Chapter 1 : Do we need clinical registries? | European Heart Journal | Oxford Academic

Tavazzi, L. () From Guidelines to Registries, in Acute Coronary Syndromes: A Handbook for Clinical Practice (eds M. E. Bertrand and S. B. King), Blackwell.

In recent years, the number of observational reports published in the medical field has exploded. Several reasons may explain this exponential and novel research trend. One is the need to know whether and how the evidence-based recommended treatments are incorporated. In chronic diseases requiring long-term therapy, such as chronic heart failure CHF , the compliance with recommended treatments is usually low, and frequently the drug doses taken are far below the recommended targets. Information about effectiveness of other doses, either lower or higher, seldom is available. Most effective drugs in CHF have many pharmacological effects some desirable, some not. We do not know the precise dose at which the drug exerts each of its effects maximally, or the relative contribution of each pharmacological effect to the net clinical effect of the drug. Moreover, as each new therapy is added to the existing list for any condition, we have no information about the continuing benefit of therapies tested before the more recent additions. Perhaps the presently recommended target doses might best be considered as thresholds beyond which drugs have not been tested, rather than as targets that must be achieved. To develop the most important aim of this study, namely the reasons why the target drug doses were not reached by most patients, the authors classified patients into three groups: Several reasons may lie behind the non-prescription or below-target doses of drugs. A recent analysis of a large European Society of Cardiology ESC registry in CHF in which the reasons for low dosing were specifically investigated revealed an overall significant rate of inappropriateness, but definitely lower than that found in the present investigation 5 Figure 1. Also the probability of successful drug up-titration may be biased due to baseline differences among patients. The authors used several methods for correction to minimize this bias: Figure 1 Reasons for non-use of recommended treatments in patients with reduced ejection fraction. This involves several aspects of the study design, including the size of the population, the setting of enrolment, and the criteria for selection of those enrolled or non-selection. The demographyâ€”age and gender, strictly interlinkedâ€”is not a marginal issue in observational studies. One of the successes in the prevention of HF is the increasing age of the patients who present with HF, with the relative increase in the burden of co-morbidities. However, the trials performed by cardiologists in cardiology settings are not very sensitive to this epidemiological evolution. The number of patients included in each centre varied widely, between 1 and , with a median of 24 patients per centre. For the same reason, cross-county or inter-regional analyses seem rather precarious. The analyses showed that countries with an easier access to medical care, a more structured primary care system, better resourcing, and quality programmes have greater levels of appropriateness of prescription of drug treatment for CHF than countries without these characteristics. However, a long list of acknowledged limitations was discussed in this report. In the study by Ouwerkerk et al. The limitations of the study briefly discussed above are substantially acknowledged by the authors, and represent the array of difficulties encountered by any group of investigators, including outstanding investigators such as those who authored this paper, in organizing vast international studies, based on a freshly created voluntary centre network, with scarce economic and personnel resources, no systematic auditing, and not supported by institutional databases. However, many things are changing across the world. The current acceleration in the development and spread of new technologiesâ€”especially Information Technology IT â€”characterizes the present time, with globalization of communication and knowledge. The incorporation of IT into the routine clinical activity of healthcare systems, generating a potentially universal Electronic Health Recording EHR network, sharable across countries, is now producing big data, collected day by day, to be interpreted and used by both scientists and public health authorities for a pragmatic, evidence-based public health management and governance.

Chapter 2 : Chronic Ischemic Cardiovascular Disease (CICD) Registry

Registries must have the size, power, accuracy and be editable leading to accurate information that has value EMRs needs to share accurate data (e.g. PCORI).

