostate Specific Antigen test in males. Imaging such as ultrasound (US), computed tomography scan of the kidney, ureter and bladder (CT-KUB), intravenous urogram (IVU), micturating cystourethrogram (MCUG) and dimercaptosuccinic acid scan (DMSA) may be needed.

TREATING UTIs

Over-The-Counter Preparation

Alkalization of urine with products such as **potassium citrate** is used to alleviate symptoms of dysuria; however evidence base is lacking. It should be used with caution in patients suffering from heart failure and hypertension

Diagnosing UTI in children (adapted into table format from NICE Guidelines 2007: Urinary Tract Infections in Children)



because of their high sodium and potassium content as well as patients on potassium sparing diuretics such as angiotensin converting enzyme Inhibitors and angiotensin receptor blockers. It should not be used in combination with nitrofurantoin because the latter needs an acidic pH to work.

Antibiotics

Table 4 shows the UTI cases isolated from the urine samples sent from the community to the Pathology Department of Mater Dei Hospital in the period January to March 2014. It shows what organisms were cultured and their sensitivities to different antibiotics.

First line antibiotics for UTIs are (Mifsud, 2013):

Nitrofurantoin provides consistent efficacy for *Escherichia coli* and *Staphylococcus saprophyticus*. It does not disturb the vaginal flora. It is not advisable for use after 36 weeks' gestation because of the risk of haemolysis if the fetus has glucose-6-phosphate dehydrogenase deficiency.

Beta-Lactam antibiotics including amoxicillin, amoxicillin/clavulanate and cephalosporins are effective but there are hypersensitivity issues.

Quinolones are contraindicated in patients prone to seizure. Tendinitis as a side effect of quinolone use has to be kept in mind. Norfloxacin and ciprofloxacin are particularly useful for upper UTIs and pyelonephritis, but nalidixic acid is not effective against *Pseudomonas*.

Co-trimoxazole: consider hypersensitivity to these drugs and contemporary drug resistance patterns before prescribing such drugs.

Antibiotic duration for UTIs depends on the type of UTI. For example for cystitis 3-5 days of antibiotics is sufficient, while for pyelonephritis up to 14 days of antibiotics may be needed. Complicated UTIs may need more prolonged treatment. Patients with risk factors such as prostatic enlargement, urologic anomaly, resistant

pathogens and recurrent UTIs usually require prolonged treatments and also combination treatments.

PROPHYLAXIS FOR RECURRENT UTIs

Advise patients to drink plenty of water, micturate frequently, double void, void after intercourse, wipe perineum front to back, avoid perfumed soaps/bubble baths and to wear cotton underwear to avoid recurrent UTIs.

Cranberry products are recommended for the prophylaxis of recurrent UTIs in premenopausal women (Health Protection Agency, 2006). Thirty-six mg/day of the active compound proanthocyanindin A is recommended. Cranberry products have not been shown to be effective for the treatment of a UTI and neither is it effective for the prophylaxis of UTIs in postmenopausal or catheterised patients. When suggesting cranberry products for the prophylaxis of UTIs, the interaction with warfarin through cytochrome P 450 is to be kept in mind.

Topical Hormone Replacement Treatment decreases recurrent UTIs in women of all ages(Health Protection Agency, 2006). In men with prostatic enlargement, finasteride and/or doxazocin helps decrease the incidence of recurrent UTIs (Health Protection Agency, 2006).

Recurrent UTIs in adults are defined as three UTIs in 12 months or two UTIs in six months(Health Protection Agency, 2006). In these cases, if symptoms are debilitating for the patient one might consider antibiotic prophylaxis, which is usually taken at night when urine flow is low. Antibiotic prophylaxis is not recommended for more than six months in view of resistance (Mifsud, 2013). Antibiotic prophylaxis is usually not recommended for catheterized patients (Mifsud, 2013).

UTIs IN CHILDREN

UTIs in children have different clinical features depending on the age group of the child. At times diagnosing UTIs in children is a challenge. Table 1 summarises the clinical features of UTIs in children.

One may diagnose UTI in children using the algorithms in Figures 3. The following lists (National Institute for Health and Care Excellence (NICE) Guidelines, 2007) may be used to come to a working diagnosis:

Children with an atypical UTI:

- Are seriously ill
- Have poor urine flow
- Have an abdominal or bladder mass
- Have a raised creatinine
- Have septicaemia
- Fail to respond to suitable antibiotics within 48 hours
- Have non-*E coli* organisms.

Table 1: UTI Features in Children (adapted into table format from NICE Guidelines 2007: Urinary Tract Infections in Children)

Age group		Symptoms and signs		
		Most common		Least common
Infants younger than 3 months		Fever Vomiting Lethargy Irritability	Poor feeding Failure to thrive	Abdominal pain Jaundice Haematuria Offensive urine
Infants and children, 3 months or older	Preverbal	Fever	Abdominal pain Loin tenderness Vomiting Poor feeding	Lethargy Irritability Haematuria Offensive urine
	Verbal	Frequency Dysuria	Dysfunctional voiding Changes to continence Abdominal pain Loin tenderness	Fever Malaise Vomiting Haematuria Offensive urine Cloudy urine

Table 2: Urine Dipstick Interpretation (WCC- white cell count; RBC red blood cells)

Nitrites	WCC	Protein	RBC	Diagnosis
+	±	±	±	Probable UTI: give Antibiotic
-	-	-	-	"Urethral syndrome". Reassure
-	+	±	±	Review sampling time. Treat if symptoms severe and send culture
-	-	±	+	Consider other causes

Table 3: Causes of pyuria without bacteriuria and causes of bacteriuria without pyuria

Pyuria without bacteriuria	Bacteriuria without pyuria
Patient on antimicrobial treatment	Urine contamination
Inadequately treated UTI	
Renal tuberculosis	Childhood UTI
Gonococcal urethritis	
Prostatitis	Bacterial endocarditis
Chlamydia trachomatis	
Leptospirosis	Diabetes Mellitus
Appendicitis	
Schistosomiasis	Enteric Fever
Papillary necrosis	
Interstitial nephritis	
Interstitial cystitis	
Polycystic kidneys	
Renal Stones	
Bladder tumor	
Chemical/Radiation cystitis	

A recurrent UTI is defined as:

- Two or more episodes of UTI with upper UTI
- One episode of UTI with upper UTI plus one or more episodes of lower UTI
- Three or more episodes of UTI with lower UTI.

