SOCIAL RESPONSIBILITY AND INTEGRITY IN HOSPITAL CARE, ISSUES THAT REMAIN MOSTLY UNDER THE RADAR

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Especially in view of the excesses that became evident in relation to the dotcom- and banking crises, social responsibility and integrity have received renewed attention in business in recent years. It may be surprising, but while scanning popular and serious medical journals, it seems that these topics are not very actively dealt with in relation to health care. The main integrity issues in the Netherlands in recent years were related to discussions on governance, mainly in relation to incidents in institutions of very well paid executives(1), conflicts of interest in relation to drug introductions such as influenza vaccines (2) or isolated privacy issues related to electronic medical records or TV exposure of suffering patients. The connection of social responsibility or integrity with quality management and innovation is seldom made in medical literature, and if so, mostly by consultants intending to extend their market or agencies concerned with their domain. It is my view however that some structural issues do exist in this field, but present themselves in a somewhat different way and this has a relation to the specific nature and culture of hospital care; somehow they remain “under the radar”.

Hospitals are characterized by Mintzberg as professional bureaucracies and professional-/medical ethics are basic elements of its operations. (3) In most western countries, health care is predominantly provided by non-profit and not-for-profit institutions; even in those countries allowing for-profit providers to be active, the percentage of market penetration is usually not more than 20-30% (4). However, many individual providers who are working on fee for service basis, and firms active in the support chain for hospitals, especially pharmaceutical companies, aim for a healthy profit on their activities. The main notable consequence of this constellation is encountered in discussions on restraint in prescribing, and appropriateness of indications. Periodically this is fuelled by data on variation in care provision. Thus far this is, again, rather seen as a discussion within the professional domain – are providers acting in a professional responsible way?- than as a matter of social responsibility or integrity. However as financial sustainability is becoming a major issue in many western countries, this might rapidly change in the coming years.

Developments in (technological) innovation and quality management rarely lead to public issues on integrity or social responsibility. One reason might be that the latter concepts are used different from other sectors. Related to the functioning of physicians, integrity is usually associated with discussions on conflicts of interest and transparency on relations with pharmaceutical companies and biomedical technology firms. Social responsibility is seldom encountered as a topic in papers in health care; in some countries such as the USA, with less well organised health care coverage and less alignment
between various services, the concept is almost directly related to community service or – outreach of their activities(5). As a kind of compensation to charging considerable amounts from insurance companies and government agencies, hospitals are expected to show their charitable side to the community. In public debates on reducing or restructuring hospitals or –departments, leading to the perception that (emergency) services may be downsized, an appeal on social responsibility is sometimes used by politicians to confront hospital management with public outrage. Although many health care trends point towards concentration of services, it is usually hard to distinguish facts from images in those cases, so I will not expand on these. Traditionally, public discussions on social responsibility concentrated on more strict medical ethical matters and most recently especially on decisions concerning abortion and end of life care. In many countries however these are settled in a kind of status quo, gradually developing in a more liberal direction.

Quality management in hospital care has developed along two lines. One (content based) approach originated from professional interest in medical quality and is dominated by medical profession; professional quality is guaranteed by training and continuous education and has a strong relation with the content of the service; what are the right things to do and how best to perform them? The relation between professional quality management and social responsibility has mainly been established on macro level; professional associations developed their quality policies both in response to criticism from society as well as an effort to improve transparency.

The other (system oriented) approach deals with organising quality as part of institutional operations, and is focused on how to do the right things within an organisational setting, whether a clinical unit, between hospital departments or in a clinical pathway. On institutional level the system approach might interact- or interfere with the individuals’ view and actions.

Although somehow out of the spotlights, it is inevitable that in some occasions discussions or issues emerge that are related to the concept of social responsibility; often these are debated upon- and organized within the institution without attracting outside attention. In this paper I will explore - in some way “unveil” - the concept of social responsibility especially in relation to recent developments in quality management and innovation in hospitals and the research environment of academic medical institutions, focusing on the organisational aspects using cases out of my personal practice as hospital board member to instruct or enrich the theory.

**Quality management and social responsibility**

Quality improvement in medical care was initiated in the late seventies by medical opinion leaders focusing on improvement of aspects of medical treatment; soon structured approaches were used such as audit- and Plan-Do-Check-Act cycles and from the nineties onwards these were also focussed on organisational issues. Professional quality management has strongly been oriented towards developing guidelines and professional education. Recently professionals are trying to retake the lead by initiating physician run clinical audit systems as a reply to the tidal wave of indicator requirements, fired of by in their view unknowledgeable bureaucrats. After a starting phase in the eighties when isolated improvement projects were introduced in hospitals, gradually a more systematic approach
towards quality management was adapted. This was often based on systems like the Total Quality Management (TQM) model of the European Foundation of Quality Management (EFQM) and these formats were often used as a basis to structure external audits and accreditation systems (6). In TQM, responding to society and to customers are important “results domains”; both however defined from an organisational performance point of view—the internal criteria for performance prevail and social responsibility as such is not commonly used or defined as an outcome parameter.

