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## Interview

# Interview with Dr. Louis B. Jacques on insurance coverage policy of CMS focusing PET imaging

— Scientific evidence and social, ethical implications  
concerning healthcare reimbursement —<sup>\*1</sup>

Louis B. Jacques<sup>\*2</sup>

Senior Vice President & Chief Clinical Officer, ADVI Reimbursement & Health Policy Consultancy

Interviewer: Chieko Kurihara<sup>\*3</sup>

Molecular Imaging Center, National Institute of Radiological Sciences (NIRS)  
(June 13, 2014, ADVI, Washington D.C., United States)

## Abstract

This is the record of an interview with Dr. Louis Jacques, M.D., Senior Vice President & Chief Clinical Officer, ADVI Reimbursement & Health Policy Consultancy, on June 13, 2014, at his office in Washington D.C., United States. He had just left CMS (Centers for Medicare & Medicaid Services) at the end of February 2014 after 11 years of contribution. He is a key-person to whom the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and Alzheimer's Association presented arguments seeking a positive decision of the CMS on Medicare coverage of beta-amyloid imaging PET (Positron Emission Tomography) scan for finding cognitive disease. He was a responsible person, as the Director, Coverage and Analysis Group, Center for Clinical Standards and Quality, at the time of final decision memo of the CMS which allowed only a 1-time scan of amyloid imaging to be covered in the CMS-approved studies under the scheme of CED (Coverage with Evidence Development).

He also talked about the profound idea of the scientific, social, and ethical implication of the diagnosis of Alzheimer's disease, as well as a rationally designed framework of the CED. We Japanese can learn much from this talk to consider future perspectives of the design of health insurance coverage of advanced medical technologies to conquer many of our incurable diseases.

## Key words

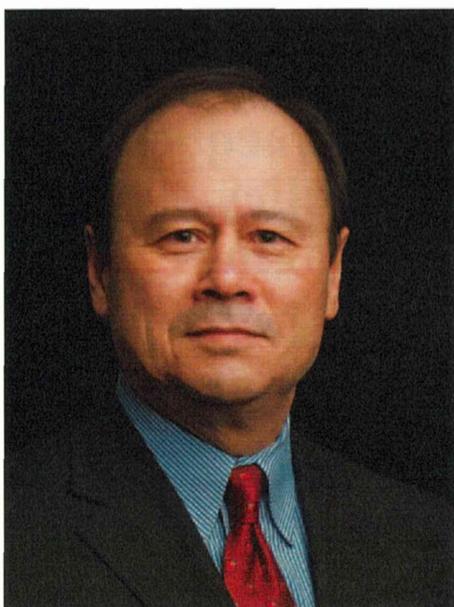
CMS (Centers for Medicare & Medicaid Services), PET (Positron Emission Tomography), amyloid-beta, CED (Coverage with Evidence Development), NOPR (National Oncologic PET Registry)

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<sup>\*2</sup> Previously, Director, Coverage and Analysis Group, Center for Clinical Standards and Quality, Centers for Medical & Medicaid services

<sup>\*3</sup> Research Center for Radiation Protection; Research Governance and Human Research Protection Office, NIRS ; Editorial staff, *Rinsho Hyoka (Clinical Evaluation)*



Dr. Louis Jacques, M.D., Senior Vice President & Chief Clinical Officer, ADVI Reimbursement & Health Policy Consultancy

Dr. Louis Jacques leads ADVI's strategic product development initiatives by spearheading focus on a top down commitment to change, recognizing that public and private payer "pay for value constructs" will require evidencing value and tying remuneration of our client's offerings to the evidencing of that value. Dr. Jacques is a graduate of Georgetown University and The University of Maryland School of Medicine.

**A Distinguished Career in Government Service and in Medicine:**

- Director, Coverage & Analysis Group (CAG), Centers for Medicare and Medicaid Services (CMS) since 2009
- Division Director, Items and Devices within CAG from 2004-2009
- Led CMS collaborations with Food and Drug Administration (FDA) including Entrepreneurs in Residence Program
- Practiced medicine as an attending physician for almost 20 years, and was an Associate Dean at Georgetown University School of Medicine before coming to CMS

**Passionate about Change and Innovation:**

- Implemented Coverage with Evidence Development (CED) under the Medicare program
  - Co-created joint parallel review pilot between CMS and FDA
  - Responsible for updating Medicare coverage in FDA IDE trials
  - Coauthored over 60 Medicare National Coverage Determinations
- Developed program oversight of the Local Coverage Determination process
  - Invited speaker at national policy and professional society meetings nationally and abroad
  - Authored or coauthored original research and commentaries in peer reviewed medical journals
  - Awarded FDA Leveraging/Collaboration Award (TVT Registry Team) 2013; FDA Parallel Review Team Award 2012; CMS Leadership Awards 2006, 2010; Golden Apple (Teaching Award - Georgetown University School of Medicine)

Source: <http://www.advi.com/>

## 1. Background of PET scan coverage

**Interviewer** Thank you so much for your acceptance of today's interview. It is fantastic that you moved from CMS (Centers for Medicare & Medicaid Services) to this company, ADVI. I came here as you were addressed in the letter of August 1, 2013<sup>1)</sup>, from Gary Dillehay, the President of the Society of Nuclear Medicine and Molecular Imaging (SNMM) of the time, requesting the CMS for coverage of amyloid-beta ( $A\beta$ ) PET imaging for dementia and neurodegenerative disease. Also I am very much interested in the scheme of CED

(Coverage with Evidence Development) and how it was implemented for PET (Positron Emission Tomography) examination. First, please introduce background story about the coverage of PET in the U.S. (United States).