Author Disclosures Key Messages Heart failure is still under-recognized and misdiagnosed. This has significant clinical implications as the prognosis of untreated or undertreated heart failure is poor, and yet very effective proven therapies are widely available to most. Diabetes can cause heart failure independently of ischemic heart disease by causing a diabetic cardiomyopathy that may manifest in the setting of normal or reduced left ventricular ejection fraction. The incidence of heart failure is 2- to 4-fold higher in people with diabetes compared to those without and, when present, occurs at an earlier age. Even though heart failure in people with diabetes should be treated similarly to heart failure in those without diabetes, they are less likely to receive appropriate therapies. The presence of diabetes should not affect the decision for treatment of heart failure. Comorbidities, such as renal dysfunction and propensity for hyperkalemia, are more prevalent in people with diabetes and may influence heart failure drug doses and monitoring of therapy but not therapeutic targets. Diabetes is a risk factor for heart failure. Symptoms of heart failure include shortness of breath, persistent coughing, fatigue, chest pain, weight gain or swelling of the feet, ankles and legs. A number of effective drug treatments are available to keep heart failure in check. Your health-care provider will discuss these with you. Certain glucose-lowering medications have the potential to worsen or help heart failure. If you have heart failure, this will influence which glucose-lowering medications your health-care provider selects for you. Introduction Type 2 diabetes often occurs in association with other cardiovascular CV risk factors, such as hypertension, dyslipidemia, smoking and obesity, which, together, are strongly associated with atherosclerosis, ischemic heart disease and left ventricular LV dysfunction 1. LV dysfunction can be clinically silent or associated with the typical clinical signs and symptoms of heart failure e. These symptoms need to be differentiated from other conditions that may have similar presentations, such as chronic obstructive pulmonary disease, pneumonia, anemia, varicose veins, depression, etc. Heart Failure in People with Diabetes The diagnosis of heart failure is made by association of typical clinical signs and symptoms with objective evidence, such as that obtained from a chest x-ray, an echocardiogram or plasma natriuretic peptide testing brain natriuretic peptide [BNP] and pro-hormone of BNP [NT-pro-BNP] 2. Documentation of systolic and diastolic myocardial function is recommended at the time of diagnosis of heart failure or with any significant change in clinical stability. The measurement of plasma BNP and NT-pro-BNP, which are acutely released by ventricular myocytes when the myocardium is stretched due to increased filling pressures, may help make an accurate diagnosis where clinical uncertainty exists 3. However, the practicing health-care provider may still under-recognize and misdiagnose heart failure. This has significant clinical implications as the prognosis of untreated or undertreated heart failure is poor, yet very effective proven therapies are widely available. The results to date are mixed, with no clear consensus to institute this strategy. A recent analysis of the Action in Diabetes and Vascular disease: However, the overlap between heart failure with preserved EF and reduced EF is considerable, and many people have a combination of systolic and diastolic dysfunction, although one is often reported to be predominant. Current tests, such as echocardiography, do usually fully characterize all aspects of systolic and diastolic dysfunction in individuals. It is recognized that diabetes can cause heart failure independently of ischemic heart disease by causing a diabetic cardiomyopathy 5. Epidemiological studies have shown that the incidence of heart failure is 2- to 4-fold higher in people with diabetes compared to those without diabetes 6,7. Additionally, studies have shown the occurrence of asymptomatic abnormalities of ventricular systolic and diastolic function, independently from ischemic heart disease or systemic hypertension. While an increase in glycated hemoglobin A1C among individuals with diabetes is a recognized risk factor for heart failure 8â€”12 , no prospective study to date has demonstrated that improved glycemic control significantly reduces the incidence of heart failure Albuminuria is also an independent risk factor for heart failure, especially in people with diabetes. In individuals with and without diabetes, an increasing urinary albumin to creatinine ratio ACR is associated with a stepwise increase 2- to 4-fold in the risk of heart failure

