Introduction

Neuro-im-aging: a clinical specialty concerned with producing images of the brain by non-invasive techniques; also: imaging of the brain by these techniques.¹

Innovations in neuroimaging technologies make non-invasive study of the human brain possible in an increasingly profound way. Neuroimaging technologies are technologies that produce images of the brain as an intact structure. Examples are functional Magnetic Resonance Imaging (fMRI), Positron Emission Tomography (PET), Electro Encephalogram (EEG) and Magneto-encephalography (MEG). Technological advances, such as increased spatial and temporal resolution and improved options for data analysis, are expected to result in more detailed views of the brain and hence increased understanding of the function, connectivity, activity and biochemistry of the brain and its disorders. This is expected to result in new and improved options for prevention, diagnosis and treatment (e.g. Ewers et al., 2011; Szymanski et al., 2010; Willmann et al., 2008). Future developments in neuroimaging technologies might therefore contribute to solutions for some of the current health challenges facing high-income countries which are the result of an ageing population, increasing numbers of chronically ill patients and rising demands for adequate evidence-based care (Schuitmaker, 2013). Moreover, ‘disorders of the brain’, comprising mental, neurological and substance use disorders, are the ‘largest contributor to the all cause morbidity burden’ as measured in Disability-Adjusted Life Year (DALY) in the European Union (Wittchen, et al., 2011, p. 672). In addition to their prevalence and high burden, many disorders of the brain are related to issues of stigma and marginalization (e.g. Reynolds, 2003). As a result, the need for improved prevention and treatment is high (Wittchen, et al., 2011). Consequently, research into the nature of brain disorders and into medical options for treatment is increasingly being undertaken by scientists, government, advocacy groups and public health authorities (Racine, 2010). Neuroimaging technologies play an important role in this research.

To date, neuroimaging technologies have contributed to insights into neural processes associated with two major types of brain disorders: mental (e.g. Malhi & Lagopoulos, 2007) and neurodegenerative (e.g. Rosas et al., 2004) disorders. Moreover, these

¹ Merriam Webster dictionary
technologies have contributed to improved diagnosis and therapies for some of these disorders and may be able to contribute to novel options for prevention. For example, Alzheimer’s disease is a degenerative brain disorder causing a major burden on society, families and the individual. In the near future, neuroimaging technologies are expected to provide more accurate tools to determine preclinical or early-stage Alzheimer’s disease, making it possible to prescribe targeted drugs to delay the onset of the disease (e.g. Ewers, et al., 2011). Another example concerns mental disorders. Diagnosis and treatment of mental disorders is currently based on external symptoms rather than on biological insights. Treatment is therefore often a case of trial-and-error in which time is needed to find adequate symptom mitigating medication or other therapy (Glahn, 2008). Neuroimaging technologies may have the potential to support the diagnosis of mental disorders in a functional, accurate and timely way and the development of novel pharmacological approaches (Willmann et al., 2008; McGuire et al., 2008). In this way, neuroimaging technologies might improve the quality of life of patients and decrease the burden of these disorders on society (Glahn, 2008).

Translation into clinical practice is, however, not straightforward. In addition to the many scientific unknowns and technological barriers that make it difficult to develop clinical applications, actors may have different ideas on what is considered advancement in this context (Racine, 2010), raising a number of concerns. For example, if early diagnosis of brain disorders does become possible, to what extent will individuals benefit from knowing they have a subclinical disorder? What is the individual and societal impact of receiving such a diagnosis before the onset of symptoms? Will a person at risk of developing a certain brain disorder endure stigmatization and discrimination when seeking medical insurance or employment? Will the growing knowledge of the brain further increase the demand for medical services, medicines and other products (Fuchs, 2006; Glannon, 2006; Illes & Racine, 2005)? Both positive and negative implications of neuroimaging are uncertain in the current, early phase of development. An important question is thus: how to manage neuroimaging innovations in order to facilitate an appropriate embedding in society?

**Innovation processes**

The linear model is a common conceptualisation of the innovation process (e.g. Rip et al., 1995). In this linear model, science invents, an application is developed by industry and this application is subsequently adopted by society. However, this model rarely corresponds with reality. Instead, innovation processes are generally complex with multiple feedback loops, user-induced innovation and external
pressures influencing developments (Caracostas & Mulder, 1998). As a consequence, a variety of specific innovation and change models have been developed to explain the role of external influences and mechanisms influencing innovation development (e.g. Geels & Kemp, 2000; Loorbach & van Raak, 2006; Rotmans et al., 2001). Given that technological innovation changes structures and competencies of established organisations, markets, user practices and policies, as well as cultural meaning (e.g. Geels, 2004), technological innovations should be regarded as socio-technical in nature (Rip et al., 2010). In other words, during the emergence of technological novelties, the socio-institutional embedding and the technology itself co-evolve (e.g. Nelson & Winter, 1982). The adoption of an innovation is therefore dependent on many dynamics and mechanisms, including societal demands and concerns. Disregard of societal demands and concerns explains, at least partially, the failure to adopt some innovations, such as genetically modified crops in Europe and subsoil CO₂ storage in the Netherlands (e.g. Chilvers & Macnaghten, 2011; ESRC, 1999).

Innovation development is evidently not autonomous of social concerns: the innovation process is subject to various socio-economic forces. Management of innovations aims to create societal benefits (including economic growth) while, at the same time, trying to limit the negative side-effects of innovations on society and the natural environment. This perspective on innovation development is increasingly referred to as Responsible Research and Innovation (RRI), defined as:

... a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society). (Von Schomberg, 2001, p.9)

Or, more broadly defined as:

Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present. (Stilgoe et al., 2013, p. 1570)

In recent years, the concept of RRI has received considerable attention from European Commission policy because of the benefits and risks of innovations in the life sciences and the challenges facing their societal embedding (Owen et al., 2012). Management of innovations is not a new phenomenon and diverse approaches incorporate RRI-related concepts, such as better foresight, more responsive and adaptive governance
and public engagement, aiming to manage innovation process and open them to societal influence (Owen & Goldberg, 2010). However, incorporating responsible innovation in early, emergent phases of scientific and technological development is still a major challenge.

This thesis addresses this challenge by aiming to identify options for interventions in the management of neuroimaging technologies in early phases of development in order to support responsible embedding of these innovations in the Dutch health system. This thesis is guided by the following principal research question: How can a more responsible process of innovation and embedding of neuroimaging technologies be facilitated in the Dutch health system?