**Jacques** Thank you for coming here for such interesting discussion. PET in the U.S. (United States) was originated as a research tool, and it wasn't until about 20 years ago that there was significant interest in using it as a mainstream medical imaging tool. That raised some challenges to the use of PET because FDG ([<sup>18</sup>F]-fluorodeoxyglucose) isn't owned by one company. Because of that it didn't seem that there was a unique responsible party to oversee the generation of clinical evidence

to determine whether or not FDG/PET imaging is clinically valuable as opposed to just being a scientific curiosity. There was a lot of political pressure in the U.S., from Congress, to cover PET scans.

**Interviewer** In the Congress?

**Jacques** I was informed at the time that the developer of PET had influence in Congress. So the Medicare program was essentially told to find a way to cover PET. So they developed this “coverage with evidence development” which is a paradigm where the PET is covered if additional clinical information is collected. That led eventually to the NOPR (National Oncologic PET Registry) registry for cancer, in the framework of CED (Coverage with Evidence Development)<sup>2, 3</sup>. There are other covered uses of PET like rubidium and ammonium for cardiology but they’re relatively smaller uses.

But it was not clear in the setting of cancer whether FDG/PET would actually be informative or not to help physicians make decisions that produce better outcomes for patients because there are some tumors that are not FDG avid, e.g., adenocarcinoma of prostate.

The Medicare rules from Congress are not very flexible so Medicare has to make decisions in certain ways; so Medicare did a series of national decisions to say first that most oncologic FDG PET was covered only with further study. We divided PET imaging into 2 big categories. If this is used to guide initial definitive anticancer therapy, we said there are PET scans leading up to the choice of the initial therapy and then there are PET scans afterwards for people who have failed therapy or who had therapy and you’re trying to monitor them for recurrence.

**Interviewer** Diagnosis and management, you mean?

**Jacques** But there’s a nuance there because Medicare originally divided PET into diagnosis,

staging, re-staging and monitoring response to therapy. That was a very awkward classification because in this space before the treatment, staging information helps to inform diagnosis, and diagnostic information helps to inform staging. It’s not like the doctor orders the test and says, “Well, you know, this is 30 percent for diagnosis and 70 percent for staging.” That’s not how it works. So instead of 4 categories, we divided it up into 2 categories. We also heard from oncologists that the concept of re-staging is not really a common paradigm in cancer because you have whatever stage you had when you were first diagnosed. Now you may be in remission but you are still stage 4 in remission. You don’t become a stage zero or a stage 1 patient.

So NOPR moved forward, looking for evidence that FDG PET imaging changes physician management of the patient in a way that improves patient outcomes. In cancer, because the treatments themselves can be lethal, there are clinical utilities from avoiding unnecessary treatment. Because so much is known about the treatment side of cancer, you could say that if you have evidence, for example, that if a woman is suspected of having cervical cancer and she has a positive supraclavicular node that cure is not expected; it’s more palliation and symptom control; so that patient would be able to avoid surgery, for example, and we think avoiding surgery if you don’t need it is a benefit for patients.

Thus, in the cancer space, we were able to say that if there was persuasive evidence that physicians were actually going to change their management that we would cover it. What was interesting, the way that PET is paid for in the U.S., the PET imager isn’t necessarily related to the cancer doctor so these people were going to be paid or not based on whether a different group of physicians were going to submit data. The oncologists, even though they didn’t get paid to participate in NOPR,

nonetheless, oncologists are, I think, accustomed to working in a protocol and to reporting the information so they kindly essentially volunteered. So over the course of about 5 years, we removed the NOPR requirement, first for PET scan in this initial period<sup>4)</sup>, and then later on in PET scan for this period after completion of initial anticancer treatment, with the exception of prostate cancer<sup>5)</sup>. PET in prostate cancer here remains non-covered.

## 2. Medicare Coverage concerning beta amyloid imaging

**Jacques** Now that is different than what happened with beta amyloid PET imaging. Because these agents are made by specific companies, there's clearly one company that's responsible for manufacturing each beta amyloid PET tracer, and they undergo formal review by the U.S. FDA (Food and Drug Administration). The reason why we covered beta amyloid PET with CED in Medicare was explained in the decision memo. One, the treatment of Alzheimer's disease is not as well developed or understood as the treatment of cancer. We had expert physicians saying even if the scan were negative they would treat the patients as if they had Alzheimer's anyway because everybody feels desperation. So there really was a lack of persuasive evidence for Medicare's purposes that beta amyloid scanning actually results in an improvement for the patients. That's why Medicare said we will only cover it in clinical study.

What's happening now is that the Alzheimer's community is working on study protocols that Medicare could cover, and one study is currently in progress. One of the challenges with Alzheimer's disease is that the amyloid-beta theory is really one of several theories. Even the FDA-approved labeling for an agent says this is not diagnostic of Alzheimer's Disease. We understand that older

patients tend to accumulate amyloid-beta anyway. So the challenge becomes if a patient is going to have amyloid-beta in their brain anyway, and if the amyloid-beta theory has not really been firmly conclusively established, finding amyloid-beta in an older patient is of uncertain clinical value unless there are meaningful treatments that would follow a positive scan result. If there is a patient with early signs and symptoms that might suggest a progression to Alzheimer's, those patients may be younger than Medicare age anyway; I mean if they're 55, it's not primarily a Medicare issue. It's really a private insurance issue.

**Interviewer** But Medicare will have impact on private companies.

**Jacques** It can. It depends. Some private companies seem to hide behind Medicare decisions even if the issues are different for a younger population or an older one. The other advantage that private companies have is they can do prior authorization. They can review the claim first and then decide whether to cover the scan. Medicare does in general not have prior authorization. The way the Medicare program is designed means that it doesn't have the national flexibility to say, "Well, this person can get a scan; not that person; this person can based on our review of their medical record."

**Interviewer** I understand. I read the final version of the decision memo by CMS<sup>6)</sup>. Your name was at the top of it, as the Director of Coverage and Analysis Group. It was dated on September 23, 2013. Now before coming here I attended the Annual Meeting of the SNMMI in St. Louis, where people discussed that it's not just clinical trial program but a NOPR registry trial could be covered by CMS. Is that correct?