Table 5 summarizes imaging tests used in children with UTIs

URETHRAL SYNDROME

Fifty per cent of women with symptoms of cystitis have negative bacteriological culture and are said to have urethral syndrome. The aetiology is unknown however it is being linked to chlamydia. Is it associated with cold, stress, sex, nylon underwear and the combined oral contraceptive (COC) pill (Health Protection Agency, 2006). Treatment may include stopping or changing the COC pill, topical oestrogen if post-menopausal or doxycycline 100mg twice daily for 14 days or azithromycin 500mg daily for 6 days. Urethral dilatation/ massage might help (Health Protection Agency, 2006).

INTERSTITIAL CYSTITIS

This condition affects predominantly middle-aged women. It can cause fibrosis of the bladder wall. The symptoms are frequency, urgency and suprapubic pain when the bladder is full. It can be misdiagnosed as recurrent UTI. The MSU C&S shows no bacteriuria. The General Practitioner/Family Doctor may consider referral to urology but there is no satisfactory treatment though antispasmodics, amitriptyline and bladder stretching may help.

Table 4: Local UTI cases January- March 2014: organisms isolated and their sensitivities (table presented by Consultant Virologist Dr. Chris Barbara during Malta College of Family Doctors Continued Medical Education activity of 01.04.2014)

Organism	Escherichia coli	Enterococcus faecalis	Klebsiella oxytoca	Klebsiella pneumoniae	Citrobacter koseri
Cases Isolated 2014 (Jan to Marc)	17	7	2	2	2
	%Sensitive	%Sensitive	%Sensitive	%Sensitive	%Sensitive
Amikacin	100.00		100.00	100.00	100.00
Ampicillin	41.18	100.00	0.00	0.00	
Co-Amoxyclav	82.35		100.00	100.00	100.00
Ceftazidime	94.12		100.00	100.00	100.00
Ciprofloxacin	94.12		100.00	100.00	100.00
Trimeth Sulfa	64.71		100.00	100.00	100.00
Cefotaxime	94.12		100.00	100.00	100.00
Ertapenem	100.00		100.00	100.00	100.00
Cefepime	94.12		100.00	100.00	100.00
Fosfomyain	100.00		100.00	100.00	100.00
Gentamicin	94.12	85.71	100.00	100.00	100.00
Imipenem	100.00	100.00	100.00	100.00	100.00
Meropenem	100.00		100.00	100.00	100.00
Nitrofurantoin	94.12	100.00	0.00	0.00	100.00
Norfloxacin	64.71		100.00	100.00	100.00
Pip/Tazobactan	100.00		100.00	100.00	100.00
Levofloxacin		100.00			
Linezolid		100.00			
Moxifloxacin		100.00			
Quinupristine Dalfopristine		0.00			
Anti-Smith Ab (Sm)		100.00			
Ampicillin/Sulbactam		100.00			
Streptomycin		71.43			
Teicoplanin		100.00			
Tigecycline		100.00			
Vancomycin		100.00			
Other organisms isolated once:	Enterobacter cloacae				
	Proteus vulgaris				
	Citrobacter freundii				

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Table 5: Imaging in children with UTIs (adapted into table format from NICE Guidelines 2007: Urinary Tract Infections in Children). NB: DMSA scan: dimercaptosuccinic acid scan; MCUG: micturating cystourethrogram

5A: Imaging in infants < 6 months of age with UTI

Test	Responds well to treatment within 48 hours	Atypical UTI	Recurrent UTI
Ultrasound during the acute infection	No	Yes	Yes
Ultrasound within six weeks	Yes	No	No
DMSA scan four to six months following the acute infection	No	Yes	Yes
MCUG	No	Yes	Yes

5B: Imaging in children > 6months of age and < 3 years of age

Test	Responds well to treatment within 48 hours	Atypical UTI	Recurrent UTI
Ultrasound during the acute infection	No	Yes	No
Ultrasound within six weeks	No	No	Yes
DMSA scan four to six months following the acute infection	No	Yes	Yes
MCUG	No	No	No

5C: Imaging in children > 3 years of age

Test	Responds well to treatment within 48 hours	Atypical UTI	Recurrent UTI
Ultrasound during the acute infection	No	Yes	No
Ultrasound within six weeks	No	No	Yes
DMSA scan four to six months following the acute infection	No	No	Yes
MCUG	No	No	No

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The Mental Health Act, 2012

Gertrude A. BUTTIGIEG

BACKGROUND

The history of mental health is tainted with a bad reputation of people with mental health problems being treated as witches and as people possessed by evil spirits. Over the years there is documented evidence of people with mental health problems being unnecessarily held in prisons and in secluded places – asylums. In the 20th century considerable improvement was made in the care and treatment of mental health disorders and people were moved to hospitals. Still there was a lot of restrictive and 'harsh' treatment which was at times considered as brutal and inhuman. The new trends of care are to give acute treatment in hospital if necessary and to move towards a more community approach. The new law aims to see people with mental health problems as full and active members of the society.