In recent years, especially related to increased cost pressure and the need to improve efficiency, evolving from the TQM approach organizational improvement activities are introduced that are often based on knowledge from operations management and operations research.

A recent survey in 47 Dutch hospitals however showed that this seems to be happening in a rather unstructured way; almost all responding hospitals indicate to be active in this field but do so with a wide range of approaches (7,8). Often they scored to use tools within approaches, but not in accordance with the approach they theoretically belong to. The widespread but seemingly still poorly structured use, could give reason to suggest that we may be facing a new transition in which quality and efficiency are to become organised in a more balanced way. It is however not clear whether this will lead to organisational formats (such as “lean hospitals”) or a tool box approach in which contingency factors determine the application of certain techniques in addition to the existing total quality management systems. When introducing efficiency improvement within hospitals, inevitably discussion starts on balancing the objectives with the viewpoints and values of the individual medical professional; however this debate seldom reaches the public domain. Recent examples of issues in which professionalism conflicted with strict efficiency in home care in the Netherlands, proves that there is a change that this will occur more frequent in the near future.

In relation to quality management, society increasingly expects hospitals to adhere to certain governance principles such as salary codes, proactive involvement of the supervisory board on quality and safety issues and active risk management. The explicit “function” (in organizational terms) of social responsibility towards the community is merely reflected in issues that usually have no direct relation with quality or innovation; it is rather reflected in demands concerning transparency or public reporting on quality issues which professionals often consider to be external bureaucratic “waste”. Earlier attempts, again mainly by consulting agencies, to extend the concept of quality management with that of responsive and sustainable behaviour did so far not lead to new models that were broadly implemented.

Case description

A major rehabilitation hospital in the Netherlands invested heavily in quality management and developing a quality management system based on the EFQM model. Research & development and innovation were important, mission driven activities. The management looked for a way to balance assurance which can have bureaucratic “side effects”, and continuous improvement as one of the fields the hospital could excel in. One of the instruments to strive for continuous improvement is close monitoring of client preferences and patient needs, and it was gradually noted that some of these needs could not be provided for, due to regulatory issues in health care. It was decided to look for
alternative/innovative ways to realise those services and for this purpose a commercial spin-off was started. Gradually this grew into a venture with considerable commercial impact with locations in various parts of the country. Parts of the proceeds were used to finance research and development in both the domain of the new venture as well as regular rehabilitation treatment. During the first years of its existence fierce debates took place within the hospital and especially with the medical staff and with the external environment on the social responsibility of the hospital in entering this field. The staff felt responsible for commercial side steps as the reputation of the hospital could be involved. Various stakeholders questioned the profit oriented approach that was new in this field in The Netherlands. Management however could provide comfort to the physicians through regular information and evaluation sessions; by observing maximum transparency on financial flows and –benefits, convince most stakeholders of the integrity of the model. With commercial ups and downs this has been actively implemented now for about twenty years. Starting commercial not for profit activities in response to closely monitored market needs can be seen as a way for health care institutions to actually fulfil their social responsibility. (9)

Quality management and innovation

In Total Quality Management one has to balance assurance characterised by its regulatory and somewhat bureaucratic focus, and improvement with its dynamic character. If managed successfully, frequent incremental improvements will result and exceptionally innovations of a more disruptive nature. In hospitals the innovations related to TQM will often become evident in service related issues. In view of the steep rise in costs concerns on the financial sustainability of health systems are increasing and governments are pushing for mechanisms to control costs; this adds to the emphasis on service efficiency improvement in most hospitals and gradually we see a further shift towards a focus on processes and logistics in TQM. Examples of these are innovative services across organisational boundaries such as stroke services and more recent teleconsultation services to upkeep the level of performance of small Intensive Care Units. Innovation related to TQM thus often has an organisational emphasis and only when a business driven value such as efficiency or financially driven priorities are conflicting with professional values, conflicts will arise. The leadership of hospitals, management and medical staff alike, will usually try to keep this discussion inside the institutional walls.