**Jacques** Yes, depending on the methodologic rigor of the registry. So the NOPR registry can be tied to a later use of Medicare claims data to see whether the patient had other outcomes. Thus, a

simple registry might not be sufficient for “coverage with evidence development” program because “coverage with evidence” program has to look at clinical outcomes. The Medicare program guidance on practices around “coverage with evidence” development has evolved since the original guidance document was published 2006<sup>7)</sup> describing CED as including both Coverage with Appropriateness Determination (CAD) and Coverage with Study Participation (CSP)<sup>3)</sup>. So coverage with evidence development initially could allow a regular registry under CAD. Later on, CAD was set apart on its own and CED reached a point where there needed to be a requirement that there be some reported outcomes about that cohort in the registry – whether it was mortality or whether it was hospitalization or something else. But fundamentally the registry worked well in the cancer imaging setting and doesn’t necessarily work quite so well in other settings.

**Interviewer** According to the discussion in the SNMMI meeting other amyloid-beta probes, not just florbetapir, are also covered by the coverage with evidence development system.

**Jacques** Yes. What Medicare does (which is what many insurance companies do) is they generally don’t cover based on the brand-name. They cover by the class. So for example, a surgical procedure maybe covered and the insurance company doesn’t necessarily get into the details of this device or that device. So with PET scanning for amyloid-beta imaging in the context of dementia, the decision applies to any subsequently approved amyloid PET imaging agent. Whether it’s flutemetamol, florbetaben or something else, they all are automatically brought into the decision. So any future FDA-approved amyloid-beta PET agent falls under the current decision and could go into coverage with evidence development.

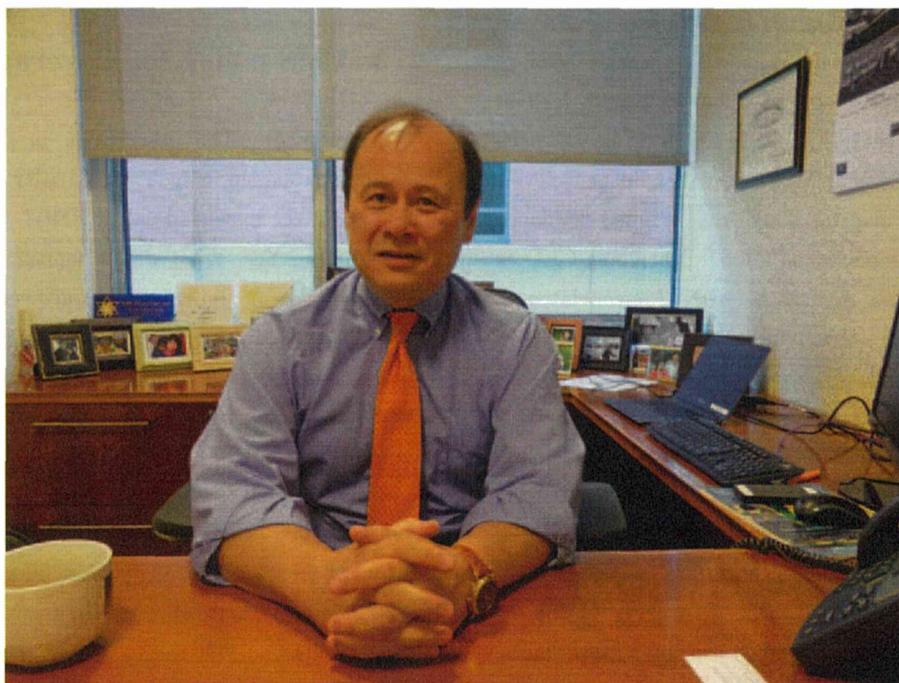
### 3. CMS policy for Coverage

**Interviewer** The description in the decision memo is explained in such way; similar to the decision about the expanded use of FDG?

**Jacques** Yes. What would happen is when the clinical trials or clinical studies are completed and published, Medicare would reconsider the policy decision and consider evidence not only through NOPR or other coverage with evidence development studies but if anyone else were doing clinical trials or clinical studies, they would go ahead and do that. They would look at that evidence as well. So whether it’s FDG in the past or amyloid-beta now, Medicare also covers in NIH trials. For example with FDG PET, the cancer imaging group at National Cancer Institute (NCI) had clinical trials where they also wanted to use PET in the protocol. Medicare paid for PET in that study because it was part of a clinical trial.

As for the amyloid imaging, because there really are apparently no effective treatments for Alzheimer’s, the interest in PET scanning seems to be if there are patients with Pick’s disease or frontotemporal dementia or something else, who should not get certain anti-cholinesterase inhibitors. There may be some benefit early in that population but not more broadly because people struggle with what to do with Alzheimer’s disease anyway. The question in the U.S. is if someone has a scan and it’s positive or negative, what do you do next? I mean the stakeholders acknowledge that there really is no need to progressively scan someone over and over again. If a patient has symptoms and don’t have significant amyloid-beta at that point, then Alzheimer’s is not the cause of their symptoms.

**Interviewer** So at this moment, the coverage is only for 1 time of scan?



**Jacques** Yes. Coverage for FDG is different. So this is in the context of a cancer therapy that clearly evolves as the patient responds to treatment or undergoes second. There are 3 PETs covered nationally here; and then the local Medicare contractors can decide if they want to cover more. For amyloid scanning, only one scan is covered. But the way Medicare system is designed, there is central Medicare and then there are about 10 local Medicare contractors that are free to make any decision as long as they don't conflict with the central one.