MENTAL HEALTH ACT, 2012

The new Mental Health Act, 2012 in the Maltese legislation is aimed to be in line and reflect changes in knowledge, medical and social developments in the field on a local level. The new law introduces the Commissioner as a monitoring body while it is the first Law in Malta of its kind which gives a legal backing to rights of users and their carers. It also aims to lead towards the necessary changes in perceptions and attitudes to ensure that people with mental health problems are considered 'full citizens'. The law outlines practices which are to be followed to reduce the compulsory length of stay in hospital and fosters more community based services.

LEGISLATIVE FRAMEWORK

The World Health Organisations (WHO, 2013) outlines the basis for sound legislation for the safeguarding of service provision in Mental Health mainly

"Mental health legislation or mental health provisions integrated into other Laws (e.g. anti-discrimination, general health, disability, employment, social welfare, education, housing, and other areas). The relevant legislation may cover a broad array of issues including access to mental health care and other services, quality of mental health care, admission to mental health facilities, consent to treatment, freedom from cruel, inhuman and degrading treatment, freedom from discrimination, the enjoyment of a full range of civil, cultural, economic, political and social rights, and provisions for legal mechanisms to promote and protect human rights (e.g. review bodies to oversee admission and treatment to mental health facilities, monitoring bodies to inspect human rights conditions in facilities and complaint mechanisms)."

The Mental Health Act covers all these aspects within the 11 sections of the Law. Section 1, The Preliminary – gives a list of definitions and outlines several new concepts which are important to bring about the desired changes of improved care and quality of life for people with mental health problems and their families. It is worth pointing out a few of these definitions:

- Custodial Care: means non medical-care that helps a person with his or her activities of daily living and not requiring constant attention of healthcare professionals.
- Health Care Professional: This means all health care professionals involved in the care of the patient. These are those registered with Medical Council, Nursing and Midwifery council, Council for Professions Complimentary to Medicine regulated by the Health Care Professions Act, and those regulated by the Acts regulating the Social Work Profession and Psychology. This change is also reflected in the emphasis in the law about the Multidisciplinary team which means a group of different healthcare professionals working together as a team in giving treatment and care to the patient and the composition of the team varies according to the patients needs.
- Involuntary Patient: means a patient who is receiving treatment and/or care in a licensed facility or in the community against his/her own will.

New definitions are also given to 'Mental Capacity', 'Mental Disorder', 'Mental Health Licensed Facility', 'Mental Welfare Officer', 'Responsible Specialist' and 'Restrictive Care' amongst others. A major change worth noting is the new concept of 'Responsible Carer'.

The new concept of Responsible Carer goes beyond the next of kin or nearest relative. It gives the patient the right to choose a person of trust who will take a direct and active part, together with the multidisciplinary team and the patient, in care decisions whilst representing the patient's interest as required.

RIGHTS OF USERS AND CARERS

The rights of users and carers are listed and defined in the third section of the law. The person with a mental health disorder shall have the right to exercise a number of civil, political, economic, social, religious, educational and cultural rights amongst others. The patients and their carers have the right to full respect of their dignity, the right to privacy and the right to receive quality treatment. The new law gives the right to the person to receive treatment of the same quality and standards as other individuals and to have their needs addressed holistically through a multidisciplinary care plan approach. Importance to care in the community is another right with the aim of facilitating the reintegration of the person in society. The right to receive timely information in an understandable form and manner together with the right to participate actively in own treatment are two new rights driven by the new legislation. Should the person lack mental capacity to understand his rights this information is given to the responsible carer within 24 hours from commencement of care episode. Another three important rights are the right to have access to clinical records; the right to communicate with the outside world and the right to receive visitors; for all three the safeguard of self and others is considered important prior to practicing the rights. Last but not least is the right to have a responsible carer of their choice.

The patients have the right for their care and rehabilitation to be continued in the community so as to facilitate their social inclusion whilst they also have the right to receive information about their disorder and available services to cater for their needs. Confidentiality of all information about themselves and their condition is assured from being revealed to third parties unless there is an emergency situation which requires life saving intervention, it is in the interest of public safety or enforced legally. Environmental aspects are also rightfully protected specifically protection from cruel, inhuman and degrading treatment and assurance of safe and hygienic environment.

The Commissioner

The Commissioner for the Promotion of Rights of Persons with Mental Disorders is established under the new Mental Health Act. The law highlights that the Commissioner is to promote and safeguard the rights of persons suffering from mental disorders and their carers and to review any policies and make the necessary recommendations to the competent authorities. The Commissioner has the authority to receive complaints and carry out investigations relevant to queries received. The new legislation specifically places the onus on the Commissioner of the inspection of all licensed mental health facilities to ascertain that patients' rights and all the provisions of the Act are upheld. The new legislation stipulates in Part 9 the criteria and regulation for the licensing of a mental health facility be it a hospital or a nursing home.

Care and Treatment

The revision in treatment options includes that treatment is to be given in the least restrictive manner possible giving the option to the person suffering from mental disorder to seek voluntary admission. The fourth section of the new law specifically provides for voluntary admissions and elaborates provisions for written informed consent (including for seclusion), the right to self-discharge, the right to be informed at the outset about the possibility of being detained involuntarily if criteria for involuntary admission are met and consultation with the patient and the responsible carer in the formulation of a multidisciplinary care plan. In particular cases where police assistance is required for safety reasons, criteria set in part 11 of the Law are to be respected.