development 10, Blockade of the renin angiotensin aldosterone system RAAS has been shown in large clinical trials of participants with cardiovascular disease CVD or diabetes to lower the risk of new-onset heart failure 15â€" Treatment of Individuals with Both Diabetes and Heart Failure In nearly every clinical trial involving people with heart failure, diabetes is present in over one-third of subjects. In the large landmark clinical trials of heart failure, subgroup analysis of populations with diabetes has shown that, despite their increased risk of morbidity and mortality, they derive greater absolute benefit from efficacious therapies as compared to people without diabetes 17â€" The primary outcome was a composite of death from CV causes or hospitalization for heart failure. An analysis of 4, participants in the trial who had a diagnosis of diabetes based on A1C or prior history demonstrated that LCZ remained similarly efficacious, regardless of glycemic status A similar finding was observed with the Systolic Heart failure treatment with the I f inhibitor ivabradine SHIFT trial 22 , a randomized trial of ivabradine vs. There were 1, participants with diabetes who achieved the primary composite endpoint of hospitalization for worsening heart failure or CV death more frequently than those without diabetes Hazard Ratio [HR] 1. Serious adverse events were not different between the ivabradine or placebo group, regardless of diabetes status. Overall, ivabradine is effective in this patient group irrespective of diabetic status. As such, heart failure in people with diabetes should be treated similarly to those without diabetes Therapeutic Considerations for Individuals with Both Diabetes and Heart Failure People with diabetes are at increased risk for development of hyperkalemia and worsening renal dysfunction in the setting of RAAS blocking agents 24â€" Clinicians should be aware of this potential complication, especially in view of current guidelines advocating the expanded use of combined RAAS blockade in people with mild-to-moderate heart failure and low EF. Three beta blockers have been shown to reduce morbidity and mortality for people with heart failure, reduced EF and diabetes: While overall glycemic control generally improves as heart failure is treated with evidence-based therapies, 30â€"32 , carvedilol, in comparison to other beta blockers, has been shown to specifically improve glycemic control 19, For this reason, some clinicians prefer carvedilol as the beta blocker of choice in people with diabetes and heart failure. While there is a theoretical concern for the occurrence of severe hypoglycemia without awareness associated with the use of nonselective beta blockers, this has not been reported in clinical trials. Numerous registries and reports indicate that persons with diabetes are less likely than those without diabetes to receive efficacious and evidence-based therapies for systolic heart failure. However, even when controlled for these conditions, the differences persist. This is particularly concerning considering the increased absolute benefit the agents confer to people with heart failure and diabetes in comparison to unselected heart failure populations. As such, health-care prescribers must be diligent in providing these therapies. Antihyperglycemic Agents and Heart Failure Despite substantial understanding of the impact of antihyperglycemic therapy upon glucose control and microvascular disease, the heart failure specific response to intensive glycemic control and the various antihyperglycemic agents discussed below remains poorly understood Metformin Metformin is an effective noninsulin antihyperglycemic agent but, based on isolated case reports and a biochemical rationale for a risk of lactic acidosis, it is approved for use under a warning in the setting of several conditions, including heart failure. Meta-analyses have evaluated the occurrence of lactic acidosis with the use of metformin over 70, patient-years or other antihyperglycemic agents over 55, patient-years and they have consistently shown no increase in lactic acidosis in the metformin group 35, In fact, CV outcomes in people with heart failure taking metformin were better than in those taking other conventional antihyperglycemic agents As such, metformin should still be considered as first-line therapy in people with diabetes with heart failure with mild-to-moderate renal dysfunction Thiazolidinediones Thiazolidinediones TZDs are known to cause fluid retention, although this is generally mild. Recent studies suggest that this is not a direct toxic effect on the myocardium. In the rosiglitazone group, the risk of heart failure death or hospitalization was doubled HR 2. These findings confirm the increased risk of heart failure events in people treated with rosiglitazone. A meta-analysis has not confirmed any difference in the risk of congestive heart failure CHF between rosiglitazone and pioglitazone 41, CV outcome trials to assess for non-inferiority CV safety or superiority of new antihyperglycemic therapies have been undertaken in different diabetic populations with pre-specified secondary heart failure endpoints reported as mandated by the Food and Drug Administration FDA in December The mechanism of