Because there is already evidence that people accumulate amyloid in their brain as they get older, and the issue is that if the symptoms comes and the scan shows you don't already have amyloid, by current definition you don't have Alzheimer's disease. You have some other kind of dementia. And because you already have a non-Alzheimer's dementia here, no one has proven the clinical value of testing you again, let's say 5 years later or 10 years later,

because you're already demented here.

**Interviewer** I understand very well. But how about if we say we cover the use of 2 or 3 PET scans in very limited well-designed clinical trial during some years to find something, for example, to assess development of the disease like accumulation of the amyloid beta, or to determine the clinical condition of these people being scanned?

**Jacques** Medicare pays the routine cost in a clinical trial as well as the investigational item or service depending on policy. But Medicare by law doesn't pay for the administrative cost in a clinical trial. Medicare primarily is an insurance agent. It's not the National Institutes of Health. The Medicare mandate really has not been around research because that is not what health insurance is primarily for. Healthcare insurance is ideally for things that are firmly established. So even if you have a clinical trial where Medicare is paying all the routine cost plus paying for one CT scan, at some point, I think the sponsor institution has to

take responsibility for some of the costs of the trial because they're the ones who are going to make the money if the trial is successful. I mean, Medicare doesn't get a share of the profit if the drug is successful.

**Interviewer** Do you mean that 2 or 3 additional scans would be regarded as a part of the clinical trial administrative cost?

**Jacques** They're clinical costs but they're non-covered clinical costs. So either the sponsoring institute (if they were NIH) or the company (if the company was the sponsor) would need to pay for those.

**Interviewer** Okay, I understand very well. It's very similar to the Japanese situation because in Japan all of these cannot be covered at this stage of clinical trial. However, I think there is a good policy of CMS, different from a policy in Japan. If it is according to the agent, this something investigational part can be covered depending on the situation, according to the decision. It seems to lead to such strategy that early approval FDA and promotion of evidence development partially covered by CMS.

**Jacques** It depends on the situation, yes.

#### 4. Ethical issues

**Interviewer** A little bit different point. In this letter from SNMMI<sup>1)</sup> addressed to you, there are a number of claims not only about coverage but also there is some ethical viewpoint mentioned here that if the coverage applies only to those entering a clinical trial, it would be something like coercion to enter the trial.

**Jacques** In any clinical research, people voice concerns about the motivations of patients. I'm not saying that these are not legitimate concerns for discussion. I'm just saying that we've clearly managed to conduct clinical research for a long period

of time, as long as the patient is adequately informed, you know. I think the issue is that maybe patients are not being told the complete story about the test. If the doctor says, "There's an Alzheimer's scan for you. We're going to help diagnose your Alzheimer's." Then the patient doesn't realize that that is a very, very shortened explanation of all the concerns around diagnosing Alzheimer's.

**Interviewer** This is an illustration<sup>8)</sup> based on their very well written literature on usage criteria of amyloid-beta imaging<sup>9)</sup>. After the publication of that literature, SNMMI developed this kind of illustration on "appropriate use" to explain how to use the amyloid-beta scan. They are saying that amyloid-beta scans should be very much carefully used to avoid abuse.

Additionally, there is some ethical standpoint in what you said about there being no treatment for Alzheimer's at this moment. There should be some kind of support for such kind of people. One good point I think is that people can manage their remaining life if they can know about their situation.

#### 5. Background culture to support elderly people

**Jacques** Given the differences between Japanese culture and American culture especially with regards to family and elderly people, in the U.S., it's not uncommon for the older person with Alzheimer's to live very far away from their family and from their children. They may well be living alone or living in a nursing home. Is Japanese society more cohesive so that the older family members aren't alone or is it starting to become more like Western societies where the grandparents are just alone?

**Interviewer** Generally it is true that there is a conventional way of life that Japanese elderly people live with their family, if comparing with

Western society. However, recent trend in Japan is that these elderly people are coming to be in hospital or some other facilities.

How do you connect this kind of social situation of Alzheimer's people with the issue on PET scan?

**Jacques** One of the things that people had suggested was that PET scans could help people with their financial planning and with things like that. The challenge is that financial planning is not a health insurance issue. There may be many things that might be beneficial for a society but it's not a health insurance role to go fix it. For example, if Medicare pays for something it would increase employment in the factory but Medicare should not be concerned that if we don't pay for this, this will close the factory in some town or unemployment or things like that. There are many things that are clearly beneficial like eyeglasses. They're cheap. They're customizable or they can work in a power failure. They help you very well. But Medicare by law cannot pay for eyeglasses or hearing aids or modifications to the home. If you have an older patient who may have osteoporosis and they may fall in their home, it might make a lot of sense to modify their home so that they are less likely to fall, and if they fall they're less likely to be injured. But health insurance generally doesn't pay for modifying your home.

**Interviewer** I understand that CMS policy is limited to the clinical benefit, not social benefit.

**Jacques** Yes, and it's the clinical benefit of the patient because there are no family insurance policies in Medicare. So if doing something to the patient helps the family member but doesn't help the patient, Medicare can't deal with it.

## 6. Clinical benefit of beta-amyloid scan

**Interviewer** In your personal opinion as a physician apart from being involved in the CMS policy, how do you think is the effect of PET scanning or amyloid PET scanning in terms of social value?

**Jacques** I think it's unclear because right now it's based on an amyloid-beta proposition which has not been definitively proven. I have an example I use. I tell men, "I have a test that is 100 percent sensitive for prostate cancer. It's a Y-chromosome. Every person who has or is going to develop prostate cancer has a Y-chromosome. If you don't have a Y-chromosome you don't get prostate cancer." So the knowledge that every men anywhere if he lives long enough will get prostate cancer, it is not really actionable because there's no preventive strategy for prostate cancer. The treatments (whether it's surgery or anything else) have side effects that people don't want. What you end up with then is a population of people who become focused on the possibility of prostate cancer when in fact they're more likely to die of heart disease or lung cancer or something else depending on their health habits. The Kaplan-Myer curve for any trial if you study it long enough everybody dies in both arms. So if we accept in the long run that we are all going to die of something, the issue is not to identify everything that might possibly kill you but to identify the things that will cause you your early death and disability that you can actually act on and do something about. Otherwise, you simply face the reality that life is short.