The law lays out provisions regulating mental capacity, with the overarching assumption that – a person suffering from a mental disorder is able and competent to make decisions unless otherwise certified by a psychiatrist. In cases where a person is considered to lack mental capacity the law provides for informed consent to be given by the responsible carer. Part 5 of the Law deals extensively with definitions and ways in which certification of mental capacity are to be conducted. In case of emergency where there is risk for self and others and the person refuses to give consent to treatment and the responsible carer cannot be identified, emergency treatment can be given to prevent further deterioration; however all decisions taken are to be backed with detailed and proper notes in person's clinical records. Admission in such urgent situations can be made even with just one signature of a medical practitioner; however the patient

Table 1: A comparison between the old and new Mental Health Act

MAXIMUM LENGTH OF STAY		
	Old law	New law
Involutary Admission for Observation	28 days	15 days (by day 10 a patient is discharged or becomes a voluntary patient or application for further treatment on an involuntary basis or community treatment order is to be made to Commissioner)
Involutary Admission Treatment Order	1 year	10 weeks
Extension for Involuntary Admission for Treatment Order	1 year	5 weeks (application by responsible specialist to be made to Commissioner accompanied by reasons and modification of the care plan)
Continuing Detention Order	2 years renewable	6 months renewable (has to be accompanied by a modified multidisciplinary care plan)

has to be assessed within 24 hours by a psychiatrist to ensure that the patient's rights are not compromised.

Significant changes in the new law are the time-frames for observation and involuntary detentions; there is a reduction in length of stay and specific procedures and documentation is necessary between one stage and another including relevant schedules with information to be submitted to the Commissioner for Mental Health (Table 1).

A community treatment order is introduced by the new law to provide for care and treatment in the community for those patients where treatment in a licensed facility is not required but meet the criteria for compulsory treatment in the community. The law outlines various parameters which need to be respected for the successful implementation of the community treatment order including a multidisciplinary care plan and the appointment of a key healthcare professional responsible for co-ordinating the necessary treatment. Rehabilitation of patients with mental health problems includes their active involvement in their own treatment plans while a more holistic multidisciplinary approach in care is being established. The law defines the term 'informed consent' whereby patients or their carers actively participate in the treatment after being given all the necessary information in an understandable language and manner.

DEALING WITH MINORS

Part 6 of the law provides special clauses with regards to treatment of individuals under 18 years old – referred to as minors. The facilities providing care for minors are required to have a specific license whilst it foresees that a minor can also give informed consent if required, so long as the minor has sufficient maturity and understanding. In the case of minors deemed to lack sufficient maturity and understanding to provide informed consent, consent shall be elicited from the responsible carer with the necessary safeguard in a situation of emergency or physical or mental deterioration of the minor. Whilst the law fosters for healthy relations between parents and minor, if there are instances where the minor's interests are not being safeguarded the Commissioner may intervene to ensure that the minor receives the required treatment and care. Periods of treatment of minors are considerably reduced and are subject to more frequent reviews (Table 2).

Special Treatments and Research

Part 7 of the Law outlines practices and procedures required for Special Treatments, Restrictive Care and Clinical Trials or other Medical or Scientific Research. Within all medical specialities, no major medical or surgical procedures can be carried out on a patient suffering from a

Table 2: A comparison between lengths of stay for adults and minors

LENGTHS OF STAY ADULTS VS MINORS		
	Old law	New law
Involuntary admission for Treatment order	10 weeks	4 weeks
Extension of Involuntary Admission for Treatment Order	5 weeks	4 weeks for a maximum stay of 12 weeks from initial date of admission
Continuing Detention Order	6 months	3 months renewable (has to be accompanied by a modified multidisciplinary care plan)

mental disorder unless such person gives a written consent. In instances where the person lacks mental capacity such consent may be signed by the responsible carer. The same criteria apply for the involvement of a patient with mental health problems in clinical trials and research. With regards to specialised mental health treatment such as Electro Convulsive Therapy, this cannot be performed unless there is the specific agreement of its benefits of two specialists and the informed consent of the patient. The Article regulates the practice of restrictive care such that it is used only as a last resort and for the shortest possible time and in the least restrictive manner possible, in the best interest of the patient. The Commissioner is to ensure that guidelines and protocols for least restrictive care are adhered to by licenced facilities.

Patients Concerned in Criminal Proceedings

Part 8 of the Law establishes practices for mental health care of persons charged with criminal offence or undergoing proceedings and/or people detained under court orders. Within this section there are minimal changes to the old law mainly in change in terminology where the term mental capacity replaces insanity and the fact that person under such conditions has to be kept within the forensic section of a licensed facility rather than openly in the mental health facility itself. The new law caters for prisoners with mental health disorders whereby it stipulates that if a person in prison develops mental health problems, if this person cannot be treated adequately in prison the person is admitted for treatment in the forensic unit and unless criteria for involuntary admission are met the patient is put on a voluntary treatment regime while prison regulations continue to apply.

Promotion of Social inclusion

People with a mental health problem fall within the definition of Vulnerable group as defined by WHO in 2013. "*Certain groups have an elevated risk of developing mental disorders. This vulnerability is brought about by societal factors and the environments in which they live. Vulnerable groups in society will differ across countries, but in general they share common challenges related to their social and economic status, social supports, and living conditions, including:*

- *Stigma and discrimination;*
- *Violence and abuse;*
- *Restrictions in exercising civil and political rights;*
- *Exclusion from participating fully in society;*
- *Reduced access to health and social services;*
- *Reduced access to emergency relief services;*
- *Lack of educational opportunities;*
- *Exclusion from income generation and employment opportunities;*
- *Increased disability and premature death."*

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The new Mental Health Act and the Family Doctor

Dr Miriam CAMILLERI

INTRODUCTION

The new Mental Health Act (2012), is expected to enter fully into force in October 2014. This Act will completely replace the Mental Health Act which we have known and worked with over the last 30 years. Essentially this new Law will bring with it challenges and opportunities for all health care professionals involved in the care of persons with mental disorders.

The new Mental Health Act follows the trend of modern legislation, which essentially adopts an individual human rights approach and places an emphasis on the protection of such rights in vulnerable groups in society, in this case persons with a mental disorder. The Act also mirrors the wider changes in knowledge, perception and attitudes towards mental diseases and mental health which have taken shape over the past decades.