action and antihyperglycemic effects of these agents are detailed in the Pharmacologic Glycemic Management of Type 2 Diabetes in Adults chapter, p. The information detailed below pertains directly to heart failure outcomes in people with diabetes. Of relevance, these trials were not heart failure trials per se and included only a small proportion of people with heart failure and reduced EF, hence the findings are limited in their generalizability to a broader heart failure population. There was an unexpected finding of increased hospitalization for heart failure noted with saxagliptin that was not seen in CV trials with the other DPP-4 inhibitors Chronic kidney disease, elevated natriuretic peptide levels and previous heart failure were associated with an increased risk for heart failure hospitalization in SAVOR-TIMI Recent post-marketing, large registries and meta-analyses demonstrate overall neutrality for the class as a whole regarding heart failure Specifically, the recommendation from the FDA for saxagliptin and alogliptin reads: In each trial, heart failure hospitalization was a pre-specified endpoint. The Liraglutide Effect and Action in Diabetes: The primary endpoint was time to death, time to rehospitalization for heart failure and time-averaged proportional change in N-terminal pro-B-type natriuretic peptide level from baseline to days. There was no difference in the primary endpoint HR 1. However, in people with diabetes, the HR was 1. These findings suggest no benefit from liraglutide in that clinical situation Furthermore, empagliflozin reduced the risk of heart failure hospitalization by a similar degree regardless of whether the participants had a prior history of heart failure or not. The mechanisms of benefit remains speculative. However, based on hierarchical sequential testing, the trial did not demonstrate a reduction in all-cause mortality and, therefore, all other prespecified endpoints were considered exploratory. Hospitalization for heart failure was reduced HR 0. Importantly, heart failure studies will soon commence utilizing SGLT2 inhibitors irrespective of glycemia status. The effect of dapagliflozin on time to first worsening heart failure event or CV death in people with heart failure and reduced EF, irrespective of glycemic status, has begun recruiting ClinicalTrials. A detailed discussion of the rationale and evidence for the treatment approach to people with heart failure is available in the Canadian Cardiovascular Society consensus recommendations http: Recommendations Individuals with diabetes and heart failure should receive the same heart failure therapies as those identified in the evidence-based Canadian Cardiovascular Society Heart Failure recommendations http: Unless contraindicated, metformin may be used in people with type 2 diabetes and heart failure [Grade C, Level 3 18,38]. Metformin should be temporarily withheld if renal function acutely worsens, and should be discontinued if renal function significantly and chronically worsens [Grade D, Consensus]. Beta blockers should be prescribed when indicated for heart failure with reduced ejection fraction, as they provide similar benefits in people with or without diabetes [Grade B, Level 2 19,33]. Starting doses of ACE inhibitors or ARBs should be halved [Grade D, Consensus] Serum electrolytes and creatinine, BP and body weight, as well as heart failure symptoms and signs, should be monitored within 7â€”10 days of any initiation or titration of therapy [Grade D, Consensus] Dose-up titration should be more gradual with monitoring of BP, serum potassium and creatinine [Grade D, Consensus].

Chapter 3 : Registry Publications

Contemporary Stroke Prevention Strategies in 11, European Patients with Atrial Fibrillation: A report from the EURObservational Research Programme on Atrial Fibrillation (EORP-AF) Long-Term General Registry: G Boriani, M Proietti,C Laroche, L Fauchier,F Marin, M Nabauer, T Potpara, G-A Dan,Z Kalarus, I Diemberger, L Tavazzi, A P Maggioni,and.