**Interviewer** So which kind of evidence should be expected and which type of study is necessary for amyloid-beta scans?

**Jacques** What would be needed in amyloid beta (because the therapeutic side is unclear) would be

evidence that patients who are managed based on a amyloid-beta scan have better outcomes than patients who are not; and that, if one uses the cancer paradigm, would be either that they are targeted for early treatment of Alzheimer's and thus they have fewer symptoms, or that a significant proportion of them are able to avoid therapies that has significant burdens, whether it's adverse events or whether it's something else. That's essentially what's needed. And because the therapeutic side of Alzheimer's is so unclear, that really requires a longer term study than if the therapies were very well known. For example, with colorectal cancer and the use of *k-ras* testing, *k-ras* testing was adopted fairly quickly because so much was known about the treatment options in colorectal cancer and what the benefit would be, whereas with Alzheimer's that's just not that clear.

## 7. Research study for future development and ethical considerations

**Jacques** This is actually about genetic testing. This is a copy of Archive Biomarkers. It's a similar issue here in the sort of what do you do, especially with Alzheimer's because what you may be dealing with are archived brain. You can have this. You can keep it.

Because in Alzheimer's, patients don't realistically get a brain biopsy so many of the studies have been based on archived tissue samples which is not unlike the paradigm in certain cancer trials. This is the chief of biometry at the National Cancer Institute so he is very influential, and he proposed an evidentiary paradigm for biomarkers to acknowledge that studying a biomarker is harder than studying a therapeutic treatment.

**Interviewer** Yes. One point you mentioned is about brain tissue examination. It's also a problem

in Japan. Some Japanese doctors are informing study subjects of their future plan to take the patient's brain tissue after their death. But some doctors are hesitant to mention such kind of things especially to very elderly patient whose brains are okay, or their cognitive situation is okay. They hesitate to explain these things to patients in clinical trial, especially if the physical condition of the elderly patient is very bad. Such kind of patient is a good recruitment candidate for study to the compare PET imaging and brain tissue. But in Japanese culture, there is hesitancy to say to these people that after your death we would like to take your tissue. I have spoken about this with some Europeans and Americans. They say this kind of thing should be explained very clearly to the patient. (This is the separate issue from the authorization of the family after the death of this research subject.) So this is a cultural difference. How do you think about this issue? This is very much ethical question, I know.

**Jacques** Clearly someone would need to give permission (whether it's the patient or whether it's their family) afterwards. Even in the U.S., autopsies are no longer routine. Most patients when they die they go to a funeral home and they go from there. Studying Alzheimer's is fraught for a number of reasons. One, it's very sensitive topic that can be politicized, it's like studying certain cancer. But at the same time, if we make decisions based on insufficient evidence because we're afraid to do the definitive thing, we run the risk of mistreating an entire generation of patients because we were not brave enough to actually either acknowledge to these patients that they were being treated on scant evidence or to say, yes, we really do need to study. It's very difficult for physicians to admit that they don't know. There's tremendous pressure to give the patient an answer even if the answer is a poorly informed answer. And I think that desperation,

unfortunately, is bad motivation for good science because desperation makes one take great leaps without actually doing good science.

**Interviewer** So you're saying that for a researcher to conduct good science, it is also necessary to support these people by telling them what will actually happen after their death, and this is valuable for good science.

**Jacques** Yes. It's something like – we may not be able to help you but we might be able to help your children – because most parents already made great sacrifices for their children even while they're alive so the idea that a parent would continue to make a sacrifice for the benefit of their children later on, I think, can be a compelling one, not only a scientific one but also a financial one. In the United States, there's a lot of conversations that the grandparents' generation has all the disposal income and the grandchildren's generation is financially facing the burden of supporting their elders meanwhile the elders are the ones with all

the money. Especially with declining birthrates, it becomes a greater and greater burden on a smaller and smaller number of people. So if there are things that can either help the younger generation scientifically/medically or help them financially by assuring that the things that they are responsible for are things that actually work as opposed to funding a generation of long experiments, social experiments, maybe that's persuasive.

## 8. Business, family, and future generation

**Interviewer** Thank you so much, it is very important point. Just one last question. Could you introduce your personal history. After working in a university hospital, you joined CMS. And what is the prospective of this company.

**Jacques** I left CMS at the end of February of this year (three months and a half before) to come and join ADVI. ADVI is a consultancy that helps



companies in the life sciences whether it's drugs, diagnostics, or devices. We also deal with health plans, drug plans, private insurance; things like that. So we're essentially a consultancy with partners and then a larger number of staff, and we work with both large companies and small companies.

**Interviewer** How about your joining CMS after your work in the university?

**Jacques** I basically went to CMS because I didn't want to miss my daughter's soccer games. My daughter played in high school, and my son also played sports. I worked at Georgetown. It was a very long drive and I was afraid I would miss some of the things with my children. And I had already been at the university then for 8 years, and I decided to work closer to home.

**Interviewer** Really. You are a good father.

**Jacques** That's why I went to Medicare – to watch my daughter's soccer games.

**Interviewer** Between your work in the university and this company, you only worked in CMS?

**Jacques** Yes. Eleven years.

**Interviewer** I heard that after you left CMS, next person is a lawyer.

**Jacques** Yes. She was my deputy. She's very good. Her name is Tamara Syrek Jensen. Here is an article written with her on the issue of reimbursement of regenerative medicine<sup>10</sup>.

**Interviewer** Thank you, it is meaningful information for Japanese readers, they are deeply interested in how to reimburse for regenerative medicine, stem cell therapy, or other kinds of advanced technologies. Is it often that lawyers get appointed to CMS positions?