WHAT IS NEW?

For the large part, the old legislation focuses on three broad sections:

(1) Compulsory Hospital Admission,
(2) Institutions providing mental health services, and
(3) Patients concerned in criminal proceedings.

The new Act still covers these three themes but also introduces seven new concepts with sections that deal with:

(1) the rights of users and carers,
(2) the establishment of a Commissioner to safeguard those rights,
(3) compulsory treatment within the community (Community Treatment Order),
(4) the certification of lack of Mental Capacity and the additional functions of curators,
(5) issues pertaining to minors receiving care in mental facilities or as dependent children of parents receiving such care,
(6) special treatments, restrictive care, and clinical trials or other research involving persons with mental disorder, and
(7) the promotion of social inclusion and elimination of all forms of discrimination on the basis of mental health status.

WHOSE REMIT IS IT?

One could argue that the Mental Health Act falls within the remit of psychiatrists and other mental health care professionals and that the role of the family doctor exists somewhere on the boundary of this "inner sanctum." This viewpoint could not be more wrong! Why?

First of all the Mental Health Act, 2012 is about all persons with mental disorder, whether residing in the privacy of their own homes, receiving care in the community or in residential accommodation, or in-patients within mental health facilities. It encompasses care provided both privately as well as within the public health service.

Secondly it is an Act which looks beyond the manifestations of the illness and emphasises the person with the illness. This is at the very core of the family doctor-patient relationship. The family doctor treats the person and not the illness and therefore will welcome the listing, for the first time, of nineteen separate rights for all persons with mental disorder. Merely by browsing through this list of rights, family practitioners may quickly understand how their role is indeed a crucial one for the mental health patient.

Under the new Act emphasis is made to select the least restrictive treatment option for the patient. Hence wherever possible, treatment in the community is to be preferred over treatment within a licensed facility (hospital).

Where care in the community cannot be selected as a primary treatment option, the emphasis then turns to aftercare and rehabilitation in the community. In both these scenarios, the family doctor is strategically placed to provide or supervise the necessary treatment in the community, and to act as the bridge between the patient and the specialist mental health services. The family doctor can be the patient's advocate, ensuring that the patient is provided with adequate information

about the illness and treatment options, and has access to appropriate services as required. The family doctor can be pivotal in actualising the right for patients to actively participate in the formulation of their own care plans and to provide informed consent as necessary. The family doctor is also well placed to encourage and guide the patient in identifying a responsible carer of his or her own choice, and to provide support and guidance to the latter. In other words the family doctor can make a big difference as to whether persons with mental health problems and their carers can actualise the rights that have been granted to them under this Act.

VOLUNTARY INPATIENT TREATMENT IN A LICENSED FACILITY

In line with the least restrictive treatment approach envisaged in the new Act, voluntary treatment is to be preferred over involuntary treatment.

Therefore should hospital in-patient treatment be considered necessary, the family doctor should in the first instance consider eliciting informed consent for a voluntary admission, provided the patient is also informed that should circumstances change and certain criteria be met, such admission could be converted to an involuntary one.

INVOLUNTARY TREATMENT IN A LICENSED FACILITY

The family doctor is often a key participant in the involuntary admission of a patient to a mental health licensed facility. Whilst an emergency involuntary admission will still be possible on the strength of one medical signature only (which is usually that of the family doctor), it is advisable for family doctors to utilise the preferred route of admission which requires a specialist psychiatric assessment and recommendation prior to admission. In either case the medical recommendation is to be done by filling in **only one form - the Second Schedule**. The Second Schedule will also include the application for admission by the responsible carer or the mental welfare officer.

There are three (3) criteria which must all be met throughout the course of an involuntary admission. These are: (a) the presence of a severe mental disorder which (b) is posing a serious risk of physical harm to self or others, and (c) failure to admit or detain the person will likely lead to a serious deterioration in his or her condition or will prevent the administration of appropriate treatment that cannot be provided safely in the community.

Involuntary admission shall always be for Observation for a maximum period of 10 days, at the end of which there can be one of four outcomes:

(1) discharge to the community,
(2) conversion to a voluntary inpatient admission,
(3) an application for an involuntary Treatment Order, or
(4) in application for a Community Treatment Order.

The last two options will necessitate the assessment of the request by the Commissioner and a final decision by Day 15 from date of admission for Observation. The maximum validity of a Treatment Order is for 10 weeks. This may be followed by an Extension of Treatment Order for a maximum of 5 weeks and eventually a Continuing Detention Order for a maximum of 6 months, renewable. At each stage the Commissioner for persons with mental disorder will need to be involved for approval. An independent peer review will be necessary for approvals of Continuing Detention Orders.

In the case of minors the maximum equivalent periods of involuntary admission which may be approved by the Commissioner are much reduced.

COMMUNITY TREATMENT ORDER

The Community Treatment Order is the preferred treatment option for a person suffering from a severe mental disorder requiring treatment in the interest of self or for the protection of others, where there is a serious history of previous failure of compliance, and where such treatment can be safely provided in the community with some extra safeguards. The family doctor is ideally placed to be an active participant in this novel treatment option which enables persons who depend on regular psychiatric treatment to be able to live safely in the community.

A community treatment order provides a family doctor with the possibility of working in tandem with a psychiatrist who remains the responsible specialist for the patient and other health care professionals within a multidisciplinary team approach. The family doctor can either sign the medical recommendation for the application for the community treatment order together with the responsible psychiatrist (Seventh Schedule) or else join the specialist team at a later stage by signing an agreement to provide the required care (Eighth Schedule).