One of the main tasks of academic medical institutions is the production of (or contributing to) innovations through translational research and translational medicine. Translational research is the continuum from basic research until first clinical implementation whereas translational medicine is the process from an early phase clinical study until implementation in practice and diffusion in the field. In order to create an organisation in which high performance is stimulated, it is essential to balance the structuring of activities, through regulation and quality assurance, with intellectual freedom and continuous professional improvement as cultural assets. Open internal review of research proposals, open internal pre-submission reviews of publications and periodic site visits to evaluate group leader performance are vested mechanisms to assure academic quality. Enforcing strict adherence to these principles is a major task of the leadership. In an academic medical institution the regulatory/assurance “axis” can however easily lead to bureaucracy and increased overhead. Balancing the two is a challenge which is also
reflected in the response to (efficiency- and performance) demands from society. Scientific performance and the production of innovations is demanded, requiring optimal investments in research staff and research infrastructure in an agile environment. In addition, regulations concerning dealing with risks from chemicals, genetically modified animals, and regulations related to research in humans are continuously growing, thus creating an inherent conflict in those two domains of social responsibilities. One of the important tasks of the executive management of academic medical institutions is balancing these interests related to differing social responsibilities. Mostly this issues present themselves in practice as unique and usually require contingent solutions As there is no legislation or evaluation framework available, involved and transparent decision making on, seems to be one of the few options to reach at least informed decisions.

Case: DNA vaccination

In the field of cancer immunology experiments are being conducted with vaccinations to stimulate the immunologic response of the body towards cancer cells; for this purpose DNA fragments are used as these are considered to be a possible focus for immunotherapy. Management of a large comprehensive cancer centre in Amsterdam decided to honour the request of senior staff to embark on a spin off for the production of DNA vaccine. Commercial facilities were hardly available and if so, extremely expensive due to monopolist positions. Having access to a pharmacy with good clinical practice- and good manufacturing practice certification, it was decided to invest in a production unit and to place this within a separate juridical entity to enable additional service provision such as sales to other research groups and in order to limit the costs. Both supervisory board and medical staff were involved in the decision. It thus became possible to play a leading role in the Netherlands and Europe in performing research with DNA based vaccines in cancer immunology. This case shows that a not for profit commercial approach enabled the institution to take part in cutting edge research which would have been very difficult or at least very costly to realise following traditional roles and regulations.

Social responsibility and biomedical innovation in academic medical centres (AMC)

Traditionally the concept of social responsibility related to biomedical innovation in AMC’s is mainly reflected in the fields of medical ethics, integrity and community involvement. In Europe, the field of medical ethics is more or less stable, and only if new developments emerge such as stem cell research, medical ethical discussions can be a consequence although lately these discussions are rather taking place in the political than in the internal organisational arena. The role of the religious denomination of institution is diminishing and clinical scientists are somehow convinced that progress is “manageable”.

An important and increasingly regulated area is that of ethical review of research projects. Regulations in this field have increased considerably and the amounts of data and files passing these committees are formidable. The increased interest for animal welfare has added to the procedural workload of committees that see the huge files for their regular meetings increase by the year. Thus balancing procedural integrity, transparency and bureaucratic burden is a gradually increasing managerial responsibility.

Scientific quality management and scientific integrity are closely related issues. In the NKI AVL we have a strict system of quality management of research reflected in a compulsory
internal review of all new research proposals before submitting them in external competitions. Periodic review of all research project leaders and their groups and open discussions on the results and regulations prevent scientific misconduct. As the institution is depending on guaranteed funding from both charity and the Ministry of Health, scientific rigour and integrity are essential for the survival and further development of the institution. Rarely occurring cases of suspected scientific misconduct are investigated most seriously and thoroughly. If needed, publications are withdrawn and pro active press releases produced to explain the situation and to up keep the reputation of the institution (10,11). Usually these matters are dealt with through regular internal review procedures and –again- very rarely this leads to public issues. However important it is not exclusively a matter for medical institutions. It is rather a matter of responsible behaviour towards society in spending the funds acquired in an appropriate way, but time and again a proactive display of “how matters are dealt with” can add to the reputation and trustworthiness of the organisation.

Social responsibility of- an community involvement by academic medical institutions can also be pursued through agenda setting or stimulating the public debate. When active on the forefront of medical science, not only strict scientific findings can be made public, often the authority built up on years of scientific work, can or must be used to feed public debate. This can be either a consequence of specific research or insights based on a wider view. It adds to the public profile of publicly funded institutions, but it can also be seen as the social responsibility of this type of organisation. Examples are public support for and -statements on anti-smoking policy, but also issues on the organisation of cancer care or matters related to tissue banking as can be demonstrated in a case. Fuelling the debate on the improvement of health care services is another example and advocating the concentration of oncologic services in cancer centres often results in fierce debate in medical journals (12,13).