**Jacques** The job historically has been filled in recent years by physicians, although Medicare as a public governmental insurer is essentially a legal entity. Medicare is not a hospital. Medicare is a creation of Congress, which means that Medicare is really the result of a legal process rather than a

medical process. So whether the head of coverage is a lawyer or a physician, I don't think ultimately matters that much because if it's run by a physician you still need legal input. If it's run by a lawyer you still need medical input. So it would be a different model but I think it could be successful with either model.

**Interviewer** So collaboration would be important.

**Jacques** Yes, because she and I had offices next to each other, so we used to talk everyday.

**Interviewer** So thank you very much. It was very precious experience to talk with you and heard about some parts of policy and philosophy of reimbursement in the U.S.

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医療機関情報統合  
Integrating the Healthcare Enterprise



IHE 放射線  
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目次	
和訳一覧	9
用語	9
統合プロファイル訳語一覧	10
トランザクション訳語一覧	10
1 前書き	13
1.1 テクニカルフレームワークの概観	13
1.2 第一巻の概要	14
1.3 想定読者	14
1.4 標準規格との関係	14
1.5 実製品との関係	14
1.6 凡例	15
1.6.1 実行役とトランザクション図および表	15
1.6.2 処理流れ図	15
1.6.3 テクニカルフレームワークの規範的および情報的内容	16
1.6.4 テクニカルフレームワークの参照	16
1.7 2013–2014年（第14年）の変更	16
1.8 注釈	16
1.9 著作権許諾	17
1.10 IHE放射線テクニカルフレームワークの開発、維持手順	17
2 統合プロファイル	20
2.1 統合プロファイル概観	25
2.1.1 予定業務流れ (Scheduled Work Flow, SWF)	25
2.1.2 患者情報整合 (Patient Information Reconciliation, PIR)	26
2.1.3 画像表示一貫性 (Consistent Presentation of Images, CPI)	26
2.1.4 群化検査提示 (Presentation of Grouped Procedures, PGP)	26
2.1.5 放射線情報利用 (Access to Radiology Information, ARI)	26
2.1.6 キー画像注釈 (Key Image Note, KIN)	26
2.1.7 単純画像数値レポート (Simple Image and Numeric Report, SINR)	26
2.1.8 基礎的安全 (Basic Security, SEC - 廃止済み)	27
2.1.9 課金情報通知 (Charge Posting, CHG)	27
2.1.10 後処理業務流れ (Post-Processing Workflow, PWF)	27
2.1.11 レポート業務流れ (Reporting Workflow, RWF)	27
2.1.12 エビデンス書類 (Evidence Document, ED)	27
2.1.13 画像用可搬媒体 (Portable Data for Imaging, PDI)	28
2.1.14 核医学画像 (NM Image, NM)	28
2.1.15 教育用ファイル・臨床試験用送出 (Teaching File and Clinical Trial Export, TCE)	28
2.1.16 施設間画像連携 (Cross-Enterprise Document Sharing for Imaging, XDS-I.b)	28
2.1.17 乳房撮影画像 (Mammography Image, MAMMO)	28
2.1.18 画像フュージョン (Image Fusion, FUS)	29
2.1.19 取込画像整合性流れ (Import Reconciliation Workflow, IRWF)	29
2.1.20 放射線被曝監視 (Radiation Exposure Monitoring, REM)	29
2.1.21 乳房撮影取得業務流れ (MAWF)	29
2.1.22 MR 拡散強調像 (DIFF)	29
2.1.23 CT/MR 造影灌流画像 (PERF)	29

2.1.24	基本画像閲覧.....	29
2.1.25	胸部 X 線写真 CAD 表示.....	29
2.1.26	画像対象変更管理.....	29
2.1.27	共同体間画像利用.....	30
2.2	他領域プロファイルのオプション.....	30
2.2.1	ITI-監査追跡と拠点認証.....	30
2.3	実行役の説明.....	30
2.4	トランザクションの説明.....	33
2.5	製品への実装.....	40
<b>3</b>	<b>予定業務流れ (SCHEDULED WORKFLOW, SWF)</b> .....	<b>42</b>
3.1	実行役/トランザクション.....	42
3.2	予定業務流れ統合プロファイルオプション.....	45
3.2.1	HL7 v2.5.1 オプション.....	47
3.3	処理の流れ.....	47
3.3.1	管理および検査実施処理流れ.....	47
3.3.2	患者更新業務流れ.....	50
3.3.3	オーダー変更業務流れ.....	52
3.3.5	非明示的後処理 (Implicit Post-Processing) .....	60
3.4	予定業務流れ (SWF) のデータモデル.....	65
3.4.1	現実世界のモデル.....	65
3.4.2	臨床での予定業務流れ構想.....	66
<b>4</b>	<b>患者情報整合 (PATIENT INFORMATION RECONCILIATION, PIR)</b> .....	<b>72</b>
4.1	実行役/トランザクション.....	73
4.2	患者情報整合オプション.....	75
4.3	身元不明患者の画像取得と情報整合.....	76
4.3.1	画像取得中の患者情報整合.....	77
4.4	使用例.....	77
4.4.1	例 1: ADT での身元不明患者登録とオーダー発行役によるオーダー発行.....	78
4.4.2	例 2: ADT での身元不明患者登録と部門システム予定・オーダー実施役によるオーダー発行.....	79
4.4.3	例 3: 身元不明患者の ADT 登録とオーダー前の撮影完了.....	80
4.4.4	例 4: 身元不明患者で部門一時 ID 割り付けと部門システム予定・オーダー実施役での予定.....	81
4.4.5	例 5: 部門システム予定・オーダー実施役での予定無しに画像取得が完了.....	82
4.4.6	例 6: 画像取得中の患者情報整合.....	84
<b>5</b>	<b>画像表示一貫性 (CONSISTENT PRESENTATION OF IMAGES, CPI)</b> .....	<b>85</b>
5.1	実行役/トランザクション.....	86
5.2	画像表示一貫性統合プロファイル オプション.....	87
5.3	画像表示一貫性処理流れ.....	88
<b>6</b>	<b>群化検査提示 (PRESENTATION OF GROUPED PROCEDURES, PGP)</b> .....	<b>90</b>
6.1	実行役/トランザクション.....	90
6.2	群化検査提示統合プロファイル オプション.....	91
6.3	群化検査提示処理流れ.....	92
<b>7</b>	<b>放射線情報利用 (ACCESS TO RADIOLOGY INFORMATION, ARI)</b> .....	<b>93</b>
7.1	実行役/トランザクション.....	94
7.2	放射線情報利用オプション.....	95