If at any time during the validity period of the Community Treatment Order (maximum 6 months) it becomes necessary to involuntarily admit the patient to a mental facility (hospital), the Order provides the ability to admit the patient for a maximum period of Observation

of 10 days. The person can then be discharged back to the community for the continuation of the remaining validity of the Community Treatment Order. The Order also has safeguards that enable forceful conveyance of the patient for psychiatric assessment if required. The police may be asked for assistance if necessary.

MENTAL CAPACITY AND THE LACK OF IT

A person suffering from a mental disorder shall be deemed able and competent to make decisions unless certified by a psychiatrist as lacking mental capacity to do so.

The practical issue with mental capacity or the lack of it, is the fine balance between autonomy and protection. For this reason the law introduces three levels of certification of lack of mental capacity

(1) a transient lack of mental capacity for a maximum period of 14 days which can be documented in the clinical file;
(2) longer periods up to 26 weeks which require approval by the Commissioner following the advice of an independent specialist; and
(3) certification of lack of mental capacity expected to last longer than 26 weeks which will need to be accompanied by applications for incapacitation or interdiction.

OTHER MATTERS

The family doctor should be aware of a few other various provisions under the new Act. These include

(1) the requirement of eliciting informed consent from minors who are deemed to have sufficient maturity and understanding to provide such consent and acting on such consent even without involving parents,
(2) the special safeguards applicable for research in persons with mental disorder and in the application of restrictive care or special treatments including electro-convulsive therapy (ECT), and
(3) restrictions in assuming a professional capacity with patients related to the third degree.

All decisions taken by the Commissioner can be appealed to in the Court of Voluntary Jurisdiction.

CONCLUSION

The new Mental Health Act provides the family doctor with a modern legislative framework which promotes the rights of the person with mental disorder whilst ensuring the required level of protection. It focuses upon abilities and maximisation of potential of the patient and his or her responsible carer and emphasises the role of multidisciplinary professional involvement. It widens the remit of mental health care away from the strict confines of the mental health institution to the wider community wherein the person with mental disorder can live and integrate as a full and inclusive member of society, be protected from all forms of discrimination, and enjoy full and equal opportunities. Indeed the Mental Health Act (2012) sets the stage upon which the family doctor can take a central and active role. It should also motivate family doctors to further develop their knowledge and skills to provide better mental health care for their clients in the community.

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SUBMITTED ARTICLE

Good Parenting

Marthese GALEA, Christopher SCIBERRAS, Mariella MANGION, Christine GALEA

INTRODUCTION

Doctors need to realize that when one of their patients becomes a parent all of a sudden, everyone around them becomes an expert on parenting. They will start getting plenty of advice which will not always be the right one. That is where we, as doctors need to be vigilant.

Parenthood can be very difficult. There is no right or wrong way of bringing up a child. This article is intended to give you the tools so you can give your patients the best advice based on the latest scientific evidence. Keep in mind that the evidence suggests that parents are happier than non-parents regardless of how tired they might feel at the end of the day. As Nelson et al. (2013) suggested, parents feel most fulfilled when they raise their children, as compared to the fulfilment they obtain from doing other things.

Ashton-James et al. (2013) also stated that the more parents put their children at the centre of their life, the more fulfilled they will feel. There is a thin line between caring deeply for the child and being obsessed with the child, which can lead to the child becoming frustrated.

A study done by Rizzo et al. (2013) found that mothers of children 5 years or younger, who "adored" their children and who went out of their way to be a better parent than the father was, had a higher chance of developing depression and feel less satisfied with their life. It is important that doctors advise these parents to cherish their child, but not at the expense of their mental and physical wellbeing.

We doctors need to tell our patients that being caring and loving does not mean that they are not disciplining their child. When it comes to discipline we have to remind our patients that it is important for them to keep in mind that certain actions and words can make the situation worse and it can backfire in the future even if the parent/s have a strong bond with the child. Wang et al. (2013) found that severe verbal discipline, such as offending the child or using swear words at the child, can result in a worse attitude in the following year. No good comes out of this type of discipline.

EASY WAY OUT

Doctors need to be practical when giving advice on parenting. Television can be an easy substitute for a babysitter. Every parent needs a break. Placing the child in front of the television can be a welcoming break. Although it can be understandable that children are encouraged to watch television we as doctors need to tell our patients that this is not ideal for a child.

According to the American Academy of Paediatrics, children less than 2 years of age should not watch television and this should be limited to 2 hours per day after 2 years of age.

The less television the child will watch, the more active he/she can be. This can lead to a less sedentary lifestyle and therefore there is less chance that the child will be obese. As concluded by Booth et al. (2014) exercise is also linked with better intellectual performance in academic subjects.

PARENTS' BEHAVIOUR WITH THE CHILD

There are many ways of disciplining/guiding a child to have the best character possible to be able to succeed in life, handle disappointments and keep away from trouble.

According to Kopko (2007) the best way to bring up a child is to use the "Authoritative style" (not "Authoritarian style"). Kopko (2007) continues by stating that the authoritative style makes the child feel welcome and loved, but at the same time the child knows that the parent is unyielding when it comes to certain issues which the parent feels are important for the child's upbringing. It is important to encourage your patients to let their children be children as they need to play and have fun, but do remind these parents that they still need to make their children aware that they need to have limitations and a degree of control. This degree can vary as the child grows older. It is important that the parent listens to the child and makes sure that the child is aware that the parent is listening. From as early as 3 years of age we can encourage the parents to start to engage in negotiations and discussions with the child.

Obviously the final decision needs to be taken by the parent. With this kind of parenting, the child feels important that his/her opinion is valued, thereby leading to a more responsible and independent child.

Always tell your patients to keep in mind that they have to present a united front when it comes to disciplining their child, and they always need to be consistent.