Case: Patient rights concerning tissue banking in the era of genomic medicine. (Summary of an article in Lancet Oncology, co-authored by WvH (14))

Recent developments in genomics have resulted in the increased availability of gene profiles for early diagnosis and prognosis in breast cancer. A request from a Dutch woman to have her tumour tissue tested years after treatment, confronted the Netherlands Cancer Institute (NKI) with questions regarding patients’ rights in relation to residual tissue storage and its use for clinical purposes. Was her tissue still available? If so, could she demand that the test be carried out or her tissue be transferred to another hospital? As it became apparent that appropriate guidance was lacking in this area, we developed guidelines on the issue, with the involvement of relevant professionals and patient representatives. Gene-expression profiling is an important development that is likely to predict the diagnosis and prognosis of malignant disease more accurately than existing parameters. Although gene-expression profiling is not yet routine, several tests are already applied in clinical practice. However, for such tests to be successful it is essential that sufficient tumour tissue is available. From international legislation and guidelines, we distinguished four general principles. First, care providers have a moral and legal obligation to protect the clinical interests of their patients and good clinical care should include securing the availability of sufficient tissue for future clinical use, and in addition access for patients to generally accepted diagnostic or prognostic tests on that tissue. Second, irrespective of whether they can be considered formal owners of their removed tissue, patients have personal rights regarding their removed bodily material.
As care providers are likely to differ in their testing policies, patients should thus also be entitled to request tissue transfer to have their tissue tested elsewhere. A third principle concerns the position of the patient’s relatives, although it is generally acknowledged that physicians have less extensive obligations to the patients’ relatives than to the patients themselves. The final principle is that in situations in which tissue has been stored for the purpose of medical care as well as scientific research and is insufficient to serve both purposes, the medical interest of the patient overrides the interest of doing research. This leads to the advise to hospitals to take responsibility to ensure that, as far as is reasonably possible, enough of a patients’ tissue is available for present or future clinical use, even many years after initial diagnosis or treatment. As to the actual application of local guidelines, it could be helpful to appoint a tissue-bank manager, responsible for matters such as the further automisation of the record keeping of specimens and the assessment and handling of tissue. The drafting and publication of this paper lead to internal debate on optimal tissue banking policies within the NKI-AVL and inspired other pathology departments to reflect on the issue.

**Conclusion**

In this essay I have tried to provide an overview of the most relevant issues in the relation between Quality Management, Technology Development and Social Responsibility and Integrity in (academic) hospital care. So far the topic mostly remains under the radar”. Social responsibility and integrity can be divided as internal policy and external policy issues:

**Social responsibility as an internal policy item**
- Medical ethics.
- Professional Integrity. Conflict of interest regulation.
- Ethical review of research.
- Governance

**Social responsibility as external policy item**
- Transparence on internal matters.
- Outreach/New service & - product development
- Agenda setting

I hope to have demonstrated that these issues play an important role in internal management but most aspects of integrity and social responsibility in hospital care remain “under the radar” of the outside world. Mainly related to incidents, either in integrity, governance or quality performance, issues become visible and often in a negative way. In the rare cases of purposely influencing public debate the role of- or activities of hospitals become visible in a positive way for the environment. Two main topics will dominate the public debate on health care in the coming decennia, balancing the surge of new technologies and ensuring a financially sustainable growth pattern for society. All future scenarios indicate that the growth in health care costs cannot maintain its present speed. The Dutch Central Planning Agency recently published an analysis in which 20-25% of the GNP will be used for health care between 2025 and 2035 and most economists consider this percentage unsustainable. This trend applies to most
western countries. This means that pressures on provider organisations and their professionals will increase and a further focusing of quality management towards efficiency of both the operations” and new technologies may be the consequence. Whether a regulated public solution, a more market like approach with more copayments and responsibility for care-users or a combination will be chosen, all scenarios require further efficiency increases and transparency (and consequently debates) on appropriateness. All lead to increased tension on the relation between the societal, institutional and individual (professional and patient’s) perspectives.

As the volume of research and development is ever increasing, with an upsurge especially in Asian and BRIC economies, a tidal wave of new drugs and technologies can be expected to arrive on the health care market. Recently Sullivan et.al. published a 40 page paper in Lancet Oncology on the financial sustainability of cancer care and it seems inevitable that gradually not just incremental cost effectiveness, but balancing costs or even the potential of cost reduction will be criteria for the introduction of new technologies(15). This supports the need for early stage involvement of a societal perspective through technology assessment knowledge into biotech research. As this will have to take place in a much earlier stage than before, researchers may feel that their academic freedom will become compromised. Whether this leads to fierce social debates remains to be seen, but the more promising added value of a new technology in combination with high expected costs for society, the larger the chance of community involvement through public debate.

The intrinsic values of medicine and nursing seem to be sufficiently strong to ensure that most issues on social responsibility and integrity are settled without much outside attention. It is hard to decide whether the growing influence of business logics will challenge this professional rigour. It is inevitable that the demand for transparency on the chosen policies and their implementation requires an increasing degree of (internal) regulation on most of above mentioned matters. Whether or not on the outside radar, as a consequence these matters will require explicit internal procedures.

**Literature**

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