7.3 多情報源オプション .....	95
7.3.1 多情報源オプションの必須条件 .....	95
8 キー画像注釈 (KEY IMAGE NOTE, KIN) .....	96
8.1 実行役/トランザクション .....	97
8.2 キー画像注釈統合プロファイル オプション .....	98
8.3 キー画像注釈のパターン .....	98
9 単純画像数値レポート (SIMPLE IMAGE AND NUMERIC REPORT, SINR) .....	99
9.1 実行役/トランザクション .....	100
9.2 単純画像数値レポート統合プロファイル オプション .....	101
9.3 診断レポート処理流れ .....	101
9.4 診断レポート使用例 .....	104
9.4.1 単純画像レポート .....	104
9.4.2 単純画像数値レポート .....	105
9.4.3 観察事項 .....	105
10 基礎的安全 (BASIC SECURITY, SEC) - 廃止 .....	105
11 課金情報通知 (CHARGE POSTING, CHG) .....	106
11.1 実行役/トランザクション .....	107
11.2 課金情報通知統合プロファイル オプション .....	108
11.3.1 使用例 .....	111
11.3.2 技術料金 .....	111
11.3.3 専門職料金 .....	111
11.4 課金情報通知のデータモデル .....	112
11.4.1 現実世界のモデル .....	112
12 後処理業務流れ (POST-PROCESSING WORKFLOW, PWF) .....	113
12.1 実行役/トランザクション .....	114
12.2 後処理業務流れ統合プロファイル オプション .....	116
12.3 実装の問題 .....	116
12.3.1 実行役群化の明瞭化 .....	116
12.3.2 入力の可用性 .....	117
12.3.3 予定業務流れ vs. 後処理業務流れにおけるエビデンス書類生成役 .....	118
12.4 後処理業務流れ .....	118
12.4.1 Computer Aided Detection 使用例 .....	118
12.4.2 三次元画像再構成使用例 .....	119
12.4.3 後処理業務流れ図 .....	119
13 レポート業務流れ (REPORTING WORKFLOW, RWF) .....	122
13.1 実行役/トランザクション .....	122
13.1.1 実行役群化の明瞭化 .....	123
13.1.2 入力可用性 Input Availability .....	124
13.2 レポート業務流れ統合プロファイルオプション .....	125
13.2.1 HL7 v2.5.1 オプション .....	125
13.3 レポート業務 .....	125
13.4 診断レポート業務使用例 .....	128
13.4.1 使用例 1: 既定レポート .....	129

13.4.2 使用例 2: 業務項目廃棄.....	130
13.4.3 使用例 3: 直接レポート作成.....	131
13.4.4 使用例 4: 読影と口述.....	132
13.4.5 使用例 5: 口述筆記.....	133
13.4.6 使用例 6: 一部完成.....	134
13.4.7 使用例 7: 最終確認.....	135
13.4.8 使用例 8: 二重読影.....	136
13.4.9 使用例 9: 比較.....	136
13.4.10 使用例 10: 閲覧.....	137
13.4.11 使用例 11: 上級読影.....	137
<b>14 エビデンス書類 (EVIDENCE DOCUMENTS, ED) .....</b>	<b>138</b>
14.1 実行役/トランザクション.....	138
14.2 エビデンス書類統合プロファイル オプション.....	140
14.3 エビデンス書類処理流れ.....	140
<b>15 画像用可搬媒体 (PORTABLE DATA FOR IMAGING, PDI) .....</b>	<b>142</b>
15.1 実行役/ トランザクション.....	143
15.2 画像用可搬媒体オプション.....	144
15.3 画像用可搬媒体処理流れ.....	144
15.3.1 使用例.....	144
15.3.2 処理流れ記載.....	145
15.4 媒体内容.....	147
15.4.1 DICOM 内容物.....	148
15.4.2 インターネット形式内容物オプション.....	148
15.4.3 その他の内容.....	148
15.5 安全とプライバシーの問題.....	148
<b>16 核医学画像 (NM) .....</b>	<b>149</b>
16.1 実行役/ トランザクション.....	149
16.2 核医学画像統合プロファイルオプション.....	151
16.3 核医学画像処理流れ.....	151
<b>17 教育用ファイル・臨床試験用送出 (TEACHIG FILE AND CLINICAL TRIAL EXPORT, TCE) . 152</b>	
17.1 実行役/トランザクション.....	153
17.2 教育用ファイル・臨床試験用送出統合プロファイル オプション.....	154
17.2.1 焼込データ匿名化オプション.....	154
17.2.2 識別情報対応付けオプション.....	155
17.2.3 ティーチングファイル追加情報オプション.....	155
17.2.4 送出待ちオプション.....	155
17.3 実装の問題.....	156
17.4 教育用ファイル・臨床試験用送出業務流れ.....	156
17.4.1 ティーチングファイル使用例.....	158
17.4.2 臨床試験での使用例.....	162
17.4.3 研究用蒐集使用例.....	163
<b>18 施設間画像連携統合プロファイル (CROSS-ENTERPRISE DOCUMENT SHARING FOR IMAGING, XDS-I) .....</b>	<b>164</b>
18.1 実行役/ トランザクション.....	165