PARENTING DURING DIFFICULT TIMES

Although the above recommendations might be seen as obvious by your patients, they are not necessarily easy to implement effectively. It is important to tell your patients to work on memorizing the advice that you give them so they can become familiar with them to the extent that they become second nature when they are correcting their child. It is important to stress on the point of not to shout and humiliate their child. Also tell your patients to never support incorrect conduct and never physically or mentally abuse their child for example by hitting him/her or by threatening him/her with physical abuse.

As highlighted in the Journal of the American Family Physicians 1999 it is important to advise your patients that if they feel constantly furious at their child or cannot control the anger, they should seek help. The parent can come to speak to you as his family doctor or you can suggest an agency that specializes in family support.

It is important that parents give their child a good role model to follow. Encourage these parents to show their child consistency, fairness, love, and decisiveness. Try to make your patients aware that the environment where the child lives needs to be safe, quiet and clean and to always reward good behaviour and highlight their child's strong points. Tell your patients to communicate with their child to help him/her understand and appropriately deal with the emotions he/she is feeling, for example anger if the child didn't get his/her way. Always remind your patients that they are no bad children, but only children with bad behaviour.

DISCIPLINE

As Howe (2010) wrote, evidence suggests that childhood can influence people in their adulthood. Therefore, it is important to encourage our patients to use the right kind of discipline.

Discipline is used to educate a child. We as doctors need to make our patients aware that no one is perfect and that everyone, including a child, can make mistakes. What is being suggested in this article is the use of positive discipline. It is important that we as educators need to encourage constructive behaviour by advising the parents to pay compliments and reward their child. It is important to stress to your patients to never give in during a tantrum or when the child is whining. Tell the parents to ignore whatever he/she is asking for during this phase. This will make the child realize that whining is not getting him/her anywhere so eventually he/she will stop this behaviour. This also applies to any requests that the child makes during improper behaviour. It is important that the parents make the child realize that he/she has responsibilities and that he/she must act on them. Cleaning up after him/her, collecting his/her toys and picking up things that he/she threw on the floor are all examples of tips that you can give to the parents for the child to do. This action can also make the child feel useful.

We have to tell our patients that punishment is something that cannot be avoided. However, we can advise the parents to change the punishment into something more meaningful by converting it into a consequence for the child. The best way to help your patients understand this is by giving examples. If the child fights with another child, the consequence can be that the child plays by him/herself. If a child does not clean up after himself/herself, their favourite toy can be taken away for some time. For a child above the age of 5 years, not watching television or not playing video games can also be a consequence that we as doctors can advise the parents to do. Always tell your patients that they need to be firm and consistent, that they need to clearly explain the consequence to the child before it is implemented, and that once the consequence is issued it cannot be revoked. Also remind your patients that a young child has not yet grasped the concept of time, and therefore a consequence needs to be implemented immediately after the child's action and that it has to be relevant to the action the child did.

CONCLUSION

It is important to make parents aware, especially if they have more than one child, that every child is different and that every child has his/her unique character. Therefore every parent needs to address every child accordingly. We need to make parents realize that they need to adapt to the child's needs, keeping the suggestions mentioned above just as a guideline.

It is also important to make parents realize that there is nothing wrong in seeking advice from a professional

such as the family doctor or paediatrician. We doctors need to be aware which governmental agencies and even private agencies we can refer our patients to if they need more specialized help in dealing with a child that has a behavioural issue. This might mean sharing information about a specific patient or his or her child. As mentioned by Wilson and Mullin (2010) giving private information about your patients to governmental or private agencies which might not be related to your practice can cause a number of challenges. These however need to be overcome for the benefit of the child. Since a family doctor is in close contact with the families of his/her practice he/she needs to be able to recognize when a child is being abused. Ideally a doctor needs to prevent child abuse by educating parents. The impact of child abuse can be devastating to a child. As Bethea (1999) wrote, children that suffer physically and mentally due to abuse can end up having repercussions in the future, such as delays in developmental milestones and anxiety syndromes.

A very important advice that we take for granted is to make your patients realize that they need to enjoy the time with their child and spend as much time with him/her as possible. The love that a parent can give to his/her child cannot be replaced by anything or anyone.

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NOTICE

Now change to clarity

"As a number of members are aware, around mid June, the much used site www.cks.org.uk (Clinical Knowledge Skills by NICE) suddenly became unavailable to Malta. Upon becoming aware of this, the Malta College of Family Doctors immediately made contact with our colleagues at the Royal College of General Practitioners who kindly put us into direct contact with NICE. We have been informed that NICE only commissions the CKS service for use within the UK, and as such does not own the rights to make this service available internationally. We have been directed to a company called Clarity (http://www.clarity.co.uk/) who are able to provide this same service to international users at a price. Negotiations with Clarity have led to us being offered an individual membership at 125 per annum.

Anyone who is interested in taking up subscription with Clarity is kindly asked to forward his/her email address to contact@mcfd.org.mt. This will then be forwarded to Clarity who in turn will contact the individual with the relevant details."