Find articles by Sana M. Cosio Find articles by Francisco G. Conroy 8Zena and Michael A. Find articles by Jennifer M. Hess Find articles by Paul L. Halperin 8Zena and Michael A. Find articles by Jonathan L. Find articles by Paulus Kirchhof M. Cosio Find articles by M. Find articles by A. Published on behalf of the American Heart Association, Inc. This article has been cited by other articles in PMC. Introduction Atrial fibrillation AF is a global health problem. The condition brings an increased risk of stroke, systemic embolism, and heart failure HF and is associated with impaired quality of life, frequent hospitalizations, and mortality. Based on key issues identified by observational studies, management of patients with AF has been informed by randomized, controlled trials RCTs that provide the main support for guideline recommendations regarding management of patients with AF and prevention of thromboembolic complications. Nevertheless, important questions regarding the clinical course, risks, and management of AF in clinical practice remain unanswered. Thus, their results are not always directly applicable to the general population or routine practice. Traditional observational studies, often limited to small patient populations and performed at a single institution, are giving way to multicenter and national registries, supported by the transfer of information to large databases. Structured data collection can inform the generation of new hypotheses and help to test established ones. Registries are also subject to limitations as well as potential confounding factors related to the population selected, number, and scope of tracked variables and prevailing concepts of the disease under investigation. The information obtained from observational and interventional studies provide different approaches that require integration of a wide array of data to derive a complete perspective on a disease or condition. This review provides an overview of available registry data on patients with AF and focuses on 3 areas at the heart of AF management: In addition to cataloging the types of registry data available, we consider how these data contribute to understanding and management of patients with AF and speculate on the future directions of observational research. We identified 34 large international or national registries of AF patients, including 17 reporting on thromboprophylaxis and stroke prevention, 8 focused on antiarrhythmic drug AAD therapy and cardioversion, 7 studying AF ablation, and 2 detailing left atrial appendage closure LAAC registries. Several registries address multiple aspects of AF diagnosis and management and could be allocated to more than 1 category. To enable some key findings to be visualized more clearly, registries that provide information on medical treatments for AF including use of agents for rhythm and rate control, warfarin, aspirin, and new oral anticoagulants [NOACs] are also shown separately in Table 5.

Chapter 4 : Real world eligibility and prognostic relevance for sacubitril/valsartan in unse

They instead rely on 'mindlines' generated by a number of sources of varying degrees of reliabitiy, collectively reinforced, resulting in individual 'internalized, tacit, guidelines'. These can be far removed from the official recommendations; however, they guide the physician in his clinical practice.

Informatics and computers Summary The provision of timely, relevant and reliable information on patient care to clinicians has been shown to drive improvements in health care quality. Well constructed clinical quality registries collect and report information on both the appropriateness of care process in keeping with clinical practice guidelines and the effectiveness of care outcomes. Notwithstanding the successful establishment of several new registries and improvements in established registries, barriers persist for clinical groups wishing to improve the quality of information and level of participation in registries in Australia. The Framework describes a mechanism by which government jurisdictions and private hospital groups can authorise and secure record-level data, within high priority clinical domains, to measure, monitor and report the appropriateness and effectiveness of health care. The provision of benchmarked information back to clinicians on the appropriateness and outcomes of care is expected to improve adherence to evidence-based practice and drive improvement in outcomes. The effectiveness of clinical quality registries registries to monitor and benchmark patient outcomes is well established. Registry data has credibility with clinicians, stimulating increased use of evidence-based clinical management, decreased variation in care and improved patient outcomes. A low capture rate renders the pool of results unrepresentative and ungeneralisable, thus weakening the power of a registry to inform policy determinations. Current reporting in Australia A small number of national registries in Australia now capture a high proportion of their eligible patient populations. Box 2 shows the high proportion of ICU admissions for which the patient received guideline-recommended care for venous thromboembolism prophylaxis each year for 5 years. The Palliative Care Outcomes Collaboration PCOC collects data from palliative care services across Australia on the length of time palliative care patients spend in the unstable phase of illness. An unstable phase ends when a new plan of care is in place, has been reviewed, and no further changes are required. A patient is considered to have an acceptable outcome if they experience no more than 3 days of instability. Information reported by the PCOC shows a considerable improvement in palliative care services achieving this benchmark over the period â€” unpublished data provided by PCOC, July Governments across Australia have developed a number of registries with a jurisdictional focus. The Victorian Department of Health and Human Services, in particular, has invested in a significant number of clinical quality registries. In some instances, substantial funding has been made available by other organisations such as the Victorian Transport Accident Commission, Medibank Private and the Movember Foundation. Some state-based registries such as the Victorian Cardiac Outcomes Registry and its counterparts in South Australia, Queensland and New South Wales are collaborating to develop nationally consistent datasets. There remains, however, limited capacity across Australia to benchmark outcomes and assess the degree with which health care aligns with evidence-based practice in a number of high priority clinical domains. In , Evans and colleagues conducted a national survey to determine the capacity of Australian clinical registries to accurately assess quality of care. Of 28 registries surveyed, the majority were found to require modifications to provide useful and reliable information for quality improvement purposes. Well constructed registries collect and report information on both the effectiveness of care outcomes and the appropriateness of care process on an ongoing basis, obviating the requirement for clinical audit. The Australian Cardiac Outcomes Registry 18 intends to develop its collection of outcomes data for patients with acute coronary syndrome along with processes of care data in line with the Guidelines for the management of acute coronary syndromes Data are collected on casemix, care processes and patient outcomes. The authors of the NHFD national report note: This has enabled the creation of day and 1-year mortality prediction models, outcomes variation comparison across hospitals and the assessment of the impact of critical variables on outcomes of interest. Process of care improvement tools have been developed and made available in a toolkit, which includes evidence-based practice algorithms, critical pathways, standardised orders, discharge