18.2 統合プロフィールオプション .....	167
18.2.1 DICOM インスタンスセットオプション .....	168
18.2.2 PDF レポートオプション .....	168
18.2.3 CDA 埋込みテキストレポートオプション .....	168
18.3 画像情報共有業務流れ .....	168
18.3.1 画像情報共有使用例の概観 .....	168
18.3.2 前提 .....	169
18.3.3 使用例 .....	170
18.3.4 問合せ .....	177
18.4 消費役の処理 .....	177
18.4.1 使用役の処理 – DICOM インスタンスセット .....	177
18.5 患者情報整合 .....	177
18.6 安全への配慮 .....	177
<b>19 乳房撮影画像 (MAMMO) .....</b>	<b>177</b>
19.1 実行役/ トランザクション .....	178
19.2 乳房撮影画像統合プロフィールオプション .....	179
19.3 乳房撮影画像プロフィール業務流れ .....	180
<b>20 画像フュージョン (IMAGE FUSION, FUS) .....</b>	<b>180</b>
<b>21 取込み情報一貫性業務流れ (IMPORT RECONCILIATION WORKFLOW, IRWF) .....</b>	<b>180</b>
21.1 実行役/トランザクション .....	181
21.2 取込み情報一貫性業務流統合プロフィールオプション .....	183
21.2.1 予定取込みオプション .....	184
21.2.2 未予定取込みオプション .....	184
21.3 統合業務処理流れ .....	184
21.3.1 取込み処理流れ .....	184
<b>22 放射線被曝監視 (RADIATION EXPOSURE MONITORING, REM) .....</b>	<b>190</b>
22.1 実行役/ トランザクション .....	191
22.2 放射線被曝監視統合プロフィールオプション .....	193
22.3 放射線被曝監視処理流れ .....	193
22.3.1 一般的な例 .....	194
22.3.2 実世界使用例 .....	195
22.3.3 REM プロファイル使用の例 .....	197
22.4 放射線被曝監視プロフィールの安全面考慮 .....	198
22.5 他プロフィールとの関係 .....	198
22.5.1 放射線部門のプロファイル .....	198
22.5.2 ITI プロファイル .....	199
<b>23 乳房撮影取得業務流れ (MAMMOGRAPHY ACQUISITION WORKFLOW, MAWF) .....</b>	<b>199</b>
<b>24 MR 拡散画像 (MR DIFFUSION IMAGING, DIFF) .....</b>	<b>199</b>
<b>25 CT/MR 造影灌流画像 (CT/MR PERFUSION WITH CONTRAST) .....</b>	<b>199</b>
<b>26 基本画像閲覧 (BASIC IMAGE REVIEW, BIR) .....</b>	<b>199</b>
<b>27 胸部 X 線写真 CAD 表示 (CHEST X-RAY CAD DISPLAY, CXCAD) .....</b>	<b>200</b>

<b>28 画像対象変更管理 (IMAGING OBJECT CHANGE MANAGEMENT, IOCM)</b> .....	<b>200</b>
28.1 実行役/トランザクション .....	200
28.2 画像対象変更管理統合プロファイルオプション .....	202
28.3 画像対象変更管理統合プロファイル実行役一括化とプロファイルの相互作用 .....	202
28.4 画像対象変更管理処理流れ .....	203
28.4.1 使用例：データ保持期限切れ .....	204
28.4.2 使用例：品質を理由とする画像拒否 .....	205
28.4.3 使用例：患者安全を理由の画像訂正 .....	206
28.4.4 使用例：撮影装置業務一覧からの誤選択の訂正 .....	207
28.5 画像対象変更管理の安全考慮 .....	212
<b>29 共同体間画像利用 (CROSS-COMMUNITY ACCESS FOR IMAGING, XCA-I)</b> .....	<b>213</b>
29.1 実行役・トランザクション .....	213
29.1.1 実行役要求事項 .....	214
29.2 共同体間画像利用オプション .....	214
29.3 XCA-I 処理流れ .....	214
29.3.1 使用例－共同体間での画像共有 .....	214
29.3.2 詳細な相互作用 .....	215
29.3.3 実行役群化の考察 .....	218
29.4 XCA-I 安全の考慮 .....	218
29.4.1 XCA リスク評価 .....	218
29.4.2 要求事項と推奨 .....	218
29.4.3 基本方針の選択 .....	219
<b>付録 A: アクセション番号 (ACCESSION NUMBER) と要求検査 ID (REQUESTED PROCEDURE ID) の明確化</b> .....	<b>220</b>
A.1 画像検査オーダーの構造 .....	220
<b>付録 B: 規格改定と追補に関する話題</b> .....	<b>222</b>
B.1 HL7 の話題 .....	222
B.1.1 Version 2.5 .....	222
B.1.2 HL7 適合性 .....	222
B.2 DICOM の話題 .....	222
<b>付録 C: 部門システム予定・オーダー実施役 (DSS/OF) と画像管理役間情報交換の概観</b> .....	<b>223</b>
C.1 患者情報の交換 .....	223
C.2 来院とオーダー情報の交換 .....	223
C.3 検査情報の交換 .....	223
<b>付録 D: IHE 統合宣言</b> .....	<b>224</b>
D.1 IHE 統合宣言の構造と内容 .....	224
D.2 IHE 統合宣言の書式 .....	225
<b>付録 E: 核医学</b> .....	<b>226</b>
E.1 はじめに .....	226
E.2 核医学業務流れ概観 .....	226
E.2.1 注射段階 .....	226
E.3 核医学業務一覧 .....	228
E.3.1 核医学業務一覧ガイドライン .....	228