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PRESENTATION: Each tablet contains 50 mg of Vildagliptin INDICATIONS: For the treatment of type 2 diabetes mellitus in adults: As monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with: metformin in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin; a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance; a thiazolidinedione in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. As triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control. **DOSAGE:** When used as monotherapy in combination with thiazolidinedione, in combination with metformin and a sulphonylurea or in combination with insulin (with or without metformin), the recommended daily dose of Vildagliptin is 100mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening. When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. Galvus can be administered with or without a meal. Doses greater than 100 mg are not recommended. Galvus is not recommended for use in children and adoloscents (< 18 years). The safety and efficacy of Galvus in children and adolescents (< 18 years) have not been established. No data are available. The recommended dose for patients with moderate/severe renal impairment is 50mg once daily. If a dose of Galvus is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. No dose adjustments are necessary in elderly patients (≥ 65 years. The safety and efficacy of Vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients **WARNINGS / PRECAUTIONS:** Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with ESRD on haemodialysis. Therefore Galvus should be used with caution in these patients. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. Liver function tests should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3xULN or greater persist, withdrawal of Galvus therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus. Clinical experience in patients with NYHA functional class III treated with Vildagliptin is still limited and results are inconclusive. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Galvus should not be administered during pregnancy or breast-feeding since no studies on the effect on human fertility have been conducted for Galvus. Should be used with caution in patients with renal impairment. Sulphonylureas are known to cause hypoglycaemia. Patients receiving Vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. Use of Vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, Vildagliptin should be discontinued; if acute pancreatitis is confirmed, Vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with Vildagliptin. As with other oral antidiabetic medicines, the hypoglycaemic effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. **ADVERSE REACTIONS:** Rare cases (>1/10,000 to <1/1,000) angioedema, abnormal liver function tests, hepatic dysfunction (including hepatitis). Monotherapy: Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Combination with metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia, hyperhidrosis, asthenia. Uncommon: fatigue. Combination with sulphonylurea: Common: tremor, headache, dizziness, asthenia, hypoglycaemia. Uncommon: constipation. Very rare: nasopharyngitis. Combination with Thiazolidinedione: Common: weight increase. oedema peripheral, Uncommon: headache, asthenia, hypoglycaemia. Combination with insulin: Common: decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease. Uncommon: Diarrhoea, flatulence. Frequency not known: urticaria, pancreatitis, hepatitis and abnormal liver function tests (reversible upon discontinuation of the medicinal product), bullous or exfoliative skin lesions. Combination with metformin and a solphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia. **LEGAL CATEGORY:** POM **PACK SIZES:** 7, 28 tablets **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/07/414/001, 003. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 4, Marsa, MRS 1000, Malta. Tel +356 21222872. 2014-MT-GAL-12-JUN-2014

Eucreas®
PRESENTATION: Each 50 mg/850 mg film-coated tablet contains 50 mg of Vildagliptin and 850 mg Metformin hydrochloride. Each 50 mg/1000 mg film-coated tablet contains 50 mg of Vildagliptin and 1000 mg Metformin hydrochloride. **INDICATIONS:** Eucreas is indicated in the treatment of type 2 diabetes mellitus patients, indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of Vildagliptin and Metformin as separate tablets. Eucreas is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea. Eucreas is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. **DOSAGE:** The dose of antihyperglycaemic therapy with Eucreas should be individualised on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg vildagliptin. Eucreas may be initiated at either the 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening. For patients inadequately controlled at their maximal tolerated dose of metformin monotherapy: The starting dose of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. For patients switching from co-administration of vildagliptin and metformin as separate tablets: Eucreas should be initiated at the dose of vildagliptin and metformin already being taken. For patients inadequately controlled on dual combination with metformin and a sulphonylurea: The doses of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) and a dose of Metformin similar to the dose already being taken. When Eucreas is used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. For patients inadequately controlled on dual combination therapy with insulin and the maximal tolerated dose of metformin: The dose of Eucreas should provide vildagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of Metformin similar to the dose already being taken. Eucreas should be taken with or just after food to reduce gastrointestinal symptoms associated with Metformin. Patients > 65 taking Eucreas should have their renal function monitored regularly. Eucreas is not recommended for use in patients less than 18 years old. For use in renal or hepatic impairment, see contraindications and precautions below or refer to the SmPC for more information. The safety and efficacy of vildagliptin and Metformin as triple oral therapy in combination with a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to Vildagliptin or Metformin hydrochloride or to any of the excipients. Diabetic ketoacidosis or diabetic pre-coma. Renal failure or renal dysfunction defined as creatinine clearance < 60 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of iodinated contrast agents. Acute or chronic disease which may cause tissue hypoxia e.g. cardiac or respiratory failure, recent myocardial infarction, shock, hepatic impairment, acute alcohol intoxication, alcoholism, lactation. **WARNINGS / PRECAUTIONS:** Eucreas is not a substitute for insulin in insulin-requiring patients and should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function could be monitored at least once yearly in patients with normal renal function and at least two to four times/year in patients with serum creatinine at the upper limit of normal and in elderly patients. Eucreas is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. LFT's should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Eucreas therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Eucreas. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. As Eucreas contains metformin, treatment should be discontinued 48 hours before elective surgery with general anaesthesia and not usually resumed earlier than 48 hours afterwards. The IV administration of iodinated contrast agents can lead to renal failure. Therefore due to Metformin active ingredient, Eucreas should be discontinued prior to or at the time of the test and not reinstituted until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. Eucreas should not be administered during pregnancy or lactation. Sulphonylureas are known to cause hypoglycaemia. Patients receiving Vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. The use of Vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, vildagliptin should be discontinued; if acute pancreatitis is confirmed, Vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with Vildagliptin. Interactions with Metformin hydrochloride that are not recommended include alcohol, cationic active substances e.g. cimetidine and intravascular administration of iodinated contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hyperglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **ADVERSE REACTIONS:** Rare cases (>1/10,000 to <1/1,000) angiodema, hepatic dysfunction (including hepatitis) have been reported with vildagliptin.
Vildagliptin Monotherapy: Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Metformin monotherapy: Very common (>1/10) Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Common: metallic taste. Combination Vildagliptin with Metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. Combination with Metformin and sulphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia, decreased blood glucose, headache, chills. Combination with insulin: Decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease, diarrhoea, flatulence. For a full list of Adverse reactions, please refer to the SmPC. **LEGAL CATEGORY:**POM **PACK SIZES:** 30, 60 film-coated tablets **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBER:** EU/1/07/425/002–003, EU/1/07/425/008-009. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available upon request from: Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 4, Marsa, MRS 1000, Malta. Tel +356 21222872 2014-MT-EUC-09-JUN-2014

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Galvus® vildagliptin

Eucreas® vildagliptin/metformin