checklists, pocket cards, and chart stickers. The toolkit also includes algorithms and dosing guides for guideline-recommended therapies and a comprehensive set of patient education materials. Participation in heart failure registries in the US has been associated with substantial improvements in the use of guideline-recommended therapies for heart failure in both the inpatient and outpatient settings. Incentives are provided to hospitals complying with routine contributions to the registries. Required datasets are succinct, thereby minimising data entry burden. This has produced high participation rates which are closely representative of the eligible population. In return hospitals and clinicians are provided with high quality reports which are up to date and risk adjusted. A comparative review by Cohen in demonstrated that the Cardiac Care Network Registry in Ontario, Canada, provides relevant clinical details with greater accuracy when compared with administrative databases. Information provided by registries therefore enjoys a high level of trust by clinicians, health managers, governments, private hospital groups and funding bodies. The use of registries to monitor health care quality and safety is supported by patients. Analyses show that as long as appropriate measures are taken to ensure data security and confidentiality, the majority of patients acknowledge the value of registries and the necessity to collect identifying data, and accept the requirement for registries to operate under opt-out consent with scope for linkage to other datasets. Aside from the principal function of monitoring and benchmarking the appropriateness and effectiveness of clinical care, registries can provide the foundation for opportunities to undertake evidence-based health care reform. The potential for articulation with best practice pricing incentive schemes has been highlighted above. Registries also provide a way of generating an early warning of lowered outcomes and a means to share learnings from high performing units, such as those with lower infection rates. Examples of other opportunities provided by registries include clinician and facility performance assessment and credentialing; greater accountability and transparency through public reporting; performance-based reimbursement; value-based purchasing; the development of evidence-based practice guidelines; enhanced post-market surveillance of medical devices and pharmaceuticals; monitoring trends in utilisation and access to care; supporting cost-effectiveness studies; and the provision of infrastructure with which to conduct clinical trials and comparative effectiveness studies. In Sweden, almost all units performing total hip arthroplasty are administering PROMs before and after surgery. There is increasing evidence that registries demonstrate good value for money, that is, improved health outcomes at lower cost. Funding aside, the principal barriers to the development of clinical quality registries in Australia are: Notwithstanding successful efforts to develop new registries 20 and improve established registries, these barriers persist for clinical groups and registry experts wishing to improve the quality of information and level of participation in registries in Australia. Beyond the barriers To address these barriers, the Australian Commission on Safety and Quality in Health Care worked with jurisdictional representatives and registry experts to develop a framework detailing national arrangements under which patient level data may be routinely and securely disclosed, collected, analysed and reported. Application of the Framework to registries provides assurances to jurisdictions, private hospital groups, clinicians and patients, that registry data and the systems that hold those data have satisfied minimum security, technical and operating standards. The development of one national registry per clinical domain â€" rather than multiple state and territory-based registries all attempting to monitor similar indicators â€" has obvious efficiencies and is more likely to attract funding. Well designed registries are an increasingly important component of clinical practice 47 and health system monitoring. The provision of timely, relevant and reliable feedback about patient care to clinicians drives improvements in health care quality. Improved reporting of registry information on the appropriateness of care is likely to improve adherence to evidence-based practice.

Chapter 5 : My Site - Chapter Treatment of Diabetes in People with Heart Failure

Well constructed clinical quality registries collect and report information on both the appropriateness of care (process) in keeping with clinical practice guidelines and the effectiveness of care (outcomes).